



AMERICAN ACADEMY OF
ORTHOPAEDIC SURGEONS

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June 23, 2020

Seema Verma, MPH
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: [CMS-5529-P] Medicare Program: Comprehensive Care for Joint Replacement Model Three-Year Extension and Changes to Episode Definition and Pricing

Submitted electronically via <http://www.regulations.gov>.

Dear Administrator Verma:

On behalf of over 34,000 orthopaedic surgeons and residents represented by the American Academy of Orthopaedic Surgeons (AAOS) and the orthopaedic specialty societies that agreed to sign on we would like to take this opportunity to thank you for your leadership during the COVID-19 pandemic.

COVID-19 Response

We appreciate the extension of the current Comprehensive Care for Joint Replacement (CJR) model Performance Year 5 to March 31, 2021 as participants may not have the opportunity to perform elective lower-extremity joint replacement surgeries currently. However, we suggest this extension be further expanded until December 31, 2021. We also support updating CJR policy for extreme and uncontrollable circumstances and applying equal financial safeguards for both fracture and non-fracture episodes during the COVID-19 pandemic.

We believe because of the current pandemic, 2020 will be a difficult year for CJR participants at various levels. Hence, we urge CMS to continue some of the flexibilities allowed under the Public Health Emergency for at least 6 more months. Going back to normalcy and resuming elective surgeries will not be quick and immediate hence the Administration needs to consider local needs as well as ease out of flexibilities.

Proposed Extension of the CJR model

Additionally, in this letter, we are pleased to provide comments on the Centers for Medicare and Medicaid Services' (CMS) Medicare Program; Comprehensive Care for Joint Replacement Model

317 Massachusetts Avenue NE
Suite 100
Washington, DC 20002-5701

PHONE 202.546.4430
www.aaos.org/dc

Three-Year Extension and Changes to Episode Definition and Pricing (CMS-5529-P) published in the Federal Register on February 24, 2020.

Our primary concerns with this proposal include:

- Continued mandatory nature of the 3-year extension period and the extension period not applied to voluntary participants.
- Inclusion of outpatient (OP) Total Knee Arthroplasty (TKA) and Total Hip Arthroplasty (THA) in the CJR episode definition.
- Introduction of the CMS-Hierarchical Condition Category (CMS-HCC) condition count and beneficiary age as risk adjustment factors to the reconciliation calculation.
- Improvements to the gainsharing cap, but no guidance to hospitals for sharing gains with orthopaedic surgeons.
- The potentially destabilizing effects of multiple target price calculation changes.

Additional suggestions are detailed in our response letter below. We thank you for your attention to these concerns and strongly urge CMS to continue to engage with key stakeholders, particularly professional associations representing musculoskeletal surgeons.

Mandatory Requirement & Exclusion of Voluntary Participants in the 3-Year Extension Period

The AAOS strongly supports voluntary bundled and episode-of-care demonstration projects. As explained in our comment letter to the initial CJR proposed rule in September 2015 and all subsequent communication on this model, we ardently believe the proposal to mandate participation in the model for all surgical episodes in each of the 34 mandatory Metropolitan Statistical Area (MSA) is flawed and should be replaced by a voluntary approach for providers and facilities.

The proposal to include all episodes and all providers and facilities in the designated MSAs will severely disadvantage those surgeons, non-physician providers, and facilities that either do not have the proper infrastructure to optimize patient care under episodes-of-care payment models and/or lack adequate patient volumes to create sufficient economies of scale. A voluntary program that allows surgeons, facilities, and non-surgical providers to tailor their episode-of-care models to their unique patient population would lead to far better patient care as well as more accurate and efficient payments.

We strongly urge CMS to revise the mandatory nature of the proposal and instead create incentives for interested participants that would reward innovation and high-quality patient care. We believe the program should be voluntary and on a nationwide basis for any set of surgeons, facilities, and providers who seek to collaborate in innovative ways to bring higher quality, improved care coordination, and to lower costs for musculoskeletal care and who have the infrastructure necessary to carry out an episode of care approach to payment and delivery. Specifically, we recommend that CMS

require that any participating entity have verifiable interoperability, infrastructure, and agreements between all necessary entities.

CJR precedence over Bundled Payment for Care Improvement (BPCI) Advanced

The CJR precedence requirement continues to be a major problem for physician group practices (PGP) that successfully lead the Lower Extremity Joint Replacement (LEJR) episodes in the BPCI model. We have discussed this earlier with you both through written comments and during face-to-face meetings with CMS leadership. We understand that CMS decided to provide precedence to CJR over BPCI Advanced in the mandatory CJR metropolitan areas to have adequate sample size for a hospital-led mandatory model evaluation. However, this extension may be an opportunity to update this policy. Since CJR is a hospital-led model, this precedence policy limits ability of physicians to lead and innovate on patient care. This precedence policy also forces PGPs successful in BPCI Advanced to lose their learning and investment in patient care improvements.

Inclusion of OP TKA & THA in the CJR Episode Definition

In the CY 2018 Outpatient Prospective Payment System (OPPS) rule, TKA was removed from the Medicare inpatient-only (IPO) list, which opened the possibility of doing the procedures in outpatient settings. Removal of THA from the IPO list followed shortly in the CY 2020 OPPS rule. Now that TKA/THA surgeries are being performed as outpatient procedures, we agree it is necessary to include them in the CJR episode definition. We are encouraged by CMS's attempt at site neutrality to the episode categorization methodology, which maps outpatient procedures to inpatient Medicare Severity-Diagnosis Related Groups (MS-DRGs). However, we remain cautiously optimistic due to the potential for driving higher risk patients to the lower cost outpatient setting. We worry mixing outpatient and inpatient cases in DRG 470 will lead to unintended consequences because regional pricing will inevitably cause competition to lower the price of procedures and the fastest way to lower cost in the short term will be to drive potentially inappropriate candidate patients into an outpatient environment. Patient safety must always be the top priority when determining site of care, and we believe that decision should be made by the operating surgeon in concert with the patient. Hence, we urge CMS to regularly analyze utilization data and monitor for significant shifts in procedure setting and/or negative outcomes. Results from these analyses should be made publicly available through peer-reviewed literature and CMMI model evaluation reports.

Introduction of Risk Adjustment Factors in Reconciliation Calculation

AAOS applauds CMS' recognition of the need for risk adjustment and we are encouraged by the inclusion of two risk adjustment factors in the reconciliation calculation. Thus far, target payment rates

in the CJR program only differentiated patients who have a major complication or emergency fractures from elective surgery. The model did not consider race or socioeconomic status (SES).¹

Any inclusion of additional risk factors is an improvement given the literature that the current CJR model may unfairly penalize hospitals that treat clinically complex patients.² CMS is proposing the CMS-Hierarchical Condition Category (CMS-HCC) condition count and beneficiary age as risk adjustment factors beginning with performance year (PY) 6. As noted in our September 2015 CJR Proposed Rule comment letter, patients with chronic illnesses and/or greater functional or cognitive limitations will generally require rehabilitation for longer periods of time in more expensive settings than “healthier” patients with fewer limitations, which can lead to great variation in post-acute cost of care.

One of the most important factors to determining post-acute care spending is patient functional status. Thus, differentiating patients and associated payments by functional status is essential. We are concerned that HCC condition count does not accurately capture post-acute care spending because the methodology is based on inpatient episodes. Many of the 83 HCC's are not relevant to TKA/THA procedures in terms of predicting cardio-pulmonary and/or prosthetic risk. Additionally, we are concerned by the application of HCC condition count for risk adjustment of TKA/THA procedures because we are not aware of this methodology previously being used for orthopaedic surgery.

As noted above, hospitals serving disadvantaged populations may be disproportionately impacted by penalties. An analysis of CJR Year 2 data showed hospitals with a high percentage of dual-eligible beneficiaries (patients with both Medicare and Medicaid insurance) were more likely than low-dual hospitals to be penalized (24.3% vs 13.7%).³ In a forthcoming AAOS Now article, Mary I. O'Connor, MD, FAAOS, et al. explains the reason for this discrepancy may be because, “safety-net hospitals often are committed to serving the most vulnerable of patients, and, even if they wanted to, may not have access to a patient population which allows them to “cherry pick” healthier patients for surgery.”⁴ Financial penalties as a result of caring for more complex patients further reinforces a system that provides fewer resources to safety-net hospitals and capitulates healthcare outcome disparities.

Starting in CY2020, Medicare TKAs can also be performed in ambulatory surgical centers (ASCs). Thus, there is potential for higher risk patients to be included in the CJR model in hospitals while lower risk patients migrate to ASCs in certain MSAs. Results from a two-year evaluation of this model

¹ Ibrahim, S. A., Kim, H., & McConnell, K. J. (2016). The CMS comprehensive care model and racial disparity in joint replacement. *JAMA*, 316(12), 1258-1259.

² Ellimootil, C., Ryan, A. M., Hou, H., Dupree, J., Hallstrom, B., & Miller, D. C. (2016). Medicare's new bundled payment for joint replacement may penalize hospitals that treat medically complex patients. *Health Affairs*, 35(9), 1651-1657.

³ Kim, H., Meath, T. H., Dobbertin, K., Quiñones, A. R., Ibrahim, S. A., & McConnell, K. J. (2019). Association of the Mandatory Medicare Bundled Payment With Joint Replacement Outcomes in Hospitals With Disadvantaged Patients. *JAMA network open*, 2(11), e1914696-e1914696.

⁴ O'Connor, M. I., Jimenez, R. L., Parks, M. L., Nelson, C. (in-press). Alternative Payment Models for Joint Replacement Threaten Safety Net Hospitals and May Diminish Access for Vulnerable Patient Populations. *AAOS Now*. Manuscript accepted for publication.

also found evidence of reductions in the percentage of patients with disabilities undergoing hip- or knee-replacement procedures in the CJR model.⁵ AAOS believes that this is an important finding because most of the savings in Medicare Part A spending for the CJR model has been as a result of the reduction in post-acute care. Individuals with disabilities and those belonging to minority groups are likely to need better quality and institutional post-acute care because of their health status and socio-economic conditions. In addition, a recent study found that in the CJR model, hospitals with a high percentage of Medicare-Medicaid dual-eligible patients must reduce spending at a higher rate than others to obtain a positive bonus despite their high share of patients with complex social and clinical needs.⁶

In addition to HCC condition count, the AAOS asks that CMS consider functional status, disability status and socioeconomic status as risk adjustment factors. Though the dual eligibility factor produced a high p-value in the linear regression analysis for episode cost, we encourage CMS to repeat the analysis using different models and methods after PY 6 and reconsider inclusion of dual eligibility in the risk adjustment calculation. A literature review on this issue should be helpful too.

Gainsharing Improvements and the Lack of Physician Leadership

We applaud the proposed elimination of the 50 percent cap on gainsharing payments. Orthopaedic surgeons, who are at the center of the care teams providing the services, should be able to share in the savings. No other party in the total episode of care is as involved in all aspects of the patient's care, and no other party is as important to the final patient outcome as the operating surgeon. However, it should be noted that many orthopaedic surgeons are not being included in these downstream distribution payments because hospitals control the bundled payment arrangements.

Per our comments to the original CJR proposed rule, the AAOS recommends revising the proposal to give operating surgeons and physician groups the ability to be in charge of the bundle, or explicitly create a mechanism allowing the surgeon or group to participate with a facility or third party to manage the episode, collect payments, recoup overpayments, and return "shared savings" across the spectrum of care. Additionally, the AAOS recommends that hospitals be explicitly restricted, in rulemaking, from putting in place provider restrictions, or from engaging in provider credentialing practices that limits the ability of physicians to perform total joint replacement procedures, even if those physicians are unwilling to sign an agreement or contract with the hospital. This proposed

⁵ Barnett, M. L., Wilcock, A., McWilliams, J. M., Epstein, A. M., Joynt Maddox, K. E., Orav, E. J., ... & Mehrotra, A. (2019). Two-year evaluation of mandatory bundled payments for joint replacement. *New England Journal of Medicine*, 380(3), 252-262.

⁶ Kim, H., Meath, T. H., Dobbertin, K., Quiñones, A. R., Ibrahim, S. A., & McConnell, K. J. (2019). Association of the Mandatory Medicare Bundled Payment With Joint Replacement Outcomes in Hospitals With Disadvantaged Patients. *JAMA network open*, 2(11), e1914696-e1914696.

provision is essential to ensure Medicare beneficiaries have freedom to choose any surgeon or provider for their services.

Potential Instability due to Multiple Target Price Changes

In response to inclusion of outpatient THA/TKA in the episode definition, several changes are being proposed to update the target price calculation. Two proposals of great concern are the high spending cap alteration and the reduction in historical data used to calculate the target price. Both changes have the potential to erroneously skew the target price, making it non-representative of actual cost of care and further worsen a “race to the bottom” for target prices, where each year hospitals must drive costs lower and lower in order to avoid repayment.

The high episode spending cap exists as a safeguard to protect hospitals from unexpected, catastrophic spending amounts. Under current regulation, high episode spending is capped at two standard deviations above the mean regional episode price; however, CMS proposes capping spending at the 99th percentile for PY 6-8 because THA and TKA spending is not normally distributed. While we agree, it is necessary to accurately identify outlier high spending amounts in the model, AAOS asks CMS to reconsider setting the cap at such a high level without precedent. Just as the two standard deviation methodology allowed too many episodes to exceed the high spending cap, the 99th percentile methodology may impose limits that are too strict. Alternatively, we suggest CMS take a more conservative approach and set the high episode spending cap at a lower percentile, perhaps the 80th or 90th. In following years, the percentile can be re-evaluated and changed if needed.

In the CJR extension, CMS is also proposing to reduce the amount of historical data used in target price calculation from the most recent three years to one year. For PY 6 this would be data from calendar year (CY) 2019. While we welcome most attempts to reduce burden, we feel this change is a misapplication of that goal with potentially harmful effects on CJR participant hospitals. Reducing data to a single year increases vulnerability for lower volume sites because the mean target price can be skewed by small cluster of outlier cases with increased costs. Any data capture that has fewer entries is going to be more volatile. It is also important to note the lack of historical cost data on outpatient TKA and THA procedures. CY 2019, the year on which PY 6 target prices are to be calculated, is only the second year for TKA being off the IPO list. There will not be outpatient claims data for THA until CY 2020/PY 7, which is problematic because elective surgeries, most of which are outpatient, are being cancelled or postponed due to the COVID-19 outbreak. As a result, we feel the most recent one year of claims data will not adequately reflect the true cost of outpatient TKA/THA, thus skewing the target price benchmarks.

Starting in CY2020, as we mentioned earlier, Medicare TKAs can also be performed in ambulatory surgical centers (ASCs). Hence, CMS should consider the impact of this policy change on hospital

case mix and subsequently on pricing CJR hospitals will be unjustly penalized if lower risk patients are migrated to ASCs.

For CJR facilities and surgeons the sustainability of the program has always hinged on the target price, thus changing the formula now that participant hospitals have become comfortable with the methodology is worrisome. In addition to reducing the amount of historical data in the target price benchmark and raising the high episode spending cap, CMS is also proposing the following changes to target price calculation:

- Removing the national trend factor update.
- Eliminating the bi-annual target price update to account for changes to the Medicare Physician Fee Schedule.
- Discontinuing the use of regional and hospital anchor weighting steps in target price methodology.

With all these updates happening at one time, it is difficult to predict how target prices will look for PY 6-8, thus it is nearly impossible for participant hospitals to prepare financially for the impact to their joint replacement programs. Furthermore, given the current national healthcare crisis due to the COVID-19 pandemic, stability in target pricing is paramount. No one can predict what the US healthcare system is going to look like after the epidemic subsides or how long it will take for our hospitals and clinical teams to rebound. For this reason, the AAOS asks CMS to minimize the number of changes made to the target price calculation for PY 6-8. Specifically, we ask that CMS reverse its proposal to use only the most recent one year of historical claims data in the target price calculation and instead continue to use the three most recent years of data.

LEJR Bundled Payment Model in Ambulatory Surgical Centers

With TKA and THA now removed from the IPO list, CMS is soliciting ideas for LEJR bundled payment models for ambulatory surgical centers (ASCs). In considering expansion of the CJR to ASCs, we ask that CMS recognize the highly variable and disjointed payment methodologies within the Medicare program, which often present barriers to site neutral payments.

AAOS recognizes that ASCs are uniquely positioned to provide lower cost, highly efficient surgical care for some patients. However, patient selection is key in the ASC setting. We urge CMS to consider patient risk factors very carefully before developing guidelines on such a model. Overall the literature discusses risk factors such as age greater than 80 years, body mass index (BMI) over 25, chronic obstructive pulmonary disease, obstructive sleep apnea, history of transient ischemic attack or stroke,

hypertension, and previous cardiac surgery as important considerations in determining suitability for ASC orthopaedic surgery.⁷

Also, surgeons in consultation with patients should make the final decision on who should undergo LEJR surgeries at an ASC. Surgeon leadership and co-leadership is essential for a successful LEJR model in ASCs. Many physicians have ownership rights at ASCs and are already participating in bundled payment contracts with commercial payers and self-insured employers across the country. Physicians are better able to take on risk by designing efficient care and eliminating waste. One key component of such a model will also involve heavy patient education and pre-operative optimization of patients. This will require significant investment in ASC resources for better outcomes. Here, our earlier comment on site-neutral payments plays a role too. ASCs and surgeons must be adequately incentivized for providing the highly efficient care that such a model will intend to deliver. As such, there is a good opportunity to advance the Administration's health care price transparency efforts through such a bundle. Ultimately, patients may be able to decide on ASCs based on quality and price.

Recognition of High Performers in the Composite Quality Score

For PY 6-8, CMS proposes a greater reduction in the discount factor assessed during the reconciliation process for high quality performers. The current 3-percentage point discount on episode target prices will remain; however, participant hospitals with "Good" and "Excellent" composite quality scores will be able to achieve a 1.5 and 3 percentage point reduction to the discount factor, respectively. Thus, for "Excellent" quality participant hospitals the discount factor is nullified.

We are very pleased with the reduction in the discount factor to better recognize "Good" and "Excellent" quality scores. However, we would also like to draw attention to the lack of measures reflective of outpatient procedure outcomes in the quality composite score. With the introduction of outpatient TKA/THA to the episode definition, it is critical to have a mechanism to measure the quality of those procedures on the back end. To evaluate outpatient procedures, we encourage CMS to add OP-36: Hospital Visits after Hospital Outpatient Surgery, which measures risk standardized hospital visits within seven days of hospital outpatient surgery. For inpatient episodes, CMS should add hospital-level 30-day risk-standardized readmission rate (RSRR) following elective primary THA and/or TKA (NQF#1551). Though some would argue adding these measures complicates the CJR model, we believe the addition of outpatient TKA/THA necessitates separate tracking of outcomes and any increase in burden is outweighed by the benefit to patient safety. Furthermore, CMS is likely already calculating these measures for CJR participant hospitals. NQF#1551 is reported for the Hospital Readmission Reduction Program and Hospital Compare and OP-36 is reported for the Hospital Outpatient Quality Reporting Program.

⁷ Makaanji, H. S., Bilolikar, V. K., Goyal, D. K., & Kurd, M. F. (2019). Ambulatory surgery center payment models: current trends and future directions. *Journal of Spine Surgery*, 5(Suppl 2), S191.

It is important for the patient experience to be reflected in the CJR model. Another way CMS can better incentivize high-quality, patient-centered care is by giving greater weight to voluntary patient reported outcome (PRO) data in the composite quality score. We recommend reducing the weight of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure (NQF #0166), which is currently at 40%, and shifting the weight to PRO data for participants who voluntarily report it. As CMS recognizes in the proposed rule, participant hospitals are becoming increasingly familiar with PRO data collection. We believe those who are investing in successfully collecting PRO data and submitting it to CMS as a part of the CJR model should be rewarded for their effort.

CMS may dually ease the burden of and incentivize greater participation in PRO data collection by encouraging use of clinical data registries. Registries can simplify the collection of voluntary PRO data for the CJR program by facilitating survey distribution and collection. For example, participant hospitals in the AAOS American Joint Replacement Registry (AJRR) can collect Veterans RAND 12 Item Health Survey (VR-12), Patient-Reported Outcomes Measurement Information System (PROMIS) Global-10 generic PRO survey, the Hip disability and Osteoarthritis Outcome Score (HOOS)/Knee injury, and Osteoarthritis Outcome Score (KOOS) Jr. data via our PRO portal. AJRR participant surgeons can view dashboards for their patients' PROMs and compare them to national scores, which allows for more time focusing on improving patient outcomes instead of dealing with PRO survey collection and follow-up activities.

Additional Comments

- Reducing the number of reconciliations to just one at six months following the end of the PY is also a welcome burden reduction. This change should enhance the predictability of the reconciliation/repayment process.
- AAOS recommends additional quality composite score incentives for registry participation. We recommend CMS designate the American Joint Replacement Registry (AJRR) as a preferred collector of quality, risk variable, and patient reported outcome data for the program. The AJRR is the only registry collecting these data elements nationally for THA/TKA procedures, thus making it an essential partner for CMS in the success of the CJR program. As you are aware, CMS is already partnering with AJRR for alternate reporting for lower extremity joint replacement episodes in the Bundled Payment for Care Improvement (BPCI) Advanced model.
- CMS should move forward as planned with the voluntary TKA/THA data threshold increases outlined in Table 5 of the proposed rule.

- We encourage CMS to explore ways to catalyze development additional quality measure concepts that reward participants for tracking post-operative outcomes, functional improvements, decreased pain, and improved range of motion.

Thank you for your time and attention to the concerns of the American Association of Orthopaedic Surgeons (AAOS) on this significant extension of the CJR program. The AAOS looks forward to working closely with CMS on further refining the program and to improving the care of musculoskeletal patients in the United States. Should you have questions on any of the above comments, please do not hesitate to contact Shreyasi Deb, PhD, MBA, AAOS Office of Government Relations at deb@aaos.org.

Sincerely,



Joseph A. Bosco, III, MD, FAAOS
President, AAOS

cc: Daniel K. Guy, MD, FAAOS, First Vice-President, AAOS
Felix H. Savoie, III, MD, Second Vice-President, AAOS
Thomas E. Arend, Jr., Esq., CAE, CEO, AAOS
William O. Shaffer, MD, FAAOS, Medical Director, AAOS
Graham Newson, Director, Office of Government Relations, AAOS

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317 Massachusetts Avenue NE
Suite 100
Washington, DC 20002-5701

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