
MEMORANDUM

To: AAHKS **From:** Epstein Becker & Green, P.C.
Date: November 6, 2019
Re: **Summary of the CY 2020 HOPPS Final Rule**

The Centers for Medicare and Medicaid Services (“CMS”) released the calendar year (“CY”) 2020 Medicare Hospital Outpatient Prospective Payment System (“HOPPS”) and Ambulatory Surgical Center Final Rule (“Final Rule”) on November 1, 2019. In September 2019, AAHKS submitted comments in response to the HOPPS Proposed Rule (“Proposed Rule”). That comment letter is attached at the end of this document.

The following is a summary of CMS actions in the Final Rule related to those comments.

I. Total Hip Arthroplasty (“THA”) and the Inpatient-Only List (“IPO”)

a. Expansion of Reimbursement for THA to Outpatient Settings

CMS earlier sought public comments on its proposal to remove CPT code 27130 (THA) from the IPO list. CMS recounted its history of discussing possible removal of THA from the IPO since 2017, along with long history of comments from surgeons and stakeholders who believed that “given thorough preoperative screening by medical teams with significant experience and expertise involving hip replacement procedures, the THA procedure could be provided on an outpatient basis for some Medicare beneficiaries.”

CMS has now finalized the removal of CPT code 27130 from the IPO in 2020, allowing hospitals to bill THA as an inpatient or outpatient procedure. CMS directly acknowledged AAHKS’s concerns that THA did not satisfy the CMS criterion used to evaluate procedures for removal from the IPO list (criterion 2, the simplest procedure described by the code may be performed in most outpatient departments, and criterion 3, the procedure is related to codes that we have already removed from the IPO list).

Nevertheless, CMS still believes that THA meets the criteria. But CMS stressed that “the decision regarding the most appropriate care setting for a given surgical procedure is a complex medical judgement made by the physician based on the beneficiary’s individual clinical needs and preferences, as well as on the general coverage rules requiring that any procedure be reasonable and necessary.”

b. Patient Selection

CMS noted that commenters in support of removal from the IPO “recognized that with careful, appropriate selection, THA could be performed in the outpatient setting with few to no complications.” CMS also saw fit to repeat the comments of orthopaedic specialty societies regarding patient selection characteristics, “that good candidates for outpatient THA have relatively low anesthesia risk, do not have significant comorbidities, have in-home support, and are able to tolerate post-surgical outpatient rehabilitation in either an outpatient facility or in the home.” CMS continued,

“[T]he appropriate site of service for THA should be based on the physician’s assessment of the patient and tailored to the individual patient’s needs . . . [P]atients with a relatively low anesthesia risk and without significant comorbidities who have family members at home who can assist them may likely be good candidates for an outpatient THA procedure . . . On the other hand, patients that require a revision of a prior hip replacement, and/or have other complicating clinical conditions, including multiple co-morbidities such as obesity, diabetes, heart disease, may not be strong candidates for outpatient THA. We also recognize that elective THA, necessitated, for example, by osteoarthritis, for a generally healthy patient with at-home support is different than THA for a hip fracture that is performed on either an emergent or scheduled basis. While the former may be appropriate for outpatient THA if the physician believes that the patient may be safely discharged on the same or next day, the latter may be more appropriate for hospital inpatient admission.”

c. OPPS Payment Level for THA and TKA

For reimbursement under the OPPS, CMS assigned THA to C-APC 5115 (Level 5 Musculoskeletal Procedures) with status indicator “J1”. In addition, CMS removed anesthesia code 01214 (anesthesia for open procedures involving hip joint; THA) as a conforming change. 2020 OPPS APC payment rates are listed below. Note, these base rates do not reflect facility specific geographic adjustments that may raise or lower ultimate payment to a facility.

CPT	2018		2019		2020	
	Weight	Rate	Weight	Rate	Weight	Rate
27130	--	--	--	--	147.2988	\$11,899.38
27447	128.7225	\$10,122.22	134.7827	\$10,713.88	147.2988	\$11,899.38

d. Impact on Comprehensive Care for Joint Replacement (“CJR”) Model and Other Bundled Payment Models

In response to concerns that the removal of THA will impact CJR and the Bundled Payments for Care Initiative (“BCPI”), CMS believes that the CMS Innovation Center may

consider making changes to the CJR and BPCI models to address the removal of THA from the IPO list and the performance of THA procedures in the outpatient setting.

II. Application of the 2 Midnight Rule to THA and Potential Site-of-Service Denials

As is the case with TKA, removal of THA from the IPO list makes the procedure subject to the Medicare *2-midnight rule*. CMS describes the rules as a benchmark, under which “surgical procedures, diagnostic tests, and other treatments would be generally considered appropriate for inpatient hospital admission and payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation.”

CMS had proposed a 1-year exemption from the Beneficiary and Family Centered Care Quality Improvement Organizations (“BFCC-QIO”) referral to Recovery Audit Contractors (“RACs”) for “patient status” reviews of the settings for the procedures removed from the IPO list. CMS believed that a 1-year exemption would be an adequate amount of time to allow providers to gain experience with application of the 2-midnight rule to these procedures and the documentation necessary for Part A payment for those patients for which the admitting physician determines that the procedures should be furnished in an inpatient setting.

In response to comments from AAHKS and others, CMS announced in the Final Rule that it would extend from one year to two years, the length of the exemption from referrals to the RACs beginning in 2020 for all procedures recently removed from the IPO list. To be clear, under this exemption, BFCC-QIOs will continue to conduct initial medical reviews for both the medical necessity of THAs, and the medical necessity of the site-of-service for THAs. However, BFCC-QIOs will not deny claims solely for violation of the 2-midnight rule. CMS says that this BFCC-QIO review has the purpose of providing education for practitioners and providers regarding compliance with the 2-midnight rule. Further, during this 2-year period, BFCC-QIOs will not refer noncompliant claims to RACs that would otherwise be in a position to conduct far-ranging audits of facility billing to estimate the rate of improper billing and a corresponding collection amount.

CMS stated that they were persuaded by comments explaining that a 2-year exemption period will allow providers time to gather information on procedures newly removed from the IPO list to help develop patient selection criteria to identify which patients are, and are not, appropriate candidates for outpatient procedures and to develop related policy protocols.

CMS further explained that the case-by-case exception under the 2-midnight rule continues to allow for Part A payment to be made, on a case-by-case basis, where the physician does not expect the patient to remain in the hospital for at least two midnights but nonetheless determines that inpatient admission is necessary based on the clinical characteristics of the patient and that determination is supported by the medical record.

III. Adding TKA to the List of Ambulatory Surgery Center (“ASC”) Covered Surgical Procedures for CY 2020

CMS continues to promote site-neutrality, where possible, between the hospital outpatient department and ASC settings. CMS therefore is finalizing its proposal to add TKA to the ASC Covered Surgical Procedures List (“CPL”) in 2020. CMS states it made this change because it believes that “there are a small number of less medically complex beneficiaries that could appropriately receive the TKA procedure in an ASC setting and physicians should continue to play an important role in exercising their clinical judgment when making site-of-service determinations, including for TKA.”

a. Patient Selection

CMS stated that it “agree[s] with commenters that the majority of Medicare beneficiaries would not be suitable candidates to receive TKA procedures in an ASC setting. Factors such as age, comorbidity, and body mass index are among the many factors that must be taken into account to determine if performing a TKA procedure in an ASC would be appropriate for a particular Medicare beneficiary.”

CMS notes that in 2016 approximately 800 TKA procedures were performed in ASCs on Medicare Advantage enrollees. CMS believes that TKA is “still predominantly performed in the inpatient hospital setting.” Based on professional claim data from 2018, 82% of TKAs performed on Medicare FFS beneficiaries were performed in the inpatient setting.

b. Reimbursement for TKA in the ASC setting

CMS has established a separate ASC reimbursement methodology for “device intensive procedures” like TKA. Under this methodology, for the device-related portion of procedure costs, the ASC is paid the same rate that would be reimbursed for the device under OPPS. For the remaining costs of the procedure, the service portion, CMS pays the ASC using the standard ASC methodology, which reimburses below the level of OPPS reimbursement. CMS does this downward adjustment to account for the lower overhead of an ASC compared to a hospital outpatient department. The ASC adjustments overall tend to be approximately 60% of Medicare OPPS rates. Then, to account for geographic differences in input prices, CMS adjusts the labor portion of each facility’s ASC rate by the local hospital wage index. CMS does not adjust the nonlabor portion of the ASC rate.

The final 2020 APC base rate for TKA is listed below. The payment rate for CPT code 27429 (Reconstruction, knee) is provided for comparison purposes.

CPT	2018		2019		2020	
	Weight	Rate	Weight	Rate	Weight	Rate
27447	--	--	--	--	180.3081	\$8,609.17
27429*	111.2415	\$5,069.83	151.2694	\$7,041.74	224.0958	\$10,717.80

c. Impact on Comprehensive Care for Joint Replacement (“CJR”) Model and Other Bundled Payment Models

CMS states that because the number of less medically complex TKA patients that could appropriately receive TKA in an ASC setting is “small”, there would not be a “substantial impact on the patient-mix for the BPCI Advanced or the CJR models.

IV. Making Hospital Standard Charges Transparent

In the Proposed Rule, CMS proposed to require hospitals to make public their standard charges (both gross charges and payer-specific negotiated charges) *for all items and services* online in a machine-readable format. CMS believes the information and format is most useful for developers who could use these data in consumer-friendly price transparency tools, or who may integrate the data into electronic medical records and shared decision making tools at the point of care.

CMS received over 1,400 comments and intends to summarize and respond to public comments on the proposed policies in a separate Final Rule on price transparency later this winter.

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,¹ 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).² 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."³ 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."⁴ 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

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

² 84 FR 39524 (Aug. 9, 2019).

³ *Id.*

⁴ 82 FR 52522 (Nov. 13, 2017) (emphasis added).

any data to confirm the safety and efficacy of outpatient THA in Medicare beneficiaries.⁵

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.

⁵ AAHKS Comment Letter on 2017 Medicare OPFS Proposed Rule (Sept. 6, 2016).

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 statement⁶ 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-surgery⁷

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.”⁸ 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.”⁹

⁶ 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/>

⁷ See 84 FR 39523.

⁸ Id.

⁹ 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.¹⁰

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,¹¹ 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.

¹⁰ [“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.

¹¹ 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).¹² 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.¹³ 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,¹⁴ 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

¹² OMB, OIRA Dashboard at www.reginfo.gov. Last uploaded Sept. 23, 2019.

¹³ See 84 FR 39526-39528.

¹⁴ 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).

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 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."¹⁵

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

¹⁵ See 84 FR 39527.

like arthroplasty where the surgeons do not have prior experience with the application of the 2-minight 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.¹⁶ 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.

¹⁶ *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.”¹⁷ 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.”¹⁸

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

¹⁷ 84 FR 39543.

¹⁸ *Id.*

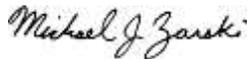
reimbursement rates with payers. Payers could identify the lowest rate disclosed between other payers and providers and set that low rate as a “ceiling” rate under a contract. While price transparency and surprise bills are an important issue, we believe solutions should be pursued that do not involve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

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

cc: **Demetrios Kouzoukas**, Principal Deputy Administrator for Medicare and Director, Center for Medicare
Elizabeth Richter, Deputy Director, Center for Medicare
Kate Goodrich, Director, Center for Clinical Standards and Quality and CMS Chief Medical Officer
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Amy Bassano, Acting Deputy Administrator for Innovation and Quality and Director, Center for Medicare & Medicaid Innovation