AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

July 9, 2020

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1735-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 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs 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 the orthopaedic specialty and state 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) 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals (CMS-1735-P) published in the Federal Register on May 11, 2020.

We commend the Centers for Medicare and Medicaid Services (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. Given the unexpected opportunity for innovation borne out of the misfortune of the COVID-19 pandemic, AAOS urges CMS to consider the value of making the following regulatory flexibilities permanent:

- **Telehealth: AAOS calls for CMS to** permanently expand telehealth technologies to allow the use of audio-only equipment for CPT codes 99212-99214 (office/outpatient E/M codes for established patients); expand virtual check-in services (HCPCS codes G2010 and G2012) to both new and established patients; waive the requirement that out-of-state physicians and non-physician practitioners, such as physical therapists, be licensed in the

state where they are providing telehealth services, as long as they are licensed in another state.

- **Workforce:** CMS should allow teaching physicians to meet the requirement to review visits furnished by residents remotely using the audio/video real-time communication technology; waive Medicare and Medicaid requirements that physicians and non-physician practitioners be licensed in the state where they are providing services. This is especially important in the many border communities in all states.

- **COVID-19:** CMS should allow practitioners to be paid for assessment and specimen collection for COVID-19 testing using the level 1 evaluation and management code (CPT code 99211); Medicare should continue to not require an order from a treating physician or non-physician practitioner as a condition of Medicare coverage of COVID-19.

- **Stark Law:** AAOS asks that current flexibilities be continued whereby hospitals and other health care providers can pay above or below fair market value to rent equipment or receive services from physicians (or vice versa); health care providers may support each other financially to ensure the continuity of health care operations; hospitals may provide benefits to their medical staff, including multiple daily meals, laundry service to launder soiled personal clothing, and child care services while the physicians are at the hospital and engaging in activities that benefit the hospital and its patients; allow the provision of items and services that are exclusively related to COVID-19 purposes, even when the provision of the items and services would exceed the annual non-monetary compensation cap; physician-owned hospitals can temporarily increase the number of their licensed beds, operating rooms, and procedure rooms; relax some of the restrictions on when group practices can furnish medically necessary designated health services in a patient's home; relax restrictions on when group practices can furnish medically necessary MRIs, CT scans or clinical lab services from locations such as mobile vans in parking lots which the group practice rents part-time.

- **Graduate Medical Education**: CMS should allow medical residents to perform their duties in alternate locations, including their home or a patient's home, as long as it meets appropriate supervision requirements; allow teaching physicians to provide low-risk, nonsurgical services with residents virtually through audio/video real-time communication.

- **Hospitals without Walls:** CMS should allow hospitals to offer hospital-based services in healthcare locations including temporary expansion sites; furnish both the inpatient and outpatient services at these temporary expansion sites; reduce the regulations surrounding conditions of participation and provider-based rules; continue to allow ambulatory surgical centers to enroll as hospitals. In this regard, AAOS particularly asks that the current ban on

the expansion of physician-owned hospitals (POHs) be lifted. As we have done in the past, we continue to urge the CMS Innovation Center (CMMI) to launch a demonstration program on the expansion of POHs.

New Hip Replacement MS-DRG Proposal

The proposal to create new Medicare Severity-Diagnosis Related Groups (MS-DRGs) 521 and 522 to account for differences in the cost of total hip arthroplasty (THA) associated with a hip fracture diagnosis appears to be a neutral act in terms of cost. **Since the current THA MS-DRG codes 469 and 470 already provide similar reimbursement for the procedures through associated diagnostic codes, and the added expense of treating hip fractures is accounted for in the Comprehensive Care for Joint Replacement (CJR) Model, AAOS recommends that the proposed new MS-DRGs 521 and 522 not be adopted.**

Moreover, we believe that it would be inappropriate to make such a substantive change to the MS-DRG system without a strong body of evidence to support proposals which directly benefit one device over another. We are not aware of any high-quality randomized controlled trials which report beneficial effect of the Zr bearing surface. Any reported beneficial effect is most likely due to selection bias (i.e., choosing younger, healthier patients for the oxidized Zr bearings), rather than any real difference in performance. This is true for registry data as well as clinical cohort studies. Among AAOS' hip replacement experts, the superiority of Zr-alloy bearings is not a generally accepted fact. In summary, while AAOS supports higher reimbursement for hip replacements with a fracture in the existing MS-DRGs 469 and 470 as well as higher target pricing for hip fractures as part of CJR, we currently do not support creating these new MS-DRGs as proposed.

New Technology Add-on Payment

AAOS' spine experts agree that the procedure and work associated with the SpineJack system is like that of kyphoplasty (CPT codes 22513-22515). Although the methods of the SpineJack procedure and kyphoplasty are materially different, in that the distraction of the vertebral body is maintained by the "jack," the essential method of treatment is similar. The estimated $100,000 cost per case with SpineJack appears quite high compared to the approximately $3,500 cost of kyphoplasty, particularly when there is no statistical difference between the two in pain relief recorded one-year post-procedure. **Given these concerns, AAOS does not support the proposal for the new technology add-on payment (NTAP) for the SpineJack system.**

Price Transparency Proposals

As we discussed in our comments on the Transparency in Coverage proposed rule (CMS-9915-P), AAOS supports efforts to provide patients with easily understandable cost and quality information to encourage the use of high-value care options. Allowing healthcare consumers to search for medical providers based on both measures of price and quality will increase patient empowerment

when making serious decisions about medical treatment. However, we encourage CMS to consider how mandating the publication of commercially negotiated rates risks devaluing independent physician's professional fees to the lowest common denominator. Such a decrease could have a chilling effect on access to care. When a physician's professional fees from commercial insurance are decreased, there is less income produced to cover the practice overhead costs. Certainly, the reimbursement rates from Medicaid and Medicare do not fulfill that. Historically, it has been this balance between the public and private markets which permit practices to remain financially viable while caring for vulnerable populations.

Although this proposal acknowledges that a market-based approach would sometimes lead to a higher reimbursement rate than the cost-based methodology, CMS similarly acknowledges that the market-based reimbursement rates in some areas are lower than the cost-based methodology. Specifically, the IPPS proposed rule quotes research findings by Maeda and Nelson[1] that state "there were some DRGs where the average [Medicare Advantage] MA price was much higher than [fee-for-service] FFS and there were some DRGs where the average MA price was a bit lower than FFS." **Considering the uncertainty of what may happen to the private payer rates in a price-transparent healthcare environment, we urge CMS to move cautiously and deliberately as they consider implementing a market-based payment methodology under the IPPS.**

Furthermore, we ask that CMS consider best practices for price transparency which have already been implemented at the state level. For example, assessing the efficacy of All-Payer Claims Databases (APCDs) vis-à-vis the proposal to release payer-negotiated rates for hospitals. Similarly, we ask that cost data is not displayed or analyzed in the absence of corresponding quality measures. It would be misleading for patient consumers, as well as CMS in their capacity as the largest healthcare payer in the United States, to update reimbursement rates based solely on measures of cost. As with any other product, decisions should be made on measures of both quality and cost.

The AAOS recently developed comprehensive definitions of quality and value in orthopaedics. Whereas quality is defined as the successful delivery of appropriate, evidence-based musculoskeletal health care 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. 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,

[1] Maeda JLK, Nelson L. How Do the Hospital Prices Paid by Medicare Advantage Plans and Commercial Plans Compare with Medicare Fee-for-Service Prices? *The Journal of Health Care Organization, Provision, and Financing.* 2018;55(1–8).

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 ask that CMS consider these definitions in their development of market-based price transparency metrics.

Prior Authorization

As it relates to the shift of the traditional Medicare IPPS to a market-based and price-transparent concept using MA rates as a comparative baseline, AAOS invites CMS to consider the impact of prior authorization in MA programs and beyond. Prior authorization processes are burdensome for physicians, undermine their training and professional judgment, and create critical delays in the care of patients. Such delays create undue barriers to care for patients, particularly older adults or those in rural areas, if they must return to a physician's office for multiple visits as a result of the delays. Although they are effective at reducing the total costs incurred by MA programs, the impact of prior authorization requirements on both patients and physicians is both significant and damaging to quality of care. According to research conducted by the Kaiser Family Foundation, 97% of MA enrollees are required to obtain prior authorization for inpatient hospital stays.[2]

As Medicare allows more musculoskeletal procedures in outpatient settings, it is important for surgeons and their patients to discuss and decide the appropriate setting of care without interference from prior authorization mandates. This is of paramount importance for the safety of Medicare beneficiaries. When considering the median payer-specific negotiated charge that the hospital has negotiated with MA organizations, it will be essential to account for the impact of prior authorization on these potentially lower costs of care. AAOS considers the care offered to America's seniors in traditional Medicare programs to be of the highest quality, and we trust that CMS will continue to build and maintain programs that reflect our shared values of safe and equitable care. Toward that end, we urge CMS to reduce prior authorization requirements across its programs and payment systems.

Graduate Medical Education

AAOS supports CMS proposals to amend the policy regarding the closing of teaching hospitals and residency programs. We believe that providing greater flexibility to residents to allow funds to be transferred temporarily for residents who are not physically present at the closing hospital or program on the day it closes will ensure continuity in training of the next generation of physicians.

Medicare and Medicaid Promoting Interoperability Programs

AAOS recognizes the importance of tracking value in the healthcare system by collecting and reporting relevant clinical outcomes. In the FY 2021 IPPS proposed rule CMS proposes to

[2] KFF analysis of CMS Medicare Advantage Enrollment and Benefit Files, 2020 https://www.kff.org/medicare/issue-brief/a-dozen-facts-about-medicare-advantage-in-2020/

publicly report electronic clinical quality measure (eCQM) data from hospitals for the calendar year (CY) 2021 reporting period. AAOS believes that measures must be meaningful and useful to the end-users, and that reporting of measures should not add substantial burden to providers. However, AAOS cautions CMS to ensure that measures are clinically significant, validated and have relevant context when deciding what measures are appropriate for publication, and which measures need additional refinement. When end-users make determinations of measures that have inaccuracies and incomplete or misleading information it can have negative impacts on patient safety.

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 2021 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,

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American Orthopaedic Foot and Ankle Society
American Orthopaedic Society for Sports Medicine
American Shoulder and Elbow Surgeons
American Spinal Injury Association
Arthroscopy Association of North America
California Orthopaedic Association
Cervical Spine Research Society
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