

September 11, 2017

VIA E-MAIL FILING

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1678-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: CY 2018 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 2018 (hereinafter referred to as “CY 2018 OPPS proposed rule” or “proposed rule”).

AAHKS is the foremost national specialty organization of more than 3,000 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 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 2018 OPPS proposed rule:

I. Removal of Total Knee Arthroplasty (“TKA”) Procedure from the Medicare Inpatient Only (“IPO”) List

CMS is proposing removal of TKA procedures from the Medicare IPO list. CMS proposes that TKA (CPT code 27447) would be assigned to C-APC 5115 (Level 5 Musculoskeletal Procedures) with status indicator “J1”. CMS believes (1) that most outpatient departments are equipped to perform TKA for Medicare beneficiaries; (2) most outpatient departments may perform TKA; and (3) the procedure is already being performed in numerous hospitals on an outpatient basis.

AAHKS Comment: In 2016, CMS sought comments from the public on whether TKA procedures should be removed from the IPO list. Specifically, CMS asked how TKA related to a list of criteria to inform whether any procedure should be removed from the IPO list. We provided responses to each of six areas of questions raised by CMS that focused on the need for criteria to determine when discharge is appropriate after TKA, which would not differ between inpatients and outpatients.

As stated in 2016, we believe most outpatient departments are not currently equipped to provide TKA to Medicare beneficiaries, and that all 27447 TKA procedures have a moderate risk for complications. We have noted 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.

CMS expects providers will “carefully develop evidence-based patient selection criteria to identify patients who are appropriate candidates for an outpatient TKA procedure as well as exclusionary criteria that would disqualify a patient from receiving an outpatient TKA procedure.” We believe 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. There is a concern that commercial payers may interpret this CMS policy as invitation to implement coverage policies driving surgeries to lower cost facilities that may not be sufficiently prepared to handle the complexities or risks associated with some TKA procedures. CMS should make forcefully clear in the Final Rule that CMS expects that surgeons will make the ultimate patient-specific decision on site selection based on the level of patient selection and education, anesthetic techniques, medical care, and post-operative care coordination.

Last year, we urged caution in considering how to modify the Comprehensive Care for Joint Replacement Model (“CJR”) and the upcoming “BPCI 2” model if the TKA procedure were to be moved off the IPO list because of adverse incentives that could be created. Only the healthiest patients should undergo outpatient TKA. Driving these patients away from Medicare bundled payment programs and into outpatient TKA would adversely impact the health status of CJR and BPCI patient populations and therefore the outcomes and costs. CMS should closely monitor the rate of outpatient TKAs in regions served by CJRs to determine if the volume is such that it is negatively impacting the economic standing of CJRs. If, over time, many patients indeed are undergoing outpatient TKA, a separate bundle could be designed for such healthier Medicare beneficiaries.

II. Possible Removal of Partial Hip Arthroplasty (“PHA”) and Total Hip Arthroplasty (“THA”) Procedures from the IPO List

When CMS solicited comments in 2016 on possible removal of TKA from the IPO list, it also received comments in support of removal of THA from the IPO list as well. CMS is seeking public comments on several questions related to the removal of PHA and THA from the IPO List.

AAHKS Comment: THA 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, THA 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 THA and consequently have led to the consideration, and relatively rare performance, of outpatient THA. Importantly, criteria for safe discharge of a patient following THA 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 THA). Given this framework, we address each of the questions that you raised in the proposed rule about the possible removal of THA procedures from the Medicare IPO List below.

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

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

- Can the simplest procedure described by CPT code 27130 be performed in most outpatient departments?

AAHKS response: There is no simple 27130 procedure; all are THA procedures with a moderate risk for complications. For the same reason as stated above, most outpatient departments are not prepared to orchestrate an outpatient THA for a Medicare beneficiary.

- Is the procedure described by CPT code 27130 sufficiently related to or similar to other procedures that have already been removed from the IPO list?

AAHKS response: The procedure described by CPT code 27130 is fundamentally different from other procedures. CMS has proposed removing CPT code 27447 from the IPO in 2018. THA and

TKA are similar in the extent of risks associated with each in moving the site of surgery to an outpatient setting.

- How often is the procedure described by CPT code 27130 being performed on an outpatient basis (either in a hospital outpatient department or ASC) on non-Medicare patients?

AAHKS response: We are aware of individual surgeons who have presented their successful experience with outpatient THA 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 THA 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 THA 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.

III. Request for Information on CMS Flexibilities and Efficiencies

CMS seeks proposals for changes within its authority that can be made to reduce unnecessary burdens for clinicians, other providers, and patients and their families, throughout the Medicare program. Changes can include payment system redesign, elimination or streamlining of reporting, monitoring and documentation requirements, aligning Medicare requirements and processes with those from Medicaid and other payers, operational flexibility, feedback mechanisms and data sharing that would enhance patient care, support of the physician-patient relationship in care delivery, and facilitation of individual preferences.

In all of our comments which follow, AAHKS is guided by its three principles for payment reform:

- Payment reform is most effective when physician-led
- The burden of excessive physician reporting on metrics detracts from care
- Patient access, especially for high-risk patients, and physician incentives must remain a focus

a. Limited Availability of Advanced Alternative Payment Models (“APMs”) Under the Quality Payment Program (“QPP”)

There are numerous reasons why Advanced APMs may be a more appropriate choice for specialist surgeons than participation in the Merit-Based Incentive Payment System (“MIPS”), particularly due to the lack of orthopaedic-specific quality measures under MIPS. Unfortunately, very few Advanced APMs have been made available by CMS to-date and few are appropriate for joint replacement surgeries. Some AAHKS members work in hospitals that are mandated to participate in CJR, which is not presently an Advanced APM.

We appreciate the August 2017 proposal by CMS to provide some CJR hospitals the option to leave the program, and to provide all CJR hospitals the ability to participate in CJR as an Advanced APM. We have requested these changes for some time and they will do much to improve the underlying program. Nevertheless, these changes mean that there may be fewer hospitals operating in the CJR in the future, and not all of them may pursue Advanced APM status. Therefore, the need for additional CMS-created Advanced APMs is more urgent than ever. In light of the commencement of the QPP, the need is so acute that providers cannot wait upon the slow process of the Physician-Focused Payment Model Technical Advisory Committee (“PTAC”) to develop Advanced APMs for consideration by CMMI, particularly as the PTAC seems currently focused on primary care models. CMS and CMMI should make voluntary, specialist-managed, episode-based Advanced APMs available as soon as possible. It is our hope that the anticipated “BPCI 2” release will satisfy these needs.

b. Improvements to Existing Bundled Payment Models (CJR & BPCI)

We are supportive of the August 2017 proposed changes to the CJR. Additional modifications are needed, however, to ensure the success of this model.

The lack of risk adjustment/stratification in the CJR penalizes the hospitals and surgeons that treat the sickest patients. Furthermore, as CJR shifts towards regional benchmarking, TJA practices that care disproportionately for medically complex patients will be in direct competition with those that treat a healthier patient base. Without incorporating risk adjustment, the CJR will create a reimbursement environment that increasingly incentivizes cherry-picking and lemon-dropping. At minimum, it would seem consistent and appropriate to use the exclusion criteria and risk adjustments already being used in the CMS hospital-level, risk-standardized payment measure that is capturing 90 day total joint costs for all hospitals.

We seek continued CMS cooperation to create risk adjustment methodology that accounts for treating high risk patients based on the quality of care delivered. AAHKS has shared with CMMI four possible risk stratification methodologies. We firmly believe that this is an important component of new payment models that will help to prevent potential barriers to access of care for high risk patients.

c. Additional Quality Measure Risk Adjustment

CMS should also ensure that appropriate risk adjustment is implemented into MIPS quality measures so that the shortcomings of CJR are not promulgated throughout the QPP. The lack of appropriate risk adjustment means that providers may be measured on factors outside their control which leads to a disequitable distribution of resources away from the costlier and more complicated patients which frustrates some providers from serving Medicare beneficiaries.

There are improvements that also may be made to measures used in Hospital Quality Programs. For example, the Readmissions Reduction Measure for TJA (NQF #1551) remains unvalidated. The measure borrows from a validation study performed on NQF #1550, which is self-refuting. Further, 1550 and 1551 are poorly risk adjusted as the C-statistics for each are only 0.65.

d. Excessive Physician Reporting

The administrative burden of reporting requirements under the Medicare program continues to increase, often overburdening physicians who are trying to focus on direct patient care. We are committed to improving outcome reporting to increase accuracy and utility, such that what is collected is useful to patients and decision makers, but doing so with a decrease in the administrative burdens on physicians. Through development of more accurate and simplified quality measures, including the effective use of endorsed registries such as the American Joint Replacement Registry (“AJRR”), this goal can be achieved.

e. Medicare Signature Requirements

For the purposes of medical review by for MACs, CERT, SMRC, and ZPICs purposes, the Medicare Program Integrity Manual (at Chapter 3 § 3.3.2.4) requires that Medicare services that are provided/ordered be authenticated by the author of the order. The guidance states that the method used shall be a handwritten or electronic signature of the provider.

We fully appreciate and support the need to prevent Medicare billing for medically unnecessary or fraudulent billing. However, such requirements for physicians to be directly involved with such administrative tasks are a part of the cumulative burdens of non-clinical responsibilities that reduce the time available to devote to patient care and interaction.

f. Inflexible and Inappropriate Medical Necessity Standards for TJA

Requirements implemented by MACs to satisfy medical necessity for TJA procedures are incompatible with the clinical needs in some patient cases and can lead to painful delays in necessary care. For example, current TJA medical necessity requirements demand that three months of conservative treatment be attempted and failed before Medicare will covers the TJA procedure. In some cases, a physician can shortly determine that three months of conservative

treatment for a patient will (1) be ineffective, (2) put the patient through undue suffering, (3) delay patient care, or (4) waste medical resources. In these cases the three month requirement can cause additional suffering for the patient and incur unnecessary expense for the Medicare program. We recommend that the Secretary provide for CMS/MAC consultations with the appropriate specialty organizations to establish criteria for medical necessity. These consultations will lead to refined coverage requirements to benefit Medicare beneficiaries who are harmed by inflexible Medical Necessity Requirements and include flexibility for cases where three months of conservative treatment is not an appropriate pre-requisite for coverage of TJA.

g. New Measures for Value Under Hospital Quality Programs and Other Medicare Programs

CMS earlier sought comment on the existing measures and methodologies within the Inpatient Prospective Payment System which could be used to measure value. There is a limit to how existing Hospital VBP quality and efficiency measures are able to realistically reflect hospital “value,” particularly as some of those surgical procedure measures were never meant to reflect “value.” Therefore, AAHKS strongly urges that any new assessment of “value” under the VBP or any other Medicare payment program be based on new measures. The TJA procedures performed by AAHKS members perfectly illustrate this issue.

The VBP Clinical Care Domain includes NQF # 1550 (Hospital-level Risk Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty), assessing complications following admission for TJA. Complications may include: acute myocardial infarction, pneumonia, or sepsis/septicemia within 7 days of admission; surgical site bleeding; pulmonary embolism or death within 30 days of admission; mechanical complications; periprosthetic joint infection; or wound infection within 90 days of admission. These factors are important measures of quality, but are far too narrow in scope to capture value of the underlying procedure. Value to the patient undergoing the procedure is measured by the patient with consideration of many more factors, including quality of life, duration of implant, and other issues beyond the 90-day timeframe of NQF # 1550.

Work is needed to develop meaningful measures that capture patient value of TJA procedures. We know that beyond cost-efficiency and short-term quality issues, our patients judge value on long-term quality of life issues such as ease of movement/discomfort, mobility, and the existence of any emerging deficiencies in the joint implant itself. AAHKS therefore recommends that CMS develop new specific measures of value through the measure development process that will eventually be incorporated into the Inpatient Quality Reporting (“IQR”) program and then the VBP program. We understand that it will be a “lengthy process” to develop new measures that appropriately reflect the value to the patient of a TJA procedure over the long-term. It would be expected to be a lengthy process if pursued correctly with input and guidance from specialty societies. We believe there is interest among measure developers to address this next level of TJA measures, drawing from patient-reported outcome measures, the AJRR, and other sources to capture the value to the patient of the full life of a

joint implant. AAHKS already has demonstrated experience in partnering with CMS, other payers, and measure developers on the adoption of other consensus outcome measures.

AAHKS opposes using VBP's existing scoring methodology to account for value based upon some combination of quality and efficiency scores. Existing VBP measures and scoring methodologies are of a limited scope and were not designed to create a quality/efficiency judgment of the value of a hospital's performance on TJA procedures for patients and payers. An approach that is based only on cost-efficiency and short-term outcomes could incentivize the provision of care that unintentionally leads to longer-term negative outcomes: use of lower-cost/lower-quality implants; decreased length of stay; insufficient use of physical therapy or home health care. This is an issue for all TJA measures and many other measures of specific surgical procedures. Furthermore, it would be a disservice to beneficiaries if publicly available VBP measures of value only reflect the short-term risks to CMS, as a payer, of complications. Again, such measures are appropriate for quality, but are only a portion of the calculations of value to the beneficiary. VBP measures should not inappropriately steer beneficiaries between providers based on a misconception of value to CMS as the payer.

h. Opioid Addiction Crisis

We are grateful for the recent attention of Secretary Price, CMS, and other agencies of the Department of Health & Human Services ("HHS") to this addiction crisis. As prescribers of pain medications, AAHKS members are aware of the risks and difficult issues faced by treating prescribers. We note that more transparent and thorough coverage of TJA procedures, when medically necessary, by both Medicare and commercial insurers, would reduce the initial need to prescribe pain medication.

AAHKS members are working to reduce opioid use through effective care management. We believe there could be value in developing a MIPS quality measure for opioid-sparing approaches to managing pain. With the opioid crisis in mind, AAHKS intends to develop an opioid-sparing pain management quality measure applicable to total joint arthroplasty. Our overall goal is to develop or identify three processes, three structural and three outcomes measures for the physician to use at their discretion to satisfy various reporting requirements. We would request that these measures be reviewed and validated by appropriate entities within HHS after they are developed.

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,

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Mark I. Froimson, MD
President

A handwritten signature in black ink, appearing to read "Michael J. Zarski". The signature is written in a cursive style with a long horizontal stroke at the end.

Michael J. Zarski, JD
Executive Director
AAHKS