AAOS
American Association of Orthopaedic Surgeons

September 9, 2024

Hon. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1809-P
P.O. Box 8010
Baltimore, MD 21244-8010

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

CMS-1809-P

Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

Executive Summary: The American Association of Orthopaedic Surgeons (AAOS), representing over 39,000 orthopaedic surgeons and residents, appreciates the opportunity to comment on the CY 2025 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule (CMS-1809-P). AAOS acknowledges several proposals that align with our commitment to improving musculoskeletal care while offering specific recommendations and expressing concerns where necessary.

- **Support for ASC Payment Rate Updates** AAOS supports CMS's continued use of the hospital market basket to update ASC payment rates. We strongly recommend that CMS adopt this methodology permanently, ensuring consistency in payment updates for ASCs.
- **ASC Covered Procedure List (ASC-CPL) Transparency** While AAOS appreciates CMS's efforts to clarify the process for submitting recommendations to the ASC-CPL, we urge the agency to enhance transparency by listing procedures submitted by stakeholders in the proposed rule, even if not proposed for inclusion. This would allow for more informed stakeholder feedback and contribute to a more inclusive decision-making process. Additionally, we advocate for the separate reimbursement of essential "add-on" services in ASCs, critical to patient safety.

- **Inpatient Only (IPO) List Decisions** AAOS remains concerned about the exclusion of certain services from the IPO list, advocating for decisions informed by expert clinical knowledge and peer-reviewed evidence. We stress the importance of allowing surgeons to determine the appropriate surgical setting without the imposition of pre-authorization requirements, ensuring patient care remains paramount.
- **Support for Device Payment Proposals** AAOS supports CMS's proposals to enhance access to innovative medical devices through add-on payments for new technologies. We encourage expanding this program to include a wider range of devices under the Transitional Coverage for Emerging Technologies (TCET) pathway, promoting competition and advancing patient care.
- **Patient-Reported Outcome-Based Performance Measures (PRO-PMs)** AAOS appreciates the adoption of the Risk-Standardized PRO-PM for Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA). However, we urge CMS to extend the voluntary reporting period to four years, consider partial-year reporting options, and address the significant costs and infrastructure challenges associated with PRO-PM implementation. We also recommend that CMS provide technical support, establish a reimbursement pathway for PRO-PMs, and consider the long-term impacts of the COVID-19 pandemic on data collection and reporting.
- **Non-Opioid Pain Relief Policies** AAOS commends CMS for proposing separate payments for non-opioid pain relief products under the OPPS and ASC payment systems, aligning with our long-standing support for non-opioid pain management. We encourage CMS to clarify whether these payments will apply to specific orthopaedic treatments such as indwelling nerve catheters and cryoneurolysis, and to continue exploring alternative chronic pain management strategies.
- **Concerns with Prior Authorization Process** AAOS supports the proposed alignment of Medicare Fee-For-Service (FFS) prior authorization review timeframes with Medicare Advantage standards but remains concerned about the overall burden of prior authorization. We recommend that CMS streamline the prior authorization process, enhance transparency, and ensure that these requirements are evidence-based and clinically appropriate to avoid delays in patient care.

AAOS
American Association of Orthopaedic Surgeons

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 and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities (CMS-1809-P) published in the Federal Register on July 22, 2024.[1]

Updates to OPPS and ASC Payment Rates

In the CY 2025 OPPS/ASC proposed rule, the Centers for Medicare & Medicaid Services (CMS) reiterated their policy of updating the ASC payment system using the productivity-adjusted hospital market basket for the period covering CY 2019 through CY 2023.[2] In CY 2024, CMS extended this policy for an additional two years, covering 2024 and 2025. In this proposed rule, CMS proposes a 2.6% increase in ASC payment rates for facilities that meet the quality reporting requirements. This adjustment is derived from a proposed hospital market basket increase of 3.0 percent, offset by a 0.4 percentage point productivity adjustment. AAOS continues to endorse the decision to extend the hospital market basket-based updates for ASCs and urges CMS to adopt this methodology for ASC payments permanently. [3]

ASC Covered Procedure List Nominations

In our previous comments on the FY 2023 proposed rule, AAOS appreciated the clarification provided by CMS regarding the submission of recommendations for the ASC Covered Procedures List (ASC-CPL) by stakeholders.[2] Medical specialty societies like ours possess the clinical expertise to recommend procedures within our specialty that can be safely performed in an ASC. However, AAOS also urges the agency to provide additional transparency to the process by including in the proposed rule the procedures that were requested by stakeholders for addition to the ASC-CPL even if CMS does not propose to add them to the list as requested. It is imperative for CMS to receive input from stakeholders on these decisions, which becomes impossible for stakeholders if they are not made aware of the services for which CMS declined recommendations for addition to the ASC-CPL.

[1] 89 Fed. Reg. 59186 (July 22, 2024).
[2] Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS). (2024, July 10). CY 2025 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule. https://public-inspection.federalregister.gov/2024-15087.pdf
[3] American Association of Orthopaedic Surgeons. (2023, September 8). AAOS Comments on the 2024 OPPS Proposed Rule. https://www.aaos.org/globalassets/advocacy/issues/aaos-fy-2024-opps-comment-letter.pdf

As CMS considers moving specific procedures to the ASC-CPL, we urge the agency to also consider the inclusion of "add-on" services that are crucial for patient safety. These add-on services, which trigger a complexity adjustment in the hospital outpatient setting, should be reimbursed separately in the ASC setting to incentivize physicians to perform these important add-on services.[4]

Changes to Inpatient Only List

For CY 2025, CMS received various requests recommending particular services be removed from the IPO list. After conducting a clinical review, CMS found insufficient evidence based on the traditional long-standing criteria and therefore is not proposing to remove any services from the IPO list for CY 2025.[1] AAOS continues to advocate for CMS to utilize relevant expert knowledge and peer-reviewed evidence in future decisions regarding the IPO list.

We would like to reiterate that the determination of appropriate surgical setting should be left to the judgement of surgeons, without mandates or pre-authorization requirements to determine inpatient vs. outpatient surgery, regardless of changes to the IPO list.[3]

Proposed OPPS Payment for Devices

AAOS appreciates CMS's efforts to enhance access to innovative technologies for Medicare beneficiaries and supports the add-on payments for new technologies with demonstrated efficacy and effectiveness. We encourage CMS to consider expanding this program to encompass a broader range of devices, thereby increasing the frequency of Medicare coverage approvals for new and promising technologies.[5]

AAOS previously expressed support for innovation and expanded coverage for devices that improve patient safety and outcomes in response to the Transitional Coverage for Emerging Technologies (TCET) proposed notice.[4] We believe it would be prudent to extend coverage to additional devices under the TCET pathway. 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.[4]

Quality Reporting Programs

AAOS appreciates CMS finalizing the *Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO-PM) for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)* in the Hospital OPD setting, with voluntary reporting from CY 2025 through CY 2027, followed by mandatory reporting from CY 2028 through CY 2031 for payment determination.[6]

---

[4] 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

[5] 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

[6] 2024 Medicare Hospital Outpatient Prospective Payment and Ambulatory Surgical Center (OPPS/ASC) Final Rule. https://www.federalregister.gov/documents/2023/11/22/2023-24293/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment.

We believe that the adoption of the PRO-PMs across settings is essential to achieving better patient outcomes. In our previous comments, we expressed our support for this measure's inclusion in both the inpatient and outpatient settings, recognizing the value it beings to the evaluation of musculoskeletal quality care.[7] We continue to note our appreciation of the inclusion of orthopaedic surgeons in the Technical Expert Panel and Expert Clinical Consultants involved in the development of this measure. Additionally, we also welcomed the adoption of the recommendations from the 2015 Patient-Reported Outcomes Summit for Total Joint Arthroplasty, particularly the section of the PROMIS-Global or the VR-12 Health Survey to measure general health alongside disease-specific instruments such as 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).[6]

Additionally, AAOS appreciates CMS's responsiveness to our advocacy for the use of registries in the collection, standardization, and submission of patient-reported outcome measures (PROMs). We also recognize the agency's consideration of Medicare enrollment and beneficiary data to identify Medicare and Medicaid dual eligibility enrollment status as a risk adjustment variable. Over the past two years, AAOS has made a significant investment, along with substantial staff and volunteer efforts, to ensure our members are well-prepared for the successful the implementation of this measure.[8] However, we must reiterate our concerns regarding the implementation of this measure and urge CMS to address these issues as the rule is put into practice.[6]

- **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 public accountability, then appropriate measurement scales must be developed and then the results must be shared transparently in an actionable manner.** CMS must share real-time data with physicians to improve shared decision-making.[6]

  An issue with using PROMs for differentiating a hospital's performance is that many of the outcomes are for reasons outside the hospital's control. For example, a study evaluating change in PROMs before and after hip replacement surgery found that most of the variation in PROMs

[7] 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-ipps-rule-comments.pdf
[8] American Association of Orthopaedic Surgeons. Patient-Reported Outcome Measures. https://www.aaos.org/quality/research-resources/patient-reported-outcome-measures/

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.[6] **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.**[6]

- **Timeline**

  While AAOS appreciates the finalized voluntary reporting periods from CY 2025 through 2027, **we continue to urge CMS to extend this period up to four years** for this PRO-PM. This extended timeline will better support surgeons and their patients in familiarizing themselves with the reporting requirements and if necessary, modify workflows.[6] An extended timeline will help with improving the learning curve among patients and surgeons. AAOS also encourages CMS to consider partial year reporting in the initial phase, such as three to six-month reporting periods before moving to a full year reporting requirement. The Joint Commission's Advanced Total Hip and Knee Replacement Certification calls for 90-day pre- and 90-day post-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). Furthermore, many of our clinicians and their teams have encountered challenges with capturing data over a one-year period. As CMS has previously noted, external factors beyond the control of the healthcare institution or surgeon can affect the ability to obtain a more longitudinal response. Therefore, an extended and phased timeline is crucial for ensuring the successful implementation of this measure.[6]

- **Associated cost and burden**

  There is significant cost associated with the adoption of PRO-PMs. While certain large health systems and centers of excellence are already ahead of the curve in adoption and learning, many health systems and smaller practices still face considerable challenges in data collection and reporting on PRO-PMs. **AAOS urges CMS to continue providing technical support and consider implementing a bonus to encourage investment, particularly among smaller health systems and those with limited infrastructure and resources.**[6]

  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.**[6]

- **Implementation difficulties**

A major obstacle to adopting PRO-PMs is the current data infrastructure. Despite widespread adoption of electronic health records (EHR) in the United States, these systems often fall short in terms of effective quality measurement and integration. While CMS's efforts to improve interoperability are likely to help in this regard, significant challenges remain, including inadequate integration of PROMs into EHRs, inconsistent data capture methods, and data contained in unstructured notes. Thus, progress in this area will require significant investments and public-private partnerships to adopt newer technologies such as machine learning and artificial intelligence for analyzing clinical notes. AAOS also understands that expert clinicians must review, and correct large-scale data gathered via machine learning technology. Without the creation of structured feedback loops, reporting on PRO-PMs will not contribute to a learning healthcare system. **We urge CMS to consider these technical difficulties and provide necessary support to facilitate the successful adoption of PRO-PMs.**

- **Reimbursement Pathway**

  Additionally, we would request that CMS consider establishing 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, followed by the American Medical Association (AMA) Current Procedural Terminology (CPT) Editorial Panel's code creation process for permanent inclusion and widespread adoption across the healthcare system.[6]

- **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.[6] 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.**[6]

Proposed CY 2025 Non-Opioid Policy for Pain Relief Under the OPPS and ASC Payment System

AAOS appreciates CMS's proposal to ensure that bundled payment policies do not create barriers to access for non-opioid pain relief products. This aligns with AAOS's longstanding support for increasing the availability of non-opioid alternatives for pain management across the continuum of care for Medicare beneficiaries. Separate and independent payment for these alternative pain relief options and treatment strategies will facilitate a shift in pain management practices, modify prescription trends, and enhance overall patient care.

AAOS continues to encourage CMS to consider a wide range of non-opioid treatments, including but not limited to intravenous acetaminophen, regional nerve blocks, icing wraps, transcutaneous stimulators, and topical analgesics. Additionally, AAOS reiterates its support for incentivizing 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.

As always, AAOS is supportive of utilization of non-opioid pain management where appropriate and commends CMS for taking steps to improve access to these treatments. AAOS continues to seek further clarity on whether the proposed separate payment would apply to specific treatments commonly used in orthopedics, such as indwelling nerve catheters and cryoneurolysis (e.g., Iovera).

Changes to the Review Timeframes for the Hospital Outpatient Department (OPD) Prior Authorization Process

For CY 2020, CMS implemented a Medicare prior authorization process for specified outpatient department services, establishing defined approval timeframes to ensure timely provider responses and the delivery of appropriate care to beneficiaries. In the 2024 CMS Prior Authorization Final Rule, CMS further refined these processes by reducing prior authorization review timeframes for certain payers, including Medicare Advantage organizations, to 72 hours for expedited requests and seven (7) calendar days for standard requests. Although Medicare fee-for-service (FFS) is not directly subject to these changes, CMS is now proposing to align the Medicare FFS standard review timeframe for HOPD services with this updated standard, reducing it from ten (10) business days to seven (7) calendar days.

AAOS is supportive of CMS's proposal to align the standard review timeframes but reiterates our concern regarding the broader use of prior authorization. These requirements impose significant burdens on physicians, undermining their training and professional expertise, and lead to substantial delays in patient care as resources and energy are diverted from optimizing care to fulfilling administrative requirements. [9] We urge CMS to continue streamlining the prior authorization process, improving transparency and communication between payers and providers, and ensuring that prior authorization requirements are evidence-based and clinically appropriate.

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 2025 OPPS/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 Lori Shoaf, JD, MA, AAOS Office of Government Relations at shoaf@aaos.org.

[9] AAOS 2024 Prior Authorization ASC Notice Response. https://www.aaos.org/globalassets/advocacy/letters/aaos-prior-authorization-asc-notice-response.pdf

AAOS
American Association of Orthopaedic Surgeons

Sincerely,

Paul Tornetta III, MD, PhD, FAAOS
AAOS President
cc: Annunziato Amendola, MD, FAAOS, First Vice-President, AAOS
Wilford K. Gibson, MD, FAAOS, Second Vice-President, AAOS
Thomas E. Arend, Jr., Esq., CAE, CEO, AAOS
Nathan Glusenkamp, Chief Quality and Registries Officer, AAOS

AAOS
American Association of Orthopaedic Surgeons

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

American Association of Hip and Knee Surgeons (AAHKS)
American Association for Hand Surgery (AAHS)
American Orthopaedic Foot & Ankle Society (AOFAS)
American Shoulder and Elbow Surgeons (ASES)
American Society for Surgery of the Hand Professional Organization (ASSH)
Campbell Clinic Orthopaedics
Cervical Spine Research Society (CSRS)
EmergeOrtho
J. Robert Gladden Orthopaedic Society (JRGOS)
Limb Lengthening and Reconstruction Society (LLRS)
Orthopaedic Rehabilitation Association (ORA)
Orthopaedic Trauma Association (OTA)
OrthoSC
Peachtree Orthopedics
Scoliosis Research Society (SRS)
United Musculoskeletal Partners (UMP)

Alabama Orthopaedic Society
California Orthopaedic Association
Colorado Orthopaedic Society
Connecticut Orthopaedic Society
Florida Orthopaedic Society
Georgia Orthopaedic Society
Illinois Association of Orthopedic Surgeons
Massachusetts Orthopaedic Association
Michigan Orthopaedic Society
Minnesota Orthopaedic Society
Missouri State Orthopaedic Association
New Hampshire Orthopaedic Society
New York State Society of Orthopaedic Surgeons
North Carolina Orthopaedic Association
North Dakota Orthopaedic Society
Ohio Orthopaedic Society
South Carolina Orthopaedic Association
South Dakota State Orthopaedic Society
Tennessee Orthopaedic Society
Texas Orthopaedic Association
Virginia Orthopaedic Society