



Via Electronic Submission (www.regulations.gov)

April 22, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5529-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: Medicare Program; Comprehensive Care for Joint Replacement Model Three-Year Extension and Changes to Episode Definition and Pricing, CMS-5529-P

Dear Administrator Verma:

The Association of American Medical Colleges (the AAMC) welcomes the opportunity to comment on the proposed rule entitled “Medicare Program; Comprehensive Care for Joint Replacement Model Three-Year Extension and Changes to Episode Definition and Pricing,” 85 *Fed. Reg.* 10516, published by the Centers for Medicare & Medicaid Services (CMS or the Agency) on February 24, 2020.

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members are all 155 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America’s medical schools, teaching hospitals and more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

The AAMC supports alternative payment models (APMs) and programs, such as accountable care organizations (ACOs) and bundled payment initiatives, that seek to promote high-quality, efficient care while retaining at their core the essential patient-physician relationship. Many teaching hospitals and health systems are participating in new payment models, including the Medicare Shared Savings Program, the Next Generation ACO Model, the Bundled Payments for Care Improvement (BPCI) Advanced Model, the Oncology Care Model, the Comprehensive Care for Joint Replacement (CJR), and others.

The proposed CJR three-year extension will continue bundled payments for Lower Extremity Joint Replacement (LEJR) episodes, while testing new innovations to the Model. While many of the proposed changes will provide benefits to both Participants and patients, there are some aspects that should be reconsidered. We urge CMS to consider the below comments in the development of the final rule.

EXECUTIVE SUMMARY OF AAMC COMMENTS

The AAMC recommends the following revisions to the CJR Three-Year Extension and Changes to Episode Definition and Pricing Proposed Rule:

- **Expand the CJR extreme & uncontrollable circumstances policy.** Continue the interim final rule's decision to extend the extreme & uncontrollable circumstances policy to cover pandemics or other public health emergencies throughout Model Years (MY) 6-8.
- **Allow Participants in voluntary Metropolitan Statistical Areas (MSAs) to continue to participate in LEJR episodes.** Allow Participants in voluntary MSAs to either join the CJR extension for MY6-8 or introduce an additional application period for BPCI Advanced to allow CJR Participants in voluntary MSAs the opportunity to continue their work in LEJR.
- **Eliminate the proposed retrospective Market Trend Factor.** Eliminate the proposed Market Trend Factor to prevent inappropriate care for patients and unfair assessments of Participants. Existing methodology appropriately accounts for target price changes using Outpatient Prospective Payment System (OPPS) and Inpatient Prospective Payment System (IPPS) updates, and the CMS discount is sufficient for CMS to receive guaranteed savings.
- **Remove the proposed annual rebasing of the baseline.** Remove annual rebasing of the baseline, as it will result in unpredictable target prices, preventing providers from planning effective care interventions.
- **Add variables to the risk adjustment, in addition to the proposed Hierarchical Condition Category (HCC) count and age variables.** Include more extensive variables to account for HCC weight, joint location, patient demographics, Medicare eligibility reason, and dually eligible status.
- **Determine attainable Patient Reported Outcome (PRO) reporting rates.** Proposed PRO reporting rates for MY6-8 are extraordinarily high and deter Participants from attempting to collect this important data. CMS should reduce the required PRO rates to increase the amount of data they receive.
- **Extend the telehealth waiver established in the Coronavirus Preparedness and Response Supplemental Appropriations Act for use in MY6-8.**¹ Include the telehealth waivers established for the COVID-19 pandemic in the CJR three-year extension final rule, as a permanent aspect of the Model.
- **Extend the beneficiary notification window to two days.** CMS should extend the beneficiary notification window by a day to relieve the burden placed on providers by requiring same-day notification.

The AAMC also supports many aspects of the CJR proposed rule, as detailed below. In particular, we support proposed policies that promote consistency across model years, support investment in quality of care, and reduce operational burdens for Participants.

AAMC COMMENTS IN FULL

COVID-19 Pandemic Response

Expand the CJR extreme & uncontrollable circumstances policy to apply to pandemics such as COVID-19 through the end of the Model. On March 30, 2020, CMS released an interim final rule that would extend the current CJR

¹ The Coronavirus Preparedness and Response Supplemental Appropriations Act. H.R.6074, 116th Congress. (2020), <https://www.congress.gov/bill/116th-congress/house-bill/6074>

extreme and uncontrollable circumstances policy to apply to the COVID-19 pandemic through MY 5. The AAMC strongly supports this policy decision. We believe that CMS should ensure that this change applies through the entire CJR Model, including the proposed three-year extension. This policy would hold clinicians harmless from performance-related penalties for the 2020 performance year, by capping actual CJR episode expenditures at the target price during a declared state of emergency.

The AAMC recommends that CMS apply this extreme and uncontrollable circumstances policy to all CJR episodes that overlap with a declared state of emergency. As proposed in the CMS interim final rule, this policy would apply to all episodes initiated during the state of emergency, as well as episodes that initiated within 30 days of the start of the declared emergency. However, since CJR episodes run for 90 days, we recommend that CMS apply the extreme & uncontrollable circumstances policy to all CJR episodes that initiated within 89 days of a declared state of emergency.

CMS must also apply these policies to state and local level states of emergency, as different regions declared emergencies earlier than the nationally declared state of emergency, based on the prevalence of COVID-19 within their region. A national state of emergency was declared on March 13, 2020 and applies retrospectively to March 1. However, Washington state declared a state of emergency on February 29, and Orange County, California declared a state of emergency on February 26. Therefore, CMS should extend the extreme and uncontrollable circumstances policy to state and local level state of emergency declarations to ensure those regions with the earliest cases are not facing undue financial burdens, as a result of COVID-19.

The AAMC further recommends that CMS consider the long-term impact on performance measures and financial benchmarks for future performance years. This will have implications for CJR benchmarking and target prices, as detailed below. The AAMC will also submit these comments in response to the CMS interim final rule, but we are including them here as well to ensure consistency across model years.

Hold clinicians and ACOs harmless from quality assessments and reporting obligations for the 2020 performance year. The impact of COVID-19 on quality measurement will be profound. This will impact admissions and readmissions and patients will likely be required to postpone certain preventive health measures to allow for the capacity to treat more serious cases. Furthermore, clinicians who would typically be involved in quality reporting may be needed to provide additional or emergency patient care. We recommend eliminating or extending all of the upcoming reporting deadlines for the 2020 performance year.

Three-Year Extension for Mandatory Participants

Maintain the proposed three-year extension to continue testing the Model. The AAMC understands CMS' desire to extend CJR for three years to test the incorporation of outpatient Total Hip and Total Knee Arthroplasty episodes, as well as other methodological changes. While the AAMC typically opposes mandatory models with immediate downside risk, in this case we understand that CMS is holding many aspects of the CJR Model constant, while testing select new aspects. The AAMC supports CMS' decision to maintain consistency between MY1-5 and MY6-8 where possible. We agree that the three-year CJR extension provides sufficient time to evaluate this new proposed policy. In addition, we appreciate the alignment between the proposed CJR timeline and the BPCI Advanced timeline, as the two models will now end at the same time. This allows CMS to evaluate both models concurrently to understand the impact of each model on the cost and quality of LEJR.

Allow Participants in voluntary MSAs and rural areas to continue participating in LEJR bundles, either by allowing voluntary and rural CJR hospitals to continue in CJR for MY6-8 or by opening a new application cycle for BPCI Advanced. The CJR proposed rule states that voluntary MSAs and rural areas will not be allowed to continue their participation in the CJR three-year extension. The AAMC requests that CMS develop policies that ensure voluntary and rural Participants have options for continued participation in LEJR episodes. CMS should consider the following two options to continue engaging these CJR Participants: (1) allow voluntary and rural CJR Participants to opt-in to the three-year CJR extension, or (2) allow voluntary and rural CJR Participants to apply for BPCI Advanced in a third application cycle, in cases where these CJR Participants are not already BPCI Advanced Participants.

Voluntary CJR Participants were early adopters of bundled payments and are committed to CMS’ goals of reducing costs while improving quality. It is critical for CMS to continue providing all CJR Participants with meaningful opportunities to participate in LEJR episodes, so they can continue investing in care transformation. Maintaining participation would create incentives for providers to further current investments to improve quality while reducing costs, and it would also allow Participants to be assessed for Qualified APM Participant (QP) status and/or be assessed under the Merit-based Incentive Payment System (MIPS) APM scoring standard. Although voluntary Participant numbers are approximately five times smaller than mandatory Participants (Table 1), a large number of voluntary providers in voluntary MSAs still chose to participate in the Model, engaging in quality improvement and cost reduction strategies. As these are the goals of CJR, continued participation in LEJR should be considered for these Participants.

Table 1: Participants by Voluntary/Mandatory Status and AAMC Membership

Hospital Category	Voluntary		Mandatory		Total	
	#	% in category	#	% in category	#	% in category
All CJR hospitals	75	16%	398	84%	473	100%
AAMC-member hospitals	4	7%	52	93%	56	100%
Non-AAMC-member hospitals	71	17%	346	83%	417	100%
All teaching hospitals	32	13%	207	87%	239	100%
Non-teaching hospitals	43	18%	191	82%	234	100%

The AAMC has identified two ways that CMS could allow voluntary and rural CJR Participants to remain in LEJR bundles after 2020. The first is to allow these Participants the opportunity to opt-in to the CJR model extension. The second is to open a new application cycle for BPCI Advanced in 2020, which would be available to voluntary and rural CJR Participants that have not yet joined BPCI Advanced. As CMS noted in the CJR proposed rule, current BPCI Advanced Participants may elect LEJR episodes in fall 2020. However, prior to the release of this proposed rule in February 2020, CMS did not clearly communicate to voluntary and rural CJR Participants that BPCI Advanced would be their only opportunity to join LEJR episodes. In fact, prior to the application deadline for the second cohort in BPCI Advanced, CMS indicated that the opposite was true, by telling CJR hospitals that they could not participate in LEJR episodes for BPCI Advanced during 2020, which at the time was to be the final episode selection period under BPCI Advanced. CMMI did not announce that BPCI Advanced would have a future episode selection period until after the second BPCI Advanced application cycle had closed. Therefore, CMS should provide voluntary and rural CJR applicants who are not currently

participating in BPCI Advanced another opportunity to apply. This will ensure a level playing field for all voluntary CJR Participants and address the lack of clarity in earlier communications.

Episode of Care Definition

Maintain the proposal to extend Total Knee Arthroplasty (TKA) and Total Hip arthroplasty (THA) to the outpatient setting but incorporate additional episode-level risk adjustments. The AAMC supports CMS' proposal to include outpatient TKA and THA procedures into the CJR episode definition. The incorporation of both inpatient and outpatient episodes will better reflect the current array of treatment options available to Medicare beneficiaries. This policy decision will also partially address differences in patient characteristics for beneficiaries that receive these procedures in inpatient versus outpatient settings. In the absence of this combined episode definition, providers treating more complex patient populations, who are more likely to require inpatient treatment, could be unfairly penalized. Research indicates that the age, sex, and comorbidity history of a beneficiary can affect the complication rate, following an outpatient TKA.² This occurs less frequently for THA, demonstrating a higher level of precaution, due to the complexity of the procedure.³ CMS should ensure they are not incentivizing clinically inappropriate care by providing one target price for both inpatient and outpatient TKA and THA. The episode definition must be accompanied by rigorous episode-level risk adjustment to minimize the impact of unmeasured variables, which would potentially unfairly reward or penalize Participants and would also confound the evaluation results. CMS proposed episode-level risk adjustments for age and HCC count. The AAMC believes CMS should add additional episode-level risk adjustment to ensure fair and accurate target prices, as detailed below.

Maintain the proposed seamless transition from MY5 to MY6. The AAMC supports CMS' decision to create a seamless transition between Model Years. In the CJR proposed rule, CMS recommends that episodes initiated on or after October 4, 2020 would be attributed to MY 6, which would match what is already in place for CJR. The AAMC encourages CMS to maintain consistency between the different CJR Model iterations, where possible, and we support a seamless transition between model years. However, we recognize that the exact dates put forward in the CJR proposed rule are likely to change, based on the fact that the CMS interim final rule on March 30, 2020 proposed a 3-month extension to MY5. In the event that the 3-month extension to MY5 impacts the dates of MY6-8, we recommend that CMS maintain the seamless transition between model years for MY5 and the new MY6 start date.

Target Price

Eliminate the introduction of the retrospective Market Trend Factor. CMS has proposed the introduction of a retrospective Market Trend Factor, which would adjust target prices based on baseline spending compared to model year spending for each Medicare Severity-Diagnosis Related Group (MS-DRG) and fracture status. The AAMC strongly opposes the introduction of the retrospective Market Trend Factor to set final target prices. As described below, the proposed use of the retrospective Market Trend Factor may have unintended

² Arshi, A., Leong, N. L., D'Oro, A., Wang, C., Buser, Z., Wang, J. C., . . . SooHoo, N. F. (2017). Outpatient Total Knee Arthroplasty Is Associated with Higher Risk of Perioperative Complications. *The Journal of bone and joint surgery. American volume*, 99(23), 1978-1986.

³ Arshi, A., Leong, N. L., Wang, C., Buser, Z., Wang, J. C., & SooHoo, N. F. (2019). Outpatient Total Hip Arthroplasty in the United States: A Population-based Comparative Analysis of Complication Rates.

consequences that would negatively affect patients. In addition, the market trend would also unfairly reduce the targets for Participants, create large operational burdens for Participants, and reduce Participant’s ability to assess their financial performance and invest in care transformation.

The AAMC has several key concerns related to the proposed retrospective Market Trend Factor:

1. **Clinical best practices should guide patient care, not financial incentives.** The current Market Trend Factor methodology for TKA and THA disincentivizes the use of the inpatient setting, despite the fact that the inpatient setting may be clinically appropriate for many patients. The proposed CMS policy would set a single target price for all LEJR bundles, whether they occur in the inpatient or outpatient setting, without adequate risk adjustment for patient characteristics. Because CMS proposes to maintain the 100% regional pricing methodology, this policy would set target prices based on the regional rate of outpatient procedures, which has the potential to create a race to the bottom. As a result, providers that are treating a higher proportion of complex patients requiring inpatient LEJR procedures will be financially penalized for providing the most clinically appropriate care.

Patients and physicians should work together to decide whether inpatient or outpatient LEJR procedures are most appropriate, taking into consideration the patient’s condition, comorbidities, and social risk factors, such as support at home. This is particularly important for THA, which only began as an outpatient procedure for the Medicare population in 2020. Clinical decisions should not be made based on financial incentives. A full list of medical and social conditions to consider excluding for an appropriate OP TKA/THA are included in Table 2 below. By maintaining the proposed Market Trend Factor policy, CMS will create unintended consequences on both the patients and providers, by pressuring more patients to receive outpatient procedures than is clinically appropriate.

Table 2: Medical and Psychosocial Exclusions for OP TKA/THA

OP TKA/THA Exclusion List			
Medical Exclusions		Psychosocial Exclusions	
Congestive Heart Failure	Vascular Disease	70 or older	Weak Social Support
BMI >35 kg/m ²	End-Stage Renal Failure	History of Anxiety or Depression	Noncompliance with Medications
Cerebrovascular Disease	Post-Op Ileus	Lives Alone	Narcotic Use
Coronary Artery Disease with Cardiac Stent	Chronic Obstructive Pulmonary Disease	Fall History	No Post-Op Caretaker
Chronic Kidney Disease	Chronic Steroid Use	Recent Hospitalization	Lack of Transportation
Hepatitis	Atrial Fibrillation	Alcohol or Drug Use	
Chronic Anemia <75	Sleep Apnea	ADL Assistance Needed	
Thrombocytopenia	HIV/AIDS	Smoking History	
Malignant Hyperthermia family history	Diabetes Mellitus	SNF Admission within 6 Months	
Hypertension		Pre-Op Mobility Range	

Source: Edwards, P. K., Milles, J. L., Stambough, J. B., Barnes, C. L., & Mears, S. C. (2019). Inpatient versus Outpatient Total Knee Arthroplasty. *The Journal of knee surgery*, 32(8), 730-735.

2. ***Retrospective target prices reduce quality improvement opportunities, increase financial uncertainty and create operational burdens for providers.*** Target prices should be determined prior to the start of a MY, so that CJR Participants can set financial targets, invest in care transformation, and track their performance throughout the MY. The proposed use of a retrospective Market Trend Factor would eliminate Participants' ability to predict their financial performance, make investments, or adjust their performance in real-time.

CMS previously tested the retrospective target price approach in the original BPCI Model, but found that the lack of a known, predictable target price was an ongoing operational challenge for Participants. CMS acknowledged this as a known issue in the original BPCI Model, and the agency responded to concerns by capping the annual update factor to mitigate the unpredictability of the targets.

3. ***CMS savings are already guaranteed through the CMS discount.*** CMS states that the Market Trend Adjustment is required to achieve CMS savings. However, CMS has already ensured that the agency will obtain savings through the CMS discount factor, which incorporates immediate, guaranteed savings on all episodes. Therefore, it is not only unnecessary for CMS to seek additional savings, as proposed through these methodological changes, but also unfair, given the increased administrative and financial burden it places on Participants. It seems contrary for CMS to guarantee additional savings for itself, while putting programs and patients at potential risk.
4. ***CMS can appropriately account for changes to target prices using the existing methodology.*** Currently, CMS sets CJR target prices prospectively, with price updates based on the OPSS and IPPS annual final rules. This approach ensures that Participants know their targets in advance, allowing them to assess their financial performance, make investments in care transformation, and improve their performance in real time. The biannual price updates ensure fair targets for CJR Participants, while the CMS discount guarantees savings for CMS.

CMS expressed concern about how to adjust future target prices based on changes in the payment methodology for home health and Skilled Nursing Facilities. However, CMS has already developed methodologies to address these payment methodology changes for the BPCI Advanced Model. CMS should apply the same methodology to adjust prospective target prices for the CJR Model.

Furthermore, the AAMC believes the use of the retrospective Market Trend Factor to set targets would result in inappropriate reductions in Participants' target prices. We disagree with CMS' contention that the observed nationwide trend towards efficient LEJR bundles would have happened without CJR. Instead, we believe that the observed nationwide trend towards reduced use of post-acute care (PAC), after LEJR, may have resulted from CJR Participant's focus on improving efficiency in PAC utilization. In other words, the investments in care transformation made by CJR Participants may have influenced the standard of care at non-CJR Participants through market competition. Therefore, we believe that this methodological change penalizes CJR Participants for leading the market toward more efficient, effective PAC use.

Based on these concerns, the AAMC strongly recommends that CMS eliminate their proposal to introduce the Market Trend Factor to the CJR target price methodology. Instead, CMS should maintain the current CJR target price methodology, which sets the targets prospectively, with updates based on the IPPS and OPSS

final rules. This approach balances the need for CMS to obtain savings, without imposing undue burdens on Participants.

Remove annual rebasing for the proposed one-year baseline. The AAMC supports CMS' decision to change the baseline from a three-year period, as in MY1-5, to a one-year baseline period in MY 6- 8. A one-year baseline is sufficient in supporting the 100% regional pricing, as the volume of episodes is large enough to provide stability with pricing from a single year's worth of data.

Annual rebasing, however, should be removed from the Proposed Rule in order to provide financial predictability for Participants. Annual updates to the baseline further reduce predictability in the target prices, making it even harder for Participants to make necessary investments in care delivery. Providers will need to understand their target prices, so they can determine appropriate care transformation and care management interventions. These aspects are key to CJR's goals as a Model.

In addition, 2020 will not provide an accurate baseline due to the impact of the COVID-19 pandemic, as mentioned above. This further establishes the need to avoid annual rebasing. Instead, CMS should use 2019 as the baseline year for MY6 (2021). The 2019 baseline year should then be held constant for MY6-8, updated annually based on a trend factor. CMS will need to develop a trend factor methodology that holds providers harmless for the 2020 performance year, due to the increased expenditure associated with COVID-19.

Maintain the proposal to cap episode costs at the 99th percentile to match the precedence established in BPCI Advanced. The current CJR Participant spending caps occur at two standard deviations from the mean. CMS proposes to replace this methodology by applying Winsorization at the 99th percentile to the baseline and performance period episodes. The AAMC supports this proposed change because Winsorization at the 99th percentile aligns with the methodology established in BPCI Advanced.

Reconciliation

Maintain the proposal to move to one reconciliation, occurring six months after the end of MY. The AAMC supports CMS' proposal to move to one reconciliation period at six months after the end of a model year. We agree with CMS' conclusion that this would be administratively simpler for Participants while providing sufficient claims runout for accurate results. By moving to one reconciliation period, CMS would also save \$240,958 total, while reducing the burden on providers.

Maintain the proposal to increase the CMS quality discount for high quality performance. The AAMC strongly supports CMS' decision to alter the variable quality discount, which rewards Participants with good and excellent Composite Quality Scores (CQS) by reducing the standard CMS discount. In other words, a higher quality discount corresponds to a lower CMS discount, resulting in a higher target price. CMS proposes to increase this quality discount for MY6-8, further rewarding high-quality providers. The AAMC strongly supports this proposed policy change, because it will further incentivize quality improvement and aligns with the Model's goals. As of MY1-2, 60% of Participants received a good quality score and 18% received an excellent quality score. More Participants will be rewarded for their work in quality, by expanding the variable discount to providers with good quality scores, increasing Participants' opportunities for care transformation efforts.

Incorporate additional episode-level risk adjustment, in addition to the proposed incorporation of age and HCC count. The AAMC strongly supports CMS’ decision to incorporate episode-level risk adjustments into the CJR Model, including age and HCC count. In addition, we strongly encourage CMS to incorporate additional patient- and episode-level characteristics. This risk adjustment is essential to ensuring that Participants are fairly assessed on their performance, particularly those treating more complex patients. The presence of this risk adjustment will also reduce confounding from unmeasured variables during the evaluation.

In addition to the proposed risk adjustments for HCC count and age, the AAMC encourages CMS to account for additional episode-level variables. These additional variables listed below correspond to the risk adjustment methodology established in BPCI Advanced. CMS should incorporate the following variables in the CJR risk adjustment:

1. **Joint Location** – Adjusting for joint location accounts for clinical complexity associated with different joint locations or procedures. Specifically, ankle procedures should be included as a variable in the risk adjustment. Ankle procedures were attached to the 469 non-fracture MS-DRG in 2018. AAMC collaborative members saw an 8% reduction in target prices for this MS-DRG, as a result. Including joint location in the risk adjustment is essential to account for the proportion of each type of procedure within a given MS-DRG.
2. **HCC Weight** – Using simple HCC counts may account for the fact that a beneficiary has comorbidities, but it does not account for the complexity associated with each individual HCC. CJR should match the methodology established in BPCI Advanced, which incorporates both the HCC count and HCC weights into the risk adjustment regression model. Certain comorbidities, such as diabetes mellitus, chronic obstructive pulmonary disease (COPD), and hypertension, have higher associated complication rates. Therefore, indicating a need to include weights, rather than HCC count alone.^{4,5} By including HCC weights, CJR can better account for a beneficiary’s unique comorbidities. A one-year lookback period for HCCs should be incorporated to include as much information on patients’ comorbidities as possible.
3. **Patient Demographics** – Including patient demographics, such as sex, helps account for differences between patients.^{6,7}
4. **Original Reason for Medicare Eligibility** – Including the original reason for Medicare eligibility will account for differences in the beneficiary population at the time of initial Medicare enrollment (e.g., based on age vs. disability).

⁴ Courtney, P. M., Froimson, M. I., Meneghini, R. M., Lee, G. C., & Della Valle, C. J. (2018). Can Total Knee Arthroplasty Be Performed Safely as an Outpatient in the Medicare Population? *The Journal of arthroplasty*, 33(7s), S28-s31.

⁵ Greenky, M. R., Wang, W., Ponzio, D. Y., & Courtney, P. M. (2019). Total Hip Arthroplasty and the Medicare Inpatient-Only List: An Analysis of Complications in Medicare-Aged Patients Undergoing Outpatient Surgery. *The Journal of arthroplasty*, 34(6), 1250-1254.

⁶ Courtney, 2018.

⁷ Gronbeck, C., Cote, M. P., & Halawi, M. J. (2019). Predicting Inpatient Status After Primary Total Knee Arthroplasty in Medicare-Aged Patients. *The Journal of arthroplasty*, 34(7), 1322-1327.

5. **Sociodemographic Status (SDS)** – In order to achieve appropriate risk adjustment, the AAMC supports the development of tools to capture SDS data that can be implemented in the future, as well as with all other models introduced by CMS. Until these tools have been established, the AAMC offers the below options to develop appropriate SDS risk adjustment:
- CMS can risk adjust for dually eligible individuals as a proxy for SDS. This, however, does not adequately represent the impact of SDS factors and we encourage this option to be used only as a temporary resolution until more accurate tools can be developed.
 - The AAMC also supports the utilization and collection of ICD-10 Z-codes to identify specific barriers to care and to allow for appropriate risk adjustment for SDS.
 - CMS should also consider using the following reports: Social Risk Factors and Performance Under Medicare’s Value-Based Purchasing Programs report and Accounting for Social Risk Factors in Medicare Payment: Criteria, Factors, and Methods, which were published by the Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine (NAM), respectively.^{8,9} These reports provide evidence-based confirmation that accounting for patients’ sociodemographic and other social risk factors is critical in validly assessing the quality of care. These reports demonstrate that hospitals caring for large numbers of disadvantaged patients are more likely to receive penalties in performance programs. Furthermore, the lack of SDS adjustments can worsen health care disparities because the penalties divert resources away from participants treating large proportions of vulnerable patients. The failure to account for SDS variables also misleads and confuses patients, payers, and policymakers by shielding them from important community factors that contribute to poor health outcomes. Both reports clearly show that there are implementable mechanisms by which SDS data elements can be incorporated into quality measures today.

The AAMC supports the following broad recommendations aligned with risk adjusting for SDS, which would apply to the CJR extension and other CMS program and models:

- Require measure developers to test a range of national-level sociodemographic data elements, as identified in the ASPE and NAM reports, into the risk adjustment methodology of accountability metrics. Both reports discuss in detail data elements that are publicly available and could be immediately tested to determine whether an empirical relationship exists between SDS and the measure’s outcomes. Such elements could include but are not be limited to income, education, neighborhood deprivation, and marital status.
- Provide hospitals with timely, confidential reports of performance on accountability measures stratified by dual eligible status or other nationally available data elements.
- CMS should implement demonstration projects to encourage hospitals to collect SDS data through their EHR. These elements could be used to supplement the claims data already captured by CMS to greatly improve the measure’s risk adjustment methodology. It is essential that CMS include vendors in these discussions.
- Where meaningful and comprehensive neighborhood level SDS-data currently exist, CMS should encourage empirical tests of quality metrics adjusted for those factors to assess the impact of the

⁸ Office of the Assistant Secretary for Planning and Evaluation, December 2016. Report to Congress: Social Risk Factors and Performance Under Medicare’s Value-Based Purchasing Program. PP. 92 Available at: <https://aspe.hhs.gov/system/files/pdf/253971/ASPESESRTCfull.pdf>.

⁹ National Academies of Medicine, 2016. Accounting for Social Risk Factors in Medicare Payment: Criteria, Factors, and Methods. Available at: <https://www.nap.edu/download/23513#>.

adjustments on local provider performance metrics. Based on the results of these tests, CMS and other agencies will be able to prioritize the national collection of data that are most essential for valid risk adjustment methodologies.

CMS should incorporate the variables above in a single regression that includes the MS-DRG and the fracture status. This will simplify CMS' calculations of the target price, while also appropriately capturing patient complexity. To account for the regional target pricing, CMS should calculate regional coefficients for each variable, controlling for potential differences in case mix between regions. Currently, CMS is proposing to incorporate the HCC and age variables using national coefficients, but this is inconsistent with the regional (rather than national) pricing methodology.

CMS should validate the risk adjustment regression model they develop to ensure it demonstrates goodness of fit. CMS should compare both exponential and linear models to evaluate the goodness of fit for each model, selecting the model that fits the data more appropriately. In addition, CMS should validate the coefficients used in their risk adjustment on a data sample that was not used to develop the coefficients (e.g., 2019 data).

Maintain the proposal to retain the 20% stop loss and stop gain amounts. The AAMC supports CMS' decision to retain the 20 percent stop loss and stop gain amount. The 20 percent stop loss is the current methodology used in both CJR and BPCI Advanced. The AAMC agrees that consistent methodology across LEJR bundles in the two models is beneficial, particularly for Participants that participate in multiple bundled payment models simultaneously. Consistent methodologies across models can assist in the evaluation process as well, holding some model design aspects constant to test innovations.

Quality Measures

Maintain the proposal to retain the existing quality measures used in MY1-5, including the TKA/THA Complication Rates and the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey results. The AAMC supports the proposal to retain the current CJR quality measures, because these measures are appropriate to the LEJR episodes and the choice to retain the same measures increases consistency across model years. Consistent methodologies minimize the burden on Participants and support the efficacy of the model evaluation.

Maintain the optional submission of PRO data but change the reporting thresholds to promote the adoption of PRO data reporting. The AAMC strongly support CMS' decision to continue collecting PRO data on a voluntary basis. We believe these patient engagement measures promote high-quality clinical care and support rewarding providers that engage in this work. The AAMC also recognizes that this measure is very difficult to collect, due to the CMS requirement that the CJR Participants collect surveys both pre- and post-procedure from each patient during specified timeframes, using the same survey instrument for each survey. Considering this difficulty, the AAMC appreciates CMS' decision to keep the PRO quality measure as optional.

The AAMC strongly recommends that CMS lower the proposed PRO data reporting thresholds for MY6-8. The AAMC believes that PRO serves as an important tool to engage patients, support shared decision-making, and improve quality of care. Therefore, we believe that CMS should create effective incentives for providers to invest in PRO data collection, as a means of accomplishing these goals, while reducing the burden on providers. As of MY3, only 10% of Participant hospitals were meeting the PRO data reporting threshold (Table 3). Academic

Medical Centers (AMCs) submitted PRO data at a rate of 16% in MY3, a higher rate than the average Participant. However, these numbers are exceedingly low and likely reflect the extremely challenging targets and specifications associated with collecting PRO data. In addition, even Participants that are reporting PRO data at higher rates are having difficulty meeting the thresholds established. Over the course of the Model, successful PRO reporting dropped from 24% in MY1, when the threshold was set at $\geq 50\%$ or ≥ 50 eligible procedures, to 10% in MY 3, where the threshold was set to $\geq 70\%$ or ≥ 100 eligible procedures. This indicates that providers are interested in collecting and sharing PRO data, but that the targets are unrealistic, which discourages provider uptake and thereby limits CMS’ access to PRO data.

CMS proposes raising this reporting requirement to 100% or 1000 patients by MY8. However, the current reporting requirements of 80% or 200 patients are already unrealistic, making the 100% or 1000 patient targets nearly unachievable.

Therefore, the AAMC recommends that CMS lower the PRO reporting thresholds for MY6-8 to the 50% threshold used in the first Model Year. CMS should work with the Quality Measurement & Value-Based Incentives Group (QMVIg) within the Center for Clinical Standards and Quality (CCSQ) to set realistic targets based on the PRO measure specifications. This would meet the Model’s policy objective of incentivizing and measuring PRO data, while setting ambitious but achievable thresholds for Participants. Furthermore, CMS should analyze the effectiveness of individual PRO measures to ensure their significance and determine appropriate thresholds for collection rates.

Table 3: PRO reporting rates

	MY1: July 2016 - August 2016	MY2: September 2016 - June 2017	MY3: July 2017 - June 2018
Hospital Category	% in category	% in category	% in category
All hospitals	24%	13%	10%
AAMC-member hospitals	36%	23%	16%
Non-AAMC-member hospitals	23%	12%	9%
All teaching hospitals	26%	15%	10%
Non-teaching hospitals	23%	12%	10%

Source: AAMC analysis of Hospital Compare Data Archive. January 2020

Waivers

Finalize the proposal to continue the use of the 3-Day Skilled Nursing Facility (SNF) Waiver and the Post-Discharge Home Visit Waiver. The AAMC supports CMS’ decision to extend both the 3-Day SNF waiver and the Post-Discharge Home Visit waiver for the 3-year extension of the CJR program. The AAMC also supports the addition of these waivers for beneficiaries receiving either a THA or TKA in the outpatient setting. These waivers provide important services, as demonstrated through MY1-5 of CJR, and CMS should attempt to maintain consistency between the original Model and the extension when possible.

Implement the telehealth waiver established in the Coronavirus Preparedness and Response Supplemental Appropriations Act for the remainder of the CJR three-year extension. The Coronavirus Preparedness and Response Supplemental Appropriations Act established the use of a nationwide telehealth waiver to assist in the current COVID-19 pandemic. The telehealth waiver allows for an expansion to the definitions for originating site, device type, and patient eligibility. We also encourage CMS to include telephone visits as a form of telehealth, as some beneficiaries may be unable or unwilling to use audio-visual equipment. Telehealth provides important services to patients that are unable to attend an in-person medical visit, due to their condition, location, patient characteristics, or home support. CMS should consider extending some aspects of the temporary telehealth waiver for MY6-8, specifically regarding the originating site expansion, making a telehealth waiver a permanent aspect of CJR.

Other Provisions

Gainsharing:

Maintain the proposal to remove the 50 percent cap on gainsharing that applied in MY1-5. The AAMC supports CMS' proposal to remove the gainsharing cap. We agree that this will reduce the administrative burden for Participants and increase consistency between CJR and BPCI Advanced.

Beneficiary Notifications:

Allow Participants an additional day to provide beneficiary notifications regarding CJR participation and patient financial responsibilities. CMS requires Participants to deliver same-day beneficiary notifications to inform patients of involvement in the Model and financial responsibilities. CJR Participants face difficulties in identifying which beneficiaries may qualify as CJR beneficiaries, which can prevent them from providing same day beneficiary notifications. Some facilities have begun the practice of notifying all potential beneficiaries, to ensure they are not penalized, but this increases the burden on providers and decreases the relevance to patients. CMS should establish a two-day window for beneficiary notifications of participation in the Model and discharge financial notices in the inpatient setting.

Outpatient TKA and THA beneficiaries are likely to be easier to identify, since they are often scheduled and elective procedures. The AAMC supports the extension of the beneficiary notification policy to beneficiaries undergoing outpatient TKA and THA but encourage CMS to consider a beneficiary notification policy that is less burdensome for providers in the inpatient setting.

Appeals Process:

Maintain the proposal to clarify language used in the appeals process. The AAMC supports CMS' proposal to clarify the language describing the appeals process.

Request for Comment on a Future Ambulatory Surgical Center Bundle

CMS should design new models to protect against unattended consequences. New models established by CMS should incentive providers to deliver high quality, appropriate care for each individual patient rather than

incentivizing reimbursements. The AAMC believes that patients should be at the center of every CMS model and that CMS should, therefore, be extremely cautious of potential unintended consequences resulting from any new model design.

CMS asked for comment on a future Ambulatory Surgical Center (ASC) LEJR Model. CMS specifically requested comments on financial accountability, site neutrality, quality measures, and payments. The AAMC offers the following points for consideration:

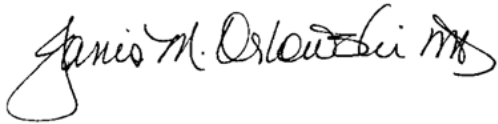
1. Any ASC-focused bundled payment should include financial accountability for physicians practicing in the ASC. The AAMC does not believe the proposed model should include shared financial accountability with hospitals, as these are separate institutions that may not have operational or financial ties to the ASCs. As a result, creating shared financial accountability would create large operational burdens and would inappropriately involve hospitals that are not directly tied to the patient's care for an outpatient TKH/THA procedure.
2. The AAMC strongly opposes site neutrality. Costs and regulatory standards are not consistent across different health care settings, including physicians' offices, hospital outpatient departments, and ASCs. Therefore, CMS should not apply site neutrality to an ASC bundle. CMS does not have the authority to make or continue the proposed cuts to provider reimbursement at excepted off-campus provider-based departments. Consistent with the federal district court's decision in the litigation surrounding these cuts, finalizing the continuation of this policy would exceed CMS's authority.
3. The AAMC strongly supports the use of quality measures that focus on outcomes. Patients should be able to compare the quality of care between ASCs and hospital outpatient departments (HOPDs) for the same services. These quality measures should be uniformly applied to all care settings where joint replacements occur (e.g., inpatient, HOPD, ASC). This may require developing new measures or re-specifying current measures.
4. CMS should implement a prospectively set target price for an ASC bundle, with a retrospective reconciliation. This should incorporate regular price updates corresponding to the final rules for OPPI, IPPS, and other relevant payment mechanisms. By establishing a prospective target price, providers can better plan clinical transformation efforts and prepare for the model. A retrospective reconciliation can be incorporated to account for hospital-specific characteristics, including patient case mix during the actual performance period.

More generally, the AAMC strongly recommends that all new and re-specified quality measures be endorsed by the National Quality Forum (NQF) to ensure that the measure is scientifically valid, reliable, and feasible, and determine whether it is appropriate for review in the NQF Social Risk trial. Any new measure should be reviewed and approved by the Measure Applications Partnership (MAP) before the measure is proposed.

CONCLUSION

Thank you for your consideration of these comments. For questions regarding the CJR Three-Year Model Extension comments, please contact Theresa Dreyer (tdreyer@aamc.org, 202-683-4673) or Erin Hahn (ehahn@aamc.org, 202-828-0963).

Sincerely,

A handwritten signature in black ink that reads "Janis M. Orlowski" followed by a stylized flourish.

Janis M. Orlowski, M.D., M.A.C.P.
Chief Health Care Officer

Cc: Keith Horvath, AAMC
Theresa Dreyer, AAMC
Erin Hahn, AAMC