AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

June 25, 2018

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1694-P
P.O. Box 8011
Baltimore, MD 21244-1850

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

Subject: (CMS-1694-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 2019 Rates; Proposed Quality Reporting Requirements for Specific Providers; Proposed Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims

Dear Administrator Verma,

On behalf of over 34,000 orthopaedic surgeons and residents represented by the American Association of Orthopaedic Surgeons (AAOS), we appreciate the opportunity to provide comments on the Centers for Medicare & Medicaid Services (CMS) Inpatient Prospective Payment System Rule (CMS-1694-P), published in the Federal Register on May 7, 2018.

We commend CMS on its efforts to improve care quality and access. The 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.

I. Promoting Interoperability

As it has in the past, 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

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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.

> ***How can CMS use the health and safety standards that are required for providers and suppliers participating in the Medicare and Medicaid programs to further advance electronic exchange of information that supports safe, effective transitions of care between hospitals and community provider?***

AAOS welcomes innovative solutions to help advance the electronic exchange of information. In the Proposed Rule, CMS suggested possible future proposals on this subject, including:

> "Requiring that hospitals transferring medically necessary information to another facility upon a patient transfer or discharge do so electronically;
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> "[R]equiring that hospitals electronically send required discharge information to a community provider via electronic means if possible and if a community provider can be identified;
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> "[A]nd requiring that hospitals make certain information available to patients or a specified third-party application (for example, required discharge instructions) via electronic means if requested."

AAOS agrees that physicians need to be able to see and integrate certain key pieces of a patient's demographics and health history into their electronic health records from other sources to provide more comprehensive care. However, we recommend setting a standard that only allows stakeholders to participate in data exchange if they can meet minimum standards for data exchange and security.

AAOS also encourages conducting all exchange openly and transparently. We suggest establishing the need for an audit log that is maintained by the data owner, where the record of source is kept, that tracks where the data was sent, who requested the information, and what information was sent. This audit trail can then be made available to the patient upon request.

One 2017 survey on adoption of these technologies concluded that, "[T]hese are organization-wide changes that will make an impact on not only the physicians and care providers but can have long lasting impact on the entire health system."[1] Accordingly, these changes should be handled cautiously and any changes to current CMS health and safety standards should only implement those solutions recognized to improve patient care and safety.

[1] "Why physicians switch electronic health record vendors," Pete Andresen, et. al., *Business & Health Administration Proceedings*, 226-134 (March 2013).

As surgical specialists, we have unique health information technology (HIT) needs and welcome proposals to accelerate HIT adoption by orthopaedic surgeons that combine adequate time for adoption, sufficient buy-in by all stakeholders, and incentives for early adopters.

AAOS continues to support differentiated payments in which bonuses might be paid to incentivize HIT adoption. 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.

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."[2] 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.

We appreciate CMS's decision to establish a 'Promoting Interoperability' score of 50 points or more in order to satisfy the requirement to report on the objectives and measures of meaningful use. AAOS agrees that the 50 point minimum score provides the necessary benchmark to encourage progress in interoperability. The reduction in the 'Provider to Patient Exchange' objective percentage between 2019 and 2020 is a move in the right direction, but we still believe 35 points on this objective is heavily over-weighted.

In the Proposed Rule, CMS seeks feedback on the question of "identifying fundamental barriers to interoperability and health information exchange, including those specific barriers that prevent patients from being able to access and control their medical records."[3] AAOS agrees that more informed patients produce better outcomes through shared decision-making by both patients and providers. However, we would urge CMS that "directly sharing" records with patients does not always translate into true value for patients. As we have in the past, AAOS continues to support efforts that produce greater transparency and consumer education in this space. However, patient records are just one means by which providers can create a forthright record of patient interactions and evaluations. However, in a number of scenarios, patients' descriptions to their providers may not always align with providers' assessments. Due to the legal sensitivities

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[2] "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.
[3] CMS–1694–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 2019 Rates," p. 20552.

involved with patient records, as well as the substantial risk of contextual misinterpretation, we would caution CMS as it tries to eliminate barriers that prevent patients from being given unfiltered access to and control of their medical records.

II. Price Transparency

> ***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?***

AAOS shares CMS's concern that patients face unwarranted challenges due to insufficient price transparency. As the Medicare Access and CHIP Reauthorization Act (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's 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,

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[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?

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.

Payers, including CMS, represent the best resource for patients seeking information about their individual costs. If it requires hospitals to make available online a list of standard charges in machine-readable format, CMS should define this term as the usual and customary charges of providers in the geographic area before the application of any discounts.

Physician Owned Hospitals (POHs)

As AAOS and several of our partners have noted earlier in our comments to CMS and the US Congress, we would like to reemphasize the importance of protecting the In-Office Ancillary Services Exception (IOASE) and the need to lift the ban on expansion and new construction of POHs. These hospitals have been shown to provide higher quality care at lower cost compared with those run by non-physicians or appointed boards. A higher percentage of POHs have

[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).

received the top 5-Star Rating by CMS than non-POH hospitals, which have considerably higher risk of complications.

III. Burden Reduction and Other Changes

20. Other Policy Changes: Other Operating Room (O.R.) and Non-O.R. Issues
e. Removal and Reinsertion of Spacer; Knee Joint and Hip Joint

AAOS appreciates and agrees with the Rule's proposal to add the four "ICD–10–PCS procedure codes to the FY 2019 ICD–10 MS–DRGs Version 36 Definitions Manual in Appendix E— Operating Room Procedures and Procedure Code/ MS–DRG Index as O.R. procedures assigned to MS–DRGs 485, 486, and 487 (Knee Procedures with Principal Diagnosis of Infection with MCC, with CC, and without CC/MCC, respectively) or MS–DRGs 488 and 489 (Knee Procedures without Principal diagnosis of Infection with CC/MCC and without CC/MCC, respectively), both in MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)."

We also appreciate and agree with the Rule's proposal "[f]or the hip procedures … to add these four ICD–10– PCS procedure codes to the FY 2019 ICD–10 MS–DRGs Version 36 Definitions Manual in Appendix E— Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures assigned to MS–DRGs 480, 481, and 482 (Hip and Femur Procedures Except Major Joint with MCC, with CC, and without CC/MCC, respectively) in MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)."

Admission Order Documentation Requirements

AAOS welcomes CMS's decision to revise the inpatient admission order policy to no longer require a written inpatient admission order to be present in the medical record as a specific condition of Medicare Part A payment. We appreciate any relief from the current regulatory burden.

"Two Midnight" Rule

CMS noted in the Proposed Rule that it is not proposing any changes with respect to the "Two-Midnight" payment policy.

Last year, CMS made TKA procedures subject to the "Two-Midnight Rule" in conjunction with the decision to move TKA off the IPO list. However, we believe that the intention of CMS supports an assumption of the appropriateness of an inpatient stay regardless of the expectation of a two-midnight stay. According to the "Two-Midnight Rule," a hospital admission should be expected to span at least two midnights to be covered as an inpatient procedure. On our one-on-one conversation with CMS staff, we have been informed that if the expected need for an

inpatient stay (i.e., defined as a need for two-midnights) is well documented on admission, early discharge is not penalized. Unfortunately, this is not well understood by many providers or hospital administrators. Prior experience with this rule has made many hospital reimbursement/compliance directors concerned that incorrect application of this rule may subject the hospitals and providers to financial penalties. Most orthopaedic surgeons had always considered TKA a major surgical procedure for elderly patients and, hence, an obvious inpatient procedure requiring significant resources. They now face pressure to move the majority of TKAs to an outpatient designation. For patients, these changes may lead to confusion over cost sharing obligations.

Under prior guidance related to the "Two-Midnight Rule;" CMS also stated that Medicare may treat some admissions spanning less than two midnights as inpatient procedures if the patient record contains documentation of medical need. Moreover, CMS expected, as stated clearly in the rule, that most TKAs would remain inpatient. The lack of clarity surrounding acceptable justification for inpatient admission spanning fewer than two midnights has led to pressure on the surgeon to make outpatient the default setting for all TKAs. Those patients for whom one midnight may be sufficient, yet are clearly not acceptable outpatient candidates, fall into a gray area forcing outpatient status. When a standard status is expected by the overwhelming majority, the burden of proof should fall on the exception, not the standard. As noted in the 2016 OPPS/ASC Final Rule, the two-midnight benchmark offers reviewers guidance on appropriate inpatient coverage, while the two-midnight presumption instructs medical reviewers on which claims to review.

In the FY 2014 Medicare Inpatient Long-term Care Hospital Prospective Payment System (IPPS/LTCH PPS) Final Rule, CMS stated that additional exceptions to the generally applicable benchmark may be identified and acknowledged "potential 'rare and unusual' circumstances under which an inpatient admission that is expected to span less than two midnights would nonetheless be appropriate for Medicare Part A payment." In the 2016 OPPS Final Rule, CMS had still only identified one "rare and unusual" exception (i.e. prolonged mechanical ventilation). However, it was stated that additional exceptions would be evaluated on a case-by-case basis. We believe that TKA should be given the same exception status as mechanical ventilation under the rare and unusual policy, to guide review by Quality Improvement Organizations (QIO), until more information is gathered. This will allow surgeons more flexibility while safely navigating the vast clinical space between outpatient and a two midnight stay.

Given the precedent, we request that CMS issue an exception from the "Two-Midnight Rule" for TKA procedures.

"Communication About Pain" in HCAHPS

Lastly, AAOS would like to reiterate our position regarding "communication about pain" in the HCAHPS. Orthopaedic surgeons are intimately aware of the difficulties of providing pain relief

amid the opioid crisis. Many orthopaedic conditions require narcotic pain management for weeks or months, particularly those involving trauma or aggressive post-surgical physical therapy. We continue to utilize multimodal pathways for pain control, thus decreasing the need for oral pain medication.

We believe that payment incentives for higher scores on the Pain Management dimension of the HCAHPS survey may have created the unintended consequence of overprescribing opiates in the inpatient setting. This scoring system of "Pain as a Fifth Vital Sign" has also created a culture of opioid expectation among patients which has made discontinuation of narcotics challenging.

AAOS maintains that it is unreasonable to expect physicians to solve the opioid crisis during a peri-surgical pain episode. It is important to distinguish between chronic and peri-surgical pain when regulating narcotic use. For example, states are restricting narcotics (i.e., the 7-day rule, required E-prescribing) and have mandated DEA logging for each narcotic prescription. These stop-gap regulations place extraordinary burden on patients and physicians treating pain in the post-operative period, when narcotics are necessary and warranted. Pain medication dosing is often increased as patients become more active in the days following hospital discharge. This leads patients to prematurely complete the 7-day supply. As can be expected, it is not uncommon for patients to suffer weekends without pain medication in the days following surgery when physicians lack access to the EHR. AAOS believes peri-surgical pain should be exempted from hard limits on duration and amount.

Orthopaedic surgeons have worked with anesthesiologists to reduce excessive opioid consumption through the use of perioperative surgical homes and other innovative tools.[9] In addition, AAOS has developed a Pain Relief Toolkit[10] for our surgeons that includes doctor-patient scripts for successfully navigating common pain reliefs situations. The toolkit is designed to promote patient safety and comfort during the peri-surgical period, implement strategies that rely on alternative pain management tools and behaviors, and promote safe use and disposal of opioids. AAOS recognizes that numerous factors play a role the current opioid crisis, including habits outside of providers' control such as combining opioids with other medicines, using opioids for something other than pain, and failure to take medicines as prescribed. There are many options available to help address this crisis short of hard limits, and AAOS understands the important role surgeons must play. Another element of AAOS' Pain Relief Toolkit is its Orthopaedic Department-Service Strategies that include, for example, using as little opioid medication as possible, checking statewide databases prior to prescribing opioids, and not prescribing opioids for new office patients with long-standing conditions. We are committed to

[9] "Role of the Perioperative Surgical Home in Optimizing the Perioperative Use of Opioids," Vetter TR and Kain ZN, Anesth Analg. 2017 Nov;125(5):1653-1657.
[10] "Pain Relief Toolkit," American Academy of Orthopaedic Surgeons, https://www.aaos.org/Quality/PainReliefToolkit/?ssopc=1.

working with all stakeholders to find innovative and proven methods to reduce opioid misuse, abuse, and addiction.

Thank you for your time and consideration of the American Association of Orthopaedic Surgeons' comments on the 2019 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,

David Halsey MD

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

American Orthopaedic Foot and Ankle Society (AOFAS)
American Association of Hip and Knee Surgeons (AAHKS)
American Shoulder and Elbow Surgeons (ASES)
Orthopaedic Trauma Association (OTA)
Musculoskeletal Tumor Society (MSTS)
Ruth Jackson Orthopaedic Society (RJOS)
Scoliosis Research Society (SRS)
American Association for Hand Surgery (AAHS)
Pediatric Orthopaedic Society of North America (POSNA)
Cervical Spine Research Society (CSRS)
Arthroscopy Association of North America (AANA)
American Orthopaedic Society for Sports Medicine (AOSSM)
American Society for Surgery of the Hand (ASSH)

Limb Lengthening and Reconstruction Society (LLRS)
Limb Lengthening and Reconstruction Society (LLRS)
Musculoskeletal Infection Society (MSIS)
American Spinal Injury Association (ASIA)