

## HEALTH LAW NEWS

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### CMS REMOVES TOTAL KNEE REPLACEMENT FROM INPATIENT-ONLY LIST

On November 1, 2017, the Centers for Medicare & Medicaid Services ("CMS") released its Calendar Year 2018 Hospital Outpatient Prospective Payment System ("OPPS") final rule. Among many other changes, CMS finalized its proposal to remove total knee arthroplasty ("TKA") from the CMS inpatient-only ("IPO") list. Effective January 1, 2018, CMS will no longer require that TKA be performed solely in the inpatient setting. This policy change has significant implications for all hospitals with orthopedic programs and in particular for those hospitals participating in the Comprehensive Care for Joint Replacement ("CJR") and Bundled Payment for Care Improvement ("BPCI") programs.

#### **IPO CONSIDERATIONS**

CMS initially proposed removing TKA from the IPO list in 2013 but declined to finalize that proposal after industry stakeholders submitted comments opposing the policy change on the grounds that it would be unsafe for Medicare beneficiaries. As it does with all procedures being considered for removal from the IPO list, CMS considered the following criteria as applied to TKA.

- 1. Whether most outpatient departments are equipped to provide the service to the Medicare population;
- 2. Whether the simplest procedure described by the applicable CPT code may be performed in most outpatient departments;
- 3. Whether the procedure is related to codes already removed from the IPO list;
- 4. Whether the procedure is being performed in numerous hospitals on an outpatient basis; and
- 5. Whether the procedure can be appropriately and safely performed in an ASC, and is on the list of approved ASC procedures or has been proposed for addition to the ASC list.

CMS emphasized that it does not require a procedure to meet all five criteria in order to be removed from the IPO List. In support of its decision to remove TKA from the IPO list, CMS found that TKA procedures met criteria 1,2 and 4. Importantly, CMS also declined to include TKA on the Ambulatory Surgical Center ("ASC") Covered Procedures List; therefore, while Medicare will cover TKA performed in hospital outpatient departments effective January 1, 2018, it still will not cover TKA in the ASC setting.

#### IMPACT OF CMS DECISION

Clinical Appropriateness. Many commenters had opposed removing TKA from the IPO list, asserting that performing TKA in the outpatient setting is not clinically appropriate for the Medicare population because Medicare beneficiaries are more likely to have comorbidities not experienced by typically younger non-Medicare patients. These commenters expressed concern that because of such comorbidities, Medicare beneficiaries face increased complications, recovery times and rehabilitation needs as compared to non-Medicare populations. In response, CMS emphasized that its decision permits, but does not require, TKA to be performed in the outpatient setting. CMS further stated that it expects physicians to continue to exercise appropriate medical judgment in selecting the TKA setting for each patient. Such judgement will likely depend on a number of factors, including the patient's comorbidities, the expected length of stay in the hospital and the patient's anticipated need for postoperative skilled nursing care.

Patient Selection. CMS declined to establish specific guidelines or content for patient selection protocols, stating instead 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." According to CMS, at least two orthopedic specialty associations submitted comments indicating that their organizations were in the process of developing evidence-based inpatient and outpatient selection protocols for TKA.

Two-Midnight Rule. Once TKA is removed from the IPO list, it will be subject to the "Two-Midnight Rule," which provides that an inpatient admission will be considered medically necessary and appropriate if the physician expects the beneficiary to require hospital care that spans at least two midnights. If the physician expects the patient to require hospital care not spanning at least two midnights, an inpatient admission may still be payable under Medicare Part A on a case-by-case basis if the documentation in the patient's medical record supports



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the admitting physician's determination that the patient requires inpatient hospital care.

CMS also finalized its proposal to prohibit Recovery Audit Contractors from denying hospital claims for patient status for TKA procedures performed in the inpatient setting for a period of two years. This will allow providers to gain experience in determining the most appropriate setting to perform TKA and to establish patient selection criteria to assist in that determination.

Bundled Payment Programs. A number of commenters suggested that removal of TKA from the IPO list will further complicate both the CJR and the BPCI initiatives. CJR and BPCI are bundled payment models that place providers at financial risk for the full episode of care for TKA procedures originating in the inpatient hospital setting. Industry stakeholders, including the American Hospital Association, expressed concern that removal of TKA from the IPO list could jeopardize the success of the CJR and BCPI programs, as shifting of healthier TKA patients to the outpatient setting would significantly alter the risk profile of the remaining patients receiving such procedures on an inpatient basis. Commenters believed that such a change in patient mix could increase the average episode cost of inpatient TKA episodes, thereby jeopardizing a hospital's ability to generate overall savings under the BPCI or CJR model.

In response, CMS expressed its belief that providers will need time to gain experience in safely shifting TKA patient to the outpatient setting. As a result, CMS does not expect a significant shift in TKA cases from inpatient to outpatient settings prior to the end of the BPCI and CJR models (September 30, 2018 and December 31, 2020 respectively). CMS plans to monitor the overall volume and complexity of TKA cases performed in outpatient settings to determine whether any future refinements to these models are warranted.

### **PRACTICAL TAKEAWAYS**

Surgeons must begin carefully evaluating patients on a case-by-case basis to determine whether an inpatient admission would be medically necessary and appropriate under the Two-Midnight Rule criteria. Similarly, hospitals should immediately begin working with orthopedists and others to develop patient selection protocols for determining whether individual TKA procedures should be performed in the inpatient versus outpatient setting.

Finally, BPCI and CJR hospitals (especially those hospitals that have the option to discontinue participation in the CJR program) should evaluate the likelihood that migration of healthier TKA patients to the outpatient setting will adversely affect financial performance under the BPCI and CJR programs. Those hospitals that continue to participate in the BPCI and CJR models should also be prepared to provide CMS with data on migration of TKA procedures to the outpatient setting over the remaining payment model performance years.

If you have questions or would like additional information about this topic, please contact:

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