AAHKS
AMERICAN ASSOCIATION OF HIP AND KNEE SURGEONS

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March 21, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Verma:

RE: REMOVAL OF TOTAL KNEE ARTHROPLASTY FROM THE MEDICARE INPATIENT ONLY LIST

We write to bring to your attention several adverse impacts stemming from confusion over the implementation of the new Medicare policy removing total knee arthroplasty ("TKA") procedures from the Medicare inpatient-only list ("IPO"). We wish to outline how the ongoing confusion is affecting providers, plans and patients, and to suggest immediate steps within the authority of the Centers for Medicare & Medicaid Services ("CMS") that would significantly mitigate the current problems.

The American Association of Hip and Knee Surgeons ("AAHKS") is the foremost national specialty organization of more than 3,400 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.

AAHKS is sharing these concerns now in order to (1) request that CMS more broadly publicize its intended TKA policy for providers and plans who do not currently understand its subtleties, and (2) inform CMS's current development of the 2019 Medicare Outpatient Prospective Payment System ("OPPS") Proposed Rule.

I. New Medicare Policy for TKA Reimbursement

a. Removal of TKA from IPO List

Following public notice and comment on the 2018 Medicare OPPS Proposed Rule, CMS finalized its proposal to remove TKA from the Medicare IPO list, effective January 1, 2018, allowing the procedure to be reimbursed as an outpatient or inpatient procedure.[1] CMS's rationale is its stated belief that TKA now satisfies CMS's previously established criteria for removing a procedure from the IPO list. Namely, (1) most outpatient departments are

[1] 82 FR 52522 (Nov. 13, 2017).

equipped to perform TKA for Medicare beneficiaries; (2) the simplest procedure described by the code may be performed in most outpatient departments; and (3) the procedure is already being performed in numerous hospitals on an outpatient basis.[2]

b. AAHKS Comments on TKA Change

AAHKS commented on CMS's proposal to remove TKA from the Medicare IPO list in the 2018 Medicare OPPS Proposed Rule, stating 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 TKA procedure as a hospital outpatient."[3] Further, CMS stated that it expects providers to develop evidence-based patient selection criteria to identify candidates for outpatient TKA, and we responded that when surgeons are free from external pressures to make a judgment, in the best interests of the patient, on the appropriate site for surgery, such criteria will be followed.

II. Critical Interaction Between TKA and the "2-Midnight Rule"

a. Application of 2- Midnight Rule through Removal of TKA from the IPO List

By removing TKA from the IPO List, the procedure becomes subject to the Medicare "2-midnight rule,"[4] under which, in general, if an admitting physician expects a beneficiary to require hospital care that spans at least 2 midnights and admits the beneficiary based on that expectation, the admission is appropriate for payment as an inpatient procedure under the inpatient prospective payment system ("IPPS"). Otherwise, the admission is likely to be considered, and reimbursed as, an outpatient procedure.

b. Trend of TKA Clinical Advances Appear to Place a Significant Volume of the Procedure in a 2-Midnight Rule "Gray Area"

On its face, the 2-midnight rule would be difficult to apply consistently to TKA because many of the TKAs performed on Medicare beneficiaries span slightly less or slightly more than 2 midnights. Since the inception of TKA, there have been many millions of patients who have been admitted to hospitals for their post-surgical care. These patients traditionally stayed in the hospital for 3-5 days and were often discharged to an inpatient rehabilitation or skilled nursing setting following their inpatient admission.

Until quite recently, the percent of patients that were institutionalized for over ten days, in hospital and in post-acute care, approached 50 percent. Patients who were more robust, had

[2] See *id*.
[3] AAHKS Comment Letter on 2018 Medicare OPPS Proposed Rule, pg. 2 (Sept. 11, 2017)
[4] Procedures on the IPO List are not subject to the 2-midnight rule.

few medical comorbidities, and/or who had reliable social support were more likely to be discharged to home with home care.

A number of clinical advances have made the care of patients facing TKA safer and more efficient. These include, among others, better pain management, opioid sparing protocols, better blood management protocols, improved surgical techniques, improved patient preparation and selection for surgery, improved patient and family education and engagement, and better infection prevention strategies. Hospitals and physicians have also invested significant time and resources into preoperative evaluation and treatment of modifiable risk factors, use of care navigators, longer coverage by physical therapists in order to help facilitate discharge, etc.

Consequently, patients are now convalescing more quickly following TKA and are finding it easier to return to their homes more reliably. Rather than being away from home for 10-14 days, as in the recent past, many can receive resource intensive interventions that span 1 to 3 days as an inpatient and can then be ready to safely continue their recovery in a non-clinical setting. This has been a great advance for patients and it would be unfortunate if the result of these advances is to drive Medicare beneficiaries into an outpatient setting when it is not clinically appropriate.

c. Exceptions Exist to the 2-Midnight Rule for "Practitioner Judgment"

While the potential for earlier discharges are an advance for Medicare beneficiaries, it does not automatically follow that all Medicare TKA admissions that span less than 2 midnights are clinically appropriate for outpatient admission. First, as CMS notes, the 2-midnight rule is not a hard and fast rule, but exists "to provide *guidance* on when an inpatient admission would be appropriate for payment under Medicare Part A."[5]

Second, recognizing the need for exceptions to accommodate a physician's clinical judgment about the most appropriate site of care for a beneficiary, CMS implemented an exception standard to the 2-midnight rule that states: "Where the admitting physician expects a patient to require hospital care for only a limited period of time that does not cross 2 midnights, an inpatient admission may be appropriate for payment under Medicare Part A based on the clinical judgment of the admitting physician and medical record support for that determination."[6]

[5] 82 FR 52,523 (Nov. 13, 2017) (emphasis added).

[6] 42 C.F.R § 412.3(d)(3). *See also*, Medicare Program Integrity Manual Ch. 6 § 6.5.2 (E)(3), "For hospital stays that are expected to span less than 2 midnights, an inpatient admission may be payable under Medicare Part A on a case-by-case or individualized basis if the medical record supports the admitting physician/practitioner's judgment that the beneficiary required hospital care on an inpatient basis despite the lack of a 2-midnight expectation"; and 82 FR 52,532 (Nov. 13, 2017), "If the physician expects the beneficiary to require hospital care that spans at least 2 midnights and admits the beneficiary based upon that expectation, the case is appropriate for payment under the IPPS."

d. CMS's Stated Policy is that the 2-Midnight Rule Should Cause Minimal Change in Current TKA Admission Status

We appreciate that the exception for practitioner judgment exists to protect the many Medicare beneficiaries for whom the TKA procedure is not expected to span more than 2 midnights but for whom an outpatient admission is not clinically appropriate. CMS explicitly notes, notwithstanding the 2-midnight rule,

> We continue to believe that the decision regarding the most appropriate care setting for a given surgical procedure is a complex medical judgment ***made by the physician based on the beneficiary's individual clinical needs and preferences*** and on the general coverage rules requiring that any procedure be reasonable and necessary.[7]

The practitioner judgment exception policy, combined with the fact that TKA is ***not*** a minor surgical procedure, accounts for CMS's statements that the beneficiaries able to receive a TKA on an outpatient basis are only "a subset of Medicare beneficiaries."[8] Similarly, CMS "do[es] not expect a significant volume of TKA cases currently being performed in the hospital inpatient setting to shift to the hospital outpatient setting as a result of removing [TKA] from the IPO list."[9] Therefore, the application of CMS guidance and policy statements related to the 2-midnight rule leads to the following conclusions: (1) for future TKAs that are expected to span more than 2 midnights, there is no change in policy related to inpatient admission status; (2) for future TKAs that are expected to span more than 24 hours, but less than 2 midnights, the practitioner judgment exception policy exists in order to allow the physician to select the most appropriate care setting base on the beneficiary's individual clinical needs.[10]

III. Unanticipated Impacts of Change in TKA Policy

a. Hospitals Assuming Most TKAs Must be Outpatient

In spite of the CMS articulation of this policy in the preamble to the 2018 Medicare OPPS Final Rule, our members report 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 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.

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[7] 82 FR 52,523 (emphasis added).
[8] 82 FR 52,524.
[9] *Id*.
[10] There are varying estimates among providers of what portion of Medicare TKA patient admissions span more than 24 hours, but less than 2 midnights.

This confusion could stem from 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, 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, which CMS abandoned prior to 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.

b. Significant Alteration to Bundled Payment Metrics

We have raised with appropriate officials within the Center for Medicare & Medicaid Innovation ("CMMI") the impact this policy change may have on our members participating in CMMI episode-based alternative payment models ("APMs") that are based around DRG 469/470. Removing lower resource utilizing, healthier patients who are able to receive TKA 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. The breadth of that impact will depend on whether hospitals recognize the exceptions to the 2-midnight rule laid out by CMS for TKA.

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

Also, we have shared with appropriate officials at CMS several concerning examples of Medicare Advantage ("MA") plans citing the removal of TKA from the IPO list as a basis to initially deny coverage for *all* TKA inpatient admissions. Absent appropriate oversight, some MA plans will continue to use any pretext based on a cursory reading of CMS policy to drive as many TKA procedures as possible to the outpatient setting.

d. Corresponding Impact on Patient Care

A safe discharge following a TKA procedure is expected to occur when a patient has an acceptably low risk of developing life-threatening complications, including, confusion, delirium, fall, wound complication, bleeding, cardiovascular instability, urinary retention and ileus. Although current advanced care protocols have reduced the incidence of many of these adverse events, predicting which patient may experience one or more of these adverse events is generally not possible. Consequently, we encourage our members to only utilize an outpatient designation for a patient when doing so does not pose the risk of making the occurrence of, or failure to detect, such an adverse event more likely. Pressure from payers or hospitals to the contrary can place beneficiaries at risk.

IV. Readily Available CMS Options to Remedy Provider and Payer Confusion

a. Promotion and Clarification of Existing Policy to Hospitals, Surgeons, and MA Plans

A significant portion of the present confusion and conflicting interpretations could be resolved immediately by CMS through wider dissemination of the currently stated intent of the policy. We request that CMS use its existing tools of the Medicare Learning Network, Open Door Forums, trade press outreach, and MAC issuances to ensure physicians, hospitals, and MA plans understand key elements of how the IPO list change and 2-midnight rule will impact TKA. Namely,

- The decision regarding the most appropriate care setting for a given surgical procedure is a complex medical judgment made by the physician
- Patients with less medical complexity who may receive this procedure safely on a hospital outpatient basis are a subset of Medicare beneficiaries
- Where the admitting physician expects a patient to require hospital care for only a limited period of time that does not cross 2 midnights, an inpatient admission may be appropriate for payment under Medicare Part A based on the clinical judgment of the admitting physician and medical record support for that determination
- CMS does not expect a significant volume of TKA cases currently being performed in the hospital inpatient setting to shift to the hospital outpatient setting as a result of removing TKA from the IPO list

CMS should make clear to MA plans that the IPO list should not be used to justify coverage policies that presume that the majority of MA enrollees would receive any TKA procedures as outpatients. Rather, MA plans are obligated to provide the same Parts A & B benefits to enrollees as are received by fee-for-service beneficiaries, and it is the expectation of CMS that outpatient TKA will be the exception and not the rule.

b. Guidance to Quality Improvement Organizations Consistent with CMS Standards in 2018 Medicare OPPS Final Rule

We appreciate that CMS defers to clinicians to develop comprehensive patient selection protocols for outpatient TKA. We note, however, some apparent inconsistencies in CMS guidance on whether inpatient or outpatient TKA is presumed to be the standard from which exceptions are made.

On the one hand, CMS statements imply that inpatient status will be the standard status for TKA for Medicare beneficiaries. As noted above, CMS "do[es] not expect a significant volume of TKA cases currently being performed in the hospital inpatient setting to shift to the

hospital outpatient setting as a result of removing [TKA] from the IPO list."[11] Also, CMS expects providers will develop patient selection protocols to "appropriately *identify these patients* . . . who are able to receive this procedure safely *on a hospital outpatient basis*."[12] This implies that, regardless of the 2-midnight rule, CMS considers the standard TKA status to be *inpatient*, while protocols will identify the patients who are an exception and may be safely treated as *outpatients*.

On the other hand, CMS's discussion of the 2-midnight guidance implies that CMS considers the standard TKA status for procedures that do not span 2 midnights to be outpatient, while only case-by-case exceptions may be made based on medical record support. Specifically, CMS states 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."[13] Further, CMS states that exceptions to the 2-midnight rule are only available "on a case-by-case basis."[14] This means that, although the physiology of Medicare patients did not change from December 31, 2017 to January 1, 2018, nor did the standard of care, inpatient status for a significant portion of TKA patients changed from being the only available option, to now quixotically being considered an exception that will only be granted on a case-by-case basis.

If CMS does not expect a significant shift of TKA cases from inpatient to outpatient, this implies that the capacity of Medicare Quality Improvement Organizations ("QIOs") may be strained when reviewing, on a case-by-case basis, every TKA that spans more than 24 hours but less than 2 midnights.

We believe these inconsistencies can be resolved through guidance to the QIOs to recognize the unique nature of TKA under the 2 midnight rule. First, QIOs should be reminded that many orthopaedic surgeons have little experience with treating TKA patients in outpatient departments or meeting documentation standards to justify an inpatient status. Second, QIOs should consider that, in TKAs, they will be faced with a large volume of intense surgical procedures on medically complex patients.

Therefore, in reviewing TKA status under the new Medicare policy, QIOs should assume inpatient status as the default status and, rather, review whether or not the medical record justifies outpatient status for that particular patient. Namely, QIOs should consider if the patient is younger, less medically complex, with no expected need for skilled post-acute care following surgery, and minimal risk of adverse events following discharge.

[11] 82 FR 52534.
[12] *Id*. (emphasis added).
[13] 82 FR 52525 (emphasis added).
[14] *Id*.

V. Study 1 to 2 Years of Impacts on TKA Before Proposing to Remove Total Hip Arthroplasty from the IPO List

Finally, in light of the confusion and misinterpretation within the health care industry over the removal of TKA from the IPO list, we believe CMS should postpone any plans to remove total hip arthroplasty ("THA") from the IPO list in 2019 or 2020. CMS must review an entire year's worth of claims data under this TKA policy and wait for input from providers who have experienced at least a full-year of the TKA policy. Any decisions that CMS makes regarding THA removal from the IPO list should be made only after assessing the full impact of the TKA removal once the entire health industry comes to a uniform interpretation of the policy.

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

Sincerely,

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