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June 15, 2022

Hon. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1771-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 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation (CMS-1771-P)

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 that agreed to sign on, we are pleased to submit comments on the *'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 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation'* (CMS-1771-P) published in the Federal Register on April 18, 2022.

Hospital Inpatient Quality Reporting (IQR) Program: Proposed Data Submission and Reporting Requirements for Patient-Reported Outcome-Based Performance Measures (PRO-PMs)

The Centers for Medicare & Medicaid Services (CMS) is considering several proposals to update the musculoskeletal measures in the Inpatient Quality Reporting Program. One of these proposals is to introduce the Hospital-Level, Risk Standardized Patient-Reported Outcomes Performance Measure (PRO-PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty

(TKA) (NQF #3559). CMS is proposing that the measure be implemented over time, with voluntary reporting periods in Calendar Year (CY) 2025 and 2026 and mandatory reporting beginning in the CY 2027/Fiscal Year (FY) 2028 payment determination.

In our formal comments on the FY 2022 IPPS proposed rule, AAOS supported the future inclusion of this measure. 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). We appreciate CMS now heeding our call for the use of registries for collection, standardization, and submission of patient reported outcome measures (PROM).¹ 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, we have several concerns with the current proposal which CMS must consider before finalizing this proposal.

• Clarification of goals

Donabedian's conceptual framework² 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 improving 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 in an actionable manner.** CMS must share real-time data with physicians to improve shared decision-making.³

¹ The AAOS American Joint Replacement Registry (AJRR) currently supports the Comprehensive Care for Joint Replacement (CJR) model PRO capture and reporting through an export file in the dashboard containing the PRO and risk variable data submitted via file or PRO portal use. This would enable us to readily support submission on behalf of our participants via CSV/XML or manual upload as noted in this proposed rule. The PROMs listed here are available for AJRR participants along with the patient-reported assessment of health literacy in the data specifications PRO questions or via our AJRR PRO portal.

² Donabedian, A. (1966). Evaluating the Quality of Medical Care. *Milbank Memorial Fund Quarterly*, 44(3),166–206.

³ Squitieri, L., Bozic, K. J., & Pusic, A. L. (2017). The Role of Patient-Reported Outcome Measures in Value-Based Payment Reform. *Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research*, 20(6), 834–836.

<https://doi.org/10.1016/j.jval.2017.02.003>

Another recommendation is to use expert judgement in interpreting outcomes after specific procedures. **We recommend analyzing hip and knee arthroplasty outcomes separately.** 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.⁴ More commonly, 80 to 85 percent of patients report being fully satisfied with their TKA on PRO measurements. For this reason, we suggest separately analyzing THA and TKA outcomes for performance measures.

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.⁵ **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.**

- **Timeline**

While we appreciate 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. An extended timeline will help with improving the learning curve among patients and surgeons. **We also recommend 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 Certification⁶ 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

⁴ Heath, E. L., Ackerman, I. N., Cashman, K., Lorimer, M., Graves, S. E., & Harris, I. A. (2021). Patient-reported outcomes after hip and knee arthroplasty: results from a large national registry. *Bone & Joint Open*, 2(6), 422-432.

⁵ Porter, M. E., Larsson, S., & Lee, T. H. (2016). Standardizing patient outcomes measurement. *N Engl J Med*, 374(6), 504-506.

⁶ [https://www.jointcommission.org/accreditation-and-certification/certification/certifications-by-](https://www.jointcommission.org/accreditation-and-certification/certification/certifications-by-setting/hospitalcertifications/orthopedic-certification/advanced-orthopedic/advanced-total-hip-and-total-knee-replacement/)

[setting/hospitalcertifications/orthopedic-certification/advanced-orthopedic/advanced-total-hip-and-total-knee-replacement/](https://www.jointcommission.org/accreditation-and-certification/certification/certifications-by-setting/hospitalcertifications/orthopedic-certification/advanced-orthopedic/advanced-total-hip-and-total-knee-replacement/)

with 1-year capture, and as you noted here, some external factors beyond health institution or surgeon control play into getting a more longitudinal response.

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

Although this measure is currently only proposed as an inpatient measure, we know from the literature that there is value in the ability to follow patients longitudinally, hence, meaningful reporting would require reporting in the outpatient setting as well. 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.**

- **Implementation difficulties**

A huge limiting factor in adopting PRO-PMs will be our data infrastructure.⁷ 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. We also understand that expert clinicians always need to review and intervene 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. **We urge CMS to consider these technical difficulties while requiring adoption of PRO-PMs.**

⁷ "Getting To The Next Generation Of Performance Measures For Value-Based Payment", Health Affairs Blog, January 29, 2019. DOI: 10.1377/hblog20190128.477681

- **Reimbursement Pathway**

Additionally, we 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.

- **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 procedures⁸ 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. 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.**

Hospital-Level, Risk Standardized Complication Rate (RSCR) Following Elective Primary THA/TKA Measure and Hospital-Level, Risk Standardized Payment Associated with an Episode of Care for Primary Elective THA and/or TKA Measure

CMS is proposing to reintroduce the Hospital-Level, Risk Standardized Complication Rate (RSCR) Following Elective Primary THA/TKA (NQF #1550) into the Hospital IQR program. While the measure was removed from the Hospital IQR program in the FY 2018 IPPS final rule to reduce provider burden since the measure was also being reported under the Hospital Value Based Purchasing (VBP) Program, the measure has been re-evaluated to expand the measure outcome. Specifically, the proposed update would add 26 ICD-10 complication codes to the measure to better capture the complication rate from THA and TKA. The same complication codes are being added to the Hospital-Level, Risk Standardized Payment Associated with an Episode of Care for Primary Elective THA and/or TKA Measure (NQF #3474). Apart from these complications, patient demographics including race, income level, and primary language were found to be associated with worsened outcomes following THA and/or

⁸ Mattingly, A.S., Rose, L., Eddington, H.S., et al. (2021). Trends in US Surgical Procedures and Health Care System Response to Policies Curtailing Elective Surgical Operations During the COVID-19 Pandemic. JAMA Network Open, 4(12),e2138038. doi:10.1001/jamanetworkopen.2021.38038

TKA.^{9,10} There is some concerning evidence within the field of quality measurement that payment programs, like the Merit-based Incentive Payment System (MIPS) and value-based care programs like the Comprehensive Care for Joint Replacement Model (CJR) subject hospitals and surgeons with higher proportions of socioeconomically disadvantaged populations to higher financial penalties,^{11, 12} where providers are penalized for patient population risk factors, rather than clinical performance. Please refer to the detailed risk factors, discussed below, that CMS must consider in future policies on improving quality of care especially those with reimbursement implications.

Request for Information on Closing the Health Equity Gap in CMS' Inpatient 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 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).
- Smoking Status – Smoking status may be reported through administrative data, but additional information may be provided from the EHR.
- Age – Age is reported in administrative data.
- Sex – Sex is reported in administrative data.
- 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.¹³

⁹ Pfefferle, K. J., Shemory, S. T., Dilisio, M. F., Fening, S. D., & Gradisar, I. M. (2014). Risk factors for manipulation after total knee arthroplasty: a pooled electronic health record database study. *The Journal of Arthroplasty*, 29(10), 2036-2038.

¹⁰ De Oliveira, G. S., McCarthy, R. J., Wolf, M. S., & Holl, J. (2015). The impact of health literacy in the care of surgical patients: a qualitative systematic review. *BMC surgery*, 15(1), 1-7.

¹¹ Rosenberg, B.L., Kellar, J.A., Labno, A., Matheson, D.H., Ringel, M., VonAchen, P., Lesser, R.I., Li, Y., Dimick, J.B., Gawande, A.A. and Larsson, S.H., (2016). Quantifying geographic variation in health care outcomes in the United States before and after riskadjustment. *PLoS One*, 11(12), p.e0166762.

¹² Thirukumar, C. P., Kim, Y., Cai, X., Ricciardi, B. F., Li, Y., Fiscella, K. A., ... & Gance, L. G. (2021). Association of the Comprehensive Care for joint replacement model with disparities in the use of Total hip and Total knee replacement. *JAMA network open*, 4(5), e2111858-e2111858

¹³ 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.¹⁴
- 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.¹⁵ In order to identify the patient’s comorbidity conditions, it is recommended that all inpatient and outpatient diagnosis codes for the prior year be evaluated.¹⁶
- 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.
- Chronic Narcotic or Pre-operative Narcotic Use – These variables affect patient outcomes and requires additional consideration. The information should be available in the EHR.

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. 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.

Add-On Payments for New Services and Technologies for FY 2023

AAOS supports add-on payments for new technologies with adequate evidence for their efficacy and effectiveness in Medicare patients. In general, AAOS is supportive of CMS working closely with the U.S. Food and Drug Administration (FDA) and their Breakthrough Devices Program to incentivize

¹⁴ 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>

¹⁵ 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>

¹⁶ National Alliance to Impact the Social Determinants of Health. (2019). (issue brief). *Identifying Social Risk and Needs in Health Care*. Retrieved from <https://www.nasdo.org/wp-content/uploads/2019/01/NASDOH-Social-Risks-Issue-Brief.pdf>

commercial sponsoring of new and innovative technologies for use in our health care delivery and treatment plans.

Moreover, AAOS recommends that the New Technology Add-on Payment (NTAP) status should also apply to drugs, diagnostics, and/or biologics subject to expedited FDA approval mechanisms for three complementary reasons. First, many innovations in musculoskeletal patient care have historically been surgical and related to medical devices; however, the current and future trends point towards biologics in a broader sense. Biologics could be drugs regulated by the FDA's Center for Drug Evaluation and Research (CDER) or human cells, tissues, and cellular and tissuebased products (HCT/P's) regulated by the FDA's Center for Biologics Evaluation and Research (CBER). Simultaneously, combination products have become the new normal. Several of the most important orthopaedic "biologics" are drug/device combinations regulated by the Center for Devices and Radiological Health (CDRH) as lead regulator, but these distinctions are likely to become increasingly blurred. Finally, the impetus behind expedited FDA approval mechanisms is common across musculoskeletal disease as few non-surgical breakthroughs have occurred for major disease such as osteoarthritis within the past regulatory framework prior to expedited reviews.

Continuing to Advance Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Hospital Quality Programs-Request for Information

CMS is seeking comments on approaches to optimize data flows for quality measurement to retrieve data from EHRs via FHIR Application Programming Interfaces (API) as well as to combine data needed for measure score calculation for measures that require aggregating data across multiple providers. CMS is also requesting information on activities related to leveraging and advancing standards for digital data and approaches to transition to the FHIR eCQM reporting as first steps in the transition to digital quality measurement.

As AAOS has stated in the past, a successful, interoperable system should not focus simply on the electronic sending, receiving, finding, integrating, and use of data from outside sources. True interoperability must allow the exchange and use of information to be secure, useful, and valuable to the patient and the provider. APIs are increasingly used across industries to accelerate progress and improve the sharing of electronic information. They enable different apps, platforms, and entities to connect and share data. AAOS supports this proposed rule's interest in accelerating the use of open APIs to improve the exchange of health information to improve patient satisfaction and care. As discussed above, such moves will enable faster implementation of PRO-PMs and other quality improvements.

In particular, the voluntary adoption of the Health Level 7 (HL7) FHIR API standards has been significant across the health care industry. Per previous estimates from the Department of Health and Human Services' (HHS) Office of National Coordinator of Health IT, roughly 51 percent of health



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IT developers have adopted a version of FHIR. Such standards are essential for enabling interoperability, and the significant adoption of a common standard may suggest a palatable step forward. For this reason, AAOS supports the proposal to use the FHIR standards as a baseline for the newly defined API standards criteria, as well as a new proposed patient and population services API criteria. Additionally, AAOS supports replacing the Common Clinical Data Set (CCDS) for information exchange for the more robust United States Core Data for Interoperability (USCDI). However, AAOS is concerned that API Data Providers may be unfairly burdened by several fees that an API Technology Supplier can charge, but there is no similar mechanism for API Data Providers to recoup such costs. API implementation costs will be shifted onto health care systems and physician practices, which could have a significant deleterious effect on smaller practices. There should be some consideration given to this and a mechanism must be created for API Data Providers to recoup these costs.

Clinical data registries are an integral component of the health care quality system. As health care costs increase and the imperative to shift towards value-based care accelerates, it becomes more critical to support these entities that effectively collect, analyze, and share important clinical information to inform treatments and improve outcomes. We recommend that data exchange parameters be harmonized between EHR vendors and registries. The HL7 FHIR standards and the USCDI data set improve the ability of registries to receive electronic health information with less effort and greater speed, since most EHR vendors that registries work with have some form of certified health IT. However, CMS should also consider the costs a registry may face to implement API functionality, the time needed to make such a transition, and the use cases that would benefit from such an arrangement. Smaller registries may find adding additional functionality to be financially cumbersome and may not have the resources to implement changes quickly if given a short timeline. Albeit such an arrangement would allow providers the ability to receive relevant clinical insights that registries produce to improve patient outcomes.

Thank you for your time and attention to the concerns of the AAOS on the significant proposals made in the FY 2023 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,

Felix H. Savoie, III, MD, FAAOS
AAOS President



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Orthopaedic specialty societies who signed on to these comments are:

Alabama Orthopaedic Society
American Association of Hip and Knee Surgeons (AAHKS)
American Orthopaedic Foot & Ankle Society (AOFAS)
American Orthopaedic Society for Sports Medicine (AOSSM)
American Shoulder and Elbow Surgeons (ASES)
American Spinal Injury Association (ASIA)
Arizona Orthopaedic Society
Arthroscopy Association of North America (AANA)
Connecticut Orthopaedic Society
Delaware Society of Orthopaedic Surgeons
Florida Orthopaedic Society
Georgia Orthopaedic Society
Limb Lengthening and Reconstruction Society (LLRS)
Louisiana Orthopaedic Association
Maryland Orthopaedic Association
Massachusetts Orthopaedic Association
Minnesota Orthopaedic Society
Musculoskeletal Tumor Society (MSTS)
Nebraska Orthopedic Society
New Jersey Orthopaedic Society
North Carolina Orthopaedic Association
North Dakota Orthopaedic Society
Ohio Orthopaedic Society
Orthopaedic Rehabilitation Association (ORA)
Orthopaedic Trauma Association (OTA)
Pennsylvania Orthopaedic Society
Rhode Island Orthopedic Society
South Carolina Orthopaedic Association
Tennessee Orthopaedic Society
The OrthoForum
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