

September 8, 2023

Hon. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1786-P
P.O. Box 8013
Baltimore, MD 21244-1850

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

Subject: CMS-1786-P

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction

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 societies and state societies that agreed to sign on, we are pleased to provide comments in response to Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction (CMS-1786-P) published in the Federal Register on July 13, 2023.

Updates to OPPS and ASC Payment Rates

In the CY 2019 OPPS/ASC final rule with comment period, the Centers for Medicare & Medicaid Services (CMS) finalized the proposal to apply the productivity-adjusted hospital market basket update

1. Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS). (2023, July 13). *CY 2024 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule*. <https://public-inspection.federalregister.gov/2023-14768.pdf>

to ambulatory surgical center (ASC) payment system rates for an interim period of 5 years (CY 2019 through CY 2023).¹ In this proposed rule, CMS proposes to continue to apply the productivity-adjusted hospital market basket updates to ASC payment system rates for an additional two years. Using the proposed hospital market basket update, CMS is proposing to update the ASC rates for CY 2024 by 2.8% for ASCs meeting relevant quality reporting requirements.¹ AAOS supports this decision to extend the hospital market basket-based updates for ASCs. In addition, AAOS requests CMS to permanently update ASC payments based on this methodology.

AAOS previously appreciated the clarification provided by CMS (in the FY 2023 proposed rule) on the submission of recommendations for ASC Covered Procedures List (ASC-CPL) 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.² While moving a particular procedure to the ASC-CPL, we 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 to create an incentive for physicians to perform the important add-on services.²

Changes to Inpatient Only List

For CY 2024, CMS received various requests recommending particular services be removed from the IPO list. CMS conducted a clinical review and determined that there was not sufficient evidence based on the traditional longstanding criteria. Therefore, CMS is not proposing to remove any services from the IPO List for CY 2024.¹ We urge CMS to consider appropriate expert knowledge and peer-reviewed evidence to make this decision in the future.

AAOS 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.²

Proposed OPPS Payment for Devices

AAOS is appreciative of CMS’ efforts to increase access to innovative technologies for Medicare beneficiaries. AAOS hopes that the agency will consider expansion of this program in the future, so that a more extensive list of devices may be approved for Medicare coverage with greater frequency.³

In response to the Transitional Coverage for Emerging Technologies (TCET) proposed notice, AAOS commented that we are supportive of innovation and increased coverage for devices that improve

2. American Association of Orthopaedic Surgeons. (2022, September 9). *AAOS Comments on the 2023 OPPS Proposed Rule*. https://www.aaos.org/globalassets/advocacy/issues/aaos-cy-2023-opps-rule-comments_final.pdf

3. American Association of Orthopaedic Surgeons. (2023, August 28). *AAOS Comments on the TCET Proposed Rule*. <https://www.aaos.org/globalassets/advocacy/issues/aaos-tcet-comment-letter.pdf>

patient safety and outcomes. AAOS believes that it would be prudent to expand coverage to similar devices under the proposed TCET pathway.³ Increased competitions among device manufacturers would, ideally, stimulate the expected benefits of an open and free market, assuming participation in an evidence-based development plan.³

Quality Reporting Programs

For FY 2024, CMS is proposing to adopt the Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO-PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the HOPD Setting (THA/TKA PRO-PM) beginning with the voluntary CYs 2025 and 2026 reporting periods, and mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination.¹

We believe this proposal is a step in the right direction. PRO-PM adoption must be encouraged across settings in the health care system to achieve better outcomes. In our FY 2023 IPPS comments, AAOS supported the inclusion of this measure in the inpatient setting. At the time, we noted our appreciation of the inclusion of orthopaedic surgeons in the Technical Expert Panel and Expert Clinical Consultants behind the development of this measure. Additionally, we were pleased to see adoption of recommendations from the 2015 Patient Reported Outcomes Summit for Total Joint Arthroplasty, particularly the selection of the PROMIS-Global or the VR-12 Health Survey to measure general health in addition to disease-specific instruments, the Hip dysfunction, and Osteoarthritis Outcome Score for Joint Replacement (HOOS, JR) and the Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR). AAOS appreciates CMS heeding our call for the use of registries for collection, standardization, and submission of patient reported outcome measures (PROM).⁴ Additionally, AAOS is pleased to see the agency consider the use of Medicare enrollment and beneficiary data to identify Medicare and Medicaid dual eligibility enrollment status among the variables for risk adjustment. However, AAOS must reiterate our concerns with adoption of this measure, and we urge CMS to consider these issues before finalizing this proposal.⁴

- **Clarification of goals**

Donabedian's conceptual framework for evaluating healthcare quality in terms of structure, process, and outcome is the classical basis for performance measures currently used. It is time for us to extend this framework to clarify goals in using patient reported outcomes to improve health care quality from the patient perspective not just for improving provider reimbursement. Orthopaedic surgeons have been at the forefront of the move to value-based care for Medicare, Medicaid, and other public programs as well as in programs instituted by commercial payers. Our surgeons are once again interested in improving musculoskeletal care outcomes; however, **if the goal of this PRO-PM reporting is adjustment of reimbursement, then appropriate measurement scales must be developed and then the results must be shared transparently**

4. American Association of Orthopaedic Surgeons. (2022, June 15). *AAOS Comments on the 2023 IPPS Proposed Rule*. <https://www.aaos.org/globalassets/advocacy/issues/aaos-fy2023-ippss-rule-comments.pdf>

in an actionable manner. CMS must share real-time data with physicians to improve shared decision-making.⁴

Another recommendation is to use expert judgement in interpreting outcomes after specific procedures. **AAOS recommends analyzing hip and knee arthroplasty outcomes separately.**⁴ THA procedures have a high success rate as measured by improvement in Quality Adjusted Life Years (QALYs). Results from a large study using registry data found that 90 to 95 percent of patients who have a THA report that they would have the surgery again at one year after surgery. While TKA also greatly improves a patient's quality of life, it does not always reach the same levels of patient satisfaction at one year. More commonly, 80 to 85 percent of patients report being fully satisfied with their TKA on PRO measurements. For this reason, AAOS suggests separately analyzing THA and TKA outcomes for performance measures.⁴

An issue with using PROMs for differentiating physician performance is that many of the outcomes are for reasons outside the physician's control. For example, a study evaluating change in PROMs before and after hip replacement surgery found that most of the variation in PROMs are due to individual patient related factors outside of the control of providers, and outcomes are governed by the quality of care received overall by a patient and not just for one acute incident involving a specialist.⁴ **Thus, the goal for PRO-PM reporting should be an improvement in whole-person care with an institutional approach covering multiple conditions and several physician specialists as well as other clinicians.**⁴

- **Timeline**

While AAOS appreciates the proposed two-year voluntary reporting period, **we urge CMS to allow for a longer timeline up to a four-year voluntary reporting period** for this PRO-PM for surgeons and their patients to familiarize themselves with the reporting requirements and if necessary, modify workflows.⁴ An extended timeline will help with improving the learning curve among patients and surgeons. AAOS also recommends partial year reporting in the beginning i.e., a three to six six-month reporting period before an entire year reporting requirement is instituted. The Joint Commission Advanced Total Hip and Knee Replacement Certification calls for 90 day pre- and 90-daypost-op (+/- 2 months) PROMs reporting. Many of our members and registry participants target this certification (The American Joint Replacement Registry (AJRR) participation is one of the requirements). Many of our clinicians and their teams have expressed challenges with 1-year capture, and as CMS has noted in the past, external factors beyond health institution or surgeon control play into getting a more longitudinal response.⁴

- **Associated cost and burden**

There are huge costs associated with adoption of such PRO-PMs. While certain large health systems and centers of excellence are already ahead of the curve in adoption and learning, most

health systems and smaller practices are far from being able to collect data and report on PRO-PMs. **AAOS urges CMS to institute technical support and a bonus to jump start investment by smaller health systems and those with limited infrastructure and resources.**⁴

We know from the literature that there is value in the ability to follow patients longitudinally, hence, meaningful reporting would require reporting in the inpatient and outpatient settings.⁴ However, that would mean huge cost burdens for outpatient practices which may not have the infrastructure and staff to implement data collection and reporting. Related to this is the issue of geographic barriers. Rural inpatient and outpatient facilities will find it more difficult to implement PRO-PMs, hence, we recommend a rural facility bonus like the one in the Quality Payment Program.⁴

- **Implementation difficulties**

A huge limiting factor in adopting PRO-PMs will be our data infrastructure. Although adoption of electronic health records (EHR) is widespread in the United States, these systems are not designed for adequate quality measurement. CMS' push to improve interoperability is likely to help in this regard but major challenges continue to be lack of integration of PROMs into EHRs, lack of uniform modes for capturing data and data contained in unstructured notes. Thus, progress in this area will require significant investments and public-private partnership in adoption of newer technology such as machine learning and artificial intelligence in analyzing clinical notes. AAOS also understands that expert clinicians always need to review and correct large scale data gathered via machine learning technology. Without creation of structured feedback loops, reporting on PRO-PMs will not lead to a learning health care system. **AAOS urges CMS to consider these technical difficulties while requiring adoption of PRO-PMs.**⁴

- **Reimbursement Pathway**

Additionally, AAOS would request CMS to consider creating a reimbursement pathway to incentivize reporting requirement for this PRO-PM in the long run. This could be done through a G-code in the medium term and then through the American Medical Association Current Procedural Terminology (CPT) Editorial Panel's code creation process for permanent inclusion and wide adoption across the health care system.⁴

- **Pandemic related issues**

As we are all aware, the COVID public health emergency disrupted our health care system with long term impacts. Health systems and physicians are reeling under extreme financial, infrastructural, and emotional stress due to the pandemic. Orthopaedic surgical patients were impacted by canceled and delayed procedures leading to significant increases in pain, fatigue and decreases in overall quality of life. CMS must take into consideration the long-term impacts of the pandemic when developing policy and analyzing results from the PRO-PM.⁴ Health care

practices also do not have the financial resources currently available to invest in advanced data systems and staffing needed to comply with PRO-PM reporting requirements. For all these reasons, we urge CMS to provide additional time and resources to clinicians and health systems for the next several years.⁴

Proposed Updates to Requirements for Hospitals to Make Public a List of Their Standard Charges

In the FY 2024 OPSS proposed rule, CMS proposes to amend several hospital price transparency (HPT) requirements with the hopes of improving monitoring and enforcement capabilities and align with the previously implemented Transparency in Coverage initiative to improve price transparency to the public.

AAOS appreciates the efforts of the Agency to foster a system of clear prices for health services.⁵ Providers, practitioners and patients benefit when healthcare decision-making is built on a mutual understanding of all aspects of treatment, including cost. According to a study by the American Psychological Association, regardless of income, over 50% of Americans report stress caused by medical bills. Developing a system where the prices for services are not a secret until the explanation of benefits statement arrives in the mail is critical to addressing this source of stress and improving the well-being of Americans.⁵

AAOS supports efforts to provide patients with easily understandable cost and quality information to encourage the use of high-value care options.⁵ Allowing healthcare consumers to search for medical providers based on both measures of price and quality will increase patient empowerment when making serious decisions about medical treatment. AAOS has supported similar efforts, including the “Procedure Price Lookup Tool” which allows patients to compare average national prices for procedures in both ambulatory surgery center and hospital outpatient department settings.⁵

AAOS urges CMS to move towards a solution that is deliberate in its approach for navigating between present regulation and a future state of health care payment—one that is both markedly helpful to patients and limited in the administrative responsibility it places on providers.⁵

Comment Solicitation on Access to Non-Opioid Treatments for Pain Relief Under the OPSS and ASC Payment System

In the FY 2024 OPSS proposed rule, CMS seeks comment on whether there are any HOPD specific payment issues CMS should take into consideration for CY 2025 and comments on any drug, biological, or medical device that a commenter believes would meet the definition of a non-opioid treatment for pain relief.¹

5. American Association of Orthopaedic Surgeons. (2020, January 29). *AAOS Comments of Transparency in Coverage Proposed Rule*. https://www.aaos.org/globalassets/advocacy/issues/price_transparency_pr_comments.pdf

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, AAOS greatly encourages 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, AAOS encourages 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 a change in pain management practices, prescription patterns and improve care.

As always, AAOS is supportive of utilization of non-opioid pain management, where appropriate and urges CMS to continue to provide reimbursement incentives to prescribers. AAOS seeks clarity on whether the “additional payment for non-opioid treatments for pain relief” would apply to indwelling nerve catheters and cryoneurolysis (e.g., Iovera), both of which are commonly used in orthopaedics.

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 FY 2024 OPPI/ASC proposed rule. 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. 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,



Kevin J. Bozic, MD, MBA, FAAOS
AAOS President

cc: Paul Tornetta III, MD, PhD, FAAOS, First Vice-President, AAOS
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Graham Newson, Vice-President, Office of Government Relations, AAOS

This letter has received sign-on from the following orthopaedic societies:

American Association for Hand Surgery (AAHS)
Arthroscopy Association of North America (AANA)
American Orthopaedic Foot & Ankle Society (AOFAS)
American Orthopaedic Society for Sports Medicine (AOSSM)
American Osteopathic Academy of Orthopedics (AOAO)
American Shoulder and Elbow Surgeons (ASES)
American Society for Surgery of the Hand Professional Organization (ASSH)
Musculoskeletal Tumor Society (MSTS)
Orthopaedic Rehabilitation Association (ORA)
Orthopaedic Trauma Association (OTA)
OrthoVirginia – Virginia Orthopedics
OrthoSC
Peachtree Orthopedics
Pediatric Orthopaedic Society of North America (POSNA)
Premier Orthopaedic Sports Medicine Associates

Alabama Orthopaedic Society
Arizona Orthopaedic Society
California Orthopaedic Association
Connecticut Orthopaedic Society
Colorado Orthopaedic Society
Delaware Society of Orthopaedic Surgeons
Florida Orthopaedic Society
Georgia Orthopaedic Society
Iowa Orthopaedic Society
Massachusetts Orthopaedic Association
Minnesota Orthopaedic Society
Missouri State Orthopaedic Association
Montana Orthopedic Society
Nebraska Orthopedic Society
New Hampshire Orthopaedic Society
New Mexico Orthopaedic Association
Ohio Orthopaedic Society
Puerto Rico Orthopaedic and Traumatology Society
South Carolina Orthopaedic Association
South Dakota State Orthopaedic Society
Tennessee Orthopaedic Society
Texas Orthopaedic Association

West Virginia Orthopaedic Society
Wisconsin Orthopaedic Society