AAHKS
AMERICAN ASSOCIATION OF HIP AND KNEE SURGEONS

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October 5, 2020

VIA REGULATIONS.GOV FILING

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1736-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 and Quality Reporting Programs; etc.

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 2021 (hereinafter referred to as "2021 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 2021 OPPS Proposed Rule:

I. CY 2021 Proposal to Eliminate the Inpatient-Only ("IPO") List – Sec. IX.B.2

CMS considers the IPO list no longer necessary and proposes to eliminate it by phasing it out over three years, beginning with the removal of approximately 300 musculoskeletal-related services from the IPO list in 2021. We wish to endorse the comments of our colleagues at the American Association of Orthopaedic Surgeons regarding this proposal. We, too, have grave concerns over unanticipated secondary and tertiary impacts on care when regulatory standards

for appropriate site of service are removed. We wish to share additional impacts from this proposal that CMS has not considered. AAHKS speaks with some authority on this as total hip arthroplasty (THA) and total knee arthroplasty (TKA) were the most recent high-volume procedures removed from the IPO list.

We appreciate that CMS says the right things regarding the physician's role in determining the clinically appropriate site of service:

> [T]he physician should use his or her clinical knowledge and judgment, together with consideration of the beneficiary's specific needs, to determine whether a procedure can be performed appropriately in a hospital outpatient setting or whether inpatient care is required for the beneficiary, subject to the general coverage rules requiring that any procedure be reasonable and necessary.[1]

In reality, however, the physician does not make this determination alone. It is our experience that when high-volume, high-value procedures are removed from the IPO list, many commercial payers and hospitals make rules establishing outpatient status as the assumed baseline status for such procedures. Many commercial payers specifically make outpatient status the baseline because they prefer reimbursing care at a lower-cost setting.

Many hospital compliance departments make outpatient status the baseline for fee-for-service (FFS) Medicare beneficiaries. This may be done for administrative simplicity, to minimize the risk of violating the 2-midnight rule, or for some other reason. Such shifts to outpatient status by hospitals following the removal of TKA from the IPO list were evident in a recent AAHKS member survey where a majority of respondents reported that their hospitals were making outpatient status the default admission status for TKA procedures.[2] In these scenarios, it falls upon the physician to advocate for an exception when clinically appropriate. Therefore, a proposal to eliminate the IPO list means that many physicians anticipate the burden of more time spent fighting with payers and facilities over the most clinically appropriate admission status for a patient.

In recent conversations, CMS leadership asked AAHKS for suggestions as to what CMS can do to minimize these likely impacts. Based on our members' experience dealing with the removal of TKA from the IPO, we have come to learn of the essential role *CMS must play in educating stakeholders on the 2-midnight rule, its exceptions, and outpatient selection criteria*. It is not a risk—but a certainty—that some facilities will attempt to make outpatient the default admission status for many procedures. Our experience is that not all hospitals review the essential physician-centric regulatory preamble language in the OPPS. In fact, a number of our members dealt with hospital legal departments that had not updated their 2-midnight rule compliance

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[1] 85 Fed. Reg. 48772, 48909 (Aug. 12, 2020).

[2] Adolph J. Yates et al, *The Unintended Impact of the Removal of Total Knee Arthroplasty from the Center for Medicare and Medicaid Services Inpatient Only List*,13 J. OF ARTHROPLASTY 12, 3602-06 (Dec. 2018).

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.

Therefore, we strongly encourage CMS to issue more guidance, like that issued specific to TKA,[3] 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 of advocating and educating their hospital billing and compliance departments on Medicare guidance on patient selection.

We appreciate CMS releasing the MLN Matters Guidance in an attempt to broaden consistent understanding of the policy. Nevertheless, in light of the removal of THA from the IPO, we again ask that additional clinical examples be added and that the guidance be extended to THA in addition to TKA. 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. Our suggestions are included in redline in the attached **APPENDIX 1.**

II. Proposed Medical Review of Certain Inpatient Hospital Admissions Under Medicare Part A for CY 2021 and Subsequent Years – Sec. X.B

For 2021 and beyond, CMS proposes to continue the 2-year exemption from site-of-service claim denials, Beneficiary and Family Centered Care-Quality Improvement Organization (BFCC-QIO) referrals to Recovery Audit Contractors (RACs), and RAC reviews for "patient status"—that is, site-of-service or the 2-midnight rule—for procedures that are removed from the IPO list. CMS seeks comment on whether that time period of two years continues to be appropriate, or if a longer or shorter period may be more warranted.

AAHKS welcomes at least two years of suspension and further believes that a longer exemption period is warranted for some procedures. While a shorter 2-year exemption might be appropriate for most procedures removed from the IPO list, the experience of our members with the removal of THA and TKA from the IPO list strongly suggests that more than two years is more appropriate for certain procedures. This is because with some high-volume subspecialty procedures, like arthroplasty, surgeons would not have prior experience with the application of the 2-midnight rule because they previously dealt solely with procedures on the IPO list. We also wish to make clear that the exemption period is not solely for the benefit of educating physicians but also to educate facilities and their compliance departments on the totality of the 2-midnight rule *and all of its exceptions*. We have been surprised by repeated evidence and

[3] *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).

statements on the parts of various hospital compliance departments or CMS contractors who are unaware of the totality of the 2-midnight rule as laid out by CMS in section X.B.2.[4]

Further, 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 QIOs use the same standards 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 construe case-by-case exceptions. Specifically, what "patient history and comorbidities and current medical needs" or what "severity of signs and symptoms" justify an exception under the policy?

As shared with CMS CCSQ and in prior years' comment letters, 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 the 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.

III. Additions to the List of ASC Covered Surgical Procedures – Sec. XIII.C.1.d

a. Clinically Appropriate Setting for THA

CMS seeks to add THA to the ASC Covered Procedures List (CPL) in 2021. We thank CMS for emphasizing that it "believe[s] that physicians play an important role and should be able to exercise their clinical judgment in making site-of-service determinations."[6] This is a fundamental concept that cannot be over-emphasized in guidance to stakeholders. It is imperative that any ASCs preparing to perform THA on Medicare beneficiaries are adequately prepared to handle the potential needs of this new population. This includes having necessary defined plans of care for each patient following THA, as well as having formal arrangements for admission to a nearby hospital if the patient is unable to return directly home following the procedure.

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[4] 85 Fed. Reg. 48772, 48937 (Aug. 12, 2020).

[5] The *BFCC QIO 2 Midnight Claim Review Guideline* includes a date stamp "Revised May 3, 2016 1:47pm", yet it lacks a title, a citation to statutory or regulatory authority, and any attribution to CMS. We recommend these elements be added so the document is given more deference and consideration by providers.

[6] 85 Fed. Reg. 48772, 48956 (Aug. 12, 2020).

b. CMS Must Clarify its Assumptions Regarding the Expected ASC THA Patient Population

We ask CMS to clarify its assumptions—and the basis of those assumptions—regarding the portion of the annual Medicare THA population that will shift to outpatient sites of service or to ASCs. When adding TKA to the ASC-CPL in 2020, CMS said 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."[7] This year, regarding THA, CMS says "there are *at least a subset* of Medicare beneficiaries who may be suitable candidates to receive THA procedures in an ASC setting based on the beneficiaries' clinical characteristics."[8]

We read this to mean that CMS expects a larger proportion of Medicare THA patients to be suitable candidates for ASCs compared to TKA patients. Is this because of differences in recovery times between the two clinical procedures or ASC preparedness for the two procedures? Or does this mean CMS now believes that the population of Medicare TKA patients who are suitable candidates for ASCs has also grown beyond a "small subset" to "at least a subset"?

We sought similar clarification in our comments to the 2021 CJR Proposed Rule, when we noted that in the CJR Proposed Rule, CMS stated "[o]ur analysis of this 2018 claim data shows that approximately *25 percent* of TKAs are being performed in the outpatient setting, annually."[9] This was in contrast to CMS's statement in the 2020 Medicare OPPS Proposed Rule that "[w]e note that TKA procedures were still predominantly performed in the inpatient hospital setting in CY 2018 (*82 percent of the time*) based on professional claims data."[10] We sought explanation of why there were two different inpatient TKA figures based on 2018 claims data.

Since CMS first proposed removing TKA from the IPO list, AAHKS prioritized tracking the changes in TJA site of services practices and the impact of Medicare policy on those practices. Medicare claims data should be the best source of information to illustrate the change in site of services practices. This information is relevant to patients, surgeons, and hospitals and ASCs, so we again ask CMS to share how TJA site of services has changed since 2017 and the basis for its beliefs regarding the portion of THA patients that are suitable ASC candidates.

c. Reimbursement for THA in the ASC Setting

Upon review of the addenda accompanying the Proposed Rule, we note that CMS projects 2021 ASC reimbursement for THA will be approximately $8,923.98. As we have stated, AAHKS

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[7] 84 Fed.Reg. 39398, 39543 (Aug. 9, 2020).
[8] 85 Fed. Reg. 48772, 48958 (Aug. 12, 2020).
[9] 85 Fed. Reg. 10516, 10518 (Feb. 24, 2020) (emphasis added).
[10] 84 Fed. Reg. 39398, 39543 (Aug. 9, 2019) (emphasis added).

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 THA available at ASCs, the proposed reimbursement rate may be so low that many ASCs will decline to perform the procedure for FFS patients. Instead, we believe that both THA and TKA warrant assignment to a higher APC level. A seventh musculoskeletal APC level would account for the greater level of preparation requisite to the successful performance of these procedures in an outpatient setting, such as discharge planning, care coordination, and acquiring durable medical equipment.

IV. Alternative Procedures for Adding Procedures to the ASC-Covered Procedures List – Sec. XIII.C.2

CMS seeks comments on two proposals for a new process by which CMS will consider adding procedures to the ASC-CPL. Under Alternative One, CMS would establish a public nomination process to add new procedures to the ASC–CPL. This process would involve soliciting recommendations from external stakeholders—like medical specialty societies and other members of the public—for procedures that may be suitable candidates to add to the ASC–CPL. AAHKS appreciates the role of medical specialty societies that CMS envisions in this approach. This would be an improvement from the current process to allow specialty societies to have a greater and more formal role in determining which procedures may be safely performed in an ASC.

However, in light of our experience with how commercial insurance plans may manipulate the public nomination process for misvalued codes, AAHKS can support Alternative One only if it includes the following standards:

- All nominations from public stakeholders must be made public upon receipt by CMS on March 1st. Experts, such as specialty societies, may need more than the 60-day comment period afforded by the annual rulemaking cycle in order to evaluate the submission and formulate a thorough response
- Public release must include releasing all materials submitted by the stakeholder in support of the nomination. This is the only way for specialty societies to fully respond to the information that is being submitted to CMS
- CMS must make clear how it will evaluate competing claims and data regarding nominations. In the Proposed Rule's preamble, CMS refers to evaluating procedures based on whether they satisfy statutory and regulatory standards. CMS also proposes parameters for nominations.[11] But how will CMS resolve competing data when evaluating certain criteria, such as "[a]*re resources and providers required for intervention generally available at nearby facilities for*

[11] 85 Fed. Reg. 48772, 48959 (Aug. 12, 2020).

intervention"?[12] This must be made clear by CMS so that specialty societies understand what information will be persuasive with CMS.

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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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cc: **Demetrios Kouzoukas**, Principal Deputy Administrator for Medicare and Director, Center for Medicare
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[12] *Id.* at 48960.

APPENDIX A

MLN Matters (SE19002) Total Knee Arthroplasty (TKA) Removal from the Medicare Inpatient-Only (IPO) List and Application of the 2-Midnight Rule

AAHKS Proposed Refinements

PROVIDER TYPE AFFECTED

This MLN Matters Special Edition Article is intended for hospital providers that submit hospital inpatient or outpatient claims for Total Knee Arthroplasty (TKA) procedures. The Two-Midnight Rule impacts acute-care hospitals, inpatient psychiatric facilities, long-term care hospitals (LTCHs), and Critical Access Hospitals (CAHs). CMS recognizes that such facilities may vary in their billing for TKAs.

CMS recognizes that a MLN article on the 2-Midnight Rule has already been published and can be found at the following link: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM10080.pdf

This article is distinguished by its focus on TKA procedures and application of the 2-Midnight Rule now that this procedure has been removed from Medicare's inpatient-only (IPO) list.
*NOTE: Throughout this document the term "Provider" when used means "Hospital".

What You Need To Know

The Centers for Medicare & Medicaid Services (CMS) removed the Current Procedural Terminology (CPT) code describing TKA procedures from Medicare's Inpatient-Only List (IPO) effective January 2018. This allows TKA procedures to be performed on an *inpatient* or *outpatient* basis. In other words, it allows Medicare payment to be made to the hospital for TKA procedures regardless of whether a beneficiary is admitted to the hospital as an inpatient or as an outpatient, assuming all other criteria are met. This does not have any impact on CMS' 2-midnight policy.

CMS policy does not dictate a patient's hospital admission status and has no default determination on whether a TKA procedures should be done on an inpatient or outpatient basis. Rather, CMS continues its long-standing recognition that the decision to admit a patient as an inpatient is a complex medical decision, based on the physician's clinical expectation of how long hospital care is anticipated to be necessary, and should consider the individual beneficiary's unique clinical circumstances. -Though, as stated when TKA was removed from the IPO, CMS believes beneficiaries who are selected for outpatient TKA would have few comorbidities and would not be expected to require SNF care following surgery.

The Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs) are contracted by CMS to review a sample of Medicare fee-for-service (FFS) short-stay inpatient claims (claims with hospital stays lasting less than 2 midnights after formal inpatient admission) for compliance with the 2-Midnight Rule.

BACKGROUND

The 2-Midnight Rule
Effective October 1, 2013, CMS finalized the 2-Midnight rule which directed how claims are to be reviewed by Medicare review contractors to determine the appropriateness of Medicare Part A payment. The regulation established two distinct but related medical review policies, the two midnight **presumption** and the two-midnight **benchmark**.

2-Midnight Presumption (helps guide contractor selection of claims for medical review): Hospital claims with lengths of stay greater than 2 midnights after the formal admission are presumed to be reasonable and necessary for Medicare Part A payment. Although these claims may be submitted among a sample of cases received, the BFCC-QIOs generally will not focus their medical review efforts on stays spanning 2 or more midnights after formal inpatient admission, absent evidence of systematic gaming, abuse, or delays in the provision of care in an attempt to qualify for the Two-Midnight presumption.

2-Midnight Benchmark (helps guide contractor reviews of short stay hospital claims for Part A payment): Hospital claims are generally payable under Medicare Part A if the admitting practitioner reasonably expects the beneficiary to require medically necessary hospital care spanning 2 or more midnights and this expectation is supported by the medical record documentation. The time a beneficiary has spent receiving hospital care prior to inpatient admission will be considered when assessing whether this benchmark is met.

CMS revised the 2-Midnight Rule, effective January 2016 in the CY 2016 Hospital Outpatient Prospective Payment System (OPPS) CMS-1633-F to add the **Case-by-Case Exception**. The case-by-case exception states that 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 documentation supports the admitting physician/practitioner's judgment that the beneficiary required hospital inpatient care despite lack of a 2-midnight expectation based on complex medical factors including but not limited to:

- Patient's history, co-morbidities, and current medical needs
- Severity of signs and/or symptoms
- Risk of Adverse Events

Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs)

BFCC-QIOs are tasked by CMS to review a sample of Medicare fee-for-service short-stay inpatient claims for compliance with the 2-Midnight Rule. CMS began using BFCC-QIOs, rather than Medicare Administrative Contractors (MAC) or Recovery Audit Contractors (RACs), to conduct the initial medical reviews of providers who submit claims for short stay inpatient admissions on October 1, 2015.

The focus of these reviews is also for BFCC-QIOs to educate admitting physicians/practitioners and providers about the Part A payment policy for inpatient admissions.
CMS instructs BFCC-QIOs to conduct routine analysis of hospital billing and target for review hospitals with high or increasing numbers of short inpatient stays that are potentially inappropriate under the 2-midnight policy.

TKAs, like any other condition or procedure not on the IPO list, are subject to medical review by CMS contractors. The review is based on documentation in the medical record that supports either the 2-Midnight Benchmark or the Case-by-Case Exception. It is important to note that CMS does NOT target condition or disease-specific claims, such as TKA procedures, for BFCC-QIO review.

BFCC-QIO reviewers look for documentation in the medical record that supports:

•the admitting physician/practitioner's reasonable expectation that the beneficiary will require medically necessary hospital services spanning 2 midnights or longer and admits the patient to the hospital based on that expectation

OR:

•the admitting physician/practitioner's judgment that the beneficiary required hospital care on an inpatient basis despite lack of a 2-midnight expectation based on complex medical factors including but not limited to

- ➢Patient's history, co-morbidities and current medical needs;
- ➢Severity of signs and/or symptoms
- ➢Risk of adverse events.

The BFCC-QIO reviews the entire medical record for supporting documentation.

What does Removing TKA from the IPO list mean?

1. This **allows** TKA procedures to be paid by Medicare FFS when performed in **either** the hospital inpatient or hospital outpatient setting, assuming all other criteria are met.
2. This **allows** TKA short-stay inpatient claims (if chosen in a sample of claims) to be reviewed by the BFCC-QIOs for compliance with the 2-Midnight Benchmark or Case-by-

Case exception (note that the two-year prohibition of RAC review for patient status continues to apply regardless of whether the case is performed on an inpatient or outpatient basis.)

NOTE: Beneficiaries who are selected for outpatient TKA would have few comorbidities and would not be expected to require SNF care following surgery. Further, the cost-sharing amount the beneficiary is responsible for will differ based on whether the surgery is performed on an inpatient or outpatient basis (and will vary based on other factors such as geographic location).

What does Removing TKA from the IPO list NOT mean?

1. It does not mean that all TKAs must be performed on a hospital outpatient/observation basis nor does it mean that there is a presumption about where TKAs are performed.
2. It does not mean that TKA Short Stay inpatient claims are targeted for review by CMS.

NOTE: As stated when removing TKA from the IPO, CMS does not expect a significant volume of TKA cases being performed in the hospital inpatient setting to immediately shift to the hospital outpatient setting as a result of removing TKA from the IPO list. Rather, CMS believes that there are a *subset* of beneficiaries with less medically complex TKA cases that could appropriately and safely be performed on an outpatient basis. Nevertheless, CMS has not made any pre-determinations on the *exact number* of patients receiving TKA procedures that should be treated as an inpatient or outpatient.

This MLN Matters article further clarifies and provides context for statements in the preamble for the CY 2018 OPPS final rule. In the CY 2018 OPPS final rule, CMS also prohibited Recovery Audit Contractor (RAC) patient status reviews for TKA procedures performed in the hospital inpatient setting for a period of two (2) years (CY 2018-2019).

Examples of TKA Cases and Rationale for Payment Determinations:

NOTE: The time a beneficiary spent as an outpatient before being admitted as an inpatient is considered during the medical review process for purposes of determining the appropriateness of Part A payment, but such time does not qualify as inpatient time. (See the Medicare Benefit Policy Manual, Chapter 1, Section 10, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c01.pdf for additional information regarding the formal order for inpatient admission.)

Case #1: Documentation Supports 2-Midnight Benchmark:

Dates of Service: On 1/6/18, patient was receiving hospital observation services; on 1/07/18, the physician order was written for inpatient admission; on 1/8/18, the patient was discharged home. (2 Midnights total; 1 Midnight after inpatient admission)
Case Summary: This 65-year-old female presented to the facility on January 6, 2018 for

elective TKA surgery. She was placed in observation after receiving routine post-operative care. She had a medical history of arthritis, diabetes mellitus, arrhythmia, sleep apnea, and chronic pain. The Physical Therapy (PT) progress notes from the morning on Post-op Day (POD) 1, indicated that the patient complained of feeling shaky and dizzy and was unable to complete her PT. The patient returned to her room, ate breakfast and her regular insulin dose was administered. Further nurse assessment noted that she remained light-headed. After a check of her blood sugar, the patient was found to be hypoglycemic and a snack was administered with improvement in her symptoms. However during afternoon PT session on POD 1, documentation in the medical record indicated that the patient again became shaky and complained of feeling hot. The patient was again returned to their room, sugars were assessed and the physician alerted—resulting in adjustments to her diabetic medications. The patient was admitted as an inpatient on 1/7/18 for continued monitoring and glucose stabilization. PT progress notes on the morning of POD 2 indicate the patient tolerated the session well, progressed as expected without other complaints. The patient was discharged 1/8/18.

Rationale for Approval: Medical management provided surgical repair, anesthesia administration, pre- and post-operative monitoring, pain and glucose management. No intraoperative complications were noted. On January 8, 2018, she was discharged home. Despite the lack of a 2 midnight stay after formal inpatient admission, the medical record documented symptoms during PT and two episodes of hypoglycemia, requiring adjustment of her insulin and close blood sugar monitoring post-op. This documentation provided a reasonable expectation, at the time the inpatient order was written, of medically appropriate hospital care spanning 2-Midnights.

Case #2: Medical Record Documentation Supports Case-by-Case Exception for "Patient History and Comorbitities":

Dates of Service: 06/28/2018 – 06/29/2018 (one midnight)
Case Summary: This 72-year-old male presented for elective primary total knee arthroplasty for osteoarthritis on June 28, 2018, and was admitted to inpatient status the same day based on past medical history and co-morbidities. His past medical history includes hypertension, mild chronic kidney disease, and paroxysmal atrial fibrillation (PAF) with a history of rapid ventricular response (RVR) and hypotension. He has one step to get into his front door and has planned for his wife and two children to help care for him after the operation. On June 29, 2018, he was discharged to home.

Rationale for Approval: This was an elective admission for a TKA. The procedure was performed without complications, the patient did not develop any new diagnoses post-admission, and the patient was quickly mobilized. The patient has adequate post-operative support and accessibility. This patient is not a safe candidate for outpatient status due to the risk of postoperative PAF with RVR provoked by the stress of surgery and possible electrolyte abnormalities likely to occur in the acute postoperative period. Therefore, it is reasonable to approve this case based upon patient history and comorbidities and current medical needs, severity of signs and symptoms, and presence of risk factors for an adverse event.

Case #3: Medical Record Documentation Supports Case-by-Case Exception for "Risk of Adverse Events":

Dates of Service: 05/15/2018 – 05/16/2018 (one midnight)
Case Summary: This 81-year-old female presented for elective primary total knee arthroplasty for osteoarthritis on May 15, 2018. Her past medical history includes hypothyroidism, glaucoma, and hypertension. Medical management provided consisted of the surgical procedure, pre- and post-operative monitoring, imaging, laboratory studies. On May 16, 2018, she was discharged to home.

Rationale for Approval: Despite hemodynamic stability, adequate pain control, and safety clearance for home from physical therapy, she is not a safe candidate for outpatient status because her age alone confers a significant risk of developing a significant adverse event in the acute postoperative period. Therefore, it is reasonable to approve this case based upon patient history and comorbidities and current medical needs, severity of signs and symptoms, and presence of risk factors for an adverse event.

Case #42: Medical Record Documentation Supports Case-by-Case Exception for "Current Medical Needs" Based on Complications that Arose During the Procedure:

Dates of Service: 02/12/2018 - 02/13/2018 (one midnight)
Case Summary: This 73-year-old male presented for elective total left knee replacement surgery on February 12, 2018, and was admitted to inpatient status the same day after developing post-operative bradycardia. He had a history of coronary artery disease, atrial fibrillation, complete heart block with pacemaker placement, diabetes, osteoarthritis, and hypertension. Medical management consisted of urgent evaluation by electrophysiology and correction of pacemaker malfunction, intravenous hydration, cardiac monitoring, laboratory testing, analgesics, antiemetics, anticoagulant, and IV antibiotic and home medications. On February 13, 2018 he was discharged to home.

Rationale for Approval: This was an elective admission for a TKA. The procedure was performed without complications, and the patient was quickly mobilized. His pain was controlled with oral pain medication soon after the procedure, however the patient demonstrated clinical decompensation of a chronic medical problem requiring urgent evaluation and treatment. The medical record documents that while this patient was previously physically active, due to the patient's extensive cardiac history with decompensation and need for urgent evaluation and treatment, it is reasonable to approve this case based upon patient history and comorbidities and current medical needs, severity of signs and symptoms, and presence of risk factors for an adverse event.

Case #53: Medical Record Documentation Did Not Support the 2-Midnight benchmark or the case by case exception:

Dates of Service: 03/6/18 - 03/07/18 (one midnight)
Case Summary: This 77 year-old female presented on March 6, 2018 for an elective TKA surgery and was admitted to inpatient status that same day. The patient had a history of gastroesophageal reflux disease. No other medical comorbidities were documented in the medical record. Medical management provided consisted of the surgical procedure of left TKA, pre- and post-operative monitoring, imaging, laboratory studies. Medications administered during this hospitalization included intravenous fluids, prophylactic antibiotics and post-op pain medication. The patient was discharged to her home on March 7, 2018. No potential intraoperative or potential post-operative complications were noted in the medical record.

Rationale: 77 year old presented for elective left TKA. Medical review is based on associated risk factors, comorbidities, and/or complications. The procedure was performed without any intraoperative complications. Patient comorbidities were minor and no adverse concerns were documented. The patient was monitored post operatively with good pain control, stable vital signs and was discharged the next day. The documentation did not support that hospital services were expected to span 2-midnights or more, nor did it support a case-by-case exception. There were no intra or post-operative complications documented in the medical record that supported inpatient status.

FREQUENTLY ASKED QUESTIONS

Question 1: Will CMS target TKA procedures for patient status review now that they are not on Medicare FFS IPO list?
Response 1: No. Claim selection is not condition or disease-specific. Sampling is done at the hospital level not at the claim level. Accordingly, TKA procedures are not targeted for review by CMS. CMS instructs BFCC-QIOs to conduct routine analysis of a sample of hospital claims with high or increasing numbers of inpatient stays less than 2-Midnights. When TKA or any type of claim is reviewed for Part A eligibility, BFCC-QIOs identify and educate the hospital on opportunities for improvement.

Question 2: Does removal of TKA from Medicare's FFS IPO list mean that this procedure should only be performed on a hospital outpatient basis?
Response 2: No. Removing a procedure from Medicare's FFS IPO list does not require the procedure to be performed on an outpatient basis. Rather, it allows the procedure to be performed in a hospital inpatient or hospital outpatient status.

Question 3: Who determines patient status as a hospital inpatient or outpatient?
Response 3: CMS continues its long-standing recognition that the decision to admit a patient as an inpatient is a complex medical decision, based on the physician's clinical expectation of how long hospital care is anticipated to be necessary, considering the individual beneficiary's unique clinical circumstances. CMS policy does not dictate patient status.

Question 4: Are patient status considerations limited only to clinical factors observed during admission?
Response 4: No. When considering the individual beneficiary's unique clinical circumstances, the physician's clinical expectation of how long hospital care is anticipated to be necessary can consider social supports home accessibility and their impact on the risk of adverse events post-operation. For example, a 68-year-old female who underdoes an elective primary total knee arthroplasty for osteoarthritis has a medical history includes obesity, well-controlled diabetes mellitus, and hypertension. Also, she lives alone on the 3rd floor of an apartment building without an elevator. Despite being hemodynamically stable and having adequate pain control after the operation, she is appropriate for inpatient status, and/or inpatient post-acute care until she is stable and mobile enough for home/self-care. Her lack of support at home and numerous steps to get to her apartment precludes safe outpatient status. As stated when TKA was removed from the IPO, CMS believes beneficiaries who are selected for outpatient TKA would have few comorbidities and would not be expected to require SNF care following surgery.

Question 54: What do BFCC-QIOs look for when evaluating a TKA or other short-stay inpatient claim, for compliance with the 2-Midnight Rule?
Response 54: BFCC-QIOs look for:
•documentation in the medical record that supports a reasonable expectation of medically necessary hospital services for 2 midnights or longer including all outpatient/observation and inpatient care time
OR
•documentation in the medical record that supports the admitting physician's determination that the patient required inpatient care despite the lack of a 2-midnightexpectation based upon complex medical factors including but not limited to:
➢Patient's history, co-morbidities and current medical needs
➢Risk of adverse events
➢Severity of signs and symptoms

Question 65: Are there plans to remove other orthopedic inpatient surgical procedures from Medicare's FFS IPO list?
Response 65: Any future plans to remove orthopedic procedures from Medicare's FFS IPO will be communicated through the rulemaking process. This allows for stakeholder comments to be submitted and reviewed prior to release of CMS final rules.