AAHKS
AMERICAN ASSOCIATION OF HIP AND KNEE SURGEONS

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VIA REGULATIONS.GOV FILING

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1753-P
P.O. Box 8010
Baltimore, MD 21244-1850

RE: Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems

The American Association of Hip and Knee Surgeons (AAHKS) appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on its hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment systems proposed rule for calendar year 2022 (hereinafter referred to as "2022 OPPS Proposed Rule" or "Proposed Rule").

AAHKS is the foremost national specialty organization of more than 4,000 physicians with expertise in total joint arthroplasty (TJA) procedures. Many of our members conduct research in this area and are experts on the evidence-based medicine issues associated with the risks and benefits of treatments for patients suffering from lower extremity joint conditions. AAHKS is guided by its three principles:

- Payment reform is most effective when physician-led;
- The burden of excessive physician reporting on metrics detracts from care; and
- Patient access, especially for high-risk patients, and physician incentives must remain a focus.

Our comment focuses on the following provisions of the FY 2022 OPPS Proposed Rule:

I. Request for Comment on Potential Future Adoption and Inclusion of a Hospital-Level, Risk-Standardized Patient Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty (Sec. XV.B.7.b)

CMS seeks stakeholder feedback on the prospect of adding the Patient-Reported Outcome-Based Performance Measure *Hospital-Level, Risk-Standardized Improvement Rate in Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty*

(NQF ID# 3559) (hereafter "THA/TKA PRO-PM") in the future as a new measure to the Outpatient Quality Reporting (OQR) Program.

AAHKS Comment: We support the future addition of the THA/TKA PRO-PM to the OQR program. Development, dissemination, and adoption of provider-developed arthroplasty outcome measures has long been a priority of AAHKS in order to truly measure the value of joint replacement to patients. For arthroplasty, PROs are the best available means for a patient-centered measurement of functional status improvement, the ultimate objective of arthroplasty. AAHKS members were involved in the Technical Advisory Group and the Technical Expert Panel that contributed to the development of this measure.

The THA/TKA PRO–PM reports the hospital-level risk-standardized improvement rate in PROs following elective primary THA/TKA for Medicare FFS beneficiaries aged 65 years and older. The THA/TKA PRO–PM uses four sources of data for the calculation of the measure:

- PRO data to measure substantial clinical improvement;
- Medicare claims data to identify eligible elective primary THA/TKA procedures for the measure cohort and additional variables for risk adjustment and accounting for response bias, including patient demographics and clinical comorbidities;
- Medicare enrollment and beneficiary data to identify race dual eligibility status;
- U.S. Census Bureau survey data to allow for derivation of a socioeconomic status (SES) index score

a. <u>Feedback on THA/TKA PRO-PM</u>

We appreciate that the measure includes two joint-specific PRO instruments, the Hip dysfunction and Osteoarthritis Outcome Score for Joint Replacement (HOOS, JR) for completion by THA recipients and the Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR) for completion by TKA recipients, as well as either the Patient-Reported Outcomes Measurement Information System (PROMIS)-Global or the Veterans RAND 12-Item Health Survey (VR–12) for risk adjustment. This aligns with recommendations of the *Patient Reported Outcomes Summit for Total Joint Arthroplasty* convened by AAHKS in Baltimore, Maryland on August 31, 2015 to obtain a consensus regarding the PROs and risk variables best suited for THA and TKA performance measures. Representatives from AAHKS, the American Association of Orthopaedic Surgeons, The Hip Society, The Knee Society, and American Joint Replacement Registry (AJRR), CMS, and the Yale-New Haven Health Services Corporation Center for Outcomes Research and Evaluation (Yale/CORE) participated to develop consensus and inform the use of PROs in the then-new Comprehensive Care for Joint Replacement Model (CJR). Clinical experts at the Summit:

- Recommended either the PROMIS Global or the VR-12 instruments to be used to collect general health information due to the redundancy that would result if CMS required both general health PRO instruments which each evaluate physical and emotional health, the

significant investment the National Institutes of Health (NIH) in the PROMIS instruments, and the adoption of PROMIS Global instruments by many facilities

- Recommended KOOS, JR instruments to be used as an efficient and reliable short-form alternative to the full KOOS instrument as the appropriate disease-specific patient survey instruments for lower extremity joint replacement due to data validations demonstrating high internal consistency for KOOS, JR. and that the short-form instrument was highly responsive to joint replacement with a near-perfect correlation with both the pain and activities of daily living/function domains of the full KOOS and the WOMAC
- Declined to endorse the full KOOS instrument due to the substantial burden the instrument's overall length and number of questions would impose on patients, orthopaedic surgeons, and their staff
- Agreed to a small set of questions for risk adjustment, still contained in the PRO-PM.

We particularly welcome the risk model developed for this measure. Since 2015, AAHKS has consistently stressed the need for a vigorous risk adjustment methodology under arthroplasty quality and performance measures. Without such risk adjustment, measures could be used to penalize the hospitals and surgeons that treat the sickest patients.

Furthermore, as the CJR and other models shift to regional benchmarking, hospitals and arthroplasty practices that disproportionately care for medically complex patients will be in direct competition with those that treat a healthier patient base. Without incorporating risk adjustment, performance measures could incentivize cherry-picking and lemon-dropping. We have long favored the inclusion in risk adjustment of sociodemographic factors of patients and their use in this measure mirrors the recent addition of socioeconomic adjustment in the CJR. To mitigate even the perception of sociodemographic risk, we recommend stratification by proportions of dual-eligibility similar to what is now used by the CMS Readmission Reduction Program; this would allow comparison of like hospitals and would harmonize with that program. We also support the extension of the postoperative assessment period to 300 to 425 days to better assess the long-term impacts of the procedure.

b. <u>Data Collection, Submission, and Implementation</u>

If and when CMS ultimately proposes formally to add this PROM-PM to the OQR, a phased implementation path will be necessary. Our members' experience with PROMs reporting in CJR participating hospitals finds that it takes several years for all the arthroplasty related care components in a hospital and surgeon practice to coordinate on the collection and reporting of PROMs. This is especially the case for reporting on outpatient procedures as the addition of outpatient THA/TKA to the CJR is a new development. Some larger, CJR-participating facilities may be ready now for mandatory reporting but smaller facilities will require several years. The PROM collection and reporting is valuable and appropriate in this case, but it is nevertheless an administrative burden on multiple parties that make a PROM capture rate of 60-70% a challenge. We recommend a two-year voluntary reporting period before reporting becomes mandatory. Further study is necessary on eventual exemption criteria for hospitals. Specifically, notwithstanding the fact that CareCompare reports the number of facility patients that are

assessed for each measure, the question remains of how small a facility or its arthroplasty volume must be before there is insufficient data to meaningfully project that quality of arthroplasty procedures using this PROM-PM.

Regarding data collection and submission, self-reporting through an arthroplasty-specific registry has several benefits. The self-reporting gives participating facilities better real-time appreciation of their current PROM performance. Further, this is an opportunity to encourage provider utilization of QCDRs, such as the American Joint Replacement Registry (AJRR), which is the registry primarily used for physician-level reporting for CJR, BPCI-A, and MIPS. AJRR supports a PROM platform for facilities to easily collect and upload PROM submissions. Additionally, AJRR has formed multiple partnerships to include more approved PROM technological vendors. These efforts have led to substantial growth in PROMs capture. By the end of 2019, 209 sites have submitted PROMs to the AJRR, which is an increase of over 13% compared to 2018. The AJRR has the additional advantage of compliance processes that audits data quality to ensure completeness of data submission.

c. Aligned PROMs Across Settings Where Elective THA/TKA are Performed

We believe the THA/TKA PRO–PM measure is appropriate to hospital outpatient departments, ambulatory surgical centers, or hospital inpatient procedures followed by observation stays. As CMS is aggressively incentivizing the performance of arthroplasty in non-inpatient settings, it is important that performance measure data is developed to compare the impact on patients across different arthroplasty sites of care. As we have noted to CMS before, little data exists on outpatient arthroplasty performance in the Medicare population. Some additional time may be necessary for ASCs and outpatient departments to develop the policies and procedures to collect and report this data, but it must be required eventually. Ideally, all Medicare arthroplasty facilities will be measured on the same mandatory performance data.

d. Considerations Unique to THA/TKA

Hospital-Level, Risk-Standardized Improvement Rate in Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (NQF ID# 3559) is a new measure but we anticipate its future value in other Medicare value-based care programs. If and when CMS is evaluating how to incorporate this THA/TKA PRO-PM into some other program to impact provider payment, CMS should establish a benchmark percentage rate of success for reaching a significant clinical improvement (the outcome of the measure) rather than requiring providers to compete for percentile rankings of success rates across tightly bunched score rates. This would help, especially in early implementation, to avoid marginalization of patients based on perceived risk factors and their possible loss of access to care.

Further, if scores are used to impact payment, CMS should consider replicating the stratified methodology of the Readmissions Reduction Program, wherein hospital performance is assessed relative to the performance of hospitals within the same peer group. We favor the method used by the Readmissions Reduction Program to stratify hospitals into five peer groups,

or quintiles, based on proportion of the patient population dually eligible for Medicare and Medicaid.

II. Inpatient Only List (Sec. IX.B.2)

a. Proposal to Halt the Elimination of the IPO List in CY 2022

Last year, CMS stated that it no longer considered the IPO list necessary to identify services that require inpatient care and began a process to phase-out the IPO list between 2021-2023. Beginning in 2021, 298 musculoskeletal-related services were removed from the list. CMS now says that maintaining the IPO list gives the agency more ability to ensure patient safety by carefully reviewing procedures one-by-one for potential removal form the IPO list. Accordingly, CMS proposes that it will preserve the IPO and that in 2022, the previously removed musculoskeletal-related CPT codes will be returned to the IPO list.

AAHKS Comment: We have grave concerns over unanticipated secondary and tertiary impacts on care when regulatory standards on appropriate site of service are removed. We have previously expressed that CMS was moving too fast in removing many procedure from the IPO list on a case-by-case basis under pre-existing regulatory standards. Therefore, we support halting the elimination of the IPO list in 2022 and returning to it those procedures that were removed en masse in 2021. Procedures should be removed after thorough evaluation confirms independent evidence that satisfies all five regulatory criteria.

b. Topics and Questions Posed for Public Comment

i. Should CMS maintain the longer-term objective of eliminating the IPO list? If so, what is a reasonable timeline for eliminating the list? What method do stakeholders suggest CMS use to approach removing codes from the list?

For the reasons stated above and below, AAHKS does not perceive a current need wholly to eliminate the IPO list.

ii. Should CMS maintain the IPO list but continue to streamline the list of services included on the list and, if so, suggestions for ways to systematically scale the list back to allow for the removal of codes, or groups of codes, that can safely and effectively be performed on a typical Medicare beneficiary in the hospital outpatient setting so that inpatient only designations are consistent with current standards of practice?

We do not see a current need to streamline the list of services on the IPO list. Procedures should be removed from the IPO list only after thorough evaluation confirms independent evidence that satisfies all five regulatory criteria:

- Most outpatient departments are equipped to perform the procedure for Medicare beneficiaries
- The simplest procedure described by the code may be performed in most outpatient departments
- The procedure is already being performed in numerous hospitals on an outpatient basis
- It would be clinically appropriate for some Medicare beneficiaries in consultation with his or her surgeon and other members of the medical team to have the option of a procedure as a hospital outpatient, which may or may not include a 24-hour period of recovery in the hospital after the operation

iii. <u>What effect do commenters believe the elimination or scaling back of the IPO list would have on safety and quality of care for Medicare beneficiaries?</u>

Removing procedures from the IPO list presents opportunities for patients and providers, but even in the best of circumstances, there are risks to patient safety and quality of care during the transition. This is the case for individually removed procedures when they rushed of the IPO list before provider consensus. This would be an even greater concern at an exponentially larger volume if the list were eliminated en masse or "streamlined."

As AAHKS has shared with CMS over the last 5 years, many of the adverse impacts from removing procedures from the IPO list arises from hospitals that drive provider admission status decisions based on perceived legal risks under the two-midnight rule. CMS should be aware for procedures that are removed from the IPO list and subject to the 2-midnight rule, site of service and admission status are not determined solely by the physician and patient. In reality, many commercial payers and hospitals establish rules making outpatient status the assumed, baseline status for such procedures. Many payers make outpatient status the baseline because they prefer reimbursing care at a lower cost setting.

Many hospital compliance departments make outpatient status the baseline for FFS Medicare beneficiaries. This may be done for administratively simplicity, to minimize risk of violating the 2-midnight rule, or some other reason. We do know that in a recent AAHKS member survey, a majority of respondents reported that their hospitals were making outpatient status the default admission status for TKA procedures. Under each of these scenarios, it falls upon the physician to advocate for an exception when clinically appropriate. Therefore, a proposal to eliminate the IPO list means that many physicians anticipate the burden of more time spent fighting with payers and facilities over the most clinically appropriate admission status for a patient.

Our members have also shared with us the following personal examples of dealing with hospitals when TKA was removed from the IPO list.[1]

> *An ASA llll risk level TKA patient with Parkinson's was denied inpatient status and while stable for 23 hour discharge, and voiding without retention signs, was sent home. I indicated ASA lll risk and readmission risk, but under the effect of CMS pay practice the utilization review staff insisted he did not qualify for inpatient stay. In less than 1 week he was readmitted with severe urinary retention, bladder distention compressed iliac veins which likely directly contributed to bilateral femoral vein DVT and PEs. He survived anticoagulation and is now doing well. Readmissions cost staggering.*

Another AAHKS physician shared the following:

> *At one of the largest multispecialty physician groups, multiple traditional Medicare patients received bills that they would not have otherwise received because their total knee was completed as an outpatient procedure instead of documented as an inpatient. One patient recently received a bill for $20,000. This new ruling is creating confusion for the patients who have no idea what the bill will be until after the surgery is completed. The surgeon and the staff are not able to tell patients what the cost will be which is really unfair to our patients. The healthy patients are being penalized for being healthy.*

Another AAHKS physician shared the following:

> *We have absolutely no useful guidance for when to admit the patient or not. Our hospital has us start with the assumption that the patient will be an outpatient. I then use known risk factors to determine when I should admit. Usually when I reach 3 (obesity, OA, DM most commonly), I will admit. It does often prompt a call from hospital administration.*

iv. <u>What effect do commenters believe elimination or the scaling back of the IPO list would have on provider behavior, incentives, or innovation?</u>

[1] *See "Unintended Impact of the Removal of Total Knee Arthroplasty from the Center for Medicare and Medicaid Services Inpatient Only List," Yates AJ, Kerr J, Della Valle CJ, Huddleston JI, Froimson MI, [Forthcoming in Journal of Arthroplasty] (discussing survey results).*

As stated above, when high volume, high value procedures are removed from the IPO list, many commercial payers and hospitals establish rules making outpatient status the assumed, baseline status for those procedures. Many payers make outpatient status the baseline because they prefer reimbursing care at a lower cost setting. Many hospital compliance departments make outpatient status the baseline for FFS Medicare beneficiaries. This may be done for administratively simplicity, to minimize risk of violating the 2-midnight rule, or some other reason. Our experience is that not all hospitals review the essential physician-centric regulatory preamble language in the OPPS. In fact, a number of our members dealt with hospital legal departments that had not updated their 2-midnight rule compliance policies to incorporate the case-by-case exception policy added by CMS in 2016. The 2-midnight rule is very complex and CMS should not put individual surgeons in the position of trying to educate hospital legal departments.

We have shared with appropriate officials at CMS several concerning examples of Medicare Advantage (MA) plans citing the removal of TKA from the IPO list as a basis to initially deny coverage for *all* TKA inpatient admissions. Absent appropriate oversight, some MA plans will continue to use any pretext based on a cursory reading of CMS policy to drive as many TKA procedures as possible to the outpatient setting. In our member in 2019, 43% of 721 respondents reported that local MA plans had changed coverage policies to declare all/majority of TKAs to be scheduled as outpatient procedures.

These actions by hospitals and plans undermine surgeon's ability to treat Medicare beneficiaries according to the principle previously articulated by CMS:

> We continue to believe that the decision regarding the most appropriate care setting for a given surgical procedure is a complex medical judgment ***made by the physician based on the beneficiary's individual clinical needs and preferences*** and on the general coverage rules requiring that any procedure be reasonable and necessary.[2]

v. <u>What information or support would be helpful for providers and physicians in their considerations of site-of-service selections?</u>

Based on the experience of our members in dealing with the removal of TKA from the IPO, we have come to learn of the essential role CMS must play in educating stakeholders on the 2-midnight rule, its exceptions, and outpatient selection criteria. It is not a risk but a certainty that some facilities will attempt to make outpatient the default admission status for many procedures. CMS has not updated its guidelines from 2018 on the intersection between TKA and the 2-midnight rule. Given the later removal of THA and the likely future removal of other procedures from the IPO, such guidance is in need of revision. Such guidance increases the likelihood of hospital awareness of CMS preamble statements on patient selection. It is a fact

[2] 82 FR 52,523 (emphasis added).

that CMS is in a better position to educate hospitals nationwide. Otherwise, individual surgeons are left in a position to advocate and educate their hospital billing and compliance departments on Medicare guidance on patient selection.

One issue that should be addressed in updated guidance is additional relevant clinical examples. We appreciate that CMS Center for Clinical Standards and Quality (CCSQ) invited AAHKS to discuss the MLN Matters Guidance in February 2019 in an attempt to broaden consistent understanding of the policy. At that meeting, CMS requested that AAHKS submit additional clinical examples that should be added to the guidance. We provided to CCSQ in May 2019 suggested additional clinical examples most relevant for the THA or TKA patients typically encountered by our members.

We request that CMS use its existing tools of the Medicare Learning Network, Open Door Forums, trade press outreach, and MAC issuances to ensure physicians, hospitals, and MA plans understand key elements of how the IPO list removal and the 2-midnight rule impact procedures. Namely, that "the decision regarding the most appropriate care setting for a given surgical procedure is a complex medical judgment made by the physician based on the beneficiary's individual clinical needs and preferences."

vi. Should CMS's clinical evaluation of the safety of a service in the outpatient setting consider the safety and quality of care for the typical Medicare beneficiary or a smaller subset of Medicare beneficiaries for whom the outpatient provision of a service may have fewer risk factors?

CMS' clinical evaluation of the safety of a service in the outpatient setting should consider the safety and quality for all types of Medicare beneficiaries, not only a smaller subset with fewer risk factors. This is because, in practice, hospitals and plans will push to move most typical Medicare beneficiaries to an outpatient setting regardless of surgeon wishes to limit such settings to the smaller subset of patients with fewer risk factors.

III. Interaction between Inpatient Hospital Admissions and the 2-Midnight Rule (Sec. X.A.2)

CMS proposes to reinstate the policy whereby procedures that are removed from the IPO list on or after January 1, 2021 are exempt from the following reviews for 2 years: Site-of-service claim denials; Beneficiary and Family-Centered Care Quality Improvement Organization (BFCC-QIO) referrals to Recovery Audit Contractor (RAC) for persistent noncompliance with the 2-midnight rule; and RAC reviews for "patient status" (that is, site-of-service).

AAHKS Comment: We request that CMS create a new exemption from site-of-service claim denials, BFCC–QIO referrals to RACs, and RAC reviews for ''patient status'' (that is, site-of-service, or the 2-midnight rule) for procedures that are removed from the IPO list. The term of this exemption should last until a removed procedure is performed in an outpatient setting a

majority of the time. Otherwise, such reviews only serve to incentivize hospitals to make outpatient status the baseline assumption for all newly removed procedures.

Such an exemption period is not solely for the benefit of educating physicians but also to educate facilities and their compliance departments on the totality of the 2-midnight rule *and all of its exceptions*. We have been surprised by repeated evidence and statements on the parts of various hospital compliance departments or CMS contractors who are unaware with the totality of the 2-midnight rule as laid out by CMS in section X.B.1.

Further, if the BFCC-QIOs are to have a meaningful impact in their provider education role under medical reviews during the exemption period, it is necessary that the QIOs are using the same standards as issued by CMS to stakeholders. CMS staff referred us to the document *BFCC QIO 2 Midnight Claim Review Guideline* which CMS shares with its QIO contractors.[3] In general, this document is an accurate and helpful description of overall claim review under all of the elements of the 2-midnight rule. However, the document does not address the fundamental question of how QIOs are construing the case-by-case exceptions. Specifically, what "patient history and comorbidities and current medical needs" or what "severity of signs and symptoms" justify and exception under the policy?

As shared with CMS CCSQ and in prior years' comment letters, anecdotal experience from our members suggests that the earlier BFCC-QIO contractors may not have been familiar with the Case-by-Case Exceptions Policy. Based on denial summaries received by some of our members, it appears that a BFCC-QIO reviewed the medical record for "documentation to support the expectation that the patient would require two midnights of medically necessary hospital care." The finding shared with providers did not address comorbidities or clinical severity addressed in the medical record. This is very concerning in light of the experience by some of our members with hospital compliance departments that were unaware of CMS' 2016 adoption of the Case-by-Case Exceptions Policy.

These concerns reiterate the need for CMS to work closely with specialty societies and hospitals to update and release helpful guidance on the 2-midnight rule as applied to procedures removed from the IPO list.

IV. Contraction of the List of ASC Covered Surgical Procedures (Sec. XIII.C)

Last year, CMS adopted a new method to add procedures to the ASC covered procedures list (CPL). What had earlier been 5 factors under which CMS would exclude procedures from the CPL were converted to 5 factors that individual physicians should consider when determining whether a procedure should be performed on a particular patient in an ASC. This had the effect of essentially adding 267 surgery/surgery-like codes to the ASC CPL. CMS now proposes that it

[3] *BFCC QIO 2 Midnight Claim Review Guideline* includes a date stamp "Revised May 3, 2016 1:47pm", yet it lacks a title, citation to statutory or regulatory authority, or any attribution to CMS. We recommend these be added so that the document is given more deference and consideration by providers.

will reverse this policy and return to its earlier policy of evaluating individual procedures for possible exclusion from the CPL based on 5 factors. This means that 267 surgery or surgery-like codes added to the CPL in 2021 will be removed in 2022.

AAHKS Comment: We welcome this proposed change for many of the reasons outlined above in relation to the IPO. Site of service decisions should be evaluated on a case-by-case basis.

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AAHKS appreciates your consideration of our comments. If you have any questions, you can reach Mike Zarski at mzarski@aahks.org or Joshua Kerr at jkerr@aahks.org.

Sincerely,

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