AAHKS
AMERICAN ASSOCIATION OF
HIP AND KNEE SURGEONS

OFFICE: 847.698.1200 • FAX: 847.698.0704 • WEB: aahks.org
9400 W Higgins Road, Suite 230 • Rosemont, IL 60018-4976

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VIA ELECTRONIC FILING

Mr. Andrew Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3321-NC
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

RE: CMS-3321-NC: Implementation of the Merit-Based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models

Dear Mr. Slavitt:

On behalf of the 2,710 members of the American Association of Hip and Knee Surgeons ("AAHKS"), thank you for providing us with an opportunity comment and offer suggestions on CMS' development of the Merit-Based Incentive Payment System, Alternative Payment Models, and other reforms under the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA").

AAHKS is the foremost national specialty organization of physicians with expertise in total joint arthroplasty ("TJA") procedures. Many of our members conduct research in this area and are expert on the evidence based medicine issues associated with the risks and benefits of treatments for patients suffering from lower extremity joint conditions. AAHKS offers these comments as the first step in anticipation of future close collaboration with CMS to ensure you benefit from our expertise and experience in TJA procedures when implementing Medicare physician payment reforms.

I. <u>The Merit-Based Incentive Payment System ("MIPS")</u>

a. Quality Performance Category

CMS seeks comments on the use of currently available quality measures and quality data reporting mechanisms, quality data accuracy, and the use of certified EHR technology to report quality data. AAHKS believes CMS must recognize that certain types of measures may be more appropriate for certain specialties and practice settings than for others. Additionally, there are a

number of methodological issues that must be addressed by CMS before moving to assigning more weight to outcome measures, including risk adjustment and attribution.

For example, there is risk for some physicians in requiring that a minimum number of measures be outcomes-based and/or weighing outcome measures more heavily. CMS is assuming that individual physicians can wield sufficient influence on which measures are developed and available to meet the needs of their patient population. Holding physicians accountable for something that is not necessarily within their direct control would be imprudent.

Such an assumption ignores infrastructure issues that may prevent the development or incorporation of appropriate outcome measures into CMS programs. Therefore, CMS should maintain flexibility by not requiring the use of any specific type of measure in the initial years of the program. A flexible approach is critical to ensuring that relevant measures are available to as many physicians as possible.

Historically, AAHKS members have primarily been assessed on readmission, re-operations, cost, and length-of-stay. Most importantly, whatever quality assessments are used, they must be risk-adjusted or else the measures lose their comparative value. Factors such as health status, stage of disease, genetic factors, local demographics and socioeconomic factors significantly impact the quality and outcomes of surgeries performed by AAHKS members. These factors must be reflected in quality assessments to accommodate real variations in patient need and the costs of care.

AAHKS urges CMS to consult with the physician specialty societies and to rely upon measure sets developed by them when determining which quality and resource use measures are appropriate for use under MIPS. AAHKS was able to provide such meaningful input to CMS related to the development of the Comprehensive Care for Joint Replacement Payment Model.

On August 31, 2015, AAHKS convened a Patient Reported Outcomes Summit for Total Joint Arthroplasty in Baltimore, Maryland. Representatives from orthopaedic organizations (AAHKS, American Association of Orthopaedic Surgeons, The Hip Society, The Knee Society, and American Joint Replacement Registry), CMS, Yale-New Haven Health Services Corporation Center for Outcomes Research and Evaluation (Yale/CORE), private payers and other stakeholders participated in the Summit. The Summit's goal was to obtain a consensus regarding the patient-reported outcomes (PRO) and risk variables suitable for total hip and knee arthroplasty performance measures. The results of the Summit were submitted to CMS as a part of AAHKS' comments on the Comprehensive Care for Joint Replacement Payment Model Proposed Rule. We look forward to additional opportunities to provide comparable input.

b. Data Accuracy

To enhance the integrity of reported data, CMS should require qualified registries, QCDRs, and EHRs to complete preliminary CMS-sponsored submission testing. In addition to testing for accuracy, CMS should assess whether participation in the registry is sufficient to collect and report meaningful data to CMS. CMS and its contractors should work with QCDR and EHR vendors in their early stages in order to integrate processes for ongoing data testing. For instance, discussions on processes for system testing should occur once a QCDR self-nominates and submits its data validation plan.

It may require substantial effort by each QCDR to ensure its file transmissions meet the form and manner of CMS specifications. However, it would be beneficial for a QCDR to be confident at the outset that its file format is accurate. To accomplish this, CMS should provide specifications and access to the testing portal to QCDRs for testing within a reasonable time period and prior to the CMS approval date. During that time, QCDRs should be able to test data for validity, as well as for data format.

c. Use of Certified EHR Technology ("CEHRT") Under the Quality Performance Category

CMS seeks comments on whether CEHRT needs to be used to transmit quality data or just to capture and/or calculate quality data metrics. CMS also seeks comments on how to assess performance on the meaningful use of CEHRT under the Meaningful Use Performance Category ("MU"). MIPS implementation is an opportunity to replace the failed MU system with an assessment of CEHRT use that is related to and respectful the actual clinical work of physicians. Presently, AAHKS members are frustrated by the cumbersome and onerous requirements of MU which are unrelated to patient care or interoperability.

Rather than promoting interoperability, MU has fostered new barriers to efficient exchange of data and information across care settings that are a barrier to innovation. Performance on the meaningful use of CEHRT should be assessed in a manner that simplifies the reporting process and is follows a functional outcomes approach, rather than one that is tied to process measures and "counting clicks" to meet thresholds. CMS should reopen Stage 3 MU to realign the program and take time to evaluate whether providers are successful under the Stage 2 Modifications rule.

d. Resource Use Performance Category

CMS seeks comments on what cost or resource use measures should be considered, and how resource use measures should be aligned with clinical quality measures. AAHKS members' experience under the Value-Based Payment Modifier ("VBP") program indicates that the eventual MIPS measurements of resource use must ultimately be implemented on a timeframe that is realistic and recognizes the other burdens physicians are faced with when attempting to move towards compliance.

Accelerated implementation schedules and insufficient provider education of parameters has made the VBP a challenge. It is unclear even now if small or medium-sized institutions are equipped to assess and supply these metrics. Also, the current inadequate risk adjustment and cost of care measures discriminate against physicians that treat high numbers of chronically ill and high risk patients.

Some specialties are developing and expanding clinical guidelines and appropriateness use criteria ("AUC"). The "Choosing Wisely" campaign is a related but different activity which was intended to promote a dialogue between patients and providers around *potentially* unnecessary tests, treatments and procedures. Neither of these concepts should be considered by CMS to be absolute recommendations regarding the appropriateness of a given test, treatment or procedure.

Presented with the general Choosing Wisely guidelines, a physician or patient may conclude that a particular recommendation is not appropriate in a given circumstance. Similarly, due to the nature of their practice, some physicians may conclude that particular recommendations do not apply to a subset of their patients. As a result, some legitimate variation in adherence to AUC and therefore average costs is to be expected. Until such issues are resolved, it would be premature to judge physicians' resource use based on AUC or Choosing Wisely guidelines.

e. Clinical Practice Improvement Activities

CMS seeks comments on potential clinical practice improvement ("CPI") activities, and how those activities should be reported, measured, and validated. There is a broad array of potential clinical practice improvement activities identified by CMS in the Physician Fee Schedule Proposed Rule.

CMS should allow for a broad interpretation of possible CPI activities. However, where professional societies have established data registries that are designated QCDRs, reporting to such QCDRs could be incentivized over other subcategories of measures as a means to further broaden the practice of routinely reporting to professional society registries. For example, the American Joint Replacement Registry ("AJRR") is the nation's largest orthopaedic registry. The expansion of collection of information through this one central registry has the potential to significantly improve orthopaedic outcomes, including patient safety.

Additionally, AAHKS supports making the use of patient satisfaction surveys as one means to satisfy CPI obligations. AAHKS believes that patients should be assessed with a general health survey and a disease specific survey such as the KOOS Jr. and HOOS Jr. surveys. This is a realistic number of questions for a patient to answer in a post-operative visit.

f. Other Measures

CMS seeks comments on how to incorporate measures used for other payment systems under the quality and resource use performance categories for MIPS. In some circumstances, the use of another provider's measures, such as hospital measures, may be appropriate for some specialties, but only after they have been aligned through re-specification, testing, and validation for use by physicians. But the use of these measures should not be mandatory. Rather, CMS should allow for the *optional* attribution of facility-based scores to physicians who practice in or are employed by that facility, and compare it to the national average for similar facilities as the benchmark.

g. Development of Performance Standards, Weighting Performance Categories, and Performance Scores and Thresholds

CMS seeks comments on the establishment of performance standards and how scoring weights should be assigned to the four performance categories: quality; resource use; clinical practice improvement activities; and meaningful use. CMS seeks comments on how to develop a methodology for assessing total performance based on performance standards for each of the four performance categories.

Physicians must be able to know who they are being compared to, what their performance thresholds are, and what precisely they are working toward. Therefore, CMS should work to reduce the current two year gap between performance period and payments years. Performance standards should not change periodically, as CMS suggests in the RFI. Rather, the standards for one performance year should remain the standards throughout the entire performance year.

MACRA requires CMS to "consider" historical performance standards, but the law does not *require* CMS to "use" historical standards. It is preferable to use some future year as the basis for determining historical performance, particularly given the large percentage of physicians who will have VBP scores that are not based on actual data and the many others who will have scores that bear little relevance to their own performance. Finally, CMS should not use a composite measure of improvement. Success in one category does not mean success in another. Likewise, failure in one category does not indicate failure in another category.

II. Alternative Payment Models

a. Payment Incentive for APM Participation

CMS seeks comment on how it should define "services furnished under this part through an EAPM entity." It is most likely that payments under an APM will be made to an entity rather than directly to a physician. CMS should require entities to provide for meaningful participation in governance by physicians whether or not the APM Entity is a physician-owned organization. If the entity is a hospital or other entity that is not physician-owned, then it should be required to

provide a means for physicians to influence the governing policies of the organization, such as through significant practicing physician representation on the governing board.

Also, CMS should allow flexibility for proposed APMs to outline different organizational structures to serve as APM Entities and different pathways by which revenues might flow through the APM. CMS should not require all APM Entities to be organized the same way, nor should it require every physician participating in an APM to obtain a new APM identification number. Different APM designs will require different types of APM Entities and a lack of flexibility in organization will only discourage various providers from working together as an APM.

b. Patient Approach

CMS seeks comment as to what methodologies could be used to attribute and count patients in lieu of using payments to determine whether a physician has met the threshold to be a qualifying or partial qualifying APM participant. Physicians should not be required to use either the patient or payments approach. They should retain the *option* to use the patient approach to calculating the share of their Medicare "business" that is attributable to one or more APMs instead of the revenue approach.

Reporting the proportion of patients who are being managed within an APM may be a more patient-centered approach than summing up revenues from the services physicians provide. In some cases, it may be simpler to determine what proportion of a physician's patient population has conditions or episodes covered by APMs than to calculate revenues attributable to APMs. APMs may be designed around higher-cost conditions; however, so some physicians may be more likely to meet the MACRA thresholds using the revenue approach.

c. Nominal Financial Risk

CMS seeks comment on what types of "financial risk" should be considered for an eligible APM entity, and what is the appropriate level of financial risk "in excess of a nominal amount" to be considered an eligible APM entity. Historically, CMS has measured financial risk in ACOs and other APMs through the total cost of care for a patient population.

CMS should consider the true variety of financial risks faced by physicians when establishing alternative payment innovations: initially establishing infrastructure for data analysis and procedures for coordinating care and sharing information; participating in a clinical data registry; jointly developing treatment plans; ongoing costs for new employees such as care managers; and foregone revenue from billable services that are reduced under an APM due to use of appropriateness guidelines and efforts to reduce emergency department visits and hospitalizations.

If these practices do not lead to financial savings, practices are at risk for losses even if the practice is not required to make a payment to CMS. The financial risk to the practice or APM Entity is that the revenue from the APM may not cover the costs of participating in it. The practice could be saving money for Medicare by reducing hospital admissions and expensive tests and procedures, but still be losing money for the practice. The definition of more than nominal financial risk should not be based on the relative gain or loss to the Medicare Trust Fund, but on how much the physician practice or APM Entity gains or loses.

d. Quality Measures for MIPS and APMs

CMS seeks comment on what criteria may be used to evaluate "comparability" to MIPS of quality measures used by an eligible APM entity. First and foremost, selection of quality measures for an APM should be based on the goals and design of the APM. If there are any MIPS measures related to the condition or disease that is managed within the APM, the APM Entity should consider whether or not to use those measures. For example, if a medical society has a registry, such as the AJRR then physician participation in the registry could be used for MIPS reporting and for an APM.

It is important that quality measure reporting for an APM be no more burdensome than under MIPS. It is also important to focus on harmonizing measures so that there are not different ways of measuring the same thing that must be used for MIPS vs. APMs and Medicare vs. other payers. Experience to date with APMs, such as a joint replacement model in Wisconsin, has found that APM measures are more likely to be based on outcomes, such as complication, readmission and reoperation rates, instead of typical PQRS measures.

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AAHKS appreciates your consideration of our comments. We look forward to working closely with CMS on the further development and implementation of MIPS and APMs. You can reach me at mzarski@aahks.org, or you may contact Joshua Kerr at jkerr@aahks.org.

Sincerely,

Michael J. Zarski, JD
Executive Director, AAHKS

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