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Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-5517-P
P.O. Box 8013
Baltimore, MD 21244-8013

Immediate Past President

Gunnar B. J. Andersson, MD, PhD, USA

RE: CMS-5517-P – Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models

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Dear Acting Administrator Slavitt:

On behalf of the International Society for the Advancement of Spine Surgery (ISASS), I am writing in regards to the notice of proposed rulemaking on the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs).

Founding Members

Stephen Hochschuler, MD, USA

Thierry Marnay, MD, France

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(the late) Charles Ray, MD, USA

ISASS is a global, scientific, and educational society of spinal surgeons and scientists organized to provide an independent venue to discuss and address the issues involved with the basic and clinical science of surgical spine care. Thank you for the opportunity to provide comments on the proposed rule and for maintaining an open dialogue with the physician community while determining how to best implement the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).

The Quality Payment Program

In issuing the proposed rule and developing the Quality Payment Program, it is apparent that CMS has listened to some of the concerns of physicians who are currently practicing in the most complex regulatory landscape in history. Physicians are often pulled away from direct patient

care to enter data into electronic health record systems and data registries that are inefficient and not clinically meaningful. A recent study by Casalino et al.¹ found that physicians and staff spend 15.1 hours per physician per week dealing with external quality measures including tracking quality measure specifications, developing and implementing data collection processes, entering information into the medical record, and collecting and transmitting data. This translates to an average cost of \$40,069 per physician per year or a combined total of \$15.4 billion annually for general internists, family physicians, cardiologists, and orthopedists in the United States. These costs generally cannot be absorbed by small and solo physician practices.

The proposed rule establishes the Quality Payment Program and creates two tracks for regulatory compliance: 1. Merit-Based Incentive Payment System (MIPS) and 2. Alternative Payment Models (APMs). If implemented properly, the Quality Payment Program presents an opportunity to simplify reporting requirements, ease administrative burdens, reduce penalties, increase incentive payments, and assist physicians who want to transition into new care delivery and payment models. However, ISASS is concerned that specialists, including spine surgeons, will have difficulty meeting the requirements of the Quality Payment Program as proposed. Regulatory reforms, including those required by MACRA, should center on designing a system that works for practices of all sizes and specialties and that compliments and streamlines the practice of medicine rather than generating additional work that takes away from direct patient care.

Program Implementation

The proposed rule contains a January 1, 2017 effective date for reporting under the Quality Payment Program, with the first payment adjustments occurring in 2019. This accelerated start date for reporting is problematic and should be pushed back to July 1, 2017, especially since the final rule will not be issued until October/November 2016. The proposed effective date of January 1, 2017 leaves physicians as little as two months to understand the requirements contained in the final rule, analyze their practice data, choose a compliance path and performance measures, train staff, and update the workflow processes and technology utilized in their practice. This timeline is unattainable, ignores the demands of physicians' daily practice, and sets the program up for failure.

In addition, the program cycle should be shortened so that the performance period is closer to when payment adjustments will be made. This allows physicians to utilize feedback from CMS to implement practice improvements and enhance performance under the Quality Payment Program in a more timely fashion. ISASS strongly urges CMS to consider implementing a trial phase from July 1, 2017 through December 31, 2017 in which physicians can begin participating in the Quality Payment Program without the consequence of negative payment adjustment. The first performance period would then begin on January 1, 2018 with payment adjustments for this performance year occurring in 2019.

Merit-Based Incentive Payment System (MIPS)

The proposed rule "streamlines" the current fragmented physician reporting programs by sunsetting the Physician Quality Reporting Program (PQRS), the Value-Based Modifier, and the Electronic Health Record Meaningful Use Program at the end of 2018. While this is certainly a

¹ Casalino, L.P., Gans, D., and R. Weber. et al. US Physician Practices Spend More than \$15.4 Billion Annually to Report Quality Measures. *Health Affairs* 35, No. 3 (2016).

step in the right direction, too many elements from these programs are being pulled into the MIPS performance categories. ISASS appreciates the flexibility proposed by CMS to allow multiple reporting mechanisms and the ability to report as an individual or as a group across the performance categories, however we are concerned that CMS continues to view the four performance categories (Quality, Resource Use, Clinical Practice Improvement Activities, and Advancing Care Information) as separate reporting programs with distinct measures, reporting criteria, and scoring methodologies. Taken together, physicians participating in MIPS will be actively reporting on approximately 23 different measures and will be passively evaluated by CMS on several more measures using claims data. This does little to reduce the complexity and financial and administrative burden that physicians currently face under the existing reporting programs.

Quality – While the Quality performance category calls for the reporting of six measures (down from nine measures under PQRS), physicians that do not report a cross-cutting measure or an outcome measure (or other high-priority measure) are at a disadvantage. Physicians can only report on measures that are applicable to their practice; certain specialists, including spine surgeons, have very few quality measures from which to choose. Developing quality measures is a time and resource intensive process and since the Quality performance category is weighted at 50% of the overall composite performance score in year 1 of MIPS, ISASS recommends eliminating the requirement to report at least one outcome measure and at least one cross-cutting measure and instead award bonus points for physicians who choose to report measures in these categories. This will allow physicians to report on any measures, regardless of category, and provide additional time to develop outcome and cross-cutting measures that are applicable to specialty practice without losing points under the Quality performance category. Additionally, CMS should also strongly consider lowering the total number of measures required for reporting and reducing the patient threshold from 80-90% of Medicare Part B patients to the existing 50% threshold in order to further reduce administrative reporting burden.

Resource Use – While there are no active reporting requirements under the Resource Use performance category, it is imperative that CMS properly define the forty-one proposed episode-based measures and the patient relationship categories in order to adequately interpret and attribute claims data, especially since physicians are subject to the measures CMS attributes to them, with no choice in measure selection. In addition to the reasons listed below, ISASS believes that the spinal fusion (SpineLumb) episode-based measure is not ready for inclusion in the Resource Use performance category because spine surgeons are not familiar with this measure, it has never been used for payment purposes, and it has not been reported through the Supplemental Quality and Resource Use Report (sQRUR), which provides feedback for physicians to use to evaluate their resource utilization. ISASS stands ready to work with CMS to improve this proposed episode-based measure.

Episode Trigger – It is unclear whether CMS intends for the proposed episode to capture all surgical procedures related to the lumbar spine or alternatively, capture only lumbar spine fusion surgeries. There are sixty-five separate CPT® and ICD-9 procedure codes listed as trigger codes for the proposed episode. These codes describe procedures ranging from the treatment of vertebral fractures to one-level anterior and posterior fusions to laminectomies and laminotomies to multi-level fusions for spinal deformity to revision surgeries. Inclusion of these sixty-five separate trigger codes creates a hugely heterogeneous patient population, which

results in large cost variation across care episodes and data that is meaningless for use in comparing care episodes. If CMS plans to use the proposed SpineLumb episode to compare surgical costs for lumbar spine surgery across physicians and subsequently make physician payment adjustments, physicians who take the most complex cases will be at a disadvantage. ISASS recommends significantly narrowing the list of trigger codes so that meaningful comparisons can be made across similar surgical cases.

Diagnosis Codes – While the proposed episode accounts for relevant ICD-9 diagnosis codes to help steer claims to an open episode, ICD-9 diagnosis codes are not utilized as part of the episode trigger. A patient’s diagnosis is very relevant to understanding the surgical case, especially in spine surgery. A lumbar fusion to treat disc degeneration is different than a lumbar fusion to treat spondylolisthesis, recurrent herniated nucleus pulposus, or iatrogenic instability. ICD-9/ICD-10 diagnosis codes, if utilized as part of the episode trigger, could serve to further refine the patient cohort in order to make more meaningful comparisons across the surgical cases of patients with similar diagnoses.

Additionally, the circumstances under which the lumbar spine surgery is performed should be accounted for within the measure. An emergency surgery to treat a traumatic spinal injury is much different than an elective surgery to treat a patient’s long-standing degenerative condition. Further, a primary lumbar fusion surgery on a previously unoperated patient is much different than a revision surgery for a failed prior fusion (pseudarthrosis). Revision surgeries can be complicated by epidural fibrosis and scarring from the primary surgery, existing hardware from the primary surgery, increased risk of incidental durotomy, and enhanced wound care issues due to compromised vascular supply or even indolent subclinical infection. ISASS recommends further refining the proposed SpineLumb measure to exclude trauma, multi-level deformity, and revision surgeries and include only elective primary surgeries to treat symptomatic or unstable degenerative conditions of the lumbar spine as part of the episode-based measure.

Clinical Practice Improvement Activities – ISASS appreciates the flexibility CMS has built into the Clinical Practice Improvement Activities performance category by not requiring physicians to choose activities within a certain number of subcategories and proposing reduced activity reporting requirements for small and rural practices. However, the number of high-weight activities should be expanded or the required activities should be reduced so that physicians are not reporting on six separate activities in order to achieve 60 points/100% of this performance category. A physician’s specialty and site of practice may limit the number and types of activities he/she can report based on the available measures. ISASS believes that this performance category should be designed in such a way that it captures what physicians are currently doing to improve their own personal practice and the practice of medicine overall, rather than creating additional requirements for programs in which physicians must participate.

Physicians spend considerable time engaged in continuing medical education (CME) and board-certification activities which ensure that physicians evolve as the technology and science of patient care evolves; accredited CME and board-certification activities should be counted as qualifying activities under this performance category. Further, physicians who are actively involved with their national, state, or specialty medical societies on projects that assist in the shift to value-based care or advance the science of their specialty should be eligible for credit under this performance category. Examples of activities include helping to design specialty-

specific alternative payment models, developing quality or outcome measures, drafting evidence-based clinical guidelines, and developing/hosting educational courses. These types of activities extend beyond the physician's brick and mortar practice to improve the clinical practice of medicine at all levels.

Advancing Care Information – While the Advancing Care Information performance category calls for the reporting of 11 measures (down from 18 measures under the Meaningful Use Program), a pass/fail element is still incorporated into the base score and subsequently the overall performance category score. Physicians do not design EHR systems, but are held accountable for their functionality. The pass/fail element should be replaced with a framework that provides credit for all measures reported. In addition, many of the measures from Stage 3 of the Meaningful Use Program have been proposed under the Advancing Care Information performance category. These measures are not necessarily useful or relevant to all practices and CMS should allow for the use of alternative measures that emphasize patient care and outcomes over administrative processes.

Alternative Payment Models (APMs)

The second compliance path for physicians under the Quality Payment Program is participation in an Advanced APM. Physicians who participate in an Advanced APM with at least 25% of their revenues or at least 20% of their patients covered by the APM in 2019, are eligible for a five percent bonus and are exempt from MIPS reporting requirements. APMs will be considered Advanced APMs if they tie physician payments to MIPS comparable quality measures, require certified EHR technology, and require physicians to assume more than nominal financial risk. Under the proposed rule, physicians will have difficulty understanding the risk of participating in an Advanced APM. Physicians should only be subject to financial risk for components of the patient's care under their control. "More than nominal financial risk" should only include the physician's services, not total expenditures under the APM.

Due to the limited number of APMs that qualify as Advanced APMs under the proposed rule, specialists have virtually no opportunity to participate under this compliance path. As such, it is anticipated that the vast majority of physicians will be participating in MIPS, at least initially, until more Advanced APMs are developed or more existing APMs transition to qualifying Advanced APMS. The process of developing APMs is time and resource intensive; many medical specialties have begun the process of developing physician-focused, specialty-specific APMs over the last several years. It is vital that CMS prioritize the development and implementation of specialty-specific Advanced APMs in order to broaden participation in this compliance path.

Thank you for your time and for your consideration of our comments. We hope that CMS maintains an open dialogue with the physician community throughout development and implementation of the Quality Payment Program; ISASS stands ready to work with CMS to further refine and improve the program. Please contact Liz Vogt, Director of Health Policy & Advocacy by email at liz@isass.org or by phone at 630-375-1432 with questions or requests for additional information.

Sincerely,

A handwritten signature in black ink that reads "Morgan P. Lorio MD". The signature is written in a cursive style.

Morgan P. Lorio, MD, FACS
Chair, Coding and Reimbursement Task Force
International Society for the Advancement of Spine Surgery