DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 510

[CMS–5529–F]

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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

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

ACTION: Final rule.

SUMMARY: This final rule extends the length of the Comprehensive Care for Joint Replacement (CJR) model through December 31, 2024 by adding an additional 3 performance years (PYs). PY 6 will begin on October 1, 2021 and end on December 31, 2022; PY 7 will begin on January 1, 2023 and end on December 31, 2023; and PY 8 will begin on January 1, 2024 and end on December 31, 2024. In addition, this final rule revises certain aspects of the CJR model including the episode of care definition, the target price calculation, the reconciliation process, the beneficiary notice requirements, and the appeals process. In addition, for PY 6 through 8, this final rule eliminates the 50 percent cap on gainsharing payments, distribution payments, and downstream distribution payments for certain recipients. This final rule extends the additional flexibilities provided to participant hospitals related to certain Medicare program rules consistent with the revised episode of care definition.

DATES: These final regulations are effective July 2, 2021.

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SUPPLEMENTARY INFORMATION:

I. Background

A. Purpose

The Comprehensive Care for Joint Replacement (CJR) model, which was implemented via notice-and-comment rulemaking and began on April 1, 2016, aims to support better and more efficient care for beneficiaries undergoing the most common inpatient surgeries for Medicare beneficiaries: Hip and knee replacements (also called lower extremity joint replacements or LEJR). This model tests bundled payment and quality measurement for an episode of care associated with hip and knee replacements to encourage hospitals, physicians, and post-acute care providers to work together to improve the quality and coordination of care from the initial hospitalization through recovery. While initial evaluation results for the first, second, and third year of the CJR model,[1] as well as an independent study in the New England Journal of Medicine,[2] indicate that the CJR model is having a positive impact on lowering episode costs when CJR participant hospitals are compared to non-CJR participant hospitals (with no negative impacts on quality of care), changes in Medicare program payment policy and national care delivery patterns have occurred since the CJR model began. In order to update the CJR model to address recent policy changes and improve the model's ability to demonstrate savings, we issued a proposed rule titled ''Medicare Program: Comprehensive Care for Joint Replacement Model Three-Year Extension and Changes to Episode Definition and Pricing'', which appeared in the February 24, 2020 **Federal Register** (85 FR 10516). In this rule, we proposed to change and extend the CJR model for an additional 3 performance years. We proposed to change the definition of a CJR model episode in order to address changes to the inpatient-only (IPO) list, which is a list published annually in the Outpatient Prospective Payment System (OPPS) rule and which contains procedure codes that will only be paid by Medicare when performed in the inpatient setting. Specifically, in response to the change in the calendar year (CY) 2018 OPPS rule (65 FR 18455), which removed the Total Knee Arthroplasty (TKA) procedure code from the IPO list, and the change in the CY 2020 OPPS rule (84 FR 61353), which removed the Total Hip Arthroplasty (THA) procedure code from the IPO list, we proposed to change the definition of an episode of care to include outpatient procedures for TKAs and to include outpatient procedures for THAs.

In addition to updating for changes in a hospital setting, the model also needed a more accurate and adaptable payment methodology that can sustain adjustments in practice and payment systems over time. Therefore, we proposed to make a number of changes to the target price calculation to improve sustainability and accuracy. Specifically, we proposed to change the basis for the target price from 3 years of claims data to the most recent 1 year of claims data to make the target price more representative of recent practice patterns, particularly post-acute care. We proposed to remove the national update factor and twice yearly update to the target prices and replace them with a retrospective trend factor at reconciliation to create greater consistency in the payment methodology with underlying practice and Medicare fee-for-service (FFS) payment system changes. We proposed to remove anchor factors and weights because they are no longer necessary and generate complexity.

Additionally, we proposed a number of changes to the reconciliation process with similar goals of sustainability and payment accuracy. We proposed to move from two reconciliation periods (conducted 2 and 14 months after the close of each performance year) to one reconciliation period that would be conducted six months after the close of each performance year to reduce hospital burden and for ease of administration. We proposed to add an additional episode-level risk adjustment beyond fracture status for greater payment accuracy. We proposed to change the high episode spending cap calculation methodology as the current methodology inaccurately capped high cost cases. We also proposed to the change the quality (effective or applicable) discount factors applicable to participants with excellent and good quality scores to better recognize high quality care.

Since we proposed to change the definition of an episode of care to include procedures performed in the hospital outpatient department, for which the beneficiary would not be admitted as an inpatient to the participant hospital, we also proposed a change to the beneficiary notification requirements (which are currently tied to inpatient admission) such that CJR participant hospitals are also required to notify the beneficiary of his or her inclusion in the CJR model if the procedure takes place in a hospital outpatient department setting. We also proposed to make changes to the dates of publicly reported data used for quality measures and patient-reported outcomes (PRO) for the 3 additional performance years to accommodate the extension period. In addition, we

[1] See evaluation reports section posted on the CJR model website at: *https://innovation.cms.gov/initiatives/cjr.*

[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.*

proposed to advance the Complications measure and Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) measure performance periods to add additional collection for PYs 6–8 in alignment with the performance periods used for PYs 1 through 5. For PRO, we proposed to advance the performance periods in alignment with previous performance periods as well as increase the thresholds for successful submission to add additional collection for PYs 6–8. Additionally, for the 3 additional performance years, we proposed to eliminate the 50 percent cap on gainsharing payments, distribution payments, and downstream distribution payments when the recipient of these payments is a physician, non-physician practitioner, physician group practice (PGP), or non-physician practitioner group practice (NPPGP) consistent with updates to other Innovation Center models. We also proposed to make changes to the appeals process in order to clarify the reconsideration review (second level appeal) process. Finally, in conjunction with the proposed change to include specific outpatient procedures in the CJR model episode definition, we also proposed to extend the waiver of the skilled nursing facility (SNF) 3-day rule and the waiver of direct supervision requirements for certain post-discharge home visits for participant hospitals furnishing services to CJR beneficiaries in the outpatient setting as well. As outlined in section II.D.1. of this final rule we are extending the model for 3 performance years to generate the necessary evaluation findings under a revised payment methodology for the agency to consider expansion of the model.

As further outlined in section II.D.2. of this final rule, we proposed that the extension of the CJR model would only apply to participant hospitals located in the 34 mandatory metropolitan statistical areas (MSAs) for whom participation has been mandatory since the beginning of the model in 2016. This proposal excludes rural and low-volume hospitals in the 34 mandatory MSAs and any voluntary hospitals in 33 voluntary MSAs that have opted into the model for PYs 3 through 5. The model currently enrolls 139 voluntary, rural, and low-volume hospitals. Excluding rural, low-volume, and voluntary hospitals from the model results in 330 hospitals in the 34 mandatory MSAs participating in PYs 6 to 8. We proposed conforming changes to the CJR model regulations at 42 CFR part 510.

This final rule also finalizes policies in two interim final rules with comment (IFCs). Specifically, the IFC titled, Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency,[3] 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 second IFC titled, Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency,[4] 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 (MS–DRGs) 521 and 522 for hip and knee procedures.

B. Summary of Costs and Benefits

As shown in our impact analysis in section IV. of this final rule, we estimate that the CJR model changes we proposed will save the Medicare program approximately $217 million over the additional 3 model years. We note that our impact analysis has some degree of uncertainty and makes assumptions as further discussed in section IV. In addition to these estimated impacts, the goal of CMS' Center for Medicare and Medicaid Innovation (Innovation Center) models is to reduce program expenditures while preserving or enhancing the quality of care. Our evaluation results document that many participant hospitals are attempting to enhance their infrastructure to support better care management and to reduce costs. We anticipate there will continue to be a broader focus on care coordination and quality improvement through the CJR model among participant hospitals and other providers and suppliers within the Medicare program that may lead to better care management and improved quality of care for beneficiaries.

C. Statutory Authority and Background

Under the authority of section 1115A of the Social Security Act (the Act), through notice-and-comment rulemaking, the Innovation Center established the CJR model in a final rule titled ''Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services'' that appeared in the November 24, 2015 **Federal Register** (80 FR 73274) (referred to in this final rule as the ''November 2015 final rule''). The CJR model is a Medicare Part A and B payment model in which acute care hospitals in certain selected geographic areas receive retrospective bundled payments for episodes of care for lower extremity joint replacement or reattachment of a lower extremity (collectively referred to as LEJR). The CJR model holds participant hospitals financially accountable for the quality and cost of a CJR model episode of care and incentivizes increased coordination of care among hospitals, physicians, and post-acute care providers. All related care covered by Medicare Parts A and B within 90 days of hospital discharge from the LEJR procedure is included in the episode of care. The first CJR model performance period began April 1, 2016. At that time, the CJR model required hospitals located in the 67 MSAs selected for participation to participate in the model through December 31, 2020 unless the hospital was an episode initiator for an LEJR episode in the risk-bearing phase of Models 2 or 4 of the Bundled Payments for Care Improvement (BPCI) initiative. Hospitals located in one of the 67 MSAs that participated in Model 1 of the BPCI initiative, which ended on December 31, 2016, were required to begin participating in the CJR model when their participation in the BPCI initiative ended.

We issued a final rule titled ''Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services; Corrections and Correcting Amendments,'' which appeared in the March 4, 2016 **Federal Register** (81 FR 11449), to correct a limited number of technical and typographical errors identified in the November 2015 final rule. We issued a final rule, which appeared in the January 3, 2017 **Federal Register** (82 FR 180), titled ''Medicare Program; Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model (CJR)'' (referred to as the ''January 2017 final rule''), to implement the creation and testing of three EPMs and to make certain refinements to better align the CJR model with the new EPMs, to make minor technical improvements to the CJR model and to create an Advanced Alternative Payment Model (Advanced APM) track within the CJR model. We

[3] 85 FR 19230.

[4] 85 FR 71142.

issued a final rule, which appeared in the May 19, 2017 **Federal Register** (82 FR 22895), titled ''Medicare Program; Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model (CJR); Delay of Effective Date,'' which finalized May 20, 2017 as the effective date of the January 2017 final rule (82 FR 180) (referred to as the ''May 2017 final rule''). The May 2017 final rule also finalized a delay to the effective date of certain CJR model regulations from July 1, 2017 to January 1, 2018. We issued another final rule, which appeared in the December 1, 2017 **Federal Register** (82 FR 57066), titled ''Medicare Program; Cancellation of Advancing Care Coordination Through Episode Payment and Cardiac Rehabilitation Incentive Payment Models; Changes to Comprehensive Care for Joint Replacement Payment Model: Extreme and Uncontrollable Circumstances Policy for the Comprehensive Care for Joint Replacement Payment Model'' (referred to as the ''December 2017 final rule''), that implemented further revisions to the CJR model, including giving rural and low-volume hospitals selected for participation in the CJR model as well as those hospitals located in 33 of the 67 MSAs a one-time option to choose whether to continue their participation in the model through December 31, 2020 (that is, continue their participation through PY5). The December 2017 final rule also finalized further technical refinements and clarifications for certain payment, reconciliation and quality provisions, and implemented a change to increase the pool of eligible clinicians that qualify as affiliated practitioners under the Advanced APM track. An interim final rule with comment period was also issued in conjunction with the December 2017 final rule (82 FR 57092) in order to address the need for a policy to provide some flexibility in the determination of episode costs for providers located in areas impacted by extreme and uncontrollable circumstances. This extreme and uncontrollable circumstances policy was adopted as final in the final rule (83 FR 26604) that appeared in the June 8, 2018 **Federal Register**, titled ''Medicare Program; Changes to the Comprehensive Care for Joint Replacement Payment Model (CJR): Extreme and Uncontrollable Circumstances Policy for the CJR Model.''

We issued the proposed rule, which appeared in the February 24, 2020 **Federal Register** (85 FR 10516), titled ''Medicare Program: Comprehensive Care for Joint Replacement Model Three-Year Extension and Changes to Episode Definition and Pricing'' (hereinafter referred to as the ''February 2020 proposed rule''). In addition, in the April 24, 2020 **Federal Register** (85 FR 22728), we published a document extending the public comment period of the February 2020 proposed rule for an additional 60 days (until June 23, 2020).

We issued an IFC, which appeared in the April 6, 2020 **Federal Register** (85 FR 19230), titled ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' (hereinafter referred to as the ''April 2020 IFC''). The April 2020 IFC (85 FR 19230) accounted for the impact of the COVID–19 public health emergency (PHE) on CJR participant hospitals. We extended PY5 through March 31, 2021 and adjusted the extreme and uncontrollable circumstances policy to account for the COVID–19 PHE by specifying that all episodes with a date of admission to the anchor hospitalization that is on or within 30 days before the date that the emergency period (as defined in section 1135(g) of the Act) begins or that occurs through the termination of the emergency period (as described in section 1135(e) of the Act); actual episode payments are capped at the target price determined for that episode under § 510.300.

Additionally, CMS issued a proposed rule, which appeared in the May 29, 2020 **Federal Register** (85 FR 32460) titled ''Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2021 Rates; Quality Reporting and Medicare and Medicaid Promotion Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals (hereinafter referred to as the ''FY 2021 IPPS/LTCH proposed rule''). In the FY 2021 IPPS/LTCH proposed rule (85 FR 32510), we solicited comment on the effect of the proposal to create new MS–DRG 521 and MS–DRG 522 on the CJR model and whether to incorporate MS–DRG 521 and MS–DRG 522, if finalized, into the CJR model's proposed extension to December 31, 2023.

We issued another IFC, which appeared in the November 6, 2020 **Federal Register** (85 FR 71142), titled ''Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' (hereinafter referred to as the ''November 2020 IFC''). In the November 2020 IFC, we implemented four changes to the CJR model. First, we extended PY5 an additional 6 months, so PY5 ends on September 30, 2021. Second, we made changes to the reconciliation process for PY5 to allow two subsets of PY5 to be reconciled separately. Third, we made a technical change to include MS–DRGs 521 and 522 in the CJR episode definition, retroactive to 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, we made changes to the extreme and uncontrollable circumstances policy for the COVID–19 PHE 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.

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

In response to the publication of the February 2020 proposed rule, we received approximately 66 timely pieces of correspondence. Contained within these 66 pieces of correspondence were approximately 810 discrete comments concerning 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. Additionally, we received many comments regarding our request for comment on new LEJR focused models that would include ASCs. These comments were from groups representing medical societies, hospital associations, hospitals, and medical centers. The remaining comments were from individual physicians and individual commenters.

We received several comments that were in general agreement with the proposed rule as well as several comments that were in general disagreement with the proposed rule. Summaries of these comments and our responses are discussed later in this section. Finally, we received several comments that are considered out of scope. Although comments that are out of the scope of this rule are not addressed with the policy responses in this final rule, we are taking each

comment into consideration and may address these comments in future rulemaking as warranted. Summaries of the public comments that are within the scope of the proposed rule and our responses to those public comments are set forth in the various sections of this final rule under the appropriate heading.

Comment: A commenter stated that the extension of the CJR model continues to raise concerns about CMS' authority to implement a mandatory model, contending that it is an unconstitutional delegation of legislative authority and unfairly targets one-fifth of hospitals and one type of procedure and medical specialty. Another commenter stated that after 5 years of mandatory participation in the CJR model, the extension provides CMS the opportunity to transition CJR to a voluntary model for PYs 6–8. The commenter contended that a mandatory requirement violates the Innovation Center's authority.

Response: For the reasons we discussed in the CJR model's November 2015 and the December 2017 final rules, we continue to believe that section 1115A of the Act and the Health and Human Services (HHS) Secretary's existing authority to operate the Medicare program authorize the CJR model, including an extension of its duration as well as its mandatory nature. Specifically, sections 1102 and 1871 of the Act give the Secretary the authority to implement regulations as necessary to administer Medicare, including testing these Medicare payment and service delivery models as was done in the November 2015 and the December 2017 final rules.

The extension we are finalizing in this final rule does not impose any permanent changes to the Medicare program; rather, as discussed elsewhere in this rule, we are extending the performance period of model test in order to evaluate the impact of changes to the model that address changes in program payment policy and national care delivery patterns. This authority also allows the Secretary to test different methods for delivering services under Medicare to determine the effectiveness of these methods. We disagree with the commenter that contended that PYs 6 to 8 should be voluntary and that mandatory participation in the extension violates the Innovation Center's authority. As outlined in the CJR model November 2015 final rule, we believe that both section 1115A of the Act and the Secretary's existing authority to operate the Medicare program authorize the CJR model extension as we have proposed and are finalizing in this final rule. Section 1115A of the Act authorizes the Secretary to test payment and service delivery models intended to reduce Medicare expenditures while preserving or enhancing quality. The 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. Under this authority, re-evaluation of policies and programs, as well as revisions through rulemaking, are within an agency's discretion. Accordingly, the agency has authority to modify a mandatory model, as was done in the December 2017 final rule.

As further discussed in section II.D.2. of this final rule, narrowing participation for hospitals in the 34 mandatory MSAs during the 3-year extension will allow CMS to minimize selection bias while evaluating the impact of the changes in this rule. Additionally, the cost to evaluate the small voluntary arm of the model for PYs 6 through 8 is costly relative to the information that would be gained from the small sample size. For these reasons, we decline to adopt the commenter's suggestion to make PYs 6 through 8 voluntary.

Comment: A commenter stated that there exists a significant administrative and management burden for providers associated with participating in multiple bundled payment initiatives simultaneously (for example, those that participate in both the BPCI Advanced model and CJR model at the same time). This commenter stated that managing multiple bundles across both models subjects participants to two different sets of financial specifications, reporting, and other measures, which is resource intensive. The commenter urged CMS to consider this burden by better aligning requirements for its various episode-based payment initiatives, including CJR and BPCI Advanced. They stated a possible solution to the administrative challenges of participating in both BPCI Advanced and CJR is to allow CJR participants the ability to participate in the lower joint Clinical Episode under BPCI Advanced rather than being required to participate in CJR.

Response: We acknowledge the commenter's suggestion to allow hospitals currently participating in both the CJR model and the BPCI Advanced model to participate in BPCI Advanced only going forward; however, we disagree that participation in both models at the same time creates too much burden on participant hospitals, because the CJR model consists of only one type of episode of care, LEJR. BPCI Advanced on the other hand has various types of clinical episodes, one of which is the Major Joint Replacement of the Lower Extremity (MJRLE). For practical purposes, LEJR and MJRLE are referring to the same type of episode composed of MS–DRGs 469 and 470. The BPCI Advanced Participation Agreement states that if a participant or, if applicable, a Downstream Episode Initiator (for example, an acute care hospital) is also participating in an Innovation Center model implemented via regulation, such as the CJR model, the participant will not be held accountable for any clinical episodes included in that model for purposes of BPCI Advanced. This means that any LEJR episodes that are triggered by a hospital participating in both BPCI Advanced and CJR models would be reconciled under the CJR model and not the BPCI Advanced model. This approach has helped reduce the risk of inconsistent requirements across the two initiatives, thereby reducing burden on participants participating in both initiatives.

CJR participant hospitals have had several years of experience with LEJR episodes focusing on quality and efficiency in the CJR model. CMS believes that participant hospital experience in the CJR model should alleviate issues with operational burden since CMS provides educational resources through the CJR Learning System and CJR Connect to assist CJR participant hospitals with managing operational processes. Moreover, CMS is committed to providing guidance regarding the changes made in this final rule relative to the previous CJR model requirements and will continue to provide educational resources during the extension for model participants.

Finally, we note that while the BPCI Advanced model and the CJR model differ in various ways, the broad goals of the models are the same: Improving quality of care while reducing overall costs during an episode of care. We believe it is reasonable for model participant hospitals in both models and Downstream Episode Initiators in the BPCI Advanced model to engage in care redesign strategies targeted at LEJR episodes, regardless of the model under which the LEJR episode is reconciled. As such, we are finalizing the extension under which certain CJR participant hospitals are required to continue to participate in the CJR model, even if they are concurrently participating in BPCI Advanced and accountable under BPCI Advanced for non-LEJR episodes.

Comment: Another commenter expressed support for proposed policies

that promote consistency across model years, support investment in quality of care, and reduce operational burdens for CJR participants. This commenter specifically stated that moving to one reconciliation period, retaining current quality measures and removing gainsharing caps under the CJR model will help minimize burden on hospitals participating in CJR and BPCI Advanced while increasing consistency between CJR and BPCI Advanced.

Response: CMS agrees with the commenter and believes that our efforts to decrease operational burden, such as moving to one reconciliation period, retaining current quality measures and, as we discuss in section II.G. of this rule, eliminating the 50 percent gainsharing cap will help to improve consistency between both models (CJR and BPCI Advanced).

Comment: Although several commenters expressed support for the model's increased focus on decreasing costs, MedPAC argued that the proposed changes do not go far enough to generate savings for the Medicare program after accounting for reconciliation payments to providers. MedPAC suggested that the model be expanded nationally to help improve cost savings and improve Medicare's sustainability. MedPAC stated that evidence shows these changes would generate more savings for the model if it was expanded nationwide to increase the number of participant hospitals.

Response: We appreciate this comment, but disagree that this model needs to be expanded nationwide for PY6 through PY8. Section 1115A(c) of the Act authorizes the HHS Secretary to expand a model, but only after taking into consideration the evaluation and after certain findings that CMS has not yet made. The model is still being evaluated for its ability to generate cost savings.

Comment: Multiple commenters expressed their support for CMS' efforts to incentivize coordinated care and improve APMs. The improvements mentioned in these comments range from improved cost savings, quality measures, and outcomes for Medicare beneficiaries. A large number of commenters discussed their support for these listed goals and many others stated it as the primary reason for supporting this final rule. Other commenters expressed the need to continue to improve these areas and other areas of healthcare delivery.

Response: We acknowledge and appreciate the commenters' remarks.

Comment: Although several commenters expressed support for the changes to the CJR model, they listed several recommendations for CMS to consider when developing models in the future. A few commenters listed that there should be an increased focus on cost savings in future models. Although no specific adjustments were suggested, the commenters believed that the Innovation Center should prioritize cost savings more to improve the long term sustainability of the Medicare program.

A significant portion of the commenters also discussed other areas of improvements for current and future models. Their suggestions included expanding the scope of the models to include services not just confined to services that are paid for by Medicare, allowing providers besides hospitals and physicians to lead models, and increasing financial incentives.

Response: We thank the commenters for taking the time to provide input on future models. As the Innovation Center continues to develop more models we are always willing to accept input from various sources.

A. Episode Definition

1. Background

The CJR model began on April 1, 2016. The CJR model is currently in its fifth performance year. The fifth performance year, which was extended to include all episodes ending on or after January 1, 2020 and on or before September 30, 2021, would necessarily incorporate episodes that began before January 1, 2020. As previously discussed in section I.C. of this final rule, the CJR model was created to bundle care for beneficiaries of Medicare Part A and Part B undergoing LEJR procedures, and in so doing, to decrease the cost and improve the quality of that care (80 FR 73274).

When the CJR model was initially established in the November 2015 final rule, the LEJR procedures on which the model is focused, specifically, those procedures for TKA, THA, and Total Ankle Replacement (TAR), were all listed on the IPO list. This meant that Medicare would only pay hospitals for these procedures when they were performed in the inpatient setting and billed through the Inpatient Prospective Payment System (IPPS). For this reason, CJR model episodes were defined to include inpatient procedures only. These TKA, THA, and TAR procedures all mapped to either Medicare Severity-Diagnosis Related Group (MS–DRG) 469 (Major Joint Replacement or Reattachment of Lower Extremity with Major Complications and/or Comorbidities (MCC)) or MS–DRG 470 (Major Joint Replacement or Reattachment of Lower Extremity without MCC). Subsequently, in acknowledgement of the fact that the data analysis performed demonstrated TAR procedures are almost always more complex and expensive to perform than TKAs or THAs, CMS finalized a policy in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38028 through 38029) to ensure that inpatient TAR procedures would always map to the higher severity MS–DRG 469 and made corresponding changes to the MS–DRG titles (MS–DRG 469 became Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement; MS–DRG 470 became Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC).

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58491 through 58502), CMS finalized two new MS–DRGs, 521 (Hip replacement with Principal Diagnosis of Hip Fracture, with MCC) and 522 (Hip replacement with Principal Diagnosis of Hip Fracture, without MCC) that encompassed a subset of hip replacement procedures that had previously mapped to MS–DRGs 469 and 470 regardless of whether or not a principal diagnosis of hip fracture was present. We modified the CJR model episode definition in the November 2020 IFC to include MS–DRGs 521 and 522, with discharges on or after October 1, 2020, in order to accommodate this change in MS–DRGs and ensure that the subset of hip replacement episodes that included a principal diagnosis of hip fracture was not dropped from the CJR model during PY 5.

When the TKA procedure described by Current Procedural Terminology (CPT) Code 27447 was removed from the IPO list in the CY 2018 OPPS final rule (82 FR 59382) effective January 1, 2018, Medicare beneficiaries undergoing outpatient TKA procedures were, by default, excluded from the CJR model. When the change to the IPO list to remove TKA procedures was proposed, CJR participant hospitals raised concerns that the less complex TKA cases would move to the outpatient setting and the remaining inpatient population would represent a more complex and costly case mix than the population used to calculate the target price. As such, many commenters on the proposed OPPS 2018 rule (82 FR 59384) expressed their concern that the target prices for the remaining inpatient CJR model episodes would be too low and would not reflect the shift in the inpatient patient population. While we noted the commenters' concerns, due to the lack of historical outpatient episode spending claims data on which to base a target price, we were not able to

recalculate target prices to reflect the movement of procedures from the inpatient to the outpatient setting at that time. We stated in the CY 2018 OPPS final rule with comment period (82 FR 59384) that we did not expect a significant volume of TKA cases that would previously have been performed in the hospital inpatient setting to shift to the hospital outpatient setting as a result of removing TKA from the IPO list. However, we also acknowledged that as providers' knowledge and experience in the delivery of hospital outpatient TKA treatment developed, there could be a greater migration of cases over time to the hospital outpatient setting. We further stated our intention to monitor the overall volume and intensity of TKA cases performed in the hospital outpatient department to determine whether any future refinements to the CJR model would be warranted.

As of May 2019, since TKAs had been performed in the outpatient setting for the full calendar year of 2018, we had 1 full year of national spending data (including time for claims run out) with which to assess the early impact of TKAs being offered to Medicare beneficiaries in the outpatient setting. Our analysis of this 2018 claims data showed that approximately 25 percent of TKAs were being performed in the outpatient setting, annually. These data also allowed us to explore spending differences between the least resource-intensive inpatient episodes and episodes based on an outpatient procedure. We used resource-intensity of inpatient episodes, as indicated by MS–DRG, as a proxy for identifying which patients may have been appropriate candidates for outpatient TKA, since the clinical information physicians use to make this judgment (for example, the patient's body mass index, smoking history, blood pressure among other clinical information) is not available on claims. Since we expected that the outpatient TKA procedures would only be performed on relatively healthy patients without complications or comorbidities and would have mapped to the MS–DRG 470 without hip fracture category had they been performed in the inpatient setting, we compared spending patterns between inpatient MS–DRG 470 without hip fracture episodes and outpatient TKA episodes (created using the same criteria as CJR model episodes, with the exception that they would have been triggered by the outpatient TKA [CPT code 27447]). Given that inpatient TKA procedures receive an MS–DRG payment while outpatient TKA procedures are paid at a lower rate as part of payment for the Ambulatory Payment Classification (APC) to which they are assigned, we removed the payments associated with the episode initiating MS–DRG and/or CPT code for TKA, specifically CPT code 27447, and focused on the remaining episode costs for any post-acute spending for these patients who we expected to be clinically similar. As we expected, post-acute spending patterns were highly similar between the inpatient MS–DRG 470/no fracture episodes and the outpatient TKA episodes, with average SNF costs of $9,229 and $9,252, and average home health costs of $3,070 and $3,074, respectively. Subsequent analysis of 2019 claims data showed similar results, with average SNF costs of $9,468 and $9,894, and average home health costs $3,060 and $3,029, respectively. This supported our belief that the outpatient TKA episodes were sufficiently comparable to MS–DRG 470/no fracture inpatient CJR model episodes that we should find a way to change the existing CJR model episode definition to encompass outpatient LEJR episodes as well as inpatient LEJR episodes.

2. Changes to Episode Definition To Include Outpatient TKA/THA

Given stakeholders' interest in opportunities to treat LEJR patients in the outpatient setting as part of a bundled payment model, we explored ways to integrate outpatient TKA into the CJR model, as well as THA, in light of the change in the CY 2020 OPPS/Ambulatory Surgical Center (ASC) final rule to remove THA from the IPO list (84 FR 61353). (We remind readers that the removal of any procedure from the IPO list does not mandate that all cases be performed on an outpatient basis. Rather, such removal allows for Medicare payment to be made to the hospital when the procedure is performed in the hospital outpatient department setting. The decision to admit a patient is a complex medical judgment that is made by the treating physician.)

However, in the case of TKA and THA, if we continued to exclude outpatient TKAs and outpatient THAs from the CJR model and did not allow CJR participant hospitals the incentive to coordinate and improve care for these outpatient episodes, it is possible that this policy decision could create an unintentional financial incentive to perform a proportion of these procedures in a more expensive inpatient setting than would otherwise be medically necessary, thereby increasing costs to the Medicare program. Continuing to exclude outpatient TKAs and outpatient THAs would also potentially reduce the generalizability of future results from the CJR model evaluation, as CJR participant hospitals would be less comparable to control group non-CJR participant hospitals that did not have the same incentive to keep TKA and THA episodes in the inpatient setting, rather than moving appropriate episodes into the outpatient setting. Therefore, to ensure that our evaluation findings are as robust and generalizable as possible, we aim to incorporate outpatient LEJR procedures in such a way that we do not incentivize participants to choose a setting based on financial considerations rather than a given patient's particular level of need.

One of CMS' recent goals has been to move toward site neutrality in pricing. For example, in the CY 2019 OPPS final rule (83 FR 58818) we finalized our policy to pay for clinic visits furnished at excepted off-campus provider-based hospital departments at an amount equal to the site-specific physician fee schedule payment rate for the clinic visit service furnished by a non-excepted off-campus provider-based hospital department. This goal was also reflected in the CY 2020 OPPS final rule (84 FR 61365), where we continued the 2-year phase-in of this site-neutral payment policy. Consistent with our goal for site neutrality, we do not want to create separate prices for inpatient and outpatient CJR model episodes. We also want to be consistent with the BPCI Advanced voluntary bundled payment model, which offers a site-neutral LEJR episode and began January 1, 2020. These considerations, in conjunction with our finding that post-acute care costs were markedly similar for inpatient short stay TKAs, identified as those DRG 470 claims with lengths of stay of 2 or fewer days, and outpatient TKAs, with much of the difference in overall episode prices accounted for by the MS–DRG payment for inpatient episodes versus the outpatient procedure rate paid through OPPS, supported our belief that we could create a site-neutral episode that would include both outpatient TKAs and the least complicated, short stay inpatient TKAs, which would group to the MS–DRG 470 without hip fracture category. However, given the remaining difference in post-acute spending, as well as the higher amount paid by Medicare for an inpatient procedure billed under the IPPS as opposed to an outpatient procedure billed under the OPPS, we recognize that simply providing the same target price for both

inpatient TKA episodes and outpatient TKA episodes, based on historical spending for the two episode types blended together, would mean that the single blended target price could potentially underestimate spending on some inpatient episodes and likewise, could potentially overestimate spending on some outpatient episodes. This would theoretically average out across all MS–DRG 470 without hip fracture episodes at the regional level during reconciliation, but given the fact that hospitals' ratio of inpatient-to-outpatient cases will vary, we believe an additional episode-specific risk adjustment to the target price is needed to account for beneficiary-specific factors other than the presence of a hip fracture. We discuss our proposal to risk adjust episodes in more detail in section II.C.4. of this final rule. We believe that our episode-specific risk adjustment methodology will incentivize clinicians to continue performing LEJR procedures in the appropriate clinical setting, particularly since performing these procedures on sicker patients in the outpatient setting could increase the risk of post-acute complications and lead to higher overall episode spending.

Therefore, beginning with our proposed PY6, we proposed to revise the definition of an episode of care in the CJR model to include permitted outpatient TKA/THA procedures. This revised definition would have applied to episodes initiated by an anchor procedure furnished on or after October 4, 2020, because the 90-day episode would end on or after January 1, 2021, which would have been the first day of PY6. We note that, due to the extension of PY5, the revised definition would now apply to episodes initiated by an anchor procedure furnished on or after July 4, 2021, because the 90-day episode would end on or after October 1, 2021. Further, we proposed to group the outpatient TKA procedures together with the MS–DRG 470 without hip fracture historical episodes in order to calculate a single, site-neutral target price for this category of episodes, given that spending on outpatient TKA episodes most closely resembles spending on MS–DRG 470 without hip fracture episodes. We proposed that prices for the other three categories (MS–DRG 469 with hip fracture, MS–DRG 469 without hip fracture, and MS–DRG 470 with hip fracture) would continue to be calculated based on historical inpatient episodes only (with the exception of outpatient THA with hip fracture, which we would expect to happen rarely if at all, as described in this section). Since MS–DRGs 521 and 522 were introduced after the proposed rule was published, and subsequently incorporated into the CJR episode definition in the November 2020 IFC, effective as of October 1, 2020, we note that the comparable groupings using the updated MS–DRGs are as follows: MS–DRG 469 without hip fracture is now MS–DRG 469, MS–DRG 469 with hip fracture is now MS–DRG 521, MS–DRG 470 without hip fracture is now MS–DRG 470, and MS–DRG 470 with hip fracture is now MS–DRG 522.

Since the proposal to remove THAs from the IPO list had recently been finalized at the time of our February 24, 2020 proposed rule, we also proposed to include outpatient THA procedures with MS–DRG 470 episodes in order to calculate a target price. Although we did not have Medicare claims data for outpatient THA at that time, as we did for outpatient TKA, we noted that the costs for TKA and THA tend to be similar, which is why the inpatient procedures are priced together in MS–DRGs 469 and 470. Outpatient THAs have been assigned to the same Comprehensive Ambulatory Payment System (C–APC) 5115 (Level 5 Musculoskeletal Procedure) as outpatient TKA (84 FR 61253). Since the display of the proposed rule, we were able to analyze episode spending for selected 2020 claims data for TKA and THA episodes performed in the hospital outpatient department. We examined average episode costs for episodes initiated between July 1 and September 30 of 2020. We chose the third quarter because volume better approximated pre-COVID–19 PHE levels than earlier quarters in 2020 when many outpatient TKA and THA procedures were suspended. Further, it was the most recent available quarter of data with completed 90-day episodes after allowing time for claims runout. We observed that average total costs for outpatient THA episodes ($14,925) and outpatient TKA episodes ($15,286) were quite similar.

Therefore, we believed that the site-neutral MS–DRG 470 price that we proposed to calculate (which would be based on a blend of inpatient TKA, inpatient THA, outpatient TKA, and outpatient THA episodes) would also be appropriate for outpatient THA episodes. However, in the case of THA, we would include any outpatient THA episodes without hip fractures in the MS–DRG 470 without hip fracture (now MS–DRG 470) episode pricing and we would include any outpatient THA episodes with hip fractures in the MS–DRG 470 with hip fracture (now MS–DRG 522) episode pricing. Compared to TKAs, which we would not expect to be performed on an outpatient basis in the presence of a hip fracture due to the added complexity of treating the hip fracture while performing the TKA, we believe that THAs with hip fractures would be somewhat more likely to be performed on an outpatient basis, since the THA could be treatment for the hip fracture. We note that most hip fracture cases involving a THA surgery typically present emergently and involve an inpatient admission, so we anticipate that few, if any, outpatient THA cases will involve hip fractures. However, we acknowledge the possibility that medical advances in the next 3 years could cause this to change. Therefore, we believe it is appropriate to separate outpatient THA into with and without hip fracture episodes that would be grouped into MS–DRG 522 and MS–DRG 470 episodes, respectively, because we expect that spending for outpatient THA with hip fracture and without hip fracture episodes would resemble spending for MS–DRG 522 and MS–DRG 470 episodes, respectively.

Given that we proposed that outpatient TKA and THA could initiate CJR model episodes, we similarly proposed that an outpatient TKA or THA, if furnished at a participant hospital during an ongoing 90-day CJR model episode, would cancel the ongoing episode and initiate a new episode. When an episode is cancelled, this means that the services associated with the cancelled episode continue to be paid under Medicare FFS, but the cancelled episode is not included in the annual reconciliation calculation. This is consistent with our current policy that inpatient hospitalizations for MS–DRGs 469, 470, 521, or 522 that occur at a participating hospital during an ongoing CJR model episode cancel the ongoing episode and initiate a new episode. We proposed to extend that policy to outpatient TKA and THA episodes.

In conclusion, an active CJR model episode initiated by a prior admission to an acute care hospital for DRG 469, 470, 521, or 522 would be cancelled, and a new CJR model episode would be initiated, if either an inpatient LEJR procedure or an outpatient TKA or THA were furnished to an eligible beneficiary at a participating hospital during the ongoing episode initiated by the first joint procedure hospitalization. Similarly, a CJR model episode initiated by a first anchor procedure (outpatient TKA or THA) would be cancelled, and a new CJR model episode would be initiated, if either an inpatient LEJR procedure or an outpatient TKA or THA were furnished to an eligible beneficiary at a participating hospital during the

ongoing episode initiated by the first anchor procedure.

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). TAR was among the procedures removed from the IPO list for CY 2021. This means that, as of January 2021, Medicare will pay each of the procedures included in the CJR model (TKA, THA, and TAR) when performed in an outpatient department of the hospital. Unlike THA and TKA, we do not expect that TAR will be widely performed in the hospital outpatient department. The procedure is much more complex than TKA or THA. In the absence of an MCC, both TKA and THA are typically paid through the less expensive MS–DRG 470, as discussed. However, Medicare always pays for TAR through the more expensive MS–DRG 469, in recognition of TAR's higher complexity and resource-intensity. We expect less complex patients to be eligible for treatment in the hospital outpatient department. Further, TAR is significantly less common than TKA and THA, comprising only 0.8 percent of all CJR episodes in 2020. For this reason, we are not incorporating outpatient TAR into the CJR episode definition. We will monitor data on TAR and consider future adjustments to the CJR episode definition, if warranted, through notice-and-comment rulemaking.

The following is a summary of the comments received and our responses.

Comment: Several commenters supported CMS' proposal to incorporate outpatient TKA and outpatient THA into the CJR model episode definition. A commenter stated they view this change as allowing the model to keep pace with the changing standards of care and clinical practices across the country. Multiple commenters stated that since CMS has authorized TKA and THA surgery to be performed in the outpatient hospital setting under the Medicare program, it is appropriate to include these procedures in the CJR model to encourage hospitals, physicians, and post-acute care providers to work together to improve the quality and coordination of care for patients in this setting. A commenter stated that they commended CMS for taking steps to align the CJR model with other value-based care initiatives, namely the BPCI Advanced model, which includes both inpatient and outpatient LEJR episodes. A commenter stated their agreement with our proposal to distinguish between outpatient THA cases with and without hip fracture, even though hip fracture cases involving THA surgery typically would involve an inpatient admission.

Response: We appreciate the commenters' support for our proposal to revise the CJR model episode definition to include outpatient TKA and THA. We agree that this change will encourage increased quality of care and care coordination across a wider range of treatment settings. We further appreciate that commenters supported our effort to better align the CJR model with BPCI Advanced, as well as our decision to distinguish between outpatient THA with and without hip fracture.

Comment: Multiple commenters recommended that CMS add a definition at § 510.2 to specify that for the CJR model purposes, ''outpatient setting'' means the hospital outpatient department (HOPD). These commenters pointed out that this would distinguish HOPDs from other alternatives to inpatient care, such as an ASC.

Response: We appreciate the commenters' suggestion, which we believe pertains to the definition of anchor procedure and its use of the term ''outpatient setting.'' We agree that the definition should be revised to clarify that by outpatient setting we mean a hospital outpatient department. We have made this change to the regulatory definition of ''anchor procedure'' at § 510.2.

Comment: A few commenters requested clarification as to how outpatient episodes and their associated costs will be identified. A commenter asked whether outpatient episodes would be identified based on the presence of CPT codes 27447 or 27130 on the claim. Another commenter noted that when a patient has outpatient surgery for joint replacement, they often spend a night in the hospital and are seen by other physicians, such as hospitalists, to manage medical issues. The commenter asked whether the services of these physicians, which would be billed to Part B using CPT codes 99201–99215, would be included in the bundle as costs. Another commenter requested clarification on whether the episode would begin on the day of surgery as reported on the claim form, and, given that the 3-day payment rule does not apply to outpatient procedures, whether any pre-operative services in the 3 days prior to surgery would be included in the episode.

Response: We appreciate the opportunity to provide clarifying details as to how outpatient TKA and THA episodes will be determined. Outpatient episodes will be identified by the presence of CPT codes 27447 (TKA) or 27130 (THA) on an outpatient claim (specifically, a hospital's institutional claim for an outpatient TKA or THA billed through the OPPS). The episode begins on the day of the anchor procedure, which will also be considered the discharge date, (that is, it would be considered day 1 of the 90-day post-acute portion of the episode).

In response to the commenter who referenced the 3-day payment rule (75 FR 50346), we note that this refers to the policy that states that a hospital (or an entity that is wholly owned or wholly operated by the hospital) must include on the claim for a beneficiary's inpatient stay, the diagnoses, procedures, and charges for all outpatient diagnostic services and admission-related outpatient non-diagnostic services that are furnished to the beneficiary during the 3-day (or 1-day) payment window. This means that such services are included under the MS–DRG payment, rather than billed separately, and in that way are reflected in the CJR model episode, even if they occur prior to the day of inpatient admission. We note that outpatient CJR model episodes will not have a comparable policy, so services provided prior to the day of the outpatient procedure will not be included in episode costs.

Our decision not to include a 3-day lookback for outpatient episodes is consistent with our decision in the November 2015 final rule to only include Part B claims for services on or after the date of admission in inpatient episode spending (80 FR 73315). Although we acknowledged at that time that there may be opportunities for care redesign and improved efficiency prior to the inpatient hospitalization, we stated our belief that these opportunities would be limited for an episode payment model focused on a surgical procedure and the associated recovery, as opposed to a different type of model that focused on decision-making and management of an underlying clinical condition itself (such as osteoarthritis). We also stated our belief that beginning the episode too far in advance of the LEJR surgery would make it difficult to avoid bundling unrelated items, and starting the episode prior to hospital admission would be more likely to encompass costs that vary widely among beneficiaries, which would make the episode more difficult to price appropriately (80 FR 73316).

However, since TKA was removed from the IPO list in 2018, we have discovered that the Part B claim for the surgeon's professional services is occasionally missing from CJR episode spending for inpatient episodes

associated with an inpatient TKA procedure. This was an extremely rare occurrence when all LEJR procedures were performed on an inpatient basis (0.2 percent of episodes in both PY1 and PY2), because the LEJR procedure would always be associated with an inpatient stay with a date of admission on or before the procedure itself, since it would not be paid for by Medicare if performed in the outpatient setting. Now that LEJR procedures can be performed on either an inpatient or outpatient basis, meaning that the LEJR procedure itself may or may not be associated with an inpatient stay, the decision of whether or not to admit the patient for an inpatient stay does not necessarily need to be made on the day of the procedure.

Since the removal of TKA from the IPO list, the frequency of CJR episodes (all of which, by definition, have been associated with an inpatient stay) that have been missing the surgeon's Part B professional claim has increased ten-fold (2.1 percent in PY3, and 2.8 percent in PY4). This omission has occurred because the date of the procedure was prior to the date of the inpatient admission. We believe that in most of these cases, the surgery is performed on an outpatient basis under the assumption that the patient will not require an inpatient admission, but the patient is subsequently determined to need more acute care and is admitted as an inpatient within 3 days. In such a case, the institutional charge for the procedure, which originally would have been billed through the OPPS, would instead be billed through the IPPS. Had the subsequent inpatient admission not occurred, the procedure would have been considered an outpatient procedure for purposes of the CJR episode definition, and it would not have triggered a CJR episode. However, as a result of the subsequent inpatient admission, the procedure would instead be associated with an institutional charge billed through the IPPS, and therefore would trigger a CJR episode even though the procedure itself predated the inpatient admission.

In the case of the subsequent inpatient admission after an outpatient LEJR procedure, most costs associated with the inpatient hospitalization would still be included in the MS–DRG payment due to the 3-day lookback period that already applies to inpatient hospitalizations, but the surgeon's professional claim (dated within 3 days prior to the date of admission in 98 percent of these cases), would not be included in CJR episode spending because it would be billed as a Part B professional claim with a date of service prior to the date of the inpatient admission. Given our clearly stated intention to include claims for Part B professional services on the date of the surgery, we are making a technical change to the services included in a CJR episode, which in PYs 6–8 will begin on the date of admission for episodes initiated by an inpatient hospitalization (that is, an anchor hospitalization) or the date of the procedure for episodes initiated by an outpatient procedure (that is, an anchor procedure). This change will only apply to episodes initiated by an inpatient anchor hospitalization that do not include a surgeon's Part B professional claim for the LEJR procedure itself because the procedure occurred prior to the inpatient admission date.

Beginning in PY6, in these cases only, we will perform a 3-day lookback to identify the surgeon's Part B professional claim and include it in episode spending. The episode start date will continue to be the date of admission on the IPPS claim associated with the anchor hospitalization that triggered the episode, rather than the procedure itself being treated as an anchor procedure and triggering the episode. To clarify the fact that the procedure would not be considered an anchor procedure in this situation, we have amended the definition of anchor hospitalization to specify that an anchor hospitalization would be initiated upon admission to an inpatient hospital stay within 3 days after an outpatient TKA or outpatient THA procedure and amended the definition of anchor procedure to specifically exclude such situations. The 3-day lookback policy for episodes triggered by an anchor hospitalization that are missing the surgeon's Part B professional claim will be specifically limited to the surgeon's Part B professional claim, such that no other claims during that 3-day period prior to the date of the inpatient admission will be pulled into the episode spending total. We have made this technical change to the regulation text at § 510.200(b)(15).

Comment: A commenter requested that we provide outpatient cost data to participant hospitals, as participant hospitals currently do not have access to the full cost of care for Medicare beneficiaries in the outpatient setting. They stated their belief that this information would help providers better understand beneficiaries' needs and how to meet those needs more cost effectively, whereas without the cost data, it would be difficult to understand the impact of the variable case mix on cost.

Response: We agree that as a result of the revised episode definition, participant hospitals will need additional data for episodes that are initiated in the outpatient setting to facilitate their success in the CJR model. We will provide participant hospitals with monthly claims data for outpatient episodes that are comparable to what they currently receive for inpatient episodes. They will have timely access to claims data across all treatment settings included in the episodes, which will allow them to better understand beneficiaries' needs and how to meet those needs in the most cost effective way while maintaining care quality.

Comment: Multiple commenters supported the proposal to create a site-neutral target price for inpatient and outpatient episodes. MedPAC stated that it supports adding LEJR procedures performed in outpatient hospital departments to the CJR model and setting site-neutral target prices for inpatient and outpatient episodes. MedPAC further stated that it agrees with CMS's proposal to base the target price for MS–DRG 470 without hip fracture on a blend of historic spending for outpatient TKA episodes, outpatient THA episodes without hip fracture, and inpatient episodes for MS–DRG 470 without hip fracture because of the cost similarity of these episodes. Another commenter stated their belief that the proposed addition of outpatient procedures as a blended, site-neutral payment adequately captures episodes that are triggered in hospital-based outpatient departments, and that the addition of hospital outpatient procedures to the CJR model will aid CMS in driving efficiency in these settings. Another commenter stated their support for including outpatient procedures in the CJR model because it decreases the incentive to perform these procedures in the inpatient setting unnecessarily on otherwise healthy patients who lack complications or comorbidities, particularly in light of the similar cost considerations for post-acute care for both inpatient and outpatient procedures.

Response: We appreciate the commenters' support for our creation of a site-neutral target price for inpatient and outpatient episodes.

Comment: A commenter stated that they support site neutral target prices, but stated that this support was contingent on the quality of the surgical care and medically necessary follow-up rehabilitation care being maintained. Another commenter similarly stated that they support site neutral target prices, but expressed concern about the potential for a site neutral inpatient/

outpatient target price to drive higher risk patients to the lower cost outpatient setting. This commenter stated their concern that hospitals would overrule the decision-making of the physician and patient as to the most appropriate setting for the patient's surgery, such that a patient who, based on the clinician's judgment and/or the patient's preference, should receive a TKA or THA on an inpatient basis would instead receive the procedure on an outpatient basis. They urged CMS to regularly analyze utilization data and monitor for significant shifts in procedure setting and/or negative outcomes, and make results from these analyses publicly available through peer-reviewed literature and CMMI model evaluation reports.

Response: We appreciate the commenters' support for our creation of a site-neutral target price for inpatient and outpatient episodes. We also acknowledge their concern about unintended consequences, where a provider might choose to steer certain patients to the outpatient setting when it is not in the best interest of, or is against the preferences of, the patient. We note that, since the IPO list was established in 2000, we have consistently stated that regardless of how a procedure is classified for purposes of payment, we expect that in every case the surgeon and the hospital will assess the risk of a procedure or service to the individual patient, taking site of service into account, and will act in that patient's best interest (65 FR 18456). We have reiterated this sentiment in rulemaking several times over the years, including the removal of TKA from the IPO list in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59383), removing THA from the IPO list in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61142), and most recently in phasing out the IPO list in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86083). The decision regarding the most appropriate care setting for a given surgical procedure is a complex medical judgment made by the physician based on the beneficiary's individual clinical needs and preferences and on the general coverage rules requiring that any procedure be reasonable and necessary (84 FR 61354). We expect hospitals to respect the decision of the physician and patient.

Additionally, as we stated in the February 2020 proposed rule, a provider who treats a patient in the outpatient setting when the inpatient setting would be more appropriate risks the patient developing complications and requiring costlier care to recover from those complications than would have been necessary if the patient's procedure had taken place in the more appropriate inpatient setting. Our episode-level risk adjustment (described in Section II.C.4) is designed to incentivize the provision of care in the appropriate setting, by increasing the episode target price for beneficiaries who are likely to require more resources and be costlier to treat, due to the complexity of their condition, and lowering the episode target price for beneficiaries who are likely to require a lower degree of care. We believe this methodology will greatly reduce the likelihood of a participant treating a beneficiary in a setting that is not concordant with the beneficiary's actual care needs.

Finally, we will continue the monitoring practices that we have had in place throughout the CJR model to identify patterns of inappropriate care, which includes monitoring the proportion of patients who are treated in the outpatient setting by CJR participant hospitals in comparison to non-CJR participant hospitals. If we see that certain hospitals are treating patients in the outpatient setting at a rate that is different from their peers and cannot be explained by aspects of the hospital's patient population such as average age, count of CMS–HCC conditions, and area-level socioeconomic factors, then we have multiple options for remediation as described in the November 2015 final rule, which include requiring the participant hospital to develop a corrective action plan and reducing or eliminating a participant hospital's reconciliation payment (§ 510.410(b)(2)). We will also continue to share changes in practice patterns and trends we identify through evaluation reports and other means.

Comment: Many commenters stated that they do not believe the episode definition should be changed at this point in time. They suggested either postponing the inclusion of outpatient episodes in the CJR model, or maintaining separate cost target categories for outpatient TKA and outpatient THA, rather than grouping them with DRG 470. A few commenters expressed their concern that the safety of outpatient TKA and outpatient THA has not been established, and that CMS does not have enough experience with these episodes to incorporate them into the CJR model.

Response: We acknowledge that, at the time that the February 2020 proposed rule was published, both TKA and THA had been removed from the IPO list relatively recently, and we appreciate the commenters' concerns about patient safety. However, the extension of PY5 through September 30, 2021 means that by the time outpatient TKA and outpatient THA episodes are incorporated into the CJR model, participant hospitals will have had just under 4 calendar years of experience with outpatient TKA and just under 2 calendar years of experience with outpatient THA. Prior to CMS' recommendation to postpone elective surgeries between March and April of 2020 due to COVID–19 PHE, the percentage of outpatient TKA episodes had been steadily increasing since outpatient TKA was removed from the IPO list as of January 2018. In February 2020, 43 percent of TKA procedures at CJR participant hospitals were performed in the outpatient setting. This suggests that hospitals had the experience of treating a substantial number of outpatient TKA patients during the two years prior to the temporary suspension of elective surgeries. The number of outpatient THA procedures beginning in January 2020 showed a similar pattern to outpatient TKA, suggesting that hospitals had a similar level of confidence in their ability to manage outpatient THA patients. After a steep decline in outpatient TKA/THA volume during the months of March and April of 2020, elective surgeries resumed in May and showed monthly volume increases through the summer of 2020, although we acknowledge that some hospitals have since chosen to postpone elective surgeries for varying periods of time due to local COVID–19 resurgences. Given the degree to which we expect outpatient TKA and outpatient THA to return to their previous volumes as a result of decreased COVID–19 hospitalizations and due to the national COVID–19 vaccination campaign currently underway, we believe that by the time PY6 begins and outpatient TKA and outpatient THA are incorporated into the CJR episode definition, hospitals will have had the opportunity to perform enough of these outpatient procedures to have gained considerable expertise in their outpatient episode management.

Regarding patient safety, we note that State and local regulations, accreditation requirements, hospital conditions of participation (CoPs), medical malpractice laws, and other CMS initiatives will continue to ensure the safety of beneficiaries receiving TKA or THA in both the inpatient and outpatient settings, so we believe that further delay is not necessary before incorporating outpatient TKA and THA into the CJR model episode definition.

In particular, the CoPs are regulations that are focused by statute almost exclusively on protecting the health and safety of all patients and are intended to be the baseline health and safety requirements on which hospitals, accreditation organizations, States and localities, and professional organizations can add and build upon with more specific and more stringent requirements. We note that the CoPs already require hospitals to be in compliance with applicable Federal laws related to the health and safety of patients (42 CFR 482.11). Additionally, there are numerous regulatory standards and provisions in the hospital CoPs at 42 CFR 482 that provide extensive patient safeguards and that provide enough room and flexibility so as to ensure that hospitals can follow nationally recognized standards of practice and of care where they are applicable and can adapt if those standards change over time through innovative new practices. We discussed these patient safeguards in more detail in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86084).

As indicated in the 2020 Quality Strategy, CMS has continued to develop safety measures and tools, like the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems Survey (OMB Control Number: 0938–1240), to help determine the safety and quality of the performance of procedures in the outpatient setting, to alleviate concerns about the safety and quality of more varied, complex procedures performed in the outpatient setting. Additionally, if a beneficiary communicates a concern about the quality of their care to the Medicare Beneficiary Ombudsman (MBO), that communication will be relayed to the beneficiary's CMS Regional Office and the CJR team for further investigation. The CJR team also regularly monitors episode claims data to identify patterns that suggest inappropriate practices on the part of a CJR participant hospital. Therefore, given CMS' developing ability to measure the safety of procedures performed in the outpatient setting and to monitor the quality of care, we do not believe a delay in incorporating outpatient TKA and THA into CJR is needed.

Comment: Multiple commenters stated their concern about introducing multiple changes to the CJR model at this time, in light of the COVID–19 PHE. They stated that the introduction of outpatient episodes with a blended inpatient/outpatient target price and new risk adjustment methodology was too much change for participant hospitals to adapt to while they are still dealing with the impacts of the COVID–19 PHE.

Response: We appreciate the commenters' concerns, and we recognize that the COVID–19 PHE has created many challenges for participant hospitals and the healthcare system as a whole. In order to support continuity of model operations and ensure that participants would not unfairly suffer financial consequences of the COVID–19 PHE due to their participation in the CJR model, we first extended PY5 by 3 months in the April 2020 IFC. Many commenters on the April 2020 IFC requested that PY5 be further extended, for a total of a 12-month extension. In the November 2020 IFC we extended PY5 by an additional 6 months for a total extension of 9 months. Although not the full 12-month extension that commenters requested, we believe that this 9-month extension will provide participant hospitals adequate time to adapt to both the COVID–19 PHE and TKA/THAs being removed from the IPO list. We reiterate that the extension of PY5 through September 30, 2021 means that by the time outpatient TKA and outpatient THA episodes are incorporated into the CJR model, participant hospitals will have had just under four calendar years of experience with outpatient TKA and just under 2 calendar years of experience with outpatient THA. As stated previously, we expect outpatient TKA and outpatient THA to return to previous volumes as a result of decreased COVID–19 hospitalizations and due to the national COVID–19 vaccination campaign currently underway by the time PY6 begins and outpatient TKA and outpatient THA are incorporated into the CJR episode definition. In February of 2020, there were approximately 13,000 TKA and 5,500 THA performed in the outpatient setting. Although the number decreased dramatically in March 2020, by June 2020 the frequency of outpatient TKA had nearly returned to pre-COVID 19 PHE levels and outpatient THA exceeded previous levels, with approximately 11,500 TKA and 6,500 THA performed in the outpatient setting that month. Therefore we believe that hospitals will have had the opportunity to perform enough of these outpatient procedures to have gained considerable expertise in their outpatient episode management and they will be able to adapt to the changes to the CJR model when they are introduced for PY6.

Comment: A commenter stated that, while they understood that CMS cited its primary reason for the extension was to test the impact of Medicare paying for TKA and THA in the hospital outpatient setting, there are a number of factors that would prove problematic for testing that episode under the CJR model. For example, they stated their belief that it would be difficult, if not impossible, to generalize any future findings from the CJR model that occur over the next several years, as these evaluation results would be confounded by the impact of the COVID–19 PHE.

Response: We acknowledge the commenter's concern about the generalizability of results due to the COVID–19 PHE. However, given the extension of PY5 through September 30, 2021 and the expectation that COVID–19's impact on participant hospitals will be greatly mitigated by an aggressive COVID–19 vaccination initiative through the first 3 quarters of 2021, we believe that the experience of CJR participant hospitals under the modified methodology will largely reflect the post-COVID–19 realities of the healthcare system that will continue for the foreseeable future. Therefore we believe that the results will be sufficiently generalizable to test the impact of CJR methodology on outpatient TKA and outpatient THA episodes.

Comment: Multiple commenters suggested that CMS create separate cost target categories for outpatient TKA and outpatient THA in the CJR model due to their assertion that the episode-level risk adjustment methodology would not sufficiently mitigate the cost differential between inpatient and outpatient episodes. They pointed out that patients who fall into a low risk category may prefer to be treated in the inpatient setting for a variety of reasons that are not captured in the risk adjustment. Other commenters stated their concern that some hospitals may be disadvantaged by a blended target price due to factors beyond the hospital's control, which are not accounted for in the risk adjustment methodology. A commenter pointed out that, while the number of TKAs and THAs performed in the outpatient setting has increased overall, the increase varies widely across hospitals, driven by a number of factors including beneficiary demographics and prevalence of comorbidities in the local market, surgeon experience and preferences, the capabilities of hospitals of various sizes, the availability of multidisciplinary care coordination and discharge planning teams, the types of post-acute care resources present within a region, population dispersion, and rurality within a hospital's referral region.

Response: We acknowledge the commenters' concerns, but we note that

the episode level risk adjustment methodology is designed specifically to address the concern that some hospitals may perform a higher percentage of inpatient episodes due to the age, health, and socioeconomic status of the surrounding patient population. For instance, if the patient population for a given participant hospital tends to be older than that of other participant hospitals, the episode level risk adjustment would adjust the target price upward (assuming the risk adjustment coefficient were greater than 1), such that a participant hospital with an older population would have a greater increase in their aggregate target price due to risk adjustment than would a participant hospital with a younger population. We further note that, although we originally did not propose to include a variable related to socioeconomic status, in response to comments and our subsequent analyses, we are including dual-eligibility in the final risk adjustment methodology as a proxy for socioeconomic status, along with the previously proposed age group and CJR HCC count (described in section II.C.4 of this final rule). Participant hospitals that treat an older, sicker, or socioeconomically disadvantaged population will have their episode target prices adjusted upwards accordingly. Our decision to remove rural and low-volume hospitals from the extension will also reduce the variation between the remaining participant hospitals in PY6–8 in terms of size, population dispersion, and rurality within participant hospitals' referral regions.

Comment: A few commenters stated concerns related to the calculations underlying our proposed changes to the target price calculation methodology and the information we provided in the proposed rule to allow commenters to understand and comment on our proposed methodology. A commenter stated their concern that CMS did not provide further information about how we analyzed the impact of the mix of inpatient versus outpatient procedures on site-neutral pricing. This commenter also stated their belief that CMS's proposal to revise the existing MS–DRG 470 without hip fracture pricing category to include both outpatient TKA and outpatient THA appeared to be based on limited data and simulated cost comparisons, and that CMS did not provide an adequate description of the methodology or access to data for independent analysis. Another commenter stated that, due to the fact that MS–DRG weights are calculated using data with a 2-year lag, the current MS–DRG 470 payment is based on costs for an overall healthier pool of patients, because healthier patients had not yet begun shifting to the outpatient setting at that time. This commenter stated their belief that the payment for MS–DRG 470 was therefore inadequate and should not be used as the basis for target prices in a mandatory model.

Response: We disagree with commenters who stated that the analyses underlying our decision to calculate a blended inpatient/outpatient target price were insufficient due to the use of simulated episode data. Although we acknowledge that actual episode data are preferable, we believe that multiple aspects of our target price methodology (for example, the use of the most recent 1 year of baseline data, risk adjustment, and the retrospective market trend adjustment) will allow for the adjustment of target prices to the extent that data from actual outpatient episodes (with TKA beginning in 2018 and THA beginning in 2020) differ from the simulated episode data we used to design the methodology. We built this flexibility into the target price methodology specifically to address the fact that patterns of care and spending can evolve over time. We note that we did not calculate a specific factor to determine the impact of site on the target price, because outpatient episodes constituted a relatively small percentage of all TKA/THAs at the time we performed our analyses, and we could not assume that such a factor would give a meaningful estimate of the impact of site on the target price over time. We further note that we have updated our analyses using 2019 claims data, which include a full year of actual outpatient TKA episodes, and the results have been consistent with those we reported based on simulated episodes from previous years (see Tables 3a and 4a in section II.C.4 of this final rule). For more specific data on the blended target price, we point commenters to Table 2a of this final rule in section II.B.2. of this final rule for preliminary regional target prices for PY6. We acknowledge that changes to the Medicare policies determining payment for TKAs/THAs have resulted in shifts in site of service that could impact the cost of episodes, but we point out that the change from using 3 years of data to 1 year of data as a baseline for target prices and our retrospective market trend adjustment are both designed to allow target prices to better reflect changes in both practice patterns and Medicare payment systems. Finally, we note that the fact that we received substantive comments on the blended target price methodology from the majority of commenters on this topic indicates that we provided an adequate level of information to enable providers to evaluate the methodology. Therefore we believe that we described our data analyses adequately and that our use of simulated episode data, with results later confirmed by analyses of actual episode data, was an appropriate basis for our decision to calculate a blended target price.

Comment: Multiple commenters requested that CMS issue a standard set of criteria to help participants determine which patients are suitable candidates for outpatient surgery. A commenter stated his or her belief that, taking into consideration the proper patient assignment and providers' clinical judgment, it would be beneficial to many CJR participant hospitals if CMS provided directional criteria for outpatient THA/TKA versus inpatient total joint replacements. They stated that a standard set of criteria would benefit many hospitals when it comes to the clinical pathways adoption rate. Other commenters pointed to the October 2018 ''Position Statement on Outpatient Joint Replacement,'' jointly issued by the American Association of Hip and Knee Surgeons (AAHKS), the American Academy of Orthopaedic Surgeons (AAOS), The Hip Society, and The Knee Society, which includes recommendations for outpatient hip and knee arthroplasty procedures to guide hospitals, surgeons, and institutions in appropriate and safe patient care. These commenters urged CMS to work with these societies to operationalize their recommendations. Another commenter provided a list of medical and psychosocial exclusion criteria that the commenter believes should be applied to outpatient TKA and THA episodes. A commenter suggested that CMS could provide guidance on predictive tools to inform discharge planning to facilitate surgeon/hospital establishment of patient risk profiles. Another commenter requested detailed guidance on the application of the 2-midnight rule to TKA and THA procedures.

Response: We acknowledge these commenters' request, but we note that CMS does not make clinical recommendations for care. We believe that the treating clinician, in partnership with the patient, is best suited to make the judgment of the appropriate clinical setting. Other government agencies, such as the Agency for Healthcare Research and Quality (AHRQ), or professional societies may provide resources to help guide clinical decisions. For guidance on the application of the 2-midnight rule to TKA and THA procedures we

refer commenters to the CY 2020 OPPS/ASC rule (84 FR 61363 through 61365).

Final Decision: After consideration of the public comments received, we are finalizing our proposal to include outpatient TKA and THA in the CJR model episode definition with a blended inpatient/outpatient target price. (The methodology for calculating this blended target price is discussed in section II.B. of this final rule.)

3. Freezing Hip Fracture List and Episode Exclusions List

In the November 2015 final rule we finalized our proposal to establish a sub-regulatory process to update both the hip fracture list (indicating the International Classification of Diseases, 9th Revision, Clinical Modification (ICD–9–CM) and ICD–10–CM codes that would designate a hip fracture for purposes of risk adjustment in the baseline period and performance period, respectively (80 FR 73544) and the episode exclusions list (indicating which services would be considered unrelated to the episode, and therefore excluded from episode spending totals in both the baseline period and performance period) (80 FR 73305). At that time, Medicare had recently transitioned from the use of ICD–9–CM codes to ICD–10–CM codes (as of October 2015), and the ICD–10–CM code list was being expanded on an annual basis. For this reason, we finalized our proposal to update both the hip fracture list and the exclusions list without rulemaking on at least a yearly basis to reflect annual changes to ICD–CM coding, annual changes to the MS–DRGs under the IPPS, and any other issues that were brought to our attention by the public throughout the course of the model test (80 FR 73305). Our first set of revisions, applicable as of October 1, 2016, added 40 additional codes within the M84 category to the original 1,152 codes on the hip fracture list and 60 additional code categories to the original 574 code categories on the episode exclusions list.

Now that Medicare has used the ICD–10–CM coding system for over five years, the rate of annual coding changes has stabilized, which has resulted in fewer, if any, changes to either the hip fracture or episode exclusions list in recent years of the CJR model. For FY 2018, the hip fracture list remained unchanged, while 28 categories were added to the episode exclusions list. For FY 2019, we did not identify any changes to the ICD–10–CM codes that would impact the hip fracture list or episode exclusions list, so they were not updated. We note that the introduction of the new MS–DRGs 521 and 522 is a different way for the IPPS grouper to assign an MS–DRG weight to a subset of existing ICD–10–CM codes to reflect a differential in the cost of the associated hospitalization, as opposed to a new category of ICD–10–CM codes that would be considered for the exclusions list. The new MS–DRGs will also mean that the hip fracture list will become irrelevant in most cases, as episodes with hip fracture will be identified by the MS–DRG rather than primary ICD–10–CM code associated with the MS–DRG. (Although the hip fracture list would be used to identify a hip fracture in the case of an outpatient THA, we expect that THA in the presence of a hip fracture will almost always be performed in the inpatient setting.) Given the relative stability of the ICD–10–CM code set used to determine hip fractures and exclusions, we proposed to discontinue our annual sub-regulatory process to update the hip fracture list and episode exclusions list. We sought comment on our proposal and whether there are any circumstances in which updates may still be needed.

Comment: A commenter did not oppose CMS' proposal to freeze the hip fracture and exclusions list.

Response: We appreciate the comment. We note that we did not receive any comments opposing our proposal to freeze the hip fracture and exclusions list.

Final Decision: After consideration of the public comments received, we are finalizing our proposal to freeze the hip fracture list and episode exclusions list.

B. Target Price Calculation

1. Background

Currently in the CJR model, 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. More specifically, we finalized in the November 2015 final rule (80 FR 73338) the method for establishing episode target prices based on 3 years of standardized historical episode spending. This historical spending is updated by trending forward the older 2 years of historical data to the most recent of the 3 years being used to set target prices (80 FR 73342). We calculate and apply different national trend factors for each combination of anchor MS–DRG (469 vs. 470) and hip fracture status (with hip fracture vs. without hip fracture). While the CJR model began with a blend of regional (''region'' defined as one of the nine U.S. Census divisions [5]) and hospital-specific spending for PYs 1 through 3, episode target prices were based on 100 percent regional spending beginning in PY4. Under current regulations, high episode spending is capped at 2 standard deviations above the mean regional episode payment, and target prices are trended forward at reconciliation to represent performance period dollars. To increase historical CJR model episode volume and set more stable target prices, CJR model episodes are pooled together and anchored by MS–DRGs 469 and 470 (80 FR 73352) factors calculated at the regional- and hospital-specific levels. Target prices are then prospectively updated to account for ongoing Medicare payment system updates (that is, Inpatient Rehabilitation Facility Prospective Payment System (IRF PPS), Physician Fee Schedule (PFS), IPPS, OPPS, and SNF PPS) to the historical episode data (80 FR 73342). Medicare payment systems do not update their rates at the same time during the year. For example, the IPPS, the IRF PPS, and the SNF PPS apply annual updates to their rates effective October 1, while the hospital OPPS and Medicare PFS apply annual updates effective January 1. To ensure we appropriately account for the different Medicare payment system updates that go into effect on January 1 and October 1, we finalized a policy to update historical episode payments for Medicare payment system updates and calculate target prices separately for episodes initiated between January 1 and September 30 versus October 1 and December 31 of each performance year. After target prices are updated for these system updates, local wage factors are used to convert standardized prices back to actual prices, and a 3 percent discount is applied to represent Medicare savings.

2. Overview of Changes to Target Price Calculation

Since the CJR model was implemented in 2016, both TKA and THA have been removed from the IPO

[5] There are four census regions—Northeast, Midwest, South, and West. Each of the four census regions is divided into two or more ''census divisions.'' Source: *https://www.census.gov/geo/reference/gtc/gtc_census_divreg.html.* Accessed on September 27, 2019.

list, as discussed in section II.A. of this final rule. In addition, there have been several other Medicare payment policy changes, such as changes to the SNF payment system to move from Resource Utilization Groups (RUGs) to the Patient Driven Payment Model (PDPM). Additionally, as noted in Table 2 in this final rule, national expenditures for LEJR procedures and associated post-acute care services have been decreasing since 2016. While average episode payments declined for both the CJR model and control group episodes during the first 2 performance years of the model, payments declined more for the CJR model episodes. Average episode payments decreased by $997 more for the CJR model episodes than for control group episodes from the baseline to the intervention period ($p<0.01$). This relative reduction equates to a 3.7 percent decrease in average episode payments for the CJR model episodes from the baseline.[6]

Trend data now shows that the decrease in national expenditures observed by the CJR model evaluation for the CJR participant hospitals and non-CJR participant hospitals for the first 2 years of the model actually began prior to the implementation of the CJR model and has continued consistently post 2016. This improved efficiency can be seen through shorter hospital stays and lower SNF usage. Table 1 shows the summarized Medicare claims data for LEJR per episode spending outside of the CJR model.

TABLE 1: AVERAGE LEJR SPENDING OUTSIDE OF THE CJR MODEL FROM MEDICARE CLAIMS DATA

Program Year	Average Cost Per Episode	Cost Trend
2014	$26,444	
2015	$26,006	−1.7%
2016	$24,925	−4.2%
2017	$24,352	−2.3%

Excluding CJR participant hospitals, national per episode costs for hip and knee replacement procedures calculated using Medicare claims data dropped by about eight percent from 2014 to 2017, largely due to reductions in the utilization of post-acute services. In analyzing Medicare claims data from the CMS Integrated Data Repository (IDR) as of April 2019, we constructed CJR model episode costs for all IPPS providers and looked at average per episode spending by region for 2016, 2017, and 2018. While per episode costs generally decreased for all regions between 2016 and 2018, most regions had a slight increase in episode spending between 2017 and 2018, as shown in Table 2.

TABLE 2: AVERAGE PER EPISODE SPENDING FOR MS-DRG 469 and MS-DRG 470 EPISODES IN 2016, 2017 AND 2018 (Includes All IPPS Hospitals, Not Just CJR Participant Hospitals)

Region	2016 Average Standardized Price Per Episode	2017 Average Standardized Price Per Episode	2018 Average Standardized Price Per Episode	Percent Change in Per Episode Price 2016 to 2017	Percent Change in Per Episode Price 2017 to 2018	Percent Change in Per Episode Price 2016 to 2018
New England	$23,627	$22,770	$22,525	-3.6%	-1.1%	-4.7%
Middle Atlantic	$23,971	$22,889	$22,922	-4.5%	0.1%	-4.4%
East North Central	$22,856	$21,968	$22,155	-3.9%	0.9%	-3.1%
West North Central	$22,280	$21,524	$21,692	-3.4%	0.8%	-2.6%
South Atlantic	$22,859	$22,029	$22,275	-3.6%	1.1%	-2.6%
East South Central	$23,649	$23,262	$23,105	-1.6%	-0.7%	-2.3%
West South Central	$25,037	$24,354	$24,649	-2.7%	1.2%	-1.5%
Mountain	$21,766	$20,954	$21,151	-3.7%	0.9%	-2.8%
Pacific	$22,158	$21,487	$21,891	-3.0%	1.9%	-1.2%
National	**$23,118**	**$22,316**	**$22,482**	**-3.5%**	**0.7%**	**-2.8%**

Although the CJR model target price methodology currently includes a DRG/hip fracture specific national trend update factor and twice yearly updates for changes in the Medicare prospective payment systems and fee schedules,

[6] See pg. 3 of the CJR Second Annual Report available on: *https://innovation.cms.gov/Files/reports/cjr-secondannrpt.pdf*

those updates do not capture shifts in spending between the target price and the model performance year and consequently, the current target prices have not accounted for nationwide reductions in LEJR spending from shifting care settings and more efficient care delivery. Therefore, we proposed to change the target price update methodology to use region/MS–DRG/hip fracture specific retrospective trend adjustments to ensure that target prices better capture spending trends and changes. We note that in considering proposed changes to the target price structure for the CJR model, we did consider an option of setting prices at the national, rather than regional level. While we did not elect to model this proposal and instead proposed to continue the regional pricing approach, we sought comment on the appropriateness of moving to national pricing approach in future years of the CJR model with the goal of removing price variation due to differences in regional care delivery patterns.

CJR model target prices are set based on 3 years of baseline data, with the 3-year baseline data updated every other year. When this policy was established we were concerned that we would not have enough claim volume in 1 or 2 years of data to set reasonably accurate hospital-specific prices, especially for smaller hospitals. Our proposed approach to target price calculation differs from the current approach as it involves setting target prices based on 1 year (the most recently available year) of baseline claims data. The baseline claims data used to establish target prices would be updated each year.

We proposed this change because our initial concern of insufficient episode volume stemmed from the fact that we incorporated hospital-specific pricing for the first 3 years of the CJR model. At this point in time, that concern has been mitigated as the baseline data used for target price calculations has moved from a blend of regional and historical baseline data (PYs 1 through 3) to 100 percent regional pricing (PYs 4 and 5). Additionally, since we proposed to include outpatient TKA/THA procedures as well as inpatient admissions for MS–DRG 469 or 470 in the CJR model episode definition (which as of October 1, 2020 has also included MS–DRG 521 and 522), we have determined that the most recently available 1 year of data will in fact be a more appropriate baseline period on which to set target prices as it contains both inpatient and outpatient LEJR claims.

As described in section II.C.6 of this final rule, a trend factor adjustment applied during reconciliation would account for shifts in the trend of national per episode spending. To the extent that the trend, which is the percent difference between 2 years of data, decreases (as illustrated in Table 2 for 2016 relative to 2018), target prices would decrease. However, if the percent difference shows an increase (as illustrated in Table 2 for 2017 relative to 2018), target prices would increase. Using 1 year of data (rather than 3) removes the need for the national trend update factor we previously used to trend forward the older 2 years of historical data to the most recent of the 3 being used to set target prices (80 FR 73342); we therefore proposed to remove the national trend update factor. We also proposed not to update the target prices twice a year for changes to Medicare Prospective Payment Systems and Fee Schedules, as we believe the new reconciliation trend factor adjustment we proposed would capture any payment changes in addition to any spending trend shifts.

Acknowledging the proposed episode definition changes described in section II.A.2 of this final rule, for the purpose of calculating CJR model episode target prices for PY6 through 8 we proposed that Part A and B Medicare claims data for beneficiaries with CJR model episodes (that is, beneficiaries with a claim for an MS–DRG 470, 469, 522 or 521 or a permitted outpatient TKA/THA procedure billed by a CJR participant hospital) would be grouped into one of the following types of CJR model episodes:

- MS–DRG 470 with hip fracture (now MS–DRG 522), which would include outpatient THA episodes with hip fracture.
- MS–DRG 470 without hip fracture (now MS–DRG 470), which would include outpatient TKA episodes and outpatient THA episodes without hip fracture.
- MS–DRG 469 with hip fracture (now MS–DRG 521).
- MS–DRG 469 without hip fracture (now MS–DRG 469).

We note that, due to the addition of MS–DRGs 521 and 522 to the CJR episode definition, we will make the following adjustment to the baseline episodes used to calculate target prices for PY6 only, because that will be the only year when the baseline data (2019) will not include the new MS–DRGs, while the performance year data will include the new MS–DRGs. For PY6 only, since target prices will be based on the original MS–DRGs but apply to performance period episodes with the new MS–DRGs, we will adjust the IPPS payment in baseline episodes with hip fracture, multiplying the baseline IPPS payment by the ratio of the new MS–DRG weights for 521 and 522 in the performance period to the MS–DRG weights for 469 and 470 in the baseline period, which will result in target prices that more accurately reflect the methodology we proposed in the February 2020 proposed rule. Our methodology assumed that the IPPS portion of TKA and THA episodes would differ only by the presence or absence of MCC, regardless of hip fracture status. That is, although we calculated target prices separately for episodes with and without hip fracture due to higher post-acute care costs for episodes with a hip fracture, the IPPS payment for MS–DRG 469 with and without hip fracture was based on a single MS–DRG weight, as was the IPPS payment for MS–DRG 470 with and without hip fracture. The introduction of separate MS–DRGs based on hip fracture status means that IPPS payments for TKA and THA episodes, which would have reflected one of two different MS–DRG weights based on MCC in the baseline, would reflect one of four different MS–DRG weights based on both MCC and hip fracture status in the performance period. For instance, in FY 2019, the weight assigned to MS–DRG 470, which included both hip fracture and non-hip fracture episodes without MCC, was 1.9898 (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FY2019-CMS-1694-FR-Table-5.zip*). In FY 2021, the year that MS–DRGs 521 and 522 became effective, the weight assigned to MS–DRG 470, which only included non-hip fracture episodes without MCC, was 1.8999, while the weight assigned to MS–DRG 522, which only included hip fracture episodes without MCC, was 2.1891 (*https://www.cms.gov/files/zip/fy-2021-ipps-fr-table-5.zip*). As we expect that FY 2022 weights for these MS–DRGs will similarly reflect greater resource utilization associated with MS–DRG 522 as compared to MS–DRG 470, using 2019 data without adjusting for the change in the MS–DRG weights could potentially cause us to overestimate the cost of appropriate care for MS–DRG 470 episodes and underestimate the cost of appropriate care for MS–DRG 522 episodes during the performance period. By overestimating or underestimating target prices in this way, we could inadvertently reduce savings for Medicare when the target price was overestimated and incentivize stinting of care when the target price was underestimated. Post-acute spending for

these episodes will be subject to the market trend factor. For PY7 through 8 target prices, both the baseline and performance period will include MS–DRG 521 and 522, so the MS–DRG adjustment will no longer be necessary, and all costs for all episodes will be subject to the market trend factor.

To then calculate target prices for PYs 6 through 8, baseline episodes would be stratified into the applicable nine geographic regions, where regional assignment for a given episode would be based on the region to which the MSA for the hospital maps under the CJR model. This would result in 36 separate episode groups, as there would be one group for each region, and MS–DRG. Within each of the 36 groups, we would then array the episode costs, and, consistent with our proposed new methodology for deriving the high episode spending cap amount, we would cap episode costs at the 99th percentile amount within each region/MS–DRG combination. We note that the proposed methodology of capping high episode spending at the 99th percentile would replace the current high episode spending cap methodology, which sets the cap at 2 standard deviations above the mean regional episode payment. We would then calculate the mean episode cost within each group of capped episodes, resulting in 36 average regional target prices. Starting in PY6, at the beginning of each performance year, these average regional target prices would be posted on the CJR model website.

Finally, we note that we proposed to remove the use of an anchor factor and regional- and hospital-specific anchor weights from the target price calculation that we established in the original November 2015 final rule (80 FR 73273). We originally included this step in the target price calculation to set more stable target prices using a greater volume of CJR model episode data, which was more of a concern when the model began due to the hospital-specific pricing component in PY1 to PY3. During PY1 through PY3, CJR model episodes anchored by MS–DRGs 469 and 470 were pooled together during target price calculations to have a greater historical CJR model episode volume and set more stable target prices, noting that the hospital-specific pooled calculations are later ''unpooled.'' Specifically, we set the MS–DRG 470 anchored episode target price equal to the target price resulting from the pooled calculations. We then multiplied that MS–DRG 470 target price by the anchor factor to produce the MS–DRG 469 anchored target prices. The calculation of the hospital weights and the hospital-specific pooled historical average episode payments is comparable to how case mix indices are used to generate case mix-adjusted Medicare payments. The hospital weight essentially counts each MS–DRG 469 triggered episode as more than one episode (assuming MS–DRG 469 anchored episodes have higher average payments than MS–DRG 470 anchored episodes) so that the pooled historical average episode payment, and subsequently the target price, is not skewed by the hospital's relative breakdown of MS–DRG 469 versus MS–DRG 470 anchored historical episodes. However, since PY4 and PY5 use only regional episode spending data to calculate target prices, and since we proposed for PYs 6 through 8 to continue to use only regional episode spending data to calculate target prices and to utilize only the most recently available year of episode data for target price calculations, we do not believe volume issues will be a concern and thus we do not believe it is necessary to continue to perform these steps. Therefore, we proposed to no longer use the regional and hospital anchor weighting steps from the original CJR model target price calculation methodology.

At the time the proposed rule was published, CMS did not have the necessary data (for example, outpatient data) to calculate and provide sample target prices reflecting the proposed changes to the target price methodology. However, we are including a sample of these target prices for PY6 in Table 2a in this final rule. While these target prices reflect the target price methodology changes described in this section, they will not be the exact target prices used for PY6. As stated in section II.B.2 of this final rule, we will post official PY6 target prices on the CMS website in June 2021. The target prices described in Table 2a of this final rule are meant to serve as an example; we will update the 2019 baseline data again before calculating the official PY6 target prices to ensure completeness of the 2019 data.

TABLE 2a: SAMPLE CJR MODEL TARGET PRICES FOR PERFORMANCE YEAR 6*

CJR Model Region	MS-DRG 469/521 With Fracture	MS-DRG 469 No Fracture	MS-DRG 522/470 With Fracture	MS-DRG 470 No Fracture
1	$47,819	$34,516	$33,694	$18,116
2	$50,173	$32,856	$35,903	$18,418
3	$46,744	$31,508	$34,086	$17,152
4	$45,193	$31,275	$34,238	$17,097
5	$47,519	$31,900	$33,999	$17,241
6	$47,180	$32,953	$33,877	$17,466
7	$52,137	$33,989	$38,471	$18,695
8	$46,127	$28,806	$33,304	$16,557
9	$46,251	$31,092	$32,959	$17,002

*Sample target prices are not risk-adjusted, normalized, or trend-adjusted.

The preliminary MS–DRG 470 target prices described in this table were calculated using the blended inpatient/outpatient target prices, as described in section II.A.2 of this final rule. We further note that the IPPS payment for

episodes with hip fracture in the baseline initiated by MS–DRGs 469 and 470 with hip fracture in 2019 will be adjusted as described in section II.B.4 of this rule so that they will be comparable to episodes initiated by the new MS–DRGs 521 and 522 during the performance year.

The following is a summary of the comments received and our responses.

Comment: Commenters in general were supportive of the proposed changes to the target price methodology but noted concern and considerations about certain changes. A commenter stated that for target price calculations, CMS should consider whether the size of the regions need to be modified based on previous years' findings or if there is significant market variability within a single region. A commenter urged CMS to evaluate the impact of the transition to regional only target pricing on safety-net hospitals that do not compete on a regional basis and that might otherwise value the predictability of target prices based on hospital-specific data.

Response: The CJR model shifted to regional only pricing starting in PY4, and final reconciliation results from PY4 are not complete at this time. However, we continue to believe that this transition to using regional only data for target price calculations will provide valuable information regarding potential pricing strategies for successful episode payment models to reduce variation in LEJR episode payments and reward hospitals for reducing payments below their regional peers. We have no evidence to date suggesting significant variation within a single region that would lead us to consider alternative geographic regions. While safety-net hospitals may value predictability of target prices based on hospital-specific data, we are committed to continuing to test the regional only approach for CJR participant hospitals, including safety-net hospitals, which could strengthen the generalizability of the evaluation results. We also consider that the proposed risk adjustment methodology, which we are adopting with modification as described in section II.C.4 of this rule, will ensure that participant hospitals treating a higher proportion of complex patients are adequately provided upward risk adjustments to their target prices as a result of those costlier patients. Additionally, since all participant hospitals participating in PY6 through PY8 will have already participated in at least one of the performance years PY1 through PY5 of the CJR model, we anticipate these hospitals will be familiar with the CJR model approach to target price calculations based on regional only data and a regression back to hospital-specific data could be confusing.

Comment: MedPAC suggested CMS move to national target prices, which should be adjusted to reflect local or regional input costs, stating this would incentivize providers in high-cost areas to reduce post-surgical service use and would reward providers in low-cost areas with larger shared savings payments than providers in high-cost areas.

Response: We understand that moving to target prices calculated from national data may enhance the incentive for some areas to reduce episode costs compared to higher cost areas, but we proposed to maintain regional only pricing to ensure stability for existing CJR model participants that will only have experience with target prices calculated from regional-only data for 2 performance years in the CJR model before PY6 begins. Due to the addition of outpatient procedures to the CJR model episode definition, we also expect that regional data is more appropriate to use for target pricing in PYs 6 through 8 given the potential variation in outpatient utilization nationally, similar to the substantial regional variation in utilization for episodes involving LEJR procedures, as referenced in the November 2015 final rule.[7] CMS appreciates MedPAC's suggestions to generate additional savings for the Medicare program by increasing the discount factor or increasing the stop-loss limit. Many of the changes CMS proposed to the CJR model payment methodology for PYs 6 through 8 are intended to be improvements to the original methodology that will increase the probability for model savings. While CMS could design a payment methodology that attributed a much larger portion of savings to the Medicare program, we must also balance the administrative burden and investments needed by participating hospitals to be successful under the model, and thus proposed a methodology—intended to ensure that CJR participant hospitals are still capable of achieving a certain level of savings for themselves in the model.

Comment: A few commenters requested that CMS ensure that any changes to the CJR model payment methodology in general account for the range of patient complexity and underlying operating costs for sites treating more complex patients in order to avoid unnecessarily penalizing high quality providers caring for complex patients.

Response: We understand the commenters' requests for a payment methodology that attempts to accurately account for variation in episode costs related to patient complexity. The CJR model initially provided risk adjustment for MS–DRG 470 and MS–DRG 469 patients with the presence of a hip fracture during PYs 1 through 5 in recognition that these patients had higher episode costs compared to non-fracture patients. We also chose that risk adjustment method to protect small and rural participants that may disproportionately have more emergent surgeries, such as hip fractures, in those low-volume settings. The proposed additional risk adjustment variables, as described in section II.C.4. of this final rule, were proposed with these same goals in mind and are meant to further increase the accuracy of target price risk adjustments for PYs 6 through 8. We also recognize that without risk adjustment the addition of outpatient TKA/THA to the CJR model episode definition, as described in section II.A.2 of this final rule, could create pressure for clinicians to recommend the lower cost outpatient setting to minimize total episode costs. The objective of the risk adjustment methodology for PYs 6 through 8 is to incentivize clinicians to continue performing LEJR procedures in the most appropriate clinical setting based on their assessment of each patients' complexity, and we appreciate that this aligns with commenters' requests for a methodology that accounts for the range of patient complexity and costs associated with treating more complex patients.

Comment: A commenter noted that in comparison to the concept of bundles in the commercial insurance market, the payment methodology in the CJR model does not include consideration of such costs and market indicators like innovation, inflation, and an increasingly expensive labor market given the lowering of unemployment. The commenter asserted that under this payment methodology, there will be a point where there will only be losses in offering THA/TKA procedures to Medicare patients leading to loss of access to these procedures.

Response: CMS notes the CJR model was specifically designed for implementation in the Medicare program, where hospitals and beneficiaries are faced with different considerations and choices in the commercial insurance market, such as payment rates and beneficiary benefits. The retrospective market trend factor

[7] Hussey PS, Huckfeldt P, Hirshman S, Mehrotra A. Hospital and regional variation in Medicare payment for inpatient episodes of care [published online April 13, 2015]. JAMA Intern Med. doi:10.1001/jamainternmed.2015.0674.

and risk adjustment components of the proposed payment methodology are intended to produce accurate target prices that reflect the average regional costs. While the market trend factor may have the effect of decreasing target prices as a result of lower performance period average costs compared to baseline costs, as we note in section II.C.6. of this final rule, the market trend factor could also have the effect of increasing target prices to reflect higher performance period average costs, including market conditions such as inflation and labor costs. We do not believe the target price methodology will have the effect of decreasing access to THA and TKA procedures given the proposed market trend factor and 1 calendar year of baseline data that should appropriately align performance period spending with baseline spending.

Comment: A few commenters stated that CMS provided insufficient data and did not fully describe the proposed target price methods and results of the simulated comparisons to allow independent analyses by stakeholders. In particular, a commenter requested that CMS make available all of the relevant data, along with a complete description of the analytic methodologies used in constructing the four target pricing episode categories, as well as sample site-neutral target prices for the nine census regions, and that the comment period be extended 60 days from the day on which the data and methodology details are provided.

Response: We recognize the commenters' interest in obtaining the data CMS used to develop the changes to the CJR model target price methodology and creating simulated comparisons of that methodology. In the February 2020 proposed rule, we provided information and data regarding our target price methodology decision making, such as our decision to adopt a blended target price for outpatient procedures given the clinical rationale to combine those episode types (that is, outpatient and inpatient episodes). In particular, we recognize the risk adjustment methodology, described in section II.C.4 of this final rule, represents a significant change in how target prices will be calculated and how episodes will be reconciled in PYs 6 through 8. We described our rationale for choosing the risk adjustment variables we are adopting in this final rule, including the analytic methodologies to calculate the risk adjustment coefficients and the exact dates of claims data used to perform the analysis. We also included a discussion in that section about our consideration for alternative analytic methodologies and our decision to employ logarithmic transformation in the exponential model used to calculate risk adjustment coefficients. Additionally, we are adding detail in that section of this final rule regarding the decision to calculate risk adjustment coefficients nationally rather than regionally. Our approach is similar, both in terms of rationale and level of detail of the analytic methods and considerations, to what we provided in November 2015 rule (80 FR 73273), and for this reason, we believe that the information we provided in the proposed rule was sufficient.

However, since some components of the target price methodology for PYs 6 to 8 are identical to the methodology used for PYs 1 to 5 and are described in depth in the final rule establishing the CJR model (80 FR 73273), such as the length of an episode or use of regional only data (recognizing use of regional data began in PY4), so we did not repeat those components in detail in the proposed rule. While CMS recognizes there is a degree of uncertainty regarding the effect of the retrospective market trend factor or other components of the target price methodology, we believe the data and information we provided in the proposed rule and this final rule are sufficient to inform stakeholders of the changes we are adopting in this final rule. Similar to the original CJR model, we intend to conduct webinars detailing the payment methodology, in addition to making available other learning on the CMS website. As stated in section II.B.2. of this final rule, we will also post applicable (site-neutral) regional target prices for each of the four episode types, as well as the risk adjustment coefficients on the CMS website prior to the start of each performance year. In this final rule, we include sample site-neutral PY6 target prices, which can be found in Table 2a of section II.B.2 of this final rule. We also posted updated PY6 risk adjustment coefficients, including the addition of the dual-eligible status risk variable, in Table 3a and Table 4a in section II.C.4 of this final rule. Since the 2019 claims data used to calculate these sample target prices and risk adjustment coefficients were unavailable at the time the proposed rule was published, we were unable to include that information in the proposed rule. We anticipate posting final PY6 site-neutral target prices and final PY6 risk adjustment coefficients on the CMS website in June 2021.

Comment: A commenter requested that CMS provide target price estimates calculated from Medicare claims data for bundles that include the status quo (current model), the proposed episode targets, and the targets if inpatient and outpatient episodes were priced separately.

Response: For a sample of the site-neutral PY6 target prices calculated using the proposed changes to the target prices methodology, we direct the reader to Table 2a in this final rule. As stated in section II.B.2 and section II.C.4 of this final rule, we will also post applicable (site-neutral) regional target prices for each of the four episode types as well as the risk adjustment coefficients on the CMS website prior to the start of each performance year. We anticipate posting PY6 site-neutral target prices and PY6 risk adjustment coefficients on the CMS website in June 2021. For an analysis of the proposed payment methodology, including the effect of excluding outpatient episodes from the episode definition, we direct readers to Table 6a and the related discussion in section IV.C. of this final rule.

Comment: A commenter requested that CMS provide clear and specific guidance on the impacts of payment adjustment changes and overlap across initiatives for organizations that participate in multiple value-based care models or programs, like the CJR model, BPCI Advanced, the Medicare Shared Savings Program (Shared Savings Program), and others.

Response: The CJR model overlap policies that applied during PYs 1 through 4 and each subset of PY5 will be applied when possible for PYs 6 through 8. However, we have determined that certain overlap policies that we proposed to apply to PYs 6 through 8 will not be feasible due to having only one reconciliation at six months after the end of the performance year, and we will no longer have a second reconciliation at 14 months after the end of the performance year. Therefore, although we are finalizing the changes to § 510.305(j)(1) that we adopted in the November 2020 IFC, which apply the provisions of that section to the subsets of PY5, we are not finalizing the changes to § 510.305(j)(1) that we proposed in the February 2020 proposed rule, which would have applied to PYs 6 through 8 our current policy of adjusting for shared savings payments when a CJR participant hospital is also a participant or provider/supplier in certain Accountable Care Organization (ACO) models or programs to which a CJR beneficiary is aligned. Those adjustments will no longer be feasible for PYs 6 through 8 because, as a result of the shorter time period between the end of the performance period and the

reconciliation calculation, we will not have access to the reconciliation data from ACO initiatives that would be necessary to allow us to perform the those adjustments.

Although not all of our proposed policies related to overlap can be maintained in PYs 6 through 8, we are maintaining the policy described at § 510.200(d)(4)(iii), which excludes certain per beneficiary per month (PBPM) payments under models tested under section 1115A of the Act. We are finalizing our proposal at § 510.200(d)(4) to extend this exclusion to episodes triggered by an anchor procedure, in addition to those triggered by an anchor hospitalization for PYs 6 through 8. In this final rule, we are also revising the list of ACO models or programs for which a prospectively aligned beneficiary is excluded from initiating a CJR episode in order to continue applying the policy specified at § 510.205(a)(6) in PYs 6 through 8. Specifically, we are replacing the reference to a Shared Savings Program ACO in Track 3 in § 510.205(a)(6)(iii) with a reference to a Shared Savings Program ACO in the ENHANCED track. Although we did not propose this change, we believe it is appropriate to include it in this final rule as a conforming change because the ENHANCED track of the Shared Savings Program is the successor of Track 3, as noted in § 425.600(a)(3), and our intention is to maintain this overlap exclusion policy.

Additionally, we are clarifying in this final rule that the overlap policies described at § 510.305(i)(1), which account for episode cancelations due to overlap between the CJR model and other CMS models and programs or for other reasons as specified in § 510.210(b), will occur at the single reconciliation during PYs 6 through 8. As described in the November 2015 final rule establishing the CJR model, we reserved these policies for the subsequent reconciliation (which takes place 14 months after the end of the performance year) to provide additional time beyond the initial reconciliation (which takes place 2 months after the end of the performance year) for claims run-out after an episode ended and to gather data about beneficiary alignment with other CMS models and programs. While we do not expect to have access to ACO reconciliation data that would allow us to perform the overlap adjustment described at § 510.305(j)(1) during PYs 6 through 8, as described previously, we do expect that ACO beneficiary alignment data will be available at the single reconciliation for PYs 6 through 8 (which will take place 6 months after the end of the PY) in order to identify episodes that are canceled in accordance with § 510.210(b). In this final rule, we are adding regulation text at § 510.305(m)(1)(v) to describe how this policy will be applied during PYs 6 through 8.

Lastly, regarding BPCI Advanced, we note the BPCI Advanced Participation Agreement (available at: *https://innovation.cms.gov/files/x/bpciadvanced-my3-am-restated-participation-agmt.pdf*) states ''In the event that a Participant or, if applicable, a Downstream Episode Initiator is also participating in an Innovation Center model implemented via regulation (for example, the Comprehensive Care for Joint Replacement (CJR) model), the Participant will not be held accountable for any Clinical Episodes included in that model for purposes of BPCI Advanced. Furthermore, in the event the Participant is located in one or more Metropolitan Statistical Areas included in an Innovation Center model implemented via regulation (for example, the CJR Model), CMS will exclude from the BPCI Advanced Reconciliation calculation all clinical episodes included in that model.''

Final Decision: After consideration of public comments we received, we are finalizing overlaps policies with some modifications. We are not finalizing the overlaps policy described in our proposed amendments to § 510.305(j)(1) because this proposal sought to continue into PYs 6 through 8 a particular overlaps adjustment calculation that is conducted during the subsequent reconciliation for which we will not have the required data available at the time of the single reconciliation for PYs 6 through 8. We are finalizing our proposal at § 510.200(d)(4) that applies the exclusion specified in § 510.200(d)(4)(iii) to episodes triggered by an anchor procedure, and we are making a conforming change to the regulation text at § 510.205(a)(6)(iii) to continue applying that overlap exclusion policy to the successor to Track 3 of the Shared Savings Program, which is the ENHANCED track. Finally, we are adding regulation text at § 510.305(m)(1)(v) to clarify how the overlaps policies described in § 510.305(i)(1) will be applied during the single reconciliation in PYs 6 through 8.

3. 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. As we stated when we finalized this policy, we chose 3 years because we wanted to ensure that we would have sufficient historical episode volume to reliably calculate target prices (80 FR 73340). We stated that our purpose for updating the baseline every other year was to achieve a balance between using the most recently available data to reflect changes in utilization and minimizing uncertainty in pricing for participant hospitals.

When we chose to use 3 years of historical data we were specifically concerned that some hospitals might not have a sufficient volume of episodes to create a reliable target price, particularly for the less frequent MS–DRG 469 episodes, because target prices in PYs 1 through 3 incorporated hospital-specific data into target prices. Hospital-specific data was incorporated into target prices to more heavily weight a hospital's historical episode data in the first 2 years of the model (two-thirds hospital-specific, one-third regional) and provide a reasonable incentive for both historically efficient and less efficient hospitals to deliver high quality and efficient care in the early stages of model implementation. Therefore, it was important in the first 3 performance years to have 3 years of historical data to ensure that individual hospitals had an adequate volume of historical episode data upon which to base target prices. However, target prices beginning with PY4 are based entirely on aggregated regional episode spending data, rather than a blend of both regional- and hospital-specific data. Our concerns relating to an adequate volume of historical episode data are therefore mitigated. We also note that we proposed additional tools meant to ensure accuracy of target pricing, specifically, the trend factor discussed in section II.C.6. of this final rule and risk adjustment discussed in section II.C.4 of this final rule, which further mitigates our concerns regarding target pricing uncertainty. Therefore, we believe that for the proposed CJR model extension, 1 year of data will be sufficient to calculate target prices for all participant hospitals.

Furthermore, given the removal of TKA from the IPO list, along with the national shift in LEJR spending, we have determined that the most recently available 1 year of data will in fact be a more appropriate baseline period on which to set target prices. Specifically, the removal of TKA from the IPO list, which has led us to propose to allow outpatient TKA procedures to trigger CJR model episodes (see section II.A of this final rule), only became effective in CY 2018. As a result, CY 2018 is the earliest year for which we will have

available data that includes both inpatient and outpatient TKAs, which will be needed to calculate a target price for a blended inpatient/outpatient TKA episode within the category of MS–DRG 470.

Therefore, for PYs 6 through 8, we proposed to use the most recently available 1 year of data prior to the start of the performance year to calculate target prices rather than the 3 years of data currently used. Under the current methodology, target prices for PYs 1 and 2 were calculated with baseline data from 2012 to 2014, PYs 3 and 4 were calculated with baseline data from 2014 to 2016, and PY5 is calculated with baseline data from 2016 to 2018. We proposed to base PY6 target prices on episode baseline data from 2019, PY7 target prices on episode baseline data from 2020, and PY8 target prices on episode baseline data from 2021. We proposed that by using only 2019 data for PY6 target prices, we would be able to capture spending patterns associated with the movement of TKA into the outpatient setting, as well as other practice trends during that year. Therefore, we stated our belief that using only the most recently available 1 calendar year of baseline data and updating that 1 year of baseline data annually will provide the best available picture of spending patterns we would expect to see during the performance period, which will allow us to calculate more accurate target prices. We sought comment on this proposal.

The following is a summary of the comments received and our responses.

Comment: Some commenters were in support of the proposed change to use 1 year of baseline data, with a few commenters stating that 1 calendar year of baseline data is sufficient in supporting the 100 percent regional pricing methodology as the volume of episodes is large enough to provide stability with pricing from a single year's worth of data. A commenter noted that 1 year of baseline data will more effectively capture Medicare payment policy changes over the last year, ensuring that the target price methodology is not an unintentional disincentive for the system of care due to not capturing appropriate costs. A commenter supported the use of 1 year of baseline data, but without the addition of outpatient TKA and THA procedures.

Response: CMS agrees with commenters that regional episode volume enables CJR model target prices to be calculated based on 1 calendar year of baseline data and that using the most recently available calendar year of data will more effectively capture Medicare payment policy changes compared to the PY1 through PY5 method that utilized 3 years of baseline data. As noted in section II.A.2 of this final rule, we are adopting the inclusion of outpatient TKA and THA procedures in the CJR model episode definition for the 3-year extension to test the model in a broader population of beneficiaries than just those in the inpatient setting. Additionally, as noted in that same section of this final rule, given stakeholders' interest in opportunities to treat LEJR patients in the outpatient setting as part of a bundled payment model, we continue to believe this is important to the model test.

Comment: Many commenters expressed concern that due to the COVID–19 PHE, baseline data from 2020 and 2021 will be inappropriate to utilize for PY7 and PY8 target price calculations without adjustment to the proposed payment methodology. In particular, a few commenters expressed concern with using only 1 year of data and noted that if some areas in a region experience a surge in COVID–19 cases while other areas do not, the regional pricing model CMS is proposing would be a less valid way to adjust target pricing. A commenter noted that CMS should use 2019 as the baseline year for PY6 hold it constant for PYs 7 and 8, updated annually based on a trend factor that CMS would develop that holds providers harmless for the 2020 performance year due to the increased expenditures associated with COVID–19. A commenter noted that CMS should work with stakeholders as it develops a method for using 2020 as a base year for target price calculation in the future. Another commenter noted that moving to a 1 year baseline period would allow for a better comparison between baseline periods in which no THA procedures were performed on an outpatient basis to performance periods in which THA was removed from the IPO list; however, this commenter also noted that CMS should postpone implementing a 1 year baseline period given the COVID–19 pandemic.

Response: CMS recognizes the concern expressed by commenters of using 2020 and 2021 baseline data for calculating target prices for PYs 7 and 8 and the potential effect of the COVID–19 PHE on that data. However, we continue to believe that using the most recently available 1 calendar year of baseline data (with the modification discussed later in this section) will more accurately capture recent trends in the LEJR market than the previous use of 3 years of data, specifically regarding the migration to outpatient procedures than using 3 years of data, given the pace of changes in practice trends. If the migration to the outpatient setting for these procedures is accelerated during PY6 as a result of the COVID–19 PHE and other changes to the LEJR market, we believe the use of 1 year of baseline data is important to more timely reflect changes in episode spending patterns and the case mix of patients receiving a procedure in the outpatient or inpatient setting. Specifically, if we relied on the original CJR model methodology of using 3 years of baseline data to calculate target prices for PY6, we would use data from 2016–2018. Using the averages over 3 years of claims data to calculate target prices instead of using 1 year (that is, calendar year 2019 claims data for PY6) could create inaccurate target prices for outpatient episodes since the data would only contain 1 year of TKA outpatient data (that is, 2018), and it would not sufficiently capture the effect of the quickly evolving trends in the LEJR space noted in section II.A.2 of this final rule. The goal of the changes and extension of the CJR model adopted in this final rule are meant to inform the design of a future LEJR model that could be certified and expanded nationally, and we continue to believe using 1 calendar year of baseline data is critical and appropriate for that future model.

We also understand and agree with commenters that baseline data from 2020 will likely not be as reflective of true market conditions as if the COVID–19 PHE had not occurred, and agree with commenters that modifications must be made to avoid using baseline data from 2020. As described in section II.D.1. of this final rule, we are finalizing the start and end dates for PYs 6 through 8 as follows: PY6 will be October 1, 2021 to December 31, 2022; PY7 will be January 1, 2023 to December 31, 2023; and PY8 will be January 1, 2024 to December 31, 2024. Given the new start and ends dates of PYs 6 through 8, our model timeline is essentially shifting forward 12 months, such that PY7 will now begin with episodes ending on or after January 1, 2023. Given the timeline shift, we will now have access to 2021 calendar year claims data prior to the start of PY7. Using 2021 claims data to calculate target prices for the new PY7 timeline aligns with our intention to use the most recently available calendar year of baseline data, described in section II.B.3 of this final rule, and allows for the omission of 2020 calendar year claims data. Therefore, to accommodate commenters' suggestions of avoiding the utilization of 2020 claims data for target price calculation and to incorporate the

revised time frames for PYs 6 through 8, we are adopting the proposed methodology for PY6 but modifying the proposed methodology in § 510.300(b)(1)(v) so the date range of claims data used to calculate target prices for PY7 is January 1, 2021 to December 31, 2021. We are also modifying § 510.300(b)(1)(vi), which specifies the date range of claims data used to calculate target prices for PY8 to be January 1, 2022 to December 31, 2022 to accommodate the shift in PY7. We agree with commenters that 2020 data could be especially difficult to use for PY7 target price calculations. While 2021 data could also have similar distortions, we anticipate the corrective mechanisms of PYs 6 through 8 payment methodology, in particular the market trend factors, will reduce this distortion. For example, the market trend factors will reduce the potential variation caused by the COVID–19 PHE in average episode costs calculated from calendar year 2021 data compared to PY7 average episode costs. Since the market trend factors are calculated at the regional- and episode type-level, we anticipate they will accurately account for the potentially distorting effect of the COVID–19 PHE. As 2020 claims data are finalized, and 2021 data become available, we will monitor the potentially distorting effects of the COVID–19 PHE on that data and determine if any adjustment is needed regarding use of the 2021 data for PY7 target prices calculations.

Similarly, we are also finalizing corresponding changes to the timing of the data used to calculate the risk adjustment factors, described further in section II.C.4 of this final rule.

Comment: Many commenters stated that 1 calendar year of baseline data would result in target prices that would be too variable, unpredictable, or susceptible to unexpected disruptions in the market compared to the 3 years of baseline data used previously. In particular, some of these commenters noted that more than 1 year of baseline data is necessary given the shift of TKA procedures to the outpatient setting in 2019, and because 2020 will be the first year of related Recovery Audit Contractor (RAC) audits and the first year THA procedures are payable in the outpatient setting. A commenter also noted that using 3 years of baseline data at the regional level creates additional stability in pricing due to the number of procedures included in the regional average compared to using a single year.

Response: CMS continues to believe the most recently available 1 calendar year of baseline data is sufficient and in fact preferred given the shift of TKA and THA procedures to the outpatient setting and other changes in the LEJR market environment, as described in section II.A.2 of this final rule. As noted previously, the timeline shift for PY7 in this final rule enables CMS to utilize 2021 calendar year claims data for PY7 target price calculations, which we anticipate will more accurately capture recent trends, such as the shift of TKA procedures to the outpatient setting, than 2020 calendar year claims data. Regarding the potential for using data from the first year of RAC audits of TKA procedures, we note that these reviews began in calendar year 2020 and, as described in section II.B.3 of this final rule, we will calculate PY6 target prices using calendar year 2019 data and PY7 target prices using calendar year 2021 data, which will omit the first year of related RAC audits (that is, calendar year 2020) for which the commenter expressed concern of use for PY7 target price calculations. We anticipate that using only the most recent year of regional data, as well as incorporating the market trend factor discussed in section II.C.6 of this final rule, target prices will be more reflective of current spending patterns than using 3 years of data. We note that although the previous CJR model method of calculating target prices utilized 3 years of baseline data, the data was trended forward by a national growth factor and would still be susceptible, albeit to a lesser degree than simply 1 year of baseline data, to unexpected disruptions in the market. We recognized this potential susceptibility and proposed the market trend factor to mitigate its potential effects. While the retrospective nature of the market trend factor will change initial target prices at the subsequent reconciliation for each performance year, we note the risk adjustment coefficients posted on the CMS website prior to the start of each performance year will be the same coefficients applied at reconciliation each year. This is meant to increase the financial predictability for participants by holding constant the coefficients that are posted on the CMS website and used for reconciliation each performance year. Lastly, since target prices in PYs 6 through 8 will not be calculated with hospital specific data, we continue to believe there is little risk that a policy of using the most recent calendar year of data would result in insufficient volume of data related to certain episode types. We understand this risk from insufficient volume is greater as a result of the effect of the COVID–19 PHE on the 2020 data and are finalizing, as described in section II.B.3. and section II.C.4. of this final rule, the policy that 2020 claims data will not be used for target price or risk adjustment coefficient calculations, respectively. As noted previously, we also believe that using the most recent calendar year of baseline data for PY6 (that is, 2019 baseline data) will generate more accurate prices for the inclusion of outpatient procedures than the previous methodology that would have used baseline data from 2016 to 2018.

Comment: Commenters noted that the CJR model's previous use of 3 years of baseline data ensured that participant hospitals, in particular high performing hospitals, would not be penalized for their own improvements in cost.

Response: We understand the concern that if the CJR model target prices were calculated with 1 year of hospital-specific baseline data alone it could be interpreted that a hospital's own improvements would inhibit their ability to achieve savings in later years of the model. However, the policy we are adopting in this final rule to use 1 year of regional only baseline data for target prices proposed for PYs 6 through 8 will consider a participant hospital's performance relative to its regional peers (instead of the hospital's own historical performance) and will incentivize participants who are already delivering high quality and efficient care while still incentivizing historically less efficient providers to improve compared to their regional peers. Additionally, as we note in section II.C.4. of this final rule, the application of coefficients from the risk adjustment methodology is intended to also have the effect of rewarding hospitals that are able to provide care to certain beneficiaries (that is, those that trigger the application of the risk adjustment coefficients, such as patients with a CJR HCC count of three) at a lower cost compared to their peers.

Comment: Another commenter stated concern that 2018–2020 national unadjusted CMS payment rates for TKA show a significant increase in the outpatient procedure payment and that this increase was overlooked by CMS.

Response: We appreciate the suggestion by the commenter to consider the recent increase in payment rates for TKA procedures. As described in section II.B.3. of this final rule regarding the use of 1 year of baseline data, and in section II.C.6. of this final rule regarding the market trend factor, we anticipate both of those factors will ensure that annual variations in average episode costs are accurately adjusted in the updated CJR model payment methodology.

Comment: A commenter recommended that CMS use 2019 data for baseline purposes to avoid continuous annual rebasing, other than to account for site of service shifts.

Response: We proposed shifting the baseline data forward for each PY to ensure the target price methodology would effectively capture trends in the LEJR market. These trends include changes in payment systems and utilization of certain services, which would not be accounted for if we used the same year of baseline data for all 3 years of the extension and only included an adjustment for site of service shifts. In particular, 2019 baseline data will not reflect the migration to the outpatient setting for THA procedures that has occurred in 2020. We do believe that 2019 data will be an adequate baseline for calculating PY6 target prices in spite of the lack of outpatient THA data, given the similarity of average episode costs between outpatient TKA and outpatient THA episodes. We believe that it is preferable for PYs 7 and 8 target prices to be based on data that includes outpatient THA episodes, and we plan to use 2021 and 2022 data, since that data will be newly available. As noted previously, we continue to believe using the most recent year of baseline data, as opposed to an adjustment we would develop each year, will more accurately capture spending trends related to site of service shifts or other market changes and is more transparent.

Comment: A few commenters recommended CMS exclude beneficiaries from the baseline that were part of other APMs, such as the CJR model, BPCI Advanced, and Medicare ACOs.

Response: The proliferation of APMs nationally represents a positive evolution in CMS' efforts to support better and more efficient care for beneficiaries. However, it also creates difficulties in discerning the effects of one APM vs. another. While the CJR model has certain overlap and beneficiary exclusion policies to ensure appropriate episode attribution during a performance year and at reconciliation, as noted in § 510.305(i) for PYs 1 through 5 and in section II.B.2 of this final rule for PYs 6 through 8, we do not exclude these beneficiaries from baseline spending because, given the increasing reach and effect of APMs, it would be less reflective of actual average costs if the costs from those beneficiaries were excluded from the CJR model target price baseline data.

Final Decision: After consideration of the public comments we received, we are finalizing as proposed that PY6 target prices will be based on episode baseline data from 2019. We are finalizing our proposal with modification to the baseline years used for PYs 7 and 8 target prices. Specifically, PY7 target prices will be based on episode baseline data from 2021, and PY8 target prices will be based on episode baseline data from 2022. These policies are finalized at 42 CFR 510.300(b)(1)(iv) through (vi).

4. Removal of Anchor Factor and Weights and Removal of the Prospective Payment System Target Pricing Updates

Since the CJR model target prices during PYs 1 through 3 were calculated using a blend of historical and regional episode costs, the primary intent of using anchor weights in the target price calculation was to increase the volume of data for statistical predictability purposes, particularly for MS–DRG 469 episodes, and to limit the degree to which a certain participant hospital's ratio of MS–DRG 469 episodes to 470 episodes would skew the pooled historical average episode payment, and subsequently the target price. We aimed to incentivize participant hospitals based on their hospital-specific inpatient and post-acute care (PAC) delivery practices for LEJR episodes. However, to incentivize both historically efficient and less efficient hospitals to furnish high quality, efficient care in all years of the model, we transitioned from primarily hospital-specific to completely regional pricing over the course of the 5 performance years (80 FR 73337).

Since we proposed for PY6 through 8 to use regional episode spending data only (no hospital-specific data) to calculate target prices, we no longer have the concern that a lack of volume of data for certain participant hospitals may limit the predictability of the target price calculation, as we did when hospital-specific data were incorporated into the target price calculation. Additionally, we no longer have the concern that a participant hospital's ratio of MS–DRG 469 to 470 episodes would skew the pooled historical average episode payment, because for PY4 and 5 we removed hospital-specific ratios of MS–DRG 469 to 470 episodes from the target price calculation. We proposed to continue this in PY6 through 8. Given that we no longer have these concerns, we also proposed to stop using the national anchor factor calculation and the subsequent regional and hospital weighting steps in the CJR model target price calculation method for PY6 through 8. Additionally, we proposed not to continue the annual updates to the target prices that account for changes in the Medicare prospective payment systems and fee schedule rates. Since we proposed (as discussed in section II.C.6. of this final rule) to add a market trend adjustment to the target prices at the time of reconciliation, which will adjust for the 2-year percent change in prices at the regional/MS–DRG level, we do not believe that the at least twice annual updates to the target prices continue to be necessary. To the extent that changes to these Medicare prospective payment systems and fee schedule rates influence episode costs, the percent difference in episode costs would account for that influence and therefore the annual updates would no longer be necessary. We sought comment on this proposal.

The following is a summary of the comments received and our responses.

Comment: A few commenters commented on the proposal to remove the anchor factor and weights and updates to the target prices as a result of prospective payment system changes, with most comments concerning the effect of other aspects of the proposed target price methodology, such as the market trend factor. Commenters stated that the existing update methodology appropriately accounts for target price changes using OPPS and IPPS updates and the CMS discount is sufficient for CMS to receive guaranteed savings. A few commenters recommended that the CJR model adopt BPCI Advanced's methodology to adjust prospective target prices for SNF and other payment system updates.

Response: As noted in the discussion before Table 6a in section IV.C. of this final rule, we proposed to remove the anchor factors and weights and updates to CJR model target prices as a result of prospective payment system changes from the CJR model payment methodology for the 3 years of the extension because they do not always account for all payment system changes. Instead of prescribing exactly how the CJR model might adjust baseline data for certain payment system changes, similar to the original CJR model and BPCI Advanced methodologies, we proposed to instead rely on the market trend factor to ensure consistency with performance year and baseline costs. We anticipate this method will be simpler than the anchor factors and weights and less burdensome to monitor than the twice annual updates testing in the CJR model PYs 1 through 5. We maintain that the proposed market trend factor will adequately account for these factors, weights, and updates.

Final Decision: After consideration of the comments we received, we are finalizing our proposal to remove the

anchor factor and weights and updates to the target prices as a result of prospective payment system changes.

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

The high episode spending cap policy was designed to prevent participant hospitals from being held responsible for catastrophic episode spending amounts that they could not reasonably have been expected to prevent, by capping the costs for those episodes. At the time the CJR model was implemented, we proposed and finalized a policy to set this high cost episode cap at 2 standard deviations above the regional mean episode price, both for calculating the target price and for comparing actual episode payments during the performance year to the target prices. When comparing actual episode payments during the performance year to the target prices at reconciliation, 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, an episode that had an actual episode cost of $45,000 would have its costs, for purposes of the model, reduced by $15,000 when the cap was applied and therefore, the cost for that episode would be held at $30,000. Consequently, assuming the target price applicable to the episode was $25,000, the provider would be responsible for repaying a specific percentage portion of a $5,000 difference rather than for repaying a specific percentage portion of a $20,000 difference (where difference is assessed by the cost, or capped cost, for the actual episode compared to the target price). When we established this policy, we assumed that the episode costs in the CJR model would be normally distributed (80 FR 73335). With a normal distribution of costs, 95 percent of episodes would have costs that are within 2 standard deviations of the mean cost. Under this assumption, episodes with costs exceeding 2 standard deviations from the mean, would qualify as statistical outliers for high episode spending and we therefore set our high episode spending cap at 2 standard deviations above the regional mean episode price.

However, in reviewing data from our CJR model experience thus far, we have observed three challenges that have limited the ability of our current 2 standard deviation methodology to appropriately cap high episode spending. First, we have observed that TKA and THA episode costs in the CJR model are not normally distributed; as such, less than 95 percent of episodes have costs that fall within 2 standard deviations of the mean. This means that TKA and THA episodes in the CJR model exceed the 2 standard deviation amount in their cost more often than other clinical episode costs that are distributed approximately normally. Second, given the reliance on only regional data for target price calculations in PY4, each subset of PY5, and proposed PY6 through 8, a participant hospital with higher-cost episodes relative to its region will benefit more from this capping method since there will be a higher probability that its episodes will be capped. This effect was not as much of a concern during PYs 1 through 3 since target prices were calculated using a blend of hospital-specific and regional costs. However, since many of the participant hospitals now participating in the CJR model (especially mandatory participants) have higher-cost episodes relative to their regions, and target prices are derived from regional-only episode data, their performance period episode costs would likely exceed the 2 standard deviation high episode spending cap amount more often than intended. In other words, assuming a normal distribution, we would expect 95 percent of episode costs to be within 2 standard deviations of the mean episode cost. As we discussed in the CJR model November 2015 final rule (80 FR 73336), our original intent in establishing the high cost episode capping policy was to mitigate the hospital responsibility for episodes with very high Medicare spending during the post-discharge 90-day episode period. However, as noted previously, TKA and THA episode prices are not normally distributed, and more than 2.5 percent of episode costs exceed the 2 standard deviation maximum threshold. Third, and similar to the first challenge that TKA and THA episode costs in the CJR model are not normally distributed or otherwise similar to other clinical episodes, CJR participant hospital performance period episode costs are not normally or otherwise similarly distributed compared to the costs used to derive the CJR model target prices. Specifically, while episode costs are closer to a normal distribution during the initial target price calculation as a result of the larger volume of data in the national summary of episode costs (that is, the episode data includes non-CJR participating hospitals), the episode costs are not normally distributed during reconciliation since episode costs at reconciliation are derived from only performance period episode costs (that is, only CJR participant hospitals).

Therefore, the current CJR model methodology that establishes a high episode spending cost cap at 2 standard deviations above the mean has not reliably produced an episode cost ceiling that applies only to very high cost episodes; rather, as a result of the episode distribution, the current methodology may result in the inappropriate capping of some episode costs. An internal analysis of CJR model episode data by CMS showed that in 2016 and 2017 respectively 70 and 83 percent of CJR participant hospitals had at least one episode capped at the high cost episode cap. While we continue to want to protect participant hospitals from exposure to very high cost episodes, we need to balance that goal with the overarching goal of the CJR model to lower costs and increase quality for LEJR procedures.

As a result, we proposed to change the methodology used in deriving the high episode spending cap amount during reconciliation, described further in section II.C.5. of this final rule. Since the current CJR model high episode spending cost capping methodology used during initial target price calculation is the same methodology used during reconciliation, we also proposed to change the methodology used in deriving the high episode spending cap amount during the initial target price calculation to match the proposed methodology used during reconciliation. Specifically, we proposed to change our method of deriving the high episode spending cap amount applied to initial target prices by setting the high episode spending cap at the 99th percentile of historical costs. Similar to the current methodology, the high episode spending cap calculation would 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 would be capped at the 99th percentile amount prior to calculating target prices for each MS–DRG and hip fracture combination for each region. We expect that this method of calculation will result in high episode spending caps that more accurately represent the cost of infrequent and potentially non-preventable complications for each category of episode, which the participant hospital could not have reasonably controlled and for which we do not want to penalize the participant hospital. We sought comment on this approach.

We did not receive comments about the proposed policy to use the 99th percentile when capping episodes prior to calculating the target prices. We are finalizing this provision without modification.

C. Reconciliation

1. Background

Currently, for PY1 through 4 and for each subset of PY5, CJR model payments are reconciled twice after the close of a performance year. 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. Each participant hospital's composite quality score for combined performance on the CJR model quality measures, specifically, the total hip arthroplasty/total knee arthroplasty (THA/TKA) Complications measure and HCAHPS Survey measure, and voluntary submission of patient-reported outcomes and limited risk variable data, is then calculated. While all participant hospitals in the CJR model are assigned a target price with a quality discount factor of 3 percent, the quality discount applicable to a specific participant hospital at reconciliation may be lowered to 2 percent in instances where the hospital earns a quality category of good, or 1.5 percent in instances where the hospital earns a quality category of excellent. Based on reconciliation results from the first 2 performance years of CJR, roughly 18 percent of CJR participant hospitals achieved quality scores of 'Excellent,' around 60 percent achieved 'Good,' around 12 percent achieved 'Acceptable' and less than 10 percent were deemed 'Below Acceptable.' An initial reconciliation is performed using claims data available 2 months after the end of the performance year, and a final reconciliation is performed 1 year later, using claims data available 14 months after the end of the performance year.

At reconciliation, all participant hospitals that achieved LEJR actual spending below the target price and achieved a minimum composite quality score were eligible to earn up to 5 percent of the difference between their target price and their actual episode costs in PYs 1 and 2; 10 percent of this difference in PY3; and 20 percent in PY4 and each subset of PY5. The limits are referred to as ''stop-gain limits'' (80 FR 73401). Any net payment reconciliation amount (NPRA) greater than the proposed stop-gain limit would be capped at the stop-gain limit.

Conversely, participant hospitals with LEJR episode spending that exceeds the target price at reconciliation are financially responsible for the difference to Medicare up to a specified repayment, or a ''stop-loss limit.'' For most participant hospitals, the stop-loss limit was 5 percent of the difference between their target price and their actual episode costs in PY2; 10 percent for PY3; and 20 percent for both PY4 and each subset of PY5. For participant hospitals that are rural hospitals, Medicare-dependent hospitals, rural referral centers, and sole community hospitals, the stop-loss limit was 3 percent for PY2; and 5 percent for PY3 through PY4, and each subset of PY5. Any reconciliation repayment amount that exceeds the proposed stop-loss limit would be capped at the stop-loss limit.

We implemented a parallel approach for the stop-gain and stop-loss limits to provide proportionately similar protections to CMS and to participant hospitals, as well as to protect the health of beneficiaries. We believe it is appropriate that as participant hospitals increase their financial responsibility, they can similarly increase their opportunity for additional payments under this model. We also believe that these changes facilitate participants' ability to be successful under this model and allow for a more gradual transition to financial responsibility under the model.

2. Overview of Changes to Reconciliation Process

In the proposed rule, we proposed changes to the CJR model reconciliation process that are intended to reduce administrative burden, to adjust target prices for beneficiary-specific risk elements, to better recognize participant providers with good and excellent composite quality scores, and to improve our ability to account for changes in payment policy and market trends in utilization. Additionally, we proposed changes to the reconciliation process that parallel the changes we propose to the target price calculations discussed in section II.B. of this final rule.

Beginning with PY6, we proposed to conduct one reconciliation per CJR model performance year, which would be initiated 6 months following the end of a CJR model performance period. This change is intended to reduce the administrative burden of a second reconciliation for Medicare and CJR participant hospitals, and it is driven by internal analyses, discussed in section II.C.3. of this final rule, that indicate the 6 months after an episode ends is sufficient time period to capture episode spending data. However, we proposed that the current CJR model post-episode spending policy, codified at § 510.305(j)(2) and § 510.2, would still apply during PY6 through 8. Additionally, we proposed conforming changes to § 510.305 such that the PY4 and 5 stop-loss limits and stop-gain limits of 20 percent would continue in place for each of PY6 through 8.

Additionally, in an effort to recognize the greater needs of certain beneficiaries that are beyond a participant hospital's control, we proposed to incorporate a risk adjustment factor for each episode's target price during reconciliation for PY6 through 8. Specifically, as discussed in section II.C.4. of this final rule, we would adjust the target price at reconciliation using two patient-level risk factors, the CJR HCC count risk adjustment factor and the age bracket risk adjustment factor.

Further, as mentioned in section II.B.5. of this final rule, we proposed to change the methodology used in deriving the high episode spending cap amount during reconciliation. For PY6 through 8 of the proposed extension, at reconciliation we would determine the high episode spending cap amount by calculating the 99th percentile of regional mean episode spending and cap episodes at that amount, in order to remove the effect of high-cost statistical outliers on average costs. We proposed this change since we have observed that CJR model episode costs are not normally distributed, as discussed in section II.B.5. of this final rule, and a greater number of CJR model episodes have exceeded the high episode spending cap amount than we intended.

We also proposed to add a market trend factor to adjust for recent variations in the underlying structure of the market. Specifically, we proposed that the market trend factor would be the regional/MS–DRG mean cost for episodes occurring during the performance year divided by the regional/MS–DRG mean cost for episodes occurring during the target price base year. For example, at the reconciliation for PY6 which will occur at the end of June of 2023 after allowing for 6 months of claims runout, we will compute the regional/MS–DRG mean cost for episodes occurring during the performance year (October 1, 2021 through December 31, 2022) and would divide that by the regional/MS–DRG mean cost for episodes that occurred during calendar year 2019 as the target prices for PY6 will be set using 2019 data. We note that we will make a minor adjustment to this methodology when we calculate PY6 target prices for MS–

DRGs 521 and 522, in order to align the methodology we proposed in the February 2020 rule with the addition of these new MS–DRGs to the CJR episode definition in the November 2020 IFC. In those instances only we will adjust the IPPS portion of episode costs for baseline episodes initiated by MS–DRG 469 and 470 with fracture, as described in section II.A.2. of this final rule. This adjustment will consist of multiplying those IPPS costs by the ratio of the MS–DRG 521 and 522 weights (which are applicable to performance period episodes) to the MS–DRG 469 and 470 weights that were applicable in the baseline period. We will make this adjustment prior to the application of the market trend factor for PY6 target prices for episodes initiated by MS–DRGs 521 and 522. This adjustment will result in target prices that more accurately reflect the methodology we proposed in the February 2020 proposed rule, which assumed that the target price for the MS–DRG and fracture status of each episode in the performance period would be based on baseline episodes with the same MS–DRG and fracture status.

Lastly, we proposed changes to the effective discount factor and applicable discount factor in § 510.315, to better recognize participant providers in the 'Good' and 'Excellent' CJR model composite quality score categories. For PY6 through 8, we proposed to continue to use 3 percentage points as the discount factor applied during calculation of regional target prices. However, we proposed to increase an individual participant hospital's potential quality incentive payment; that is, we proposed a larger reduction in the discount factor based on the composite quality score. The opportunity for this larger reduction in the discount factor was proposed because we anticipate that the proposed changes to the target price methodology, discussed in section II.B. of this final rule, will better align the target prices with actual spending during a performance year. While more accurate initial target prices will enhance stability for participant hospitals at reconciliation, it also means the quality adjusted target price and actual episode spending will align more closely over time and we want to ensure that we continue to recognize high quality participant hospitals by giving them a larger portion of the achieved savings. As a result, for PY6 through 8, we proposed a 1.5 percentage point reduction to the applicable discount factor for participant hospitals with ''good'' quality performance and a 3-percentage point reduction to the applicable discount factor for participant hospitals with ''excellent'' quality performance.

The following is a summary of the comments received and our responses.

Comment: A commenter provided general feedback on the proposed changes to the reconciliation process and supported CMS' proposed policy to maintain the 20 percent stop-loss and stop-gain limit amounts from PYs 1 through 5 of the CJR model, noting that this policy is consistent across other models and will assist in the model evaluation process.

Response: We recognize consistent policies across CMS APMs can aid model participants as well as CMS evaluators and we have adopted policies that align with other APMs, such as the policy in this final rule to eliminate the 50 percent cap on gainsharing payments, distribution payments, and downstream distribution payments, where possible and appropriate. We appreciate the commenters' support for the CJR model stop-loss and stop-gains policy amounts that align with the amounts with other models, such as the BCPI Advance model.

Comment: MedPAC suggested that CMS should focus on changes to the model that could generate net savings for the Medicare program instead of redistributing all of them back to providers, such as increasing the percentage of losses for which hospitals are responsible.

Response: CMS appreciates MedPAC's suggestions to generate additional savings for the Medicare program by increasing the stop-loss limit. Many of the changes CMS proposed to the CJR model payment methodology for PY6 through 8 are intended to be improvements to the original methodology that will increase the probability for model savings. While CMS could design a payment methodology that attributed a much larger portion of savings to the Medicare program by increasing the stop-loss limit amount, we must also balance the administrative burden and investments needed by participating hospitals to be successful under the model, and thus proposed to continue the stop-loss limit from PYs 1 through 5 for PYs 6 through 8 that is intended to ensure that CJR participant hospitals are still capable of achieving a certain level of savings for themselves in the model.

3. Changes to Frequency and Timing of Reconciliation

As noted in section II.B.1. of this final rule, following the completion of performance years 1 through 4 and each subset of performance year 5, participant hospitals that achieve episode spending below the applicable target price and achieved a minimum composite quality score have been eligible to earn a reconciliation payment from Medicare for the difference between the target price and actual episode spending, up to a specified cap (see 80 FR 73337 for a detailed discussion of CJR model episode pricing). The retrospective process reconciles a participant hospital's actual episode payments against the target price 2 months after the end of each of performance years 1 through 4 and the first subset of performance year 5. More specifically, we use claims data that is available 2 months after the end of a performance year and carry out the NPRA calculation described in § 510.305 to make a reconciliation payment or repayment amount, as applicable. Fourteen months after the end of each of performance years 1 through 4 and performance year subset 5.1, CMS performs an additional calculation, using claims data available at that time, to account for final claims run-out and any additional episode cancelations due to overlap between the CJR model and other CMS models and programs, or for other reasons as specified in § 510.210(b). The subsequent reconciliation calculation is applied to the previous calculation of NPRA for a performance year to ensure the stop-loss and stop-gain limits are not exceeded for a given performance year. The difference between the initial and final reconciliation amount from this calculation, if different from zero, is calculated and added to the NPRA for the subsequent performance year in order to determine the net reconciliation payment or repayment amount. CMS performs these same calculations for performance year subset 5.2. However, with the initial reconciliation occurring 5 months after the end of performance year subset 5.2 and the final reconciliation occurring 17 months after the end of performance year subset 5.2.

When we first adopted the process to perform a reconciliation calculation 2 months after the conclusion of a performance year, with a subsequent reconciliation calculation 12 months later, the policy reflected the assumption that it was necessary to allow sufficient time for routine monitoring, review, and adjustment (80 FR 73386). However, internal analyses and monitoring of CJR model claims data from PYs 1 and 2 indicated that the full 14 months is not necessarily required to sufficiently capture claims run out and overlap with other models.

For example, the number of episodes attributed to PY1 increased by slightly less than 1 percent from the initial to subsequent reconciliation and total reconciliation payments for PY1 decreased by about 6 percent between the initial and subsequent reconciliation. The PY2 subsequent reconciliation process showed a similar trend; that is the attributed episode count increased by about 1 percent and total reconciliation payments decreased by around five percent. While we are not able to accurately predict or quantify the dollar impact shifts between the initial and final reconciliations for individual CJR participant hospitals, anecdotally, based on reconciliations of the first 2 performance years of the CJR model, some CJR participant hospitals owed over $100,000 because their initial reconciliation payments were too high relative to their final reconciliation payments. Other CJR participant hospitals who ultimately saw their reconciliation payments increase from initial to final reconciliations increased by amounts under $60,000.

In the proposed rule, we stated that we recognized shifting reconciliation amounts, especially those that result in unanticipated repayments, could be problematic for some providers. By allowing a longer period for claim run out prior to initiating the first and only reconciliation, we stated our belief that we could provide a more predictable and stable reconciliation process for CJR participant hospitals without significantly impacting the accuracy of the reconciliation payment and/or repayment amounts. Regarding the impact of this change on other models and programs that use CJR reconciliation data to perform their own overlap calculations, we stated that we did not anticipate that the change to the frequency and timing of the CJR model reconciliation would create new difficulties for CMS Innovation Center models and the Shared Savings Program when they account for overlap with CJR. Specifically, in regards to the Shared Savings Program, we noted that the Shared Savings Program only uses finalized data in its financial reconciliation calculations, and CJR initial reconciliation data are not considered final.

We proposed to conduct one reconciliation for each of PY6 through 8, 6 months following the end of a performance year. For instance, for PY6 (which includes all CJR model episodes ending on or after October 1, 2021 and on or before December 31, 2022), we proposed to reconcile a participant hospital's CJR model actual episode payments against the applicable target prices one time only, based on claims data available on July 1, 2023. As discussed previously, our internal analyses indicate the timing of this proposed reconciliation methodology will allow enough time to adequately capture episode costs. This methodology would also reduce the administrative burden associated with an extra reconciliation calculation on CMS and participant hospitals. Additionally, we believe this new methodology will enhance participant hospitals' ability to predict the outcome of reconciliation calculations, since they will no longer need to include unanticipated adjustments for prior year performance.

We also proposed that current CJR model post-episode spending policy, codified at § 510.305(j)(2) and § 510.2, would still apply during PYs 6 through 8. Specifically, we proposed that we would maintain the policy that 30-day post-episode spending for episodes attributed to all IPPS hospitals would be calculated to determine the value that is 3 standard deviations greater than the regional average 30-day post-episode spend and to determine if a participant hospital has excessive average 30 day post-episode spending. The spending amount exceeding 3 standard deviations above the regional average post-episode payments for the same performance year is subtracted from the net reconciliation or added to the repayment amount for the subsequent PYs 1 through 4. While this calculation is performed at the subsequent reconciliation for PYs 1 through 4 and each subset of PY5, we note that internal analyses and monitoring of CJR model claims data from PYs 1 and 2 indicate that the full 14 months is not necessarily required to sufficiently capture claims run out. Unlike the high cost episode spending cap policy, the 30-day post-episode spending policy only assesses episode costs 30 days following the end of an episode; this distribution is more ''normal'' than the high cost episode cap distribution that assesses the full 90-day episode costs. There have been few issues with the post-episode spending methodology to date.

The following is a summary of the comments received and our responses.

Comment: A number of commenters supported the proposal to move from 2 reconciliations, conducted 2 months and 14 months after the end of the performance year, to one reconciliation, conducted 6 months after the end of the performance year. Commenters stated their belief that 6 months was an adequate period of claims run-out to capture episode costs and that the change to one reconciliation would significantly reduce administrative burdens on hospitals. A commenter estimated that CMS would save $240,958 by moving to one reconciliation period. A commenter stated that this change would simplify participating hospitals' communication with the physicians with whom they have gainsharing agreements. Another commenter pointed out that this change would reduce the potential for secondary reconciliations that result in a participant owing a repayment, which would provide more certainty for providers.

Response: We appreciate the commenters' support for our proposal to move in PY6 from 2 reconciliations for each performance year to one reconciliation for each performance year. We agree with the commenters that 6 months is an adequate period of claims runout, and that this change will both reduce administrative burden on participants and also eliminate the uncertainty of whether the second reconciliation would result in the participant owing a repayment. We also agree that moving to one reconciliation period would result in a net savings to CMS, as the reconciliation calculation would include only 1 performance year's worth of data which would simplify the reconciliation process.

Comment: Multiple commenters stated that they generally supported the change to one reconciliation, but also had concerns about the change. Multiple commenters requested that we consider strategies to mitigate cash flow issues that could occur during the initial transition. A commenter requested additional clarity on how the transition would occur. Multiple commenters expressed their concern about the lack of a timely feedback loop to providers, stating that there is a long time between the beginning of the performance year and the reconciliation. A commenter requested that CMS develop a tool for participants that would take into account the adjustments CMS makes at reconciliation, such as application of the risk factor multipliers, using the best available data. They stated their belief that this would help participants gauge their performance, with the understanding that the results would be estimates and would vary from the final reconciliation results. Another commenter requested details on our planned approach for claims data sharing.

Response: In response to commenters' concerns about cash flow issues resulting from the change from 2 reconciliations to one reconciliation, we point out that we have historically

conducted one reconciliation process in each performance year, issuing combined results from the initial reconciliation of the most recently completed performance year and the final reconciliation from the previous performance year. Therefore, the frequency of reconciliation processes proposed for PYs 6 through 8 will align with the commenters' experience, but whereas prior reconciliation processes represented 2 different performance years, beginning in PY6 that process will only represent 1 performance year. Additionally, as a result of the extension of PY5 through September 30, 2021 and the division of PY5 into two subsets for purposes of reconciliation (PY5.1 and PY5.2), we will perform both the subsequent reconciliation of PY5.2 and the single reconciliation of PY6 in calendar year 2023. Rather than a transition year when the final reconciliation for the previous performance year is delayed, participants will receive two separate reconciliation reports in the same calendar year, thus mitigating concerns that a delay in reconciliation during the transition year could negatively impact cash flow or prevent timely feedback in their reconciliation report. Finally, we remind commenters that participants in the CJR model continue to bill and be paid through normal Medicare FFS processes throughout the model for Part A and Part B services furnished to beneficiaries during a CJR model episode.

In response to the commenter's general request for clarification about the transition from two reconciliations to one reconciliation, we wish to further clarify how certain policies that were previously applied at the subsequent reconciliation will be applied at the single reconciliation for PYs 6 through 8. As described previously in section II.B.2., certain overlap policies will continue to be applied at the single reconciliation for PYs 6 through 8, but the ACO overlap adjustment calculation, which we proposed in § 510.305(j)(1) to continue applying to PYs 6 through 8, will no longer be feasible because the necessary data will not be available six months after the performance year. For this reason, we are not finalizing our proposed amendments to § 510.305(j)(1) (though we are finalizing the changes we adopted in the November 2020 IFC). However, we will be able to apply the overlap policy described in § 510.305(i)(1), which cancels certain episodes due to overlap between the CJR model and other specified CMS models and programs, at the single reconciliation, so we have added § 510.305(m)(i)(v) to specify that we will apply that overlap policy at the single performance year reconciliation for each of PYs 6 through 8.

Similarly, we proposed in § 510.305(j)(2) to continue our policy of conducting a post-episode spending calculation in PYs 6 through 8. However, the post-episode spending calculation has previously been conducted at the subsequent reconciliation in order to allow additional time for claims run-out beyond the 2 months that precede the initial reconciliation. For PYs 6 through 8, we believe that the six month interval between the end of the performance year will provide sufficient time for claims run-out, given that the 30-day post-episode spending period for the last episodes in a given performance period will end on January 30 of the following year, leaving five additional months of claims run-out before the single reconciliation. Rather than finalize our proposal to incorporate the post-episode spending policy for PYs 6 through 8 into § 510.305(j)(2), we have instead added § 510.305(m)(i)(vi) to clarify that the post-episode spending calculation will take place at the single reconciliation for PYs 6 through 8.

Since the target price methodology will differ in a number of ways between PY subset 5.2 and PY 6, we are also clarifying how we will treat episodes that begin during PY 5.2 but end, and are therefore reconciled, in PY 6. In § 510.300(a)(3) we stated that episodes that straddled performance years or performance year subsets would be subject to the target price applicable to the start date of the episode. This means that there will almost certainly be CJR episodes that have a performance year 5.2 target price but are reconciled in performance year 6. In the proposed rule, we stated at § 510.301 that beginning in PY 6, we would further adjust the target price computed under § 510.300 for risk and market trends to arrive at the reconciliation target price amount. However, PY 5.2 target prices were designed to apply to inpatient episodes only, incorporating adjustments for MS–DRG and fracture status without additional beneficiary-level risk adjusters, and incorporating a prospective update factor rather than a retrospective market trend adjustment. Therefore, we believe it would not be appropriate to further adjust a PY 5.2 target price for beneficiary-level risk factors and a retrospective market trend at the PY 6 reconciliation. In order to be consistent with our policy at § 510.300(a)(3), but also accommodate the difference in target price calculation methodology between PY 5.2 and PY 6, we are modifying our proposed text at § 510.301 to specify that episodes subject to a PY 5.2 target price but reconciled in PY 6 would not have their target price further adjusted for risk and market trends.

In response to the commenters' concerns about timely feedback on their model performance, we note that providing two reconciliation reports in the transition year also mitigates concerns that a delay in reconciliation would prevent participant hospitals from receiving timely feedback in their reconciliation report. We also point out that we continue to provide a monthly claims data feed including all claims for services included in a given episode. This provides timely feedback that can be used by participants to identify cost drivers, identify opportunities for greater care coordination, and gauge their performance in the model. Further, we will be incorporating claims data for outpatient episodes, CJR HCC count, participant age bracket, and dual eligibility status, as well as providing the regression coefficients that will be used at reconciliation to risk adjust target prices at the episode level. We believe that these data will provide the necessary information to help participants gauge their performance in the model and perform preliminary estimates of the adjustments that will be made at reconciliation.

Comment: A few commenters recommended that CMS maintain the current practice of performing two reconciliations for each performance year. A commenter stated their concern that the proposed revised process will compromise physicians' engagement in care redesign plans and follow-up actions to achieve the objectives of the plan. Another commenter stated that the change would result in payments being further removed from physician behavior. They stated their concern that this could result in incentive payment delays and diminish the impact of such payments on physician behavior.

Response: We acknowledge that the time lag between when physician services are performed and when reconciliation reports and potential reconciliation payments are received may be a challenging aspect of the CJR model. However, we disagree that the change to one reconciliation will impact physician engagement significantly more than the current reconciliation process does. In the initial years of the model, the first reconciliation involved episodes that had ended between 2 and 14 months prior to when the claims data were pulled, with an additional 2 to 4 months of time to complete the

reconciliation calculations and deliver reconciliation reports, and allow a 45-day window for participant hospitals to appeal their results before we finalized them. This resulted in reconciliation payments being made, or repayments being owed, from 6 to 18 months after the episodes had ended, dependent on how early or late in the year the episodes ended. The results of the initial reconciliation would not be finalized until an additional year afterwards. The new reconciliation policy effective PY6 will consist of one reconciliation of episodes that ended 6 to 18 months prior to when the claims data are pulled, with reconciliation payments made, or repayments owed, 10 to 22 months after the episodes had ended. Although this represents a four month shift, we note that physicians will benefit from knowing that reconciliation results, while arriving a few months later than they currently do, will not be subject to any additional reconciliation in the future. We encourage participants who have found effective ways to engage with physician participants to continue these efforts.

Final Decision: After consideration of the comments we received, we are finalizing our proposal to move to one reconciliation for each performance year, beginning 6 months after the end of the performance year. However, for greater clarity, we are not finalizing our proposed changes to § 510.305(j)(1) and (2) to extend previous overlap calculations and post-episode spending calculations to PYs 6 through 8, since they were previously applied at the subsequent reconciliation. As discussed above, we are adding § 510.305(m)(1)(v) to address overlaps for PYs 6 though 8. We are adding § 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. Additionally, we are modifying our 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.

4. Additional Episode-Level Risk Adjustment

When we originally proposed the CJR model pricing methodology, we proposed to provide each hospital with a separate target price for episodes initiated by MS–DRG 469 versus MS–DRG–470, because MS–DRGs under the IPPS are designed to account for some of the clinical and resource variations that exist and that impact hospitals' costs of providing care (80 FR 73338). Specifically, MS–DRG 469, which focuses on costlier and complex hip and knee procedures involving patients with major complications and comorbidities, has a higher relative weight than MS–DRG 470, which ensures that the Medicare payment for MS–DRG 469 is higher than that for MS–DRG 470. However, in response to comments requesting further risk adjustment, we finalized a policy to risk adjust target prices based on the presence of hip fractures (80 FR 73339). We stated our belief that adding hip fracture status to our risk adjustment approach would capture a significant amount of patient-driven episode expenditure variation. The impact of hip fractures on inpatient costs associated with a hip replacement was acknowledged by CMS' decision to create two new MS–DRGs (521 and 522) for hip replacements in the presence of a primary hip fracture (85 FR 58432). We incorporated these new MS–DRGs into the CJR model episode definition as of October 1, 2020 via the November 2020 IFC. Thus, we have been providing four separate target prices to each participant hospital. Prior to October 1, 2020, these target prices were based on the combination of the MS–DRG to which the IPPS admission was grouped (469 or 470) and whether or not the patient had a hip fracture. Since October 1, 2020, when MS–DRGs 521 and 522 were implemented, we no longer need to stratify MS–DRG 469 and 470 episodes by fracture status, as episodes with a hip fracture are assigned instead to one of the two new MS–DRGs.

Given our proposal to specify that permitted outpatient LEJR procedures can initiate a CJR model episode, we recognize that additional risk adjustment is needed in order to account for variability within the four categories of target price. As we note previously in section II.A. of this final rule, we recognize that a single blended target price for the MS–DRG 470 category in particular could potentially underestimate spending on some inpatient episodes and likewise, could potentially overestimate spending on some outpatient episodes. This will theoretically average out across all MS–DRG 470 without hip fracture episodes at the regional level during reconciliation, but given the fact that participant hospitals' ratio of inpatient-to-outpatient cases will vary, we proposed to make an episode-specific adjustment to each target price.

The CJR model policy of adjusting target prices for MS–DRG 469 and 470 based on the presence of hip fracture was originally intended to allow us to include beneficiaries who receive LEJR procedures due to hip fractures in the CJR model, while acknowledging their typically greater health care needs by providing a target price that is based on payment for services furnished in the historical CJR model episode data for Medicare beneficiaries with hip fractures in order to account for a significant amount of beneficiary-driven episode expenditure variation. With the same goal in mind of recognizing the greater needs of certain beneficiaries that are beyond a participant hospital's control, we proposed an additional risk adjustment methodology for PYs 6 through 8. We note that in exploring options for a risk adjustment methodology, we considered a number of factors that are not included in the proposed methodology because they were not strong predictors of episode 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, and/or conflicted with overall bundled payment initiatives. The factors we considered include: Dual eligibility (beneficiaries enrolled in Medicare Part A and/or Part B and receiving full Medicaid benefits); discharge status (the care setting for the beneficiary post procedure); joint region (hip, knee, or ankle); gender; CMS–HCC risk scores (both community and institutional); rural/urban designation of the participant hospital; clinical setting (inpatient or outpatient); rehospitalization rate (presence of hospital admission post procedure); and indices of social determinants of health at the ZIP Code level (for example, participant hospitals receiving a certain level of Medicare disproportionate share payments). After conducting a variety of analyses and regressions, we proposed to incorporate the additional risk adjustment into the CJR model pricing based on CMS–HCC condition count and beneficiary age.

The first part of the proposed methodology takes into account the total number of clinical conditions per beneficiary by assessing the count of CMS–HCC conditions, referred to as the CJR HCC count risk adjustment factor. While we proposed to name this risk adjustment factor the ''CMS–HCC condition count'' in the proposed rule, we are 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. This approach parallels the risk adjustment model used in the Medicare Advantage program that began with Medicare Advantage payments in 2020, which include variables that take

into account the number of conditions a beneficiary may have and makes an adjustment as the number of conditions increase in order to implement section 1853(a)(1)(I)(i)(I) of the Act (42 U.S.C. 1395w–23(a)(1)(I)(i)(I)), as added by section 17006(f) of the 21st Century Cures Act. Similarly, we chose to include risk adjustment variables that account for the total number of conditions of a beneficiary initiating a CJR model episode.

The count variables for CJR HCC count risk adjustment in the CJR model would be a series of binary, yes/no variables, meaning that a beneficiary does or does not meet the criteria for having a given number of CMS–HCC conditions. We proposed to use five CJR HCC count variables, representing beneficiaries with zero, one, two, three, or four or more CMS–HCC conditions. We proposed to estimate a coefficient from the subgroup of beneficiaries in the sample with the specific count of conditions for each count variable (as described later in this section). For example, all beneficiaries with two CMS–HCC conditions would receive a coefficient that is estimated independently of the coefficient for beneficiaries with zero, one, three or four conditions. The coefficient for the two CJR HCC count variable would represent the expected marginal cost of having any two CMS–HCC conditions, as compared to having zero CMS–HCC conditions.

The second part of the proposed risk adjustment methodology is meant to account for average anticipated episode costs associated with the age of a CJR beneficiary. Similar to the strategy for incorporating the CJR HCC count, we would create binary, yes/no variables for beneficiaries that fall into certain age ranges. We proposed four age variables for the risk adjustment methodology to represent beneficiaries aged less than 65 years, 65 years 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. We proposed to estimate a coefficient from the subgroup of beneficiaries in the sample in each age range (as described further later in this section). We proposed that, for applying the coefficient to a given reconciliation target price at reconciliation, we would select the age bracket coefficient based on the patient's age on the date of admission for the anchor hospitalization or the date of the anchor procedure.

The CMS–HCC risk adjustment model is prospective; it uses a profile of major medical conditions in the base year, along with demographic information (for example, age, sex, Medicaid dual eligibility, disability status), to predict Medicare expenditures in the next year. It is calibrated on a population of FFS beneficiaries entitled to Part A and enrolled in Part B, because CMS has complete Medicare expenditure and diagnoses data for this population. The proposed risk adjustment method for the CJR model would also be prospective in that it would 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. Given the timing of this rule and the time to receive and process CMS–HCC condition count data, we proposed utilizing beneficiary CMS–HCC condition count and age data from a baseline of January 1, 2019 to December 31, 2019 to calculate coefficients for both risk adjustment variables for PY6. Similarly, we proposed utilizing beneficiary CMS–HCC condition count and age data from January 1, 2020 to December 31, 2020, and from January 1, 2021 to December 31, 2021 to calculate coefficients for both risk adjustment variables for PYs 7 and 8, respectively. While this should appropriately capture CMS–HCC condition count data for almost all beneficiaries, for any beneficiaries with missing CMS–HCC condition count data we would apply a CJR HCC count risk adjustment coefficient of one, so that their missing CMS–HCC condition count would neither adjust risk up nor down from the average regional target price based in the calculation of the coefficient.

For PYs 6 through 8, coefficients for the risk adjustment variables would be calculated prospectively, prior to the beginning of each performance year, using a linear regression model. In essence, this regression model approach would allow us to estimate the impact of CJR HCC count and age bracket on the episode cost of an average beneficiary, based on typical spending patterns for a nationwide sample of beneficiaries with a given number of CMS–HCC conditions and within a given age bracket. We proposed an exponential model, with the dependent variable equal to the ratio of the individual episode cost to the regional target price, since it will make it less difficult and simpler to estimate the proportional increase or decrease for each independent variable that can be directly applied to adjust the regional target prices. In statistical terms, linear regression models assume a linear relationship between a dependent variable and one or more explanatory variables, and the associated statistical inference typically reflects an assumption of a normal distribution of the error variance (that is, the discrepancy between observed values of the dependent variable and what would be predicted by the model). As we stated in section II.B.5 of this final rule, when costs are normally distributed, 95 percent of the costs are truly within 2 standard deviations of the mean, with only 5 percent of episodes having costs that are much higher than the average cost or much lower than the average cost. As we have previously observed, TKA and THA episode costs in the CJR model are not normally distributed; that is, less than 95 percent of the costs fall within 2 standard deviations of the mean. This means that TKA and THA episode costs in the CJR model will inherently exceed the 2 standard deviation threshold more often than other clinical episode costs that are distributed normally.

Exponential models, such as the risk adjustment model we proposed, are commonly estimated by transforming the equation to logs through logarithmic transformation. In transforming our proposed exponential model, the dependent variable becomes the difference in the logs of the individual episode costs and the applicable regional MS–DRG target prices and the proportional increases or decreases for each independent variable are obtained by exponentiating the regression coefficients of the log-transformed model.

Estimating the logged version of such a model could be problematic when de-transforming the logged results to their original form (that is, dollars), but this concern is not relevant since we are simply proposing to utilize the ratios from the logged version of the model. Further, we believe that the MS–DRG target pricing differentiation already explains a portion of the cost differences in CJR model episodes. Therefore, rather than using the log of the episode cost, we proposed to use the differential between the log of the episode cost and the log of the episode target price so as to focus only on the cost difference not already reflected in the existing target prices.

Specifically, for each episode in the national sample, grouped into its appropriate category based on 36 combinations of the 9 regions and the 4

MS–DRG categories, we would subtract the log transformed episode target price for that category from each log transformed standardized episode cost.[8] We note that prior to computing the log values of the episode costs, we ranked the episode costs and determined the 99th percentile (high episode cost cap) amount for each region/MS–DRG combination. We then replaced the actual cost amount for each episode that exceeded the applicable 99th percentile amount with that 99th percentile amount, consistent with our proposal to update the methodology used in deriving the high episode spending cap amount.[9] We note that we purposely applied the high cost episode cap prior to computing the regression as we are looking to compute a risk adjustment for the dollars involved in the model. Since we have a high episode cost cap such that no episode will ever cost more than the cap amount, we wanted to ensure the risk adjustment coefficient explained the difference between the capped costs and the target price so we could adjust the targets appropriately. Then, we would regress, or determine the strength of the relationship between each risk adjustment factor and episode costs, these amounts (the costs from episodes of care furnished to any eligible beneficiary in FFS Medicare from the applicable baseline calendar year who is entitled to Part A and enrolled in Part B and has an episode triggered by a claim for a MS–DRG 469, 470, 521 or 522, or permitted outpatient TKA/THA CPT code) onto their CJR HCC count and age bracket. The resulting coefficients associated with CJR HCC count and age bracket (after exponentiating the coefficients in order to ''reverse'' the logarithmic transformation we performed earlier on episode costs for purposes of the regression calculation), would be referred to as the CJR HCC count risk adjustment factor and the age bracket risk adjustment factor. Because the coefficients are calculated at the national level, the average risk score in a given region and MS–DRG category may not be equal to one. As a result, the target price for a beneficiary could have a positive or negative risk adjustment applied even if that beneficiary's risk score is equal to the average risk of the regional population on which their target price was based. We considered alternative approaches of calculating coefficients separately for each region or applying risk-standardization to the regional target price prior to applying the beneficiary-specific risk score. However, we did not pursue these alternatives in an effort to minimize complication. We solicited comment on whether additional calculations steps should be included in order to ensure that the average risk score in a given region and MS–DRG category is equal to one.

An example of the regression output from this model is provided in Table 3. The output provided in Table 3 was calculated using the ''2018 HCC payment year file'' data, which is derived from national episode claims data dated January 1, 2017 to December 31, 2017 for MS–DRG 469, MS–DRG 470, and the permitted outpatient TKA/THA CPT code. The ''Pr > √t√'' column indicates the probability value, or p-value, that the effect of the risk adjustment factor is explained by that risk adjustment factor alone. Small p-values, typically less than 0.05, indicate strong evidence that the effect can be attributed to the risk adjustment factor. As described later in this section, the high p-value for the Dual Eligibility factor influenced our decision to not choose that risk adjustment factor. Indicated by the ''e^x'' column, the risk adjustment coefficients represent the anticipated marginal cost associated with each specific risk adjustment factor. For example, the 1.116 value in Table 3 for beneficiaries Age 85+ indicates that beneficiaries 85 years and older are anticipated to increase marginal episode costs by 11.6 percent. These coefficients would be posted on the CMS website prior to each PYs 6 through 8, along with the average regional target prices, as described in section II.B.2 of this final rule.

[8] We requested comment on specification checks that should be conducted and on revisions, such as a switch to a fixed effects model, that would facilitate such additional analysis.

[9] We requested comment on the impact of this practice on the statistical validity of the model.

TABLE 3: REGRESSION OUTPUT FROM LOG LINEAR REGRESSION MODEL

Parameters	Model Estimates	Standard Error	t Value	Pr > |t|	e^x
Intercept	-0.08756	0.002127	-41.17	<.0001	0.916
Age 85+	0.109515	0.002573	42.56	<.0001	1.116
Age 75 to 84	0.012587	0.00219	5.75	<.0001	1.013
Age 65 to 74	-0.05192	0.002134	-24.33	<.0001	0.949
Age Under 65					1
Dual Eligibility[*]	0.001991	0.002787	0.71	0.4748	1.002
CJR HCC Count = 4	0.226897	0.001721	131.81	<.0001	1.255
CJR HCC Count = 3	0.140797	0.001893	74.4	<.0001	1.151
CJR HCC Count = 2	0.095357	0.001534	62.16	<.0001	1.100
CJR HCC Count = 1	0.047497	0.001314	36.14	<.0001	1.049
CJR HCC Count = 0					1

[* While we did not propose to include dual eligibility status in Medicare and Medicaid as a risk adjustment factor, it is included in this table to demonstrate the criteria we used to determine appropriate factors. The regression analysis was run without the Dual Eligibility variable, with no apparent impact on the other coefficient estimates. The results displayed for this variable in this table represent a definition of dual-eligibility that includes beneficiaries enrolled in Medicare Part A and/or Part B and receiving full or partial Medicaid benefits]

An updated example of the regression output from this model is provided in Table 3a, which was calculated using national episode data from January 1, 2018 to December 31, 2018 (prior to the introduction of MS–DRGs 521 and 522), for MS–DRG 469, MS–DRG 470, and the permitted outpatient TKA/THA CPT code. When CMS updated the data in Table 3, we also 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. As noted in section II.C.4 of the proposed rule, our intention was to only include beneficiaries receiving full Medicaid benefits and not those only receiving partial Medicaid benefits. The correction in the programming to only include beneficiaries fully eligible for Medicaid benefits, as well as enrolled in Medicare Part A and/or Part B, demonstrates that there is strong evidence to suggest that the correctly defined dual eligibility status variable alone has a statistically significant effect on episode costs. Specifically, CMS observed a p-value of <0.0001 for the correctly defined variable using the 2017 claims data that was used for Table 3 in the proposed rule, as well as using the 2018 claims data used to calculate the results in Table 3a in this final rule.

TABLE 3a: REGRESSION OUTPUT FROM LOG LINEAR REGRESSION MODEL

Parameters	Model Estimates	Standard Error	t Value	Pr > |t|	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

[* The results displayed for this variable in this table represent a definition of dual-eligibility that only includes beneficiaries enrolled in Medicare Part A and/or Part B and receiving full Medicaid benefits]

We proposed to conduct this linear regression model on updated baseline data and post the coefficients on the CMS website prior to the start of each of the performance years (6 through 8). By re-running the linear regression model each year based on more recent, nationwide data (including both CJR model and non-CJR episodes), we will more accurately account for changes in spending patterns that disproportionately impact certain subgroups within our two risk adjustment variables of CJR HCC count and age bracket. For instance, if a new LEJR-related treatment were introduced during the baseline period, but it was only appropriate for use in patients under the age of 85, then the risk for increased episode costs relative to the regional mean episode cost associated with being in the age brackets for beneficiaries under age 85 would be impacted differently than the risk of being in the 85+ age bracket. By re-running the linear regression model each year and updating the risk adjustment coefficients, we would be able to more accurately risk adjust at the episode level for all categories of beneficiaries at reconciliation.

At reconciliation, after actual performance year episode costs are capped at the proposed 99th percentile consistent with our proposal to update the methodology used in deriving the high episode spending cap amount, the transformed risk adjustment coefficients for the two variables from the log-linear regression would be applied to quality adjusted target prices based on the applicable episode region and MS–DRG. However, since the age and the CJR HCC count variables are inherently included in the regional target price, as regions with a higher proportion of older beneficiaries or beneficiaries with higher CJR HCC counts tend to have higher average episode costs, we propose to apply a normalization factor to remove the overall impact of adjusting for age and CJR HCC counts on the national average target price. This normalization factor would be the national mean of the target price for all episode types divided by the national mean of the risk-adjusted target price. For example, if the average target price for all episodes (average of all 36 MS–DRG 469, MS–DRG 470, MS–DRG 521, and MS–DRG 522, applied to all episodes in a year) is $22,000 and the average of target prices for the same set of episodes once risk adjustments are applied is $23,158, then the normalization factor would be computed as 0.95 ($22,000 divided by $23,158). We would then apply the normalization factor to the previously calculated, beneficiary-level, risk adjusted target prices specific to each episode region and MS–DRG combination. These normalized target prices would then be further adjusted for market trends (as detailed at § 510.301) and quality performance (as specified at § 510.300), prior to being compared to the episode costs (after episode costs are reduced for high episode spending as specified at § 510.300 and/or extreme and uncontrollable conditions under § 510.305). We note in this final rule we are making a technical change to the description of this process at § 510.301(a)(5)(iv) to streamline the regulation text.

For example, 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 episode during PY6. Assume that the total actual cost for this episode was $21,900, which for purposes of this example we will assume is under the high cost episode cap amount and thus no capping needs to be applied to the actual costs and that the beneficiary was treated at a CJR participant hospital with a composite quality score of 'Good' with a 1.5 percent withhold.

Assuming the target price for region 4 DRG 470 is $17,097 (reflects a 3 percent quality withhold), the normalization factor in effect for PY6 is 0.95, and the market trend factor is 1.023, the target price applied for reconciling this episode would be computed as follows:

Step 1. Risk adjust the target –Assuming the value shown in TABLE 4: RISK FACTOR MULTIPLIERS FOR THE CJR MODEL FOR ALL AGE BRACKET AND CJR HCC COUNT COMBINATIONS of this proposed rule are in effect for purposes of this example, locate the appropriate risk adjustment co-efficient combination for a CJR HCC count of 4 and age of 70 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 of 0.95:

$23,308.34 * .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 of 'Good' (1.5 percent withhold rather than 3 percent) by restoring 3 percent and then adjusting to withhold 1.5 percent:

$22,652.21 * 100/97 = $23,352.79
$23,352.79 * .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. We previously considered making risk adjustments based on a participant hospital's average HCC score for patients with anchor hospitalizations (80 FR 73338). However, we did not propose this policy because the HCC score was developed for applications in generalized population health and might not be appropriate for use in predicting expenditures for specific clinical episodes over a shorter period of time. We proposed to use the CJR HCC count and age variables as risk adjustment factors, as we believe that these variables do improve the predictability to our target pricing, even though they are not as fully comprehensive as the HCC score variable. As noted in the ''e^x'' column of Table 3, the risk adjustment coefficients vary across groups consistent with expected increases in severity, and the coefficients are monotonic with respect to expected severity (with the exception of the under 65 age group, which is expected to be relatively expensive due to the high volume of disabled beneficiaries in that age group). Additionally, we proposed to use CJR HCC count and age because based on internal regression analyses using the coefficients from Table 3, those factors contribute an additional 7.1 percent of statistically significant predictability to our target price calculation. This improved accuracy in target pricing is especially important since early evaluation results from the CJR model that indicate a higher proportion of episodes are exceeding the high-cost episode cap than initially anticipated. Using the values from Table 3, we constructed Table 4 to illustrate the risk factor permutations for each Age Bracket and CJR HCC count category. Additionally, in this final rule, we used the values from Table 3a to construct an updated version of Table 4, which is Table 4a in this final rule. Table 4a illustrates the risk factor permutations for each Age Bracket and CJR HCC count category, as well as the dual-eligibility status factor. For PYs 6, 7 and 8, we proposed to publish updated versions of Tables 3a and 4a on the CMS website prior to the beginning of each performance year based on the data from the applicable baseline calendar year in order to communicate the specific risk factors applicable in a given performance year.

TABLE 4: RISK FACTOR MULTIPLIERS FOR THE CJR MODEL FOR ALL AGE BRACKET AND CJR HCC COUNT COMBINATIONS

Age Bracket	CJR HCC Count = 4	CJR HCC Count = 3	CJR HCC Count = 2	CJR HCC Count = 1	CJR HCC Count = 0
Age 85+	1.401	1.285	1.228	1.171	1.116
Age 75 to 85	1.271	1.166	1.114	1.063	1.013
Age 65 to 74	1.191	1.092	1.044	0.996	0.949
Age Under 65	1.255	1.151	1.1	1.049	1

TABLE 4a: RISK FACTOR MULTIPLIERS FOR THE CJR MODEL FOR ALL AGE BRACKET, CJR HCC COUNT, AND DUAL-ELIGIBILITY STATUS 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

Our intent with the proposed risk adjustment methodology is to reduce the need for application of the high-cost episode cap by more accurately setting and adjusting target prices, although our proposed new methodology for deriving the high episode spending cap amount may also reduce instances when the cap applies. This approach is responsive to commenters in past CJR model proposed rules that indicated the accuracy of target prices benefits participants by increasing financial predictability of participation in the model.

We also considered, as a risk adjustment variable, a beneficiary's dual-eligibility status in Medicare and Medicaid, or a variable to potentially control for social determinants of health and patient economic demographics. As noted in section II.C.4 of this final rule, CMS updated the data in Table 3 with calendar year 2018 claims data and the correct definition of a dual-eligible beneficiary, and Table 3a demonstrates that there is strong evidence to suggest that the dual eligibility status variable alone has a statistically significant effect on episode costs. Specifically, CMS observed a p-value of <0.0001 for the correctly defined dual-eligibility status variable using calendar year 2018 claims data. As previously noted, other variables considered but not chosen due to similar lack of additive predictive power were rural or urban designation of the participant hospital and ZIP Code level. While we did not propose to include dual-eligibility status as a risk adjustment variable, we sought comment on the inclusion of this and other risk adjustment variables in the model to account for such patient characteristics. Additionally, we chose binary variables to represent the risk adjustment factors since it is a generally accepted common practice in similar regression analyses, and for simplicity purposes in our model. However, we sought comment on alternative methods for expressing these factors in our exponential risk adjustment model.

The following is a summary of the comments received and our responses.

Comment: Many commenters were in support of the proposed episode-level risk adjustment. All commenters that commented about using age as a risk adjustment variable were in support of the proposal. While most commenters were in support of using CJR HCC count as a variable, some commenters recommended adjustments. In particular, commenters recommended adjusting the methodology to account for the severity, or weight, of certain HCC conditions instead of the count of conditions alone. In particular, a commenter requested that CMS consider the relative impact on the perioperative period of some of the cardiovascular/pulmonary codes versus more chronic diseases that might be impactful longitudinally but do not have as much effect in an acute intervention setting. A commenter expressed support for the proposed risk adjustment variables, but recommended CMS strengthen its approach to quality measurement given the movement to the outpatient setting for these procedures.

Response: We appreciate that many commenters supported the proposed risk adjustment variables and methodology. When developing the proposed risk adjustment methodology for the 3-year extension of the CJR model, we did consider including specific adjustments for the weight and severity of certain HCC conditions. However, we encountered problems with insufficient claim volume for certain HCC conditions, and when they were included in the regression modeling, they did not contribute any material improvement in statistical predictability of the regression model compared to simply using HCC condition count alone. As noted in section II.C.4 of this final rule, simplicity has been an important consideration as we introduced the proposed risk adjustment methodology, and we determined HCC condition count would be a more transparent approach to risk adjustment than if we had included a more complex approach with specific HCC conditions included in the regression modeling. CMS appreciates the commenters' suggestion to consider the relative impact on the perioperative period of some of the cardiovascular/pulmonary HCC condition codes versus more chronic diseases. Similar to our decision to not include a site of setting risk adjustment variable, we chose to exclude specific adjustment for certain HCC conditions in the regression model to avoid

creating incentives that may motivate participant hospitals to focus on coding certain HCC conditions due to their exaggerated effect in the risk adjustment methodology compared to other HCC conditions. As noted in section II.F.2 of this final rule, we believe the proposed quality measures, in conjunction with the proposed risk adjustment methodology, will ensure our inclusion of outpatient procedures in the model does not negatively impact beneficiary quality of care or safety.

Comment: Some commenters recommended calculating the coefficients at the regional level instead of the proposed national level, citing the need to capture unobserved socioeconomic characteristics or other factors that vary by region. Some commenters recommended the effect of the risk adjustment variables be limited so they could only increase target prices (that is, do not apply any coefficients lower than 1.0), stating the purpose of the risk adjustment multiplier is to reduce the need for a high episode cap due to it being raised to the 99th percentile of historical costs. A commenter recommended that CMS calculate risk adjustment variables in a single regression that includes the MS–DRG and the fracture status. A commenter stated that since target prices reflect regional baseline costs, CMS should consider normalizing based on regional case mix.

Response: We appreciate the suggestions from commenters on the calculation of the risk adjustment coefficients. We did sample coefficients calculated at the regional level and observed similar average effects compared to our nationally calculated coefficients. In particular, we observed only a 0.1 percent difference in r-squared, or the goodness of fit measure that measures the strength of the relationship between the model and the dependent variable, between the two regression models. We anticipate the additional inclusion of dual-eligibility status as a risk adjustment variable in this final rule will capture some of the unobserved socioeconomic characteristics that may vary by region. We are also choosing to calculate the risk adjustments at the national level to reduce 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. While CMS maintains the purpose of the risk adjustment methodology, as well as other proposed changes to the CJR model payment methodology meant to reduce the need for the high episode spending cap, we also designed the risk adjustment methodology to accommodate our inclusion of the outpatient and inpatient episode target price. Since outpatient procedures may be less costly than inpatient procedures for patients that share similar characteristics, we determined it would be inappropriate to limit the effect of the risk adjustment methodology to only increase target prices. While CMS considered the approach of using a single regression that includes the variables that define the 36 MS–DRG and regional combinations and used that regression to predict the mean episode cost, we believed it would be simpler and equally effective to utilize a risk adjustment process that supplemented the existing structure and did not change the existing use of the 36 target price groups by defining the dependent variable in the regression as costs not already captured by the 36 target price group means. Lastly, we agree that target prices reflect regional baseline costs, but disagree that after risk adjustment, they should be normalized by region. We believe it would be inappropriate because the resulting effect would be that the risk adjustment process would only account for differences in severity within and not across regions.

Comment: 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. In particular, a commenter noted that this variable should be included because it is associated with the likelihood of readmissions for Medicare beneficiaries undergoing these procedures, as evidenced by its inclusion as a stratified risk adjustment variable in the Hospital Readmissions Reduction Program. A commenter stated they appreciated the comprehensive description of CMS' analysis in the proposed rule, including its finding regarding dual-eligible status, and recommended that CMS explore proxy measures of socioeconomic status if dual-eligibility is found to not be a significant predictor in the model.

Response: We originally included the dual-eligibility status variable in our risk adjustment regression in an attempt to include an adjustment for a variable to potentially control for social determinants of health and patient economic demographics. We ultimately chose not to propose inclusion of this variable due to a p-value 0.4748 that was calculated using 2018 claims data. However, as noted in section II.C.4. of this final rule, when CMS updated the data in Table 3 with 2019 claims data we also 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. As noted in section II.C.4. of the proposed rule, our intention was to only include beneficiaries receiving full Medicaid benefits and not those receiving partial Medicaid benefits. The correction in the programming to only include beneficiaries fully eligible for Medicaid benefits, as well as enrolled in Medicare Part A and/or Part B demonstrates that there is strong evidence to suggest that the correctly defined dual-eligibility status variable alone has a statistically significant effect on episode costs. Specifically, CMS observed a p-value of <0.0001 for the correctly defined variable using the 2018 data that was used for Table 3 in the proposed rule, as well as using the 2019 data used to calculate the results in Table 3a in this final rule. As a result of this new evidence that suggests the dual-eligibility status variable alone does have a statistically significant effect on episode costs, and in response to comments, we are adding full dual-eligibility status as a risk adjustment variable to the CJR model in this final rule. Similar to the other risk adjustment variables, the dual-eligibility status variable will be a binary (yes or no) variable that indicates a beneficiary was enrolled in Medicare Part A and/or Part B and receiving full Medicaid benefits.

Since we are finalizing an update to the target price methodology, as described in section II.B.3. of this final rule, such that target prices for PYs 6, 7, and 8 will be calculated with episode baseline data from 2019, 2021, and 2022, respectively, we are finalizing corresponding changes to the data used to calculate the risk adjustment coefficients. In particular, we are finalizing that the coefficients for each of the three risk adjustment variables will be calculated from Medicare claims data dated January 1, 2019 to December 31, 2019 for PY6 and PY7, and from January 1, 2021 to December 31, 2021 for PY8. As noted previously, we agree with commenters that use of 2020 data should be avoided. Therefore, similar to declining to rely on the 2020 claims data used to calculate target prices as a result of potential distorting effects on the data due to the COVID–19 PHE, we are also not using that year of data for risk adjustment calculation purposes. In particular, we will hold the CJR HCC count risk adjustment factor coefficients

calculated with claims data dated January 1, 2019 to December 31, 2019 for PY6 constant for PY7, since we are making corresponding changes to target price calculations to avoid using 2020 baseline data for target prices. Risk adjustment coefficients would then be updated and posted on the CMS website before PY8 begins, using claims data dated January 1, 2021 to December 31, 2021. As noted in section II.B.3 of this final rule, we anticipate the corrective mechanisms of the PY6 methodology will reduce the distortion potentially caused by the COVID–19 PHE in the 2021 data. As 2021 data become available, we will monitor the potential effects of the COVID–19 PHE on that data and determine if any adjustment is needed regarding use of the 2021 data for PY8 risk adjustment coefficient calculations. All three risk adjustment factor coefficients will be posted on the CMS website prior to the start of each performance year, along with the applicable target prices. We appreciate that commenters were generally in favor of adding this dual-eligibility status, or another variable, to capture the effect of a beneficiary's socioeconomic status on their episode costs.

Comment: Some commenters were in support of adding other risk adjustment variables, including functional status, disability status, joint location, reason for Medicare eligibility, post-discharge destination, urban/rural patient address, patient demographics, sociodemographic status, marital status, race, ethnicity, income, and education.

Response: CMS appreciates the additional risk adjustment variables that commenters suggested. We anticipate our addition of the dual-eligibility status variable in this final rule may satisfy some of the recommendations from commenters to consider an additional risk adjustment variable that would adjust target price costs based on a patient's demographics, socioeconomic status, and other similar factors. As noted in section II.C.4 of this final rule, we designed the risk adjustment methodology to serve as a progressive step from the original CJR model methodology that adjusted MS–DRG 469 and 470 target prices based on fracture status alone. However, we must balance our objective to test innovative risk adjustment methodologies with the mandatory nature of the CJR model. We anticipate that some of the hospital participants that are selected for participation in the CJR model are not those that would have otherwise voluntarily chosen to participate in an APM and may not be as familiar with the related alternative forms of payment, such as the proposed risk adjustment methodology, so we intended to reduce complexity of the risk adjustment methodology by only selecting the most important risk adjustment variables. CMS also was limited in our ability to consider some risk adjustment factors, such as a patient's income or education, given the difficulty in consistently and accurately capturing this data and using it for risk adjustment purposes. As a result, we chose to limit the complexity of the risk adjustment methodology and are not including other factors at this time.

Comment: Some commenters requested additional information about the process of calculating the episode-specific adjustments, with a commenter suggesting that CMS validate both exponential and linear risk adjustment regression models with 2019 data to evaluate goodness of fit. A commenter requested information on the factors that CMS chose not to include, specifically whether the mix of inpatient versus outpatient episode was a rejected factor. A commenter asked whether a sub-group analysis was done for the higher quintile cost groupings of the proposed risk adjustment variables to see if the effects of those risks become more apparent for poor urban populations, especially for the more specific grouping of very high cost outliers, stating that this this would also impact the proposed elimination of the outlier caps.

Response: As described in section II.C.4 of this final rule, CMS tested the proposed risk adjustment regression model using 2019 Medicare claims data. We determined that in addition to the risk adjustment variables originally proposed (age and CJR HCC count), the dual-eligibility status variable was also statistically significant, which led us to include that variable in the risk adjustment methodology described in this final rule. While we considered a linear regression model, we chose the exponential model because it yielded factors that can be applied directly to (that is, multiplied times) the existing target prices as proportional adjustments. The exponential model also yielded plausible statistically significant estimates of the effects for the proposed variables and added explanatory power. CMS did consider whether to include site of setting as a risk adjustment variable in the regression modeling. However, given the significant effect this variable would have on target prices (as a result of the variation in outpatient and inpatient episode costs), we did not propose to include it as a risk adjustment variable. We continue to assert that the risk adjustment methodology, with the addition of dual-eligibility status as a variable, that we are adopting in this final rule will effectively capture the associated costs with CJR beneficiaries in either setting and will not infringe on the patient-doctor decision-making. Regarding the comment that suggested CMS conduct a sub-group analysis for the higher quintile cost groupings of the proposed risk adjustment variables to see if the effects of those risks become more apparent for poor or urban populations, we anticipate the addition of the dual-eligibility status variable should help address this potential differential in effect size given the income limitations associated with beneficiaries enrolled in Medicaid

Comment: Other commenters requested clarification on the timeframe that would be used to count the number of HCCs a beneficiary has, which should give providers a better understanding of the methodology and its effects. A commenter asked whether the HCCs will be captured through outpatient ICD–10 codes as well as inpatient, and for what preceding period.

Response: We noted in the proposed rule that we would utilize beneficiary CMS–HCC condition count and age data from a baseline of January 1, 2019 to December 31, 2019 to calculate coefficients for both risk adjustment variables for PY6, data from January 1, 2020 to December 31, 2020 for PY7, and data from January 1, 2021 to December 31, 2021 for PY8. As described in section II.B.3. of this final rule, while the same date ranges for data will be used to calculate the CJR HCC count, age, and dual-eligibility status risk adjustment variables, we will calculate coefficients for PY6 and PY7 using claims data dated January 1, 2019 to December 31, 2019, and coefficients for PY8 using claims data dated January 1, 2021 to December 31, 2021. Specifically, we will hold constant for PY7 the risk adjustment coefficients we calculate for PY6. We will post the applicable risk adjustment coefficients on the CMS website prior to the start of each performance year, along with the target prices applicable to that subsequent performance year. We believe that in general, holding constant the risk adjustment coefficients that are posted on the CMS website prior to the start of a performance year until they are used at reconciliation will be responsive to commenters that expressed concern about the proposed retrospective market trend factor of the proposed payment methodology. We also clarify that this HCC data will be captured for beneficiaries receiving both inpatient and outpatient procedures.

Comment: A commenter recommended that since there is variability in the content of patients' medical records which may result in a hospital not capturing all of the patient's conditions, CMS should provide education to providers participating in the model and practitioners to better ensure they are aware of this change once finalized. A commenter requested that CMS provide HCC data in the current model year before finalizing the proposed rule, to allow participants to fully understand the implications of the proposed risk adjustment methodology.

Response: We appreciate the recommendation that given the variability in the content of patients' medical records and its potential effect of not capturing all of a patient's conditions, CMS should provide education to providers participating in the model and practitioners. We will ensure this is appropriately provided in CJR model educational material and communications. Given the timing of this final rule and the PY5 operations currently underway in the CJR model, we are unable to retroactively provide current CJR participant hospitals HCC data. However, we are aware that the HCC data and the proposed risk adjustment methodology as a whole will be new to CJR participant hospitals in PY6, we plan to ensure these topics are effectively communicated to participants prior to the start of PY6 through webinars, communications, and other learning material.

Comment: Some commenters expressed concern at the timing of baseline data used to calculate the coefficients, noting that adjustments will be needed for PY7 given that COVID–19 will result in 2020 volume of elective hip and knee surgeries that does not reflect the typical spending pattern of a hospital or region. A commenter suggested CMS consider how COVID–19 may necessitate a new HCC condition that could alter the proposed risk adjustment methodology.

Response: As noted in section II.C.4 of this final rule, we are committed to testing the proposed risk adjustment methodology for the proposed 3-year extension of the CJR model. However, we also understand that due to the COVID–19 PHE, baseline data from 2020 will likely not be as reflective of true market conditions for PY7. As noted in section II.B.3 of this final rule, as a result of potential data issues due to the COVID–19 PHE, we are finalizing that PY6 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. Similarly, we are finalizing corresponding changes to the timing of risk adjustment data to avoid the potential in distorting effects of the COVID–19 PHE on the 2020 data. In particular, PY6 and PY7 risk adjustment coefficients will be calculated based on claims data from January 1, 2019 to December 31, 2019, and PY8 risk adjustment coefficients will be calculated based on claims data from January 1, 2021 to December 31, 2021. We will monitor the need for future adjustments to 2021 risk adjustment data as well.

Comment: A commenter stated that CMS proposed to create an episode-specific adjustment for each target price to account for a participant hospital's varying case mix and requested that CMS clarifies how it will calculate the proposed episode-specific adjustment.

Response: While CMS proposed episode-level risk adjustment to account for the age and number of HCC conditions a certain beneficiary may have, we did not propose a general case-mix adjustment, such as a hospital's case mix indexes (CMI) for discharges which would be the sum of the average DRG relative weight of a hospital's discharges (as described on the CMS website: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download-Items/CMS022630*).

Comment: A few commenters expressed concern about applying the proposed risk adjustment methodology to both inpatient and outpatient episodes, stating that the relationship between excess costs and HCC condition count varies significantly between episodes that originate in the inpatient versus outpatient setting, and additional risk adjustment must be incorporated. Similarly, a commenter stated that the proposed risk adjustment methodology will not account for beneficiary-specific factors in situations where the same patient can have an elective procedure done in either inpatient or outpatient setting.

Response: We anticipate that since the CJR HCC count risk adjustment factor will be calculated from annual HCC data, and not the HCC data documented on claims specifically related to a procedure, any variation in costs between episodes that originate in the inpatient versus outpatient setting is warranted and will appropriately account for the characteristics of those beneficiaries that are associated on average with more or less costs. CMS is not indicating that the proposed risk adjustment factors will capture patient preferences, or other beneficiary-specific factors, in situations where the same patient can appropriately have an elective procedure in either the inpatient or outpatient setting. We proposed the risk adjustment factors because we believe they will appropriately account for some of the episode cost differences related to those factors. We maintain that the decision for site of setting is a collaborative choice made by clinicians and patients and intentionally avoided using risk adjustment factors that could affect the nature of that decision.

Comment: A few commenters suggested that CMS use the same risk adjustment model that is currently used in the BPCI Advanced model, and a commenter suggested that CMS adopt the Alternative Payment Condition Count (Alternative PCC) model since it includes new HCCs for Dementia and Pressure Ulcers. Similarly, a commenter suggested that CMS consider the benefit of aligning risk adjustment across models where it makes sense, using the most appropriate factors including an ability to adapt for changes in condition instead of relying too heavily on past behavior as the key predictor of the future, particularly to account for changing clinical practice patterns, and accounting for the number of chronic conditions of an individual.

Response: We recognize the benefit of payment policy alignment across models, including the BPCI Advanced. Given the unique mandatory nature of participation in the CJR model, however, CMS strives to ensure transparency in the model's payment methodology. We must assume that some of the participants that were selected for participation in the CJR model are not those that would have otherwise voluntarily chosen to participate in an APM and may not be as familiar with the related alternative forms of payment, such as the bundled payments in the CJR model. As a result, simplicity has been a tenet of the CJR model's payment methodology, which led us to propose the age and CJR HCC count risk adjustment methodology for the proposed 3 additional years of the model. As CMS analyzes the results of more complicated risk adjustment methodologies, such as those in BPCI Advanced or those referenced by the commenter that would use the most appropriate factors (for example, including an ability to adapt for changes in condition), we will consider their effectiveness and appropriateness for adoption in other potential mandatory models. As described in section II.C.4 of this final rule, CMS selected the CJR

HCC count variable given the recent recognition and adoption of the HCC condition count variable described in section 17006(f) of the 21st Century Cures Act, which is similar to the HCC condition count variable in the Alternative PCC model. We consider this variable a potentially effective and simple risk adjustment variable that would be appropriate for the CJR model, but we do not believe the entire Alternative PCC model would be appropriate for the CJR model since it is meant to more comprehensively assess this risk of an entire patient population for Medicare Advantage, unlike the episode-level risk adjustment proposed for the 3 additional years of the CJR model.

Comment: A commenter stated that insufficient information was provided to reach a conclusion on whether the risk adjustment method is appropriate. Another commenter responded to our request for comment on specification checks that should be conducted for the risk adjustment calculation and on revisions, such as a switch to a fixed effects model that would facilitate such additional analysis and stated the provider community lacks the necessary information to meaningfully comment on such a change and that if CMS would like substantive comments on a model that is different than the model proposed, CMS should provide the details of such a model.

Response: We note and are concerned that the commenter believes insufficient information was provided to reach a conclusion on the appropriateness of the proposed risk adjustment method. We strived to notify the public of the proposed risk adjustment method in the most comprehensive manner, while balancing the burdens associated with regulatory review. As described in section II.C. of this final rule, we will post documentation about the applicable target prices and risk adjustment coefficients on the CMS website prior to the start of each performance year. As is standard CJR model policy, we will also answer any participant hospital questions regarding the risk adjustment methodology at the CJR mailbox: *cjrsupport@cms.hhs.gov.* We believe the level of detail we provided in the proposed rule was sufficient for the provider community to comment on, as evidenced by the fact that the vast majority of commenters on this topic provided substantive comments, and only one commenter expressed concern, which indicates that commenters had enough information to meaningfully comment. When considering the additional risk adjustment for the 3-year extension of the model, we considered various statistical models, including a fixed effects model, to determine the effect of the risk adjustment variables and described these considerations and our decision making process in section II.C.4. of the proposed rule. Since this is a new risk adjustment method for the CJR model, we also sought comment broadly on whether a fixed effects, or any other statistical model, would be advantageous and whether CMS should consider alternatives. While we did not receive specific comments recommending other statistical models to consider, if CMS determines that an alternative statistical model could be more appropriate, we will address the details of such a model in future rulemaking.

Final Decision: After consideration of comments received, we are finalizing the proposed risk adjustment methodology policy, with the following adjustments. We will add dual-eligibility status as a risk adjustment factor (defined as beneficiaries enrolled in Medicare Part A and/or Part B and receiving full Medicaid benefits on the first day of the CJR model episode) along with the existing factors of a beneficiary's age and CJR HCC count, as described at § 510.301(a)(1). We also note a numbering change to § 510.301(a)(1)(ii) in this final rule to ensure clarity regarding the age bracket variables. Additionally, the data used to calculate all risk adjustment coefficients for PY6 will be derived from Medicare claims data from January 1, 2019 to December 31, 2019; these coefficients will be held constant and used for PY7. The coefficients for PY8 will be derived from Medicare claims data from January 1, 2021 to December 31, 2021.

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

As discussed in section II.B.5. of this final rule, the high episode spending cap amount was designed to prevent providers from being held responsible for catastrophic spending amounts that they could not reasonably have been expected to prevent, such as post-acute care, related hospital readmissions, and other items and services related to the LEJR episode, by capping costs for those episodes at 2 standard deviations above the regional mean episode price in calculating the target price and in comparing actual episode payments during the performance year to the target prices. However, the current methodology for setting the high episode spending cap amount has not been as successful when applied to actual performance period episode spending at reconciliation, illustrated by the fact that we have observed a high percentage of episodes exceed the cap during reconciliation, which indicates that the cap may not reflect true outlier costs. This may be partly explained by the fact that the TKA and THA procedure episode costs are not distributed normally. As discussed in section II.B.5 of this final rule, many LEJR episodes fall above 2 standard deviations from the mean at reconciliation (a much greater deviation than would occur if the costs were distributed normally). As a result, for PYs 6 through 8, we proposed to change our method 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. Similar to the current methodology, the high episode spending cap amounts applied during reconciliation for each MS–DRG would be derived from performance year regional spending. Total episode costs above the 99th percentile would be capped at the 99th percentile amount, and these capped episode amounts would be used when comparing performance year costs to target prices during reconciliation. We expect that this method of calculation will result in high episode spending cap amounts that more accurately represent the cost of infrequent and potentially non-preventable complications for each category of episode, which the participant hospital could not have reasonably controlled and for which we do not want to penalize the participant hospital. We proposed conforming changes to § 510.200. The following is a summary of the comments received and our responses.

Comment: Many commenters stated that the proposed cap is similar to spending cap policies for other CMS payment models and were supportive of consistency across CMS models wherever feasible. A few commenters recommended that if CMS finalizes the proposed high cost episode spending cap at the 99th percentile, then CMS should adjust the stop-loss and stop-gain limit amounts to be 10 percent to account for these higher expenditures being included.

Response: We appreciate that stakeholders recognize the potential benefit of aligning policies across models and the CJR model's intention to align where possible and appropriate. Given the similarity in the CJR model and the BPCI Advanced model, it makes sense to align the high episode spending cap for proposed PYs 6 through 8 with BPCI Advanced's existing policies and

maintain the 20 percent stop-gain and stop-loss limits.

Comment: Some commenters opposed the proposed methodology for determining the high cost episode spending cap amount at reconciliation. A commenter stated that for a subset of elective LEJR patients, despite optimal care being provided prior to surgery, unexpected and severe complications do occur, and the proposed cap at the 99th percentile does not appropriately protect hospitals from incurring undue penalties because of these complications. Some commenters suggested we continue to use the current 2 standard deviation spending cap for high cost episodes, and other commenters recommended setting the cap at the 98th, 95th, 90th, or 80th percentiles. A commenter stated that the proposed high episode spending cap is arbitrary and there is no clear rationale for decreasing the number of episodes that can be capped to 1 percent.

Response: We maintain that the risk adjustment methodology described in this final rule, with the addition of the dual-eligibility status variable, will effectively adjust target prices to account for characteristics of certain LEJR patients that are associated with higher costs. As we state in section II.C.5. of this final rule, we anticipate the other changes to the target price methodology we are adopting for PYs 6 through 8 also will limit the occurrence and need for the high episode spending cap used at reconciliation compared to the payment methodology for PYs 1 through 5. In particular, the policy to cap high cost episodes at the 99th percentile during reconciliation is consistent with, and mirrors the policy we are adopting in section II.B.5 of this final rule to calculate CJR model target prices during PYs 6 through 8 by capping high cost episodes in the baseline data at the 99th percentile. The alignment of these high cost episode caps is necessary to ensure they are symmetrically applied to episode costs during the target price calculation and reconciliation for each performance year. This is consistent with the high episode spending cap used in BPCI Advanced model. We analyzed internally the effect of adopting a high episode spending cap at the 98th percentile using the same 2018 claims data used to calculate the risk factor multipliers in Table 4 of this final rule. We observed 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, which was contrary to our intention to change the high cost episode spending cap. As a result, we did not consider percentiles lower than 98th, such as 95th, 90th, or 80th as commenters suggest, and are adopting the 99th percentile in this final rule.

Final Decision: After consideration of comments received, we are finalizing the proposed policy to change our method 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.

6. Changes to Trend Factor Calculation

A limitation of the CJR model target price methodology for PYs 1 through 5 is the absence of a trend factor calculation at reconciliation to incorporate and be responsive to ongoing practice changes in the joint replacement space. When we designed the original target price methodology, we did not anticipate the nationwide downward trend in use of post-acute care services. This decrease in use, corresponding to a decrease in average LEJR episode prices, was seen in both CJR model and non-CJR participant hospitals, representing an underlying trend in LEJR episode spending patterns that was neither specific to, nor driven by, CJR participant hospitals. This generalized downward trend was not incorporated into CJR model target prices, leading to artificially inflated target prices for CJR model episodes. Our goal is to reward CJR participant hospitals for decreased spending based on improved coordination and quality of care related to their participation in the CJR model, not to reward decreases in spending that likely would have occurred even in the absence of the model, as evidenced by comparably decreased spending in non-CJR participant hospitals. If the CJR model were to continue to provide artificially inflated target prices, the model would not decrease Medicare spending over time.

Another major change that is not accounted for in CJR model target price methodology is the recent restructuring of the SNF payment system in the FY 2019 SNF PPS final rule (83 FR 39162). The original CJR model methodology assumed that the SNF payment system would retain the same structure, but would update prices on an annual basis, which would be reflected in the trend factor. However, effective October 1, 2018, we finalized a policy to change the case-mix methodology used to set payment rates for SNFs, which was implemented starting on October 1, 2019 (83 FR 39162). The existing case-mix classification methodology, the Resource Utilization Group, Version IV (RUG–IV) model has been replaced by a new case-mix methodology called the PDPM. The new case mix methodology is designed to focus on the patient's condition and resulting needs for care, rather than on the amount of care provided, in order to determine Medicare payment. This structural change to the SNF payment system means that, if we were to try to adapt the existing CJR model trend factor methodology, prior year SNF spending can no longer be simply updated, but rather would need to be translated to reflect a different SNF payment methodology. A similar payment system change was finalized for the Home Health Prospective Payment System (HH PPS) in the CY 2019 HH PPS final rule (83 FR 56406) which updated the period of care and other methodological components of the HH PPS effective January 1, 2020. Similar to the FY 2019 SNF PPS updates, we anticipate the new strategy we proposed would account for these trends.

The inability to integrate both generalized spending trends not driven by the CJR model, and major payment system changes, in combination with the fact that outpatient TKA data were not available prior to 2018, have led us to propose a new way to account for trend in CJR model target prices.

Rather than the national update factor and biannual Medicare prospective payment and fee schedule update methodology we currently apply to historical episode spending in order to trend target prices forward prospectively (80 FR 73342), we proposed 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.

Specifically, after the beneficiary-level, risk adjusted target prices are normalized, as described in section II.B.5 of this final rule, the next step before reconciling expenditures would be to apply a market trend factor to the target prices. The market trend factor would be the regional/MS–DRG mean cost for episodes occurring during the performance year divided by the regional/MS–DRG mean cost for episodes occurring during the target price base year. For example, the PY6 market trend factor for MS–DRG 470 in Region 1 would be calculated as the Region 1 mean episode costs for MS–DRG 470 episodes ending between January 1, 2021, to December 31, 2021, divided by the Region 1 mean episode costs for MS–DRG 470 without hip fracture episode ending between January 1, 2019, to December 31, 2019.

We note that after applying the adjustment to the IPPS payment for episodes with MS–DRGs 469 and 470 with fracture, they will be comparable to MS–DRGs 521 and 522 in the performance period, as described in section II.A.2. of this final rule, no further adjustment to the market trend will need to be performed. As a result, we would calculate 36 market trend factors during reconciliation, one for each MS–DRG and region combination. These market trend updates would then be applied to the normalized target prices discussed in section II.B.5 of this final rule. The resulting target prices would be the final target prices used when reconciling performance year episode costs. We proposed utilizing the regional mean episode costs as a basis for the market trend factor update calculation, but we sought comment on alternatively using the regional median episode costs for this calculation.

Combined with our proposal to use 1 calendar year of baseline data to calculate CJR model target prices for PYs 6 through 8 (discussed in section II.B.3. of this final rule), the proposed changes to our trend factor calculation methodology will allow us to capture both trends in spending patterns and payment system updates in a simplified, retrospective manner. The following is a summary of the comments received and our responses.

Comment: Some commenters generally agreed with the proposed market trend factor, with some agreeing in particular with the proposal to calculate the market trend factor at the regional level. 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 not apply the market trend factor and instead only update target prices to reflect updates to Medicare payment systems and fee schedules (consistent with the model's current approach). Similarly, a commenter suggested that if CMS finalizes their proposed market trend factor they also implement a cap of 1 percent on changes in utilization-related pricing factors.

Response: CMS appreciates the supportive comments received regarding the proposed market trend factor, in particular, our proposed method to calculate the factor at the regional level. Given the variable trends in the LEJR market, as discussed in section II.B. of this final rule, as well as the potential disruption created by the COVID–19 PHE, CMS determined it would not be appropriate to limit the effect of the market trend factor (for example, limited by decreases to target prices as suggested by MedPAC, or limited by decreases or increases of 1 percent as another commenter suggested). We believe that in conjunction with the other payment methodology policies in this final rule, such as the proposed use of a 99th percentile high cost episode cap for target price and reconciliation calculations and the 20 percent stop-gain and stop-loss limits, it is not necessary to impose a cap or limit on the effect of the market trend factor and that doing so could actually be inappropriate if there are significant variations in market conditions in the baseline data period compared to each performance year.

Comment: Many commenters were generally opposed to the proposed market trend factor, and some commenters suggested the existing twice annual update for payment system changes is sufficient. Many commenters stated the market trend factor is unnecessary and expressed concern that participants may have fewer opportunities to track and improve performance and that financial predictability may be lost if it is finalized. In particular, a few commenters noted that target price volatility resulting from the market trend factor would strain a hospital's relationship with the physicians with whom it has entered into gainsharing agreements to improve outcomes for Medicare beneficiaries.

Response: As noted in the discussion before Table 6a of section IV.C. of this final rule, we anticipate the market trend factor will alleviate the need for the twice annual update for payment system changes and that it will actually capture these changes more accurately than the twice annual update methodology. In particular, the previous update methodology was prescriptive of which payment systems it would update target prices for, and it did not anticipate the addition of a new payment system (for example, the SNF PDPM) and was unable to adjust for this update. Since the market trend factor is rooted in episode costs and agnostic to a change in any one particular payment system, we believe it will more appropriately account for differences between baseline and performance period spending than the previous twice annual update. Additionally, while the market trend factor may have the effect of decreasing target prices as a result of lower performance period average costs compared to baseline costs, as we note in section II.C.6 of this final rule, the market trend factor could also have the effect of increasing target prices to reflect higher performance period average costs. This could be particularly important if there is an innovative new device introduced for LEJR patients that increases average episode costs, or as a result of significant changes in patient case mix (for example, the potential impact of the COVID–19 PHE).

CMS recognizes the retrospective nature of the market trend factor may create uncertainty for participant hospitals. However, we believe it is important to balance this uncertainty with the need to accurately account for changes in the market. As noted in section II.A.2 of this final rule, the LEJR market in particular is undergoing many changes with the movement to outpatient procedures in 2018 and 2020. We determined that the uncertainty of the retrospective trend adjustment is appropriate to ensure accurate target prices for both hospital participants and any physicians with whom they enter gainsharing agreements, and that it is a necessary and important component of the entire CJR model payment methodology adopted for PYs 6 through 8, especially given the use of 1 year of baseline data. In this final rule, we also attempted to increase target price predictability for participant hospitals by providing sample target prices in Table 2a and by clarifying that the CJR HCC count coefficients posted on the CMS website prior to the start of each performance year will not change or be updated at reconciliation.

Comment: Some commenters stated the market trend factor would unfairly lead to decreased target prices for well-performing CJR model participant hospitals over time and would penalize the provider unnecessarily and obstruct their ability to continue delivering quality care at reduced costs. Some commenters stated that the proposed market trend factor is unnecessary for CMS to seek additional savings and is unfair given the increased administrative and financial burden it places on participants.

Response: Many of the CJR model payment methodology changes CMS is adopting in this final rule for PYs 6 through 8 are interdependent, and we believe will only be successful if implemented together. For example, the addition of outpatient procedures to the episode definition, which will create site-neutral target prices that are adjusted based on patient characteristics (age, CJR HCC count, and dual-eligibility status), is only possible if the risk adjustment methodology described in section II.C.4. of this final rule is simultaneously implemented. If the risk adjustment methodology were not also implemented, the regionally calculated

site-neutral target prices could be inappropriately low for inpatient episodes at certain participant hospitals or inappropriately high for outpatient episodes at other participant hospitals based on the fact that the target prices will be calculated by blending the generally lower-cost outpatient episodes with generally higher-cost inpatient episodes. Similarly, we are only able to adopt the use of 1 year of baseline data for target price calculation purposes for PYs 6 through 8 if we are also able to simultaneously adopt the market trend factor, which is meant to ensure consistency between baseline and performance period spending patterns. We recognize the use of 1 calendar year of baseline data compared to 3 years of data could create increased variation between performance period and baseline spending patterns and are adopting the market trend factor in response to this potential increase in variation. We are also adopting a simplified version of the CJR model payment methodology in this final rule by removing the twice annual update for payment system changes, and this would also not be possible without the market trend factor that is intended to accomplish the same effect of updating for payment system changes. In conjunction with these policies, we anticipate the proposed market trend factor will ensure consistent and more accurate pricing when comparing the baseline period to the performance year than the CJR model payment methodology used for PYs 1 through 5. CMS also asserts that our use of regional only data for target price calculations in PYs 6 through 8 (instead of using hospital-specific data that could penalize a hospital for its own improvements and potentially limit the hospital's ability to achieve savings) will still create an opportunity for participants to utilize the CJR model flexibility (for example, gainsharing agreements), achieve lower average episode spending compared to their regional peers, and achieve savings in the CJR model during PYs 6 through 8. We realize more accurate target prices could mean lower target prices (if average LEJR episode spending continues to decrease over time), but as noted previously and in section II.C.4. of this final rule, we also anticipate that the proposed risk adjustment methodology will appropriately adjust target prices based on certain beneficiary characteristics and that this risk adjustment methodology is an improvement from the previous methodology that simply adjusted target prices based on the presence of a hip fracture.

Comment: A few commenters suggested calculating the market trend factor after excluding beneficiaries receiving an LEJR procedure from a participant in either the CJR model or BPCI Advanced, or after excluding beneficiaries aligned to a Medicare ACO. Some commenters opposed the proposed policy to calculate a blended target price with inpatient and outpatient episodes and recommended CMS create separate target prices. As a result of these changes, the commenters noted that the market trend factor would similarly need to be calculated separately for inpatient and outpatient episodes. Similarly, some commenters noted that the market trend factor methodology is a disincentive for use in the inpatient setting. Specifically, the commenters state that because CMS proposes to maintain the 100 percent regional pricing methodology, the proposed market trend factor would set target prices based on the regional rate of outpatient procedures, which has the potential to create a race to the bottom and unfairly penalize providers treating a higher proportion of complex patients.

Response: Similar to our policy to include CJR model, BPCI Advanced, and Medicare ACO beneficiaries in the baseline data to more accurately reflect national average spending patterns, we determined that it would be appropriate to also include these beneficiaries in the market trend factor calculation. As noted in section II.C.2. of this final rule, when CMS proposed the blended target price, we also proposed the risk adjustment factors to account for the potentially higher costs associated with certain patients that would likely be more appropriate for the inpatient versus outpatient setting. We continue to believe the risk adjustment methodology will accomplish this, and we also believe the model's quality measures, noted in section II.F. of this final rule, and other CMS penalties associated with patient complications will effectively guard against inappropriate outpatient utilization. CMS recognizes that incorporating outpatient procedures into the target price methodology, with 100 percent regional data used for target price calculations, would in general have the effect of decreasing target prices, as is evidenced in the sample target prices in Table 2a of this final rule. However, we do not believe this will constantly decrease target prices, or create a race to the bottom, or unfairly penalize providers treating a higher proportion of complex patients because the effect of the risk adjustment will be to increase target prices for episodes for such beneficiaries. In particular, as noted in Table 4a of this final rule, the risk adjustment factors could have the effect of increasing target prices up to 250 percent for a beneficiary that is dual-eligible, 85 years or older, and with four or more HCC conditions.

Comment: A commenter noted that since episode costs are not normally distributed, the median cost is more appropriate than the mean to calculate the market trend factor since it is a non-parametric (not normally distributed, or asymmetrical) measure of central tendency.

Response: CMS recognizes that since episode costs are not normally distributed, the median could be considered a more appropriate variable to calculate the market trend factor compared to the mean. We completed internal analysis of the potential effect of using the median to calculate the market trend factor and observed a nominal difference compared to using the mean of episode costs. In particular, the trend factors calculated using means were 0.01 higher than trend factors calculated using medians. The differences in trend factors by region and MS–DRG ranged between −0.03 and 0.10. This effect is not surprising, as the distribution of standardized CJR model episode costs is right-skewed, meaning it is not normally distributed and more episodes have average costs that are above the median. Given the relative small difference in effect, and the benefit that using the mean of episode costs could have for participant hospitals (that is, increasing target prices more compared to the median), we continue to believe the mean of episode costs is more appropriate for calculating the market trend factors.

Comment: A commenter agreed with the theory of a trend factor but suggested the CJR model adopt a prospective trend factor, similar to BPCI Advanced. Similarly, another commenter urged CMS to consider methodologies to incorporate trend factors directly into the target price on a prospective basis while retaining reasonable savings potential for both CMS and model participants. A commenter suggested that a baseline combination of historical data and regional pricing would create a more reasonable trend adjustment that does not unfairly penalize hospitals for performing well in the model. A commenter requested that CMS recognize in the calculation of the regional trend factor an amount to reflect the contribution of CJR model incentives to reduce spending for post-

acute care above the secular trend in FFS spending.

Response: CMS understands the request of participant hospitals to incorporate a prospective market trend factor in the CJR model, similar to BPCI Advanced. As noted in section II.A.2. of this final rule, the LEJR market is currently evolving with TKA and THA shifting to the outpatient and ASC setting. The unknown effect of this migration, compounded by the potential effects of the COVID–19 PHE, elevates the importance of a mechanism to retrospectively adjust target prices at reconciliation and we maintain the market trend factor must be applied retroactively to be effective in this regard. As we note in section II.B.3. of this final rule, we recognize 2020 calendar year claims data may not be reflective of PY7 market conditions as a result of the COVID–19 PHE and are modifying our target price calculation such that PY7 target prices will be calculated using 2021 calendar year claims data instead of the proposed 2020 calendar year claims data. While 2021 data could also have distortions as a result of the COVID–19 PHE, we anticipate the corrective mechanisms of the PYs 6 through 8 payment methodology, in particular the market trend factor, will reduce this distortion. For this reason, we do not believe it is necessary to prospectively provide for a separate adjustment because we anticipate the market trend factor, as a result of its ability to retrospectively adjust target prices at reconciliation for variation that occurred between the baseline and performance period, will reduce the potential necessity to adjust 2021 data to account for the effect of the COVID–19 PHE.

We also note that the BPCI Advanced's prospective Peer Adjusted Trend (PAT) Factors approach is more complex than the market trend factor we are adopting in this final rule and relies on adjustments for peer group characteristics, time trends, and interactions (as described further on the CMS website here: *https://innovation.cms.gov/files/x/bpciadvanced-targetprice-my3.pdf*). Given the potential burden of implementing a more complex approach for mandatory CJR model participant hospitals that may not be familiar with intricate risk adjustment methods compared to voluntary participants in BPCI Advanced, as well as the administrative cost of calculating this factor each year, we do not believe it would be appropriate for use in the CJR model. Given the proposed use of regional only data in the target price calculations, we determined it would be inappropriate and inconsistent to include hospital-specific historical data in the market trend factor calculation since it could potentially penalize hospitals for their own improvement in historical episode costs. As noted in section II.B.3. of this final rule, we will not exclude beneficiaries from the baseline data used for target price calculations that were aligned under an APM, such as the CJR model, BPCI Advanced, or a Medicare ACO initiative, because we believe their inclusion is more reflective of the true average costs of care given the proliferation of APMs. Similarly, we do not believe it would be appropriate to include adjustments in the market trend factor to account for the effect of CJR model incentives compared to FFS spending because we consider these effects and their impact on costs to be reflective of the true average costs of care. Lastly, we believe this adjustment could make the market trend factor overly complex and difficult to update for the potentially different effects of the payment methodology changes in this final rule compared to the CJR model payment methodology in PYs 1 through 5.

Final Decision: After consideration of comments received, we are finalizing the proposed policy to include a market trend factor that will be the regional/MS–DRG mean cost for episodes occurring during the performance year divided by the regional/MS–DRG mean cost for episodes occurring during the target price base year.

7. Changes to Composite Quality Score Adjustment

When setting an episode target price for a participant hospital, we currently apply a 3 percentage point discount to establish the episode target price that applies to the participant hospital's episodes during that performance year. We established this policy because we expect participant hospitals to have significant opportunity to improve the quality and efficiency of care furnished during episodes in comparison with historical practice, because this model facilitates the alignment of financial incentives among providers caring for beneficiaries throughout the episode. This discount serves as Medicare's portion of reduced expenditures from the episode, with any episode expenditure below the target price potentially available as reconciliation payments to the participant hospital where the anchor hospitalization occurred.

For PYs 1 through 5, a 1 percentage point reduction is applied to the 3 percent 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, for PYs 1 through 5, a 1.5 percentage point reduction is applied to the 3 percent discount factor for participant hospitals with excellent quality performance, defined as composite quality scores that are greater than 15.0.

While we did not propose to change the 3 percentage point discount factor, we proposed to increase a participant hospital's ability to reduce the discount factor as a result of its composite quality score. We proposed this change in recognition that the proposed changes to the target price calculation (discussed in section II.B. of this final rule), intended to increase the accuracy of target prices compared to actual performance period spending may also narrow the potential for participant hospitals to earn reconciliation payments. For PYs 1 and 2, a large majority of CJR participant hospitals received a reconciliation payment: 44 percent of CJR participant hospitals received reconciliation payments in both performance years and an additional 33 percent received a reconciliation payment in 1 of the 2 performance years; 23 percent never received reconciliation payments.

Because of these more accurate target prices, and the fact that all participant hospitals would be at financial risk during PYs 6 through 8, we determined that a more generous composite quality score adjustment to the discount factor is appropriate. The composite quality score adjustment for PYs 1 through 5, with a maximum potential for a 1.5 percentage point reduction to the discount factor, could potentially force the target amounts calculated under the proposed methodology (discussed in section II.B. of this final rule) under an appropriate actual cost amount, which is not the intent of the model. While the discount factor was meant to serve as Medicare's portion of reduced expenditures from an episode, we determined that the proposed changes to the target price methodology are adequate to maintain an appropriate level of reduced expenditures for Medicare while rewarding participant hospitals with high composite quality score. For further information on the anticipated model savings as a result of the proposed target price changes, see section IV.C. of this final rule.

As a result, we proposed that, for PY6 through 8, a 1.5 percentage point reduction be applied to the 3 percent 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, we proposed that a 3 percentage point reduction be applied to the 3 percent 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 will effectively be eliminated for the applicable performance year.

Comment: Several commenters support the proposal to increase the quality score adjustment to a 1.5 percentage point reduction to the applicable discount factor for participant hospitals with ''good'' quality performance and a 3 percentage point reduction to the applicable discount factor for participant hospitals with ''excellent'' quality performance.

Response: We thank the commenters for their support on this topic.

Comment: MedPAC suggested that CMS could 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.

Response: CMS appreciates MedPAC's suggestions to generate additional savings for the Medicare program by increasing the discount factor. Many of the changes CMS proposed to the CJR model payment methodology for PY6 through 8 are intended to be improvements to the original methodology that will increase the probability for model savings. While CMS could design a payment methodology that attributed a much larger portion of savings to the Medicare program through a higher discount factor, we must also balance the administrative burden and investments needed by participating hospitals to be successful under the model, and thus propose to maintain the 3 percent discount factor that is intended to ensure that CJR participant hospitals are still capable of achieving a certain level of savings for themselves in the model.

Final Decision: After consideration of the public comments we received, we are finalizing the proposed change to percentage reduction to the discount factor for participant hospitals with good and excellent quality performance.

D. Three-Year Extension (PYs 6 Through 8)

1. PYs 6 to 8 Timeframe

As noted in sections II.B. and II.C. of this final rule, we proposed changes to the CJR model target price methodology and the reconciliation process primarily to account for the removal of TKA and THA procedures from the IPO list and analysis of the reconciliation process for CJR model PYs 1 to 2 that indicates the process is not functioning as initially intended (for example, a larger number of episodes are being capped by the high episode spending cap amount than we anticipated). We proposed to extend the CJR model for an additional 3 years to run through December 31, 2023, to allow sufficient time to evaluate the impact of the changes we proposed to resolve these concerns. We proposed that, while PY6 episodes would end on or after January 1, 2021, PY6 episodes would start as of the later of October 4, 2020, or the date on which the final rule becomes effective. We solicited comment on our proposed start date of PY6, determining that this additional time is needed to complete the model test to generate the necessary evaluation findings for an expansion. Extending the model for 3 additional performance years will allow the Innovation Center to test and evaluate the model while promoting the alignment of quality with financial accountability. We proposed to change the regulations under 42 CFR part 510 to reflect this extension.

Further, the November 2020 IFC extended PY5 an additional 6 months to end on September 30, 2021. As a result of this new PY5 end date, we sought comment in the November 2020 IFC on the duration of PY6 of the CJR model. In particular, we sought comment on the potential for PYs 6 through 8 to remain 12 month performance years or for increasing the duration of PY 6 to 15 months.

Comment: Many commenters noted concerns regarding the impact of the COVID–19 PHE on the performance period. Some commenters expressed concern that the public health emergency (PHE) impact may endure far beyond the proposed timeline and requested that the CJR model be terminated at the conclusion of PY5 without the proposed 3 year extension. Furthermore, due to the serious complications suffered by older adults and those with underlying health conditions, it was recommended that the U.S. health system limit non-emergency, elective services to help prevent further exposure of the virus and to preserve essential medical supplies. Some commenters requested that CMS hold hospitals harmless from penalties for the 2020 performance year due to their focus on defeating COVID–19. In addition, requests for adjustments to financial expenditures, performance scores and risk adjustment were made for PY5 and PY6 due to hospital resources being shifted to combat the virus. Many commenters also noted concerns regarding the impact of the COVID–19 PHE on participants' financial stability to maintain administrative, post-acute care and care management infrastructure absent the reconciliation payments that would be anticipated from participation in the CJR model.

Response: We understand commenters' concerns regarding the effect of the COVID–19 PHE on CJR participant hospitals and the health care system as a whole. We do not believe terminating the model at the end of PY5 would be the appropriate response to dealing with the COVID–19 PHE. As outlined in section II.K. of this final rule, we adopted policies in the April 2020 IFC and the November 2020 IFC to provide flexibilities for CJR participant hospitals during the PHE. In the April 2020 IFC, we originally extended PY5 to March 31, 2021 and we adjusted the extreme and uncontrollable circumstances policy to provide generous financial safeguards for CJR participant hospitals during the emergency period. In the November 2020 IFC, we adjusted the extreme and uncontrollable circumstances policy to provide a more targeted adjustment so that safeguards continue to apply for CJR episodes during which a CJR beneficiary receives a positive COVID–19 diagnosis. We also extended PY5 an additional six months to end on September 30, 2021.

Comment: A commenter requested PY5 be extended until December 31, 2021, such that PY7 and PY8 would start January 1, 2023 and January 1, 2024, respectively, citing as a benefit alignment between performance and calendar years. Another commenter recommended keeping PYs 6 through 8 as 12 months, but did not cite a specific reason.

Response: CMS agrees with the commenter that cited a preference for alignment of calendar and performance years for PYs 6 through 8, as this adds operational simplicity to the model design and follows the same alignment of PYs 1 through 5 that is already familiar to participant hospitals.

Comment: Commenters appreciated the continuous operation of the CJR model without interruption, but expressed concerns that the timeline proposed was unrealistic. Commenters stated that the ramp-up period required considerable re-tooling for the revisions proposed and recommended delaying the PY6 start date to at least six months after publication of the final rule or until the beginning of 2022.

Response: We appreciate the views of our commenters in our efforts to uphold

continuity in the CJR model. We are adopting an episode definition change in order to address changes to the IPO list that now allow for TKA and THA to be treated in the hospital outpatient setting. In addition, this rule adopts changes to the CJR model target price methodology and reconciliation process. We believe that these changes will not require participants to rebuild operational processes because the fundamental characteristics of the model, a bundled payment for a 90-day LEJR episode, have not changed. CMS will continue to provide the same support and resources to participant hospitals during the extension period as we did throughout the original performance period of the model.

Comment: Several commenters supported the 3-year extension of the CJR model.

Response: We appreciate the support given by the commenters in favor of the 3-year extension to the CJR model.

Comment: Commenters encouraged CMS to maintain a seamless transition between model years, particularly between PY5 and PY6. Some commenters requested clarification on how the 3-month extension of PY5, to March 31, 2021 which was established in the April 2020 IFC, will impact the proposed rule.

Response: We agree with the commenters that maintaining a seamless progression between PY5 and PY6 is critical. In the November 2020 IFC, CMS implemented an additional six-month extension to PY5 such that PY5 will now end on September 30, 2021. PY6 will start at the conclusion of PY5 and will run until December 31, 2024, thus creating no gap between performance years and realizing full continuity in the model. The extension of PY5 impacts the October 4, 2020 date used as a deadline for rural reclassification status. The new date will be July 4, 2021 to accommodate the revised start date of PY6, which is October 1, 2021.

Comment: A commenter requested clarification on what will happen at the conclusion of the 3-year extension, along with what changes will take effect. Another commenter suggested that CMS continue to support value-based payment models by creating a sustainable payment pathway for participants who are committed to moving away from FFS care.

Response: We appreciate the comment and will continue to monitor and evaluate model performance through the 3-year extension. CMS is dedicated to testing alternatives to FFS care and improving value based payment models. Any potential future changes to the CJR model will be done via notice-and-comment rulemaking.

Comment: A commenter suggested termination of the CJR model at the conclusion of PY5 and instead suggested developing a pathway for hospitals to become voluntary episode initiators for BPCI Advanced. Other commenters questioned the necessity of the 3-year extension stating that no new information would be gathered that has not already been realized during the model's five-year run.

Response: We appreciate the comments. However, initial evaluation results [10] for the first and second year of the CJR model indicate that the CJR model is having a positive impact on lowering episode costs while maintaining care quality. Despite these positive initial evaluation results, the changes we are making to the CJR model in this final rule will allow the CJR model to adapt to market conditions and provide additional time to assess these changes and evaluate their impact.

Final Decision: As a result of the adjusted PY5 end date to September 30, 2021, and in consideration of the comments we received regarding this topic in the November 2020 IFC, as outlined in section II.K. of this final rule, we are finalizing in this final rule that PY6 will be 15 months, such that it will begin with episodes ending on or after October 1, 2021 and end with episodes ending on or before December 31, 2022. We are also finalizing corresponding changes to the start and end dates for PYs 7 and 8. In particular, PY7 will begin with episodes ending on or after January 1, 2023 and end with episodes ending on or before December 31, 2023. Additionally, PY8 will begin with episodes ending on or after January 1, 2024 and end with episodes ending on or before December 31, 2024.

2. Participant Hospital Definition

In the December 2017 final rule (82 FR 57074) CMS established that effective with PY 3 the MSAs in the CJR model were split into 34 mandatory MSAs and 33 voluntary MSAs, and effective February 1, 2018 model participation would not be required for rural and low-volume hospitals in mandatory MSAs or for all hospitals in voluntary MSAs. CMS provided rural and low-volume hospitals in mandatory MSAs and all hospitals in voluntary MSAs a one time opt-in to continue in the model for PY 3 to PY 5. We updated the definition of participant hospital in the December 2017 final rule, to reflect that beginning February 1, 2018, a participant hospital (other than a hospital excepted under § 510.100(b)) is one of the following: A hospital with a CMS Certification Number (CCN) primary address located in a mandatory MSA as of February 1, 2018 that is not a rural hospital or a low-volume hospital on that date; or a hospital that is a rural hospital or low-volume hospital with a CCN primary address located in a mandatory MSA that makes an election to participate in the CJR model in accordance with § 510.115; or a hospital with a CCN primary address located in a voluntary MSA that makes an election to participate in the CJR model in accordance with § 510.115. The CJR model does not include geographically rural areas; however, some hospitals in the MSAs in the CJR model are considered to be rural for other reasons, such as reclassifying as rural under the Medicare wage index regulations. For purposes of the CJR model, a rural hospital means an IPPS hospital that is located in a rural area as defined under § 412.64 of this chapter; is located in a rural census tract defined under § 412.103(a)(1) of this chapter; or has reclassified as a rural hospital under § 412.103 of this chapter. Additionally, for purposes of this model, a low-volume hospital means a hospital identified by CMS as having fewer than 20 LEJR episodes in total across the 3 historical years of data used to calculate the performance year 1 CJR episode target prices.

As noted in the previous paragraph, CMS provided rural and low-volume hospitals in mandatory MSAs and all hospitals in voluntary MSAs a one time opt-in to continue in the model for PY 3 to PY 5. Of the 400 hospitals eligible to opt-in to PY 3 to PY5, 91 hospitals opted in to continue participating. These 91 hospitals consist of 15 rural hospitals and 1 low-volume hospital in the 34 mandatory MSAs, and 75 hospitals in the 33 voluntary MSAs. Five of the 75 hospitals in the 33 voluntary MSAs are also classified as rural hospitals. As discussed later in this section, this final rule removes 139 voluntary, low volume, and rural hospitals from this model starting in PY 6 due to numerous hospitals in mandatory MSAs reclassifying as rural hospitals for wage index purposes. At the time of this final rule, an additional 48 hospitals in the 34 mandatory MSAs have reclassified as rural.

Hospitals volunteering to participate introduce selection bias because hospitals that are ready and able to participate and keep episode spending under the target price would likely select to continue in the model while

[10] Evaluation report located on the CJR Model website—*https://innovation.cms.gov/innovation-models/cjr.*

hospitals not able to keep episode spending under their target price would likely not participate. This conclusion is further supported given that, measured based on reconciliation payments, most opt-in hospitals financially benefited from participation in the CJR model in the first 2 performance years, which likely influenced their decision to continue participation in PY3 through PY5 of the model. We are evaluating the 75 hospitals who self-selected to continue participation in the model who are located in the 33 voluntary MSAs (voluntary opt-in hospitals) separately from our evaluation of the hospitals that were required to participate (mandatory hospitals) to avoid introducing selection bias into evaluation findings and improve generalizability of findings to all hospitals. It is costly to evaluate the small voluntary arm of the model for PYs 6 through 8 relative to the information that would be gained from the small sample size.

In the February 2020 proposed rule, we proposed to change the definition of participant hospital so only participant hospitals with a CCN primary address in the 34 mandatory MSAs that are not considered low-volume or rural hospitals would continue in the model for the extension. We proposed to exclude participant hospitals in the 34 mandatory MSAs that are low-volume hospitals or rural hospitals (meaning that the participant hospital received a notification from CMS dated prior to October 4, 2020 that they have been designated as a rural hospital), and other participant hospitals with a CCN primary address located in the 33 voluntary MSAs. We did not propose to provide any additional opt-in period for PYs 6 to 8 for previous participant hospitals that opted-in the CJR model, including low-volume hospitals and rural hospitals in the 34 mandatory MSAs, or for any hospitals located in the 33 voluntary MSAs. We designed the CJR model to require participation by hospitals in order to avoid the selection bias inherent in provider's choice of participation (80 FR 73278). Narrowing participation to hospitals in the 34 mandatory MSAs during the 3-year extension will allow CMS to minimize selection bias while evaluating the impact of the changes in this rule.

At the time the proposed rule was issued, we believed that the BPCI Advanced model was an ideal fit for hospitals seeking to voluntarily participate in a clinical episode-based payment model for LEJR once CJR concluded. The BPCI Advanced model offered an LEJR episode that includes outpatient TKA procedures as of January 1, 2020. BPCI Advanced is a voluntary model and held its application period for participation as of January 1, 2020 during the spring and summer of 2019. This application period was open to acute care hospitals, physician group practices, and other entities such as post-acute care providers, and while CJR participant hospitals could not elect LEJR participation under the BPCI Advanced model for 2020, selecting to participate in at least one other BPCI Advanced bundled payment episode for 2020 would have allowed these providers to add LEJR episode participation at the end of their CJR model participation (the end of PY5). Since the CJR model originally was to have ended on December 31, 2020, we anticipated that any participant hospitals interested in pursuing voluntary participation in a bundled payment model already would have applied to participate in BPCI Advanced, of which 40 participant hospitals are concurrently participating in BPCI Advanced for non LEJR episodes.

We proposed to use the notification date of the rural reclassification approval letter as the determining factor for participation in the CJR model for PYs 6 through 8, since it is an objective factor for determining participation based on rural reclassification. For PYs 6 through 8, we proposed that hospitals who applied for rural reclassification pursuant to 42 CFR 412.103 and have been notified by CMS before October 4, 2020 that their application for rural status has been approved will no longer be participating in the model beginning PY6 (that is, for any episodes beginning on or after October 4, 2020). We proposed that participant hospitals reclassified as rural that were notified that their application for rural status has been approved on or after October 4, 2020 (even if the effective date of the rural reclassification is retroactively effective prior to notification) would continue to participate in the CJR model for PYs 6 through 8 and remain the financially accountable entities for PYs 6 through 8. Rural reclassification requests that are submitted in accordance with § 412.103 could take several months to be reviewed and approved by the CMS Regional Office. The CJR model team will make every effort to timely post an accurate list of PY5 participant hospitals identified as having rural status prior to the notification deadline on the CJR model page (*https://innovation.cms.gov/initiatives/cjr*) and will conduct email and/or phone outreach with these providers. Because the rural reclassification review process occurs on a rolling basis, we acknowledge that a delay in communication and notification may occur between the CMS Regional Office and the CJR model team. Accordingly, if hospitals who have been notified of their rural status before the notification deadline receive communications from the CJR model team that suggest their continued participation in the CJR model, it is only due to the delay in CMS internal communications between the CMS Regional Office and the CJR model team. The CJR model team will discontinue model communications to hospitals that were notified of rural status by CMS prior to the notification deadline as soon as the CJR model team is informed of the hospital's rural status. Any hospital who is notified of rural status prior to the notification deadline should disregard these CJR model communications as they do not suggest the hospital's continued participation in the model for PYs 6 through PY8.

Comment: Many commenters expressed concern regarding the exclusion of rural and low-volume hospitals in the mandatory 34 MSAs and hospitals in the voluntary 33 MSAs from the CJR model extension, requesting that CMS either allow voluntary participants to continue participation in the CJR model or, in the alternative, open a new application cycle for BPCI Advanced. Commenters noted that voluntary hospitals did not apply to participate in BPCI Advanced because they were participating in the CJR model at that time and now the application period has closed leaving many hospitals without an option to join any bundled payment model for LEJR episodes. Some commenters believe that rural hospitals participating the CJR model that chose to opt-in will lose their ability to continue providing reductions in costs and improvements in care without continued support from CMS through the CJR model (including monthly data feeds, the ability to share savings with physicians and have the financial resources to maintain program oversight and population health management). Some commenters stated that the cost of care for patients who otherwise would have been included in the CJR model would increase, however they did not provide any evidence of how cost of care would increase for their patients, if they were no longer in the model. Other commenters suggested that excluding willing hospitals from participating in value-based programs goes against the ideal and goals of moving the health care system from ''volume to value.''

Response: We appreciate the concerns of the commenters and we understand that CJR participant hospitals that opted into the model may wish to continue; however, based on preliminary evaluation findings that will be included in the upcoming 4th year evaluation report the participation of voluntary hospitals resulted in significant net losses and therefore continuing to include these hospitals is likely to continue to reduce the overall cost savings of the model. When given the option of volunteering for a model, hospitals typically choose to participate when it is both financially advantageous and provides an opportunity to improve clinical care. A participant hospital's ability to earn reconciliation payments in connection with reduced FFS claims payments does not necessarily lead to overall Medicare savings as reconciliation payments are based on a target price established for broader hospital participation. Further, the continued cost to evaluate the small voluntary arm of the model is excessive relative to the information we would gather from a small sample that is not generalizable. Since the CJR model, as originally designed, would have ended on December 31, 2020, we anticipated that participant hospitals interested in pursuing voluntary participation in a bundled payment model already would have applied to participate in BPCI Advanced during that model's application period. For CJR participant hospitals that participate in BPCI Advanced in any episode other than joint replacement, these hospitals could have elected to participate in joint replacement episodes for CY 2021 when they are no longer in the CJR model. At the time this final rule is published, 139 hospitals will not continue in the model for PY6 through PY8. These 139 hospitals consist of 1 low-volume hospital, 63 rural hospitals, and 75 hospitals in voluntary MSAs. Further, for the 139 participant hospitals whose participation in the CJR model will end, 40 of these hospitals are enrolled in BPCI Advanced and could potentially join BPCI Advanced for LEJR. For hospitals who are unable to participate in either the CJR model or BPCI Advanced model, CMS is regularly reviewing opportunities for model development in the future and will alert hospitals of any opportunities that become available.

Comment: Some commenters noted that selection bias should not be a factor in excluding participation of voluntary hospitals. A commenter recommended removing voluntary hospitals retrospectively from the larger sample for purposes of evaluation. Another commenter stated that CMS is simply renaming ''mandatory'' participants ''voluntary'' participants because these hospitals volunteered to remain in the CJR model after PY2 and therefore the argument regarding selection bias is unpersuasive. In contrast, MedPAC submitted comments recommending that CMS should focus on changes to the model that could generate net savings for the Medicare program.

Response: CMS recognizes the commenters' concerns, however, the CJR model is largely a randomized, mandatory participation model. Once hospitals that were previously mandatory in PY 1 and PY 2 became voluntary in PY 3 and were given the opportunity to opt-in, selection bias was introduced since hospitals that were successful in the model chose to opt-in. All hospitals that were mandatory after the opt-in period continue to be mandatory for the extension except those hospitals that were reclassified as rural or are low-volume hospitals. CMS is not allowing any hospital that voluntarily opted into the model to continue participation for PYs 6 through 8. Likewise, the mandatory design presents CMS with a valuable opportunity to see what kind of utilization patterns occur in high-cost areas when providers are faced with strong incentives to reduce spending and cannot simply opt out of a model. As recommended by MedPAC, at this time, CMS is focused on changes to the model that could generate net savings for the Medicare program instead of redistributing savings back to providers. As previously indicated, internal analyses suggest that voluntary hospitals are less likely to contribute to potential model savings than mandatory hospitals.

Comment: A couple of commenters inquired about the future of the CJR model and suggested that the model become a fully voluntary model after the 3-year extension. Further, commenters believe that the CJR model should be expanded nationally at the conclusion of the 3-year extension. For the 3-year extension, a commenter suggested instituting the CJR model in a larger number of areas, such as the 67 MSAs that were originally included in the model.

Response: We appreciate the comment and will continue to monitor and evaluate model performance through the 3-year extension. Continuing with the 34 MSAs is a sufficient geographic scope to test the changes in the CJR model 3-year extension, while potentially reducing costs to Medicare. In its comment, MedPAC stated its belief that CMS should focus on changes to the model that could generate net savings for the Medicare program and therefore changing certain policies in the CJR model may allow Medicare to generate savings and increase the likelihood that the CJR model could expand after PY 8. Any potential expansion of the CJR model will be done via notice and comment rulemaking as required by section 1115A(c) of the Act.

Comment: A commenter requested that CMS clarify what criteria would qualify a hospital as a low-volume hospital in the 34 mandatory MSAs.

Response: Section 510.2 defines a low-volume hospital as a hospital identified by CMS as having fewer than 20 LEJR episodes in total across the 3 historical years of data used to calculate the PY1 CJR model episode target prices.

Comment: A small number of commenters expressed concerns that the CJR model did not create enough incentives to avoid financial losses. These participant hospitals stated that they fulfilled their obligations and should now be afforded an opportunity to select participation based on their mission, abilities, and market realities. They stated that the CJR model extension creates greater risk for losses without giving the hospitals an opportunity to disengage from the model and recommended finding a way to reinvigorate the options of bundled arrangements with CMS.

Response: We thank the commenters, however, CMS will continue to require hospitals in the 34 mandatory MSAs to participate in the CJR model because, based upon initial evaluation results for PYs 1 and 2, these geographic areas have significant opportunity for reducing episode spending while improving quality of care under the model. The 34 mandatory MSAs have more opportunity because these are the medium and high cost areas and, therefore, there is significant opportunity for improvement. Similarly, we believe that at this point in the CJR model it is most prudent for us to continue the model in these geographic areas because these participant hospitals have already implemented infrastructure changes as well as received initial financial and quality results for the first four performance years.

Comment: Some commenters provided recommendations for changes to the evaluation methodology. A commenter stressed the importance of incorporating health equity in the model evaluation approach and another requested that the evaluation include all

providers influencing the outcomes of patients in the CJR model.

Response: CMS will continue to evaluate the impact of the model on vulnerable populations and investigate claims and utilization across the entire episode and also longer-term outcomes in the patient survey thereby capturing the influence of various providers on model outcomes.

Comment: A commenter expressed concern about how the evaluation will differentiate the changes in cost due to the model and those driven by the ongoing transition in the care setting for services related to MS–DRG 469 and 470.

Response: The model evaluation uses a difference-in-differences design to estimate the differential change in outcomes between the baseline and the intervention period for episodes initiated at CJR participant hospitals and hospitals relative to those initiated at control group hospitals. The difference-in-differences method controls for trends that may affect both CJR model and control group hospitals, such as major policy changes. In addition, the evaluation further adjusts estimates for beneficiary, market, and hospital characteristics that can vary over time and between the CJR model and control group.

Final Decision: After consideration of the public comments we received, we are finalizing our policies with modification to account for PY6 start date as discussed in section II.D.1. of this final rule. The extension of PY5 impacts the proposed October 4, 2020 date used as a deadline for rural hospital status. Therefore, the new date will be July 4, 2021 to accommodate the revised start date of PY6, which is October 1, 2021.

All hospitals with a CCN primary address located in the 33 voluntary MSAs as well as hospitals with a CCN primary address in the 34 mandatory MSAs that are low-volume or rural hospitals will be excluded from PYs 6 through PY8. Hospitals who applied for rural reclassification pursuant to 42 CFR 412.103 (rural hospitals include any scenario outlined in § 412.103(a), which includes rural referral centers (RRCs) as set forth in § 412.96) and have been notified by CMS before July 4, 2021 that their application for rural status has been approved will no longer be participating in the model beginning in PY6 (that is, for any episodes beginning on or after July 4, 2021). Participant hospitals reclassified as rural that are notified that their application for rural status has been approved on or after July 4, 2021 (even if the effective date of the rural reclassification is retroactively effective to before July 4, 2021) will continue to participate in the CJR model for PYs 6 through 8 and remain the financially accountable entities for PYs 6 through 8. Rural reclassification requests that are submitted in accordance with § 412.103 could take several months to be reviewed and approved by the CMS Regional Office. The CJR model team will make every effort to post an accurate list of PY5 participant hospitals identified as having rural status prior to July 4, 2021 on the CJR model page (*https://innovation.cms.gov/initiatives/cjr*) and will conduct email and/or phone outreach with these providers. Accordingly, if hospitals who have been notified of their rural status before July 4, 2021 receive communications from the CJR model team that suggest their continued participation in the CJR model, it is only due to the delay in CMS internal communications between the CMS Regional Office and the CJR model team. The CJR model team will discontinue model communications to hospitals that were notified of rural status by CMS prior to July 4, 2021 as soon as the CJR model team is informed of the hospital's rural status.

E. Participant Hospital Beneficiary Notification and Discharge Planning Notice

1. Participant Hospital Beneficiary Notification

Under current regulations, the participant hospital detailed notification informs Medicare beneficiaries of their inclusion in the CJR model and provides an in-paper, detailed explanation of the model, either upon admission to the participant hospital if the admission is not scheduled in advance, or as soon as the admission is scheduled. We proposed to change the definition of an episode of care to include outpatient procedures, for which the beneficiary would not be admitted to the participant hospital. We also proposed to add the definition of anchor procedure to mean a TKA or THA procedure that is permitted and payable by Medicare when performed in the outpatient setting and billed through the OPPS. We believe that the beneficiary should be notified of his or her inclusion in the CJR model whether the procedure takes place in an inpatient or outpatient setting. Therefore, we proposed changes for the participant hospital detailed notification at 42 CFR 510.405(b)(1) to clarify that if the anchor procedure or anchor hospitalization is scheduled in advance, then the participant hospital must provide notice as soon as the anchor procedure or anchor hospitalization is scheduled. Further, we proposed if the anchor procedure or anchor hospitalization is not scheduled in advance, then the notification must be provided on the date of the anchor procedure or date of admission to the anchor hospitalization.

We currently state that in circumstances where, due to the patient's condition, it is not feasible to provide the detailed notification when scheduled or upon admission, the notification must be provided to the beneficiary or his or her representative as soon as is reasonably practicable but no later than discharge from the participant hospital accountable for the CJR model episode. We proposed to clarify that this policy applies only to inpatient hospital admissions. The purpose of this policy is to promote hospital care for the beneficiary first if it is not reasonably practicable to provide the notification upon admission. For example, if a beneficiary requires emergent care, the focus of the hospital should not be on providing a notification, but on the beneficiary. In contrast, outpatient procedures are generally scheduled and non-emergent. Therefore, we do not believe this policy is applicable to outpatient procedures, and did not propose to allow this type of beneficiary notification in cases of outpatient procedures.

We believed these proposals would require changes to the participant hospital detailed notification provided on the CJR model web page. CMS will update the participant hospital notification model document accordingly.

Comment: All commenters supported CMS' proposal that beneficiaries should be notified of their inclusion in the CJR model whether the procedure takes place in an inpatient or outpatient setting, noting that patients should be equipped with the information necessary to keep them engaged and make well-informed decisions about their care. Many commenters also noted that there is a narrow opportunity for hospitals to provide the participant hospital notification as patients do not come into the hospital until the day of the procedure, and that doctors should be allowed to provide participant notifications before the surgery instead of the CJR participant hospital. Some commenters that supported the proposed policy also recommended changing the time period when a participant hospital notification is required. Specifically, a couple of commenters requested to relieve the notification requirement for providing same day notification or allow for more time to provide the participant hospital

notification when the procedure is scheduled in advance. Also, a commenter requested more time to provide the notification citing CJR participant hospitals face difficulties in identifying which beneficiaries may qualify as CJR beneficiaries, which can prevent them from providing same day beneficiary notifications. Other commenters requested that CMS use less burdensome requirements for providers such as the BPCI Advanced model notification policy.

Response: We appreciate commenters' support of our proposal to notify beneficiaries of their inclusion in the model whether the LEJR procedure is in an inpatient or outpatient setting. After considering commenters' requests to provide more expansive and less burdensome timeframes, we explored other Innovation Center models' beneficiary notification requirements. Specifically we considered BPCI Advanced's beneficiary notification policy, as BPCI Advanced is a similar episode based payment model where episodes can occur in an inpatient or outpatient setting. BPCI Advanced requires that prior to discharge from the inpatient stay or prior to the completion of the outpatient procedure, as applicable, the BPCI Advanced Participant shall ensure that the BPCI Advanced beneficiary receives a copy of a beneficiary notification. Therefore after evaluating comments and other Innovation Center policies, we are amending our beneficiary notification timing requirements so that prior to discharge from the anchor hospitalization, or prior to discharge from the anchor procedure, as applicable, the participant hospital must provide the CJR beneficiary with a participant hospital beneficiary notification. We believe that amending our proposal to incorporate BPCI Advanced's policy will allow CJR participant hospitals more time to provide the participant hospital beneficiary notification, streamline timing requirements and adhere to commenters' request to remove the requirement that a notification must be provided upon admission for an LEJR procedure or upon arrival for an outpatient LEJR procedure. In response to comments received, specifically in regards to the difficulties of identifying CJR beneficiaries, we are amending our policy allowing participant hospitals more time to provide the participant hospital beneficiary notification, in turn providing the participant hospital more time to identify the CJR beneficiaries.

Comment: Some commenters supported CMS' proposal and recommended that CMS create one notification letter for all advanced APMs, including BPCI Advanced, noting that this would be less confusing for beneficiaries as they currently receive significant amounts of paperwork, and this would reduce the administrative burden placed on providers in multiple models.

Response: We acknowledge the commenters' recommendation. We will consider these recommendations as the CJR model progresses and for future model development at the Innovation Center.

Final Decision: After consideration of comments, we are finalizing our proposal with modification and will amend the timing requirements for the participant hospital beneficiary notification so that prior to discharge from the anchor hospitalization, or prior to discharge from the anchor procedure, as applicable, the participant hospital must provide the CJR beneficiary with a participant hospital beneficiary notification.

2. Discharge Planning Notice

Under current regulations, a participant hospital must provide the beneficiary with a written notice of any potential financial liability associated with non-covered services recommended or presented as an option as part of discharge planning, no later than the time that the beneficiary discusses a particular post-acute care option or at the time the beneficiary is discharged, whichever occurs earlier (42 CFR 510.405(b)(3)). Given our proposal as described in section II.A.2. of this final rule to change the definition of an episode of care to include outpatient procedures, for which the beneficiary would not be admitted to the participant hospital, we proposed to clarify the requirements of the discharge planning notice. We believe the beneficiary must be notified of his or her possible financial liability associated with non-covered post-acute care whether the procedure takes place in an inpatient or outpatient setting. Therefore, we proposed that a participant hospital must provide the beneficiary with a written notice of any potential financial liability associated with non-covered services recommended or presented as an option as part of discharge planning, no later than the time that the beneficiary discusses a particular post-acute care option or at the time the beneficiary is discharged from an anchor procedure or anchor hospitalization, whichever occurs earlier.

Comment: A couple of commenters noted for outpatient episodes the discharge planning notification requirement is unclear and can become problematic when a discharge plan is uncertain at the time of procedure scheduling or when a previously discussed plan must be revised on the date of the procedure. These commenters ask CMS to consider revising the timing standard for the discharge planning notification, requiring only ''best efforts'' to provide notification by the time of discharge from the hospitalization or outpatient setting.

Response: We appreciate the recommendations about the discharge planning notification. To be clear, we do not require the discharge planning notice to be provided at time of scheduling. We require the participant hospital provide the beneficiary with a written discharge planning notice either when a post-acute care option is discussed with the beneficiary or when the beneficiary is discharged from an anchor procedure or anchor hospitalization, whichever occurs earlier. We understand that some commenters find this policy problematic in that post-acute care plans can change after being discussed with a beneficiary. We understand that post-acute care plans can change after the first discussion, but providing the discharge plan notification to beneficiaries when plans are first discussed allows beneficiaries to be notified of potential financial liability associated with non-covered services recommended or presented as an option as part of discharge planning. Also, this allows beneficiaries to be aware of potential financial costs associated with post-acute care options whether or not the original discharge plan is followed.

Final Decision: After consideration of public comments, we are finalizing our discharge planning notice requirements as proposed.

F. Quality Measures and Reporting

The two quality measures included in the CJR model are the THA and/or TKA Complications measure (NQF #1550) and the HCAHPS Survey measure (NQF #0166). The model also incentivizes the submission of THA/TKA PRO and limited risk variable data. We proposed to advance the Complications and HCAHPS performance periods for PYs 6 through 8 in alignment with the performance periods used for PYs 1 through 5. For PRO, we also proposed to advance the performance periods in alignment with previous performance periods as well as make changes to the thresholds for successful submission. We proposed to make these changes to the thresholds for successful submission as participant hospitals gain experience

with PRO and to continue the trend of increased thresholds set by the earlier performance years of the model. These proposed changes are outlined in Table 5.

In response to the new start and end dates for PYs 6 through 8, we are finalizing § 510.400(b)(4)) to reflect the revised pre- and post-op collection periods for PRO quality data. For PYs 6 through 8, CMS will extend the post-op PRO data collection window 2 additional months to accommodate for patients that may schedule post-op appointments beyond 365 days. This will allow an opportunity for participant hospitals to complete their post-op PRO assessment. The post-op PRO data collection window is normally from April 1st through June 30th every year; the new window will be from April 1st through August 31st. The extended window will total 14 months compared to the original proposed 12 month window. The start of post-op PRO data collection window for PY6 will remain unchanged, but will extend an additional 2 months (April 1, 2020 through August 31, 2021). However, as a result of the PY5 extension we will shift the PY6 pre-op PRO data collection window 1 year later than originally proposed to April 1, 2021 through June 30, 2022 to align with the start and end dates of PY6 through PY8. Please refer to section II.D.1. of this final rule for complete timeline changes to the 3-year extension of performance years.

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TABLE 5. PROPOSED POTENTIAL PERFORMANCE PERIODS FOR PRE- AND POST-OPERATIVE THA/TKA VOLUNTARY DATA SUBMISSION

Model Year	Performance Period	Patient Population Eligible for THA/TKA Voluntary Data Submission	Requirements for Successful THA/TKA Voluntary Data Submission
2021	July 1, 2019 through June 30, 2020.	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2019 and June 30, 2020.	Submit POST-operative data on primary elective THA/TKA procedures for ≥80% or ≥200 procedures performed between July 1, 2019 and June 30, 2020.
2021	July 1, 2020 through June 30, 2021.	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2020 and June 30, 2021.	Submit PRE-operative data on primary elective THA/TKA procedures for ≥90% or ≥500 procedures performed between July 1, 2020 and June 30, 2021.
2022	July 1, 2020 through June 30, 2021.	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2020 and June 30, 2021.	Submit POST-operative data on primary elective THA/TKA procedures for ≥90% or ≥500 procedures performed between July 1, 2020 and June 30, 2021.
2022	July 1, 2021 through June 30, 2022.	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2021 and June 30, 2022.	Submit PRE-operative data on primary elective THA/TKA procedures for 100% or ≥1,000 procedures performed between July 1, 2021 and June 30, 2022.
2023	July 1, 2021 through June 30, 2022.	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2021 and June 30, 2022.	Submit POST-operative data on primary elective THA/TKA procedures for 100% or ≥1,000 procedures performed between July 1, 2021 and June 30, 2022.
2023	July 1, 2022 through June 30, 2023.	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2022 and June 30, 2023.	Submit PRE-operative data on primary elective THA/TKA procedures for 100% or ≥1,000 procedures performed between July 1, 2022 and June 30, 2023.

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TABLE 5a. REVISED PERFORMANCE PERIODS FOR PRE- AND POST-OPERATIVE THA/TKA VOLUNTARY DATA SUBMISSION

Model Year	Performance Period	Patient Population Eligible for THA/TKA Voluntary Data Submission	Requirements for Successful THA/TKA Voluntary Data Submission
2021	July 1, 2019 through June 30, 2020.	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2019 and June 30, 2020.	Submit POST-operative data on primary elective THA/TKA procedures for ≥80% or ≥200 procedures performed between July 1, 2019 and June 30, 2020.
2022.....	July 1, 2021 through June 30, 2022.	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2021 and June 30, 2022.	Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% or ≥300 procedures performed between July 1, 2021 and June 30, 2022.
2023.....	July 1, 2021 through June 30, 2022.	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2021 and June 30, 2022.	Submit POST-operative data on primary elective THA/TKA procedures for ≥80% or ≥300 procedures performed between July 1, 2021 and June 30, 2022
2023	July 1, 2022 through June 30, 2023.	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2022 and June 30, 2023.	Submit PRE-operative data on primary elective THA/TKA procedures for ≥85% or ≥400 procedures performed between July 1, 2022 and June 30, 2023.
2024.....	July 1, 2022 through June 30, 2023.	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2022 and June 30, 2023.	Submit POST-operative data on primary elective THA/TKA procedures for ≥85% or ≥400 procedures performed between July 1, 2022 and June 30, 2023.
2024	July 1, 2023 through June 30, 2024.	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2023 and June 30, 2024.	Submit PRE-operative data on primary elective THA/TKA procedures for ≥90% or ≥500 procedures performed between July 1, 2023 and June 30, 2024.

Comment: Several commenters did not support the proposal to increase the patient-reported outcomes submission thresholds in PYs 6, 7 and 8 for pre-op and post-op data. Commenters expressed that the proposed increases were unrealistic and extreme, and that PRO submission continues to provide burden to the participant hospitals.

Response: We thank the commenters for their remarks. In the November 2015 CJR final rule, we finalized a policy whereby the thresholds for successful submission increased as participant hospitals gained experience with PRO over the performance years. We stated our belief that having increased THA/TKA recipient data would result in a more reliable measure that is better able to assess hospital performance than a measure created from a less representative patient sample. Therefore, we finalized the requirement at 80 percent of the eligible elective primary THA/TKA patients. We believed acquisition of 80 percent of the eligible elective primary THA/TKA patients would provide representative data for measure development while decreasing patient, provider and hospital burden. We believed that over time hospitals will become more adept at collecting this data, and it was reasonable to gradually increase the expected response rates to successfully fulfill the THA/TKA voluntary PRO and limited risk variable data collection and therefore proposed the increased changes to the thresholds for successful submission in order to obtain a more reliable measure.

Due to lessons learned and feedback from current CJR participant hospitals, we are revising the threshold requirements down from 100 percent as originally proposed. While PRO data submission is voluntary, to date participant hospitals have expressed challenges to reach current benchmarks in PY5 (≥80% or ≥200 eligible procedures). Both participant hospitals and key stakeholders have commented that requiring 100 percent submission is neither feasible nor realistic for participant hospitals. As a result we are revising the thresholds as explained in Table 5a (Revised Performance Periods for Pre- and Post-Operative THA/TKA Voluntary Data Submission), while also maintaining accountability of the PRO data collection from CJR participant hospitals.

Comment: Some commenters support the continuation of the PRO measures in the CJR model extension stating the consistency of methodologies over the years overall minimizes the burden on participant hospitals and supports the efficacy of the model evaluation. A commenter suggested that CMS monitor any changes in patient outcomes now that outpatient surgeries have been added.

Response: We thank the commenters for their support and suggestions. We will take these recommendations into consideration in our future measure development and testing efforts.

Comment: A commenter suggested to include an adjuster to the Composite Quality Score (CQS) depending on the setting of the procedure (inpatient versus outpatient).

Response: We thank the commenter for their support and suggestion. We will take this suggestion into consideration as a candidate for future inclusion in our measure development and testing efforts.

Comment: Several commenters discussed suggestions to inform CJR participant hospitals if and when PRO measure data will be shared publicly. A few commenters stated they were discouraged by not receiving feedback about results to date. Commenters stated that it would be beneficial if CMS released a better means of reporting, which include live and robust dashboards with detailed data for quality review and improvement. A commenter recommended to move forward with testing of a TKA/THA PRO based performance measure.

Response: We thank the commenters for their support and suggestion. We appreciate the desire for frequent data updates for this model. CMS is continuing to assess the results of the data submitted with goals of using the data for future measure development and reporting.

Comment: Several commenters did not support or remained skeptical of the inclusion of HCAHPS in the CJR model because it is an overall measure of all patients receiving hospital services that is not specific to lower-extremity joint replacements. Therefore, the commenters contend HCAHPS does not reflect quality for targeted episodes of care. In addition, the commenters state the measure is too narrow because it only encompasses patient experience during the inpatient hospital stay and does not capture information about patient experience in the outpatient setting. For these reasons, commenters did not believe that the measure captures the correct information, and it will be of limited value to clinicians for quality improvement and limited opportunities to achieve the maximum quality points.

Response: We appreciate the concerns from the commenters about the broad patient population covered by this measure. Although the HCAHPS Survey encompasses a broader range of patients than the model episode definitions, we are not aware of evidence that patient experience of care differs markedly from those of the larger group of eligible patients after patient-mix adjustment for service line (surgery) and age have been applied. Having all patients responding to the survey helps to inform hospitals on areas for improvement. We decline to adopt the commenters' suggestion to remove this component from of the CJR model composite quality score.

Comment: A few commenters support advancing the HCAHPS measure in the CJR model extension stating the consistency of the quality measures allows participants to effectively carry over operational improvements they have already put in place.

Response: We thank the commenters for their support and agree with their reasoning.

Comment: Several commenters discussed suggestions to reconsider the appropriateness of the current components of the Composite Quality Score (CQS) to adjust for inpatient and outpatient procedures. They stated that there is a lack of measures of outpatient procedure outcomes in the CQS and that current measures are not ideal for outpatient procedures and will skew quality of care data.

Commenters suggested adding the Forgotten Joint Score, Hospital-level 30-day risk-standardized readmission rate (RSRR) following elective primary THA and/or TKA (NQF #1551) in the inpatient setting. Other commenters suggested to consider readmission rates, Excess Days in Acute Care (EDAC), Risk Standardized Hospital Visits within 7 days of Hospital Outpatient Surgery, and Hospital Visits after Hospital Outpatient Surgery (OP–36) in the outpatient setting.

Commenters have also suggested adding additional CQS incentives for voluntary documentation of preventative tools, such as Risk Assessment and Predictive Tool (RAPT), and for participation in quality, risk variable, and PRO data submission to nationally recognized registries. Another commenter suggested CMS develop additional concepts to reward participants for tracking post-operation outcomes. Commenters also stated the current components of the CQS lack risk adjustment for sociodemographic status. Another commenter suggested CMS to consider using measures that would more accurately measure quality during the performance year in question. Finally, a commenter suggested CMS consider using a measure that would more accurately measure quality during the performance year in question.

Response: We thank the commenters for their support and suggestions to implement quality measures across the care continuum. We did not propose alterations to the components of the CQS in the CJR model 3-year extension, and we decline to adopt the commenters' suggestion that we do so now. We recognize that there may be some gaps in the current quality measures relative to other settings in which patients receive care. CMS does not provide recommendations for the setting where a procedure is performed. We will take these recommendations into consideration in our future measure development.

Comment: A commenter suggested to adjust quality measures for COVID–19.

Response: We appreciate the concern from the commenter about such adjustments. We have not made specific changes to data collection related to the COVID–19 PHE. However, in light of the IFC extensions, the pre-op and post-op collection windows have been adjusted to accommodate changes in performance year dates.

Comment: Several commenters discussed suggestions to adjust the weighting of the CQS. The commenters suggested increasing the weighting of the PRO data submission component and eliminate or reduce the weighting of the HCAHPS. Other commenters suggested to eliminate or reduce the weighting of the HCAHPS and reassign the weighting to the TKA/THA complications component.

Response: We thank the commenters for their suggestions. We did not propose alterations to the components of the CQS in the CJR model 3-year extension and decline to adopt these suggested changes.

Comment: Several commenters discussed several suggestions for CMS to improve the quality incentives of the CJR model. The commenters believed that CMS should shift to a payment system based on a participant's quality score from the pay for reporting system currently in place. The commenters argued it would help improve quality measures greatly among participants by increasing the financial incentives participants would receive.

Response: CMS would like to thank to commenters for their suggestions. They will be taken into consideration for future change to the model or future models, if warranted.

Final Decision: After consideration of the public comments we received, we are modifying the PRO and Risk Variable Submission Requirements to reduce the percentage and procedure PRO data submission thresholds for PYs 6 through 8. Please refer to Table 5a Revised Performance Periods for Pre- and Post-Operative THA/TKA Voluntary Data Submission. The post-op collection window for PYs 6 through 8 will be extended an additional 2 months. The extended window will total 14 months compared to the original proposed 12 month window. The start of post-op collection window for PY6 will remain unchanged, but will extend an additional 2 months (April 1, 2020 through August 31, 2021). However, we will shift the PY6 pre-op collection window 1 year later than originally proposed to April 1, 2021 through June 30, 2022. We are also making a technical correction to Section 510.400(b)(2)(ii) introductory text by removing the phrase ''of the program'' and adding in its place the phrase ''of the model.''

G. Financial Arrangements: Elimination of 50 Percent Cap on Gainsharing Payments, Distribution Payments, and Downstream Distribution Payments

Currently, participant hospitals may engage in financial arrangements under the CJR model. Starting with the November 2015 CJR model final rule (80 FR 73412 through 73437) participant hospitals have been allowed to enter into sharing arrangements to make gainsharing payments to certain providers and suppliers with which they were collaboratively caring for CJR beneficiaries and to allow CJR collaborators that are physician group practices to enter into distribution arrangements to share those gainsharing payments with certain PGP members. In the January 2017 final rule (82 FR 180) we finalized a full replacement of the prior CJR model regulations in order to revise and refine these requirements to allow for—(1) participant hospitals to enter into sharing arrangements with additional categories of CJR collaborators, including certain ACOs, hospitals, CAHs, NPPGPs and therapy group practices (TGPs); (2) ACOs, PGPs, NPPCGs and TGPs that are CJR collaborators to enter into distribution arrangements with certain entities and individuals; and (3) PGPs, NPPGPs and TGPs that received distribution payments from ACOs to enter into downstream distribution arrangements to share distribution payments with certain of their members. We believe these opportunities outlined in the January 2017 final rule (82 FR 531 through 554) for the individuals and entities that engage in beneficiary care, care redesign and care management to share in the financial risk and rewards of the CJR model promote accountability for the quality, cost, and overall care for CJR beneficiaries.

In order to ensure that goals of the CJR model are met, and to ensure program integrity and protection from abuse, the CJR model has many requirements for these financial arrangements. According to § 510.2 a gainsharing payment means a payment from a participant hospital to a CJR collaborator, under a sharing arrangement, composed of only reconciliation payments or internal cost savings or both; a distribution payment means a payment from a CJR collaborator that is an ACO, PGP, NPPGP, or TGP to a collaboration agent, under a distribution arrangement, composed only of gainsharing payments; and a downstream distribution payment means a payment from a collaboration agent that is both a PGP, NPPGP, or TGP and an ACO participant to a downstream collaboration agent, under a downstream distribution arrangement, composed only of distribution payments. Among other requirements, the CJR model has always included a cap on certain gainsharing payments and distribution payments to physicians, non-physician practitioners, and PGPs equal to 50 percent of the total Medicare approved amounts under the Physician Fee Schedule for items and services that are furnished to beneficiaries by that individual or entity during the performance year. As the CJR model has evolved, this cap has been retained and broadened to apply to gainsharing payments to NPPGPs, to distribution payments to non-physician practitioners, PGPs and NPPGPs, and to downstream distribution payments to non-physician practitioners and physicians. Accordingly, under the current regulations at § 510.500(c)(4)(i) and (ii), the total amount of gainsharing payments for a performance year paid to physicians, non-physician practitioners, physician group practices (PGPs), and non-physician practitioner group practices (NPPGPs) must not exceed 50 percent of the total Medicare approved amounts under the Physician Fee Schedule for items and services that are furnished to beneficiaries during episodes that occurred during the same performance year for which the CJR participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being made. Distribution payments to these individuals and entities are similarly limited as specified in § 510.505(b)(8)(i) and (ii), and downstream distribution payments are similarly limited as specified in § 510.506(b)(8). However, based on comments received over the course of this model, our experience over time,

and our desire to allow consistent flexibilities across models, we proposed to eliminate these caps for episodes ending after December 31, 2020.

The need for the caps has been the subject of extensive comment since the start of the CJR model. In the initial CJR model proposal in July 2015 (80 FR 41198) we emphasized that the payment arrangements must be actually and proportionally related to the care of the beneficiaries in the CJR model and proposed a cap on gainsharing payments to individual physicians, non-physician practitioners, and PGPs equal to 50 percent of the Medicare-approved amounts under the PFS for items and services billed by that individual or PGP and furnished to the participant hospital's CJR beneficiaries. As discussed in the November 2015 final rule (80 FR 73420 through 73422), many commenters opposed the proposed cap on the total amount of gainsharing payments for a calendar year that could be paid to a PGP or an individual physician or non-physician practitioner who is a CJR collaborator, arguing that the 50 percent figure is arbitrary and should be removed. Other commenters asserted that a PGP that is a CJR collaborator should have the freedom to determine the most appropriate way to distribute gainsharing payments, given the multiple disciplines involved in patient care. Additionally, some commenters requested that internal cost savings be treated separately from reconciliation payments under the cap on gainsharing payments. Other commenters urged CMS to apply the same cap to the CJR model as is applied to Model 2 of the BPCI initiative. In our response, we acknowledged the many perspectives of the commenters on the proposed cap on gainsharing payments to physicians, non-physician practitioners, and PGPs in the CJR model. We stated that the purpose of the cap is to serve as a safeguard against the potential risks of stinting, steering, and denial of medically necessary care due to financial arrangements specifically allowed under the CJR model by providing an upper limit on the potential additional funds a physician, non-physician practitioner, or PGP can receive for their engagement with participant hospitals in caring for CJR model beneficiaries beyond the FFS payments that those suppliers are also paid and that are included in the actual episode spending calculation for the episodes. Moreover, we affirmed our intent to align the cap in the CJR model with the 50 percent cap on gainsharing payments to physicians and non-physician practitioners in the BPCI initiative, and noted that participants in BPCI had not voiced significant complaints that this moderate financial limitation had hampered their ability to engage physicians and non-physician practitioners in care redesign to improve episode quality and reduce costs. Accordingly, we concluded the 50 percent cap on gainsharing payments was an appropriate condition for the CJR model at that time. This final rule also established a framework for distribution payments and applied the cap to those payments as well.

In August 2016, when we proposed to expand the range of permissible financial arrangements to include additional parties and to allow for downstream distribution arrangements, we proposed to apply the 50 percent cap to those payment arrangements well. As discussed in the January 2017 EPM final rule (82 FR 458 through 460), commenters were again of mixed views on these caps. While several commenters, including MedPAC, supported the caps, most commenters either recommended that CMS eliminate the caps for PGPs, eliminate the caps altogether for PGPs, physicians, and non-physician practitioners, or apply the caps on a different basis than CMS' proposal of 50 percent of the Medicare-approved amounts under the PFS for items and services furnished by the physician or non-physician practitioner. In our response, we stated our continued belief that the caps served as a safeguard against the potential risks of stinting, steering, and denial of medically necessary care due to financial arrangements specifically allowed under the model. We again emphasized that we applied the 50 percent cap in both the CJR model and the BPCI initiative, and participants in neither model had voiced significant complaints that this financial limitation had hampered their ability to engage physicians, non-physician practitioners, and PGPs in care redesign to improve episode quality and reduce costs.

In our subsequent CJR model rulemaking, we did not propose changes to the caps, but as described in the December 2017 final rule (82 FR 57083), we again received comments both for and against these policies. Several commenters supported the current 50 percent gainsharing cap. Other commenters offered a variety of recommendations for changing the gainsharing limitations. In our response, we stated that we would continue to consider the issues raised by commenters as we moved forward with the CJR model and other models. Based on further consideration, we believe the commenters who opposed the caps presented the more compelling policy argument that these caps are arbitrary and limiting.

The burdens associated with caps in the CJR model outweigh the potential benefits of these payment limitations. The caps were adopted and retained based on the belief that these limits on the potential financial rewards available via gainsharing payments, distribution payments and downstream distribution payments were needed to prevent physicians and non-physician practitioners from stinting, steering, and denial of medically necessary care. However, as we have continued to monitor the CJR participant hospitals and CJR model claims data we have not seen evidence suggesting that the financial arrangements in the CJR model have adversely impacted beneficiary access to care. We believe other limitations on the financial arrangements in the CJR model, including the express prohibitions in the CJR model regulations on financial arrangements to induce clinicians to reduce or limit medically necessary services or restrict the ability of a clinician to make decisions in the best interests of its patients, are sufficient and more reasonably targeted restrictions to prevent financial arrangements from resulting in the harms the caps were intended to address.

Moreover, as commenters have consistently noted over the years, the caps in the CJR model constrain options to incentivize the clinicians who are supporting the care of CJR beneficiaries and participant hospitals and others incur administrative burden to monitor their compliance with these caps. Commenters previously argued that CJR collaborators should have the freedom to determine the most appropriate way to distribute gainsharing payments. Commenters contend the cap dampens the ability of gainsharing to support physician behavior change by reducing payments to a nominal amount. Accordingly, we believe maintaining these caps is unnecessary and unduly burdensome on the participant hospitals participating in the CJR model.

Additionally, we note that in 2018 we revised our policies for BPCI Advanced such that BPCI Advanced Participants may execute an amendment, which would, among other things, eliminate the 50 percent cap on NPRA Shared Payments and Partner Distribution Payments (*https://innovation.cms.gov/Files/x/bpciadvanced-my3-mutual-amendment.pdf*). Previously, commenters stated that having different policies between models could create the potential for an uneven playing

field. Accordingly, the elimination of the caps in the CJR model would improve consistency across the CJR model and BPCI Advanced model. We believe that if the CJR model and BPCI Advanced model do not align, a consequence may be confusion among participants and sharing arrangements may not be used therefore impeding the CJR model's goal to support better and more efficient care for beneficiaries undergoing hip and knee replacements.

We proposed to eliminate the 50 percent cap on gainsharing payments, distribution payments, and downstream distribution payments when the recipient of these payments is a physician, non-physician practitioner, physician group practice (PGP), or non-physician practitioner group practice (NPPGP) for episodes that begin on or after January 2, 2021. We proposed that these changes would apply to episodes on or after January 2, 2021 to align with the timing for the other policy changes we proposed in the proposed rule.

We sought comment on our proposals to eliminate the 50 percent cap on gainsharing payments, distribution payments, and downstream distribution payments when the recipient of these payments are a physician, non-physician practitioner, physician group practice (PGP), or non-physician practitioner group practice (NPPGP).

Comment: Several commenters support our proposal to eliminate the 50 percent cap on gainsharing payments, distribution payments, and downstream distribution payments when the recipient of these payments are a physician, non-physician practitioner, physician group practice (PGP), or non-physician practitioner group practice (NPPGP). Specifically, MedPAC commented that although they previously supported inclusion of the 50 percent cap on gainsharing payments in the CJR model, MedPAC now supports CMS's proposal to eliminate the cap, and agrees with CMS that elimination of the cap reduces the administrative costs that hospitals and other entities incur in monitoring their compliance. MedPAC also agreed with CMS that the cap imposes an administrative burden that makes it more difficult for hospitals and other entities to provide gainsharing payments, and that the elimination the 50 percent cap would make the CJR model more consistent with the BPCI Advanced model, which simplifies CMS's oversight of the models. Further MedPAC and other commenters highlighted that CMS should continue to monitor the quality of care and the mix of beneficiaries who receive LEJR procedures to ensure that eliminating the cap on gainsharing payments does not lead to lower quality or patient selection. Lastly, MedPAC recommended that CMS should use evaluation methods in the 2019 CJR model evaluation report to evaluate whether eliminating the cap on gainsharing payments affects patient selection.

Response: We appreciate the positive feedback on the proposed policy, and agree with commenters that eliminating the 50 percent cap reduces administrative cost, administrative burden and aligns with BPCI Advanced's policy. We acknowledge commenters' recommendation that CMS monitor participant hospitals and ensure that elimination of the cap does not have negative implications. As explained in the proposed rule, we monitor CJR participant hospitals and CJR model claims data closely and will continue these monitoring efforts to ensure eliminating the cap does not lead to lower quality care, patient selection bias, or other negative effects. Lastly, MedPAC's recommendation as to the evaluation of this policy is appreciated, and will be taken into consideration when evaluating future performance years.

Comment: Some commenters that support the proposal to eliminate the 50 percent cap noted their disappointment that the policy is limited to physicians, non-physician practitioners, physician group practices, and non-physician practitioner group practices because they believe post-acute care providers, playing a key role in the CJR model, should be offered the same financial incentives. These commenters believe this proposal likely exacerbates disparate treatment of PAC providers in comparison to physicians regarding gainsharing payments.

Response: We agree with the commenters that PAC providers play a key role in the CJR model. In this response, PAC providers include: Skilled Nursing Facilities; Home Health Agencies; Long Term Care Hospitals; Inpatient Rehabilitation Facilities; Therapist in private practice; Comprehensive Outpatient Rehabilitation Facility; a provider of Outpatient Therapy Services; Hospitals, Critical Access Hospitals; and Therapy Group Practices. PAC providers that are in CJR model financial arrangements have never had a cap on gainsharing payments, therefore, there was no need remove a cap that never existed. We appreciate the time and effort PAC providers put into the CJR model, however we disagree that our policy creates disparate treatment that negatively impacts them given PAC providers never had the cap on gainsharing payments.

Comment: Several commenters made recommendations regarding financial arrangements that were not discussed in our proposal, such as mandating CJR participant hospitals to provide gainsharing opportunities and adding requirements that internal costs savings cannot be tied to joint implant pricing.

Response: We appreciate the commenters' suggestions and may consider them in future model development.

Final Decision: After consideration of the public comments we received, we are finalizing our proposed policies to eliminate the 50 percent caps with a modification to account for the extension of PY5. We proposed regulatory text to eliminate the caps for episodes that begin on or after January 2, 2021 to align with the anticipated start of PY6. As discussed previously, after the publication of the February 2020 proposed rule, we extended PY5 from December 31, 2020 to March 31, 2021 in the April 2020 IFC, and then extended PY5 an additional six months to September 30, 2021 to account for the impact of the COVID–19 PHE on CJR participant hospitals. Accordingly, in order for the proposal to eliminate the 50 percent caps on gainsharing payments, distribution payments, and downstream distribution payments when the recipient of these payments is a physician, non-physician practitioner, PGP, or NPPGP to take effect as intended for episodes that begin in PY6, the regulatory text implementing this proposal for episodes that begin on or after January 2, 2021 must be altered to account for the new end date of PY5. Therefore, we are finalizing our proposal as modified to eliminate the 50 percent cap on gainsharing payments, distribution payments, and downstream distribution payments when the recipient of these payments is a physician, non-physician practitioner, PGP, or NPPGP for episodes that end on or after October 1, 2021.

H. Waivers of Medicare Program Rules

In the November 2015 final rule (80 FR 73273), we stated that it may be necessary and appropriate to provide additional flexibilities to participant hospitals in the model, as well as other providers that furnish services to beneficiaries in CJR model episodes. The purpose of such flexibilities is to increase CJR model episode quality and decrease episode spending or internal costs or both of providers and suppliers that results in better, more coordinated care for beneficiaries and improved financial efficiencies for Medicare,

providers, and beneficiaries. These additional flexibilities were implemented through our waiver authority under section 1115A of the Act, which affords broad authority for the Secretary to waive Medicare program requirements as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models.

Section 510.610 of the regulations waives the 3-day hospital stay requirement before a beneficiary may be discharged from a hospital to a qualified SNF, which we define as a SNF that is rated an overall of 3 stars or better for 7 of the last 12 months on the Nursing Home Compare website, but only if the SNF is identified on the applicable calendar quarter list of qualified SNFs at the time of the CJR beneficiary's admission to the SNF. The calendar quarter list of qualified SNFs is available under Participant Resources on the CJR model web page at *https://innovation.cms.gov/initiatives/CJR.* This waiver applies to episodes being tested under the CJR model beginning in PY2. All other Medicare rules for coverage and payment of Part A-covered SNF services continue to apply.

In the December 2017 final rule (82 FR 180), we added additional protections in the event a CJR beneficiary is discharged to a SNF without a qualifying 3-day inpatient stay, but the SNF is not on the qualified list as of the date of admission to the SNF, and the participant hospital has failed to provide a discharge planning notice, as specified in § 510.405(b)(3). We specified in that situation, CMS will make no payment to the SNF for such services; the SNF will not charge the beneficiary for the expenses incurred for such services; the SNF must return to the beneficiary any monies collected for such services; and the hospital must be responsible for the cost of the uncovered SNF stay.

We proposed to extend these additional flexibilities to hospitals furnishing services to beneficiaries in the hospital outpatient setting as well. As discussed in section II.A.2. of this final rule, we proposed to change the definition of an episode of care to include procedures performed in the hospital outpatient department. We also proposed to add the definition of anchor procedure to mean a TKA or THA procedure that is permitted and payable by Medicare when performed in the hospital outpatient setting and billed through the OPPS. Therefore, based upon this proposal, when we use the term ''discharge'' under the Medicare Program Rule waivers, we intend for this term to apply to both anchor hospitalizations and anchor procedures.

We do not anticipate that a beneficiary who receives a LEJR procedure in the hospital outpatient setting would generally need a SNF stay, since we expect that patients who are selected for outpatient LEJR procedures would generally be a healthier population than those who are selected for inpatient procedures. However, in the event that a participant hospital performs an LEJR procedure in the hospital outpatient setting and due to unforeseen circumstances, the beneficiary needs a SNF stay and has not had a qualifying 3-day inpatient stay, we do not want the beneficiary to be held financially liable for these costs. In accordance with section 1861(i) of the Act, beneficiaries must have a prior inpatient hospital stay of no fewer than 3 consecutive days in order to be eligible for Medicare coverage of inpatient SNF care. We refer to this as the SNF 3-day rule. If this requirement is not met, then the beneficiary may be liable for the cost of the SNF stay. Additionally, we want to protect beneficiaries in the event that a participant hospital makes a choice that is based on billing, rather than on clinical needs. While this behavior is prohibited under the model and would actionable under § 510.410, we proposed to add this additional safeguard so that a beneficiary would not be responsible for the expense. We proposed to amend § 510.610 by redesignating paragraphs (a) as (a)(1) and (a)(2), (a)(1) as (a)(2) and (a)(2) as (a)(3) and amending paragraph (b)(1) to reflect these proposals.

Additionally, § 510.600 of the regulations waives the direct supervision requirement to allow clinical staff to furnish certain post-discharge home visits under the general, rather than direct, supervision of a physician or non-physician practitioners. This waiver allows a CJR beneficiary who does not qualify for home health benefits to receive up to nine post-discharge visits in his or her home or place of residence any time during the episode. All other Medicare rules for coverage and payment of services incident to a physician's service continue to apply. We proposed to update § 510.600(b)(1) so that this program rule waiver applies for LEJR procedures performed in the outpatient setting as well. As mentioned previously, when we use the term ''discharge'' under the Medicare Program Rule waivers, we intend for this term to apply to both anchor hospitalizations and anchor procedures.

We sought comment on our proposals to apply CMS program rule waivers to LEJR procedures performed in the outpatient setting.

Comment: Many commenters supported our proposal to extend the waiver of the SNF 3-day rule and direct supervision requirement to beneficiaries receiving an LEJR in the outpatient setting, noting that these waivers provide important services, as demonstrated through PYs 1 through 5 and that CMS should attempt to maintain consistency between the original CJR model performance period and the extension when possible. Commenters urged CMS to finalize this policy as proposed, stressing that this policy accounts for unforeseen circumstances where beneficiaries need a SNF stay after receiving an LEJR procedure in the outpatient setting.

Response: We appreciate commenters support to extend the waiver of the SNF 3-day rule and direct supervision requirement to beneficiaries receiving an LEJR in the outpatient setting, and agree with commenters that this policy maintains consistency into PYs 6 through 8 as well as accounts for unforeseen circumstances where beneficiaries need a SNF stay after receiving an anchor procedure. In general for the waiver of direct supervision, CMS waives the requirement in § 410.26(b)(5) of this chapter that services and supplies furnished incident to a physician's service must be furnished under the direct supervision of the physician (or other practitioner) to permit home visits. The services furnished under this waiver are not considered to be hospital services, even when furnished by the clinical staff of the hospital. In § 510.600(b), we specifically refer to circumstances of when this waiver may be used. Also as noted in § 510.600(d), this waiver does not change other Medicare rules for coverage and payment of services incident to a physician's service. We note that in the CY 2020 OPPS/ASC final rule with comment period (CMS–1717–FC), we changed the generally applicable minimum required level of supervision for hospital outpatient therapeutic services from direct supervision to general supervision for services furnished by all hospitals, including Critical Access Hospitals (CAHs).

Comment: A few commenters do not believe the waiver of the SNF 3-day rule should be applied in the outpatient setting, noting that facilities performing outpatient procedures should send beneficiaries to home health or therapy because these cases should be less complex and require less intensive post-

acute care. Additionally, commenters requested clarification on the policy proposed and when and how the 3-day SNF waiver could be applied in the hospital outpatient setting. Also, commenters asked whether the stay billable by the SNF to Medicare Part A would be accounted for in calculating the episode.

Response: We understand that generally a beneficiary receiving an LEJR procedure in an outpatient setting should not need a SNF stay and, as noted previously, we do not anticipate that a beneficiary who receives an LEJR procedure in the outpatient setting will need a SNF stay, and the use of the waiver in this circumstance will be seldom. However, in the event that a participant hospital performs an LEJR procedure in the outpatient setting and, due to unforeseen circumstances, the beneficiary needs a SNF stay and has not had a qualifying 3-day inpatient stay, we do not want the beneficiary to be held financially liable for these costs.

We acknowledge the proposed language for coverage of a SNF stay after an anchor procedure was not clear and did not indicate a qualifying time period between the anchor procedure and SNF stay. Though we believe this waiver will unlikely be used, holding participant hospitals similarly accountable whether the waiver is used for an anchor hospitalization (in an inpatient setting) or for an anchor procedure (in an outpatient setting) provides consistency for participant hospitals in using the waiver. Therefore to provide consistency and clarification, we are amending the proposal for anchor procedures in that, for episodes being tested in PYs 6 through 8 of the CJR model, CMS waives the SNF 3-day rule for coverage of a SNF stay for a beneficiary who is a CJR beneficiary on or after 30 days of the date of service of the anchor procedure, but only if the SNF is identified on the applicable calendar quarter list of qualified SNFs at the time of the CJR beneficiary's admission to the SNF. CMS determines the qualified SNFs for each calendar quarter based on a review of the most recent rolling 12 months of overall star ratings on the Five-Star Quality Rating System for SNFs on the Nursing Home Compare website. Qualified SNFs are rated an overall of 3 stars or better for at least 7 of the 12 months. Providing a 30 day window here is the same flexibility provided for anchor hospitalizations since when a CJR beneficiary receives an inpatient LEJR procedure, the 3-day SNF waiver is available for use within 30 days from the beneficiary's discharge date. This 30 day window is the current Medicare policy regarding SNF admission, specifically under Medicare beneficiaries must meet the ''3-day rule'' before SNF admission. The 3-day rule requires the beneficiary to have a medically necessary 3-day-consecutive inpatient hospital stay and does not include the day of discharge, or any pre-admission time spent in the emergency room (ER) or in outpatient observation, in the 3-day count. SNF extended care services are an extension of care a beneficiary needs after hospital discharge or within 30 days of their hospital stay (unless admitting them within 30 days is medically inappropriate).

Participant hospitals must correctly communicate to SNFs and beneficiaries (and/or their representatives) the number of inpatient days and outpatient stay, so all parties fully understand the potential payment liability.

CMS will communicate new and revised policies to the Medicare Administrative Contractors and provide additional billing guidance to participant hospitals once processes are implemented. In amending the proposed policy, if a CJR beneficiary receives an outpatient LEJR procedure, the 3-day SNF waiver is available for use within 30 days from the date of service of the anchor procedure, but only if the SNF is identified on the applicable calendar quarter list of qualified SNFs at the time of the CJR beneficiary's admission to the SNF. Here, the SNF stay is covered under the waiver and billable by the SNF to Medicare. Also, this stay would be included in the episode cost, barring any other unknown variable. This waiver only applies to the 3-day SNF rule, and therefore all other Medicare SNF coverage rules apply.

Comment: Some commenters suggested CMS waive additional Medicare rules, such as the post-acute care transfer policy when beneficiaries are discharged to home health agencies (HHAs) that commit to coordinating with their hospital partners would help support care transitions without penalizing CJR participant hospitals.

Response: We thank the commenters for their suggestions. We have not proposed to add additional waivers, but may consider these suggestions in future model development.

Final Decision: After consideration of the public comments we received, we are finalizing our proposal to amend our policy regarding use of the 3-day SNF waiver for an outpatient LEJR episode at § 510.610. Specifically, for episodes being tested in PYs 6 through 8 of the CJR model, CMS waives the SNF 3-day rule for coverage of a SNF stay within 30 days of the date of service of the anchor procedure for a beneficiary who is a CJR beneficiary on the date of service of the anchor procedure, but only if the SNF is identified on the applicable calendar quarter list of qualified SNFs at the time of the CJR beneficiary's admission to the SNF.

I. Appeal Procedures

In the November 2015 final rule (80 FR 73411), we finalized an appeal process for participant hospitals to dispute matters that are not precluded from administrative or judicial review. Under § 510.310(a), a participant hospital may appeal certain calculations related to payment by submitting a timely notice of calculation error. Participant hospitals must provide written notice of a calculation error within 45 days of the date the reconciliation report is issued if they believe a calculation error was made. A participant hospital may appeal CMS' response to the notice of a calculation error by requesting reconsideration review by a CMS official. The request for a reconsideration review must be received by CMS within 10 calendar days of the response to the notice of a calculation error. The reconsideration review request must provide a detailed explanation of the basis for the dispute and include supporting documentation for the participant hospital's assertion that CMS or its representatives did not accurately calculate the NPRA the reconciliation payment, or the repayment amount in accordance with § 510.305. The reconsideration review is an on-the-record review (a review of briefs and evidence only); it is not an in-person hearing. Under the process we finalized in 2015, a CMS reconsideration official notifies the hospital in writing within 15 calendar days of receiving the participant hospital's reconsideration review request of the date, time, and location of the review; the issues in dispute; the review procedures; and the procedures (including format and deadlines) for submission of evidence (the ''Scheduling Notice''). The CMS reconsideration official must take all reasonable efforts to schedule the review to occur no later than 30 calendar days after the date of the Scheduling Notice. The CMS reconsideration official issues a written determination within 30 days of the review. The determination is final and binding.

We proposed to revise the § 510.310(b)(4) to clarify that the reconsideration review process is an on-the-record review, not an in-person review. The existing language at

§ 510.310(b)(4)(i) requires the reconsideration official to give hospitals the date, time, and location of the review. While we believe providing participant hospitals with information about the review is important, after careful review of the language we believe this language could cause confusion as to whether the participant hospital needs to attend the reconsideration review and whether the CJR model team will receive the Scheduling Notice and notice of the review procedures. Therefore, we proposed to remove paragraph (b)(4)(i) and to revise the introductory text of paragraph (b)(4) to clarify that 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. Additionally, we proposed to modify § 510.310(b)(4)(iv) (which will be renumbered § 510.310(b)(4)(iii)) to clarify that the parties may submit briefs and evidence in support of their positions. The reconsideration official will conduct an on-the-record review of the briefs and evidence provided by the parties. We proposed to make conforming changes to delete § 510.310(b)(5) (as it references a scheduled review in accordance with § 510.310(b)(4)(i), which we proposed to delete) and to revise § 510.310(b)(7) (which will be renumbered § 510.310(b)(6)) to state that the CMS reconsideration official issues a written determination within 30 days of the deadline for submission of all briefs and evidence. We sought comment on our proposal.

Comment: A commenter supported CMS' proposal to clarify the language describing the appeals process.

Response: We appreciate the commenter's support.

Final Decision: After consideration of the public comment we received, we are finalizing the proposal without modification.

J. Request for Comment on New LEJR-Focused Models That Would Include ASCs and That Could Involve Shared Financial Accountability

While we continue to believe that the CJR model is helping to improve care for joint replacements in the inpatient and outpatient hospital setting, we recognize that lower joint procedures are gradually being transitioned into ASCs. Specifically, in the CY 2020 OPPS/ASC final rule (84 FR 61253), CMS finalized a proposal to add TKAs to the ASC covered procedures list. In the proposed rule we stated our belief that continued improvements and advances in medical technologies and surgical techniques could make ASCs an appropriate setting for THAs at a future point in time. Subsequently, in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85866), CMS finalized a proposal to remove TAR and certain other orthopedic procedures from the IPO list and allow all procedures not on the IPO list to be paid when furnished in both the outpatient hospital and ASC settings. This means that all procedures included in the CJR model can, as of CY 2021, be performed in the ASC setting as well as the outpatient and inpatient hospital setting. Given that trends in care settings were continuing to transition in this direction at the time that the CJR February 2020 proposed rule was published, we solicited comment on how we might best conceptualize and design a future bundled payment model focused on LEJR procedures performed in the ASC setting. Further, while the CJR model established hospitals as the financially accountable entity, we sought comment on how a new model could better recognize the role of the surgeons and clinicians in LEJR episodes. Who should participate in the model and should the reconciliation payment and/or repayment obligations be shared between the facility and the rendering surgeon to better encourage collaboration? Are there any other clinicians who should share directly in the financial accountability? In general, would a prospective bundled payment or a retrospective target price benchmarked payment model approach work best? What types of quality measures would participants need to track and report? Should the model be ASC specific or site-neutral such that inpatient, outpatient hospital and ASC service sites would be paid the same rate, regardless of where the procedure was performed?

We appreciate the comments received and are taking each comment into consideration. We will continue to seek input from stakeholders as we consider future models that will incorporate ASCs.

K. April 2020 IFC and November 2020 IFC

As discussed in section II.D.1. of this rule, the April 2020 IFC extended PY5 through March 31, 2021, and adjusted the extreme and uncontrollable circumstances policy to account for the COVID–19 PHE by specifying that all episodes with a date of admission to the anchor hospitalization that is on or within 30 days before the date that the emergency period (as defined in section 1135(g) of the Act) begins or that occurs through the termination of the emergency period (as described in section 1135(e) of the Act), actual episode payments are capped at the target price determined for that episode under § 510.300. Comments on these policies and our responses are outlined in sections II.G.2. and II.G.5. of the November 2020 IFC. In this final rule, we are finalizing the CJR related provisions in the April 2020 IFC.

In section II.G. of the November 2020 IFC, we implemented four changes to the CJR model. First, we extended PY5 an additional six months, so PY5 ends on September 30, 2021. Second, we made changes to the reconciliation process for PY5 to allow two subsets of PY5 to be reconciled separately. Third, we made a technical change to include MS–DRGs 521 and 522 in the CJR episode definition, retroactive to 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, we 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. We received five comments on the CJR related provisions in the November 2020 IFC. Comments on these policies and our responses are outlined in this section hereafter.

1. Extension of Performance Year 5 to September 30, 2021

Comment: Commenters supported the extension of PY5 to September 30, 2021 agreeing with CMS that if PY5 ended on March 31, 2021 it would create disruption to the model, which could be disruptive to hospitals and patient care, especially during the PHE. A commenter requested that we make the CJR model voluntary after March 31, 2021 or terminate the model due to the COVID–19 PHE. Another commenter requested that we extend PY5 to December 31, 2021 or until the end of the COVID–19 PHE in order to contain the impact of the COVID–19 PHE within PY5.

Response: We agree with commenters that ending PY5 on September 30, 2021 lessens the chance of disruption to the model and provides participant hospitals with additional relief and stability in model operations. We understand the commenter's concern in regards to the COVID–19 PHE and the progression of the model, but as we discussed in section II.D.1. of this final

rule, we believe this concern is alleviated by the extreme and uncontrollable circumstances policy that is in place to deal with CJR beneficiaries with a COVID–19 diagnosis after March 31, 2021. In addition, we considered extending PY5 to December 31, 2021, however, as noted previously the extreme and uncontrollable circumstances policy provides no downside risk for all participant hospitals that have an episode with a date of admission to the anchor hospitalization that is on or within 30 days before the date that the emergency period began until March 31, 2021 or the last day of such emergency period, whichever is earlier. This policy provides no downside risk for hospitals for the majority of 2020. Further, the new policy we adopted in the November IFC provides for no downside risk for CJR beneficiaries that have a COVID–19 diagnosis on a claim during a CJR episode for episodes that start on or after March 31, 2021, for the remainder of the model. As discussed in section II.G.5. of the November 2020 IFC, we believe these policies will still alleviate commenters' concern by containing the impact and financial risks to participant hospitals, as they operate the CJR model in conjunction with the COVID–19 PHE.

Final Decision: After considering the comments received, we are finalizing without modification that PY5 extends to September 30, 2021. The definition of performance year reflects this finalization as well as incorporates the date ranges of PY6 through PY8 for the extension.

2. Additional Reconciliations for Performance Year 5

Comment: Most commenters support the policy to conduct two reconciliations for PY5, specifying that conducting two reconciliations for PY5 in order to break up what would otherwise be a 21-month gap between reconciliation payments during the COVID–19 PHE is favorable to participant hospitals.

Response: We appreciate the support by commenters and agree that providing two reconciliation periods allows participant hospitals the opportunity to receive a reconciliation payment, if applicable, on a timelier schedule rather than having an extended gap between reconciliation payments.

Final Decision: After considering the comments received, we are finalizing without modification that, within PY5, CMS separately performs the reconciliation processes for PY subsets 5.1 and 5.2. This policy is finalized throughout 42 CFR part 510.

3. DRG 521 and DRG 522

As outlined in section II.G.4. of the November 2020 IFC, we received 3 comments in response to the February 2020 proposed rule and 20 comments in response to the FY 2021 IPPS/LTCH proposed rule addressing the effects of the proposed new MS–DRGs on the CJR model. For a discussion of those comments, please section II.G.4. of the November 2020 IFC (85 FR 71170 and 71171.

Comment: Most commenters support the addition of MS–DRGs 521 and 522, and the addition of these MS–DRGs to be retroactive to October 1, 2020. Commenters highlighted that it is administratively simpler for CJR participant hospitals and associated surgeons to continue performing hip fracture THAs under the CJR model arrangements than to begin removing cases from the CJR model. Commenters also stated that maintaining hip fractures in the CJR model means those procedures remain subject to the value-based care incentives of the CJR model. A commenter on the November 2020 IFC, opposed the addition on MS–DRGs 521 and 522, suggesting that CMS monitor the episodes mapped to the new MS–DRGs and conduct periodic data analyses to ascertain the actual financial impact of the MS–DRG additions to the CJR model.

Response: We appreciate the support of many commenters on adding MS–DRG 521 and 522 as of October 1, 2020 and agree that it is administratively simpler for CJR participants to continue performing hip fracture THAs under the CJR model arrangements than to begin removing cases from the CJR model. We agree that maintaining hip fractures in the CJR model means those procedures remain subject to the value-based care incentives of the CJR model. As discussed in section II.G.4. of the November 2020 IFC, we believe that failure to retroactively incorporate MS–DRGs 521 and 522 into the CJR model as of October 1, 2020 is detrimental to participant hospitals because it would have resulted in approximately 20–25 percent of all LEJR episodes to be dropped from the CJR model. The categories of episodes that may have been dropped tend to be associated with emergent surgeries, high-costs, and complex post-acute care needs. Dropping these episodes from the model would have created confusion, and increased administrative burden for participant hospitals, and removed the opportunity for participant hospitals to earn reconciliation payments by coordinating care for these complex, high-cost episodes. Regarding the comment that CMS monitor the episodes mapped to the new MS–DRGs and conduct periodic data analyses to ascertain the actual financial impact of the MS–DRG additions to the CJR model, CMS currently monitors and completes analyses on MS–DRGs 521 and 522. This is because, historically, the CJR model episode definition included MS–DRG 469 (Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC) and MS–DRG 470 (Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC). For purposes of calculating quality adjusted target prices, we further subdivided episodes within each MS–DRG based on the presence or absence of a primary hip fracture. Therefore, the creation of two new MS–DRGs, 521 and 522 (Hip Replacement with primary hip fracture, with and without major complications and comorbidities), respectively is a mere seamless transition for CMS to monitor these DRGs and operationally is a seamless transition for participant hospitals, which continue to bill Medicare FFS as usual for hip replacements with hip fractures. The new MS–DRGs are incorporated into the CJR episode reconciliation data system, and are included in participant hospitals' monthly data feeds.

Final Decision: After considering the comments received, we are finalizing without modification that, as of October 1, 2020, the CJR model includes episodes when the MS–DRG assigned at discharge for an anchor hospitalization is one of two new MS–DRGs we adopted in the FY 2021 IPPS/LTCH final rule (85 FR 58432): MS–DRG 521 (Hip Replacement with Principal Diagnosis of Hip Fracture with Major Complications and Comorbidities (MCC)) and MS–DRG 522 (Hip Replacement with Principal Diagnosis of Hip Fracture, without MCC).

4. Changes to Extreme and Uncontrollable Circumstances Policy for the COVID–19 PHE

In the April 2020 IFC we developed an extreme and uncontrollable circumstances adjustment for the COVID–19 PHE to provide financial safeguards for participant hospitals that have a CCN primary address that is located in an emergency area during an emergency period, as those terms are defined in section 1135(g) of the Act, for which the Secretary issued a waiver or modification of requirements under section 1135 of the Act on March 13, 2020, effectively applying the financial safeguards to all participant hospitals. These financial safeguards, wherein

actual episode payments are capped at the target price determined for that episode, applied to fracture or non-fracture episode with a date of admission to the anchor hospitalization that is on or within 30 days before the date that the emergency period (as defined in section 1135(g) of the Act) begins or that occurs through the termination of the emergency period (as described in section 1135(e) of the Act). Ultimately, this policy removed downside risk for all participant hospitals until the COVID–19 PHE ends.

We received comments on both the April 2020 IFC and the CJR February 2020 proposed rule about the extreme and uncontrollable circumstances adjustment, and responded to these comments in section II.G.5. of the November 2020 IFC. After consideration of comments as discussed in section II.G.5. of the November 2020 IFC, in the November 2020 IFC, CMS amended the policy, such that for a fracture or non-fracture episode with a date of admission to the anchor hospitalization that is on or within 30 days before the date that the emergency period (as defined in section 1135(g) of the Act) begins or that occurs on or before March 31, 2021 or the last day of such emergency period, whichever is earlier, actual episode payments are capped at the quality adjusted target price determined for that episode under § 510.300. However, in order to account for CJR beneficiaries with a positive COVID–19 diagnosis during a CJR episode that initiates after March 31, 2021 or the last day of the PHE, whichever occurs earlier, we capped actual episode payments at the quality adjusted target price for the episode, effectively waiving downside risk for all episodes with actual episode payments that include a claim with a COVID–19 diagnosis code.

Comment: In regards to the extreme and uncontrollable circumstances policy for COVID–19 adopted in the November 2020 IFC, some commenters believe that CMS should revert back to the policy in the April 2020 IFC and waive downside risk for all episodes until the PHE ends. These commenters noted that though CMS portrayed LEJR procedures as being on the rise, hospitals are still experiencing a decline in LEJR procedures when comparing 2019 and 2020 data, and that the latest spike in COVID–19 cases likely will depress that volume through the winter months so it continues to be appropriate to hold hospitals as risk bearing entities harmless from downside risk through the winter.

Most commenters supported CMS' decision to develop a specific COVID–19 policy so participant hospitals are held harmless if a CJR beneficiary has a positive COVID–19 diagnosis during a CJR episode. A commenter asked when the beneficiary has to have COVID–19 in order for the financial safeguards to apply.

Response: We appreciate the comments on the November 2020 IFC extreme and uncontrollable circumstances policy for the COVID–19 PHE. On January 7, 2021, the Secretary renewed the COVID–19 PHE effective January 21, 2021. Because the policy we adopted in the November 2020 IFC provides that the downside risk waiver applies only to episodes with a date of admission to the anchor hospitalization that occurs on or before the earlier of March 31, 2021 or the end of the emergency period, and the emergency period now will extend beyond March 31, 2021, the extreme and uncontrollable circumstances policy set forth at § 510.305(k)(4) will not apply to episodes that are initiated on or after April 1, 2021.

We understand commenters' concern about the PHE and recommendation that CMS should revert back to the policy in the April 2020 IFC, ultimately waiving downside risk for all episodes until the PHE ends. As noted previously, the current public health emergency was renewed effective January 21, 2021, and will be in effect for 90 days. Further, the Acting Secretary of Health and Human Services expressed to Governors that the PHE will likely remain in place for the entirety of 2021, and that when a decision is made to terminate the declaration or let it expire, HHS will provide states with 60 days' notice prior to termination.[11] In light of the continued renewal of the PHE, waiving downside risks for all episodes until the PHE ends could threaten the ability of the CJR model to generate any savings over the course of the model, especially given the potential for the PHE to remain in place for the entirety of 2021. Because the agency's authority to conduct models is constrained to those anticipated to reduce program expenditures, CMS is therefore unable to revert back waiving downside risk for all episodes until the PHE ends. Also, we understand the commenters' feedback that hospitals experienced a decline in LEJR procedures when comparing 2019 and 2020 data. However the difference in episodes volume is not only in response to the COVID–19 PHE, but also other factors such as LEJR procedures being performed in the outpatient and ambulatory surgery setting. Despite all factors, episode volume is experiencing an upward trend since June 2020 and averaging at 50 percent or more when comparing episode volume between 2019 and 2020 post June 2020. Table 5b depicts recent Medicare claims data comparing February to December of 2019 and February to November of 2020. These numbers reflect episode volume for each month, accounting for any CJR episode that began within that month.

TABLE 5b—CJR EPISODE VOLUME COMPARISON

	February	March	April	May	June	July	August	September	October	November	December
2019	6,212	6,174	6,514	6,020	5,833	6,059	5,839	6,122	7,014	5,546	4,739
2020	5,252	3,379	878	2,252	4,036	3,860	3,738	3,845	3,691	3,187	2,504

L. Coordination With Other Agencies

Impacts created by payment changes under this model are entirely internal to HHS operations; coordination with other agencies is not required outside of the usual coordination involved in the publication of a HHS regulatory changes.

III. Collection of Information Requirements

As stated in section 1115A(d)(3) of the Act, Chapter 35 of title 44, United States Code, shall not apply to the testing and evaluation of models under section 1115A of the Act. As a result, the information collection requirements contained in this final rule need not be reviewed by the Office of Management

[11] *See. Public-Health-Emergency-Message-to-Governors.pdf* (*georgetown.edu*).

and Budget. However, we have summarized the information collection requirements in the Regulatory Impact Analysis section of this final rule.

IV. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (CRA) (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year). This final rule implements proposed changes and extension of the CJR model; these provisions impact a subset of hospitals under the IPPS. The Office of Management and Budget has designated this final rule as an ''economically significant'' rule under E.O. 12866 and a ''major rule'' under the Congressional Review Act (CRA).

B. Statement of Need

Initial reports from the Innovation Center evaluation contractor as well as an independent study in the New England Journal of Medicine [12] 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. Specifically, for PY1, without considering net reconciliation payments earned under the CJR model, the Innovation Center evaluation contractor observed that the total episode payments decreased 3.3 percent, or $910 per episode, more for CJR model episodes than control group episodes in the difference in difference analysis.[13] Further, the second annual CJR model evaluation report, released on June 27, 2019, has found that CJR model episode payments decreased by 3.7 percent more over the first 2 years of the CJR model. These decreases in payments have likely reduced Medicare program spending over the first 2 performance years of the model by an estimated $17.4 million (with a range of Medicare losses of $41.1 million to Medicare savings of $75.9 million, due to uncertainty in per episode savings).[14] From these observations, it appeared that continuing to bundle lower joint payments would assist the Innovation Center in meeting its goal to reduce expenditures while preserving or enhancing the quality of care.

However, since these initial evaluation results, the traditional Medicare FFS program has shifted in ways that limit the model's long-term ability to achieve savings, and we have determined that the changes adopted in this final rule are necessary for the following reasons. First, to address changes in the CY 2018 OPPS final rule (65 FR 18455) to the IPO list (published annually in OPPS rule) to remove the TKA procedure code, as well as the recent removal of the THA procedure code from the IPO list in the CY 2020 OPPS final rule (84 FR 61353), we proposed to change the definition of an Episode of care to include outpatient procedures for TKAs and THAs. Additionally, we believe it is necessary to adjust target pricing to ensure that target prices better capture spending trends and changes, by using more recent historical spending data that includes outpatient TKA and inpatient TKA/THA claims, as well as outpatient THA claims that will be included in CY 2021 and CY 2022 data, and in order to parallel the proposed changes to the reconciliation process with the changes we proposed to the target price calculations. We also proposed to conduct one reconciliation per CJR model performance year, which would be initiated six months following the end of a CJR model performance period. This change is intended to reduce the administrative burden of an additional reconciliation for Medicare and CJR participant hospitals. In an effort to remain consistent with BPCI Advanced, we proposed to eliminate the 50 percent cap on gainsharing payments, distribution payments, and downstream distribution payments when the recipient of these payments is a physician, non-physician practitioner, PGP, or NPPGP for episodes beginning on or after April 1, 2016 and ending on or before December 31, 2020 to remain consistent with the other policy changes made in the proposed rule. We believe that participant hospitals, CJR collaborators, collaboration agents, and downstream collaboration agents are now accustomed to the episode-based CJR model payment methodology and that administrative burden should be reduced and further flexibility should be offered to allow hospitals to share internal savings or earned reconciliation payments by removing the gainsharing cap. We proposed to adjust the composite quality score discount in recognition that the proposed changes to the target price calculation (discussed in section II.B. of this final rule), intended to increase the accuracy of target prices compared to actual performance period spending may also narrow the potential for participant hospitals to earn reconciliation payments. Because of these more accurate target prices, and the fact that all participant hospitals would be at financial risk during PYs 6 through 8, we determined that a more generous composite quality score adjustment to the discount factor is appropriate for hospitals ranked in the good and excellent CJR model quality categories.

In this final rule we also note that the third annual CJR model evaluation report, released in November 2020, found that for mandatory CJR participant hospitals, the CJR model resulted in decreases in average payments for both the inpatient only and all LEJR episodes (inpatient and outpatient) during the first 3 performance years. Specifically, payments decreased by $1,378 more for all CJR model LEJR episodes (inpatient and outpatient) than for control group episodes, or 4.7 percent from CJR model baseline payments. For the inpatient only episodes, payments decreased by $1,540 more than for control group episodes, or 5.3 percent from CJR model baseline payments. After accounting for the reconciliation payments, net savings from mandatory hospitals totaled $61.6 million (or 2 percent savings from baseline) for all LEJRs and $76.3 million (or 2.5 percent savings from baseline) for inpatient only episodes. From these recent observations, it continues to appear that bundling lower joint payments will assist the Innovation

[12] 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.*

[13] For the CJR first annual evaluation at a glance and full report see *https://innovation.cms.gov/Files/reports/cjr-fg-firstannrpt.pdf* and *https://innovation.cms.gov/Files/reports/cjr-firstannrpt.pdf.*

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

Center in meeting its goal to reduce program expenditures while preserving or enhancing the quality of care.

When we proposed this rule, we believed a 3-year extension was necessary to allow for enough time and information to reasonably evaluate the proposed changes. While the COVID–19 PHE will necessitate adjustments to the evaluation of the changes we are adopting in this final rule, we continue to believe they are improvements to the CJR model that will increase the probability of model savings compared to the original CJR model payment methodology (as described in Table 6a. of this final rule). Additionally, we continue to believe the CJR model promotes alignment of quality and financial accountability in the LEJR space and should continue to be tested through an extension of the model.

C. Anticipated Effects

In prior sections of this final rule, we discuss our proposals to amend the regulations governing the CJR model. We present the following estimated overall impact of the proposed changes during the 3-year proposed extension. Table 7 summarizes the estimated impact for the proposed changes to the CJR model for the proposed 3-year extension of the model from April 1, 2021 through December 31, 2023. This table was created using 2018 claims data that was available at the time the proposed rule was published. Table 7a in this final rule is an updated version of the table calculated using 2019 claims data.

There were approximately 470 providers participating in the CJR model as of October 2019. By limiting participation to the non-rural, non-low-volume providers physically located in the 34 mandatory MSAs, we expect approximately 330 participants in the CJR model for the 3-year extension, dependent on changes in rural reclassification status or mergers. Specifically, we anticipate removing around 75 providers located in the 33 MSAs that were changed to voluntary and removing around 45 providers for rural reclassification status. For purposes of modeling this impact, using the 2019 Medicare claims data pulled from the Chronic Conditions Warehouse in February of 2021 and limiting the analysis to non-rural, non-low-volume providers located in the 34 mandatory MSAs, we had 330 eligible providers with CJR model episode claims data. Projected CJR model episode volume increases from 2021 to 2024 follow Medicare enrollment assumptions included in the 2020 Medicare Trustees Report.[15] Price updates for 2019 to 2020 follow FFS unit cost increases by service category for 2018 to 2020. The weights for each service category were developed using 2019 episode spending data. For 2021 to 2024, price updates were assumed to equal the market basket minus multifactor productivity (MFP) growth, or roughly the approximate price update that is built into the Trustees Report model.

We are assuming that participants would reduce episode spending by 1 percent during PY6 due to their participation in the model. In PY7 and PY8, we assume that participant hospitals' spending would grow at the same rate as spending by non-participating hospitals in their respective regions. We make these assumptions given that the most recent CJR model evaluation report showed that participant hospitals reduced spending by 5.3 percent for inpatient episodes during the first 3 years of the CJR model. Specifically, we are assuming that participant hospitals will have more difficulty producing additional savings over time. Since LEJR episode costs have been declining, there is some uncertainty around how much more efficient participant hospitals, clinicians and the associated post-acute care providers can be in terms of further reducing the costs of LEJR episodes. However, as the CJR model shares the extra savings back to participant hospitals, we do not anticipate large changes in the impact analysis as a result of changes in the assumption that participant hospitals would have difficulty producing additional savings over time. We assumed that if the CJR model were not extended, participant hospitals would increase their episode spending by 2.65 percent as a response to the model ending, which is half of the savings shown by the evaluation for the first 3 years of the CJR model.

We noted in the proposed rule that we did not make any assumptions about behavioral changes in the post-acute care space that may result from significant payment policy changes finalized in the FY 2019 SNF (83 FR 39162) and CY 2019 HH (83 FR 56406) rules for implementation with FY 2020 and CY 2020, respectively, as we did not yet have claims experience with these new methodologies in place. Behavioral changes stemming from these policies could have impacts upon our CJR model savings estimate that we were unable to quantify at that time. However, we have not updated our assumptions in this final rule about behavioral changes in the post-acute care space that may result from the payment policy changes noted previously since the COVID–19 PHE will likely impact the effect of these policies in CY 2020 claims data, and as noted in section II.B.3. of this final rule, we are omitting the use of 2020 claims data for target price and risk adjustment coefficient calculations.

While we are not using CY 2020 claims data to update our previous assumptions about behavioral changes in the post-acute care space that may have resulted from the payment policy changes referenced previously given the potential effect of the COVID–19 PHE on that data, we are adding certain assumptions to this final rule based on CY 2020 claims data because there is no other source of data to make these assumptions and they are also informed by CY 2018 and CY 2019 claims data. In particular, we used CY 2020 claims data to estimate the effect on overall LEJR spending in 2020 from two payment changes in 2020; the effect of the payment policy changes to TKA procedures performed in the ASC setting and THA procedures performed in the hospital outpatient setting, as described later in this section. We determined it appropriate to add these assumptions based on CY 2020 claims data since CY 2019 and prior year claims data does not include these two policy changes that only became effective in 2020. Additionally, we determined it appropriate to utilize CY 2020 data for this purpose since the overall LEJR spending and site of service utilization assumptions are also informed by data from CY 2018 and CY 2019. As noted later in this section regarding the effect on LEJR spending from THA procedures being performed in the outpatient setting in 2020, we did include basic considerations for the potential effect of the COVID–19 PHE on these general estimates. In contrast, we chose not to update assumptions about specific changes, such as behavioral changes in the post-acute care space, given the increased uncertainty of the magnitude and directional effect of COVID–19 PHE on those specific aspects of LEJR spending and since the assumptions would only be informed by CY 2020 claims data (unlike the overall LEJR spending and site of service assumptions informed also by CY 2018 and CY 2019 data).

TKA procedures in the ASC setting are eligible for Medicare payment as of January 1, 2020. In the OPPS CY 2020 final rule (84 FR 61388), we agreed with

[15] See page 176 of the 2020 Annual Report of the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds which can be found on: *https://www.cms.gov/files/document/2020-medicare-trustees-report.pdf.*

commenters who stated that the majority of Medicare beneficiaries would not be suitable candidates to receive TKA procedures in an ASC setting, based on factors such as age, comorbidity, and body mass index that should be taken into account to determine if performing a TKA procedure in an ASC would be appropriate for a particular Medicare beneficiary. However, we further stated that we believe there are a small number of less medically complex beneficiaries that could appropriately receive the TKA procedure in an ASC setting and physicians should exercise clinical judgment when making site-of-service determinations, including for TKA. Since ASC procedures are not included in the CJR model extension, the agency's policy choice to allow Medicare payment for TKA procedures in the ASC setting could result in a decrease in the number of CJR model TKA episodes. However, we assume ASC procedures will only account for approximately five percent of LEJR procedures during the CJR model extension, and thus the changes in CJR episode volume would likely be small such that only the magnitude of this CJR model impact estimate would change. As noted previously, we determined it appropriate to utilize CY 2020 claims data to inform this assumption since 2020 is the first year TKA procedures in the ASC setting became eligible for Medicare payment.

THA procedures were removed from the IPO list, effective January 1, 2020. We acknowledge that it is possible this change could result in reductions in THA episode costs should some percentage of inpatient THA procedures move into the OPPS setting over the next several years. Analysis of 2020 claims data from an external analytic contractor indicates during 2020, THA procedures in the OPPS setting accounted for approximately 10 percent of all LEJR episodes. Additionally, compared to inpatient THA episodes, episode spending for THA procedures in the OPPS setting was approximately 30 percent less in 2020. We assume the reduction in episode costs for THA procedures in the OPPS setting during 2020 was partially a result of the effect of the COVID–19 PHE, which likely had the effect of shifting less complex and costly patients to the OPPS setting in an effort to avoid inpatient hospital utilization. Therefore, we assumed overall LEJR spending decreased by 2 percent in 2020 as a result of this setting change.

The calculations shown in Table 7 estimated that, in total, the proposed changes to the CJR model would result in a net Medicare program savings of approximately $269 million over the 3 proposed performance years (2021 through 2023). We sought comment on our assumptions and approach. The updated calculations shown in Table 7a in this final rule estimated that, in total, the changes we are adopting in this final rule to the CJR model would result in net Medicare program savings of approximately $217 million over the 3 proposed performance years (2021 through 2024).

The following Table 6 summarizes the anticipated impact of certain provisions of this final rule. While the table does not include all the provisions in this final rule, it includes those provisions for which we determined there was the potential for a significant change in costs or savings related to a change in the model's major policies. We did not include policies for which we determined there would not be the potential for changes in costs or savings, such as the removal of the gainsharing caps that were in place PYs 1 through 5. We were unable to provide discrete estimates associated with each of these provisions at the time the proposed rule was published due to lack of calendar year 2019 claims data availability. This table includes a qualitative estimate of the possible costs/savings to Medicare resulting from each provision in this final rule. The ''Notes'' column provides additional background when necessary.

TABLE 6: ANTICIPATED IMPACTS BY FINAL PROVISION RELATIVE TO ORIGINAL CJR MODEL POLICIES 2021-2023

Provision	Direction of Transfers (labeled "Costs/Savings" in the proposed rule)	Transfers	Notes
Changes to episode definition to include outpatient TKA/THA	Cost		The bulk of data used to set target prices under original CJR methodology would not include many OPPS knee episodes and would include no OPPS hip episodes until proposed PY7. Therefore, if we were to make no changes to the current CJR target price methodology and were only to add outpatient TKA/THA procedures to the CJR episode definition, targets would be based on inpatient hospitalization costs and subsequent post-acute care and would likely be inappropriately high relative to OPPS episode costs.
Freezing hip fracture list and episode exclusions list	Zero Impact		We have not needed to update the fracture/episode exclusion list to any degree of significance for the first 5 years of CJR and do not anticipate changes in the next 3 years so we assume this will have a zero impact.
Capping high episode spending at the 99th percentile (rather than 2 standard deviation methodology)	Savings		The 99th percentile high episode cap will be higher than the 2 standard deviations of mean episode cost such that more costs per episode will be considered relative to the target and reconciliation payments may decrease slightly while reconciliation obligations may increase slightly.
Use of the most recently available 1year of data to calculate target prices (rather than most recent 3 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		Updating the target price data set to use a time period closer to the model, removing anchor weighting and discontinuing the FFS updating (in favor of a trend update at reconciliation) should ensure the targets are better aligned to actual expected episode spending.
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)	Cost or Savings Trend Ratio		The trend factor will incorporate all differences in average episode costs between year used for target price and actual model so to the extent FFS payment updates have increased, the trend could be greater than 1 which could increase targets and the model cost; if, despite FFS increases overall ,episode spending decreases then targets will decrease and savings will result.

Provision	Direction of Transfers (labeled "Costs/Savings" in the proposed rule)	Transfers	Notes
Incorporating a risk adjustment for beneficiary specific CJR HCC 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 we anticipate a net impact of zero for this provision.
Increasing hospital quality incentive payments (that is, a 1.5 percentage point reduction to the applicable discount factor for participant hospitals with "good" quality performance and a 3 percentage point reduction to the applicable discount factor for participant hospitals with "excellent" quality performance).	Zero Impact		We believe this provision will be redistributive among participants but that it will not have an overall impact on the model given the other changes we proposed to the pricing methodology.
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		We assume that those participants who voluntarily opted to continue in CJR as of PY3 were doing well in the CJR model and that removing them from the model will likely result in a smaller reconciliation payout which will create some savings relative to current CJR reconciliation spending.

We are updating Table 6 from the proposed rule with Table 6a, which includes a discussion of the transfer amounts for certain provisions in this final and the considerations that frame the assumptions for each provision. While we noted in the proposed rule that Table 6 would reflect the transfer amounts relative to the original CJR model provisions, we are clarifying that the transfer amounts included in Table 6a are transfer amounts of each provision relative to the CJR model extension payment methodology with or without that provision. This clarification is also noted in the Transfers column in Table 6a in this final rule. We chose to display the transfer amounts this way after we determined that certain provisions in the CJR model extension methodology were incomparable to the original CJR model methodology and could lead to misleading transfer amount assumptions. Additionally, certain provisions in the final rule would have different impacts if applied to the original CJR model methodology together or separately.

For example, as a result of the SNF PDPM that was implemented on October 1, 2019 (83 FR 39162), we have observed changes in average SNF episode costs in CJR model episodes. Under the CJR model methodology, which utilizes the most recent 3 years of data for target price calculations and updates that data every other year and updates target prices twice annually for prospective payment systems updates, we would not completely account for the effect of the SNF PDPM payment change in PYs 6 through 8. Specifically, the 3 years of historical data would only include a portion of time when the new PDPM was implemented (as PY6 target prices would be calculated with 2016–2018 data and PY7 and PY8 target prices would be calculated with 2018–2020 data), and the twice annual updates in the CJR model original methodology that would include a SNF Services Update Factor would not be correctly updated because that methodology relies on the former RUG–IV Case-Mix Adjusted Federal Rates. This would create inaccurate target prices, which could lead to higher model transfer costs if the effect of the SNF PDPM payment change would be to lower target prices. While the provision to rely on only the most recent year of historical data for target price calculations would help remedy this and could lead to model transfer savings, the market trend factor would also help eliminate the delay in adjusting for lower SNF episode costs in historical target pricing data. While we consider all the provisions as improvements related to the original CJR model methodology, which are meant to generate transfer savings or zero amounts, the transfer assumptions in Table 6a are relative to the CJR model extension methodology with or without each provision; they are not relative to the original CJR model provisions.

Table 6a: ANTICIPATED IMPACTS BY FINAL PROVISION

Provision	Direction of Transfers (labeled "Costs/Savings" in the proposed rule)	Transfers (relative to the methodology without each final provision)	Notes
Changes to episode definition to include outpatient 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. Using 2019 CJR average standardized payment data, we determined that excluding OPPS TKA episodes in the CJR Extension target price modeling would lead to a higher target price for the DRG 470/no fracture episode category across all 9 CJR regions, ranging from 4% to 9% higher. This range was used to calculate the associated transfer estimate. It should be noted that 2019 data indicates a material increase in the number of outpatient procedures compared to 2018. The 2018 and 2019 data also supports the assumption that outpatient procedures are lower cost, such that excluding outpatient procedures from the baseline data would likely result in higher target prices. Additionally, if the outpatient episode mix continues to trend upwards, the magnitude of excluding these outpatient episodes from the base data will continue to increase.
Freezing hip fracture list and episode exclusions list	Zero Impact	NA	NA
Capping high episode spending at the 99th percentile (rather than 2 standard deviation methodology)	Savings	4,875,000	Using 2019 average standardized cost data, we compared the percentage difference in calculating average target prices using the 99th percentile high-cost outlier cap vs. using a 2 standard deviation cap. Holding other current CJR extension assumptions constant, we see a consistent increase by approximatively 2% in target prices when applying 99th percentile regional high episode caps, which we estimated will contribute to approximately $1,500,000 in savings for each of the PYs 6 through 8.

Provision	Direction of Transfers (labeled "Costs/Savings" in the proposed rule)	Transfers (relative to the methodology without each final provision)	Notes
Use of the most recently available 1year of data to calculate target prices (rather than most recent 3 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	NA	Using 2016-2018 average standardized payments, we compared the percentage change in average target prices using 3 years of data and applying the original CJR national growth factor methodology versus the most recent 1 year of data to calculate target prices. When using 3 years of data, we observed higher target prices for DRG 470 no fracture category episodes across all regions. Analysis based on inpatient episode comparison shows that as hospitals improved efficiency, the average prices for the DRG 470 no fracture category episodes decreased by up to 4% (and decreased by 3-6% for all episode types) across the 9 CJR regions in comparing 2019 data alone versus the data from 2016 -2018. For this analysis, however, we did not include a specific transfer amount given the uncertainty in attributing that amount to the provision versus market fluctuations related to outpatient procedures emerging in 2018. In general, the downward trend in average payments supports our provision that utilizing more recent data will better reflect program efficiencies achieved and the service mix to outpatient. Additionally, utilizing the most recent year of data will help limit variations in the target price at reconciliation that would occur as a result of the proposed market trend factor.
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, we observed a decreasing trend in CJR regional average episode prices. To estimate the impact of the market trend factor, we used 2017 data as the baseline for calculating target prices, which would be reconciled in 2019 under the new methodology. We observed regional average target prices for inpatient episodes that were approximately 1-3% higher than if we had included the market trend factor. It should be noted that the impact of the market trend factor in relation to other potential market fluctuations could increase or decrease average target prices each year. Additionally, OPPS TKA episodes were excluded from this calculation because they were not present in the 2017 data. As a result of our proposed provision to use the most recently available 1 year of data to calculate target prices, the impact of the market trend factor is smaller than it would have been had we followed the original CJR methodology and used 3 years of historical data.
Incorporating a risk adjustment for beneficiary specific CJR HCC count and age bracket	Zero Impact	NA	NA

Provision	Direction of Transfers (labeled "Costs/Savings" in the proposed rule)	Transfers (relative to the methodology without each final provision)	Notes
Increasing hospital quality incentive payments (that is, a 1.5 percentage point reduction to the applicable discount factor for participant hospitals with "good" quality performance and a 3 percentage point reduction to the applicable discount factor for participant hospitals with "excellent" quality performance)	Costs	27,000,000	While we determined a more generous composite quality score adjustment to the discount factor is appropriate for hospitals ranked in the good and excellent CJR model quality categories for PYs 6 through 8, maintaining the policies applicable to PYs 1 through 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	We analyzed the effect of this provision by assuming the opt-in low-volume, rural, and voluntary hospitals that participated in PY 4 of the model would participate in PYs 6 through 8. Since the total NPRA for these hospitals was approximately $53,000,000 in PY 4, we assumed this would be the approximate cost per year if those hospitals were included in PYs 6 through 8. However, this transfer amount does not include considerations regarding the redistributive effect to model savings or costs as a result of the changes to the payment methodology (for example, the new risk adjustment variables in this final rule). While we continue to assume that these hospitals would achieve positive NPRA if included for the 3 PYs of the extension (and thus, increase model costs), we assume it would be to a lesser degree than in PYs 1 through 5 of the model.

*Transfer amounts are noted in average annual savings or costs expected over the 3 years of the extension.

Burden reductions should result from other proposals. Specifically, we proposed the move from two to one reconciliation should effectively cut the level of effort participants and the agency need to expend on reconciliation in half. Assuming a rate of $33.89 per hour for an accountant (*https://www.bls.gov/ooh/business-and-financial/accountants-and-auditors.htm*) and an average of 15 hours to review each report for each of the 474 participant hospitals at 2 months then again at 14 months could cost approximately $481,916. Moving to only one report for each performance year should reduce that cost by $240,958 to approximately $240,958. Likewise, 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 for items and services furnished by that physician or non-physician practitioner to the participant hospital's CJR beneficiaries during CJR model episodes that occurred during the same performance year for which the participant hospital accrued internal cost savings or earned a reconciliation payment will no longer be necessary should our proposal to remove the 50 percent cap be finalized. Given our most recent review, 159 CJR participant hospitals have CJR collaborators that are physicians. Assuming an average of 10 collaborators per participant and 20 hours to review each collaborator's Part B claim totals by accountants at an hourly rate of $33.89, each participant could have spent approximately $6,778 on the reviews for a total of $1.1 million across all 159 participants with CJR collaborators. Our proposal to remove the 50 percent cap should therefore reflect a burden reduction around $1.1 million. While we are unable to quantify the change to be had by our proposals to modify beneficiary notice requirements for model inclusion, discharge planning notices, and our extension of waivers for Medicare program rules, we believe having uniform requirements regardless of procedure setting for CJR beneficiaries will help participants to streamline the administrative procedures they put in place for the CJR model and that this streamlining will reduce the effort participants need to expend in complying with the CJR model regulations.

TABLE 7: FINANCIAL IMPACT FOR THE PROPOSED CHANGES AND THREE-YEAR EXTENSION OF THE CJR MODEL
[Figures are in $ millions, negative values represent savings]

Year	2021	2022	2023	Total
Episode Spending with Model	$1,505	$1,582	$1,661	$4,748
Episode Spending without Model	1,533	1,623	1,703	4,859
Reconciliation	-50	-53	-55	-158
Total Impact	-78	-94	-97	-269

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

Our analysis in Table 7 from the proposed rule was informed by the target price and episode spending calculations produced by an external analytic contractor using 2018 claims data and presented the transfer payment effects of the proposed rule to the best of our ability. The updated analysis in Table 7a in this final rule was informed by calculations produced by the same external analytic contractor using 2019 claims data and presents the updated transfer payment effects of the final rule to the best of our ability.

TABLE 7a: FINANCIAL IMPACT FOR THE FINAL CHANGES AND THREE-YEAR EXTENSION OF THE CJR MODEL
[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	$1,422	$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.

The following Table 8 summarizes the financial impact of the proposal across 3 relevant years as well as two alternative scenarios: (1) If the CJR model were discontinued; and (2) if the CJR model were extended with changes to the episode definition to include outpatient TKA/THA but no other proposed changes. This table includes the full amount of FFS episode payments and any rows that show the model extending also includes any reconciliation payments related to the model. This table shows costs/savings (costs are represented as positive amounts and savings as negative amounts) imposed on non-federal entities (that is, participating medical facilities) as well as net transfers of federal funds (that is, increases in Medicare program expenditures are indicated as positive amounts and decreases in Medicare program expenditures are indicated as negative amounts).

TABLE 8: NET FINANCIAL IMPACTS UNDER PROPOSAL AND ALTERNATIVE SCENARIOS ($ in millions) 2021-2023

Scenario	Costs/Benefits	Transfers
Net financial impact of extending CJR model with all proposed changes	0	4,626
Net financial impact of extending CJR model including outpatient TKA/THA in episode definition, but including no other proposed changes	0	4,965
Net financial impact of ending CJR model	0	4,859

Note: Row 1 of Table 8 reflects the value shown in Table 7 row 1 (episode spending with model) less the reconciliation payment amount shown in row 3 of Table 7. Row 3 of Table 8 shows the total spend without the model as shown in Table 7.

In this final rule, we have updated Table 8 with Table 8a, based on the new assumptions regarding financial impact of the CJR model noted in Table 7a. We excluded impact assumptions for the alternative scenario from Table 8, (2) if the CJR model were extended with changes to the episode definition to include outpatient TKA/THA but no other proposed changes, in Table 8a since we determined this scenario is not practically feasible. As noted in section II.C.6. of this final rule, many of the CJR model payment methodology changes CMS is adopting in this final rule for PYs 6 through 8 are interdependent, and we believe will only be successful if implemented together. We determined it is not practical to consider scenario (2), adding outpatient TKA/THA to the episode definition with none of the other proposed changes, because the CJR model extension payment methodology relies on the risk adjustment mechanism to appropriately account for the variation in inpatient procedure costs compared to the OPPS setting. Additionally, similar to the updates to Table 6a in this final rule, we determined comparing certain provisions of the CJR model extension methodology to the original CJR model methodology could lead to misleading transfer amount assumptions.

TABLE 8a: NET FINANCIAL IMPACTS UNDER FINAL RULE AND ALTERNATIVE SCENARIOS ($ in millions) 2021-2024

Scenario	Costs/Benefits	Transfers
Net financial impact of extending CJR model with all proposed changes	0	4,388
Net financial impact of ending CJR model	0	4,605

Note: Row 1 of Table 8a reflects the value shown in Table 7a row 1 (episode spending with model) less the reconciliation payment amount shown in row 3 of Table 7a. Row 2 of Table 8 shows the total spend without the model as shown in Table 7a.

We received no comments about the anticipated financial effects specified in the proposed rule or about our assumptions and approach regarding Table 7 or Table 8. We have provided approximate updates to these tables based on our current assumptions regarding the LEJR market environment.

D. Effects on Beneficiaries

We believe the refinements to the CJR model adopted in this final rule would not materially alter the potential effects of the model on beneficiaries. We believe the changes would not alter the effects of the model on beneficiaries because the changes predominantly alter how hospitals interact with the model, rather than how beneficiaries receive care. We do not expect that CJR participant hospitals will conduct a larger share of LEJR procedures in the outpatient setting than non-CJR participant hospitals. We believe that the combination of our episode-level risk adjustment methodology, with the fact that sicker patients who are inappropriately treated in the outpatient setting would potentially have complications requiring readmissions or other expensive post-acute care as a result of the inappropriate care setting for the original procedure, will incentivize physicians to make the appropriate clinical judgment based on the individual beneficiary's needs.

We received no comments on this section of the proposed rule and therefore are finalizing this section without modification.

E. Effects on Small Rural Hospitals

Section 1102(b) of the Act requires CMS to prepare a RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, a small rural hospital is defined as a hospital that is located outside of an MSA and has fewer than 100 beds. We note that, according to this definition, the CJR model has never included any rural hospitals given that the CJR model only includes hospitals located in MSAs. However, for purposes of our policy to provide a more protective stop-loss policy for certain hospitals, in the November 2015 final rule we revised our definition of a rural hospital to include an IPPS hospital that is either located in a rural area in accordance with § 412.64(b) or in a rural census tract within an MSA defined at § 412.103(a)(1), or has reclassified to rural in accordance with § 410.103.

The changes to, and extension of, the CJR model as laid out in this final rule are focused on high cost urban area MSAs and exclude participant hospitals that are rural hospitals as of July 4, 2021 from participation. We note that the hospitals with rural status that opted to continue to participate in the CJR model after February 1, 2018 were defined as rural based on their urban to rural reclassifications governed by § 412.103 and were also qualified as rural referral centers (RRCs) (see § 412.96), which are high-volume acute care hospitals that treat a large number of complicated cases. None of these hospitals were geographically rural for purposes of section 1102(b) of the Act. Therefore, we are not preparing an analysis for section 1102(b) of the Act because we have

determined, and the Secretary certifies, that the changes to, and extension of, the CJR model will not have a significant impact on the operations of a substantial number of small rural hospitals. We received no comments on this section of the proposed rule and therefore are finalizing this section without modification.

F. Effects on Small Entities

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. We estimated that most hospitals and most other providers and suppliers are small entities, either by virtue of their nonprofit status or by qualifying as small businesses under the Small Business Administration's size standards (revenues of less than $8.0 to $ 41.5 million in any one year; NAIC Sector-62 series). States and individuals are not included in the definition of a small entity. For details, see the Small Business Administration's website at *https://www.sba.gov/document/support-table-size-standards.* For purposes of the RFA, we generally consider all hospitals (NAICS code 622110 or 622310) and other providers and suppliers to be small entities. We believe that the provisions of this final rule relating to acute care hospitals will have some effects on a substantial number of other providers involved in these episodes of care including surgeons and other physicians (NAICS code 621111), SNFs (NAICS code 623110), physical therapists (NAICS code 621340), and other providers. Although we acknowledge that many of the affected entities are small entities, and the analysis discussed throughout this final rule discusses aspects of the CJR model that may or would affect them, we have no reason to assume that these effects would reach the threshold levels of 3 or five percent of revenues used by HHS to identify what are likely to be ''substantial'' or ''significant'' impacts, respectively.

Using the table of Small Business Size Standards Matched to NAICS codes released by the U. S. Small Business Administration,[16] we determined that HHAs are considered small businesses if annual revenues are less than $16 million, and SNFs are considered small businesses if annual revenues are less than $20 million. Using the Medicare Cost report data from 2017,[17] only 353 HHAs of the 10,413 that filed cost reports were not considered small businesses. Similarly, only 1,199 SNFs of the 14,764 that filed cost reports were not considered small businesses. CJR model historical experience has demonstrated that HHAs benefit from the model through increased referrals and HHA utilization. While the CJR Model Third Annual Evaluation Report could not draw conclusions on the model's effect on HHA payments, it does note that the proportion of CJR patients first discharged to an HHA increased 21.9% from the CJR baseline proportion during PYs 1–3.[18] In contrast, SNFs experience decreases in overall Medicare payments compared to baseline estimates (15.4 percent during PYs 1–3) as a result of the model.[19] While the Evaluation Report indicates the model affected these entities as such, only a small proportion of the total bed days in SNFs are covered by Medicare, which limits the degree of impact on the overall revenues of those entities. Based on 2017 cost report data, only 12.9 percent of all bed days in SNFs were covered by Medicare FFS while Private Payer, Managed Care and Medicaid accounted for the remaining 87.1 percent.[20] Additionally, although LEJR procedures (MS–DRGs 469 and 470) are among the most common surgical procedures undergone by Medicare beneficiaries, they are only about 5 percent of all acute hospital discharges.[21] We assume that all or almost all of these entities will continue to serve these patients, and to receive payments commensurate with their cost of care. Hospitals currently experience frequent changes to payment (for example, as both hospital affiliations and preferred provider networks change) that may impact revenue, and we have no reason to assume that this will change significantly under the changes.

We received no comments on this section of the proposed rule and therefore are finalizing this section without modification.

G. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number providers participating in CJR, or 470 providers as of October 2019, would be the number of reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that some reviewers chose not to comment on the proposed rule. However, for the purposes of our estimate we assume that each reviewer reads approximately 100 percent of the rule.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $110.74 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm.* Assuming an average reading speed, we estimate that it would take approximately 2.3 hours for staff to review this final rule. For each entity that reviews the rule, the estimated cost is $254.70 (2.3 hours × $110.74). Therefore, we estimate that the total cost of reviewing this regulation is $119,709 ($254.70 × 470 reviewers).

H. Accounting Statement

As required by OMB Circular A–4 under Executive Order 12866 (available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*) in Table 9, we have prepared an accounting statement showing the classification of transfers, benefits, and costs associated with the provisions in this proposed rule. The accounting statement is based on estimates provided in this regulatory impact analysis. As described in Table 7, we estimate the proposed 3-year extension and changes to the CJR model will result in savings to the federal government of $269 million over the 3 performance years of the model from 2021 to 2023. The following Table 9 shows the annualized change in— (1) net federal monetary transfers; and (2) potential reconciliation payments to participating hospitals net of repayments from participant hospitals that is associated

[16] U.S. Small Business Administration: Table of Small Business Size Standards Matched to North American Industry Classification System Codes is accessible at: *https://www.sba.gov/sites/default/files/2019-08/SBA%20Table%20of%20Size%20Standards_Effective%20Aug%2019%2C%202019_Rev.pdf.*

[17] 2017 Medicare Cost Report data accessible at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports.*

[18] See pg. 61 of the CJR Model Third Annual Evaluation Report accessible at: *https://innovation.cms.gov/data-and-reports/2020/cjr-thirdannrpt.*

[19] See pg. 58 of the CJR Model Third Annual Evaluation Report accessible at: *https://innovation.cms.gov/data-and-reports/2020/cjr-thirdannrpt.*

[20] 2017 Medicare Cost Report data accessible at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports.*

[21] Medicare Inpatient Claims data from January-December 2019, Chronic Conditions Warehouse.

with the provisions of the proposed rule as compared to baseline. In Table 9, the annualized change in payments based on a 7 percent and 3 percent discount rate, results in net federal monetary transfer from the participant IPPS hospitals to the federal government of $83 million and $86 million, respectively.

TABLE 9—ACCOUNTING STATEMENT ESTIMATED IMPACTS
[Estimate amounts are in $ millions]

Category	Estimates	Units		
		Year Dollar	Discount Rate	Period Covered
Transfers				
Annualized Monetized ($million/year)	83	2019	7%	2021 - 2024
	86	2019	3%	2021 - 2024
From Whom to Whom	Participant IPPS to Federal Government			

The updated accounting statement in this final rule is based on estimates provided in this regulatory impact analysis in this final rule. As described in Table 7a, we estimate the extension and changes to the CJR model will result in savings to the federal government of $217 million over the 3 performance years of the model from 2021 to 2024. The following Table 9a in this final rule shows the annualized change in— (1) net federal monetary transfers; and (2) potential reconciliation payments to participating hospitals net of repayments from participant hospitals that is associated with the provisions of this final rule as compared to baseline. In Table 9a in this final rule, the annualized change in payments based on a 7 percent and 3 percent discount rate, results in net federal monetary transfer from the participant IPPS hospitals to the federal government of $59 million and $63 million, respectively.

TABLE 9a—UPDATED ACCOUNTING STATEMENT ESTIMATED IMPACTS
[Estimate amounts are in $ millions]

Category	Estimates	Units		
		Year Dollar	Discount Rate	Period Covered
Transfers				
Annualized Monetized ($million/year)	59	2020	7%	2021 - 2024
	63	2020	3%	2021 - 2024
From Whom to Whom	Participant IPPS to Federal Government			

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. In 2021, that threshold is approximately $158 million. This rule will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

I. Analysis of Regulatory Alternatives

As noted previously, Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives. In developing the proposed rule, we considered a number of regulatory alternatives. These include—

- 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.4. of the proposed rule ''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.6. of this final rule ''Changes to Trend Factor Calculation'')

These regulatory alternatives and their potential costs and benefits are explored in more detail later in this section.

In developing this final rule, as we believe it would be good for the CMS Innovation Center to consider a wider range of participants for future LEJR models, we considered broadening and modifying the types of entities that may initiate an episode under the CJR model. However, the CJR model as established in notice-and-comment rulemaking, limited participants to hospitals. As the impetus for proposing this extension was that the active model is currently showing promise in terms of reducing costs while maintaining quality and we wished to continue that momentum, we were limited by timing. Further, we would likely have needed to reconsider and broaden the geographic scope of the model were we to extend participant types since the original model geography was based on hospital specific criteria. Further, we believe that broadening and modifying who may

initiate an episode would unnecessarily complicate the evaluation and limit the generalizability of the results affecting the ability of this model being certified in the future. Therefore, we did not propose to include additional participants in the proposed CJR model extension but rather solicited comment in section II.J. of this final rule on how a future LEJR model that incorporated other entities in addition to hospitals might be structured.

We received many comments related to future LEJR models and the incorporation of other entities in addition to hospitals. A summary of those comments can be found in section II.J. of this final rule.

In developing our risk adjustment methodology approach, although we proposed to calculate coefficients at the national level, we also considered 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.4. of this final rule ''Additional Episode-Level Risk Adjustment''). As we believe regional differences in risk for CJR HCC count and age should already be accounted for via our region/MS–DRG pricing strategy we proposed the computationally less complex national approach although we sought comment on a regional calculation of coefficients.

After consideration of the public comments we received, we are finalizing the proposed policy to calculate the risk adjustment coefficients at the national level without applying risk standardization to the regional target price prior to applying the beneficiary-specific risk score. A summary of those comments and our responses can be found in section II.C.4. of this final rule.

Finally, in developing our methodology for the market trend factor update calculation, we considered utilizing the regional median episode costs as a basis for the market trend factor update calculation, as medians are generally recognized as the preferred measure of central tendency for data that is not normally distributed. However, we did not propose to use the median in the market trend factor update, as discussed in section II.C.6. of this final rule, because we determined using the mean only resulted in a small difference in effect (the trend factors calculated using means were 0.01 higher than trend factors calculated using medians), and using the mean could benefit participant hospitals (that is, increase target prices more compared to the median). Further, using the mean aligns the trend calculation with the methodology for deriving the target prices for the model, which also relies on the mean rather than the median.

After consideration of the public comments we received, we are finalizing the proposed policy to calculate the market trend factor using the mean of episode costs instead of the median. A summary of comments received regarding this alternative policy and our responses can be found in section II.C.6. of this final rule.

I, Elizabeth Richter, Acting Administrator of the Centers for Medicare & Medicaid Services, approved this document on April 23, 2021.

List of Subjects in 42 CFR Part 510

Administrative Practice and Procedure, Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 510—COMPREHENSIVE CARE FOR JOINT REPLACEMENT MODEL

■ 1. The authority citation for part 510 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

■ 2. Section 510.2 is amended by:
■ a. Adding a definition for ''Age bracket risk adjustment factor'';
■ b. Revising the definition of ''Anchor hospitalization'';
■ c. Addng definitions for''Anchor procedure'', ''BPCI Advanced'', ''CJR HCC count risk adjustment factor'', and ''Dual-eligibility risk adjustment factor'';
■ d. Revising the definitions of ''Episode of care (or Episode)'' and ''Net payment reconciliation amount (NPRA)'';
■ e. Adding the definitions for ''OPPS'' and ''OP THA/OP TKA'';
■ f. Revising the definitions of ''Participant hospital'', ''Performance Year'', ''Quality improvement points'', and ''Reconciliation payment''; and
■ g. Adding the definition for ''Reconciliation target price''.

The additions and revisions read as follows:

§ 510.2 Definitions.

* * * * *

Age bracket risk adjustment factor means the coefficient of risk associated with a patient's age bracket, calculated as described in § 510.301(a)(1).

* * * * *

Anchor hospitalization means the initial hospital stay upon admission for a lower extremity joint replacement, for which the institutional claim is billed through the IPPS. Anchor hospitalization also includes an inpatient hospital admission within 3 days after an outpatient Total Knee Arthroplasty (TKA) or Total Hip Arthroplasty (THA).

Anchor procedure means a TKA or THA procedure that is permitted and paid for by Medicare when performed in a hospital outpatient department (HOPD) and billed through the OPPS, except when the beneficiary is admitted to an inpatient hospital stay within 3 days after the TKA or THA.

* * * * *

BPCI Advanced stands for the Bundled Payments for Care Improvement Advanced Model.

* * * * *

CJR–HCC condition count risk adjustment factor means the coefficient of risk associated with a patient's total number of CMS Hierarchical Condition Categories, calculated as described in § 510.301(a)(1).

* * * * *

Dual-eligibility risk adjustment factor means the coefficient of risk associated with beneficiaries that are eligible for full Medicaid benefits or beneficiaries that are not eligible for full Medicaid benefits, calculated as described in § 510.301(a)(1).

* * * * *

Episode of care (or Episode) means all Medicare Part A and B items and services described in § 510.200(b) (and excluding the items and services described in § 510.200(d)) that are furnished to a beneficiary described in § 510.205 during the time period that begins with the beneficiary's admission to an anchor hospitalization or, on or after July 4, 2021, the date of admission to an anchor hospitalization or the date of the anchor procedure, as applicable, and ends on the 90th day after the following, as applicable:

(1) The date of discharge from the anchor hospitalization (with the day of discharge itself being counted as the first day of the 90-day post-discharge period); or

(2) The date of service for the anchor procedure.

* * * * *

Net payment reconciliation amount (NPRA) means the amount determined in accordance with § 510.305(e) or (m).

* * * * *

OPPS stands for the outpatient prospective payment system.

OP THA/OP TKA means a total hip arthroplasty or total knee arthroplasty, respectively, for which the institutional

claim is billed by the hospital through the OPPS.

* * * * *

Participant hospital means one of the following:

(1) During performance years 1 and 2 of the CJR model and the period from January 1, 2018 to January 31, 2018 of performance year 3, a hospital (other than a hospital excepted under § 510.100(b)) with a CCN primary address located in one of the geographic areas selected for participation in the CJR model in accordance with § 510.105.

(2) Between February 1, 2018 and September 30, 2021 a hospital (other than a hospital excepted under § 510.100(b)) that is one of the following:

(i) A hospital with a CCN primary address located in a mandatory MSA as of February 1, 2018 that is not a rural hospital or a low-volume hospital on that date.

(ii) A hospital that is a rural hospital or low-volume hospital with a CCN primary address located in a mandatory MSA that makes an election to participate in the CJR model in accordance with § 510.115.

(iii) A hospital with a CCN primary address located in a voluntary MSA that makes an election to participate in the CJR model in accordance with § 510.115.

(3) Beginning October 1, 2021, a hospital that is not a rural hospital or a low-volume hospital as defined in § 510.2, as of July 4, 2021 (based on the date of the CMS notification letter and not the effective date of the rural reclassification, if applicable) with a CCN primary address located in a mandatory MSA.

* * * * *

Performance year means one of the years in which the CJR model is being tested. Performance years for the model correlate to calendar years with the exceptions of performance year 1, which is April 1, 2016 through December 31, 2016, performance year 5, which is January 1, 2020 through September 30, 2021, and performance year 6 which is October 1, 2021 through December 31, 2022. For reconciliation purposes, performance year 5 is divided into two subsets, performance year subset 5.1 (January 1, 2020 through December 31, 2020) and performance year subset 5.2 (January 1, 2021 through September 30, 2021).

* * * * *

Quality improvement points are points that CMS adds to a participant hospital's composite quality score for a measure if the hospital's performance percentile on an individual quality measure for performance years 2 through 4 and 6 through 8, or for performance year subsets of performance year 5, increases from the previous performance year or performance year subset by at least 2 deciles on the performance percentile scale, as described in § 510.315(d). For performance year 1, CMS adds quality improvement points to a participant hospital's composite quality score for a measure if the hospital's performance percentile on an individual quality measure increases from the corresponding time period in the previous year by at least 2 deciles on the performance percentile scale, as described in § 510.315(d).

* * * * *

Reconciliation payment means a payment made by CMS to a CJR participant hospital as determined in accordance with § 510.305(f) or (l).

* * * * *

Reconciliation target price means, for performance years 6 through 8, the target price applied to an episode at reconciliation, as determined in accordance with § 510.301.

* * * * *

■ 3. Section 510.100 is amended by revising paragraph (a) to read as follows:

§ 510.100 Episodes being tested.

(a) *Initiation of an episode.* An episode is initiated when, with respect to a beneficiary described in § 510.205—

(1) The participant hospital admits the beneficiary for an anchor hospitalization; or

(2) On or after July 4, 2021, an anchor procedure is performed at the participant hospital.

* * * * *

■ 4. Section 510.105 is amended by adding paragraph (a)(3) to read as follows:

§ 510.105 Geographic areas.

(a) * * *

(3) Beginning with performance year 6, only the 34 MSAs designated as mandatory participation MSAs as of performance year 3.

* * * * *

■ 5. Section 510.120 is amended by revising paragraph (a) introductory text to read as follows:

§ 510.120 CJR participant hospital CEHRT track requirements.

(a) *CJR CEHRT use.* For performance years 2 through 8, CJR participant hospitals choose either of the following:

* * * * *

■ 6. Section 510.200 is amended by—

■ a. Revising paragraph (a);
■ b. Adding paragraph (b)(15);
■ c. Revising paragraph (c);
■ d. Revising paragraphs (d)(4) introductory text, and (d)(6);
■ e. Adding paragraph (d)(7)
■ f. Revising paragraphs (e)(2), (e)(3) introductory text, and (e)(4) introductory text; and
■ g. Adding paragraph (e)(5).

The revisions and additions read as follows:

§ 510.200 Time periods, included and excluded services, and attribution.

(a) *Time periods.* All episodes must begin on or after April 1, 2016 and end on or before December 31, 2024.

(b) * * *

(15) The surgeon's Part B claim for the LEJR procedure dated within the 3 days prior to an inpatient admission, if the LEJR procedure was performed at the participant hospital on an outpatient basis but the patient was subsequently admitted as an inpatient, resulting in an anchor hospitalization.

(c) *Episode attribution.* All items and services included in the episode are attributed to the participant hospital at which the anchor hospitalization or anchor procedure, as applicable, occurs.

(d) * * *

(4) Items and services unrelated to the anchor hospitalization or the anchor procedure. Excluded services include, but are not limited, to the following:

* * * * *

(6) For performance years 1 through 4 and for performance year subsets 5.1 and 5.2, payments for otherwise included items and services in excess of 2 standard deviations above the mean regional episode payment in accordance with § 510.300(b)(5).

(7) For performance years 6 through 8 only, payments for otherwise included items and services in excess of the 99th percentile of regional spending, ranked within each region, for each of the four MS–DRG target price categories, as specified in § 510.300(a)(1) and (6), for performance years 6 through 8, in accordance with § 510.300(b)(5).

* * * * *

(e) * * *

(2) For performance years 1 through 5 only, on an annual basis, or more frequently as needed, CMS updates the list of excluded services to reflect annual coding changes or other issues brought to CMS' attention.

(3) For performance years 1 through 5 only, CMS applies the following standards when revising the list of excluded services for reasons other than to reflect annual coding changes:

* * * * *

(4) For performance years 1 through 5 only, CMS posts the following to the CMS website:

* * * * *

(5) For performance years 6 through 8, the list of excluded services posted on the CMS website as it appears at the beginning of performance year 5 will apply and will not be updated.

■ 7. Section 510.205 is amended by revising paragraph (a)(6)(iii) to read as follows:

§ 510.205 Beneficiary inclusion criteria.

(a) * * *

(6) * * *

(iii) A Shared Savings Program ACO in the ENHANCED track (formerly Track 3).

* * * * *

■ 8. Section 510.210 is amended by revising paragraphs (a) and (b)(1)(ii) to read as follows:

§ 510.210 Determination of the episode.

(a) *General.* (1) An episode begins with the admission of a Medicare beneficiary described in § 510.205 to a participant hospital for an anchor hospitalization and ends on the 90th day after the date of discharge, with the day of discharge itself being counted as the first day in the 90-day post-discharge period.

(2) On or after July 4, 2021, an episode—

(i) Begins and ends in the manner specified in paragraph (a)(1) of this section; or

(ii) Begins on the date of service of an anchor procedure furnished to a Medicare beneficiary described in § 510.205 and ends on the 90th day after the date of service of the anchor procedure.

(b) * * *

(1) * * *

(ii) Is readmitted to any participant hospital for another anchor hospitalization, or, on or after July 4, 2021, receives an anchor procedure at any participant hospital.

* * * * *

■ 9. Section 510.300 is amended by—

■ a. Revising paragraph (a)(2) through (a)(4);

■ b. Adding paragraphs (a)(6), and (b)(1)(iv) through (vi); and

■ c. Revising paragraphs (b)(2)(iii), (b)(5), and (c)(3)(iii).

The revisions and additions read as follows:

§ 510.300 Determination of episode quality-adjusted target prices.

(a) * * *

(2) *Applicable time period for performance year or performance year subset episode quality-adjusted target prices.* For performance years 1 through 4 and performance year subset 5.1 only, episode quality-adjusted target prices are updated to account for Medicare payment updates no less than 2 times per year, for updated quality-adjusted target prices effective October 1 and January 1, and at other intervals if necessary.

(3) *Episodes that straddle performance years, performance year subsets, or payment updates.* The quality-adjusted target price that applies to the episode is one of the following:

(i) For episodes beginning on or after April 1, 2016 and ending on or before September 30, 2021, the date of admission for the anchor hospitalization.

(ii) For episodes beginning on or after July 4, 2021 and ending on or after October 1, 2021, the date of the anchor procedure or the date of admission for the anchor hospitalization, as applicable.

(4) *Identifying episodes with hip fracture.* CMS develops a list of ICD–CM hip fracture diagnosis codes that, when reported in the principal diagnosis code files on the claim for the anchor hospitalization or anchor procedure, represent a bone fracture for which a hip replacement procedure, either a partial hip arthroplasty or a total hip arthroplasty, could be the primary surgical treatment. The list of ICD–CM hip fracture diagnosis codes used to identify hip fracture episodes can be found on the CMS website. Beginning on October 1, 2020, hip fracture episodes initiated by an anchor hospitalization will be identified by MS–DRGs 521 and 522.

(i) For performance years 1 through 5 only, on an annual basis, or more frequently as needed, CMS updates the list of ICD–CM hip fracture diagnosis codes to reflect coding changes or other issues brought to CMS' attention.

(ii) For performance years 1 through 5 only, CMS applies the following standards when revising the list of ICD–CM hip fracture diagnosis codes.

(A) The ICD–CM diagnosis code is sufficiently specific that it represents a bone fracture for which a physician could determine that a hip replacement procedure, either a Partial Hip Arthroplasty (PHA) or a THA, could be the primary surgical treatment.

(B) The ICD–CM diagnosis code is the primary reason (that is, principal diagnosis code) for the anchor hospitalization.

(iii) For performance years 1 through 5 only, CMS posts the following to the CMS website:

(A) Potential ICD–CM hip fracture diagnosis codes for public comment; and

(B) A final ICD–CM hip fracture diagnosis code list after consideration of public comment.

(iv) For performance years 6 through 8, the hip fracture diagnosis code list posted at *https://innovation.cms.gov/Files/worksheets/cjr-icd10hipfracturecodes.xlsx* as it appears at the beginning of performance year 5 will not be updated. The hip fracture diagnosis code list will be used to identify hip fracture episodes initiated by an anchor procedure in performance years 6 through 8.

* * * * *

(6) For episodes beginning on or after July 4, 2021 that are initiated by an anchor procedure, permitted OP TKAs and OP THAs are grouped with MS–DRG 470 or MS–DRG 522 episodes as follows:

(i) Permitted OP THAs with hip fracture group with MS–DRG 522.

(ii) Permitted OP THAs without hip fracture and permitted OP TKAs group with MS–DRG 470.

(b) * * *

(1) * * *

(iv) Episodes beginning in 2019 for performance year 6.

(v) Episodes beginning in 2021 for performance year 7.

(vi) Episodes beginning in 2022 for performance year 8.

(2) * * *

(iii) Regional historical episode payments for performance year 4, for each subset of performance year 5, and performance years 6 through 8.

* * * * *

(5) *Exception for high episode spending.* (i) For performance years 1 through 4, and for performance year 5, each subset thereof, episode payments are capped at 2 standard deviations above the mean regional episode payment for both the hospital-specific and regional components of the quality-adjusted target price.

(ii) For performance years 6 through 8, episode payments are capped at the 99th percentile of regional spending for each of the four MS–DRG categories, as specified in § 510.300(a)(1) and (6).

* * * * *

(c) * * *

(3) * * *

(iii) In performance years 4, each subset of performance year 5, and performance years 6 through 8, 3.0 percent.

* * * * *

■ 10. Section 510.301 is added to read as follows:

§ 510.301 Determination of reconciliation target prices.

Beginning with performance year 6, the quality-adjusted target price computed under § 510.300 is further adjusted for risk and market trends as described in this section to arrive at the reconciliation target price amount, with the exception of episodes that are reconciled in performance year 6 but subject to a performance year subset 5.2 target price. Specifically:

(a) *Risk adjustment.* (1) The quality-adjusted target prices computed under § 510.300 are risk adjusted at a beneficiary level by a CJR HCC count risk adjustment factor, an age bracket risk adjustment factor, and a dual-eligibility status risk adjustment factor. All three factors are binary, yes/no variables, meaning that a beneficiary either does or does not meet the criteria for a specific variable.

(i) The CJR HCC count risk adjustment factor uses five variables, representing beneficiaries with zero, one, two, three, or four or more CMS–HCC conditions.

(ii) The age bracket risk adjustment factor uses four variables, representing beneficiaries aged—

(A) Less than 65 years;

(B) 65 to 74 years;

(C) 75 years to 84 years; or

(D) 85 years or more.

(iii) The dual-eligibility status factor uses two variables, representing beneficiaries that are eligible for full Medicaid benefits or beneficiaries that are not eligible for full Medicaid benefits.

(2) All three factors are computed prior to the start of performance years 6 and 8 via a linear regression analysis. The regression analysis is computed using 1 year of claims data as follows:

(i) For performance year 6, CMS uses claims data with dates of service dated January 1, 2019 to December 31, 2019.

(ii) For performance year 7, CMS uses the same regression analysis results and corresponding coefficients that were calculated for performance year 6.

(iii) For performance year 8, CMS uses claims data with dates of service dated January 1, 2021 to December 31, 2021.

(3)(i) The dependent variable in the annual regression that produces the risk adjustment coefficients is equal to the difference between the log transformed target price calculated under § 510.300 and the capped episode costs as described in § 510.300(b)(5)(ii).

(ii) The independent variables are binary values assigned to each CJR HCC count variable, age bracket variable and dual-eligibility status variable.

(iii) Using these variables, the annual regression produces exponentiated coefficients to determine the anticipated marginal effect of each risk adjustment factor on episode costs. CMS transforms, or exponentiate, these coefficients in order to ''reverse'' the previous logarithmic transformation, and the resulting coefficients are the CJR HCC count risk adjustment factor, the age bracket risk adjustment factor, and the dual-eligibility status factor that would be used during reconciliation for the subsequent performance year.

(4)(i) At the time of reconciliation, the quality adjusted target prices computed under § 510.300 are risk adjusted at the beneficiary level by applying the applicable CJR HCC count risk adjustment factor, the age bracket risk adjustment factor, and the dual-eligibility risk adjustment factor specific to the beneficiary in the episode.

(ii)(A) For the CJR HCC count risk adjustment factor, applicable means the coefficient that applies to the CMS–HCC condition count for the beneficiary in the episode;

(B) For the age bracket risk adjustment factor, applicable means the coefficient for the age bracket into which the beneficiary falls on the first day of the episode; and

(C) For the dual-eligibility risk adjustment factor, applicable means the coefficient for beneficiaries that are eligible for full Medicaid benefits on the first day of the episode.

(5)(i) The risk-adjusted target prices are normalized at reconciliation to remove the overall impact of adjusting for age, CJR HCC count, and dual-eligibility status on the national average target price.

(ii) The 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.

(iii) CMS applies the normalization factor to the previously calculated, beneficiary-level, risk-adjusted target prices specific to each episode region and MS–DRG combination (as specified in paragraph (a)(4) of this section).

(iv) These normalized target prices are then further adjusted for market trends (as specified in paragraph (b) of this section) and quality performance (as specified at § 510.300) to become the reconciliation target prices, which are compared to actual episode costs at reconciliation, as specified in § 510.305(m)(1)(i).

(b) *Market trend adjustment factor.* (1) The risk-adjusted quality-adjusted target price computed under § 510.300 and paragraph (a) of this section is further adjusted for market trend changes at the region and MS–DRG level.

(2) This adjustment is accomplished by multiplying each risk-adjusted quality-adjusted target price computed under § 510.300 and paragraph (a) of this section by the applicable market trend adjustment factor.

(3) The applicable market trend adjustment factor is calculated as the percent difference between the average regional MS–DRG episode costs computed using the performance year claims data and comparison average regional MS–DRG fracture episode costs computed using historical calendar year claims data used to calculate the regional target prices in effect for that performance year.

■ 11. Section 510.305 is amended by—

■ a. Revising paragraphs (b), (d) heading, and (e) introductory text;

■ b. Adding paragraphs (f)(1)(iv) through (vi);

■ c. Revising paragraph (i); and

■ d. Adding paragraphs (l) and (m).

The revisions and additions read as follows:

§ 510.305 Determination of the NPRA and reconciliation process.

* * * * *

(b) *Reconciliation.* (1) For performance years 1 through 4 and for each subset of performance year 5, CMS uses a series of reconciliation processes, which CMS performs as described in paragraphs (d) and (f) of this section after the end of each performance year, to establish final payment amounts to participant hospitals for CJR model episodes for a given performance year.

(2) For performance years 6 through 8, CMS conducts one reconciliation process, which CMS performs as described in paragraphs (l) and (m) of this section after the end of each performance year, to establish final payment amounts to participant hospitals for CJR model episodes for a given performance year.

(3) Following the end of each performance year, for performance years 1 through 4 and for performance year 5, each subset thereof, CMS determines actual episode payments for each episode for the performance year (other than episodes that have been canceled in accordance with § 510.210(b)) and determines the amount of a reconciliation payment or repayment amount.

* * * * *

(d) *Annual reconciliation for performance years 1 through 5.*

* * * * *

(e) *Calculation of the NPRA for performance years 1 through 5.* By comparing the quality-adjusted target prices described in § 510.300 and the participant hospital's actual episode spending for each of performance years 1 through 4, and for performance year

5, each subset thereof, and applying the adjustments in paragraph (e)(1)(v) of this section, CMS establishes an NPRA for each participant hospital for each of performance years 1 through 4 and for performance year 5, each subset thereof.

* * * * *

(f) * * *

(1) * * *

(iv) Results from the performance year 6 reconciliation and post-episode spending calculations as described in paragraph (m) of this section are added together in order to determine the reconciliation payment or repayment amount for performance year 6.

(v) Results from the performance year 7 reconciliation and post-episode spending calculations as described in paragraph (m) of this section are added together in order to determine the reconciliation payment or repayment amount for performance year 7.

(vi) Results from the performance year 8 reconciliation and post-episode spending calculations as described in paragraph (m) of this section are added together in order to determine the reconciliation payment or repayment amount for performance year 8.

* * * * *

(l) *Annual reconciliation for performance years 6 through 8.* (1) Beginning 6 months after the end of each of performance years 6 through 8, CMS does all of the following:

(i) Performs a reconciliation calculation to establish an NPRA for each participant hospital.

(ii) For participant hospitals that experience a reorganization event in which one or more hospitals reorganize under the CCN of a participant hospital, performs—

(A) Separate reconciliation calculations for each predecessor participant hospital for episodes where the anchor hospitalization admission or the anchor procedure occurred before the effective date of the reorganization event; and

(B) Reconciliation calculations for each new or surviving participant hospital for episodes where the anchor hospitalization admission or anchor procedure occurred on or after the effective date of the reorganization event.

(2) CMS—

(i) Calculates the NPRA for each participant hospital in accordance with paragraph (m) of this section including the adjustments provided for in paragraph (m)(1)(vii) of this section; and

(ii) Assesses whether participant hospitals meet specified quality requirements under § 510.315.

(m) *Calculation of the NPRA for performance years 6 through 8.* By comparing the reconciliation target prices described in § 510.301 and the participant hospital's actual episode spending for the performance year and applying the adjustments in paragraph (m)(1)(vii) of this section, CMS establishes an NPRA for each participant hospital for each of performance years 6 through 8.

(1) In calculating the NPRA for each participant hospital for each performance year, CMS does the following:

(i) Determines actual episode payments for each episode included in the performance year (other than episodes that have been canceled in accordance with § 510.210(b)) using claims data that is available 6 months after the end of the performance year. Actual episode payments are capped at the amount determined in accordance with § 510.300(b)(5)(ii) for the performance year, the amount determined in paragraph (k) of this section for episodes affected by extreme and uncontrollable circumstances, or the target price determined for that episode under § 510.300 for episodes that contain a COVID–19 Diagnosis Code as defined in § 510.2.

(ii) Multiplies each episode reconciliation target price by the number of episodes included in the performance year (other than episodes that have been canceled in accordance with § 510.210(b)) to which that episode reconciliation target price applies.

(iii) Aggregates the amounts computed in paragraph (m)(1)(ii) of this section for all episodes included in the performance year (other than episodes that have been canceled in accordance with § 510.210(b)).

(iv) Subtracts the amount determined under paragraph (m)(1)(i) of this section from the amount determined under paragraph (m)(1)(iii) of this section.

(v) Performs an additional calculation using claims data available at that time, to account for any episode cancelations due to overlap between the CJR model and other CMS models and programs, or for other reasons as specified in § 510.210(b).

(vi) Conducts a post-episode spending calculation as follows: If the average post-episode Medicare Parts A and B payments for a participant hospital in the performance year being reconciled is greater than 3 standard deviations above the regional average post-episode payments for that same performance year, then the spending amount exceeding 3 standard deviations above the regional average post-episode payments for the same performance year is subtracted from the net reconciliation or added to the repayment for that performance year.

(vii) Applies the following prior to determination of the reconciliation payment or repayment amount:

(A) *Limitation on loss.* Except as provided in paragraph (m)(1)(vii)(C) of this section, the total amount of the NPRA for a performance year cannot exceed 20 percent of the amount calculated in paragraph (m)(1)(iii) of this section for the performance year. The post-episode spending calculation amount in paragraph (m)(vi) of this section is not subject to the limitation on loss.

(B) *Limitation on gain.* The total amount of the NPRA for a performance year cannot exceed 20 percent of the amount calculated in paragraph (m)(1)(iii) of this section for the performance year. The post-episode spending calculation amount in paragraph (m)(vi) of this section are not subject to the limitation on gain.

(C) *Limitation on loss for certain providers.* Financial loss limits for rural hospitals, SCHs, MDHs, and RRCs for performance years 6 through 8. If a participant hospital is a rural hospital, SCH, MDH, or RRC, the amount cannot exceed 5 percent of the amount calculated in paragraph (m)(1)(iii) of this section.

(2) [Reserved]

* * * * *

■ 12. Section 510.310 is amended by—

■ a. Removing paragraph (b)(4)(i);

■ b. Redesignating paragraphs (b)(4)(ii), (iii), and (iv) as paragraphs (b)(4)(i), (ii), and (iii);

■ c. Revising newly redesignated paragraph (b)(4)(iii);

■ d. Removing paragraph (b)(5);

■ e. Redesignating paragraph (b)(6) and (7) as paragraph (b)(5) and (6); and

■ f. Revising newly redesignated paragraph (b)(6).

The revisions read as follows:

§ 510.310 Appeals process.

* * * * *

(b) * * *

(4) * * *

(iii) The procedures (including format and deadlines) for submission of briefs and evidence.

* * * * *

(6) The CMS reconsideration official makes all reasonable efforts to issue a written determination within 30 days of the deadline for submission of briefs and evidence. The determination is final and binding.

* * * * *

■ 13. Section 510.315 is amended by revising paragraphs (d), (f)(1), and (f)(2) to read as follows:

§ 510.315 Composite quality scores for determining reconciliation payment eligibility and quality incentive payments.

* * * * *

(d) *Quality improvement points.* (1) For performance year 1, if a participant hospital's quality performance percentile on an individual measure described in § 510.400(a) increases from the corresponding time period in the previous year by at least 2 deciles on the performance percentile scale, then the hospitals is eligible to receive quality improvement points equal to 10 percent of the total available point for that individual measure up to a maximum composite quality score of 20 points.

(2) For each of performance years 2 through 4, each of performance year subsets 5.1 and 5.2, and each of performance years 6 through 8, if a participant hospital's quality performance percentile on an individual measure described in § 510.400(a) increases from the previous performance year or performance year subset by at least 2 deciles on the performance percentile scale, then the hospital is eligible to receive quality improvement points equal to 10 percent of the total available point for that individual measure up to a maximum composite quality score of 20 points.

* * * * *

(f) * * *

(1) *Performance years 1 through 5.* For performance years 1 through 5—

(i) A 1.0 percentage point reduction to the effective discount factor or applicable 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; or

(ii) A 1.5 percentage point reduction to the effective discount factor or applicable discount factor for participant hospitals with excellent quality performance, defined as composite quality scores that are greater than 15.0.

(2) *Performance years 6 through 8.* For performance years 6 through 8—

(i) A 1.5-percentage point reduction to the effective discount factor or applicable 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; or

(ii) A 3-percentage point reduction to the effective discount factor or applicable discount factor for participant hospitals with excellent quality performance, defined as composite quality scores that are greater than 15.0.

* * * * *

■ 14. Section 510.400 is amended—

■ a. In paragraph (b)(2)(i) by removing the phrase ''over the 5 years'' and adding in its place the phrase ''over the first 5 years'';

■ b. In paragraph (b)(2)(ii) introductory text by removing the phrase ''of the program'' and adding in its place the phrase ''of the model''; and

■ c. By adding paragraph (b)(4).

The addition reads as follows:

§ 510.400 Quality measures and reporting.

* * * * *

(b) * * *

(4) For years 6 through 8 of the model the following data are requested by CMS for each performance period as follows:

(i) Year 6 (October 1, 2021 to December 31, 2022). Submit—

(A) Post-operative data on primary elective THA/TKA procedures for ≥80% or ≥200 procedures performed between July 1, 2019 and June 30, 2020; and

(B) Pre-operative data on primary elective THA/TKA procedures for ≥80% or ≥300 procedures performed between July 1, 2021 and June 30, 2022.

(ii) Year 7 (2023). Submit—

(A) Post-operative data on primary elective THA/TKA procedures for •80% or •300 procedures performed between July 1, 2021 and June 30, 2022; and

(B) Pre-operative data on primary elective THA/TKA procedures for ≥85% or ≥400 procedures performed between July 1, 2022 and June 30, 2023.

(iii) Year 8 (2024). Submit—

(A) Post-operative data on primary elective THA/TKA procedures for ≥85% or ≥400 procedures performed between July 1, 2022 and June 30, 2023; and

(B) Pre-operative data on primary elective THA/TKA procedures for ≥90% or ≥500 procedures performed between July 1, 2023 and June 30, 2024.

* * * * *

■ 15. Section 510.405 is amended by revising paragraphs (b)(1) and (3) to read as follows:

§ 510.405 Beneficiary choice and beneficiary notification.

* * * * *

(b) * * *

(1) *Participant hospital beneficiary notification*—(i) *Notification to beneficiaries.* Each participant hospital must provide written notification to any Medicare beneficiary that meets the criteria in § 510.205 of his or her inclusion in the CJR model.

(ii) *Timing of notification.* Prior to discharge from the anchor hospitalization, or prior to discharge from the anchor procedure, as applicable, the participant hospital must provide the CJR beneficiary with a participant hospital beneficiary notification as described in paragraph (b)(1)(iv) of this section.

(iii) *List of beneficaries receiving a notification.* The participant hospital must be able to generate a list of all beneficiaries receiving such notification, including the date on which the notification was provided to the beneficiary, to CMS or its designee upon request.

(iv) *Content of notification.* The beneficiary notification must contain all of the following:

(A) A detailed explanation of the model and how it might be expected to affect the beneficiary's care.

(B) Notification that the beneficiary retains freedom of choice to choose providers and services.

(C) Explanation of how patients can access care records and claims data through an available patient portal, and how they can share access to their Blue Button® electronic health information with caregivers.

(D) A statement that all existing Medicare beneficiary protections continue to be available to the beneficiary. These include the ability to report concerns of substandard care to Quality Improvement Organizations or the 1–800–MEDICARE helpline.

(E) A list of the providers, suppliers, and ACOs with whom the CJR participant hospital has a sharing arrangement. This requirement may be fulfilled by the participant hospital including in the detailed notification a Web address where beneficiaries may access the list.

* * * * *

(3) *Discharge planning notice.* A participant hospital must provide the beneficiary with a written notice of any potential financial liability associated with non-covered services recommended or presented as an option as part of discharge planning, no later than the time that the beneficiary discusses a particular post-acute care option or at the time the beneficiary is discharged from an anchor procedure or anchor hospitalization, whichever occurs earlier.

(i) If the participant hospital knows or should have known that the beneficiary is considering or has decided to receive a non-covered post-acute care service or other non-covered associated service or supply, the participant hospital must notify the beneficiary that the service would not be covered by Medicare.

(ii) If the participant hospital is discharging a beneficiary to a SNF prior

to the occurrence of a 3-day hospital stay, and the beneficiary is being transferred to or is considering a SNF that would not qualify under the SNF 3-day waiver in § 510.610, the participant hospital must notify the beneficiary in accordance with paragraph (b)(3)(i) of this section that the beneficiary will be responsible for payment for the services furnished by the SNF during that stay, except those services that would be covered by Medicare Part B during a non-covered inpatient SNF stay.

* * * * *

■ 16. Section 510.500 is amended by revising paragraphs (c)(4)(i) and (ii) to read as follows:

§ 510.500 Sharing arrangements under the CJR model.

* * * * *

(c) * * *

(4) * * *

(i) For episodes beginning on or after April 1, 2016 and ending on or before September 30, 2021, in the case of a CJR collaborator who is a physician or non-physician practitioner, 50 percent of the Medicare-approved amounts under the PFS for items and services furnished by that physician or non-physician practitioner to the participant hospital's CJR beneficiaries during CJR model episodes that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being made.

(ii) For episodes beginning on or after April 1, 2016 and ending on or before September 30, 2021, in the case of a CJR collaborator that is a PGP or NPPGP, 50 percent of the Medicare-approved amounts under the PFS for items and services billed by that PGP or NPPGP and furnished to the participant hospital's CJR beneficiaries by the PGP members or NPPGP members respectively during CJR model episodes that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being made.

* * * * *

■ 17. Section 510.505 is amended by revising paragraphs (b)(8)(i) and (ii) to read as follows:

§ 510.505 Distribution arrangements.

* * * * *

(b) * * *

(8) * * *

(i) For episodes beginning on or after April 1, 2016 and ending on or before September 30, 2021, in the case of a collaboration agent that is a physician or non-physician practitioner, 50 percent of the total Medicare-approved amounts under the PFS for items and services furnished by the collaboration agent to the participant hospital's CJR beneficiaries during CJR model episodes that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being distributed.

(ii) For episodes beginning on or after April 1, 2016 and ending on or before September 30, 2021, in the case of a collaboration agent that is a PGP or NPPGP, 50 percent of the total Medicare-approved amounts under the PFS for items and services billed by that PGP or NPPGP for items and services furnished by PGP members or NPPGP member respectively to the participant hospital's CJR beneficiaries during CJR model episodes that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being distributed.

* * * * *

■ 18. Section 510.506 is amended by revising paragraph (b)(8) to read as follows:

§ 510.506 Downstream distribution arrangements.

* * * * *

(b) * * *

(8) Except for a downstream distribution payment from a PGP to a PGP member that complies with § 411.352(g) of this chapter, for episodes beginning on or after April 1, 2016 and ending on or before September 30, 2021 the total amount of downstream distribution payments for a performance year paid to a downstream collaboration agent who is a physician or non-physician practitioner and is either a member of a PGP or a member of an NPPGP must not exceed 50 percent of the total Medicare-approved amounts under the PFS for items and services furnished by the downstream collaboration agent to the participant hospital's CJR beneficiaries during a CJR model episode that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the distribution payment being distributed.

* * * * *

§ 510.600 [Amended]

■ 19. Section 510.600 is amended in paragraph (b)(1) by removing the phrase ''an anchor hospitalization'' and adding in its place the phrase ''an anchor hospitalization or anchor procedure.''

■ 20. Section 510.610 is amended—

■ a. By revising paragraph (a); and

■ b. In paragraph (b)(1), removing the phrase ''qualifying inpatient stay.'' and adding in its place the phrase ''qualifying inpatient stay or anchor procedure.''

The revision reads as follows:

§ 510.610 Waiver of SNF 3-day rule.

(a) *Waiver of the SNF 3-day rule*—(1) *Performance year*—(i) *Performance years 2 through 5.* For episodes being tested in performance years 2 through 5 of the CJR model, CMS waives the SNF 3-day rule for coverage of a SNF stay for a beneficiary who is a CJR beneficiary on the date of discharge from the anchor hospitalization, but only if the SNF is identified on the applicable calendar quarter list of qualified SNFs at the time of the CJR beneficiary's admission to the SNF.

(ii) *Performance years 6 through 8.* (A) For episodes being tested in performance years 6 through 8 of the CJR model, CMS waives the SNF 3-day rule for coverage of a SNF stay within 30 days of the date of discharge from the anchor hospitalization for a beneficiary who is a CJR beneficiary on the date of discharge from the anchor hospitalization, but only if the SNF is identified on the applicable calendar quarter list of qualified SNFs at the time of the CJR beneficiary's admission to the SNF.

(B) For episodes being tested in performance years 6 through 8 of the CJR model, CMS waives the SNF 3-day rule for coverage of a SNF stay within 30 days of the date of service of the anchor procedure for a beneficiary who is a CJR beneficiary on the date of service of the anchor procedure, but only if the SNF is identified on the applicable calendar quarter list of qualified SNFs at the time of the CJR beneficiary's admission to the SNF.

(2) *Determination of qualified SNFs.* CMS determines the qualified SNFs for each calendar quarter based on a review of the most recent rolling 12 months of overall star ratings on the Five-Star Quality Rating System for SNFs on the Nursing Home Compare website. Qualified SNFs are rated an overall of 3 stars or better for at least 7 of the 12 months.

(3) *Posting of qualified SNFs.* CMS posts to the CMS website the list of qualified SNFs in advance of the calendar quarter.

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Dated: April 27, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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