

February 28, 2018

Seema Verma, MPH
Administrator
Centers for Medicare and Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244

Re: Decision to take Total Knee Arthroplasty out of the Medicare Inpatient Only List and the unintended consequences of this change in policy.

Dear Administrator Verma:

On behalf of over 34,000 orthopaedic surgeons and residents represented by the American Association of Orthopaedic Surgeons (AAOS) as well as the orthopaedic specialty societies and state societies who agreed to sign on, we would like to comment on the Centers for Medicare and Medicaid Services' (CMS) decision to take Total Knee Arthroplasty (TKA) out of the Medicare Inpatient Only (IPO) List. As you are aware, this decision was finalized via Hospital Outpatient Prospective Payment (OPPS) - Notice of Final Rulemaking with Comment Period 2018 (CMS-1678-FC). AAOS is supportive of this decision and would like to ensure that the policy change is implemented as intended by CMS and in the best interest of Medicare enrollees.

In response to this proposal earlier in the year (i.e., CMS-1678-P), AAOS had commented that

"We support the removal of TKA from the IPO list contingent upon several issues.

- *The determination of how to best provide adequate and timely care to a Medicare beneficiary should fall under the purview of the patient-surgeon relationship, as these are the individuals who shoulder the risk of these procedures.*
- *The AAOS calls for clear criteria for surgical site selection. Not all ASCs nor all outpatient departments are the same.*
- *Another unintended consequence of forcing care into the outpatient setting becomes apparent when commercial payers follow CMS, the healthcare market leader. These payers will have considerable power to drive patient care to specific facilities and restrict patient access to ASCs based on cost alone.*

- *An outpatient TKA procedure would be appropriate only for carefully selected patients who are in excellent health, with no or limited medical comorbidities and sufficient caregiver support. It is important to note that the less invasive unicondylar arthroplasty, or partial knee replacement (CPT 27446), currently performed successfully in the outpatient setting, is not entirely like total knee arthroplasty. However, we have serious concerns with this model's design and the application requirements that we discuss below."*

Misinterpretation of the OPPS 2018 Final Rule

One of the unintended consequence of this policy change has been a lot of confusion on the part of a variety of stakeholders regarding how to interpret this new rule. Hospitals, surgeons, and payers are interpreting the rule from different perspectives and have been sharing differing guidance.

The hospital or Medicare Advantage plan directing the site of service decision over the operating surgeon's discretion is also in contradiction to CMS' intent in the final rule (CMS-1678-FC). Specifically, CMS points to the beneficiary's physician as the medical professional responsible for determining the care setting in this rule. We are concerned that unqualified decision making on the site of service will harm Medicare beneficiaries, especially those who have multiple risks such as co-morbidities, advanced age and live with other social factors that are not conducive to an outpatient procedure.

It is our understanding that the IPO list status of a procedure has no effect on the Medicare Physician Fee Schedule (MPFS) professional payment for the procedure. Physicians will continue to be paid the same regardless of the site of service. We also understand that the facility payment under the OPPS will be lower than under the inpatient Medicare Severity Diagnosis Related Group (MS-DRG) system. However, many physicians have been advised by their hospitals, plans or compliance experts that their reimbursements may be affected by this change in policy. AAOS has been undertaking member information updates on this. However, a more definitive guidance from CMS in this regard will be very helpful for all stakeholders.

Interplay of TKA policy and Medicare's "Two-Midnight Rule"

CMS made TKA procedures subject to the "Two-Midnight Rule" in conjunction with the decision to move TKA off the IPO list. However, we believe that the intention of CMS supports an

assumption of the appropriateness of an inpatient stay regardless of the expectation of a two-midnight stay. According to the “Two-Midnight Rule,” a hospital admission should be expected to span at least two midnights to be covered as an inpatient procedure. On our one-on-one conversation with CMS staff, we have been informed that if the expected need for an inpatient stay (i.e., defined as a need for two-midnights) is well documented on admission, early discharge is not penalized. Unfortunately, this is not well understood by many providers or hospital administrators. Prior experience with this rule has made many hospital reimbursement/compliance directors concerned that incorrect application of this rule may subject the hospitals and providers to financial penalties. Most orthopaedic surgeons had always considered TKA a major surgical procedure for elderly patients and, hence, an obvious inpatient procedure requiring significant resources. They now face pressure to move the majority of TKAs to an outpatient designation. For patients, these changes may lead to confusion over cost sharing obligations.

Under prior guidance related to the “Two-Midnight Rule;” CMS also stated that Medicare may treat some admissions spanning less than two midnights as inpatient procedures if the patient record contains documentation of medical need. Moreover, CMS expected, as stated clearly in the rule, that most TKAs would remain inpatient. The lack of clarity surrounding acceptable justification for inpatient admission spanning fewer than two midnights has led to pressure on the surgeon to make outpatient the default setting for all TKAs. Those patients for whom one midnight may be sufficient, yet are clearly not acceptable outpatient candidates, fall into a gray area forcing outpatient status. When a standard status is expected by the overwhelming majority, the burden of proof should fall on the exception, not the standard. As noted in the 2016 OPPI/ASC Final Rule, the two-midnight benchmark offers reviewers guidance on appropriate inpatient coverage, while the two-midnight presumption instructs medical reviewers on which claims to review. In the FY 2014 Medicare Inpatient Long-term Care Hospital Prospective Payment System (IPPS/LTCH PPS) Final Rule, CMS stated that additional exceptions to the generally applicable benchmark may be identified and acknowledged “potential ‘rare and unusual’ circumstances under which an inpatient admission that is expected to span less than two midnights would nonetheless be appropriate for Medicare Part A payment”. In the 2016 OPPI Final Rule, CMS had still only identified one “rare and unusual” exception i.e., prolonged mechanical ventilation. However, it was stated that additional exceptions would be evaluated on a case-by-case basis. We believe that TKA should be given the same exception status as mechanical ventilation under the rare and unusual policy, to guide

review by Quality Improvement Organizations (QIO), until more information is gathered. This will allow surgeons more flexibility while safely navigating the vast clinical space between outpatient and a two midnight stay. Given the precedent, we request CMS to issue an exception from the “Two-Midnight Rule” for TKA procedures.

Recovery Audits

CMS finalized that Recovery Audit Contractors (RAC) will not begin to audit TKA cases for site of service until 2020 and these audits will not be retroactive. We support this decision and believe that the delay in RAC audits for a period of two years will allow providers sufficient time to gain experience with performing these procedures in the outpatient setting. We have advised our members that if RACs occasionally question early discharge for patients, this can and should be appealed. Also, all inpatient admissions should be properly documented. However, health systems and compliance experts have told us that they cannot go by the rule making assurance and believe that audits can be retroactive. CMS staff advised us that QIOs should be involved in these scenarios. Hence, we request the CMS Center for Clinical Standards and Quality (CCSQ) to urgently direct QIOs to get involved and take up any compliance questions and issues related to potential audits.

Medicare Advantage issues

This issue of wrongly defaulting TKA cases to the outpatient setting is especially concerning for surgeons and patients in Medicare Advantage (MA) plans across the country. The AAOS has heard several anecdotes from surgeons across teaching hospitals, community hospitals, urban and rural hospitals that MA plans are requiring all TKA procedures to be done in the outpatient setting or otherwise denying claims. We have collected actual denial statements and have forwarded them to the CMS staff working on Part C issues. For example, an 88-year old MA plan enrollee in Florida was denied an inpatient TKA procedure. This was subsequently reversed on a peer-to-peer appeal discussion but it is a prime example of how elderly Medicare beneficiaries are at risk over unthoughtful denials. AAOS also engaged in a teleconference with appropriate CMS staff on this topic on February 28, 2018, and is in the process of developing a formal written statement to you. We request CMS to use its MA plan oversight authority to intervene and ensure that MA plan beneficiaries are not at an unfair disadvantage over their FFS counterparts.

Implications for Medicare FFS Payment Models

Although CMS had clearly delineated the requirements of this policy implementation in the 2018 OPPTS Final Rule (CMS-1678-FC), there are several issues that are arising for participating stakeholders. This has created significant challenges for orthopaedic surgeons, their Medicare patients, and for us in providing adequate member education. The AAOS has also presented these issues on a teleconference on February 5, 2018, with the leadership and staff of the Hospital and Ambulatory Policy Group (HAPG) in the Center for Medicare as well as on a teleconference on February 26, 2018, with the leadership of the Innovation Center at CMS. We have also had continuous staff-level communication among AAOS staff and CMS staff at the Center for Medicare and at the Innovation Center on these issues.

Defaulting all TKA procedures to outpatient status: While some hospitals understand the intent of the CMS Final Rule referenced above, a number of hospitals are apparently directing TKA patients to a site of service that is clearly in contradiction to CMS' stated positions as indicated in the agency's responses to the public comments accompanying the final rule. This misinterpretation is likely to impact the Comprehensive Care for Joint Replacement (CJR), Bundled Payment for Care Improvement (BPCI) and BPCI Advanced models despite CMS' expectation that most TKA cases will not be performed in the outpatient setting. The Innovation Center staff have assured us that they are reconsidering target pricing calculations based on the TKA decision. We urge you to expedite this process so that these payment model participants are not negatively impacted.

Concentration of medically complex patients: Contrary to CMS' expectation, more and more TKA cases are being pushed to the outpatient setting, thereby creating a situation in which most medically complex, high comorbid patients will remain inpatient as they are deemed too high risk not to hospitalize. This change in patient mix has significant implications for BPCI, BPCI Advanced and CJR models.

The AAOS has been running an active member education program and communication on this issue. Based on our understanding of the situation and our discussion with CMS staff, we recommend the following:

1. CMS urgently directs QIOs to expeditiously address these complaints to protect Medicare beneficiaries from unnecessary risk.
2. CMS formally advises all providers and hospitals that:

- Removal of TKA from the IPO list does not require the procedure to be performed on an outpatient basis.
 - Until the establishment of evidence-based patient selection criteria for inclusion and exclusion of appropriate candidates for an outpatient TKA procedure, the procedure should default to inpatient.
 - The patient's operating surgeon, not hospital staff, is responsible for determining the medical necessity of a TKA patient's site of service.
3. Allow a CPT code to trigger a BPCI episode: As removal of TKA from the IPO list rule was not contemplated within the design or historic pricing of BPCI, inclusion of outpatient TKAs in BPCI seems reasonable adjustment considering this radical policy change and the fact that BPCI physicians maybe be financially penalized for making site of care decisions in the spirit of the new policy.
 4. In lieu of #3 above, exclude BPCI TKAs from this new policy, e.g. all BPCI TKAs must stay inpatient, until clear and vetted evidenced-based patient selection criteria are established for qualifying Medicare beneficiaries as appropriate candidates for an outpatient TKA.
 5. In lieu of #s 3 and 4 above, or other modifications that will limit physician financial risk because of significant changes in patient mix, release BPCI Model 2 PGP participants from all downside risk for lower extremity joint replacements.
 6. In the absence of changes to the outpatient TKA policy and to ensure establishment of accurate pricing in BPCI Advanced, TKAs should be removed from baseline pricing in BPCI Advanced.

We hope that you will take note of our feedback and work on guidance such that the unintended consequences of this policy change are addressed with all stakeholders and medically necessary care is not hampered for Medicare beneficiaries. This is also important so that other orthopaedic procedures which you may consider moving out of the IPO list in the coming years do not experience the same issues. We thank numerous CMS staff from the HAPG, CMMI and Part C groups who participated in teleconferences with us and have responded to our emails and phone calls on specific questions. If you have any questions on our

comments, please do not hesitate to contact William Shaffer, MD, AAOS Medical Director by email at shaffer@aaos.org.

Sincerely,

A handwritten signature in black ink that reads "William J. Maloney". The signature is written in a cursive style with a large, sweeping flourish at the end.

William J. Maloney, MD

President, American Association of Orthopaedic Surgeons

cc: David A. Halsey, MD, AAOS First Vice-President

Kristy L. Weber, MD, AAOS Second Vice-President

Thomas E. Arend, Jr., Esq., CAE, AAOS Chief Executive Officer

William O. Shaffer, MD, AAOS Medical Director

The following orthopaedic specialty and state orthopaedic societies have agreed to sign-on to our comments:

American Association of Hip and Knee Surgeons (AAHKS)

American Orthopaedic Foot and Ankle Society (AOFAS)

American Orthopaedic Society for Sports Medicine (AOSSM)

Arthroscopy Association of North America (AANA)

Musculoskeletal Tumor Society (MSTS)

Ruth Jackson Orthopaedic Society (RJOS)

Society of Military Orthopaedic Surgeons (SOMOS)

The Hip Society (HIP)

The Knee Society (KNEE)

Alabama Orthopaedic Society
Arkansas Orthopaedic Society
California Orthopaedic Association
Colorado Orthopedic Society
Connecticut Orthopaedic Society
Eastern Orthopaedic Association
Florida orthopedic Society
Indiana Orthopaedic Society
Iowa Orthopedic Society
Kansas Orthopaedic Society
Louisiana Orthopaedic Association
Maryland Orthopaedic Association
Massachusetts Orthopaedic Association
Mid-America Orthopaedic Association
Minnesota Orthopaedic Society
Mississippi Orthopaedic Society
Nevada Orthopaedic Society
New Hampshire Orthopaedic Society
New York State Society of Orthopaedic Surgeons, Inc
North Dakota Orthopaedic Society
Ohio Orthopaedic Society

Pennsylvania Orthopaedic Society
Rhode Island Orthopaedic Society
South Carolina Orthopaedic Association
Southern Orthopaedic Association
Tennessee Orthopaedic Society
Virginia Orthopaedic Society
West Virginia Orthopaedic Society
Western Orthopaedic Association