

September 6, 2016

VIA E-MAIL FILING

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1656-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: CY 2017 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Proposed Rule

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 system proposed rule for calendar year 2017 (hereinafter referred to as “CY 2017 OPPS proposed rule” or “proposed rule”).

AAHKS is the foremost national specialty organization of 2,900 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 offers these comments in anticipation of continued close collaboration with CMS to ensure Medicare hospital outpatient payment reforms benefit from our expertise and experience in TJA procedures.

Our comments focus on the following provisions of the CY 2017 OPPS proposed rule:

I. Removal of Total Knee Arthroplasty Procedure from the Medicare Inpatient Only List – Section IX.C.

Each year, CMS uses established criteria to review the Medicare Inpatient Only (“IPO”) list and determine whether or not any procedures should be removed from the list. Three factors are used to determine placement on the IPO list: (1) the invasive nature of the procedure; (2) the need for at least 24 hours of postoperative care; and (3) the underlying physical condition of the patient who would require the surgery.

CMS is seeking comments on whether total knee arthroplasty (“TKA”), described by CPT code 27447, should be removed from the IPO list in a subsequent year. TKA was placed on the IPO list in 2000. In 2013, CMS proposed that the procedure be removed from the IPO list because the procedure could be appropriately provided and paid for as a hospital outpatient procedure for some Medicare beneficiaries. Based on adverse public comments, the removal of CPT code 27447 was not finalized in 2013. CMS notes in the proposed rule that, due to recent innovations in technology, TKA now may involve minimally invasive techniques, improved perioperative anesthesia, alternative postoperative pain management, and expedited rehabilitation protocols. CMS requests information relative to the proposed removal of TKA from the IPO, including how such removal may impact the testing of TKA episode-based payment models under the Comprehensive Care for Joint Replacement (“CJR”) Model and the Bundled Payments for Care Improvement (“BPCI”) Initiative.

AAHKS Comment:

As CMS is aware, TKA 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, TKA 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 TKA and consequently have led to the consideration, and relatively rare performance, of outpatient TKA. Importantly, criteria for safe discharge of a patient following TKA do not differ between “inpatient” and “outpatient”. Both must have: resumed an oral diet, have adequate oral analgesia, have intact urinary function, be able to tolerate food and water, be able to mobilize safely for the environment to which they going, and have no intervening complication. (These “criteria” are used to determine appropriate candidates for discharge after TKA). Currently, institutions are financially penalized if patients remain less than 2 days following a TKA, with waivers granted to those participating in CJR or BPCI. We feel strongly that the focus should be on patients meeting “criteria” for safe discharge rather than arbitrary time periods that are not based on a patient’s actual condition. As a result, we strongly urge CMS to remove financial penalties for patients discharged prior to 2 midnights. It is also appropriate to address the proper mechanism for hospital admission for patients who are treated in an ASC who fail to meet “criteria” and require hospital admission so that it is not inappropriately considered a “readmission”.

Given this framework, we address each of the questions that you raised in the proposed rule about the possible removal of TKA procedures from the Medicare IPO List below.

- Are most outpatient departments equipped to provide TKA to some Medicare beneficiaries?

AAHKS response: Most outpatient departments are not currently equipped to provide TKA to Medicare beneficiaries. Execution of outpatient TKA 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. AAHKS is not aware of any data to confirm the safety and efficacy of outpatient TKA in Medicare beneficiaries.

- Can the simplest procedure described by CPT code 27447 be performed in most outpatient departments?

AAHKS response: There is no simple 27447 procedure; all are TKA procedures with a moderate risk for complications. For the same reason as stated above, most outpatient departments are not prepared to orchestrate an outpatient TKA for a Medicare beneficiary.

- Is the procedure described by CPT code 27447 sufficiently related to or similar to the procedure described by CPT code 27446 (i.e., is the procedure under consideration for removal from the IPO list related to codes that CMS has already removed from the IPO list)?

AAHKS response: The two procedures described by CPT codes 27447 and 27446 are fundamentally different. CPT code 27447 describes a much more significant operation with more intra-operative and post-operative work, greater potential complications and generally different patient populations as procedure candidates. Specifically, instrumentation of the femoral canal is routine in TKA, and may contribute to pulmonary and secondary cardiac compromise. This is not routine in the unicompartmental knee arthroplasty procedures described by CPT code 27446. As such, CPT codes 27447 and 27446 are not sufficiently similar that any conclusions about CPT code 27446 can be assumed accurate about CPT code 27447.

- How often is the procedure described by CPT code 27447 being performed on an outpatient basis (either in a hospital outpatient department or ASC) on non-Medicare patients?

AAHKS response: AAHKS is aware of individual surgeons who have presented their successful experience with outpatient TKA 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.

- 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 TKA procedure as a hospital outpatient, which may or may not include a 24-hour period of recovery in the hospital after the operation?

AAHKS response: 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. 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.

- How could CMS modify the CJR and BPCI models if the TKA procedure were to be moved off the IPO list? How should CMS reflect the shift of some Medicare beneficiaries from an inpatient TKA procedure to an outpatient TKA procedure in the CJR and BPCI model pricing methodologies, including target price calculations and reconciliation processes? What are the post-discharge care patterns for Medicare beneficiaries that may receive an outpatient TKA procedure if it were removed from the IPO list and how is this similar or different from these beneficiaries' historical post-discharge care patterns?

AAHKS response: We agree that caution is required, in particular to preserve the innovative force of bundled payments. By its nature, only the healthiest patients should undergo outpatient TKA. Driving these patients away from bundles into outpatient TKA would adversely affect the population health of CJR and BPCI and therefore the outcomes and costs. Alternatively, there would also be a perverse incentive to eschew outpatient TKA to ensure institutional bundle success. Although there is one projection that 20 percent of all TJA procedures will be done as outpatient procedures by 2025, the rates among Medicare beneficiaries will be much lower and current rates of outpatient TKA among Medicare beneficiaries are extremely low. Therefore, we would recommend allowing the current CJR and BPCI projects to continue to provide innovation regarding care provided to total joint patients. If, over time, many patients indeed are undergoing outpatient TKA, a separate bundle could be designed for such healthy Medicare beneficiaries.

II. Pain Management Measures and Reporting in Outpatient and Ambulatory Surgery Settings – Sections XIII.B.5.c. and XIV.B.4.c.

Currently there are no standardized surveys available to collect information about a patient's experience with surgeries or procedures performed within a hospital outpatient department or ASC. Some hospital outpatient departments and ASCs conduct their own studies but the lack of standardization makes it difficult to compare quality across these facilities. The Outpatient and Ambulatory Surgery Assessment of Healthcare Providers and System ("OAS CAHPS") Survey, based on the Hospital Consumer Assessment of Healthcare Providers and Systems ("HCAHPS"), was created as part of the Department of Health and Human Services Transparency Initiative to fill this gap and measure experience with outpatient and ambulatory care.

The OAS CAHPS contains 37 questions on topics such as access to care, communications, experience at the facility, and interactions with facility staff. The survey will also contain two global rating questions and ask for self-reported health status and basic demographic information. CMS proposes to adopt five survey-based measures from the OAS CAHPS Survey for CY 2020 payment determination and subsequent years.

AAHKS Comments: We support CMS’s efforts to assess patients’ experience of care following a procedure or surgery in a hospital outpatient department or ASC. Further, we agree with CMS’s inclusion of risk adjustment factors for the OAS CAHPS Survey measures in order to achieve the goal of fair comparisons across all hospitals. We agree that the survey-based measures should be adjusted for patient characteristics such as age, education, overall health status, overall mental health status, type of surgical procedure, and how well the patient speaks English.

In addition, we strongly believe in the value of specialty-specific patient-reported measures addressing experience and outcomes that can be integrated into practice and that are reflective of quality. We believe that CMS should focus on adopting consensus patient-reported outcomes measures and we recommend CMS continue to partner with specialty societies to be informed on the latest developments in specialty-specific patient experience surveys.

III. Proposed Removal of HCAHPS Pain Management Measures Under the Hospital Value-Based Purchasing Program – Section XIX.B.

CMS is proposing to remove the Pain Management dimension of the HCAHPS Survey for purposes of the Hospital Value-Based Purchasing (“VBP”) Program, beginning with the fiscal year (“FY”) 2018 program year.

CMS has received feedback that some stakeholders are concerned about the pain management dimension questions being used in the Hospital VBP Program, believing that the linkage of these particular questions to the Hospital VBP Program payment incentives creates pressure on hospital staff to prescribe more opioids in order to achieve higher scores. CMS proposes to remove the pain management dimension of the HCAHPS Survey for purposes of the Hospital VBP Program “in an abundance of caution.” While CMS develops new pain management questions, HCAHPS Survey data on all dimensions of care, including pain management, will continue to be publicly reported under the Hospital Inpatient Quality Reporting (“IQR”) Program, but the pain management dimension will not be applied to scores under the Hospital VBP Program.

AAHKS Comments: We agree with CMS that pain management is an important dimension of the quality of care a patient receives. However, hospital payment incentives under the Hospital VBP Program should not be structured in such a manner to cause hospitals to change their opioid prescribing patterns in order to achieve higher scores on the HCAHPS pain management dimension. We agree with CMS’s proposal to remove the HCAHPS pain management dimension from scoring in the Hospital VBP Program for FY 2018 and to develop modified pain management questions for the HCAHPS Survey.

Similar to the OAS CAHPS Survey measures, pain management questions should focus on communication with the patient regarding pain management rather than pain control, for example through the prescribing of opioids. Specifically, pain management questions should recognize that pain management takes a variety of forms and is not managed by medication

alone. Further, we agree with CMS that appropriate pain management should include communication with patients about pain-related issues, setting expectations about pain, shared decision-making, and proper prescription practices. Accordingly, any revised pain management questions should reflect these practices. Finally, as CMS continues to move payments toward episode-based payment models, we encourage the use of pain management questions that assess and address pain over an entire episode of care, rather than assessing the inpatient experience only.

IV. Off-Campus Provider-Based Departments – Section X.A.

The proposed rule implements section 603 of the Bipartisan Budget Act of 2015 (“section 603”), which requires that certain items and services furnished in certain “off-campus” provider-based departments (“PBDs”) will not be paid for under the OPPTS, but instead will be paid for “under the applicable payment system” beginning on January 1, 2017. CMS identifies the Medicare Physician Fee Schedule (“MPFS”) as the “applicable payment system” for such items and services.

Under this “site-neutral” payment proposal, physicians furnishing services in these “off-campus PBDs” would be paid based on the professional claim and would be paid at the non-facility rate for services which they are permitted to bill. However, there currently is no mechanism for an off-campus PBD to bill and receive payment for services under a payment system that is not the OPPTS. For 2017 only, CMS proposes to allow hospitals to enroll the off-campus PBD as the provider/supplier it wishes to bill as in order to meet the requirements of that payment system (such as an ASC, a physician group practice, or a community mental health center that bills for partial hospitalization programs). CMS intends that this payment proposal would be a one-year transitional policy while CMS continues to explore operational changes that would allow an off-campus PBD to bill and receive payment for services under a payment system that is not the OPPTS.

AAHKS Comments: We urge CMS to allow for payment for services under the OPPTS when an off-campus PBD has to move or relocate, expands the services that it provides, or undergoes a change of ownership when such changes are necessary. Further, we disagree with CMS’s proposal to provide no payment to an off-campus PBD in CY 2017 unless that facility re-enrolls as a provider under a different payment system, and meets the requirements of that payment system.

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

Sincerely,

A handwritten signature in black ink that reads "Michael J. Zarski". The signature is written in a cursive, flowing style.

Michael J. Zarski, JD
Executive Director
AAHKS