AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

July 10, 2017

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9928-NC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Subject: (CMS–9928–NC)
Medicare Program; Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act & Improving Healthcare Choices To Empower Patients

Dear Administrator Verma:

On behalf of over 18,000 board-certified orthopaedic surgeons represented by the American Association of Orthopaedic Surgeons (AAOS), we appreciate the opportunity to provide comments on the Centers for Medicare and Medicaid Services (CMS) Reducing Regulatory Burdens request for information (CMS-9928-NC). We urge the Administration to consider the recommendations listed below, which address the needs of our surgeons and the goal of high-quality patient care. We also support efforts to ensure access to medical care by improving and maintaining health insurance coverage.

MACRA: MIPS
We are pleased that CMS agreed to our request for 2017 to be treated as a "transition year", with a gradual buildup starting in 2018. However, we believe there should be no penalties for failing to meet the minimum reporting requirements during the transition. With the implementation of Medicare Access and CHIP Reauthorization Act (MACRA) under CMS' Quality Payment Program (QPP), as well as numerous other regulatory changes, physicians are navigating a complex new reporting system. Indeed, many are still working to understand the new requirements and prepare necessary infrastructure and education.

Additionally, AAOS encourages removal of the requirement to report on all patients going forward. It is widely known that orthopaedic medicine lacks validated patient reported outcome-based performance measures (PRO-PM) and has few process measures. AAOS suggests that in

317 Massachusetts Avenue NE
Suite 100
Washington, D.C. 20002-5701
PHONE 202.546.4430
www.aaos.org/dc

areas where there are no validated clinical-level quality measures, and until the time these are developed, physicians be allowed to participate in the Merit-Based Incentive Payment System (MIPS) voluntarily.

MACRA: APM Demonstrations

The AAOS commends the Administration's efforts to initiate various payment, quality, and delivery models under MACRA. We support the commitment of all stakeholders to develop and evaluate payment methodologies which incentivize coordination of care and curb health care inflation. However, mandatory bundled and episode-of-care payment models are flawed, in that they force many surgeons and facilities into models, while lacking familiarity, experience, and/or proper infrastructure to support care redesign. Specifically, the Comprehensive Care for Joint Replacement (CJR) and the Surgical Hip and Femur Fracture Treatment (SHFFT) models require mandatory participation for all surgical episodes triggered by MS-DRGs 469-470 and MS-DRGs 480-482, respectively, in each of the 67 randomly selected Metropolitan Statistical Area (MSA). These models should be replaced by a voluntary payment model for providers and facilities. To this end, we appreciate that CMS has delayed the effective start date of the SHFFT model and we would like to thank CMS for considering additional review and comment rule-making to modify the policy. CMS recently predicted that approximately 100% of eligible clinicians in some of the Advanced APMs will be Qualifying Participants (QP) in performance year 2017 and will receive the 5% bonus. However, it should be noted that this prediction is based on models such as the Comprehensive Primary Care Plus (CPC+) Model, without any scope for specialist participation. Although the Oncology Care Model (OCM)—Two-Sided Risk Arrangement and the Certified Electronic Medical Record Technology (CEHRT) track of the CJR model are Advanced APMs for performance year 2017, CMS did not make predictions for these models. Further, as noted above, this Advanced APM track of CJR has been delayed until January 1, 2018. With the Bundled Payment for Care Improvement (BPCI) initiative models still not qualifying as Advanced APMs, the CEHRT/Advanced APM track in CJR is likely to be the only opportunity for orthopaedic surgeons to participate in Advanced APMs. Thus, we urge CMS to expand on specialist-focused Advanced APMs that will allow for greater participation by specialists. We would urge CMS to reconsider the MSA selection criteria used earlier and expand these models under the Advanced BPCI model. The current BPCI initiative is already a nationwide program, without the MSA restrictions or eligible case thresholds. This design has enabled the expansion of care redesign for elective and trauma cases well beyond the limits of major metropolitan areas. BPCI is a proven model for expanding care for both physician groups and hospitals in large and small markets and, as such, can be built upon and expanded in its next iteration.

The mandatory model designs include all episodes, providers, and facilities. Those surgeons, non-physician providers, and facilities that lack the infrastructure to optimize patient care under episodes-of-care payment models and/or adequate patient volumes to create economies of scale will be severely disadvantaged. A voluntary program in which providers tailor their episode-of-

care models to a particular patient population would optimize patient care and result in payment accuracy and efficiency. We also maintain that verifiable interoperability, infrastructure, and agreement between all entities is imperative to the success of Advanced Payment Models (APM). Until such time as these issues have been addressed, mandatory participation is premature.

Furthermore, we would like to echo our earlier recommendation to explicitly place a surgeon as head, or co-head, of episodes, which would significantly reduce barriers to achieving high quality patient outcomes. It is the orthopaedic surgeon who is involved in the patient's care throughout the episode-of-care- including the pre-operative workup, surgery, inpatient and postoperative care in rehabilitation facilities, at home, and in the physician's office. No other party in the total episode-of-care is as involved in all aspects of the patient's care, and no other party is as important to the final patient outcome, as the operating surgeon. Therefore, it is logical that all episodes treated under the program be overseen by orthopaedic surgeons and not an acute care hospital facility. In addition, we believe the surgeon bears the most risk and, ultimately, is best able to discern the optimal means to improve quality and efficiency. We recommend that CMS create a mechanism for a surgeon or physician group to participate with a third party who manages the episode, payments, and "shared savings" distributions. Finally, AAOS recommends that CMS eliminate all limits on gainsharing among providers to allow flexibility for allocating CMS payments across program teams in ways that maximize incentives. While we support measures to disincentivize overprovision of services, there should be no restriction on payment for cost-controlling services within an episode.

2015 Edition CEHRT

We strongly urge the Administration to remove the requirement for providers to upgrade to 2015 Edition CEHRT. The most recent requirements for CEHRT were approved in 2015, but most EHR developers have not yet met them. Only 54 of the over 3,700 EHR products are currently certified and posted on the Certified Health IT Product List (CHPL). Physicians should not be subject to financial penalties under the QPP and Meaningful Use (MU) because vendors have not certified their 2015 Edition products in a timely manner. CMS should continue to allow the use of both 2014 and 2015 Editions and permit participants to meet modified Stage 2 MU and Advancing Care Information (ACI) measures.

Global Codes Reporting and Data Collection

The AAOS is concerned about the requirement that all providers use G-codes for all post-operative patient encounters. In addition to being unnecessarily burdensome, it represents an overreach according to the language in MACRA calling for CMS to collect data on resources used in the post-operative global period. While reviewing the requirements for reporting post-operative visits (99024), AAOS has uncovered many errors in the long descriptors on the code list published on the CMS website. We identified a 26% error rate in the long descriptors for just the musculoskeletal codes (20000 series). For example, the long descriptor listed for code 29822

is arthroscopy, shoulder, surgical; capsulorrhaphy. This descriptor is incorrect and should read arthroscopy, shoulder, surgical; debridement, limited. These errors are not insignificant and are causing tremendous confusion for providers in an already demanding reporting environment. AAOS believes these errors will cause the data collected to be incorrect and requests that the mandatory reporting period scheduled to begin on July 1, 2017, be postponed until the corrections can be made and provider education efforts reinstated with the corrected information. While AAOS acknowledges CMS' response to our comments in this regard, even requiring mandatory reporting from all providers furnishing global surgery services in Florida, Kentucky, Louisiana, Nevada, New Jersey, North Dakota, Ohio, Oregon, and Rhode Island will be unduly burdensome for providers. AAOS strongly urges CMS to significantly revise their proposed methodology to not use the G-codes as proposed, to not make the claims reporting universal to all Medicare providers using global period codes, and to utilize representative samples of services and other approaches that are likely to yield more reliable and accurate data without imposing major burdens on hundreds of thousands of providers.

Translation and Interpreting Services

The AAOS urges the Administration to remove the burdensome requirements in the Affordable Care Act (ACA) for insurers and the healthcare industry to provide translation and interpreting services for limited English proficiency (LEP) individuals. In certain settings, such as rural areas, it is difficult to procure translation and interpreting services.

Ban on Balance Billing

The ban on balance billing under the Medicare program has further impacted the ability of providers to cover the widening gap between inadequate Medicare payments and the cost of providing services. The AAOS believes that, in the absence of reimbursement that reflects the full costs of care for Medicare beneficiaries, the federal rules prohibiting balance billing should be repealed and insurers should be forbidden from including balance billing prohibitions in physician insurer contracts. The AAOS believes that repeal of the ban on balance billing will help providers close the gap between inadequate Medicare payments and the cost of providing services to seniors.

Medicare Claims Data

The AAOS is deeply concerned about CMS's continued refusal to implement Section 105(b) of the MACRA statute. The law included a provision, Section 105, "Expanding the Availability of Medicare Data," which was to have taken effect on July 1, 2016 and would have granted Qualified Clinical Data Registries (QCDRs) access to real-time Medicare claims data for quality improvement and patient safety purposes. Unless QCDRs can validate their data with real-time Medicare and non-Medicare claims data, their findings exist in a virtual vacuum and are of little benefit. With validation, QCDRs can provide CMS with information that can both save lives and incur significant cost savings for the Medicare program. AAOS urges CMS to implement Section 105(b) of MACRA and grant QCDRs access to real-time Medicare claims data.

IPAB Repeal
AAOS opposes the Independent Payment Advisory Board (IPAB) and supports repeal of this entity and has been working with the US Congress as they undertake health care reform. IPAB's mandate to contain Medicare costs will likely subject physicians to unfair cuts in reimbursement. IPAB is severely constrained in what it can recommend to slow the pace of Medicare spending growth. IPAB recommendations cannot increase beneficiary premiums or cost-sharing and cannot reduce benefits in any way. IPAB cannot recommend tax increases. The only options available are adjustments to what Medicare pays for various medical services. Because hospitals are exempt from cuts until 2020, the burden of payment reductions will fall heavily on physicians.

The AAOS recognizes the importance of lowering health care costs and we are committed to improving the value of health care. Medicare payment policy requires a broad and thorough analysis of the effects on all providers and beneficiaries. Unfortunately, IPAB threatens unnecessary and harmful cuts to physicians causing undue burden on physicians and their practices.

Stark Law
While the Stark Law is structured to control the volume of referred services, it is a strict liability statute that leads to heavy penalties for unintentional and technical errors by physicians and their staff. Liability statutes, such as the Stark Law, do not encourage physicians to participate in coordinated care models. The BPCI initiative and CJR model reveal weaknesses in current law. The costs of compliance and disclosures required can be prohibitive for small and medium-sized physician practices participating in these models. Physician referrals in Accountable Care Organizations (ACOs) are theoretically exempt from the Stark Law requirements through fraud and abuse waivers. There should be similar exceptions/protections to physicians participating in APMs. 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.

Physician-Owned Hospitals
Physician-owned hospitals (POH) 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 received the top 5-Star Rating by CMS than non-POH hospitals, which have considerably higher risk of complications. Having physician- controlled operations, these hospitals are more agile. They are able to shift focus and address frontline issues without the administrative red-tape that cripples larger hospital systems. They contribute to local economies and meet a growing demand for health care services, especially in rural areas. Concerns that POHs could

have an incentive to serve only the most profitable patients have been proven baseless. A comprehensive peer-reviewed study published by the British Medical Journal found that, overall, "physician-owned hospitals have virtually identical proportions of Medicaid patients and racial minorities and perform very similar to other hospitals in terms of quality of care."

We encourage the Secretary to explore all regulatory avenues to lift the arbitrary ban on new and expanding POHs. The Secretary has broad authority in creating a new demonstration project through the Center for Medicare and Medicaid Innovation for POHs which would include a waiver or exemption that would allow POHs to expand if they are accepted into the program. We also encourage the Secretary to explore a defined process for states to waive the Affordable Care Act's provisions on POHs through state and regional waivers. Based on legal analysis of the relevant statutes, regulations, and guidance regarding state section 1115 waivers and the POH restrictions, the secretary has broad authority to modify section 1877 and lift the POH moratorium. The Stark Law, which has not been updated statutorily for more than two decades, limits the full potential of POHs as innovative health care delivery models. Its implementation has not realized the goal of decreasing medical costs. Rather, it has resulted in large hospital systems that disincentivize competition. These hospital systems are absorbing surrounding medical practices, becoming de facto monopolies. The presence of physician-owned hospitals serves to incentivize traditional hospitals to improve, innovate, and control costs. Additionally, as rural hospital failures accelerate, physicians (or physician-led groups) should be allowed to purchase them outright or partner in a joint venture with the current management structure. This is just another way to preserve access to rural medical care while driving downs costs and increasing quality care.

Opioid Epidemic

Orthopaedic surgeons are intimately aware of the difficulties of providing pain relief amidst 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 opioids 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.

We appreciate the proposed change in the Pain Management category of HCAHPS, but maintain that it is unreasonable to expect physicians to solve the opioid crisis during an acute pain episode. It is important to distinguish between chronic and acute 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

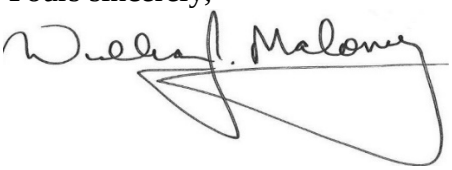
extraordinary burden on patients and physicians treating acute pain in the post-operative period, when narcotics are necessary and warranted. Pain medication dosing is often increased as patients become more active in the days following hospital discharge. This leads patients to prematurely complete 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 EMR.

Publication of Quality Assurance Activity
We support efforts that produce greater transparency and consumer education. However, we strongly oppose the publication of quality improvement surveys and plans of correction by accrediting organizations (AO) in current form. Quality Assurance (QA) committees and documentation have been held as non-discoverable in medico-legal actions by most states (Kentucky being an exception). To make the list of discrepancies public would essentially negate this protection. Without a proper determination of which elements should be made public, and sufficient time for AOs to standardize their reports for reasonable comparison, there is substantial risk of contextual misinterpretation. AOs must prepare the information in a way that limits unintended consequences when published. It is imperative to ensure that the accredited entities do not minimize safety concerns for fear of public reprisal or extricate themselves from the accreditation process, altogether. This proposal of publication goes against quality assurance activities across health systems.

We recognize and appreciate that CMS has recently released a number of RFIs and has encouraged stakeholder input on new policies to better achieve transparency, flexibility, program simplification, and innovation. In addition, we look forward to commenting on other proposals for updating Medicare-QPP policies, particularly on new and redesigned APMs that allow for specialist physician participation and leadership.

Thank you for your time and consideration of the suggestions of the American Association of Orthopaedic Surgeons for reducing the regulatory burden on physicians. If you have any questions regarding our comments, please do not hesitate to contact William Shaffer, MD, AAOS Medical Director by email at shaffer@aaos.org.

Yours sincerely,



William J. Maloney, MD
President, AAOS

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

American Alliance of Orthopaedic Executives (AAOE)
American Association of Hip and Knee Surgeons (AAHKS)
American Orthopaedic Foot and Ankle Society (AOFAS)
American Shoulder and Elbow Surgeons (ASES)
Arthroscopy Association of North America (AANA)
Cervical Spine Research Society (CSRS)
J. Robert Gladden Orthopaedic Society (JRGOS)
Limb Lengthening and Reconstruction Society (LLRS)
Musculoskeletal Infection Society (MSIS)
Musculoskeletal Tumor Society (MSTS)
North American Spine Society (NASS)
OrthoForum
Orthopaedic Rehabilitation Association (ORA)
Orthopaedic Trauma Association (OTA)
Pediatric Orthopaedic Society of North America (POSNA)
Ruth Jackson Orthopaedic Society (RJOS)
Scoliosis Research Society (SRS)
The Hip Society (HIP)
The Knee Society (KNEE)

Cc: David A. Halsey, MD, First Vice-President, AAOS
Kristy L. Weber, MD, Second Vice-President, AAOS
Thomas E. Arend, JR., Esq., CAE, CEO, AAOS
William O. Shaffer, MD, Medical Director, AAOS