AAOS
American Association of Orthopaedic Surgeons

September 9, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1772-P
P.O. Box 8010, Baltimore, MD 21244-1850.
Submitted electronically via ***http://www.regulations.gov***

Subject: CMS-1772-P

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating

Dear Administrator Brooks-LaSure:

On behalf of over 39,000 orthopaedic surgeons and residents represented by the American Association of Orthopaedic Surgeons (AAOS) and the orthopaedic specialty and state societies that agreed to sign on, we are pleased to provide comments on the Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating (CMS-1772-P) published in the Federal Register on July 15, 2022.

The AAOS appreciates the ongoing efforts of the Centers for Medicare and Medicaid Services (CMS) to create policies that address health care cost inflation and expand access to care. We request continued support and ease of physician burden from the Department of Health and Human Services (HHS) as physicians navigate patient care, financial and practice management challenges exacerbated by the pandemic.

Rural Emergency Hospitals (REH) Physician Self- Referral Law Update

This rule proposes updates to the Stark law to incorporate the new REH provider type in its scope by adding a new exception for ownership in an REH and by revising certain existing exceptions for compensation arrangements by an REH. Broadly speaking, AAOS welcomes the increased latitude for physicians to form value-based enterprises. As we have stated previously, care coordination is an essential element of a value-based healthcare system, and we hope that these proposed updates will improve the quality of care and health outcomes for the rural populations who have limited access to health care. AAOS believes that physician self-referral law flexibilities will ensure and expand the ability of physicians to address patient needs in rural communities especially for emergent care.

With the recent surge in rural hospital closures, we also urge CMS to consider additional Stark law flexibilities in rural communities like those allowed during the COVID-19 public health emergency. Although the Stark Law sharply restricts physician ownership in hospitals, **AAOS urges CMS to allow physician-owned hospitals to increase the number of their licensed beds, operating rooms, and procedure rooms (subject to applicable State licensing laws) in rural areas.** A physician with investments in rural spoke hospitals should be permitted certain financial support, such as through a no-interest loan, so that the physician's practice and the hospital can remain financially viable.

Changes to the Inpatient Only List

AAOS is supportive of removing CPT code 22632, *Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (list separately in addition to code for primary procedure*) from the Inpatient Only list. CPT code 22632 is an add-on code that is typically billed with the primary procedure described by CPT code 22630, *Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar*, which was removed from the IPO list in CY 2021. AAOS believes that since there is enough evidence that the primary procedure i.e., arthrodesis can be done safely in the hospital outpatient setting, it is logical to pay for the add-on code in the outpatient setting as well. **We would like to reiterate that surgeons should decide on the actual setting of surgery and there should not be any mandates and pre authorizations necessary to determine inpatient vs. outpatient surgery even if a procedure moves out of the IPO list.**

However, we are concerned that CMS is proposing to assign CPT code 22632 to status indicator "N" which means that payment is packaged, therefore no separate ambulatory payment classification (APC) payment will be allowed. These are device intensive procedures and not allowing for separate payments of devices and ancillary services is problematic for providers. **We urge CMS to consider a separate cost-based payment system for devices under OPPS and thereby not finalize the N indicator for this procedure.**

Prior Authorization

AAOS has serious concerns with the increased use of prior authorization in the Outpatient Prospective Payment System. These concerns were previously raised in our comments on the 2020 and 2021 OPPS proposed rule, and remain at present given that this year's proposed rule would expand prior authorization requirements to:

1. Superseding Physician Autonomy

AAOS is concerned that requiring approval from a third-party removed from clinical decision-making erodes the doctor-patient relationship, and the ability to make decisions that are in the best interest of the patient. Clinicians go through years of training, and patients share personal information that dictates what type of care they seek, where, and how it is delivered. In fact, in this very rule, CMS notes that "the physician should use his or her clinical knowledge and judgment, together with consideration of the beneficiary's specific needs, to determine whether a procedure can be performed appropriately in a hospital outpatient setting or whether inpatient care is required for the beneficiary". We would agree with this sentiment but are concerned with the words that follow "subject to the general coverage rules requiring that any procedure be reasonable and necessary". This last portion remains vague: are those who create the general coverage rules the arbiters

of "reasonable and necessary"? This has the potential to supersede the process by which clinicians spend years training, get licensed, credentialed and certified to practice medicine.

2. *Increasing Administrative Burden and Negative Impacts on Patient Care*

The stated intent of these new requirements is to ensure that care is "medically necessary" and to reduce unwarranted variation. However, the approach of requiring documentation for all instances where these codes are used does not accomplish this goal – it assumes that all uses of these codes are suspect. It also creates additional burden for clinicians who are appropriately utilizing these codes. Unfortunately, patients may also suffer as a result of these across-the-board requirements. Necessary patient care could be significantly delayed, which could lead to adverse patient outcomes. Additional resources and energy may be diverted away from optimizing patient care and towards fulfilling these new administrative requirements.

In addition to broader prior authorization concerns, AAOS is troubled by the methodological approach CMS has taken to identify codes for new prior authorization requirements. CMS acknowledges "a rate of increase higher than the expected rate is not always improper", but their analysis focuses primarily on utilization as a predictor of value, with little consideration for clinical quality metrics and patient-reported outcomes. CMS explains that they "considered the data" and "believe the increases in the utilization rate for this service are unnecessary", but there is no clinical explanation for how this conclusion was reached, and whether or not application of these procedures produced better quality and outcomes for patients.

This new approach by CMS to increase the amount of prior authorization requirements for clinicians will set a very dangerous precedent. This is the second time that CMS is proposing new prior authorization requirements in the OPPS, and we urge reconsideration of these policies. Providers already face significant operational challenges to ensure patients receive appropriate, timely and effective care. Indeed, the unrelenting public health emergency has only exacerbated this. The addition of external, third-party requirements in order to complete an internal process only adds to this challenge. AAOS requests that this proposal be formally removed from the final CY 2023 OPPS rule.

ASC Covered Procedure List Nomination

AAOS appreciates the clarification provided by CMS in this rule on submission of recommendations for ambulatory surgical center (ASC) Covered Procedures by stakeholders. Medical specialty societies like ours have the clinical expertise to recommend procedures in our specialty that can be safely performed in an ASC. We also urge CMS to consider "add-on" services for a particular procedure that are important and significant for patient safety. Add-on services that trigger a complexity adjustment in the hospital outpatient setting payment must be paid separately in the ASC setting so as to create an incentive for physicians to perform the important add-on services.

Payment for Non-Opioid Products Under Section 6082 of the Support Act

The AAOS supports incentives to increase the availability of non-opioid alternatives for pain management. For example, there has been some success with intravenous acetaminophen, as an alternative to opioids, but high cost may limit its use. Also, we greatly encourage other effective forms of pain management, such as regional nerve blocks, icing wraps, transcutaneous stimulators, and topical analgesics. To ensure access to opioid use disorder treatment for Medicare beneficiaries across the continuum of care,

CMS must allow for separate payment for non-opioid alternatives for pain management in outpatient settings. Additionally, we encourage CMS to incentivize payment for alternative chronic pain management treatments such as acupuncture, chiropractic services, osteopathic manipulation, cognitive behavioral therapy, and physical therapy*, when appropriate*, in outpatient settings of care. Unbundled and stand-alone payment for these alternative medications and treatment plans will ensure change in pain management practices, prescription patterns and improve care.

Promoting Competition and Transparency Regarding the Effects of Provider Mergers, Acquisitions, Consolidations, and Changes in Ownership

AAOS appreciates the Administration's recognition of the impact that consolidation is having on the healthcare industry and the ensuing "whole-of-government" approach to preventing mergers and promoting competition across industries. Recently, AAOS released a FAQ on Consolidation[1] that touches on several of the themes that CMS is seeking feedback on. Beyond the broader impact of hospital consolidation, which shifts the landscape of inpatient and outpatient care, it is important to consider the unique role that private practice consolidation also plays in orthopaedic surgery. According to research published in JAMA, private equity firms acquired 355 physician practices from 2013-2016.[2] While orthopaedic surgeons and their practices accounted for a slim percentage of the total acquisitions during that time, more recent data suggests that the pace of this is increasing. In 2020, 49 private equity transactions occurred in orthopaedics. These include deals to deliver health care services at locations including ambulatory surgical centers as well as orthopaedic urgent care centers.[3] A working paper published by the Federal Trade Commission on the effects of a merger of six orthopaedic practices found that while prices rose for some commercial payers, the increases were not the same across all payers and plans.[4]

With these statistics in mind, we request that CMS continue to invest in research on the impact of all types of healthcare consolidation on access to, and quality of, care for musculoskeletal patients. While the pandemic has had an influence on the market factors that impact the pace of the consolidation of physician practices and hospitals, this is likely to shift yet again when the health care system enters a post-COVID era. Further study and evaluation will be required to understand the real-world impact on surgeons, patients and other health care professionals going forward.

OPPS Payment for Software as a Service

The AAOS supports reimbursement for use of 'Software as a Service' (SaaS) technology platforms and services. The recent pandemic has increased the speed of adoption of these technologies in health care and is likely to impact clinical trials, data interoperability, remote patient monitoring and rare disease research. Increased use of machine learning and artificial intelligence in orthopaedics has been able to improve diagnostic accuracy, identify the most critical patients and reduce human error in diagnostics and treatment.

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[1] https://www.aaos.org/globalassets/advocacy/issues/faqs-on-hospital-consolidation.pdf
[2] Gondi S, Song Z. Potential Implications of Private Equity Investments in Health Care Delivery. JAMA. 2019;321(11):1047–1048. doi:10.1001/jama.2019.1077
[3] Vector Medical Group, "Private Equity Driving Consolidation Across Orthopedic Healthcare: Q&A with Dana Jacoby and Gary Herschman" https://www.ebglaw.com/insights/gary-herschman-discusses-private-equity-drivingconsolidation-across-orthopedic-healthcare-in-qa-with-dana-jacoby/
[4] https://www.ftc.gov/system/files/documents/reports/price-effects-merger-evidence-physicians-market/working_paper_333.pdf

We foresee SaaS use in pre-optimizing patients for orthopaedic surgeries, aiding in actual surgery and easing post-operative patient monitoring to improve outcomes. We also see more use of SaaS platforms in reporting patient reported outcome measures (PROM). As more musculoskeletal procedures get reimbursed in the outpatient setting, it is logical to reimburse for these services in the outpatient setting. **We, however, urge CMS to ensure adequate data security and patient data safety while incentivizing the use of cloud-based platforms.**

Thank you for your time and attention to the concerns of the American Association of Orthopaedic Surgeons (AAOS) on the significant proposals made in the CY 2023 OPPS/ASC proposed rule. The AAOS looks forward to working closely with CMS on further improving the payment system, and to enhancing the care of musculoskeletal patients in the United States. More specifically, we would like to have a focused discussion on musculoskeletal procedures in the Medicare IPO List while CMS develops policy around it. Should you have questions on any of the above comments, please do not hesitate to contact Shreyasi Deb, PhD, MBA, AAOS Office of Government Relations at deb@aaos.org.

Sincerely,

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American Association of Hip and Knee Surgeons
American Orthopaedic Foot & Ankle Society
American Orthopaedic Society for Sports Medicine
American Osteopathic Academy of Orthopedics
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