

June 28, 2021

Hon. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1752-P
P.O. Box 8013
Baltimore, MD 21244-1850

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

Subject: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Changes to Medicaid Provider Enrollment; and Proposed Changes to the Medicare Shared Savings Program (CMS-1752-P)

Dear Administrator Brooks-LaSure:

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 in response to the Medicare Program; Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals and the Long-Term Care Hospital (LTCH) Prospective Payment System and Proposed Policy Changes and Fiscal Year (FY) 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Changes to Medicaid Provider Enrollment; and Proposed Changes to the Medicare Shared Savings Program (CMS-1752-P) published in the Federal Register on April 27, 2021.

Future Inclusion of Hospital-Level, Risk Standardized Patient Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty (NQF# 3559) in the Hospital IQR Program

CMS is considering future inclusion of Hospital-Level, Risk Standardized Patient Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty (NQF# 3559) to the Hospital IQR Program in the proposed rule and is seeking stakeholder feedback on numerous aspects of implementation. Specifically, the Agency requests input on a phased implementation approach, timing and duration of reporting periods, data collection and submission, and threshold requirements. Most significant for orthopaedic surgeons is the idea of expanding the measure to non-inpatient

settings, which is an important consideration given the recent removal of TKA and THA procedures from the Inpatient Only List in the CY 2018 and CY 2020 OPPS/ASC final rules, respectively.

In general, AAOS is supportive of the recommended measure, NQF# 3559. We appreciate the inclusion of orthopaedic surgeons in the Technical Expert Panel and Expert Clinical Consultants behind the development of this measure. Additionally, we are 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).

There is a long history of using PROMs in orthopaedic research and clinical care, from which invaluable insight into the barriers to successful measurement and quality improvement can be gained. According to the AAOS Position Statement 1188 on Principles for Musculoskeletal Based Patient Reported Outcome-Performance Measurement Development, “efforts to incorporate PRO measurement into routine clinical practice have been more challenging, though significant progress has been made in developing and validating PROMs for specific musculoskeletal disorders or treatments and those that give a broader picture of general health status.”¹ Some specific challenges to applying PRO measurement in routine clinical care are implementation and response rates.

AAOS strongly supports the use of registries for collection, standardization, and submission of PROMs to CMS. The Agency may ease implementation and improve response rates by encouraging use of clinical data registries that aid participant hospitals in PRO data collection. For example, participant sites in the AAOS American Joint Replacement Registry (AJRR) can collect Veterans RAND 12 Item Health Survey (VR-12), Patient-Reported Outcomes Measurement Information System (PROMIS) Global-10 generic PRO survey, the Hip disability and Osteoarthritis Outcome Score (HOOS)/Knee injury, and Osteoarthritis Outcome Score (KOOS) Jr. data via our PRO portal. AJRR participant sites and individual surgeons can view dashboards for their patients’ PROMs and compare them to national scores, which allows clinicians to spend more time focusing on improving patient outcomes instead of dealing with PRO survey collection and follow-up activities. For registry-based PROMs reporting, CMS should seek to ensure that measures are reported via QCDRs with demonstrated capabilities to report the specific PROM.

The importance of risk adjustment in measuring and comparing PRO-PMs cannot be overstated. We support the risk adjustment model utilized in NQF #3559, which calculates a hospital-specific risk-standardized improvement rates (RSIRs) that produces a performance measure per hospital and

¹ American Academy of Orthopaedic Surgeons. (2018, March). *Principles for Musculoskeletal Based Patient Reported Outcome-Performance Measurement Development*. AAOS Position Statement 1188.

<https://www.aaos.org/contentassets/1cd7f41417ec4dd4b5c4c48532183b96/1188-principles-for-musculoskeletal-based-patient-reported-outcome-performance-measurement-development.pdf>

accounts for patient case mix.² However, it should be noted that dual eligibility is not included in the risk adjustment model for NQF# 3559. An analysis of Comprehensive Care for Joint Replacement Model Program Year 2 data showed hospitals with a high percentage of dual-eligible beneficiaries (patients with both Medicare and Medicaid insurance) were more likely than low-dual hospitals to be penalized (24.3% vs 13.7%).³ Financial penalties as a result of caring for more clinically and/or socio-economically complex patients further reinforces a system that provides fewer resources to safety-net hospitals and capitulates healthcare outcome disparities. In this way, we ask that CMS consider additional socio-economic risk stratification in measure implementation to avoid unintended consequences.

In summary, we applaud the Agency for taking this important step towards implementing performance measures based on outcomes that matter most to our patients, and look forward to working with you to implement these measures in an effort to provide feedback to clinical teams and ultimately improve patient health outcomes following these life altering procedures.

Request for Information (RFI) on Proposed Quality Data Reporting Requirements for Specific Providers and Suppliers Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Hospital Quality Programs

CMS is considering expanding and establishing policies for data aggregation, measure calculation, measure reporting process integrity, and market innovation to third-party aggregators, including, but not limited to, Health Information Exchanges, Qualified Registries, and Qualified Clinical Data Registries (QCDRs). The AAOS Registries have achieved QCDR designation, and we can attest to the significant resources required to operate and maintain a QCDR. As a part of the Quality Payment Program (QPP) QCDR self-nomination process, CMS already requires thorough measure testing and validation to ensure measure calculation and reporting integrity. Rather than creating separate, and potentially disjointed criteria and processes, CMS should borrow the established policies from the QPP and align wherever possible. Additionally, the AAOS recommends CMS apply full credit to any registry achieving QPP QCDR designation for similar Hospital Quality Program requirements.

Furthermore, in any proposals on standards for measure calculation, CMS should carefully consider the types of data readily available for submission from electronic records versus data types that would require manual abstraction from medical records. While the proposals in this rule are directed at hospitals, it is important to realize the trickle-down impact to healthcare providers as the end users of the systems collecting data for measure calculation.

² Yale New Haven Health Services Corporation – Center for Outcomes Research and Evaluation. (2021, March). *Patient-Reported Outcomes (PROs) Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital Level Performance Measure Version 1.0 Methodology Report*.

³ Kim, H., Meath, T. H., Dobbertin, K., Quiñones, A. R., Ibrahim, S. A., & McConnell, K. J. (2019). Association of the Mandatory Medicare Bundled Payment With Joint Replacement Outcomes in Hospitals With Disadvantaged Patients. *JAMA network open*, 2(11), e1914696-e1914696.

CMS is also considering the future potential development of a common portfolio of digital quality measures (dQMs) across its regulated programs, agencies, and private payers. In general, AAOS is supportive of policies that seek to simplify quality reporting for our members with caveats. It is important that efforts to standardize measures do not interfere with the flexibility for measure developers to innovate in the QCDR measure space. Transparency is the crux of widespread adoption of a common measure portfolio; thus, we believe specifications for the CMS-developed dQMs are made available publicly, in a timely manner, and at no cost.

We are alarmed by the mention of policies regulating market innovation without further context. From a measure developer perspective, concerns about intellectual property are raised. Though we understand CMS will not be responding to specific comments submitted in response to this Request for Information in the FY 2022 IPPS/LTCH PPS final rule, we appreciate the opportunity to provide comments and look forward to greater transparency and communication from CMS on this and the other proposals in this RFI.

Request for Information on Closing the Health Equity Gap in CMS Hospital Quality Programs

AAOS appreciates the opportunity to comment on the Agency's request for information on closing the health equity gap in CMS Hospital Quality Programs. As we have stated in prior comments, AAOS is supportive of gathering meaningful patient data to support both the individual and population-level mitigation of health disparities. We request that CMS consider the following determinants which are of particular relevance to musculoskeletal care:

- Body Mass Index (BMI) – The actual height and weight should be recorded. The BMI should not be captured from the administrative data. The height and weight are currently being recorded in many electronic health records (EHR).⁴
- Smoking Status – Smoking status may be reported through administrative data, but additional information may be provided from the EHR.⁵
- Age – Age is reported in administrative data.⁶
- Sex – Sex is reported in administrative data.⁷
- Back Pain – Back pain would be a patient-reported variable and recorded in the EHR. It has been noted to influence outcomes of joint replacement patients.⁸

⁴ ASPE (2016). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Available: <https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs>

⁵ Ibid

⁶ Ibid

⁷ Ibid

⁸ Karran, E. L., Grant, A. R., & Moseley, G. L. (2020). Low back pain and the social determinants of health: a systematic review and narrative synthesis. *Pain*, 161(11), 2476–2493. <https://doi.org/10.1097/j.pain.0000000000001944>

- Pain in non-operative lower extremity joint – Pain in a non-operative lower extremity joint would be a patient-reported variable and recorded in the EHR. It has been noted that pain in other extremities can influence the outcome of a total joint replacement.⁹
- Health Risk Status – The actual comorbidities that should be included need further investigation. Both the Charlson morbidity index and the Elixhauser morbidity measure may identify appropriate comorbid conditions.¹⁰ In order to identify the patient's comorbid conditions, it is recommended that all inpatient and outpatient diagnosis codes for the prior year be evaluated.¹¹
- Depression/Mental Health Status – The Patient-Reported Outcomes Measurement Information System (PROMIS) Global or VR-12 will collect this variable, as well as the administrative data.¹²
- Chronic Narcotic or Pre-operative Narcotic Use – These variables affect patient outcomes and requires additional consideration. The information should be available in the EHR.¹³

In addition to the above clinical factors which impact outcomes on the individual level, we ask that CMS also consider access to transportation, social support, and health literacy.¹⁴ These factors all contribute to a patient's successful treatment and lead to improved outcomes for both chronic and acute musculoskeletal care. Particularly in light of the disparities made evident during the pandemic, it is essential that patients and physicians have the tools to support a robust model of shared decision-making.

Moreover, AAOS has developed comprehensive definitions of quality and value in orthopaedics. Whereas quality is defined as the successful delivery of appropriate, evidence-based musculoskeletal healthcare in an effort to achieve sustained patient-centered improvements in health outcomes and quality of life exemplified by a physician-led musculoskeletal team focused on the individual patient's preferences in the delivery of care that is safe, accessible, equitable, and timely; and that fosters evidence-based innovation essential for the advancement of professional and scientific knowledge.

⁹ Perruccio, A. V., Power, J. D., Evans, H. M., Mahomed, S. R., Gandhi, R., Mahomed, N. N., & Davis, A. M. (2012). Multiple joint involvement in total knee replacement for osteoarthritis: Effects on patient-reported outcomes. *Arthritis care & research*, 64(6), 838–846. <https://doi.org/10.1002/acr.21629>

¹⁰ Austin, S. R., Wong, Y. N., Uzzo, R. G., Beck, J. R., & Egleston, B. L. (2015). Why Summary Comorbidity Measures Such As the Charlson Comorbidity Index and Elixhauser Score Work. *Medical care*, 53(9), e65–e72. <https://doi.org/10.1097/MLR.0b013e318297429c>

¹¹ National Alliance to Impact the Social Determinants of Health. (2019). (issue brief). *Identifying Social Risk and Needs in Health Care*. Retrieved from <https://www.nasdoh.org/wp-content/uploads/2019/01/NASDOH-Social-Risks-Issue-Brief.pdf>

¹² Oak, S. R., Strnad, G. J., Bena, J., Farrow, L. D., Parker, R. D., Jones, M. H., & Spindler, K. P. (2016). Responsiveness Comparison of the EQ-5D, PROMIS Global Health, and VR-12 Questionnaires in Knee Arthroscopy. *Orthopaedic Journal of Sports Medicine*, 4(12), 232596711667471. <https://doi.org/10.1177/2325967116674714>

¹³ Kidner, C. L., Mayer, T. G., & Gatchel, R. J. (2009). Higher opioid doses predict poorer functional outcome in patients with chronic disabling occupational musculoskeletal disorders. *The Journal of bone and joint surgery. American volume*, 91(4), 919–927. <https://doi.org/10.2106/JBJS.H.00286>

¹⁴ Artiga, S., & Hinton, E. (2018). (issue brief). *Beyond Health Care: The Role of Social Determinants in Promoting Health and Health Equity* Kaiser Family Foundation. Retrieved from <https://files.kff.org/attachment/issue-brief-beyond-health-care>

Value is defined as the relationship of a patient-centered health outcome to the total cost required to reach that outcome, given that care is: evidence-based, appropriate, timely, sustainable, and occurs throughout a full cycle of musculoskeletal care for a patient's condition; and that cost of musculoskeletal care is an investment and includes consideration of greater lifestyle and economic impacts.

We encourage CMS to consider these definitions vis-à-vis the goals of assessing quality and value in an equitable health care environment.

Breakthrough Devices

AAOS supports the applications for two orthopaedic devices proposed for add-on payments through the Alternative Pathway for Breakthrough Devices Application. Our member experts find the introduction and payment for the Aprevo Intervertebral Body Fusion Device and the Cerament G injectable bone-void filler to be appropriate. We appreciate CMS' continued approval of orthopaedic devices which advance the care of musculoskeletal disorders and improve patient's quality of life.

Graduate Medical Education

AAOS is pleased by the proposed distribution of 1,000 new residency slots to hospitals in rural areas and those which serve geographies designated as Health Professional Shortage Areas (HPSAs). Moving forward, we ask that CMS also consider the value of residency slots designated to address the dual-realities of an aging population and the impact of musculoskeletal issues on the overall burden of disability in the United States.¹⁵ This is particularly salient when considering that rural training programs have an inherent bias toward primary care physician training, as most specialties, including orthopaedic surgery, do not meet the volume thresholds in rural areas necessary to support the creation of residency programs. We ask that CMS consider the prioritization of additional residency training funds in rural areas to ensure that all types of physicians can meet the needs of their patients irrespective of geography.

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 2022 IPPS 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. 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,

¹⁵ United States Bone and Joint Initiative. (n.d.). *Impacts of Aging*. BMUS: The Burden of Musculoskeletal Diseases in the United States. <https://www.boneandjointburden.org/fourth-edition/ig0/impacts-aging>.



Daniel K. Guy, MD, FAAOS
President, AAOS

cc: Felix H. Savoie, III, MD, FAAOS, First Vice-President, AAOS
Kevin J. Bozic, MD, MBA, FAAOS, Second Vice-President, AAOS
Thomas E. Arend, Jr., Esq., CAE, CEO, AAOS
Nathan Glusenkamp, Chief Quality and Registries Officer, AAOS
Graham Newson, Director, Office of Government Relations, AAOS

Alabama Orthopaedic Society
American Alliance of Orthopaedic Executives
American Association for Hand Surgery
American Association of Hip & Knee Surgeons
American Orthopaedic Foot and Ankle Society
American Orthopaedic Society for Sports Medicine
American Society for Surgery of the Hand
Arizona Orthopaedic Society
Arkansas Orthopaedic Society
Arthroscopy Association of North America
Cervical Spine Research Society
Connecticut Orthopaedic Society
Delaware Society of Orthopaedic Surgeons
Florida Orthopaedic Society
Georgia Orthopaedic Society
Iowa Orthopaedic Society
Kansas Orthopaedic Society
Louisiana Orthopaedic Association
Maryland Orthopaedic Association
Massachusetts Orthopaedic Association
Michigan Orthopaedic Society
Minnesota Orthopaedic Society
Missouri State Orthopaedic Association
Montana Orthopedic Society
Nebraska Orthopedic Society
New York State Society of Orthopaedic Surgeons
North Carolina Orthopaedic Association

North Dakota Orthopaedic Society
Ohio Orthopaedic Society
Orthopaedic Rehabilitation Association
Pediatric Orthopaedic Society of North America
Pennsylvania Orthopaedic Society
Rhode Island Orthopedic Society
Ruth Jackson Orthopaedic Society
Scoliosis Research Society
South Carolina Orthopaedic Association
South Dakota State Orthopaedic Society
Tennessee Orthopedic Society
Texas Orthopaedic Association
The OrthoForum
Virginia Orthopaedic Society
Washington State Orthopaedic Association
West Virginia Orthopaedic Society
Wisconsin Orthopaedic Society
Wyoming Orthopaedic Society