DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 510

[CMS–5529–P]

RIN 0938–AU01

Medicare Program: Comprehensive Care for Joint Replacement Model Three-Year Extension and Changes to Episode Definition and Pricing

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise certain aspects of the Comprehensive Care for Joint Replacement (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 proposed performance years 6 through 8, it would eliminate the 50 percent cap on gainsharing payments, distribution payments, and downstream distribution payments for certain recipients. This proposed rule would also extend the additional flexibilities provided to hospitals related to certain Medicare program rules consistent with the revised episode of care definition. Additionally, the proposed rule would allow time to test the proposed changes by extending the length of the CJR model for an additional 3 years, through December 31, 2023, for certain participant hospitals. Finally, it solicits comment on how we might best conceptualize and design a future bundled payment model focused on lower extremity joint replacements (LEJR) procedures performed in the ambulatory surgical center (ASC) setting.

DATES: To be assured consideration, comments on this proposed rule must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on April 24, 2020.

ADDRESSES: In commenting, please refer to file code CMS–5529–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5529–P, P.O. Box 8013, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5529–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Nora Fleming, (410) 786–6908.

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

I. Background

A. Purpose

The Comprehensive Care for Joint Replacement (CJR) model, which was implemented 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. As discussed in greater detail in section I.C. of this proposed rule, the CJR model was established through notice and comment rulemaking. While initial evaluation results for the first and second year of the CJR model [1] indicate that the CJR model is having a positive impact on lowering episode costs when CJR participant hospitals are compared to non-CJR hospitals (with no negative impacts on quality of care), changes in program payment policy and national care delivery patterns have occurred since the CJR model began. In order to better evaluate the model with these changes addressed, this rule proposes to change and extend the CJR model for an additional 3 performance years. First, we propose to change the definition of a CJR '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 that contains procedure codes that will only be reimbursed 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) that removed the Total Knee Arthroplasty (TKA) procedure code from the IPO list, and the change in the CY 2020 OPPS rule (84 FR 61353) that removed Hip Arthroplasty (THA) procedure code from the IPO list, we are proposing to change the definition of an 'episode of care' to include outpatient (OP) procedures for TKAs (OP TKAs) and to include outpatient procedures for THAs (OP THAs).

We are also proposing to make a number of changes to the target price calculation. Specifically, we are proposing to change the basis for the target price from 3 years of claims data to the most recent one year of claims data, to remove the national update factor and twice yearly update to the target prices that accounts for prospective payment system and fee schedule updates, to remove anchor factors and weights, and to change the high episode spending cap calculation methodology. Additionally, we are proposing a number of changes to the reconciliation process. Specifically, we are proposing to move from 2 reconciliation periods (conducted 2 and 14 months after the close of each performance year) to one reconciliation period that would be conducted 6 months after the close of each performance year, to add an additional episode-level risk adjustment beyond fracture status, to change the high episode spending cap calculation methodology used at reconciliation, to add a retrospective market trend adjustment factor, and 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. Although the improvements we are

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

proposing to make to the target price calculation and reconciliation process could potentially improve the accuracy of CJR episode pricing in performance year (PY) 5, we are not proposing that these changes apply to PY 5 because this proposed rule would not be finalized and effective until close to the end of PY 5.

Since we are proposing 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 are also proposing a change to the beneficiary notification requirements (which are currently tied to 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 an outpatient setting. We are also proposing to make changes to the dates of publicly-reported data used for quality measures and patient-reported outcomes (PRO) for the three additional performance years. We propose to advance the Complications and Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) performance periods in alignment with the performance periods used for performance years 1 through 5. For PRO, we are also proposing to advance the performance periods in alignment with previous performance periods as well as increase the thresholds for successful submission. Additionally, for the 3 additional performance years, we are proposing 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). We are also proposing 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 episode definition, we are also proposing 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 to hospitals furnishing services to CJR beneficiaries in the outpatient setting as well. To allow time for us to evaluate the impact of these changes, we are proposing to extend the CJR model for an additional 3 years, performance years 6 through 8, for participant hospitals located in the 34 mandatory metropolitan statistical areas (MSAs) (except for rural hospitals and low-volume hospitals). We are proposing conforming changes to the CJR regulations at 42 CFR part 510.

Lastly, noting that TKA procedures will be covered by Medicare in the ambulatory surgical center (ASC) setting beginning January 1, 2020 (84 FR 61253) and that certain other LEJR procedures may eventually also be covered by Medicare in the ASC setting, we are also soliciting comment on the design of a potential future bundled payment model for LEJR procedures in the ASC.

B. Summary of Costs and Benefits

As shown in our impact analysis in section IV. of this proposed rule, we estimate that the CJR model changes we are proposing will save the Medicare program approximately $269 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. of this proposed rule. In addition to these estimated impacts, the goal of CMS' Center for Medicare and Medicaid Innovation (Innovation Center) models are to reduce expenditures while preserving or enhancing the quality of care. In addition, many participants are attempting to enhance their infrastructure to support better care management and reducing costs. We anticipate there will continue to be a broader focus on care coordination and quality improvement through the CJR model among 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'' published in the November 24, 2015 **Federal Register** (80 FR 73274) (referred to in this proposed 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 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.

In the March 4, 2016 **Federal Register** (81 FR 11449), we published 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'', that corrected a limited number of technical and typographical errors identified in the November 2015 final rule. On January 3, 2017, we published a final rule (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 Alternate Payment Model (Advanced APM track within the CJR model. On May 19, 2017, we published a final rule (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). The May 2017 final rule also finalized a delay to the effective date of certain CJR regulations from July 1, 2017 to January

1, 2018. On December 1, 2017, we published another final rule (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 in this proposed rule 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. 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 June 8, 2018 final rule (83 FR 26604), titled ''Medicare Program; Changes to the Comprehensive Care for Joint Replacement Payment Model (CJR): Extreme and Uncontrollable Circumstances Policy for the CJR Model,'' and effective on July 9, 2018.

II. Provisions of the Proposed Rule

A. Episode Definition

1. Background

The CJR model began on April 1, 2016. The CJR model is currently nearing completion of the fourth performance year, which includes episodes ending on or after January 1, 2019 and on or before December 31, 2019. The fifth performance year, which includes all episodes ending on or after January 1, 2020 and on or before December 31, 2020, would necessarily incorporate episodes that began before January 1, 2020. As previously discussed in section I.C. of this proposed 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 finalized 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 providers 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 onto either Medicare Severity-Diagnosis Related Group (MS–DRG) 469 (LEJR with complications and/or comorbidities) or MS–DRG 470 (LEJR without complications and/or comorbidities). Subsequently, in acknowledgement of the fact that TAR procedures are almost always more complex and expensive to perform than TKAs or THAs, CMS finalized a policy in the FY 2017 IPPS final rule to ensure that TARs would always map to MS–DRG 469, which reimburses at a higher rate than MS–DRG 470, to compensate for complications and comorbidities (81 FR 56815).

When the TKA procedure described by 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 OP TKA procedures were, by default, excluded from the CJR model. When the change to the IPO list to remove TKA procedures was proposed, CJR participants 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 episodes would be too low and would not reflect the shift in 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 have been performed in the outpatient setting for the full calendar year of 2018, we have one 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 claim data shows that approximately 25 percent of TKAs are 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 OP 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 OP 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 OP TKA episodes (created using the same criteria as CJR episodes, with the exception that they would have been triggered by the OP 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 APC to which they are assigned, we removed the payments associated with the episode initiating 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. This supported our belief that the outpatient TKA episodes were sufficiently comparable to MS–DRG 470/no fracture inpatient CJR episodes that we should find a way to change the existing CJR episode definition to encompass outpatient LEJR episodes as well as inpatient LEJR episodes.

2. Changes to Episode Definition To Include OP 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 OP TKA into the CJR model, as well as THA, in light of the recent change in the CY 2020 OPPS final rule to remove THA from the IPO list, which was recently finalized (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.) We do not anticipate that TARs will be removed from the IPO list due to their complexity. If we continued to exclude OP TKAs and OP THAs from the CJR model and did not allow CJR hospitals the incentive to coordinate and improve care for OP 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 OP TKAs and OP THAs would also potentially reduce the generalizability of future results from the CJR model evaluation, as CJR hospitals would be less comparable to control group non-CJR 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 assure that our evaluation findings are as robust and generalizable as possible, we aim to incorporate OP 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.

Consistent with our goal for site neutrality, as evidenced, for example, in the CY 2019 OPPS final rule (83 FR 58818) where 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, as well as in the CY 2020 OPPS final rule (84 FR 61365) where we continued the two-year phase-in of this site neutral payment policy, we do not want to create separate prices for inpatient and outpatient CJR episodes. We also want to be consistent with the BPCI Advanced voluntary bundled payment model, which will be offering a site-neutral LEJR episode beginning 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 OP 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 proposed 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 PY 6, we are proposing to revise the definition of an 'episode of care' in the CJR model to include permitted OP TKA/THA procedures. This revised definition would apply 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 be the first day of PY 6. Further, we are proposing to group the OP 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 OP TKA episodes most closely resembles spending on MS–DRG 470 without hip fracture episodes. 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.

Since the proposal to remove THAs from the IPO List has recently been finalized, we also propose to include outpatient THA procedures with MS–DRG 470 episodes in order to calculate a target price. Although we do not have Medicare claims data for OP THA at this time, as we currently do for OP TKA, we note 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. OP THAs have been assigned to the same Comprehensive Ambulatory Payment System (C–APC) 5115 (Level 5 Musculoskeletal Procedure) as OP TKA (84 FR 61253). Therefore, we believe that the site-neutral MS–DRG 470 price that we propose to calculate (which would be based on a blend of inpatient TKA, inpatient THA, OP TKA, and OP THA episodes) would also be appropriate for OP THA episodes. However, in the case of THA, we would include any OP THA episodes without hip fractures in the MS–DRG 470 without hip fracture episode pricing and we would include any OP THA episodes with hip fractures in the MS–DRG 470 with hip fracture episode pricing. Compared to TKAs, which we expect would rarely 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 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 do not anticipate that any OP 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 OP THA into with and without hip fracture episodes that would be grouped into MS–DRG 470 with hip fracture and MS–DRG 470 without hip fracture episodes, respectively, because we expect that spending for OP THA with hip fracture and without hip fracture episodes would resemble spending for MS–DRG 470 with hip fracture and MS–DRG without hip fracture episodes, respectively.

Given that we are proposing that OP TKA and THA would initiate CJR episodes, we are similarly proposing that an OP TKA or THA, if furnished at a participant hospital during an ongoing 90-day CJR 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 normally 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–DRG 469 or 470 that occur at a participating hospital during an ongoing CJR episode cancel the ongoing episode and initiate a new episode. We are proposing to extend that policy to OP TKA and THA episodes. In conclusion, then, an active CJR episode initiated by a prior admission to an acute care hospital for DRG 470 or 469, would be cancelled, and a new CJR episode would be initiated, if either an inpatient LEJR procedure or an OP 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 episode initiated by a first anchor procedure (OP TKA or THA) would be cancelled, and a new CJR episode would be initiated, if either an inpatient LEJR procedure or an OP TKA or THA were furnished to an eligible beneficiary at a participating hospital during the ongoing episode initiated by the first anchor procedure.

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 3 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 CJR. 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. The stability of ICD–10–CM codes has meant that MS–DRGs 469 and 470 have also experienced minimal change in recent years in terms of codes designating hip fracture and codes representing excluded services. Given the recent stabilization of the coding systems used in CJR, we are proposing to discontinue our annual sub-regulatory process to update the hip fracture list and episode exclusions list. We seek comment on our proposal and whether there are any circumstances in which updates may still be needed.

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 469 without hip fracture, MS–DRG 470 with hip fracture, 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 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 [2]) and hospital-specific spending for performance years 1 through 3, episode target prices were based on 100 percent regional spending beginning performance year 4. 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 episode volume and set more stable target prices, CJR 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

[2] 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.

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 Proposed Changes To Target Price Calculation

Since the CJR model was implemented in 2016, both TKA and THA have been removed from the IPO list, as discussed in section II.A. of this proposed 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, recent analysis by the Office of the Actuary has shown that national expenditures for LEJR procedures sand associated post-acute care services have been decreasing since 2016. While average episode payments declined for both CJR and control group episodes during the first two performance years of the model, payments declined more for CJR episodes. Average episode payments decreased by $997 more for CJR episodes than for control group episodes from the baseline to the intervention period ($p<0.01$). This relative reduction equates to a 3.7 percent decrease in average episode payments for CJR episodes from the baseline.[3]

Trend data now shows that the decrease in national expenditures observed by the CJR evaluation for CJR and non-CJR participants 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 8 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 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 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 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, 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 are also proposing to change the target price

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

update methodology to a 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 changes to propose to the target price structure for CJR, we did consider an option of setting prices at the national, rather than regional level. While we did not elect to model this proposal for this proposed rule and are instead proposing to continue the regional pricing approach, we seek 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 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 one 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 are proposing 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 (performance years 1 to 3) to 100 percent regional pricing (performance years 4 and 5). Additionally, since we are proposing to include OP TKA/THA procedures as well as inpatient admissions for MS–DRG 469 or 470 in the CJR episode definition, 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 proposed 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, noting that 2019 data is not yet available for analysis), 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 are therefore proposing to remove the national trend update factor. We are also proposing 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 are proposing in this rule in section II.C.6. of this proposed rule 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 proposed rule, for the purpose of calculating CJR episode target prices for performance years 6 through 8 we propose that Part A and B Medicare claims data for beneficiaries with CJR episodes (that is, beneficiaries with a claim for an MS–DRG 470 or MS–DRG 469, or a permitted OP TKA/THA procedure billed by a CJR participant hospital), would be grouped into 1 of the following types of CJR episodes:

- MS–DRG 470 with hip fracture (which would include OP THA episodes with hip fracture).
- MS–DRG 470 without hip fracture (which would include OP TKA episodes and OP THA episodes without hip fracture).
- MS–DRG 469 with hip fracture.
- MS–DRG 469 without hip fracture.

To then calculate target prices for performance years 6 through 8, these 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, MS–DRG, and hip fracture combination. 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/hip fracture 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 performance year 6, at the beginning of each performance year, these average regional target prices would be posted on the CJR website.

Finally, we note that we are proposing 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 episode data, which was more of a concern when the model began due to the hospital-specific pricing component. CJR episodes anchored by MS–DRGs 469 and 470 are pooled together during target price calculations to have a greater historical CJR 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 multiply that MS–DRG 470 target price by, 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 performance years 4 and 5 use only regional episode spending data to calculate target prices, and since we are proposing for performance years 6 to 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 are proposing to no longer use the regional and hospital anchor weighting steps from the original CJR target price calculation methodology.

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 performance years 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 performance year 4 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 are proposing additional tools meant to ensure accuracy of target pricing, specifically, the trend factor discussed in section II.C.6. of this proposed rule and the risk adjustment discussed in section II.C.4. of this proposed rule, which further mitigates our concerns regarding target pricing uncertainty. Therefore, we believe that for the proposed CJR 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 one 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 OP TKA procedures to trigger CJR episodes (see section III.A. of this proposed 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 without hip fracture.

Therefore, for the proposed performance years 6 through 8, we propose to use the most recently available one year of data available 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 performance years 1 and 2 were calculated with baseline data from 2012 to 2014, for performance years 3 to 4 were calculated with baseline data from 2014 to 2016, and for performance year 5 are calculated with baseline data from 2016 to 2018. We propose to base performance year 6 target prices on episode baseline data from 2019, performance year 7 target prices on episode baseline data from 2020, and performance year 8 target prices on episode baseline data from 2021. By using only 2019 data for performance year 6 target prices, we will 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 believe that using only the most recently available, 1 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 seek comment on this proposal.

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

Since CJR target prices during performance years 1 to 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 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 are proposing for performance years 6 to 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 performance years 4 to 5 we removed hospital-specific ratios of MS–DRG 469 to 470 episodes from the target price calculation. We propose to continue this in proposed performance years 6 to 8. Given that we no longer have these concerns, we also propose to stop using the national anchor factor calculation and the subsequent regional and hospital weighting steps in the CJR target price calculation method for performance years 6 to 8. Additionally, we propose 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 are proposing (in section II.C.6. of this proposed 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/OP TKA/THA procedure/hip fracture 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 seek comment on this proposal.

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 performances year 4 to 5 and proposed performance years 6 to 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 performance years 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. As we discussed in the CJR 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 CJR 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 episode data by OACT showed that in 2016 and 2017 respectively 70 and 83 percent of CJR participants had at least 1 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 are proposing to change the methodology used in deriving the high episode spending cap amount during reconciliation, described further in section II.C.5. of this proposed 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 propose 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 propose 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 seek comment on this approach.

C. Reconciliation

1. Background

Currently, for each performance year, CJR payments are reconciled twice; at 2 and then 14 months 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 providers achieved quality scores of 'Excellent', around 60 percent achieved 'Good', around 12 percent achieved 'Acceptable and less than 10% 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 performance years 1 and 2; 10 percent of this difference in performance year 3; and 20 percent in performance years 4 and 5. 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 performance year 2; 10 percent for performance year 3; and 20 percent for both performance years 4 and 5. 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 performance year 2; and 5 percent for performance years 3 through 5. 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 hospital participants, 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 Proposed Changes to Reconciliation Process

In this proposed rule, we are proposing changes to the CJR 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 are proposing changes to the reconciliation process that parallel the changes we propose to the target price calculations discussed in section II.B. of this proposed rule.

Beginning with performance year 6, we are proposing 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 proposed rule, that indicate 6 months after an episode ends are sufficient time to capture episode spending data. However, we propose that the current CJR post-episode spending policy, codified at §§ 510.305(j)(2) and 510.2, would still apply during performance years 6 through 8. Additionally, we propose conforming changes to § 510.305 such that the performance year 4 and 5 stop-loss limits and stop-gain limits of 20 percent would continue in place for each of performance years 6 through 8.

Additionally, in an effort to recognize the greater needs of certain beneficiaries that are beyond a participant hospital's control, we are proposing to incorporate a risk adjustment factor for each episode's target price during reconciliation for performance years 6 through 8. Specifically, as discussed in section II.C.4. of this proposed rule, we would adjust the target price at reconciliation using two patient-level risk factors, the CMS–HCC condition count risk adjustment factor and the age bracket risk adjustment factor.

Further, as mentioned in section II.B.5. of this proposed rule, we are proposing to change the methodology used in deriving the high episode spending cap amount during reconciliation. For performance years 6 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 are proposing this change since we have observed that CJR episode costs are not normally distributed, as discussed in section II.B.5. of this proposed rule, and a greater number of CJR episodes have exceeded the high episode spending cap amount than we intended.

We are also proposing to add a market trend factor to adjust for recent variations in the underlying structure of the market. Specifically, we are proposing that the market trend factor would be the regional/MS–DRG/fracture mean cost for episodes occurring during the performance year divided by the regional/MS–DRG/fracture mean cost for episodes occurring during the target price base year. For example, at the first reconciliation for performance year 6 (calendar year 2021), which, as proposed, will occur in June of 2022, we would compute the regional/MS–DRG/fracture mean cost for episodes occurring during 2021 and would divide that by the regional/MS–DRG/fracture mean cost for episodes that occurred during calendar 2019 as the target prices for performance year 6 will be set using 2019 data.

Lastly, we are proposing changes to the effective discount factor and applicable discount factor in § 510.315, to better recognize participant providers in the 'Good' and 'Excellent' CJR composite quality score categories. For performance years 6 through 8, we are proposing to continue to use 3 percentage points as the discount factor applied during calculation of regional target prices. However, we are proposing to increase an individual participant hospital's potential quality incentive payment; that is, we are

proposing a larger reduction in the discount factor based on the composite quality score. The opportunity for this larger reduction in the discount factor is being proposed because we anticipate that the proposed changes to the target price methodology, discussed in section II.B. of this proposed 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 performance years 6 through 8, we are proposing 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.

3. Changes to Frequency and Timing of Reconciliation

As noted in section II.B.1. of this proposed rule, following the completion of a performance year, participant hospitals that achieve episode spending below the applicable target price and achieved a minimum composite quality score were currently 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 episode pricing). The retrospective process reconciles a participant hospital's actual episode payments against the target price 2 months after the end of a performance year. 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 performance year, 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.

We finalized the process to perform a reconciliation calculation 2 months after the conclusion of a performance year, with a subsequent reconciliation calculation 12 months later, under 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 claims data from performance years 1 and 2 indicates 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 performance year 1 increased by slightly less than 1 percent from the initial to subsequent reconciliation and total reconciliation payments for performance year 1 decreased by about 6 percent between the initial and subsequent reconciliation. While the performance year 2 subsequent reconciliation process is still ongoing, initial estimates show a similar trend; that is the attributed episode count increased by about 1 percent and total reconciliation payments decreased by around 5 percent. While we are not able to accurately predict or quantify the dollar impact shifts between the initial and final reconciliations for individual CJR participants, anecdotally, based on reconciliations of the first 2 performance years of the CJR model, some CJR participants owed over $100,000 because their initial reconciliation payments were too high relative to their final reconciliation payments. Other providers who ultimately saw their reconciliation payments increase from initial to final reconciliations increased by amounts under $60,000. We recognize that 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 believe we could provide a more predictable and stable reconciliation process for CJR participants without significantly impacting the accuracy of the reconciliation payment and/or repayment amounts. Additionally, we do not anticipate the change to the frequency and timing of CJR reconciliation will create difficulties accounting for overlap with other CMS Innovation Center models and the Medicare Share Savings Program (SSP). Since the two-month, initial reconciliation data is not considered final, and overlap with other models and SSP is only accounted for using final reconciliation data from the 14-month subsequent reconciliation, the proposed changes to the frequency and timing of CJR reconciliation should actually enable overlap accounting to occur eight months earlier than in CJR performance years 1 to 5.

As a result, we are proposing to conduct one reconciliation for each of performance years 6 through 8, 6 months following the end of a performance year. For instance, for performance year 6 (which includes all CJR episodes ending on or after January 1, 2021 and on or before December 31, 2021), we propose to reconcile a participant hospital's CJR actual episode payments against the applicable target prices one time only, based on claims data available on July 1, 2022. 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.

As noted previously, we propose that current CJR post-episode spending policy, codified at §§ 510.305(j)(2) and 510.2, would still apply during performance years 6 through 8. Specifically, 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 performance year for years 1 through 4. 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.

For performance year 5, under current CJR regulations, the spending amount is assessed independently for year 5. Under our proposed policies, we note that the final performance year 5 reconciliation will be conducted slightly before we initiate the performance year 6 reconciliation, and we are proposing to net the final performance year 5 amount against the performance year 6 amount prior to issuing a reconciliation payment or demanding a repayment amount.

4. Additional Episode-Level Risk Adjustment

When we originally proposed the CJR 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. Thus, we currently provide four separate target prices to each participant hospital 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.

Given our proposal to specify that permitted OP LEJR procedures can initiate a CJR 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 III.A. of this proposed 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 would 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 are proposing to make an episode-specific adjustment to each target price.

The CJR model currently includes adjustments to MS–DRG 469 and 470 target prices based on the presence of hip fracture. This policy allows 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 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 are proposing an additional risk adjustment methodology for performance years 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 (that is, beneficiaries enrolled in Medicare Part A and/or Part B and receiving full Medicaid benefits), discharge status (that is, the care setting for the beneficiary post procedure), joint region (that is, hip, knee, or ankle), gender, CMS–HCC condition count, CMS–HCC risk scores (both community and institutional), rural/urban designation of the participant hospital, clinical setting (that is, inpatient or outpatient), rehospitalization rate (that is, 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 are proposing to incorporate the following additional risk adjustment into the CJR 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 CMS–HCC condition count. This approach parallels the approach taken in Medicare Advantage, which is responsive to 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, which requires CMS to make improvements to risk adjustment for 2019 and subsequent years, and which states that, among other things, ''[t]he Secretary shall take into account the total number of diseases or conditions of an individual enrolled in an MA plan. The Secretary shall make an additional adjustment under such subparagraph as the number of diseases or conditions of an individual increases.''

Like the other variables in the CMS–HCC model, the count variables for the purposes of risk adjustment in CJR 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 propose to use five CMS–HCC condition count variables, representing beneficiaries with zero, one, two, three, or four or more CMS–HCC conditions. We propose to estimate a coefficient from the subgroup of beneficiaries in the sample with the specific count of conditions for each count variable (as described further 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 CMS–HCC condition 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 CMS–HCC condition count, we would create binary, yes/no variables for beneficiaries that fall into certain age ranges. We propose four age variables for the risk adjustment methodology to represent beneficiaries aged less than 65 years, 65 to 74 years, 75 years to 84 years, and 85 years or more, based on the patient's age at the time the HCC files were created. We propose to estimate a coefficient from the subgroup of beneficiaries in the sample in each age range (as described further later in this section). We propose 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 CJR 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 propose 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 performance year 6. Similarly, we propose 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 performance years 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 CMS–HCC condition 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 PY 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 CMS–HCC condition 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 propose an exponential model, with the dependent variable equal to the ratio of the individual episode cost 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 proposed 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 CJR 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 CJR 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 are proposing, 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/Fracture 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/hip fracture target pricing differentiation already explains a portion of the cost differences in CJR episodes. Therefore, rather than using the log of the episode cost, we are proposing 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/permitted OP TKA/THA/hip fracture status categories, we would subtract the log transformed episode target price for that category from each log transformed standardized episode cost.[4] 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/hip fracture 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.[5] 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 co-efficient 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 (that is, 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, MS–DRG 470 or permitted OP TKA/THA HCPCS code) onto their CMS–HCC condition count and age bracket. The resulting coefficients associated with CMS–HCC condition 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 CMS–HCC condition 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/permitted OP TKA/THA/hip fracture status category may not be equal to 1. 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

[4] We request 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.

[5] We request comment on the impact of this practice on the statistical validity of the model.

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 solicit 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/permitted OP TKA/THA/hip fracture status category is equal to 1.

An example of the regression output from this model is provided in Table 3, which was calculated using national episode data from January 1, 2018, to December 31, 2018, for MS–DRG 469, MS–DRG 470, and the permitted OP TKA/THA HCPCS 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 of performance years 6 through 8, along with the average regional target prices, as described in section II.B.2. of this proposed rule.

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
CMS–HCC Count = 4	0.226897	0.001721	131.81	<.0001	1.255
CMS–HCC Count = 3	0.140797	0.001893	74.4	<.0001	1.151
CMS–HCC Count = 2	0.095357	0.001534	62.16	<0001	1.100
CMS–HCC Count = 1	0.047497	0.001314	36.14	<.0001	1.049
CMS–HCC Count = 0	.....	.....	.....	.....	1

[* While we do 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.]

We are proposing 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 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 CMS–HCC condition 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 beneficiary level target prices based on the applicable episode region, MS–DRG, and hip fracture status. However, since the age and the CMS–HCC condition count variables are inherently included in the regional target price, as regions with a higher proportion of older beneficiaries or beneficiaries with higher CMS–HCC condition 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 CMS–HCC condition count 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 470 no fracture, MS–DRG 470 fracture, MS–DRG 469 no fracture and MS–DRG 469 fracture 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, MS–DRG, and hip fracture status combination. These normalized target prices would then be further adjusted for market trends (as proposed 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).

For example, a 70-year-old beneficiary with an HCC count of 4, located in the West North Central Division, region 4, has an MS–DRG 470 no fracture episode during performance year 6. Assume that the total actual cost for this episode was

$17,900, 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 hospital with a composite quality score of 'Good' with a 1.5 percent withhold.

Assuming the target price for region 4 DRG 470 no fracture is $17,550 (reflects a 3 percent quality withhold), the normalization factor in effect for performance year 6 is 0.95, and the market trend factor is 1.023, the 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 CJR for All Age Bracket and HCC Count Combinations of this proposed rule are in effect for purposes of this example, locate the appropriate risk adjustment co-efficient combination for an HCC of 4 and age of 70 which is listed as 1.191 and multiply the target price of $17,550 by that value:

$17,550 * 1.191 = $20,902.05

Step 2. Normalize the risk adjusted target price by multiplying it by the normalization factor of 0.95:

$20,902.05 * .95 = $19,856.95

Step 3. Apply the market trend factor:

$19,856.95 * 1.023 = $20,313.66

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

$20,313.66 * 100/97 = $20,941.91

$20,941.91 * .985 = $20,627.79

Once the applicable risk adjusted, normalized, trend adjusted and quality adjusted target price is computed, the actual episode costs of $17,900 would be compared to the target of $20,627.79 and this episode would therefore show a savings of $2,727.79. 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 are instead proposing to use the CMS–HCC condition 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 as 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 are proposing to use CMS-HCC condition 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 CJR 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 HCC count category. For performance years 6, 7 and 8, we are proposing to publish updated versions of Tables 3 and 4 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 CJR FOR ALL AGE BRACKET AND HCC COUNT COMBINATIONS

Age bracket	CMS–HCC Count = 4	CMS–HCC Count = 3	CMS–HCC Count = 2	CMS–HCC Count = 1	CMS–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

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 proposed rules that indicated the accuracy of target prices benefits participants by increasing financial predictability of participation in the model.

We also considered proposing, 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. However, after including the CMS-HCC condition count and age variables in regression model, the subsequent addition of the dual-eligibility status variable was negligible in terms of enhancing ability of the methodology to accurately predict changes in target price (that is, as shown in Table 3 its p-value was 0.4748, demonstrating that there is weak evidence to suggest that the dual eligibility status variable alone has a statistically significant effect on episode costs). 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 are not proposing to include dual-eligibility status as a risk adjustment variable, we seek 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 seek comment on alternative methods for expressing these factors in our exponential risk adjustment model.

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

As discussed in section II.B.5. of this proposed 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 proposed 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 performance years 6 through 8, we propose 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/permitted OP TKA/THA and hip fracture combination 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 are proposing conforming changes to § 510.200.

6. Changes to Trend Factor Calculation

A limitation of the target price methodology we have discovered and are proposing to address as part of this change and extension 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 and non-CJR hospitals, representing an underlying trend in LEJR episode spending patterns that was neither specific to, nor driven by, CJR participants. This generalized downward trend was not incorporated into CJR target prices, leading to artificially inflated target prices for CJR 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 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 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 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 will be implemented starting on October 1, 2019 (83 FR 39162). The existing case-mix classification methodology, the Resource Utilization Group, Version IV (RUG–IV) model will be replaced by a new case-mix methodology called the Patient-Driven Payment Model (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 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 proposed in this section of this rule would account for these trends.

The inability to integrate both generalized spending trends not driven by CJR, and major payment system changes, in combination with the fact that OP TKA data were not available prior to 2018, have led us to propose a new way to account for trend in CJR 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 propose 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 proposed 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/fracture mean cost for episodes occurring during the performance year divided by the regional/MS–DRG/fracture mean cost for episodes occurring during the target price base year. For example, the performance year 6 market trend factor for MS–DRG 470 without hip fracture in Region 1 would be calculated as the Region 1 mean episode costs for MS–DRG 470 without hip fracture episodes ending between 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. As a result, we would calculate 36 market trend factors during reconciliation, one for each MS–DRG/fracture status and region combination. These market trend updates would then be applied to the normalized target prices discussed in section II.B.5. of this proposed 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 seek comment on alternatively using the regional median episode costs for this calculation.

Combined with our proposal to use 1 year of baseline data to calculate CJR target prices for performance years 6 to 8 (discussed in section II.B.3. of this proposed 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.

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 performance years 1 through 5, a one 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 performance years 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 are not proposing to change the 3 percentage point discount factor, we are proposing to increase a participant hospital's ability to reduce the discount factor as a result of its composite quality score. We propose this change in recognition that the proposed changes to the target price calculation (discussed in section II.B. of this proposed 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 performance years 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 one of the two 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 performance years 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 performance years 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 proposed 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 reduce 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 proposed rule.

As a result, we are proposing that, for performance years 6 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 are proposing 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 would effectively be eliminated for the applicable performance year.

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

As noted in sections II. and III. of this proposed rule, we are proposing changes to the CJR 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 performance years 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 are proposing 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 are proposing to resolve these concerns. CMS proposes 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 solicit comment on our proposed start date of PY 6. We have determined 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 these the model while promoting the alignment of quality with financial accountability. We propose to change the regulations under 42 CFR part 510 to reflect this extension.

The changes and extension will apply only to those participant hospitals with a CMS Certification Number (CCN) primary address in the 34 mandatory MSAs, excluding participant hospitals in those mandatory MSAs that are ''low-volume hospitals'' or that have received a notification from CMS dated prior to October 4, 2020 that they have been designated as ''rural hospitals'' (each as defined in 42 CFR 510.2) and that voluntarily elected to participate in the CJR model for performance years 3 through 5. We are not proposing to provide any additional opt-in period for these hospitals (low-volume hospitals and rural hospitals with a CCN primary address in a mandatory MSA) or for any hospitals with a CCN primary address located in the 33 voluntary MSAs and therefore, participation of these hospitals in the model will end at the end of performance year 5. We originally designed the CJR model to require participation by hospitals in order to avoid the selection bias inherent to any model in which providers may choose whether to participate (80 FR 73278). Narrowing participation for hospitals in the 34 mandatory MSAs during the proposed 3 year extension will allow CMS to minimize selection bias while evaluating the impact of the changes proposed in this rule. In the December 2017 CJR final rule (82 FR 57074), CMS finalized a policy to exclude rural and low volume hospitals from the CJR model. Although we allowed for a one time voluntary opt-in for rural and low-volume hospitals for performance years 3 to 5, very few hospitals, 86 out of close to 400 eligible providers, opted to continue participating in years 3 to 5.

The cost to evaluate the small voluntary arm of the model for years 6–8 would be excessive relative to the information we could glean from the small sample size. We already have evaluation data on voluntary LEJR bundled payment model participation from the Bundled Payments for Care Improvement (BPCI) model, which ended on September 30, 2018 and we are actively gathering more data on LEJR bundles from both the current CJR model performance years 3 through 5 and from the BPCI Advanced Model which is currently running. All national hospitals were able to volunteer for Bundled Payments for Care Improvement Advanced (BCPI Advanced), a voluntary bundled payment model which tests the same DRG's as CJR. We believe that BPCI Advanced is an ideal fit for hospitals seeking to voluntarily participate in a clinical episode-based payment model for LEJR. Specifically, among other episodes it offers, BPCI Advanced offers a LEJR episode for BPCI Advanced which includes outpatient TKA procedures as of January 1, 2020. BPCI Advanced is also voluntary, 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 for 2020, selecting to participate in at least one other BPCI Advanced bundled payment episode for 2020 would allow these providers to add LEJR episode participation at the end of CJR performance year 5. Since the CJR model, under our existing regulations, would end on December 31, 2020, we anticipate that any participant hospitals interested in pursuing voluntary participation in a bundled payment model already would have applied to participate in BPCI Advanced.

We have decided to use the notification date of the rural reclassification approval letter as the determining factor of participation in the CJR model for PY 6 through PY 8, since it is an objective factor for determining participation based on rural reclassification. Thus, for PY 6 through PY 8, 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 PY 6 (that is, for any episodes beginning on or after October 4, 2020). Participant hospitals reclassified as rural that are 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 to *before* October 4, 2020) will continue to participate in the CJR model for PY 6 through PY 8 and will remain the financially accountable entities for PY 6 through PY 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 CMS model team will make every effort to post an accurate list of performance year 5participant hospitals identified as having rural status prior to October 4, 2020 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 October 4, 2020 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 October 4, 2020 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 October 4, 2020 should disregard these CJR model communications as they do not suggest the hospital's continued participation in the model for proposed PY 6 through PY 8.

E. Participant Hospital Detailed Notification and Discharge Planning Notice

1. Participant Hospital 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. In this proposed rule, as discussed in section II.A.2. of this proposed rule, we are proposing 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 are also proposing to add the definition of 'anchor procedure' to mean a TKA or THA procedure that is permitted and reimbursable 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 propose 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 propose 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.

Lastly, 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 episode. We are proposing 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 not believe this policy is applicable to outpatient procedures, and do not propose to allow this type of beneficiary notification in cases of outpatient procedures.

We believe these proposals would require changes to the participant hospital detailed notification provided on the CJR web page and if these proposals are finalized, CMS would update the participant hospital notification provided accordingly.

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 in section II.A.2. of this proposed 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 propose 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 propose 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.

F. Quality Measures and Reporting

The two quality measures included in the CJR model are the total hip arthroplasty and/or total knee arthroplasty (THA/TKA) Complications measure (NQF #1550) and the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure (NQF #0166). The model also incentivizes the submission of THA/TKA patient-reported outcomes (PRO) and limited risk variable data. We are proposing to advance the Complications and HCAHPS performance periods for model years 6 through 8 in alignment with the performance periods used for performance years 1 through 5. For PRO, we are also proposing to advance the performance periods in alignment with previous performance periods as well as make changes to the thresholds for successful submission. We propose 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 the table.

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

Model year	Performance period	Duration of the performance period (months)	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.	24	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.	24	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.	24	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.	24	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.

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 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 EPM final rule (82 FR 180) we finalized a full replacement of the prior CJR 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, non-physician provider group practices (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 EPM 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 are proposing 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 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 CJR 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 CJR 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 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 CJR 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 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 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 advance our longstanding policy goal of consistency across the CJR and BPCI Advanced models. 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 are proposing 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 1, 2021. We have proposed for these changes to apply to episodes on or after January 1, 2021 to align with the timing for the other policy changes in this proposed rule.

We seek 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).

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 episodes. The purpose of such flexibilities is to increase CJR 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 performance year 2. 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 that in that situation, that 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.

In this proposed rule, we propose to extend these additional flexibilities to hospitals furnishing services to beneficiaries in the outpatient setting as well. As discussed in section II.A.2. of this proposed rule, we are proposing to change the definition of an 'episode of care' to include outpatient procedures. We are also proposing to add the definition of 'anchor procedure' to mean a TKA or THA procedure that is permitted and reimbursable by Medicare when performed in the 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 outpatient setting will need a SNF stay. However, in the event that a participant hospital performs an LEJR procedure in the outpatient setting and due to unforeseen circumstances, the beneficiaries 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 are proposing to add this additional safeguard so that a beneficiary would not be responsible for the expense. We propose 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 9 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 propose 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 seek comment on our proposals to apply CMS program rule waivers to LEJR procedures performed in the outpatient setting.

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 Medicare Shared Savings Program appeal provisions at § 425.804(b), (c), and (e) are applicable to reviews conducted pursuant to the reconsideration review process for CJR. The CMS reconsideration official issues a written determination within 30 days of the review. The determination is final and binding.

In this proposed rule, we propose 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 are proposing 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 propose 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 propose 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 are proposing 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 seek comment on our proposal.

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 Ambulatory Surgical Centers (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. Continued improvements and advances in medical technologies and surgical techniques may make ASCs an appropriate setting for THAs at a future point in time. Given that trends in care settings continue to transition in this direction, we are soliciting 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 seek 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 and ASC service sites would be paid the same rate, regardless of where the procedure was performed?

K. Coordination With Other Agencies

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

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 proposed rule need not be reviewed by the Office of Management and Budget. However, we have summarized the anticipated information collection requirements in the Regulatory Impact Analysis section of this proposed rule.

IV. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (CRA) (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This proposed rule proposes the change 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 proposed 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 [6] indicate that the model in performance year 1 and 2 resulted in modest cost reductions with quality of care maintained and no increases in case complication. Specifically, for performance year 1, 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 episodes than control group episodes in the difference in difference analysis.[7] Further, the second annual CJR evaluation report, released on June 27, 2019, has found that CJR 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 two 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).[8] From these observations, it appears that continuing to bundle lower joint payments will 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, and we have determined that the proposed changes 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 are proposing 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 become available beginning in CY 2020, and in order to parallel the proposed changes to the reconciliation process with the changes we propose to the target price calculations. We are also proposing to conduct one reconciliation per CJR performance year, which would be initiated 6 months following the end of a CJR 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 the new BPCI Advanced initiative, we are proposing 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 1, 2021 to remain consistent with the other policy changes made in this proposed rule. We believe that participant hospitals, CJR collaborators, collaboration agents, and downstream collaboration agents are now accustomed to the episode-based CJR 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 propose 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 proposed 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 performance years 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 quality categories.

We believe a 3-year extension is necessary to allow for enough time and information to reasonably evaluate the

[6] 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.*

[7] 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.*

[8] 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.*

proposed changes we discuss previously. Extending the model for a term of 3 years would allow the Innovation Center to test and evaluate the proposed changes while promoting the alignment of quality with financial accountability.

C. Anticipated Effects

In prior sections of this proposed 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 January 1, 2021 through December 31, 2023.

There are approximately 470 providers participating in CJR 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 350 participants in the CJR model for the proposed 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 that we could also remove around 45 providers for rural reclassification status. For purposes of modeling this impact, using the 2018 Medicare claims data pulled from the Chronic Conditions Warehouse in April of 2019 and limiting the analysis to non-rural, non-low volume providers located in the 34 mandatory MSAs, we had 330 eligible providers with CJR episode claims data. Projected CJR episode volume increases follow Medicare enrollment assumptions included in the 2019 Medicare Trustees Report. Price updates for 2018 to 2020 follow FFS unit cost increases by service category for 2018 to 2020. The weights for each service category were developed using 2018 episode spending data. For 2021 to 2023, 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 in 2021 compared to their respective regions. In 2022 and 2023, we assume that participant hospitals' spending would grow at the same rate as their respective regions. We make these assumptions given that the most recent CJR evaluation report showed that participant hospitals reduced spending by 3.7 percent during the first 2 years of CJR. 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 produce additional savings over time. We are assuming that if the CJR model were not extended, participant hospitals would increase their episode spending by 1.9 percent as a response to the model ending, which is half of the savings shown by the evaluation for the first 2 years of CJR.

We note 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 do not yet have any claims experience with these new methodologies in place. Behavioral changes stemming from these policies could have impacts upon our CJR savings estimate that we are unable to quantify at this time.

TKA procedures in the ambulatory surgery center (ASC) setting are eligible for Medicare payment as of January 1, 2020. Since ASC procedures are not included in the proposed CJR model extension, we note that the number of CJR TKA episodes could decrease as a result of this policy change. However, given that we had no claims experience from which to draw at the time we prepared this impact analysis, we did not have a basis from which to estimate this potential decrease in TKA episodes. Therefore, assumptions resulting from this payment change have not been included in this financial impact estimate. In the OPPS CY 2020 Final rule (84 FR 61388), we stated that we agreed with commenters who stated that the majority of Medicare beneficiaries would not be suitable candidates to receive TKA procedures in an ASC setting, noting that factors such as age, comorbidity, and body mass index are among the many factors that must 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 that we believe physicians should continue to play an important role in exercising their clinical judgment when making site-of-service determinations, including for TKA. Therefore, while we are unable to estimate volume changes due to the change to allow TKA procedures in the ASC setting, we anticipate that the volume, if any, would likely be small such that only the magnitude of this CJR impact estimate would change.

Total hip arthroplasty procedures were removed from the Inpatient Only List, effective January 1, 2020. We acknowledge that it is possible that this change could result in reductions in hip procedure costs should some percentage of inpatient THA procedures move into the OPPS setting over the next several years. We note that we did not make any specific assumptions about decreasing episode costs for any of the hip episodes used in this impact analysis. However, we also note that since target prices are subject to a retrospective trend adjustment, the effects of this payment change to allow THA procedures in the OPPS setting should be captured in the target price resulting in a minimal financial impact to the CJR model.

The calculations shown in Table 7 below 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 seek comment on our assumptions and approach.

The following table summarizes the anticipated qualitative impact of each of the discrete provisions of this proposed rule. Although we are unable to provide discrete estimates of costs, savings, and transfers associated with each of these provisions at this time, we will provide a more detailed cost-benefit impact analysis of these discrete provisions in the final rule. This table includes a qualitative estimate of the costs/savings imposed on non-federal entities (that is, participating medical facilities) as well as transfers of federal funds relative to the original CJR model provisions. The ''Notes'' column provides additional background when necessary.

TABLE 6—QUALITATIVE ANTICIPATED IMPACTS BY PROPOSED PROVISION RELATIVE TO ORIGINAL CJR MODEL POLICIES 2021–2023

Provision	Costs/savings	Transfers	Notes
Changes to episode definition to include OP 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 OP 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 two 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 one year of data to calculate target prices (rather than most recent three years of data), removal of regional and hospital anchor weighting factor(s) from target price calculation, and discontinuing twice annual updates to the target prices to account for changes in the Medicare prospective payment systems and fee schedule rates.	Savings		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.
Incorporating a risk adjustment for beneficiary specific CMS–HCC condition count and age bracket.	Zero Impact		This risk adjustment is designed to increase target prices somewhat for beneficiaries with increasing age and/or HCCs; it will lower targets somewhat for younger beneficiaries with fewer or no HCCs. The presumption is that episode costs for older, more complex beneficiaries should be higher than average and for younger, less complex beneficiaries they should be lower than average so 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 are proposing 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.

Burden reductions should result from the three other proposals we are making in this rule. Specifically, our proposal to 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 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 participants 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 burden reduction 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 CJR

[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 presented the transfer payment effects of the proposed rule to the best of our ability.

The following table summarizes the financial impact of the proposal across three 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 OP 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 OP 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.

D. Effects on Beneficiaries

We believe the refinements to the CJR model proposed in this proposed rule would not materially alter the potential effects of the model on beneficiaries. We believe the proposed changes would not alter the effects of the model on beneficiaries because the proposed changes predominantly alter how hospitals interact with the model, rather than how beneficiaries receive care. We do not expect that CJR hospitals will conduct a larger share of LEJR procedures in the outpatient setting than non-CJR hospitals. We believe that the combination of our proposed 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.

E. Effects on Small Rural Hospitals

The change and extension are focused on high cost urban area MSAs and exclude participant hospitals that are rural hospitals as of December 31, 2020 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 all rural based on urban to rural reclassifications governed by § 412.103 and were also qualified as rural referral centers (RRCs) (see § 412.96). RRCs are high-volume acute care hospitals that treat a large

number of complicated cases. Therefore, we do not believe this model will have an impact on small rural hospitals.

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 $7.5 to $38.5 million in any 1 year; NAIC Sector-62 series). States and individuals are not included in the definition of a small entity. For details, see the Small Business Administration's website at *http://www.sba.gov/content/smallbusiness-size-standards.* For purposes of the RFA, we generally consider all hospitals and other providers and suppliers to be small entities. We believe that the provisions of this proposed rule relating to acute care hospitals will have some effects on a substantial number of other providers involved in these episodes of care including surgeons and other physicians, SNFs, physical therapists, and other providers. Although we acknowledge that many of the affected entities are small entities, and the analysis discussed throughout this proposed rule discusses aspects of the CJR model that may or would affect them, we have no reason to assume that these effects would reach the threshold level of 3 percent of revenues used by HHS to identify what are likely to be ''significant'' impacts. 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 proposed in this proposed rule.

G. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed 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 proposed rule, we assume that at least one individual at most participant providers currently participating in CJR, that is approximately 470, will review this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this proposed rule. It is possible that not all commenters will review the rule in detail, and it is also possible that some reviewers may not choose 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 $109.36 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 the staff to review the proposed rule. For each entity that reviews the rule, the estimated cost is $251.53 (2.3 hours × $109.36). Therefore, we estimate that the total cost of reviewing this rule is $118,336 ($251.78 × 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 (A) net federal monetary transfers, and (B) potential reconciliation payments to participating hospitals net of repayments from participant hospitals that is associated with the provisions of this proposed rule as compared to baseline. In Table 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	2121–2023
	86	2019	3	2121–2023
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 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately $154 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.

Executive Order 13771 (January 30, 2017) requires that the costs associated with significant new regulations ''to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' The E.O. 13771 designation of this rule will be informed by public comments received.

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 this 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 this 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 proposed 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 proposed 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. New participant types for the CJR model would require more lead time to put in place preparations for entering the model and this would necessitate a long delay between the end of performance year 5 and the initiation of performance year 6, which would really be performance year 1 for new participants. 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 this proposed CJR model extension but rather are soliciting comment in section II.J. of this proposed rule on how a future LEJR model that incorporated other entities in addition to hospitals might be structured.

In developing our risk adjustment methodology approach, although we are proposing 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 proposed rule ''Additional Episode-Level Risk Adjustment''). As we believe regional differences in risk for HCC count and age should already be accounted for via our region/MS–DRG/hip fracture pricing strategy we are proposing the computationally less complex national approach although we are seeking comment on a regional calculation of coefficients.

Finally, in developing our proposed 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 a better measure of central tendency. However, we did not propose to use the median in the market trend factor update as discussed in section II.C.6. of this proposed rule ''Changes to Trend Factor Calculation'' of this proposed rule because we thought it would be more appropriate to use the mean here such that the low and high data points of pricing were captured and reflected in the trend. Further, using the mean keeps the trend calculation aligned with the methodology for deriving the target prices for the model as the target prices use the mean rather than the median.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

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 proposes to amend 42 CFR chapter IV as follows:

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, 1315(a), and 1395hh.

■ 2. Section 510.2 is amended by—
■ a. Adding definitions in alphabetical order for ''Age bracket risk adjustment factor'', ''Anchor procedure'', ''BPCI Advanced'', and ''CMS–HCC condition count risk adjustment factor'';
■ b. Revising the definition of ''Episode of care (or Episode)'' and ''Net payment reconcilation amount (NPRA)'';
■ c. Adding definitions in alphabetical order for ''OPPS'' and ''OP THA/OP TKA'';
■ d. Revising the definitions of ''Participant hospital'', ''Quality improvement points'', and ''Reconcilation payment''; and
■ e. Adding a definition in alphabetical order 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 procedure means a Total Knee Arthroplasty (TKA) or Total Hip Arthroplasty (THA) procedure that is permitted and reimbursable by Medicare when performed in the outpatient setting and billed through the OPPS.

* * * * *

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

* * * * *

CMS–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).

* * * * *

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 and after October 4, 2020, the date of admission to an anchor hospitalization or the date of the anchor procedure, as applicable, and ends on the 90th day after either of 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).

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

* * * * *

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

* * * * *

OPPS stands for the outpatient prospective payment system.

OP THA/OP TKA means a total hip arthroplasty or total knee arthroplasty, respectively, each as performed in the outpatient setting.

* * * * *

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 December 31, 2020, 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 January 1, 2021, a hospital (that is not a rural hospital or a low-volume hospital as defined in § 510.2 as of October 4, 2020 (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.

* * * * *

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 8 increases from the previous performance year 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) and (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 October 4, 2020, the participant hospital admits the beneficiary for an anchor hospitalization, or an anchor procedure is performed at the participant hospital.

* * * * *

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

§ 510.105 Geographic areas.

(a) * * *

(3) Beginning with performance year 6, only the 34 selected 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 paragraphs (a), (c), (d)(4) introductory text, and (d)(6);

■ b. Adding paragraph (d)(7);

■ c. Revising paragraphs (e)(1) and (2) and paragraphs (e)(3) introductory text and (e)(4) introductory text; and

■ d. 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, 2023.

* * * * *

(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 5 only, 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/permitted OP TKA/THA/hip fracture 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) * * *

(1) The list of excluded MS–DRGs, ICD–CM diagnosis codes, and CMS model PBPM payments are posted on the CMS website.

* * * * *

(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 not be updated.

■ 7. 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 October 4, 2020, 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 October 4, 2020, receives an anchor procedure at any participant hospital.

* * * * *

■ 8. Section 510.300 is amended by—

■ a. Revising paragraphs (a)(2) and (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 episode quality-adjusted target prices.* For performance years 1 through 5, 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.

* * * * *

(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 for performance years 1 through 5 can be found on the CMS website.

(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 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 or anchor procedure.

(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.

* * * * *

(6) *For episodes beginning on or after October 4, 2020 that are initiated by an anchor procedure,* permitted OP TKAs and OP THAs will be grouped with MS–DRG 470 episodes as follows:

(i) Permitted OP THAs with hip fracture group with MS–DRG 470 with hip fracture.

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

(b) * * *

(1) * * *

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

(v) Episodes beginning in 2020 for performance year 7.

(vi) Episodes beginning in 2021 for performance year 8.

(2) * * *

(iii) Regional historical episode payments for performance years 4 through 8.

* * * * *

(5) *Exception for high episode spending.* (i) For performance years 1 through 5, 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/permitted OP TKA/THA/hip fracture categories, as specified in § 510.300(a)(1) and (6).

* * * * *

(c) * * *

(3) * * *

(iii) In performance years 4 through 8, 3.0 percent.

* * * * *

■ 9. 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 trend as described in this section to arrive at the reconciliation target price amount. Specifically:

(a) *Risk adjustment.* (1) The beneficiary-level target prices computed under § 510.300 is be risk adjusted by a CMS–HCC condition count risk adjustment factor and an age bracket risk adjustment factor. Both factors are binary, yes/no variables, meaning that a beneficiary either does or does not meet the criteria for a specific variable.

(i) The CMS–HCC condition 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 less than 65 years, 65 to 74 years, 75 years to 84 years, or 85 years or more.

(2) Both factors are computed annually prior to the start of each performance year 6 through 8 via a linear regression analysis. The annual regression analysis is computed using the one year of claims data applicable to that performance years' target price calculation as specified in § 510.300(b) and the most recently available CMS–HCC yearly file.

(i) For performance year 6, CMS uses the CMS–HHC yearly file for CY 2019;

(ii) For performance year 7, CMS uses the CMS–HHC yearly file for CY 2020;

(iii) For performance year 8, CMS uses the CMS–HHC yearly file for CY 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 CMS–HCC condition count variable and each age bracket 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 be the CMS–HCC condition count risk adjustment factor and the age bracket risk adjustment factor that would be used during reconciliation for the subsequent performance year.

(4)(i) At the time of reconciliation, the beneficiary-level target prices computed under § 510.300 is risk adjusted by applying the applicable CMS–HCC condition count risk adjustment factor and the age bracket risk adjustment factor specific to the beneficiary in the episode.

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

(5)(i) The risk-adjusted target prices are normalized at reconciliation to remove the overall impact of adjusting for age and CMS–HCC condition count 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, MS–DRG, and hip fracture status 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), 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).

(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, MS–DRG/permitted OP TKA/THA/hip fracture 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 fracture 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.

■ 10. Section 510.305 is amended by—

■ a. Revising paragraph (b), the paragraph (d) subject heading, and paragraphs (d)(1) introductory text, (e) introductory text, and (e)(1)(i);

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

■ c. Revising paragraphs (i), (j)(1) introductory text, and (j)(2); 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 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 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 episodes for a given performance year.

(3) Following the end of each performance year, for performance years 1 through 8, 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.* (1) Beginning 2 months after the end of each of performance years 1 through 5, CMS does all of the following:

* * * * *

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

(1) * * *

(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 2 months after the end of the performance year. Actual episode payments are capped at the amount determined in accordance with paragraph (b)(5)(i) of this section for the performance year or the amount determined in paragraph (k) of this section for episodes affected by extreme and uncontrollable circumstances.

* * * * *

(f) * * *

(1) * * *

(iv) In each case as subject to paragraph (f)(1)(iii) of this section, results from the performance year 5 reconciliation as described in paragraph (i) of this section and the performance year 5 post-episode spending and ACO overlap calculations as described in paragraph (j) of this section are added to the performance year 6 NPRA in order to determine the reconciliation payment or repayment amount.

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

(vi) Results from the performance year 7 reconciliation as described in paragraphs (m) of this section and the performance year 7 post-episode spending and ACO overlap calculations as described in paragraph (j) of this section are added to the performance year 8 NPRA in order to determine the

reconciliation payment or repayment amount.

(vii) The reconciliation or repayment amount will be assessed independently for performance year 8 in 2024.

* * * * *

(i) *Subsequent reconciliation calculation.* (1) For performance years 1 through 5, 14 months after the end of each performance year 1 through 5, 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).

(2) The subsequent calculation for performance years 1 through 4 occurs concurrently with the first reconciliation process for the following performance year.

(i) If the result of the subsequent calculation is different than zero, CMS applies the stop-loss and stop-gain limits in paragraph (e) of this section to the aggregate calculation of the amounts described in paragraphs (e)(1)(iv) and (i)(1) of this section for that performance year (the initial reconciliation and the subsequent reconciliation calculation) to ensure such amount does not exceed the applicable stop-loss or stop-gain limits.

(ii) Because performance year 5 is the last year for which a subsequent reconciliation will occur, that subsequent reconciliation will be conducted slightly before the performance year 6 reconciliation described in paragraph (m) of this section, and any amounts different than zero that do not exceed the applicable stop-loss or stop-gain limits will be included when calculating reconciliation for performance year 6 and prior to issuing a reconciliation payment or demanding a repayment amount.

(j) * * *

(1) In order to account for shared savings payments, CMS reduces the reconciliation payment or increase the repayment amount for the subsequent performance year (for years 1 through 8) by the amount of the participant hospital's discount percentage that is paid to the ACO in the prior performance year as shared savings. (This amount will be assessed independently for performance year 8 in 2025.) This adjustment is made only when the participant hospital is a participant or provider/supplier in the ACO and the beneficiary in the CJR episode is assigned to one of the following ACO models or programs:

* * * * *

(2) If the average post-episode Medicare Parts A and B payments for a participant hospital in the prior performance year is greater than 3 standard deviations above the regional average post-episode payments for the 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 amount for the subsequent performance year for performance years 1 through 7, and assessed independently 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)(iv) 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)(v) 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 or the amount determined in paragraph (k) of this section for episodes affected by extreme and uncontrollable circumstances.

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

(A) Except as provided in paragraph (m)(1)(v)(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 and ACO overlap calculation amounts in paragraphs (j)(1) and (2) of this section are not subject to the limitation on loss.

(B) 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 and ACO overlap calculation amounts in paragraphs (j)(1) and (2) of this section are not subject to the limitation on gain.

(C) 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]

* * * * *

■ 11. Section 510.310 is amended by —

■ a. Removing paragraph (b)(4)(i);

■ b. Redesignating paragraphs (b)(4)(ii) through (iv) as paragraphs (b)(4)(i) through (iii);
■ c. Revising newly redesignated paragraph (b)(4)(iii);
■ d. Removing paragraph (b)(5);
■ e. Redesignating paragraphs (b)(6) and (7) as paragraphs (b)(5) and (6); and
■ f. Revising newly redisgnated 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 will make 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.

* * * * *

■ 12. Section 510.315 is amended by revising paragraphs (d) and (f)(1) and (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 performance years 2 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 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.

* * * * *

(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.

* * * * *

■ 13. Section 510.400 is amended—
■ a. In paragraphs (b)(2)(i) and (ii) by removing the phrase ''over the 5 years'' and adding in its place the phrase ''over the 8 years''; and
■ b. 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 (2021). 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 ≥90% or ≥500 procedures performed between July 1, 2020 and June 30, 2021.

(ii) Year 7 (2022). Submit—

(A) Post-operative data on primary elective THA/TKA procedures for •90% or •500 procedures performed between July 1, 2020 and June 30, 2021; and

(B) Pre-operative data on primary elective THA/TKA procedures for 100% or ≥1,000 procedures performed between July 1, 2021 and June 30, 2022.

(iii) Year 8 (2023). Submit—

(A) Post-operative data on primary elective THA/TKA procedures for 100% or •1,000 procedures performed between July 1, 2021 and June 30, 2022; and

(B) Pre-operative data on primary elective THA/TKA procedures for 100% or •1,000 procedures performed between July 1, 2022 and June 30, 2023.

* * * * *

■ 14. 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 detailed notification.* 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.

(i) *Timing of notification.* The notification must be delivered at the following times:

(A) 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.

(B) 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, as applicable.

(C) In anchor hospitalization circumstances where, due to the patient's condition, it is not feasible to provide notification at the times specified in paragraphs (b)(1)(i)(A) or (B), 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 where the anchor hospitalization occurs.

(D) 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.

(ii) *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.

* * * * *

■ 15. 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 December 31, 2020, 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 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 December 31, 2020, 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 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.

* * * * *

■ 16. 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 December 31, 2020, 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 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 December 31, 2020, 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 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.

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■ 17. 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 December 31, 2020 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 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.

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§ 510.600 [Amended]

■ 18. 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.''

■ 19. 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.* 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 for a beneficiary who is a CJR beneficiary on the date of discharge from the anchor hospitalization or the date of service of the anchor procedure, as applicable, 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: December 2, 2019.

Seema Verma,

Administrator, Centers for Medicare and Medicaid Services.

Dated: December 19, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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