AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

September 7, 2018

Seema Verma, MPH
Administrator,
Centers for Medicare & Medicaid Services
Department of Health and Human Services,
Attention: CMS-1695-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Subject: [CMS-1695-P] Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model

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 societies that agreed to sign on, we are pleased to provide comments on the Centers for Medicare and Medicaid Services' (CMS) Medicare Program Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems and Quality Reporting Programs and Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model (CMS-1695-P) published in the Federal Register on July, 31 2018.

Hospital Outpatient Payment System (OPPS)

Site Neutrality Expansion

CMS included several proposals in the OPPS proposed rule aimed at correcting payment disparities for services provided in different settings. The AAOS believes that services provided at off-campus provider-based departments (PBD) are identical to those at independent physician

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practices paid through the physician fee schedule (PFS).

Method to Control for Unnecessary Increases in the Volume of Outpatient Services
The AAOS supports the proposal to apply an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD for the clinic visit service, as described by HCPCS code G0463 by departments that bill the "PO" modifier. The AAOS believes that all outpatient clinic visits should be paid similarly, regardless of whether the practice is hospital-owned. Should this proposal be finalized, CMS must take steps to control for an unintended alteration in referral patterns. Many hospital systems include on-campus and/or excepted off-campus facilities, as well as nonexcepted off-campus PBDs. Many of those nonexcepted PBDs, which will receive the PFS payment rate, were private practices before their absorption into a larger hospital system. We fear that hospitals would be incentivized to steer patients to higher cost facilities, which could have significant financial ramifications for nonexcepted off-campus PBDs. In addition to increased costs, there is a risk of creating closed networks and decreasing access.

CMS also requested comment on how to expand these changes to include additional items and services paid under the OPPS that may represent unnecessary increases in hospital outpatient department utilization. Hospitals are able to create significant shifts in care delivery that do not necessarily benefit our patients, as we saw with the implementation of the total knee arthroplasty (TKA) policy change. Given the widespread misinterpretation of last year's OPPS rule, many hospitals forced all TKA patients to the outpatient setting, leaving orthopaedic surgeons without alternatives for their patients. The AAOS believes that the selection of appropriate candidates for the outpatient setting should fall to the surgeon. Moreover, the ideal outpatient facility should be determined between the surgeon and patient. Some orthopaedic procedures, such as total shoulder arthroplasty (TSA), can be done safely, efficiently, and for less cost in ASCs[1]. In addition, the AAOS is working on co-branding ASC certifications with The Joint Commission. For this reason, and because of the recent actions of hospitals, the **AAOS recommends concurrently adding to the ASC-covered list any orthopaedic procedure removed from the Medicare inpatient-only (IPO) list.** We urge CMS to consider this direct move of TSA, currently on the IPO (under Medicare), to ASCs rather than via the hospital outpatient departments.

[1] Refer to:

1. "Neer Award 2016: Outpatient total shoulder arthroplasty in an ambulatory surgery center is a safe alternative to inpatient total shoulder arthroplasty in a hospital: a matched cohort study," Journal of Shoulder and Elbow Surgery, T. J. Brolin, R. P. Mulligan, F. M. Azar, & T. W. Throckmorton, 26(2), 204-208 (2017).
2. "Ambulatory total shoulder arthroplasty: a comprehensive analysis of current trends, complications, readmissions, and costs," The Journal of Bone and Joint Surgery, J. M. Cancienne, S.F. Brockmeier, L.V. Gulotta, D.M. Dines, & B.C. Werner, 99(8), 629-637 (2017).
3. "Outpatient total shoulder arthroplasty: a population-based study comparing adverse event and readmission rates to inpatient total shoulder arthroplasty," Journal of Shoulder and Elbow Surgery, T.S. Leroux, B.A. Basques, R.M. Frank, J.W. Griffin, G.P. Nicholson, B.J. Cole, ... & Verma, N. N. 25(11), 1780-1786 (2016).

Expansion of Services at an Off-Campus PBD
The AAOS commends CMS for efforts to expand the application of site neutral payments to additional items and services. Expansion of services would have an adverse effect on the control of unnecessary utilization of PBDs. **The AAOS supports the proposal to pay excepted off-campus PBDs under the PFS for new services lines.** Additionally, we do not believe that a 12-month baseline period is necessary. A 6-month baseline period would adequately capture any service line initially intended for provision at a PBD.

Payment Changes for Drugs and Biologicals
The AAOS supports the extension of the 340B payment change to non-excepted HOPDs that are paid under the PFS.

OPPS Ambulatory Payment Classification (APC) Policies
Musculoskeletal Procedures (APCs 5111 through 5116)
The AAOS appreciates efforts to create more granularity surrounding APCs. We do have concerns surrounding the methodology that will be undertaken in this effort. As you know, TKA was removed from the IPO list for 2018. This procedure was assigned to APC 5115. Although CMS intended for this to affect a small number of beneficiaries, Medicare Advantage plans began to unilateral deny inpatient TKA. Discharge planning, care coordination, and durable medical equipment for these procedures performed on the Medicare population require a greater level of intensity in care coordination. We believe that arthroplasty requires significant resource use that satisfies requirements for a higher APC. Should an additional level be created between APC 5115 and 5116, we expect that **TKA and any future arthroplasty procedures removed from the IPO list would warrant assignment to the higher APC level**. This applies to all procedures recommended by the AAOS through the 2018 OPPS rulemaking (i.e., shoulder, ankle, and hip arthroplasty).

Request for Progress on Education Initiatives on TKA Policy Change
As we briefly mentioned above, since January 1, 2018, when TKA came off the IPO list, hospital systems and Medicare Advantage plans misinterpreted this policy change. Hospitals have required TKA cases to be initially booked as outpatient and MA plans are, by default, denying inpatient authorization. This has led to confusion, increased burden, and, potentially, a negative impact on patient safety and outcomes. Over the last several months, AAOS and American Association of Hip and Knee Surgeons (AAHKS) have worked continuously with various CMS teams to communicate these issues and work towards a solution. We have met with your staff several times and have provided all requested materials, including peer-reviewed articles on TKA setting of care, patient outcomes, clinical practice guidelines, inpatient definition for arthroplasties, and nationally representative data on health system response to this policy. We are deeply appreciative of the efforts of the staff at the CMS Center for Medicare and at the Center for Clinical Standards and Quality to develop educational materials and webinars clarifying this CMS policy change. However, there has been considerable delay in coordination among various CMS policy and quality teams. In fact, a recent AAHKS survey confirmed that 60 percent of their members continue to encounter forced outpatient TKAs at

their institutions[2]. **We urgently request that you and your leadership team provide guidance and necessary approvals on these efforts.**

Ambulatory Surgical Center (ASC) Payment System

ASC Payment Methodology

The AAOS commends CMS for the proposal to use the hospital market basket to update the ASC payment system. The Consumer Price Index for All Urban Consumers (CPI-U) is not a good indicator of costs of goods affecting ASCs. The use of the CPI-U methodology results in a more volatile update factor that does not accurately predict ASC costs. ASC and HOPD rates continue to diverge under different update methodologies. The gap between the two payment systems is creating financial incentives to use the HOPD rather than the ASC setting. This is an opportunity to promote payment parity across sites of service.

We agree that the proposal to apply the additional 0.75 hospital adjustment would work against the goals of applying the hospital market basket to the payment update. It counters efforts to further curb unnecessary utilization of higher cost sites of service.

Device-Intensive Procedure Criteria

The AAOS supports the proposal to allow procedures that involve single-use devices to qualify as device-intensive procedures, regardless of whether they stay in the body at the end of the procedure. **The AAOS also agrees that the proposal to lower the device offset percentage threshold from 40 percent to 30 percent will help ensure more appropriate payment.** Allowing a greater number of procedures to qualify as device-intensive will encourage the provision of these services in the ASC setting.

Review of Recently-Added Procedures to the ASC Covered Procedures List (CPL)

The AAOS maintains that the safety of our patients is our greatest priority. Any action required to ensure the safe provision of services is fully supported. We agree that review of procedures being performed in the outpatient setting should be undertaken periodically. The proposal to review data for procedures added to the ASC CPL is reasonable in the early years of a new setting. However, **performance year 2018 may be too soon to retrieve sufficient data on procedures added to the CPL in 2017.** The move to the ASC setting is not likely to be instantaneous. Therefore, procedures added to the CPL in the previous year may not have a meaningful number of procedures for proper evaluation. When there is a small sample size, a single adverse event will significantly skew data, inappropriately branding a procedure as unsafe. We would expect full transparency of any methodology undertaken and resultant analytics. ASCs and other stakeholders must be able to review and offer alternative data and metrics before any action is taken that would alter the CPL.

Separate Payment for Non-Opioid Pain Management Treatments

[2] "Unintended Impact of the Removal of Total Knee Arthroplasty from the Center for Medicare and Medicaid Services Inpatient Only List," Yates AJ, Kerr J, Della Valle CJ, Huddleston JI, Froimson MI, [Forthcoming in Journal of Arthroplasty].

The AAOS supports incentives to increase the availability of non-opioid alternatives for pain management. For example, there has been some success with intravenous acetaminophen, as an alternative to opioids, but high cost may limit its use. Also, we greatly encourage other effective forms of pain management, such as regional nerve blocks, icing wraps, transcutaneous stimulators, and topical analgesics.

Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers

As it has in the past, the AAOS strongly supports the development of interoperability standards for all Electronic Health Records (EHR). We also support the development of appropriate standards for meaningful use of electronic health records 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 their professional organizations in cooperation with government agencies. The process should emphasize the requirements for the highest level of quality patient care while recognizing the limits and clinical specialty focus of physicians who use the systems.

If CMS were to propose a new CoP/CfC/RfP standard to require electronic exchange of medically necessary information, would this help to reduce information blocking as defined in section 4004 of the 21st Century Cures Act?
As CMS continues to implement the requirements of MACRA, the 21st Century Cures Act, and other regulatory policy goals, the AAOS encourages it to closely align the standards of each program to avoid confusing and inconsistent regulatory requirements that will only make compliance more costly and difficult for all providers, but particularly those in small, solo, and rural settings.

The AAOS continues to support differentiated payments in which bonuses might be paid to incentivize health IT adoption. We also encourage CMS to pursue the regulatory avenues available to stimulate greater interoperability. However, revising CMS's conditions of participation (CoP), conditions for coverage (CfC), or requirements for participation (RfP) will not overcome the significant challenge posed by information blocking alone. Imposing a blanket requirement that does not take into account the differential leverage between various stakeholders would not solve the underlying problem.

As the Office of the National Coordinator explained in its 2015 report to Congress on the subject, providers often have less power to solve this particular obstacle to interoperability. "Having made these investments, providers may be financially and otherwise unable to switch to superior technologies that offer greater interoperability, health information exchange capabilities, and other features. These switching costs make it easier for developers to engage in

information blocking without losing existing customers."[3] The AAOS believes any solution should target intransigent developers but also recognize the cost burden of certain requirements, particularly for small private practitioners, and for practitioners in rural areas.

Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information:

What types of information would be most beneficial to patients, how can hospitals best enable patients to use charge and cost information in their decision-making, and how can CMS and providers help third parties create patient-friendly interfaces with these data?
The AAOS shares CMS' concern that patients face unwarranted challenges due to insufficient price transparency. As MACRA envisioned, healthcare in the United States should be oriented toward delivery of high quality and value-based care. Giving patients more information on their healthcare is an important step toward that goal. Yet transparency alone – and relying on the patient to make those decisions alone – will never be enough in the absence of comprehensive work from all stakeholders to move toward value-based care. Relatedly, providing pricing information alone does not help patients understand that information nor does it consider other measures of patient satisfaction. Equally important is preserving the value of physicians' services for their patients.

One complication to providing greater transparency in healthcare pricing is the unique nature of assessing the quality of healthcare services for many patients. In fact, a study in the New England Journal of Medicine has explained that, "Timely and salient comparative quality information is often unavailable, so patients may rely on cost as a proxy for quality. The belief that higher-cost care must be better is so strongly held that higher price tags have been shown to improve patients' responses to treatments through the placebo effect."[4] CMS' movement toward rewarding quality care should not be superseded by hasty price transparency solutions.

Studies have repeatedly demonstrated that simply providing price transparency tools to patients have had mixed results.[5] According to one study, "Price transparency tools may result in lower prices for a selected set of services, but the tools have little impact on overall spending because of the small percentage of people who use them."[6] In addition to the limited use of these tools,

[3] "Report on Health Information Blocking," Office of the National Coordinator (April 2015), p. 23, https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf.
[4] "Increased Price Transparency in Health Care — Challenges and Potential Effects," The New England Journal of Medicine, Anna D. Sinaiko, PhD, et. al., 891-894 (March 2011).
[5] "Would Greater Transparency And Uniformity Of Health Care Prices Benefit Poor Patients?" Margaret K. Kyle and David B. Ridley, Health Affairs, 1384–1391 (October 2007); "Examining A Health Care Price Transparency Tool: Who Uses It, And How They Shop For Care," Anna D. Sinaiko and Meredith B. Rosenthal, Health Affairs, 35:4 (April 2016).
[6] "Offering A Price Transparency Tool Did Not Reduce Overall Spending Among California Public Employees And Retirees," Health Affairs, Sunita Desai, et. al., 1401–1407 (August 2017).

patients are also often unwilling to switch providers,[7] and "[u]sing price transparency websites to choose providers is complicated for patients, given the wide array of services a person can receive and the complexity of billing and navigating different types of out-of-pocket spending (that is, deductibles, coinsurance, and copays).[8]

Giving patients access to median Medicare costs at a given hospital for a particular procedure would allow this information to be accessible in a single online repository. CMS already has access to this information and could provide sufficient clarity to inquiring patients about their expected portion of the estimated, median cost.

Should health care providers be required to inform patients how much their out-of- pocket costs for a service will be before those patients are furnished that service? What can be done to better inform patients of these obligations? Should health care providers play any role in helping to inform patients of what their out-of- pocket obligations will be?
The AAOS would like to highlight another impairment to full transparency. Many physicians have multiple contracts with carriers where the actual price for a procedure is unknown as carriers will only supply the surgeon with a sample of the twenty most common procedures. In these circumstances, many surgeons do not actually know what price will be paid for a specific procedure for a specific patient's health plan. This arrangement is by some carriers' design so that one surgeon group does not know what another is being paid in a specific region, and it can serve to prevent price-setting. AAOS asks CMS to remain cognizant of such gaps in providers' price knowledge as it works to craft solutions, and recognize the need for an all-inclusive plan that involves participation by all stakeholders.

How should we define "standard charges" in provider and supplier settings?
Payers, including CMS, represent the best resource for patients seeking information about their individual costs. CMS should define this term as the usual and customary charges of providers in the geographic area before the application of any discounts.

Thank you for your time and consideration of the American Association of Orthopaedic Surgeons' suggestions. We commend CMS on its continued efforts to improve care quality and access. 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,

David Halsey MD

David A. Halsey, MD

[7] "Americans Support Price Shopping For Health Care, But Few Actually Seek Out Price Information," Ateev Mehrotra, et. al., Health Affairs, 1392–1400 (August 2017).
[8] Desai (August 2017).

President, AAOS

Cc: Kristy L. Weber, MD, First Vice-President, AAOS
Joseph A. Bosco, III, Second Vice-President, AAOS
Thomas E. Arend, Jr., Esq., CAE, CEO, AAOS
William O. Shaffer, MD, Medical Director, AAOS

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

Alabama Orthopaedic Society
American Association of Hip and Knee Surgeons (AAHKS)
American Orthopaedic Foot and Ankle Society (AOFAS)
American Orthopaedic Society for Sports Medicine (AOSSM)
American Shoulder and Elbow Surgeons (ASES)
American Society for Surgery of the Hand (ASSH)
American Spinal Injury Association (ASIA)
Arthroscopy Association of North America (AANA)
California Orthopaedic Association
Cervical Spine Research Society (CSRS)
Connecticut Orthopaedic Society
Florida Orthopaedic Society
J. Robert Gladden Orthopaedic Society (JRGOS)
Limb Lengthening and Reconstruction Society (LLRS)
Louisiana Orthopaedic Association
Maryland Orthopaedic Association
Massachusetts Orthopaedic Association
Michigan Orthopaedic Society
Musculoskeletal Infection Society (MSIS)
North American Spine Society (NASS)
North Dakota Orthopaedic Association
Oregon Orthopaedic Association
Orthopaedic Trauma Association (OTA)
Pediatric Orthopaedic Society of North America (POSNA)
Pennsylvania Orthopaedic Society
Rhode Island Orthopaedic Society
Ruth Jackson Orthopaedic Society (RJOS)
Scoliosis Research Society (SRS)
South Carolina Orthopaedic Association
Tennessee Orthopaedic Association
Texas Orthopaedic Association
Utah Orthopaedic Society
Virginia Orthopaedic Society
American Alliance of Orthopaedic Executives (AAOE)