AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

November 16, 2015

Andrew M. Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3321-NC2
P.O. Box 8016
Baltimore, MD 21244-1850
Submitted electronically via http://www.regulations.gov

Subject: [CMS-3321-NC2] Medicare Program: Request for Information Regarding Implementation of the Merit-Based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models

Dear Acting Administrator Slavitt:

On behalf of the members of the American Association of Orthopaedic Surgeons (AAOS), we appreciate the opportunity to provide comments on CMS' Request for Information (RFI), CMS-3321-NC2, published in the *Federal Register* on October 20, 2015. The RFI solicits input on the implementation of select provisions of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) including aspects of the Merit-Based Incentive Payment System (MIPS), developing and promoting alternative payment models (APMs), and encouraging creating physician-focused payment models (PFPMs).

In the October 20 *Federal Register* notice, CMS presented their requests for stakeholder input in a descending order of categorized priorities, as noted in Section II, Subsection A. Please note AAOS has provided responses to those Priority Categories and Sub-Subsections relevant to the practice of orthopaedics, in this descending order. In addition, we focus on entire Sub-Subsections as noted in CMS-3321-NC2 and specific Subsections of particular categories as noted in CMS-3321-NC, the initial RFI published in the *Federal Register* on October 1, 2015. Unless otherwise noted, the following comments are in response to CMS-3321-NC2, the preferred focus for responses, according to CMS.

Priority Category One

Sub-Subsection 3: Quality Performance Category

AAOS commends CMS for seeking information regarding implementation of the Merit-based Incentive Payment System (MIPS), Promotion of Alternative Payment Models (APMs), and

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Incentive Payments for Participation in Eligible APMs. However, in order to ensure CMS' proposals are appropriate for all practitioner types, AAOS believes CMS must work closely with AAOS and other specialty societies throughout the drafting process. Furthermore, AAOS recommends that CMS provide information on its policies to implement the MIPS prior to the release of the CY 2017 MPFS Proposed Rule, such as in the CY 2016 interim final rule or a separate rule specific to the MIPS.

As specialty physicians, orthopaedic surgeons face unique technology challenges, ranging from certification issues to collection of specialty-appropriate data, as well as the larger issues impacting all physicians such as interoperability and cost. We appreciate CMS's efforts in providing resources to the health care community, but because surgical specialists have unique Health Information Technology (HIT) needs, we believe CMS needs to develop improved, specialty-specific tools. As noted in previous communications, the AAOS is ready to work with CMS in establishing specialty-specific standards and performance measures for all orthopaedic treatment domains.

In order to implement all of the proposed standards, orthopaedic surgeons would spend an excessive amount of time directly entering patient data not essential to the diagnosis and treatment of musculoskeletal conditions or injuries into their EHR systems. We feel that orthopaedic surgeons are better served concentrating their time and efforts in recording data that are germane to the musculoskeletal issues for which the patient seeks his or her care, and not on non-essentials elements of the patients' history. For example, when evaluating and treating a 56 year-old female patient with a wrist or hip fracture, the orthopaedic surgeon should document additional patient-specific information on osteoporosis. However, when treating a patient for hip arthritis, conducting tests and documenting information on hypertension at each appointment is not likely to yield meaningful improvement in blood pressure management. An appropriate frequency of measurement criterion and referral to another physician to treat the comorbidity is necessary, otherwise there is an inappropriate burden placed on the specialist community. These examples demonstrate appropriate action for value-based documentation of comorbidities in terms of identification, evaluation, and management.

For orthopaedic surgeons, there are few clinical data registry reporting options, and the largest Registry now in operation, The American Joint Replacement Registry, is organized to collect data from hospitals rather than orthopaedic surgeon practices. There are no qualified clinical data registries tracking patient outcomes for other orthopaedic procedures that involve implanting a device. AAOS recommends the engagement options and proposed measures by CMS include the stipulation that the orthopaedic surgeon be given credit for meeting

measurement requirements if the admitting hospital is submitting data on the orthopaedic surgeon's patient cases to a qualified clinical data registry at any time during the reporting period.

The AAOS is appreciative of CMS' focus on aligning various physician payment, efficiency, and quality improvement reporting programs to reduce the burden on eligible professionals and group practices that participate in those programs. Improvements and increased flexibilities should encourage more widespread physician participation.

Sub-Subsection 3: Quality Performance Category

b. Data Accuracy [CMS-3321-NC]

The Qualified Clinical Data Registry (QCDR) program shows great promise, but is still in its infancy and entities need adequate time to accommodate the current rules without increasing their burden with additional rules at this time. The AAOS feels the proposal to require QCDRs to publicly report the title and description of the measures a QCDR reports for purposes of the Physician Quality Reporting System (PQRS) and the performance measure results is reasonable, and appreciates CMS' allowance of the QCDR to select the public reporting method. However, the AAOS is very concerned with the proposal that data be available on a constant basis and be continuously updated, potentially creating an administrative burden on the QCDR. Greater flexibility in the data reporting timeframe would be ideal.

The AAOS agrees with the 2016 Medicare Physician Fee Schedule (MPFS) Final Rule (FR) provision that CMS will continue to make available for public reporting on Physician Compare all individual EP-level QCDR PQRS and non-PQRS measure data that have been collected for at least a full year. We also agree that group practice level QCDR PQRS and non-PQRS measure data that have been collected for at least a full year be available for public reporting.

The AAOS appreciates that CMS is focusing on aligning QCDR measure reporting across all eligible professionals and group practices. AAOS agrees that QCDRs should publicly report data annually in the year following the year the measures are reported and that QCDR PQRS and non-PQRS measures that have been collected for less than a full year are not subject to public reporting. We are also appreciative of CMS' focus on aligning various physician payment, efficiency, and quality improvement reporting programs to reduce the burden on eligible professionals and group practices that participate in those programs. Improvements and increased flexibilities should encourage more widespread physician participation in the PQRS and related Medicare quality measure improvement programs for years to come.

The AAOS agrees that CMS should require QCDRs to provide specified information to CMS at the time of self-nomination to ensure QCDR data is valid. AAOS urges CMS to evaluate the

requirements entities must meet to become QCDRs. We are concerned about which entities can apply to be a QCDR, whether the requirements for self-nomination are sufficient, and if this process is monitored by CMS. Our focus is patient safety and collecting accurate data. We want to ensure there are no inappropriate organizations collecting data.

We are pleased CMS has responded to stakeholder feedback to allow QCDRs the ability to submit quality measures data for group practices. The AAOS supports the MACRA legislation allowing QCDRs access to Medicare claims data upon request, and at no charge, for purposes of linking Medicare data with clinical outcomes data to perform risk-adjusted, scientifically valid analyses and research to support quality improvement, patient safety, and reduced costs to the Medicare program. We urge CMS to ensure that QCDRs be provided access to Medicare claims data, as required by law, on July 1, 2016 and that the process for obtaining such data be convenient, timely, and affordable.

Priority Category Two

Sub-Subsection 2: Virtual Groups

MACRA requires the Secretary to establish a process to allow an individual MIPS EP or a group practice of not more than 10 MIPS EPs to elect for a performance period for a year to become a virtual group with other such MIPS EPs or group practices. CMS currently uses a variety of identifiers in association for an EP under different programs. For example, under the PQRS for individual reporting, CMS uses a combination of a Tax Identification Number (TIN) and a National Provider Identifier (NPI) to assess eligibility and participation, where each unique TIN and NPI combination is treated as a distinct EP and is separately assessed for purposes of the program. Other programs use either one or the other identifiers or a combination of both. The virtual group option under the MIPS allows a group's performance to be tied together even if the EPs in the group do not share the same TIN. CMS will need to select and operationalize a specific identifier to associate with an individual MIPS EP or a group practice. AAOS recommends this identifier be one already used by the EP, such as the NPI, rather than creating yet another numerical sequence to identify each EP.

The AAOS believes group size should not be a determining factor in allowing EPs to participate in a virtual group; in other words, there should be no limit on size for a potential group with the condition that it can be reasonably managed. Also, there should be no geographic limitations on MIPS EPs electing to become a virtual group. Virtual groups are more than reporting mechanisms because once formed, they become a legal entity. Solo and small practices can join together in "virtual groups" and combine their MIPS reporting and AAOS supports this approach.

Sub-Subsection 3: Development of Performance Standards

Performance metrics remain a challenge across all CMS programs. Working toward uniformity of measures can simplify data collection and evaluation and minimize duplication of effort on measure development. Measures currently used for Individual Quality Reporting (IQR) and PQRS should be applied, as needed, to bundled models. More specialty measures are needed in IQR and PQRS and it would be beneficial to have performance measures that relate to the outcomes of bundled episodes included in IQR and PQRS. As existing measures are replaced with improved measures, new measures should be developed that will apply across MIPS and APMs, including bundled payment initiatives.

We are generally supportive of CMS efforts to improve patient care and efficiency through quality measurement and payment evaluation. We commend CMS for convening a national Technical Expert Panel (TEP) with broad participation of orthopaedic surgeons to inform the development of the Hospital-Level Episode of Care Measure for Elective Primary THA and/or TKS. We agree with CMS that well-designed risk-adjusted payment measures can be a useful complement to quality measures and we would only support resource use measures that are closely paired with quality measures. Given the lack of rigorous evidence available at this time, the AAOS urges extreme caution in undertaking significant changes. Alternatively, we advocate for taking a more systematic, incremental approach to alternative payment models that maximizes voluntary participation and testing of multiple models to allow for innovation in delivery and payment.

Priority Category Three

Sub-Subsection 7: Other Measures

As we move towards the implementation of MIPS and APMs there are some areas that need immediate attention from all stakeholders, including CMS, which should incorporate:

- Developing specific quality measures for orthopaedic surgery that can be utilized and implemented across the entire specialty; and
- Refining the criteria to better reflect the unique characteristics of surgical specialty practices.

We recommend CMS look specifically at developing measures that encourage team-based care. We know team training can significantly reduce medical errors, especially in the operating room, and we believe measures encouraging this approach to care are an important and manageable improvement in quality measures for orthopaedic surgery.

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We are committed to assisting CMS in developing measures such as the ones described above. In addition, AAOS can assist by organizing panels of orthopaedic surgeons to define quality measures for treating arthritis of the shoulder, elbow, hip, knee, and ankle, as well as other high-value musculoskeletal conditions, or other high-cost, high-morbidity orthopaedic conditions including hip fractures in older adults. We believe including such quality measures would meet MACRA requirements and would facilitate adoption among orthopaedic surgeons and encourage participation in the Medicare program, thereby increasing patient access to orthopaedic care.

Sub-Subsection 9: Flexibility in Weighting Performance Categories

MACRA allows for flexibility in weighting performance categories for providers. By combining the three individual programs, MIPS simplifies the application of incentives and penalties while still relying on the performance measurement rules of the individual programs. A point system would yield a better composite score than other options. In addition, flexible criteria should be established to better reflect the unique characteristics of surgical specialty practices. Orthopaedics is a prime example. Currently there are not enough orthopaedic measures to satisfy the current PQRS reporting requirements. AAOS member physicians commonly find few measures which reflect their specialty. Given this limited number of specialty specific measures, flexibility and weighting should be modified as a way to level the scoring to account for these limitations, at least until additional orthopaedic measures are developed.

Sub-Subsection 10: MIPS Composite Performance Score and Performance Threshold

AAOS believes a composite score should be utilized. According to the Act, the methodology should provide for a composite assessment for each MIPS EP for the performance period for the year using a scoring scale of 0 to 100. CMS is required to compute a performance threshold to which the MIPS EP's composite performance score is compared for purposes of determining the MIPS adjustment factor for a year. The performance threshold must be either the mean or median of the composite performance scores for all MIPS EPs with respect to a prior period.

Sub-Subsection 11: Public Reporting

AAOS supports public reporting to include individual EP and group-practice level quality measurement data if such data is evidence-based, clinically relevant, appropriately risk-adjusted, actionable, and fairly and accurately collected as well as evaluated prior to public release. We support public reporting as a means to empower patients and increase transparency and provider accountability as long as it minimizes the burden of data collection on patients, physicians, and hospitals.

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Section II, Subsection B: Alternative Payment Models [CMS-3321-NC]

The AAOS strongly supports efforts by CMS to make appropriately structured alternative payment models (APMs) available to physicians and other providers, including bundled and episode-of-care payment models. We have supported previous efforts by CMS through the Center for Medicare and Medicaid Innovation (CMMI) in the area of musculoskeletal care where current initiatives under the Bundled Payments for Care Initiative (BPCI) address episode-based payment approaches to delivering care to beneficiaries with multiple types of clinical episodes, including musculoskeletal conditions. The Acute Care Episode (ACE) demonstration project also involved musculoskeletal episodes, specifically total knee and total hip replacements. AAOS has supported these initiatives and believes that properly constructed episode-of-care models and bundled payments have the potential to generate savings for Medicare while having positive effects on patient care. In fact, many AAOS members have been leaders in developing, implementing, and evaluating episode-of-care payments under the ACE Demonstration Project and the BPCI.

The AAOS notes that while episode-of-care models have shown potential to reduce costs, this potential has not been definitively validated in rigorously tested studies comparing patient outcomes and cost efficiencies under episode-of-care models versus alternative approaches. Given this lack of rigorous evidence, the AAOS urges extreme caution in undertaking significant changes and alternatively advocates for taking a more systematic, incremental, approach to APMs that maximizes voluntary participation and testing of multiple models to allow for delivery and payment innovation.

To this end, the AAOS strongly recommends that prior to MACRA implementation, CMS must first demonstrate infrastructural readiness on a meaningfully nationwide level. At a minimum, we believe at least 85% of eligible hospitals need to have critical infrastructure in place while eligible professionals (EPs) including physicians, physician assistants, nurse practitioners, and physical therapists must demonstrate its utilization as defined under Stage 2 Meaningful Use criteria – which places an emphasis on health information exchange between providers to improve care coordination for patients – with the potential to advance to Stage 3. Infrastructural support remains incomplete, with Meaningful Use attestation at 18% and 48% for physicians and hospitals, respectively. By making infrastructure readiness a condition of MACRA implementation, CMS will have time to monitor progress and determine what is and is not working to incentivize infrastructure development. The AAOS also urges CMS to carefully review and evaluate current alternative payment models tested under CMS (and private payer) initiatives such as the BPCI program. These initiatives are ongoing and it is incumbent on CMS to validate alternative payment model success both in terms of cost savings and most importantly, the quality of patient care and improved outcomes.

The AAOS strongly supports *voluntary* bundled and episode-of-care pilot projects. We believe initial programs should be voluntary and on a nationwide basis for any set of surgeons, facilities,

and providers who seek to collaborate in innovative ways to bring higher quality, improved care coordination, and to lower costs for musculoskeletal care and who have the infrastructure necessary to carry out an episode-of care-approach to payment and delivery. Specifically, we recommend CMS require any participating entity have verifiable interoperability, infrastructure, and agreements between all necessary entities.

Our recommendation to explicitly place a surgeon as head, or co-head, of episodes 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, from the pre-operative workup, to the surgery itself, to inpatient post-operative care, to the post-operative care provided 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 an orthopaedic surgeon bears the most risk throughout the episode-of-care and ultimately has the most insight into the best pathways to improving patient care quality and efficiency and should therefore lead the bundled payment initiative. We recommend the operating surgeons and physician groups have the ability to be in charge of the bundle, or explicitly create a mechanism allowing the surgeon or group to participate with a facility or third party to manage the episode, collect payments, recoup overpayments, and return "shared savings" across the spectrum of care. Having the hospital in charge of the bundle provides the hospital inappropriate leverage over surgeons and other participants and could allow some hospitals to exclude surgeons and other care providers if those parties don't wish to meet the hospital's terms.

AAOS recommends that CMS eliminate all limits on gainsharing among providers to give providers flexibility to allocate the CMS payment among the members of program teams in ways that maximize incentives for each specific team, as opposed to a one-size-fits-all model. Prohibiting compensation to any provider designed to reward them for increases in the number of procedures they perform must continue, but there would be no ban on payments that help control costs within a CMS episode.

Section II, Sub-Subsection 1d: Nominal Financial Risk [CMS-3321-NC]

AAOS believes well-designed incentive programs assign physicians some amount of nominal financial risk in providing care for patients. However, this should be done with significant caution and calibration in order to render all inputs as precise as possible. For example, instead of risk-adjusting payments based only on the characteristics that affect hospital costs, payments should also be risk-adjusted based on patients' functional status and other characteristics that affect the types of post-acute care they need. Physicians should assess their patients' functional status and other health problems and assign the patients to one of several acuity/risk levels.

Instead of imposing requirements for use of health information technology that are not grounded in any evidence of patient benefit, the program should give physicians and other providers as much flexibility as possible to deliver services using different approaches and techniques to improve patient outcomes, identify which services and information systems have the greatest benefits for patients at an affordable cost, and distribute payments based on the costs actually incurred by the providers on the team. This would allocate some risk to physicians and other providers but in an incremental method. If CMS assigns financial risk to physicians, they should regularly assess the efficacy of the approach and be capable of rapidly adjusting if there is not verifiable evidence of success.

Section II, Sub-Subsection f3: Use of EHR Technology [CMS-3321-NC]

Since enactment of the HITECH Act, AAOS has engaged in a continuing campaign to educate orthopaedic surgeons on the value and benefits of using EHR technology. Despite these efforts and the incentives offered by CMS, to date only 18% of eligible professionals (EPs) have attested to Meaningful Use (MU) criteria for Stage 2. Our members are reporting impediments impacting their ability to achieve MU program goals. The primary reason for lack of adoption of EHR for MU cited by our members has been the lack of requirements appropriate for specialty physician practices. For instance, there are only two approved clinical quality measures that fall within orthopaedic surgery – osteoporosis and back pain. Most orthopaedic surgeons have a specialty interest in areas such as adult reconstruction, sports medicine, foot and ankle procedures, or upper extremity care such that osteoporosis and back pain are not a component of everyday practice. A more robust use of technology is necessary to achieve higher rates of successful participation. It is urgent we work together towards the goal of bringing along those surgeons who have been unable or unwilling to qualify for MU of EHR. It is most critical to maintain access of Medicare patients to orthopaedic surgical services, and to further the goals of the ONC and CMS to allow better interconnectivity and improved quality of care.

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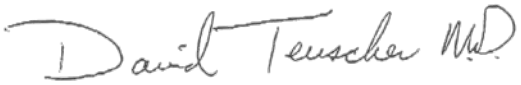
Thank you for your time and attention to the American Association of Orthopaedic Surgeons' (AAOS') selected responses to CMS' Request for Information (RFI) to help inform the design and implementation of various MACRA provisions, particularly those related to the MIPS. Written and enacted to reform physician payment in the United States, the AAOS looks forward to working closely with CMS to ensure physician payment reform ultimately improves the care of musculoskeletal patients. Should you have questions on any of the above responses to the RFI, please do not hesitate to contact AAOS' Medical Director, William O. Shaffer, MD, at 202-548-4430 or via email at shaffer@aaos.org.

Sincerely,



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