AAOS
American Association of Orthopaedic Surgeons

June 8, 2023
Hon. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1785-P
P.O. Box 8013
Baltimore, MD 21244-1850

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

Subject: CMS-1785-P

Medicare Program; Proposed Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2024 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Rural Emergency Hospital and Physician-Owned Hospital Requirements; and Provider and Supplier Disclosure of Ownership

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 the Medicare Program; Hospital Inpatient Prospective Payment System (IPPS) for Acute Care Hospitals and the Long-Term Care Hospital (LTCH) Prospective Payment System and Policy Changes and Fiscal Year (FY) 2024 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Rural Emergency Hospital and Physician-Owned Hospital Requirements; and Provider and Supplier Disclosure of Ownership (CMS-1785-P) published in the Federal Register on April 10, 2023.

Proposed FY 2024 Applications for New Technology Add-on Payments (Alternative Pathways)

CMS is seeking comments on the following applications for new technology-add-on payments, following approval from the Food and Drug Administration (FDA) as a Breakthrough Device by July 2, 2023:

One application of relevance to AAOS is the 4WEB Medical Inc.'s application for the 4WEB Medical Ankle Truss

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1. *2024 Hospital Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital Prospective Payment System (LTCH PPS) Proposed Rule*. https://www.govinfo.gov/content/pkg/FR-2023-05-01/pdf/2023-07389.pdf

System (ATS), utilizing a tibiotalocalcaneal (TTC) fusion system with a premarket authorized TTC nail to manage ankle bone defects that occur after a failed ankle arthrodesis or arthroplasty.[1] Physicians have utilized this ATS for many years. A cohort study demonstrated that this ATS resulted in significant functional improvements among study participants with low complications and subsequent surgical interventions.[2] AAOS recommends developing peer-reviewed literature and independent evidence on this technology.

This proposed rule also discusses 4WEB Medical Inc.'s application for Total Ankle Talar Replacement, for new technology add-on payments for FY 2024. [1] Incidence of talar avascular necrosis (AVN) are very low, depending on the population studied, and other factors, falling from 0.01% to 0.08%.[3] AAOS encourages further exploration on the advancements in technology, their cost-effectiveness and utilization of total ankle arthroplasty vs. ankle fusion. AAOS members also note that it may take some time to establish larger numbers of prospective studies to determine the cost effectiveness of talar replacement.

An application for the Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) System was submitted by Zimmer Biomet. However, the kinematic data generated by the CTE with CHIRP System has not demonstrated any clinical benefits or outcomes and is not intended to be utilized for clinical decision-making. [4] The CHIRP System is only intended to be used with Zimmer Biomet Patient Specific Components and poses additional cost to Total Knee Arthroplasty (TKA) implants ($850.85 for one knee (or $1,701.70 for two knees) for FY 2024.) [1] Hence, AAOS raises the following questions on this proposal:

1. Would the indications for the use of this component be for medical research only? If so, would the proprietary nature of the component limit access to the data received?
2. Would community orthopaedic surgeons be implanting this and then have the ability to share the data?
3. Would the generated data be available for use by joint replacement data registries?

Graduate Medical Education

AAOS believes that Graduate Medical Education (GME) is imperative to the prosperity of our health care systems and must be invested in financially to ensure quality patient care from adequately trained physicians. [5] AAOS recommends that physician manpower policies be developed in a deliberate and careful manner, considering the factors that influence how physicians choose their specialties. Furthermore, physician manpower policies should

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2. Corr D, Raikin J, O'Neil JT, Raikin SM. Outcomes of Tibiotalocalcaneal Arthrodesis using a Custom Three-Dimensional Printed Titanium Truss Implant. *Foot & Ankle Orthopaedics*. 2020;5(4):24730114205S0017. doi:https://doi.org/10.1177/2473011420s00177
3. Waseem S, Nayar SK, Vemulapalli K. Paediatric talus fractures: A guide to management based on a review of the literature. *Injury*. 2022;53(3):1029-1037. doi:https://doi.org/10.1016/j.injury.2021.12.024
4. *CANARY Canturio ™ Tibial Extension with CHIRP ™ System Surgical Technique*. Accessed May 19, 2023. https://www.zimmerbiomet.com/content/dam/zb-corporate/en/education-resources/surgical-techniques/specialties/knee/persona-iq/3640.1-US-en%20Persona%20IQ%20Canary%20Medical%20Surgical%20Technique1.pdf
5. *AAOS Position Statement. The Financing of Graduate Medical Education*. Accessed May 19, 2023. https://www.aaos.org/globalassets/about/position-statements/1109-the-financing-of-graduate-medical-education.pdf

be designed in such a way that they do not endanger the quality of graduate medical education in specialties where shortages are expected.[5] Attempts to increase the number of physicians in specific specialties by reducing training in others will impede access to care. [5]

CMS has made efforts to expand regulations regarding GME, and in the 2023 Medicare Outpatient Prospective Payment System (OPPS) final rule, CMS finalized certain payment policies and conditions of participation to establish rural emergency hospitals (REHs) as a new Medicare provider type, effective January 1, 2023.[6] In this proposed rule, CMS proposes that beginning October 1, 2023, "REHs may decide to be a non-provider site such that if the requirements are met, a hospital can include the FTE residents training at the REH in its direct GME and IME FTE counts for Medicare payment purposes, or, the REH may decide to incur direct GME costs and be paid based on reasonable costs for those training costs."[1] AAOS is pleased with this proposal and supports payments for GME at REHs to meet the needs of patients, as it expands the number of GME training positions supported by the federal government.[5] This proposal will improve workforce shortages in rural areas.

Hospital Value Based Purchasing (VBP) Program Proposed Policy Changes| Proposed Substantive Measure Updates to Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)

CMS is proposing to adopt substantive measure updates to the Hospital-level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) beginning with the FY 2030 program year. [1] Specifically, in the FY 2023 IPPS/LTCH PPS final rule CMS finalized updates to the THA/TKA Complication measure in the Hospital VBP Program, including updates to the end measure calculations. By including these substantive measure updates in the Hospital VBP Program, 26 additional mechanical complications ICD-10 codes would be included in the measured outcome. Some of these additional codes would capture diagnoses such as joint prosthesis, a bone plate of the pelvis, femur, tibia, or fibula, etc.[1]

AAOS supports the inclusion of the 26 additional mechanical complication ICD-10 codes. These codes are clinically appropriate to be paired with joint arthroplasty and will improve this measure's accuracy. AAOS members strive to improve overall patient safety and reduce avoidable complications, which can lead to better long-term outcomes for patients undergoing THA and TKA. We are also supportive of the addition of these measures to the Hospital VBP Program, however, AAOS is concerned about how the addition of these mechanical complication ICD-10 codes will negatively impact orthopaedic surgeons working in small community hospitals. Despite the many challenges these small hospitals may face with limited resources, infrastructure, and specialized expertise, orthopaedic surgeons serve patients requiring total joint arthroplasties at such facilities. These surgeons are focused on maximizing outcomes, preventing para operative and post operative complications, as well as preventing a need for readmission. Over the years, orthopaedic surgeons working in small community

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6. *CY 2023 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule.* https://www.govinfo.gov/content/pkg/FR-2023-05-01/pdf/2023-07389.pdf

hospitals or in other settings with limited resources have adhered to strict criteria on BMI, cardiac comorbidities, Hgb A1C, and preoperative Mupiricin nasal use, and more. AAOS is concerned about how these new measures will negatively impact outcomes for patients with osteoporosis and osteopenia. To illustrate further, some of the outcomes are beyond the control of the surgeon: a surgeon cannot prevent a patient from falling and suffering periprosthetic fractures that have nothing to do with the quality of placement of the total joint components. An unintended consequence of including these complications measures may be 'cherry picking' and 'lemon dropping' of patients which in turn will exacerbate outcomes disparities in the Medicare population.

Physician Self-Referral and Physician Owned-Hospitals

CMS proposes revisions to the regulations implemented in the physician-owned hospital (POH) expansion exception process, separating them from the requirements that a hospital must satisfy under the rural provider and whole hospital exception. In this proposed rule, CMS will only consider expansion exception requests from eligible hospitals, clarifying the data and information that must be included in an expansion exception request. CMS stated that hospitals meeting the baseline criteria would have the potential to expand facility capacity to 200 percent of its baseline number of operating rooms, procedure rooms, and beds. CMS would be prohibited from approving further expansion exception requests exceeding 200 percent of its baseline facility capacity. [1] As we commented previously, AAOS encourages CMS and the U.S. Department of Health and Human Services (HHS) Secretary to explore all regulatory avenues for lifting the arbitrary ban on new and expanding POHs.[7] Since passage of the Patient Protection and Affordable Care Act of 2010 ("ACA"), POHs have consistently demonstrated that they reduce costs while delivering a high quality of care to patients. For example, a systematic review published by the Mercatus Center[1] found that POHs provide either higher quality care at a lower cost with greater efficiency, or equivalent care, when compared to other community hospitals. The most recent CMS Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) data shows that POHs have markedly higher patient experience ratings compared to all hospitals. In addition, specialty POHs (e.g., cardiology and orthopaedic) were found to deliver higher quality care than non-profit hospitals, with lower rates of hospital readmission or mortality for high-risk surgery. [8] Therefore, AAOS asks that the expansion exception process for POHs should be eligibility based, allowing these hospitals to serve vulnerable populations as needed, and lifting the restrictions of two years between request for expansion and/or an overall increase of the 200 percent facility capacity. These restrictions create huge barriers to the delivery of high-quality health care by POHs. Studies have shown that POHs consistently deliver better outcomes.[9]

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7. *AAOS 2022 OPPS Letter.* https://www.aaos.org/globalassets/advocacy/issues/aaos-2022-opps-letter.pdf
8. Brian J. Miller et al., Cost and Quality of Care in Physician-Owned Hospitals: A Systematic Review, MERCATUS CENTER (Sept. 7, 2021), https://www.mercatus.org/research/research-papers/cost-and-quality-care-physician-owned-hospitalssystematic-review

Further, CMS is proposing to reinstate restrictions for hospitals that meet the criteria for a "high Medicaid facility" expansion exception request. These restrictions were removed in the calendar year (CY) 2021 Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center final rule. **AAOS requests that CMS does not finalize this proposal** because these facilities service many patients with lower incomes and other socioeconomic disadvantages. It is well known that health outcomes are correlated with income, with lower income populations usually having poorer outcomes. Moreover, higher Medicaid facilities are more likely to have greater financial constraints since Medicaid reimbursement typically lags Medicare and other commercial insurance payments. In addition, high Medicaid facilities tend to service minority patients in greater numbers. Thus, restricting expansion of high Medicaid facilities will further exacerbate existing health care delivery and therefore, health outcome disparities in the United States.

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 Hospital Inpatient Prospective Payment System (IPPS) and Long-Tern Care Hospital Prospective Payment System (LTCH PPS) Proposed Rule. 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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AAOS President

cc: Paul Tornetta III, MD, PhD, FAAOS, First Vice-President, AAOS
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9. Burky A. Study: Physician-led hospitals earn nearly 7 times higher patient experience rating. Fierce Healthcare. Published September 28, 2022. https://www.fiercehealthcare.com/providers/physician-led-hospitals-earn-nearly-7-times-higher-patient-experience-rating-study#:~:text=Physician%2Dled%20hospitals%20outperformed%20their,non%2Dphysician%2Dled%20hospitals

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

Arthroscopy Association of North America (AANA)
American Orthopaedic Foot & Ankle Society (AOFAS)
American Orthopaedic Society for Sports Medicine (AOSSM)
American Society for Surgery of the Hand Professional Organization (ASSH)
Orthopaedic Rehabilitation Association (ORA)
Scoliosis Research Society (SRS)

Colorado Orthopaedic Society
Connecticut Orthopaedic Society
Florida Orthopaedic Society
Georgia Orthopaedic Society
Iowa Orthopaedic Society
Louisiana Orthopaedic Association
Maryland Orthopaedic Association
Massachusetts Orthopaedic Association
Michigan Orthopaedic Society
Missouri State Orthopaedic Association
Montana Orthopedic Society
Minnesota Medical Association
Nebraska Orthopedic Society
Ohio Orthopaedic Society
Pennsylvania Orthopaedic Society
South Carolina Orthopaedic Association
South Dakota State Orthopaedic Society
Tennessee Orthopaedic Society
Texas Orthopaedic Association
Virginia Orthopaedic Society
Wisconsin Orthopaedic Society