AAHKS
AMERICAN ASSOCIATION OF HIP AND KNEE SURGEONS

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VIA REGULATIONS.GOV

Centers for Medicare & Medicare Services
U.S. Department of Health and Human Services
Attention: CMS-6082-NC
P.O. Box 8016
Baltimore, MD 21244-8016.

RE: Request for Information: Reducing Administrative Burden to Put Patients over Paperwork

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 request for information (hereinafter referred to as "RFI") on transforming the Medicare and Medicaid programs by putting additional focus on patient-centered care, innovation, and outcomes.

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 in using evidence based medicine to better define the risks and benefits of treatments for patients suffering from lower extremity joint conditions. In all of our comments, 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 comments on the RFI are as follows:

I. Modification or streamlining of reporting requirements, documentation requirements, or processes to monitor compliance to CMS rules and regulations

a. Extensive and Sustained Education on the 2-Midnight Rule and Its Exceptions is Needed for Providers and Reviewers as More Procedures are Removed from the Inpatient Only List

CMS removed total knee arthroplasty (TKA) from the inpatient only (IPO) list effective 2018. CMS is currently considering removing total hip arthroplasty (THA) from the IPO in 2020.

Our experience is that significant confusion among providers and program auditors can be expected initially when high-volume procedures are removed from the IPO and made subject to the 2-midnight rule. We appreciate the work of CMS to-date to educate providers on the primary role that physicians should play in identifying the most clinically appropriate admission status for patients. Nevertheless, we share here what we have learned over the last two years and emphasize the need for enhanced and continued education as another high-volume procedure, THA, come off the IPO.

i. Hospital Confusion

The role of clinical judgment by the practitioner is of utmost importance in the novel area of outpatient TKA and THA. The peer-reviewed literature contains examples of case series from select institutions with selected patient populations that have been able to perform TKA in the outpatient setting with attendant same day discharge. However, generalizing this experience to a broader population of patients and providers should be done with caution, as these institutions may have specific characteristics, including robust outpatient surgery programs with extensive experience, elements and pathways that enable early discharge in the outpatient setting. The challenge faced by our members has been in dealing with hospitals, Medicare reviewers, and private plans that do try to generalize to the entire Medicare population the experience of those few Medicare beneficiaries for whom outpatient joint replacement is clinically appropriate.

In 2018 and into 2019, many of our members reported that some hospitals were implementing policies to not submit claims for any exceptions to the 2-midnight rule for TKA procedures that span than 2 midnights. Other hospitals have expressed to surgeons their expectation that most TKAs for Medicare beneficiaries will be performed on an outpatient basis. Either action is inconsistent with Medicare policy.

We believe this confusion stems from several sources. First, many hospitals likely did not read the 2018 Medicare OPPS Final Rule preamble language discussing exceptions for TKA procedures spanning less than 2 midnights. Second, some hospitals may have outdated policies on the 2-midnight rule. Our members have been confronted with hospital policies on the 2-midnight rule that are based solely upon procedures listed on the "rare and unusual exception" list, which CMS abandoned prior to 2016.[1]

Third, in spite of CMS's 2-year suspension of Recovery Audit Contractor (RAC) reviews of TKA admission status, many hospitals are very reluctant to make any exception to the 2-midnight rule based on prior experience with RACs. Some hospitals remain concerned over the possibility of retrospective reviews of TKA admission status after the 2-year period because they are not confident that the CMS policy on TKA exceptions to the 2-midnight rule has been thoroughly explained to RACs, Medicare Administrative Contractors (MACs), and other reviewers of claims.

[1] Many surgeons and hospitals are unaware of the very important Case-by-Case Exception Policy that CMS implemented in 2016 to protect patients.

Fourth, 2018 was the first time hospitals were faced with such high-volume procedures coming off the IPO list and newly being subjected to the 2-midnight rule. It is noteworthy that the annual volume of Medicare TKA procedures (approximately 306,000) is nearly 10 times greater than the volume of the next most common procedure removed from the IPO list prior to 2017 (code 22551 – arthrodesis), and nearly 6 times greater than the volume of the next most common procedure removed from the IPO list in 2017 (code 22842 – posterior segmental instrumentation). The volume is such that facilities lack the resources to devote to seeking the permitted case-by-case exceptions for all of them.

Finally, TKA and THA outpatient admission for the fee-for-service Medicare population has not previously been allowed, so the specialty societies have not yet developed clinical patient selection criteria for Medicare outpatient TKA and THA. Therefore, physicians, facilities, and QIOs are unsure how to determine that "the documentation in the medical record supports the admitting physician's determination that the patient requires inpatient hospital care" as opposed to outpatient care. We appreciate that CMS defers to clinicians to develop comprehensive patient selection protocols for these procedures. But until such agreed upon clinical standards are fully developed, there is a lack of any known standard for appropriate admission status review.

ii. Illustrative Case Studies and Clarifications for Addition to MLN Guidance

For those surgeons who are aware of CMS' Case-by-Case Exception Policy under the 2-midnight rule, there is a sense of frustration over the lack of clear standards for what clinical scenarios will be considered justified for a case-by-case exception. Many orthopaedic surgeons, especially those who have solely performed procedures on the IPO list, have no experience with the case-by-case exception policy. CMS' Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs) have been reviewing TKA procedures and approving or denying case-by-case exceptions, but it is unknown to providers what standards they were basing their decisions on.

We appreciate CMS releasing the MLN Matters Guidance (SE19002 Revised, Jan. 24, 2019) in an attempt to broaden consistent understanding of the policy. The guidance has been considered helpful by many of our members. Nevertheless, in light of the likely removal of THA from the IPO and the doubling of the volume of cases for which admission status is in controversy, CMS should strengthen its MLN guidance to address even more joint replacement-related questions that are presently arising. We have shared some of the following suggestions with the CMS Center for Clinical Standards and Quality (CCSQ) previously and we look forward to expanded MLN guidance in 2020.

First, under CMS policy, a case-by-case exception can be appropriate based on patient history, co-morbidities, and risk of adverse events. However, the January 2019 MLN guidance provides only one clinical example of a case-by-case exception and that is post-operative complication. The MLN clinical examples do not address patient history or co-morbidities.

Second, as discussed in our February 14, 2019 meeting with CCSQ, we suspect that some hospitals are switching to default outpatient status, regardless of the patient's clinical status, in the interest of administrative simplicity. This can lead to patients being forced into discharge when they may be clinically stable, but physically unable to care for themselves. This in turn significantly increases the risk of an adverse event or accident that will lead to a readmission.

We have stated in our Outpatient Joint Replacement position statement[2] that social support and environmental factors (family or professional outpatient support) must be considered to determine if the outpatient setting is indeed the safest and most appropriate setting for a patient. As we recommend to our members, a *"full discussion with the patient and family as to the risks and potential benefits of same-day discharge after hip and knee replacement be carried out."* We believe that without socio-demographic considerations, patients, surgeons and hospitals in underserved communities will bear a disproportionate burden and unintended consequence of the IPO change for TKA and THA.

The MLN guidance should also make clear to hospitals that social supports and environmental factors should be considered by a hospital before discharging to the home following an invasive procedure like TKA. Several institutions proactively use predictive tools to inform discharge planning after critical surgeries including orthopaedic ones. A large academic health system in the northeast US uses a discharge risk assessment tool that focusses on parameters such as "lives alone," "pain," "prior hospitalization," "depression," "functional status," "high risk medications," and "health literacy."[3] We propose that CMS and its contractors either recommend an existing tool or provide guidance on using such a tool so that it is easier for surgeons and the hospitals to establish risk profile of patients.

iii. CMS Contract Reviewers Lack Transparent Standards

As discussed with CMS CCSQ in February, providers are unclear how BFCC-QIOs were interpreting and applying the Case-by-Case Exceptions Policy in their reviews of TKA cases under the 2 midnight rule. Such information would better inform providers of when an exception is or is not justified and worth the time and effort to appeal for both TKA and THA.

CMS staff referred us to the document *BFCC QIO 2 Midnight Claim Review Guideline* which CMS shares with its QIO contractors.[4] 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

[2] Endorsed by The American Academy of Orthopaedic Surgeons, The Hip Society and The Knee Society: Position of the American Association of Hip and Knee Surgeons. Outpatient Joint Replacement. Available: http://www.aahks.org/position-statements/outpatient-joint-replacement/

[3] Ohta, B, Mola, A, Rosenfeld, P and Ford, S 2016 Early Discharge Planning and Improved Care Transitions: Pre-Admission Assessment for Readmission Risk in an Elective Orthopedic and Cardiovascular Surgical Population. International Journal of Integrated Care, 16(2): 10, pp. 1–10, DOI: http://dx.doi.org/10.5334/ijic.2260

[4] *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.

exceptions. Specifically, what "patient history and comorbidities and current medical needs" or what "severity of signs and symptoms" justify an exception under the policy.

As shared with CCSQ, anecdotal experience from our members suggests that the BFCC-QIO, KEPRO was not be familiar with the Case-by-Case Exceptions Policy. Based on denial summaries received from KEPRO by some of our members, it appears that KEPRO reviewed the medical record for "documentation to support the expectation that the patient would require two midnights of medically necessary hospital care." The KEPRO analysis 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.

We are aware that CMS has suspended short-stay claim reviews by the BFCC-QIOs until a new national contract for such is awarded later in 2019. This new national contract is an opportunity for CMS to simultaneously assure providers that claims under the 2-midnight rule will be reviewed under transparent standards that are known to providers. Such transparent standards should: (1) require contractors to continue beyond Step 4 (Expectation of Medically Necessary Hospital Services Spanning 2 Midnights) all the way through Step 6 (Case-by-Case Exception); and (2) specify what "patient history and comorbidities and current medical needs" or what "severity of signs and symptoms" justify and exception under the policy.

b. Stark Law Compliance Costs for Regulated Entities

The cost of compliance to health care organizations implicated under the physician self-referral law (Stark Law) is immense. Yet, it seems that when CMS performs its required regulatory impact statement about physician self-referral law, estimating the cost of compliance, it so underestimates the hours resources that will need to be spent reviewing and understanding the regulations as well as the organization's physician financial relationships to ensure they remain in compliance.

Over the last 25 years, multiple restructurings are undertaken every time CMS releases a new legal interpretation that expands the reach of designated health services, or limits the availability of an exception. In addition, parties to a transaction, such as a hospital acquisition, spend a lot of time and money in performing diligence reviews of every arrangement for procedural Stark Law violations like unsigned agreements, late payments, etc. This often results in cumbersome reviews of multiple arrangements, including old relationships since some of the exceptions CMS created inexplicably may only be used once in a three-year period.

Additionally, as a way to minimize risk, potential buyers often require self-disclosures to be made to CMS for procedural violations, like late signatures or expired agreements. This often requires the seller to place into reserve large escrows based on the total dollar amount of physician referrals, despite that fact that CMS self-disclosures are routinely settled on fractions of the Medicare quantification. Because of the lag in response time by CMS, these large sums of money can sit in escrow for many years while the parties await the results of CMS's review and

settlement of the disclosure. All of this comes at a time when providers should be spending more time and resources on providing quality, cost effective care. The millions of dollars held in escrow or spent to diligence procedural defects in contracts could be used to invest in health care infrastructure, such as enhanced electronic medical records, care coordination, or to increase staffing.

While CMS has reformed certain aspects of the Stark Law to reduce the burden and improve clarity regarding certain requirements within the exceptions, the analysis still requires a highly detailed review of the facts and circumstances of the arrangement and all available documentation. This may have reduced the number of self-disclosures that ultimately are made, but it does not alleviate the time and resource burden on providers to conduct an analysis of compliance with technical Stark requirements. Moreover, reducing the documentation burden associated with the Stark Law would be consistent with CMS's other initiatives to streamline patient service documentation requirements for physicians.[5] The burdensome cost of compliance first impacts group practices, many of which stopped providing one stop shopping for their patients because the regulatory requirements to do so were too onerous. Many have even ceased private practice altogether.

c. Expanding Stark Law Risk Sharing Exceptions to Account for Expansion Value-Based Care Arrangements

The Stark "risk sharing" exception was designed to remedy the unintended consequence of the Stark Law's impact on private pay relationships, but in its focus on "enrollees", MCOs and risk sharing, the exception is not sufficiently broad to free up innovation in the private pay context.

Innovative alternative payment arrangements such as ACOs and bundled arrangements do not necessarily have "enrollees", do not necessarily involve MCOs, and may not involve "risk sharing" in the traditional sense of the term. In spite of broad regulatory preamble language that is intended to be helpful, many health care stakeholders believe that the plain language of the exception cannot be met because they are participating in a capitated arrangement. We are also concerned that the exception does not protect incentives for care coordination and integration outside of these formalized arrangements.

The language at 42 CFR § 411.357(n) on "Compensation pursuant to a risk sharing arrangement" should be replaced with "Services to the extent they are subject to a risk sharing arrangement." Additionally, the advent of ACOs suggests that the application only to "enrollees of a health plan" is antiquated and the language should be replaced with the word "patients". To the extent CMS believes this would result in too broad an exception, the protection could be limited only to designated health services subject to the risk arrangement.

[5] *See* 83 Fed. Reg. 35704,35832-35848 (July 27,2018).

We also believe that the risk sharing exception should be moved to the General Exceptions at § 411.355 which apply to both ownership and compensation arrangements. Risk sharing arrangements largely eliminate the need for physician self-referral restrictions because they act inherently to control overutilization. As such, we think that the Stark Law protections available for risk sharing should apply to ownership interests as well as compensation engagements, and thus the exception should be moved from the exceptions related to compensation arrangements to the General exceptions portion of the regulation that applies to both ownership and compensation exceptions.

II. Enabling of operational flexibility, feedback mechanisms, and data sharing that would enhance patient care, support the clinician-patient relationship, and facilitate individual preferences

a. Design Opioid Prescriber Outlier Communications to Avoid Discouraging Clinically Appropriate Prescribing

On October 24, 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery & Treatment (SUPPORT) for Patients & Communities Act was enacted. Section 6065 of that law requires the Secretary to "establish thresholds, based on prescriber specialty and geographic area, for identifying whether a prescriber in a specialty and geographic area is an outlier prescriber of opioids as compared to other prescribers of opioids within such specialty and area." The Secretary must begin providing an Annual Notification to "outlier prescribers" no later than January 1, 2021.

We thank CMS for the opportunity to participate in listening sessions with specialty societies to determine how to define "specialty" and "geographic area". We also wish to emphasize that the eventual outlier notices that will be sent should be clearly identified to prescribers as informational only. CMS's data does not enable it to assess whether a particular prescribers outlier prescribing practices are justified by patient need or not. The context of the outlier notice is important to convey lest a prescriber become "spooked" by seeing themselves as an outlier and immediately change prescribing practices that were otherwise justified for fear of sanction. CMS must also make clear before commencing the outlier notices whether or not the notices will be accessible to state medical boards.

Finally, CMS should use its maximum administrative flexibility to establish outlier thresholds that are not bound solely by "specialty" or "geographic area" standards mentioned in the SUPPORT Act. As was made clear during listening sessions, meaningful differences in appropriate opioid prescribing practices are distinguished not by specialty or geographic area, but by type of practice, patient panel, type of pain (acute vs. chronic), and access to alternative pain management tools in the area.

b. Revisions to the Comprehensive Care for Joint Replacement Model (CJR)

We are aware and CMS and the Innovation Center are already contemplating reforms the CJR model for the next performance period beginning in 2021. We emphasize here some suggestions that remain relevant to our members as when we first shared them in 2016. Rulemaking next year for the new 2021 performance period will be an ideal opportunity to update and improve CJR.

CMS should allow physicians with requisite qualifications to participate in the CJR as episode initiators and conveners. The CJR model does not allow for physicians to manage care provided under the bundled payment. CMMI should utilize the practice allowed under the BPCI-A of allowing non-physician organizations to serve as "conveners". Such measures would make increase the leverage physicians have within facilities to ensure care coordination decisions are being made in the best interest of the patient.

c. Inflexible and Inappropriate Medical Necessity Standards for TJA

Requirements implemented by MACs to satisfy medical necessity for TJA procedures are incompatible with the clinical needs in some patient cases and can lead to painful delays in necessary care. For example, current TJA medical necessity requirements demand that three months of conservative treatment be attempted and failed before Medicare will covers the TJA procedure. In some cases, a physician can shortly determine that three months of conservative treatment for a patient will (1) be ineffective, (2) put the patient through undue suffering, (3) delay patient care, or (4) waste medical resources. In these cases the three month requirement can cause additional suffering for the patient and incur unnecessary expense for the Medicare program. We recommend that the Secretary provide for CMS/MAC consultations with the appropriate specialty organizations to establish criteria for medical necessity. These consultations will lead to refined coverage requirements to benefit Medicare beneficiaries who are harmed by inflexible Medical Necessity Requirements and include flexibility for cases where three months of conservative treatment is not an appropriate pre-requisite for coverage of TJA.

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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,

Michael P. Bolognesi, MD, President

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