



AMERICAN ACADEMY OF
ORTHOPAEDIC SURGEONS

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September 27, 2019

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1717-P
P.O. Box 8013
Baltimore, MD 21244-1850

Submitted electronically via <http://www.cms.gov>

Subject: (CMS-1717-P)

Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals

Dear Administrator Verma:

On behalf of over 34,000 orthopaedic surgeons and residents represented by the American Association of Orthopaedic Surgeons (AAOS) and the orthopaedic specialty societies that agreed to sign on, we are pleased to provide comments on the Centers for Medicare and Medicaid Services' (CMS) Medicare Program Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems and Quality Reporting Programs, Price Transparency of Hospital Standard Charges, Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services (CMS-1717-P) Proposed Rule published in the Federal Register on August 9, 2019.

Proposed Procedures and the Inpatient Only List

Notwithstanding our support of patient choice, the proposal to move total hip arthroplasty (THA) to an outpatient hospital setting is rash. THA is an invasive procedure for which a limited set of patients are strong candidates for the hospital outpatient department (HOPD). Considering the confusion precipitated by the removal of total knee arthroplasty (TKA) from the inpatient only (IPO) list in 2018, it is troubling to imagine the ways this change may be misconstrued by payers. **AAOS strongly opposes the removal of THA (CPT code 27130), from the Medicare inpatient-only list at this time.**

Hospitals are able to create significant shifts in care delivery that do not necessarily benefit our patients, as we saw with the implementation of the TKA policy change. Given the widespread

misinterpretation of the 2018 OPPI rule, many hospitals forced all TKA patients to the outpatient setting, leaving orthopaedic surgeons without alternatives for their patients. AAOS believes that the selection of appropriate candidates for the outpatient setting should fall to the surgeon. Moreover, the ideal setting for surgery should be determined between the surgeon and patient. In some cases, a patient may be clinically stable but lack the resources to care for themselves once they go home. This can lead to an increased risk for adverse events or accidents that end in hospital readmission. AAOS requests that CMS consider the following patient social factors when analyzing the implications of removing THA from the IPO: “lives alone,” “pain,” “prior hospitalization,” “depression,” “functional status,” “high risk medications,” and “health literacy.”¹

We are particularly surprised that CMS would propose this change based on the conclusion that it meets just two of the five criteria for removal from the IPO. Although the five criteria for removal are:

- “1. Most outpatient departments are equipped to provide the services to the Medicare population.
2. The simplest procedure described by the code may be performed in most outpatient departments.
3. The procedure is related to codes that we have already removed from the IPO list.
4. A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis.
5. A determination is made that the procedure can be appropriately and safely performed in an ASC and is on the list of approved ASC procedures or has been proposed by us for addition to the ASC list.”

It is troublesome that CMS chose only criteria 2 and 3 as the basis for the decision. While those factors are important, as they speak to the nature of the procedure in relation to other procedures, it does not bode well that the rationale omits whether or not outpatient facilities are equipped and appropriate, or whether or not the procedure is performed safely in these settings a majority of the time.

AAOS requests that CMS refrain from removing any procedures from the IPO list until the issues that surfaced with the removal of TKA are fully resolved.

Updates to the List of ASC Covered Procedures

We support the proposal to add TKA (CPT code 27447) to the ASC Covered Procedures List (CPL). AAOS recognizes that a certain group of Medicare beneficiaries may be strong candidates for TKA in the ASC setting. Though, we are concerned about the implementation of this policy change given the historical confusion surrounding the removal of TKA from the IPO. A TKA procedure in an ASC would be appropriate only for carefully selected patients who are in excellent health, with no or limited medical comorbidities and sufficient caregiver support. Just as was the case when TKA was proposed for removal from the IPO, it is important to note that the less invasive unicondylar arthroplasty, or partial knee replacement (CPT code 27446),

¹ Ohta, B, Mola, A, Rosenfeld, P and Ford, S 2016 Early Discharge Planning and Improved Care Transitions: Pre-Admission Assessment for Readmission Risk in an Elective Orthopedic and Cardiovascular Surgical Population. International Journal of Integrated Care, 16(2): 10, pp. 1–10, DOI: <http://dx.doi.org/10.5334/ijic.2260>

currently performed successfully in the outpatient setting, is not entirely similar to total knee arthroplasty. There are significant differences between partial and total knee arthroplasty, particularly when patellar resurfacing is performed as part of a TKA. Aside from requiring a larger incision for greater exposure, TKA is a significantly more invasive procedure with a greater risk of complications, such as bleeding, deep vein thrombosis, and pulmonary embolism. Best practices for lowering the incidence of adverse events will require a more comprehensive and extensive perioperative plan than for unicondylar replacement. For instance, post-operative limitations for those undergoing TKA necessitate physical therapy and pain management leading to greater use of ancillary services in the postoperative and preoperative periods.

AAOS agrees that the safety of patients should be the primary priority when TKA is performed in the ASC setting. To bolster safety initiatives, we support CMS' proposal requiring ASCs to have defined plans of care for each beneficiary following a surgical procedure. We strongly disagree with other CMS ideas that would increase administrative burden, such as CMS' proposal to establish minimum experience requirements for ASCs that will be eligible for Medicare reimbursement for TKA or issuance of a new modifier that indicates the physician's belief that the beneficiary would not be expected to require active care or monitoring following the first midnight.

CMS rightly defers to practitioners for developing patient selection and exclusionary criteria for identifying appropriate patients for an outpatient TKA procedure. **We urge CMS to emphasize, via rule making, to all stakeholders and review contractors that only surgeons and physicians have the expertise to determine patient selection for TKAs at ASCs.** 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. A shared decision-making model requires the primacy of the doctor-patient relationship. Ultimately, the surgeon must be the final arbiter of the appropriate site for the surgical procedure. **Again, we ask that this be explicitly stated in the final rule.**

AAOS calls for clear criteria for surgical site selection. Not all ASCs nor outpatient departments are the same. Further, local ASCs have their own criteria for whether a particular patient may have surgery at their facility. CMS must ensure that patients rejected by an ASC have other local inpatient hospital or hospital outpatient department (HOPD) options. The determination of surgical site selection must be weighed in light of local conditions to assess basic patient safety. In addition to the capabilities of a specific facility to treat certain orthopaedic conditions, after care must be available. That being said, rigid criteria for a patient being treated as an outpatient or in the ambulatory setting may not meet these local conditions. Should home care or transportation be unavailable, the ambulatory option should not be pursued. Otherwise, the patient may be forced into a distant and unfamiliar care setting, thus obviating the advantages of the outpatient or ambulatory care.

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 appropriate settings of care based on cost alone. Forcing care to the outpatient or ambulatory

setting could result in significant further stresses in isolated rural care settings. To this end, AAOS requests patient selection and risk stratification protocols that will harmonize the differing criteria of HOPDs and ASCs.

AAOS supports the removal of CPT codes 63265-63268 (laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural) from the IPO. These procedures can be performed minimally-invasively and with quick recovery times. Of course, stringent patient selection must be made when determining strong candidates for these procedures in the outpatient setting. Although we have concerns regarding the reimbursement process for these codes in the outpatient setting, as with the effect of TKA removal from the IPO, physicians and patients should have the definitive choice for most appropriate site-of-service depending on the patient's health, post-operative support system, and insurance coverage.

We are encouraged to see HCPCS codes 0554T, 0555T, 0556T, and 0557T (bone strength and fracture risk using finite element analysis of functional data, and bone mineral density, utilizing data from a computed tomography scan) included as new additions to the July 2019 updated list of HCPCS codes. Increasing access to these diagnostic scans has the potential to provide patients with more precise tools for treating osteoporosis.

Updates to the Ambulatory Surgical Center Payment System

CMS is proposing to add TKA (CPT code 27447) to the ASC CPL for CY 2020 at a payment rate of \$8,639.97 and allograft implant knee with scope (CPT code 29867) at a payment rate of \$8,517.88

We appreciate the proposal to suspend for one year any Beneficiary and Family Centered Care-Quality Improvement Organizations (BFCC-QIO) referrals to RACs for procedures that are removed from the IPO list. However, given the complexity surrounding the two-midnight rule and the confusion that ensued following the removal of TKA from the IPO in 2018, **AAOS requests that CMS extend the time period to two years instead of one.** AAOS is supportive of the proposed exception to the two-times rule for APC-5112 (Level 2 Musculoskeletal Procedures).

Outpatient Quality Reporting

AAOS is supportive of the proposed addition of new patient safety measures to the Hospital Outpatient Quality Reporting (OQR) program. We believe that ASC-2: Patient Fall and ASC-3: Wrong Site, Wrong Side, Wrong Procedure, Wrong Implant, and ASC-4: All-Cause Hospital Transfer/Admission are all beneficial to improving patient outcomes. This update further reinforces the standardization of quality between ASCs and HOPDs. Furthermore, we support the proposed inclusion of NQF# 0514-MRI Lumbar Spine for Low Back Pain in the Hospital OQR program for CY 2022. However, we feel it is best to leave the optimal site of service to the patient and physician.

Level of Supervision of Outpatient Therapeutic Services in Hospitals and Critical Access Hospitals

AAOS supports the proposal to change the minimum level of supervision for hospital outpatient therapeutic services from direct supervision to general supervision in all settings.

OPPS Transitional Pass-Through Payment for Additional Costs of Drug, Biologicals, and Radiopharmaceuticals

Given that many orthopaedic biologics are currently exempt from the Food and Drug Administration's (FDA) regulation and Medicare's broad definition of "biologic," it is possible that these therapies may be covered. However, many of the stem cell and other biologic products currently in the spotlight for their use in orthopaedics are exempt from regulation under section 361 of the Public Health Service Act. We encourage CMS to align their definition of "biologic" to only those products regulated by the FDA or as outlined in section 351 of the Public Health Service Act, thereby limiting coverage to those products with proven safety and effectiveness data.

Price Transparency

AAOS appreciates CMS' efforts to improve price transparency and lower costs for consumers. We believe that allowing healthcare consumers to search for medical providers based on both price and quality will further increase patient empowerment when making serious decisions about medical treatment. The proposal to have 300 shoppable services posted on consumer-friendly websites is certainly a step in this direction.

However, AAOS is apprehensive about the accuracy and maintenance of such databases as it can be difficult to verify that the information found on such websites is regularly updated. Although the proposed rule names a 12-month update, we believe that more frequent changes in commercial payer rates could cause that information to become inaccurate. While we recognize the added burden of more frequent updates, we would urge CMS to consider alternative methods to produce updates with more regularity. Yet, transparency alone – and relying on the patient to make those decisions alone – will never be enough in the absence of comprehensive work from all stakeholders to move toward value-based care. Relatedly, providing pricing information alone does not help patients understand that information nor does it consider other measures of patient satisfaction.

Equally important is preserving the value of physicians' services for their patients.

One complication to providing greater transparency in healthcare pricing is the unique nature of assessing the quality of healthcare services for many patients. In fact, a study in the *New England Journal of Medicine* has explained that, "Timely and salient comparative quality information is often unavailable, so patients may rely on cost as a proxy for quality. The belief that higher-cost care must be better is so strongly held that higher price tags have been shown to improve patients' responses to treatments through the placebo effect."² CMS' movement toward rewarding quality care should not be superseded by hasty price transparency solutions.

Studies have repeatedly demonstrated that simply providing price transparency tools to patients have had mixed results.³ According to one study, "Price transparency tools may result in lower

² "Increased Price Transparency in Health Care — Challenges and Potential Effects," *The New England Journal of Medicine*, Anna D. Sinaiko, PhD, et. al., 891-894 (March 2011).

³ "Would Greater Transparency And Uniformity Of Health Care Prices Benefit Poor Patients?" Margaret K. Kyle and David B. Ridley, *Health Affairs*, 1384–1391 (October 2007); "Examining A Health Care Price Transparency Tool: Who Uses It, And How They Shop For Care," Anna D. Sinaiko and Meredith B. Rosenthal, *Health Affairs*, 35:4 (April 2016).

prices for a selected set of services, but the tools have little impact on overall spending because of the small percentage of people who use them.”⁴ In addition to the limited use of these tools, patients are also often unwilling to switch providers,⁵ and “[u]sing price transparency websites to choose providers is complicated for patients, given the wide array of services a person can receive and the complexity of billing and navigating different types of out-of-pocket spending (that is, deductibles, coinsurance, and copays).⁶

We are concerned by CMS’ prospective consideration to include “the services provided by physicians and non-physician practitioners who are not employed by the hospital, but who provide services at a hospital location” in the definition of “items and services.” **The notion that CMS can impose regulations on private physicians is both antithetical to a free-market economy and counter to the surprise billing solutions that AAOS supports.**

Our suggestions for remedying this issue include maintaining and robustly enforcing accurate and timely physician directories to prevent carriers from continuing to provide patients with inaccurate directories; providing accurate and timely fee schedules to patients and physicians to improve cost transparency; offering out-of-network options to ensure that patients have choices when their network does not offer access to the physicians patients need; and when there are no specialists in a network who can meet a patient’s need and a non-network provider must deliver specialty care, insurers should compensate those providers at their full fee while adding no additional cost burden to the patient. In these cases, the insurer has created an inadequate network, and they should bear the entire responsibility of ensuring patient access outside of what is available in the network.

Prior Authorization

Despite the increasing costs of health care spending in the United States, AAOS does not support the implementation of enhanced prior authorization requirements as a means for controlling spending. Prior authorization processes are burdensome for physicians and undermine their training and professional judgment and create critical delays in the care of patients. The proposals outlined in this rule for new prior authorization processes for certain covered outpatient procedures suggest additional burdensome requirements, including provisional affirmations for procedures that will certainly lead to greater confusion when claims are denied. CMS’ proposal to issue non-emergent decisions within 10 business days and within two business days for expedited reviews “when a delay could seriously jeopardize the beneficiary’s life, health, or ability to regain maximum function” is simply too long. Such delays create undue barriers to care for patients, particularly older adults or those in rural areas, if they have to return to a physician’s office for multiple visits as a result of the delays.

Given the current stagnation in reforming prior authorization processes, we are supportive of CMS’ proposal to at least mitigate some of the burden associated with the program through the proposed exemptions. We believe that it is reasonable to exempt from the prior authorization

⁴ “Offering A Price Transparency Tool Did Not Reduce Overall Spending Among California Public Employees And Retirees,” Health Affairs, Sunita Desai, et. al., 1401–1407 (August 2017).

⁵ “Americans Support Price Shopping For Health Care, But Few Actually Seek Out Price Information,” Ateev Mehrotra, et. al., Health Affairs, 1392–1400 (August 2017).

⁶ Desai (August 2017)

process those practitioners who achieve a prior authorization provisional affirmation rate of at least 90 percent. We encourage CMS to consider other ways to minimize the burden for providers and patients as they operate within the current framework of prior authorization.

Thank you for your time and consideration of the American Association of Orthopaedic Surgeons' suggestions. We commend CMS on its continued efforts to improve care quality and access. If you have any questions on our comments, please do not hesitate to contact William Shaffer, MD, FAAOS, AAOS Medical Director by email at shaffer@aaos.org.

Sincerely,

A handwritten signature in cursive script that reads "Kristy Weber".

Kristy L. Weber, MD, FAAOS
President, AAOS

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