



AMERICAN ACADEMY OF
ORTHOPAEDIC SURGEONS

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June 24, 2019

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Attention: **CMS-1716-P**
P.O. Box 8013
Baltimore, MD 21244-1850

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

**Subject: (CMS-1716-P)
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 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals**

Dear Administrator Verma,

On behalf of over 34,000 orthopaedic surgeons and residents represented by the American Association of Orthopaedic Surgeons (AAOS), and on behalf of the members of the orthopaedic state and specialty societies who have agreed to sign on, we appreciate the opportunity to provide comments on the Centers for Medicare & Medicaid Services (CMS) Inpatient Prospective Payment System Rule (CMS-1716-P), published in the Federal Register on May 3, 2019.

We commend CMS on its efforts to improve health care quality and access. This proposed rule touches on several issues which directly impact our membership, and we hope that you will take our comments into consideration when making any final changes in policy.

Inpatient Payment Updates

We are pleased with the proposal to increase operating payment rates by approximately 3.2% in FY2020 for acute care hospitals that participate in the Medicare inpatient quality programs and use electronic health records (EHR).

In response to comments in last year's IPPS, CMS has sought to reduce the disparity among urban and rural hospitals. CMS aims to implement this by increasing the wage index for low wage index (below 25th percentile) hospitals and decreasing the wage index for high wage index

(above 75th percentile) hospitals to maintain budget neutrality. CMS plans to have this policy in effect for four years starting in 2020 and will place a cap of 5% on any decrease in a hospital's wage index from the hospital's final wage index in FY 2019. AAOS agrees with CMS that rural communities are under-served and have high need for health care, yet rural hospitals find it difficult to hire physicians and other clinicians. This proposal to rebalance the wage index is likely to improve access to care for rural communities and make rural hospitals financially sustainable. However, it must be noted that this policy may disadvantage certain urban high wage index hospitals which provide important health care access to vulnerable urban populations in inner cities.

New Technology Add-On Payments

AAOS believes that the proposals regarding New Technology Add-On Payments (NTAP) are steps in the right direction. We are supportive of the proposal to limit, for two years, the add-on payment eligibility requirements to only the cost criterion for medical devices that are part of the Food and Drug Administration's (FDA) 'Breakthrough Devices Program'. This new FDA program aims *"to provide patients and health care providers with timely access to these medical devices by speeding up their development, assessment, and review, while preserving the statutory standards for premarket approval, 510(k) clearance, and De Novo marketing authorization, consistent with the Agency's mission to protect and promote public health."*¹ It is encouraging to note that CMS and FDA are working in tandem to enable patient access to new technologies and thereby, save or improve the quality of numerous lives. AAOS shares the concern that real-world evidence on outcomes for new devices are often limited when they are first approved and hence it is especially difficult for sponsors to meet the clinical improvement criterion currently necessary to qualify for NTAP.

AAOS also supports the CMS proposal to increase the NTAP for new technology devices beginning in FY 2020. Currently, in addition to the Medicare Severity Diagnosis Related Group (MS-DRG) payment, CMS makes an add-on payment equal to the lesser of: (1) 50% of the cost of the new medical technology or (2) 50% of the amount by which the costs of the new technology exceed the DRG payment. CMS has proposed increasing this amount from 50% to 65% of the cost of the new technology/device. While we appreciate CMS' attempt to improve financial incentives and Medicare beneficiary access to expensive new technology, we must note that for certain devices and treatments that increase may not be enough.

CMS should further evaluate the viability of expanding NTAP beyond Breakthrough Devices, to encompass products that come to market via more traditional regulatory pathways. The shelf-life of innovative technologies is decreasing rapidly, as the iterative nature of improvements occurs ever more quickly. In recognition of this shift, FDA is exploring updates to the 510(k) pathway

¹ U.S. Food and Drug Administration (FDA) (2019). Breakthrough Devices Program. Available: <https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program>

to reflect the changing environment and to respond to the increasingly complex nature of medical devices. The lag between marketing approval and CMS coverage means that Medicare participants are unable to access many of these new products which may more dramatically reduce morbidity and mortality than previous generations of technologies.

AAOS also supports the proposal to continue add-on payments for the two approved chimeric antigen receptor (CAR) T-cell therapies. AAOS urges CMS to extend the increased add-on payments for new technology to all care delivery settings beyond hospitals.

Potential Revisions to the New Technology Add-On Payment Substantial Clinical Improvement Criterion: Request for Information

AAOS is pleased that CMS is going to provide greater clarity and new guidance on the “substantial clinical improvement criterion” and on “how CMS evaluates new technology applications for add-on payments”.²

AAOS is encouraged by the efforts of CMS to seek input on the sources and types of information that will inform determinations of substantial clinical improvement for novel devices. However, the gap between “safe and effective” and “reasonable and necessary” continues to serve as a barrier to Medicare participants as they seek to access novel therapies. As FDA evolves their regulatory framework to increasingly include real-world evidence, post-market data, and patient preferences, the gap grows even wider. CMS should seek opportunities to collaborate with FDA to bridge this gap and move toward a harmonized set of criteria for making regulatory decisions.

The current criteria for establishing significant clinical improvement do not describe how a patient’s preference for a specific treatment modality might be factored into CMS’ evaluation. CMS should work with FDA to incorporate a spectrum of patient risk tolerance, representative of the diverse patient population they serve, to inform decision-making. FDA is actively seeking input regarding patient preference-sensitive areas that may impact benefit-risk assessment and guide post-market evaluation of technologies. This feedback may also support CMS in their ongoing efforts to identify and incorporate appropriate data for determining significant clinical improvement.

While assessing clinical outcomes and patient-reported outcomes, CMS can refer to our past work in this area. AAOS along with orthopaedic specialty societies identified several consensus-

² Centers for Medicare and Medicaid Services (2019). Fiscal Year (FY) 2020 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long-Term Acute Care Hospital (LTCH) Prospective Payment System Proposed Rule and Request for Information. Fact Sheet. Available: <https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2020-medicare-hospital-inpatient-prospective-payment-system-ipps-and-long-term-acute>

recommended patient-reported outcome measures (PROM)³ for collection of orthopaedic quality data based on the following criteria:

- Open access to the PROM (i.e. no cost for the instrument itself)
- Patient reported outcomes only (no surgeon entered data)
- Multiple entry platforms (digital, paper, web)
- Approximately 20 questions or less
- Clinically meaningful (responsiveness)
- One generic quality of the PROM
- No more than three joint or disease specific PROMs
- CAT version available (preferable)

Based on these criteria, to assess general quality of life, we recommend using

- Veteran: Rand 12
- PROMIS: (PROMIS 10 or CAT)
- EUROQOL 50 (EQ 50)

We also recommend the Single Assessment Numeric Evaluation (SANE) instrument for treatment outcome in shoulder and elbow surgery. You will find a full list of recommended instruments on our website.⁴

Graduate Medical Education

AAOS supports expansion of physician resident training in rural areas which have acute physician shortage. Currently, critical access hospitals (CAH) are not considered non-provider sites. This proposed rule seeks to modify this policy by allowing hospitals to claim residents training in a CAH in its full-time employee count if the non-provider setting requirements are met. This policy change will incentivize hospitals to invest more in graduate medical education and indirect medical education thereby improving the pool of residents and physicians in rural areas.

Social Determinants of Health

AAOS supports the proposal to collect data on social determinants of health (SDOH) per the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 to better inform quality measures and resource measures. We have long urged the Innovation Center to include SDOH principles in their model design and evaluation and are pleased to know that CMS

³ AAOS (n.d.). Patient Reported Outcome Measures. Available: <https://www.aaos.org/prom/?ssopc=1>

⁴ Ibid.

supports the Assistant Secretary for Planning and Evaluation's (ASPE)⁵ assessment that value-based payment models require information and tracking of social risk factors to reduce disparities in health care.

We recognize and appreciate the in-depth research in this field conducted by the National Academy of Medicine⁶ as well as the ASPE. We would also like CMS to refer to additional research in this area.⁷ Apart from the current proposal to collect data on “race, ethnicity, preferred language, interpreter services, health literacy, transportation, and social isolation”, AAOS would like to again highlight the following parameters which are especially 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.
- **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.
- **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. 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.
- **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.

⁵ 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-medicare's-value-based-purchasing-programs>

⁶ Dzau, V. J., M. McClellan, J. M. McGinnis, and E. M. Finkelman, editors. 2017. Vital directions for health & health care: An initiative of the National Academy of Medicine. Washington, DC: National Academy of Medicine

⁷ Alderwick, H., & Gottlieb, L. M. (2019). Meanings and Misunderstandings: A Social Determinants of Health Lexicon for Health Care Systems. The Milbank Quarterly. DOI:10.1111/1468-0009.12390

- **Socioeconomic Status** – This variable affects patient outcomes and requires additional consideration. Further evaluation is required regarding how the data could be collected.

Future Desired List of Social Risk Variables

- Literacy
- Marital Status
- Live-in Home Support
- Family Support Structure
- Home Health Resources

Hospital Risk Reduction Program

The Hospital Readmissions Reduction Program (HRRP) includes the risk-adjusted readmissions rate for elective total hip arthroplasty/total knee arthroplasty (THA/TKA). To determine the reduction, a hospital's three-year risk-adjusted readmission rate is calculated. CMS estimates that 2,599 hospitals will experience reductions in base DRG payments that will result in \$550 million in savings. However, the ultimate cost of care may not result in such significant savings if patients who should have been readmitted are forced to seek emergency treatment for later catastrophic conditions. While the intent of the HRRP is clear, there is concern that the penalty associated with excess readmissions could lead to denial of care to high-risk patients or denial of care to those readmitting to the same hospital system.

There are four HRRP-related proposals. Of them, AAOS supports measure standardization across quality reporting and payment programs. However, given the investment in time and resources that are necessary to develop more appropriate new measures, we urge CMS to be mindful about retiring existing topped-out quality measures before identifying and adopting replacement measures.

Promoting Interoperability

AAOS strongly supports the development of interoperability standards for all EHR. We also support the development of appropriate standards for meaningful use of EHRs by government agencies and private carriers which balance the needs of patients and their families, physicians and their staff, and regulators. We believe these standards should be collaboratively developed by physicians through professional organizations in cooperation with government agencies.

Health Information Exchange Across Payers

AAOS supports the proposal⁸ to require Medicare Advantage plans, Medicaid managed care plans, Children's Health Insurance Plan managed care entities, and Qualified Health Plans in the Federally Facilitated Exchanges (FFE) to coordinate and exchange the U.S. Core Data for Interoperability (USCDI) data set between health plans. Patients often switch between health plans and information can be easily lost. By requiring electronic health information to be transferred across health plans, patients can attain a more robust and comprehensive understanding of their health across their lifetime. AAOS agrees with CMS that this proposal could also reduce the burden on providers by preventing unnecessary letters of medical necessity, inappropriate instances of step therapy, and repeated utilization reviews, risk screenings, and assessments.

Thank you for your time and consideration of the American Association of Orthopaedic Surgeons' comments on the 2020 Inpatient Prospective Payment System Proposed Rule. If you have any questions on our comments, please do not hesitate to contact William Shaffer, MD, AAOS Medical Director by email at shaffer@aaos.org.

Sincerely,



Kristy L. Weber, MD
President, American Association of Orthopaedic Surgeons (AAOS)

cc: Joseph A. Bosco, III, MD, AAOS First Vice-President
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⁸ Centers for Medicare and Medicaid Services (2019). Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally Facilitated Exchanges and Health Care Providers CMS-9115-P. Federal Register: 2019-02200

The following state and orthopaedic specialty societies agreed to sign on to this letter:

Alabama Orthopaedic Society
American Alliance of Orthopaedic Executives
American Association of Hip and Knee Surgeons
American Orthopaedic Foot and Ankle Society
American Orthopaedic Society for Sports Medicine
American Shoulder and Elbow Surgeons
American Society for Surgery of the Hand
American Spinal Injury Association
Arizona Orthopaedic Society
Arthroscopy Association of North America
California Orthopaedic Association
Cervical Spine Research Society
Connecticut Orthopaedic Society
Delaware Society of Orthopaedic Surgeons
Georgia Orthopaedic Society
Illinois Association of Orthopaedic Surgeons
Iowa Orthopaedic Society
J. Robert Gladden Orthopaedic Society
Kentucky Orthopaedic Society
Limb Lengthening and Reconstruction Society
Louisiana Orthopaedic Association
Maryland Orthopaedic Association
Massachusetts Orthopaedic Association
Minnesota Orthopaedic Society
Musculoskeletal Tumor Society
Nevada Orthopaedic Society
New Hampshire Orthopaedic Society
New York State Society of Orthopaedic Surgeons
North Carolina Orthopaedic Association
North Dakota Orthopaedic Society
Ohio Orthopaedic Society
OrthoForum
Orthopaedic Rehabilitation Association
Orthopaedic Trauma Association
Pediatric Orthopaedic Society of North America
Pennsylvania Orthopaedic Society
Rhode Island Orthopaedic Society
Ruth Jackson Orthopaedic Society
Scoliosis Research Society
Tennessee Orthopaedic Society

Texas Orthopaedic Association
Virginia Orthopaedic Society