

Attorneys at Law

MEMORANDUM

To: AAHKS From: Epstein Becker & Green, P.C.

Date: November 17, 2017

Re: Summary of the CY 2018 OPPS Final Rule

The Centers for Medicare and Medicaid Services (CMS) published the calendar year (CY) 2017 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System Final Rule on November 13, 2017.

- The final rule raises *overall* rates by 1.35% for 2018, based on the projected hospital market basket increase of 2.7% minus a 0.6% productivity adjustment required by the Affordable Care Act (ACA). 2018 is the final year of the ACA adjustment, thus payment year 2019 and beyond are likely to exceed the 2% update.
- CMS is finalizing a policy that will pay for separately payable, non-pass-through drugs purchased at a discount through the 340B drug pricing program at the average sales prices (ASP) minus 22% rather than ASP plus 6%.
- CMS is maintaining 2017 levels of payment for skin substitutes for 2018. CMS will continue to analyze reform of skin substitute payment.
- To continue CMS work on bundled payments under OPPS, CMS packaged payments for low-cost drug administration services (less than \$100) into ambulatory payment classification (APC) payment categories.

The following is a summary of CMS actions in the final rule related to the comments submitted by AAHKS.

I. Removal of Total Knee Arthroplasty Procedure from the Medicare Inpatient Only List

CMS proposed removal of TKA procedures from the Medicare IPO list. In 2013, CMS had 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 now 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.

a. AAHKS Comments:

AAHKS stated that most outpatient departments are not currently equipped to provide TKA to Medicare beneficiaries, and that all CPT 27447 TKA procedures have a moderate risk for complications. 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. AAHKS further stated that CMS should make clear in the Final Rule that it 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.

b. Outcome in Final Rule:

CMS finalized the proposal to remove TKA from the IPO beginning in 2018. This means that Medicare will now reimburse TKA procedures performed in an inpatient \underline{or} outpatient facility.

<u>Reimbursement</u> – For reimbursement for the procedure in an outpatient department, the services described by CPT code 27447 will be assigned to APC-5115 with status indicator "J1".

<u>Review of Literature</u> – CMS said that in evaluating this proposal they considered stakeholder input along with recent peer-reviewed publications reporting the feasibility of outpatient TKA with positive results; that is, that TKA outpatients did not experience higher rates of complications or readmissions in comparison to TKA inpatients.

<u>Patient Selection Criteria</u> - CMS defers to providers to 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. CMS reiterated 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."

<u>Impact on CJR and BPCI</u> – AAHKS commented that driving TKA patients away from Medicare bundled payment programs and into outpatient procedures would adversely impact the health status of CJR and BPCI patient populations and therefore the outcomes and costs as well. AAHKS asked CMS to closely monitor the rate of outpatient TKAs in regions served by CJRs to determine if the volume is such that is it negatively impacting the economic standing of CJRs.

CMS responded that it does not expect a "substantial impact on the patient-mix for the BPCI and CJR models" in the short-term from this change.

<u>Impact of "2 Midnight Rule"</u> – With TKA being removed from the IPO, the procedure will now be subject the 2 midnight rule, which was established to provide guidance on when an admission would be appropriate for payment as an inpatient procedure under Medicare Part A. The rule was implemented to reduce payment for services rendered in medically-unnecessary setting (observational stays or outpatient procedures under the inpatient payment system).

CMS provided guidance that TKA will be appropriate for payment as an inpatient procedure if (1) the physician expects the beneficiary to require hospital care that spans at least 2 midnights and admits the beneficiary based upon that expectation, or (2) the physician expects the patient to need less than 2 midnights of hospital care but the documentation in the medical record supports the admitting physician's determination that the patient requires inpatient hospital care.

Interaction with "3 Night Stay" Standard for Skilled Nursing Facility (SNF)Admissions — By statute, Medicare beneficiaries must have a prior inpatient hospital stay of no fewer than 3 consecutive days to be eligible for Medicare coverage of inpatient SNF care. That has not changed with this final rule. CMS expects that Medicare beneficiaries who are selected for outpatient TKA would be less medically complex cases with fewer comorbidities and would not be expected to require SNF care following surgery. Rather, CMS believes such beneficiaries would likely be appropriate for discharge to home (with outpatient therapy. CMS noted that Medicare Advantage plans may elect to provide SNF coverage without imposing the SNF 3-day qualifying stay requirement.

II. <u>Possible Removal of Partial Hip Arthroplasty ("PHA") and Total Hip</u> 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. In 2017, CMS sought additional public comments on several questions related to the removal or PHA and THA from the IPO List.

a. AAHKS Comment:

AAHKS provided responses to each of six areas of questions raised by CMS related to THA. AAHKS's comments focused on the need for criteria to determine when discharge is appropriate after THA, which would not differ between inpatients and outpatients. AAHKS urged CMS to remove financial penalties for patients discharged prior to 2 midnights and 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". AAHKS stated that most outpatient departments are not currently equipped to provide THA to Medicare beneficiaries, and that all THA procedures have a moderate risk for complications. AAHKS 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 THA procedure as a hospital outpatient.

b. Outcome in Final Rule:

CMS noted that it received numerous comments from stakeholders, including physicians and other care providers, individual stakeholders, specialty societies, hospital associations, hospital systems, ASCs, device manufacturers, and beneficiaries. CMS reports hospital systems and associations, as well as specialty societies and physicians, stated that it would not be clinically appropriate to remove PHA and THA from the IPO list, indicating that the patient safety profile of outpatient THA and PHA in the non-Medicare population is not well established.

Commenters representing orthopedic surgeons also stated that patients requiring a PHA for fragility fractures are by nature higher risk, suffer more extensive comorbidities and require closer monitoring and preoperative optimization; therefore, it would not be medically appropriate to remove the PHA procedure from the IPO list. Ambulatory surgery centers, physicians, and beneficiaries, supported the removal of PHA and THA from the IPO list. These commenters stated that the procedures were appropriate for certain Medicare beneficiaries and most outpatient departments are equipped to provide THA to some Medicare beneficiaries. They also referenced their own personal successful experiences with outpatient THA.

Ultimately, CMS did not make any decisions in the final rule regarding removal of THA or PHA from the IPO list. CMS stated that it will consider all of the comments in future policy making.

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