AAHKS
AMERICAN ASSOCIATION OF HIP AND KNEE SURGEONS

OFFICE: 847.698.1200 • FAX: 847.698.0704 • WEB: aahks.org
9400 W Higgins Road, Suite 230 • Rosemont, IL 60018-4976

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VIA EMAIL

Alec Alexander, Deputy Administrator and Director
Center for Program Integrity
Centers for Medicare & Medicare Services
7500 Security Boulevard, Baltimore, MD 21244

RE: Request for Information: The Future of Program Integrity

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 strategies and tools to elevate CMS's program integrity efforts.

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:

QUESTION 4. PROVIDER EDUCATION

I. Background – Source and Extent of Provider Confusion over Reimbursement Rules

Our members have recent firsthand experience of the importance of provider education as it pertains to proper documentation and program integrity. When CMS removed total knee arthroplasty (TKA) from the Medicare inpatient only (IPO) list, effective January 1, 2018, it created significant confusion among providers and program auditors. However, it should have been expected when a high-volume procedure like TKA is removed from the IPO and made subject to the 2-midnight rule for the first time.

In finalizing this policy for 2018, CMS described the interplay between outpatient TKA and the 2 midnight rule under which CMS considers the standard TKA status for procedures that do not span 2 midnights to be *outpatient*, while case-by-case exceptions may be made only based on medical record support. Specifically, CMS stated that "an inpatient admission is *generally* appropriate . . . if the physician . . . admits the patient based on the expectation that the patient will need hospital care that crosses at least 2 midnights."[1] Further, CMS stated that exceptions to the 2-midnight rule are only available "on a case-by-case basis."[2]

In spite of the CMS articulation of this policy, our members experienced an unprecedented amount of confusion and inconsistent interpretation by hospitals. Some hospitals are interpreting the policy consistent with the discussions above. Others, however, are implementing internal policies that they will not submit claims for *any* exceptions to the 2-midnight rule for TKA procedures that span more than 24 hours, but less than 2 midnights. Other hospitals have expressed to surgeons their expectation that most TKAs for Medicare beneficiaries will be performed on an outpatient basis.

From our analysis, this confusion can be attributed to several reasons. 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 recently been confronted with hospital policies on the 2-midnight rule that are based upon procedures listed on the "rare and unusual exception" list, an outdated policy that CMS revised in 2016.

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.

Fourth, hospitals have dealt with procedures coming off the IPO list and newly being subjected to the 2-midnight rule, but never for a procedure of such high volume. 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.

[1] 82 FR 52525 (emphasis added).
[2] *Id*.

Finally, TKA 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. 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. Without such agreed upon clinical standards, there is a lack of any known standard for appropriate admission status review. We appreciate that CMS defers to clinicians to develop comprehensive patient selection protocols for outpatient TKA. While AAHKS is presently developing a position statement on clinically appropriate outpatient joint replacement, an industry-wide accepted standard does not yet exist.

II. CMS Should Provide Stakeholder Tailored Education For High Volume Procedure Changes e.g. codes removed from the IPO list

It is specifically in a situation such as this, when high volume procedures are subject to the 2 midnight rule for the first time, that extensive provider education by CMS is vital. As CMS is removing total hip arthroplasty (THA) from the IPO in 2020, this presents a fresh opportunity for CMS provider education to prevent the confusions experienced in 2018 for TKA.

AAHKS strongly encourages CMS to issue THA-specific Medicare Learning Network (MLN) guidance, like that issued specific to TKA,[3] to educate hospitals on the full extent of 2-midnight rule exceptions and how they interact with a procedure like THA. Such guidance should include the education on patient selection. In the experience of our members since 2018, many hospitals were unfamiliar with outpatient TKA selection criteria and the existence of a case-by-case exception policy to the 2-midnight rule. Perhaps THA could be included in revised MLN guidance addressing TKA and THA procedures under the 2-miniught rule.

a. Illustrative Case Studies and Additions to MLN Guidance on Arthroplasty Procedures Under the 2-Midnight Rule

The 2019 MLN Matters Guidance released in 2019[4] was appreciated as an attempt to broaden consistent understanding of the policy. The guidance has been helpful to many of our members. We also assume these guidelines will also ensure CMS's Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs) are conducting short stay admission reviews under consistent standards.

Nevertheless, we share additional clinical examples that should be added to the guidance to make it more relevant to the THA or TKA patients typically encountered by our members. We will consider the MLN guidance to contain problematic gaps until these clinical scenarios are all included. We last provided these suggestions to the CMS Center for Clinical Standards and

[3] See MLN Matters, *Total Knee Arthroplasty (TKA) Removal from the Medicare Inpatient-Only (IPO) List and Application of the 2-Midnight Rule*, SE19002 (Jan. 24, 2019).
[4] Id.

Quality (CCSQ) in May 2019 and have followed up multiple times. The guidelines should include clinical scenarios that illustrate the following different categories:

- Medical Record Documentation Supports Case-by-Case Exception for "Patient History and Comorbidities"
- Medical Record Documentation Supports Case-by-Case Exception for "Risk of Adverse Events"
- Medical Record Documentation Supports Case-by-Case Exception for "Current Medical Needs" Based on Complications that Arose During the Procedure

III. CMS Should Ensure Enforcement Guidance to BFCC-QIOs is Consistent with that Articulated to Providers

If the BFCC-QIOs are to have a meaningful impact in their provider education role under medical reviews of short stay THA and TKA admissions, 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.[5] 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, 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.

The removal of THA from the IPO in 2020 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.

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[5] *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.

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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

Michael J. Zarski, JD, Executive Director