

September 27, 2019

**VIA REGULATIONS.GOV FILING**

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1717-P  
P.O. Box 8013  
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 2020 (hereinafter referred to as “2020 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 2020 OPPS Proposed Rule:

**I. Total Hip Arthroplasty (“THA”) and the Inpatient-Only List (“IPO”) – Sec. IX.B.1**

CMS seeks to remove CPT code 27130, associated with THA, from the IPO list. As such, hospitals would be able to bill Medicare for THA performed during a hospital outpatient stay. Medicare would continue to reimburse hospitals for THA as an inpatient procedure if the patient’s admission spans at least two midnights. Our following comments on this topic (1) mirror feedback provided to CMS in 2017 in response to a request for information regarding

THA,<sup>1</sup> and (2) are informed by our member experiences and observations since the removal of TKA from the IPO in 2018.

*a. Criteria for Removal from the IPO*

CMS seeks comment on its conclusion that THA satisfies two of CMS's established criteria to identify procedures for removal from the IPO. Namely, Criteria 2 (The simplest procedure described by the code may be performed in most outpatient departments); and Criteria 3 (The procedure is already being performed in numerous hospitals on an outpatient basis).<sup>2</sup> We use this opportunity to repeat some of the responses to these questions that AAHKS offered in 2017.

Regarding Criteria 2 (Can the simplest procedure described by CPT code 27130 be performed in most outpatient departments?), it is the experience of AAHKS that there is no simple 27130 procedure. All are THA procedures with a moderate risk for complications. To date, very few outpatient departments combine excellent patient selection and education, tailored anesthetic techniques, well done surgery, good medical care, and exceptional post-operative care coordination. Very few hospitals have executed all of these elements to date.

Regarding Criteria 3, (The procedure described by CPT code 27130 is sufficiently related to or similar to other procedures that have already been removed from the IPO list), it is the experience of AAHKS that the CPT code 27130 is fundamentally different from other procedures that have been removed from the IPO. CMS removed CPT code 27447 from the IPO in 2018, but we consider THA and TKA similar only to the extent of risks associated with each in moving the site of surgery to an outpatient setting.

We consider it noteworthy that, according to CMS's analysis, THA *does not* satisfy Criteria 1, "Most outpatient departments are equipped to perform THA for Medicare beneficiaries."<sup>3</sup> This contrasts with CMS's earlier coming to the opposite conclusion that *TKA does satisfy* Criteria 1, that "most outpatient departments are equipped to perform TKA for Medicare beneficiaries."<sup>4</sup> This mirrors what AAHKS told CMS in 2016 regarding THA:

Most outpatient departments are not currently equipped to provide THA to Medicare beneficiaries. Execution of outpatient THA requires excellent patient selection and education, tailored anesthetic techniques, well done surgery, good medical care, and exceptional post-operative care coordination. Very few hospitals have executed all of these elements to date. We are not aware of any data to confirm the safety and efficacy of outpatient THA in Medicare beneficiaries.<sup>5</sup>

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<sup>1</sup> See AAHKS Comment Letter on 2018 Medicare OPPS Proposed Rule (Sept. 11, 2017).

<sup>2</sup> 84 FR 39524 (Aug. 9, 2019).

<sup>3</sup> *Id.*

<sup>4</sup> 82 FR 52522 (Nov. 13, 2017) (emphasis added).

<sup>5</sup> AAHKS Comment Letter on 2017 Medicare OPPS Proposed Rule (Sept. 6, 2016).

We will also use this opportunity to repeat what we have previously shared with CMS regarding IPO removal Criteria 4 and 5. For Criteria 4, “How often is the procedure described by CPT code 27130 being performed on an outpatient basis (either in a hospital outpatient department or ASC) on non-Medicare patients?” We are aware of individual surgeons who have presented their successful experience with outpatient THA at various professional symposia; it should be noted that, by default of the current rule being considered, those patients are not covered by Medicare. We are unaware of peer-reviewed literature identifying how often the procedure is performed on an outpatient basis regardless of population.

Criteria 5, “Would it 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 THA procedure as a hospital outpatient, which may or may not include a 24-hour period of recovery in the hospital after the operation? In a setting with excellent patient selection and education, tailored anesthetic techniques, well done surgery, good medical care, and exceptional post-operative care coordination, it may be clinically appropriate for some Medicare beneficiaries to have the option of a THA procedure as a hospital outpatient. Given the current state of peer-reviewed literature on this topic, guarantees should not be given to willing patients that same-day discharge will be accomplished in all cases.

*b. Postponing THA Removal for Continued TKA Outpatient Adoption*

Regarding removal of THA from the IPO, we prefer that more time is given for health providers and plans to familiarize themselves with proper patient selection for TKA in the outpatient setting before proceeding with removing THA from the IPO. The concept under the Medicare program of identifying whether a FFS patient is a candidate for an inpatient or outpatient surgical procedure is unrelated to considerations faced by surgeons in managing THA patients.

THA is a substantial surgery with the potential for significant complication and is generally performed in older patients with multiple age-related comorbidities. As a result, THA has traditionally been performed exclusively in the hospital setting with routine inpatient hospitalization. Improvements in techniques and perioperative care, along with recent financial pressures, have significantly reduced length of stay following THA and consequently have led to the consideration, and relatively rare performance, of outpatient THA. Importantly, criteria for safe discharge of a patient following THA does not differ between “inpatient” and “outpatient”. Both must have: (1) resumed an oral diet, (2) have adequate oral analgesia, (3) have intact urinary function, (4) be able to tolerate food and water, (5) be able to mobilize safely for the environment to which they going, (6) and have no intervening complication. These “criteria” are used to determine appropriate candidates for discharge after THA.

Nevertheless, if CMS proceeds with removing THA from the IPO, AAHKS acknowledges that in a setting with excellent patient selection and education, tailored anesthetic techniques, well done surgery, good medical care, and exceptional post-operative care coordination, it may

be clinically appropriate for some Medicare beneficiaries to have the option of a THA procedure as a hospital outpatient.

*c. CMS Correctly Identifies Essential Patient Selection Criteria for Outpatient THA*

Notwithstanding the comments above, we wish to thank CMS for its strong statements in the preamble on the importance of appropriate patient selection and the role of physicians in making that determination. The preamble language will be useful in physician interactions with facilities, payers and program auditors to ensure that any availability of THA in the outpatient setting is not abused.

We have stated in our Outpatient Joint Replacement position statement<sup>6</sup> 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 a THA policy change.

CMS is correct to note the following characteristics as indicative of good candidates for an outpatient THA procedure:

- Relatively low anesthesia risk and without significant comorbidities who have family members at home who can assist them
- Able to tolerate outpatient rehabilitation in either an outpatient facility or at home post-surgery<sup>7</sup>

On the other hand, CMS appropriately notes that “patients with multiple medical comorbidities, aside from their osteoarthritis, would more likely require inpatient hospitalization and possibly post acute care in a skilled nursing facility or other facility.”<sup>8</sup> CMS is also correct to emphasize that optimizing outpatient hip replacement outcomes depends upon protocols that “manage all aspects of the patient’s care, including the at-home preoperative and postoperative environment, anesthesia, pain management, and rehabilitation to maximize rapid recovery, ambulation, and performance of activities of daily living.”<sup>9</sup>

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<sup>6</sup> 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/>

<sup>7</sup> See 84 FR 39523.

<sup>8</sup> Id.

<sup>9</sup> Id.

*d. Essential Role of CMS in Educating Providers on Patient Selection Criteria for Outpatient THA*

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. It is not a risk but a certainty that some facilities will attempt to make outpatient the default admission status for all THA procedures. We can suspect whether this is 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.<sup>10</sup>

The TKA experience tells us that not all hospitals review essential Medicare regulatory preamble language. CMS statements included in the Proposed Rule preamble need to be made directly available to hospitals to ensure hospitals do not improperly pressure THA to be performed on outpatient status. Therefore, we strongly encourage CMS to issue THA-specific MLN guidance, like that issued specific to TKA,<sup>11</sup> to increase the likelihood of hospital awareness of CMS preamble statements on patient selection. It is a fact 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.

*e. Opportunity for Medicare Advantage Plans to Deny Coverage of Inpatient TKAs*

We also encourage CMS to monitor Medicare Advantage (“MA”) plans for concerning behavior following any removal of THA from the IPO. As we have shared previously with CMS, our members have concerning anecdotal experience of some 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 THA procedures as possible to the outpatient setting. Further, if any plan denies its enrollees the option of inpatient THA when medically appropriate, the plan will not be adhering to its obligation to make *all* Medicare FFS benefits available to its enrollees. In our member survey in 2018, 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.

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<sup>10</sup> [“The Unintended Impact of the Removal of Total Knee Arthroplasty from the Center for Medicare and Medicaid Services Inpatient Only List,”](#) *Journal of Arthroplasty*, December 2018.

<sup>11</sup> See MLN Matters, *Total Knee Arthroplasty (TKA) Removal from the Medicare Inpatient-Only (IPO) List and Application of the 2-Midnight Rule*, (Jan. 24, 2019).

*f. Impact on Comprehensive Care for Joint Replacement Model (CJR) and Other Bundled Payment Models*

We note that the OMB Office of Information and Regulatory Affairs is presently reviewing a draft proposed rule entitled, *Comprehensive Care for Joint Replacement Model Three Year Extension and Modifications to Episode Definition and Pricing* (CMS-5529-P).<sup>12</sup> If THA is removed from the IPO in 2020, CMS must incorporate corresponding alterations to the CJR, Bundled Payments for Care Initiative (BPCI) Advanced Models, and any other episode-based alternative payment models (“APMs”) that are based around DRG 469/470. Removing lower resource utilizing, healthier patients who are able to receive THA procedures on an outpatient basis from the denominators for cost and quality performance metrics will impact most members’ ability to achieve quality goals and target pricing.

**II. Short Inpatient Hospital Stays – Sec. X.B**

*a. Essential Role of CMS in Educating Providers on Patient Selection Criteria for Outpatient THA*

With the removal of TKA from the IPO in 2018, we have learned of the importance of CMS educating providers on the interaction of such procedures with the 2-midnight rule. This is especially the case for high volume procedures like TKA and THA, which dwarf in volume any other procedures previously removed from the IPO. It is also the case that most surgeons specializing in elective TKA and THA historically have no exposure or experience with the 2-midnight rule.

We wish to thank CMS for the extensive and clarifying overview of the 2-midnight rule guidance included in the Proposed Rule preamble.<sup>13</sup> CMS should continue to use any vehicle to educate stakeholders on the rule and its difference exceptions. This was made clear to AAHKS in 2018 following removal of TKA from the IPO when a number of our members were dealing 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. Again, we thank CMS for including this information.

AAHKS strongly encourages CMS to issue THA-specific MLN guidance, like that issued specific to TKA,<sup>14</sup> to educate hospitals on the full extent 2-midnight rule exceptions and how they interact with a procedure like THA. Such guidance could include the education on patient selection criteria discussed earlier. 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

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<sup>12</sup> OMB, OIRA Dashboard at [www.reginfo.gov](http://www.reginfo.gov). Last uploaded Sept. 23, 2019.

<sup>13</sup> See 84 FR 39526-39528.

<sup>14</sup> See MLN Matters, *Total Knee Arthroplasty (TKA) Removal from the Medicare Inpatient-Only (IPO) List and Application of the 2-Midnight Rule*, (Jan. 24, 2019).

exception policy to the 2-midnight rule. Perhaps THA could be included in revised MLN guidance addressing TJA procedures under the 2-midnight rule.

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

We appreciate CMS releasing the MLN Matters Guidance in 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, in light of the potential removal of THA from the IPO, we again share additional clinical examples that should be added to the guidance. These additional clinical examples are relevant for 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 Quality in May 2019. 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

*c. Program Audits of THA Under the 2-Midnight Rule*

CMS proposes to establish a one-year exemption from medical review referral to Recovery Audit Contractors (RACs) for noncompliance with the 2-midnight rule for any procedures removed from the IPO list in 2020. Specifically, these procedures would not be considered by the BFCC-QIOs in determining whether a provider exhibits persistent noncompliance with the 2-midnight rule for purposes of referral to the RAC. Nor would these procedures be reviewed by RACs for "patient status." CMS states that during this period, BFCC-QIOs would have the opportunity to review such claims in order to provide education for providers regarding compliance with the 2-midnight rule, but that "claims identified as noncompliant would not be denied with respect to the site-of-service under Medicare Part A."<sup>15</sup>

AAHKS believes that such an exemption period should last at least two years based on our experience with TKA. Perhaps a one-year exemption is appropriate for most procedures that are removed from the IPO, but two years is more appropriate for high volume procedures like

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<sup>15</sup> See 84 FR 39527.

arthroplasty where the surgeons do not have prior experience with the application of the 2-midnight rule.

Our members are still reporting ongoing confusion at some hospitals on this issue with TKA. Further, CMS's MLN guidance on TKAs under the 2 Midnight Rule was released only in January 2019 and still contains some gaps in relevant clinical scenarios. We may consider an exemption period of less than two years to be appropriate if and when MLN guidance with all relevant clinical scenarios is in wide-distribution.

*d. Consistent Guidance to BFCC-QIOs*

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.<sup>16</sup> 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.

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.

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<sup>16</sup> *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.

**III. Proposed Additions to the List of Ambulatory Surgery Center (ASC) Covered Surgical Procedures for CY 2020 – Sec. XIII.C.1.d.(1)**

*a. Clinically Appropriate Setting for TKA*

CMS seeks to add TKA to the ASC Covered Surgical Procedures List (CPL) in 2020. We thank CMS for emphasizing that “there is a small subset of Medicare beneficiaries who may be suitable candidates to receive TKA procedures in an ASC setting based on their clinical characteristics,” and that “physicians should continue to play an important role in exercising their clinical judgment when making site-of-service determinations, including for TKA.”<sup>17</sup> These are fundamental concepts that cannot be over-emphasized in guidance to stakeholders. We appreciate that CMS wishes “to ensure that Medicare Part B payment will only be made for TKA procedures performed in the ASC setting when that setting is clinically appropriate.”<sup>18</sup>

Further, it is imperative that ASCs are adequately prepared to handle the potential needs of this new population. This includes having necessary defined plans of care for each patient following TKA, as well as having formal arrangements for admission to a nearby hospital if the patient is unable to return directly home following the procedure.

*b. Reimbursement for TKA in the ASC Setting*

Upon review of the addenda accompanying the proposed rule, we note that CMS projects 2020 ASC reimbursement for TKA will be approximately \$8,639.97. As we have stated, AAHKS believes CMS should act slowly and carefully in expanding the settings and status where Medicare arthroplasty procedures may be performed and reimbursed. Nevertheless, we observe that if CMS’s goal is to make TKA available at ASCs, the proposed reimbursement rate may be low enough that many ASCs will decline to perform the procedure for FFS patients. CMS should closely evaluate whether that rate will succeed in accomplishing CMS’s goal of making TKA procedures in ASCs available to Medicare beneficiaries who are not enrolled in MA.

**IV. Making Hospital Standard Charges Transparent – Sec. XVI.**

In the Proposed Rule, CMS seeks to require hospitals to publicize their standard charges, including payer-specific negotiated charges, for all items and services online in a machine-readable format. CMS further proposes “consumer-friendly” transparency for gross standard charges and payer-specific negotiated charges for a limited set of “shoppable services.” Shoppable services are those that can be scheduled by a health care consumer in advance, such as joint arthroplasty.

AAHKS does not support any actions by the Medicare program to collect or disclose providers’ payer-specific negotiated rates. Making public what has historically been proprietary, confidential negotiated rates would limit providers’ leverage in negotiating private

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<sup>17</sup> 84 FR 39543.

<sup>18</sup> *Id.*

reimbursement rates with payers. Payers could identify the lowest rate disclosed between other payers and providers and set that low rate as a “ceiling” rate under a contract. While price transparency and surprise bills are an important issue, we believe solutions should be pursued that do not involve undermining the historic principles of achieving efficient prices through confidential negotiations with competing payers.

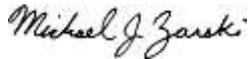
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AAHKS appreciates your consideration of our comments. If you have any questions, you can reach Mike Zarski at [mzarski@aaahks.org](mailto:mzarski@aaahks.org) or Joshua Kerr at [jkerr@aaahks.org](mailto:jkerr@aaahks.org).

Sincerely,



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