June 27, 2016

Andrew M. Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5517-P, PO Box 8016
Baltimore, MD 21244-8016

VIA ELECTRONIC FILING

**Re: [CMS-5517-P] Proposed Rule: 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**

Dear Mr. Slavitt:

The Spine Intervention Society (SIS), a multi-specialty association of 3,000 physicians dedicated to the development and promotion of the highest standards for the practice of interventional procedures in the diagnosis and treatment of spine pain, would like to take this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule on the Medicare Program's Merit-based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule and Criteria for Physician-Focused Payment Models [CMS-5517-P] published in the Federal Register [42 CFR Parts 414 and 495] on May 09, 2016.

## Merit-based Incentive Payment System (MIPS)

### Time Frame

SIS is pleased with the new and more flexible reporting requirements that streamline the multiple Medicare physician quality reporting programs into a single system. However, given that these regulations will not be finalized until the fall of 2016, it will be burdensome, if not impossible, for physicians to be prepared for full implementation with 2017 as the first performance period for a 2019 payment year. Hence, we strongly recommend that 2017 should be treated as a 'transition year' when clinicians would initiate gathering data, but the first performance year would commence in 2018 with 2019 as the first payment year. We believe that the two-year lag between performance and payment years is problematic for physicians; the delay in feedback does not allow physicians to effectively manage their performance to meet the levels required across the four performance categories.

**Size and Characteristics of Physician Practice**

SIS appreciates the financial investments in education and technical assistance for small and solo practices, as well as the embedded flexibilities in the proposed rule for such practices. However, we request that CMS raise the current proposed low-volume threshold exclusions (less than or equal to $10,000 in Medicare charges and less than and equal to 100 Medicare patients). With reference to Table 63 (MIPS Proposed Rule Estimated Impact On Total Allowed Charges By Specialty: Mid-Point Estimate), it is evident that specialty physicians are more likely to have an aggregate negative adjustment on their charges. Table 64 (MIPS Proposed Rule Estimated Impact On Total Allowed Charges By Practice Size) shows that while physician practices of less than 10 clinicians would account for almost 70 percent of the MIPS penalties in 2019, it is even worse for solo practices with 87 percent of the penalties. According to Table 64, for practices with two to nine clinicians, the aggregate dollar amount of potential penalties for not submitting claims is $279 million, compared to 100 or more clinicians at $57 million. For solo clinicians, it is $300 million.

In addition, the proposed new scoring design will disproportionately disadvantage solo and smaller practices. For example, per these proposed rules, the threshold for successfully submitting claims based on measures has been increased from 50 percent under the Physician Quality Reporting System (PQRS) to 80 percent for Part B claims and 90 percent for registries and electronic health records. Smaller practices will find it extremely difficult, if not impossible, to report under these complicated guidelines and may not be able to reach these higher thresholds, both of which will result in penalties under the MIPS program. This is a serious concern in spite of the recent communication from CMS that the data presented in these tables are dated and could be updated in the final rules. We recommend CMS take additional action to reduce the projected impact on small or solo practices. SIS proposes that the threshold for successfully submitting claims is maintained at 50 percent at this time.

SIS also recommends that CMS develop a uniform definition of "small practices." Currently, the rules consider a practice size of 10 clinicians eligible for some exclusions and a group practice size of 15 clinicians for other exclusions. We recommend adoption of 10 clinicians or less as the threshold definition of "small practices."

**Weighting of Performance Categories**

SIS is concerned that the proposed rule's performance categories' relative weights intend to vary over time, with the weight of resource use increasing each year. We believe it is more appropriate for quality measures to remain the most heavily weighted in the MIPS scoring for all years of the program. For example, by Year 3, the weights on quality and resource use categories become the same. This design assumes that costs are fully under the control of physicians. In reality, resource use is affected by a plethora of factors and stakeholders including physicians, other healthcare providers, facilities, vendors, regional markets, and payers. We urge CMS to not increase the weight of resource use until such cost data are more reliably verified and tracked, and the underlying methodology of the performance category is transparent and available to all stakeholders.

**MIPS Performance Category: Quality**

It is encouraging to note that the proposed rule offers significant changes from the current Physician Quality Reporting System (PQRS) by reducing reporting burden, providing greater flexibility, and allowing multiple reporting vehicles. The number of measures to be reported under this category is reduced (from nine to six), with no domain requirement, along with flexible scoring that recognizes all of a MIPS-eligible clinician's efforts above a minimum level of effort and rewards performance that goes above and beyond the norm. However, physician specialties that lack validated outcome measures or "high priority" measures are likely to be at a disadvantage under this category. This is especially problematic for spine interventionalists for whom appropriate, specialty-specific quality measures do not exist. As in the past, SIS is eager to work with CMS and other collaborative measure development bodies to increase the availability and validity of outcome and process measures for interventional spine care. It is important for CMS to provide assistance and financial support to medical associations and other stakeholders interested in advancing and measuring high quality care.

The proposed rule increases the threshold for the successful submission of claims based on measures from 50 percent under PQRS to 80 percent for Part B claims. Moreover, the proposed rule includes administrative claims-based population measures that were previously part of the Value-based Payment Modifier (VM) program. It is important to note that such measures were developed for use at the facility (inpatient and outpatient hospital) level and have less reliability and relevance when applied at the clinician level (both individual and group). SIS requests that CMS decrease the threshold levels for quality reporting, expand exemptions, and develop payment modifier measures that have higher reliability at the clinician level.

**MIPS Performance Category: Advancing Care Information (ACI)**

SIS approves of the elimination of the current Meaningful Use (MU) threshold requirements, allowing for clinicians to participate both individually and as a group as well as the accompanying simplification of measures. The ACI performance score (80 points) allows some flexibility for specialty physicians and practices of varying sizes. The allowance of an additional bonus point for reporting to public health registries is encouraging in terms of the Secretary's overall goals of "Better, Smarter, Healthier." However, we continue to have concerns, especially on issues of interoperability and infrastructure readiness.

The proposed rule changes the scoring methodology without changing the actual measures. The base performance (50 points) would continue to have a pass/fail element, including a requirement for a security risk analysis which has proven to be challenging for most physicians. Also, the expansion of the 90-day reporting period to a full calendar year is problematic for new participants. Overall, the new ACI performance category regulations are complex and may not fit well within the larger MIPS program scoring methodology.

SIS is concerned that measuring various aspects of interoperability (electronically sending, receiving, finding, and integrating data from outside sources, and subsequent use of information received electronically from outside sources) may not adequately address both the exchange and use components of §106(b)(1) of the MACRA. We are also concerned that true interoperability is not a possibility for most private practitioners or even employed physicians.

**MIPS Performance Category: Resource Use**

The proposed rule states that this category will use administrative claims data and would not have additional reporting requirements for clinicians. However, while this reduces the reporting burden on physicians, much of the "costs" of practicing medicine are not subject to any oversight or control by physicians. As discussed above, resource use is affected and determined by a myriad of factors and stakeholders including physicians, other healthcare providers, facilities, vendors, regional markets, and payers. Thus, without the ability to influence or set all the moving parts that are reflected in the administrative claims data, it is unfairly burdensome on physicians to be rated on resource use.

While we support using episode groups to assess physician cost/resource use, many of the episodes mentioned in Table 4 of the proposed rule [TABLE 4: Proposed Clinical Condition and Treatment Episode-based Measures Developed Under Section 1848(n)(9)(A) of the Act (Method A)] are not sufficiently developed to be part of an accurate resource use measurement and tracking set. We recommend that the final rule include better definitions of episode and care groups that take into account the difficulty of accurate attribution for diagnoses that commonly have multiple co-morbidities, multiple conditions, and multiple providers involved in the patient's course of care. The more complex the diagnostic and treatment course, the more difficult accurate attribution is within the Resource Use measurement category.

**MIPS Performance Category: Clinical Practice Improvement Activities (CPIA)**

Clinicians commonly participate in various clinical improvement activities that do not include financial incentives but are for clinical or patient experience improvement only. Such activities are opportunities for categorization under this performance category and could reward practices for actions that currently are not recognized under quality incentive programs. SIS is interested in CMS' proposal for an annual call for activities to build the CPIA inventory and a proposal to conduct a study to understand the diversity of CPIA across practice size and location. However, we believe that CMS should accept and solicit suggestions and recommendations for clinical practice improvement activities from multiple sources, and not limit input to a small number of panels and commenters. While this may require additional effort by the Agency, it is consistent with the spirit of the MACRA legislation and transparency efforts by CMS.

**<u>Alternative Payment Models (APMs)</u>**

SIS has consistently requested reductions in unnecessary and burdensome requirements to qualify as part of a new or "Advanced" Alternative Payment Model which cause resources to be spent on administrative costs rather than patient care. We also

recommend the creation of a clearly defined pathway for rapid approval and implementation of physician-focused APMs. It is heartening to note that MIPS APMs will have their resource use component weight reduced to zero with the 10 percent reassigned to increase weights for CPIA and ACI, thereby creating a pathway of qualification from MIPS APMs to Advanced APMs (A-APMs). However, we believe the proposed rule's standards for consideration as a meaningful participant in an advanced APM are too great for most physicians in the United States to qualify under this pathway. We believe the actual result on the Medicare program will be the opposite of that intended by MACRA, with reduced incentives for physicians to participate and initiate new and innovative models for payment and delivery. We encourage CMS to revise this section in the final rule to expand opportunities for physicians to qualify as advanced APMs. Without further revision, Advanced APMs under the MACRA regulations will be of very limited use for physicians across the country. This is especially true for physicians in small or solo practices, or not part of large hospital systems. An unintended consequence of MACRA may be that small or solo practices are not able to develop and test new payment models because they are not sufficiently incentivized by the delivery and reimbursement system. This was expressly not the intent of the legislation, and CMS should see the Advanced APM mechanism as an opportunity to encourage small practices to experiment with their reimbursement models and revise the final rule accordingly.

One possible avenue for revision is within the proposed rule's definition of Medical Home Models. Under the proposed rule's definition, the focus is on primary care and accountability of empaneled patients across the care continuum. We urge CMS to consider an alternative definition of Medical Home Models such that specialty physicians and clinicians are correctly attributed to their patients, especially when they play the role of the primary physician consultant, and accordingly, receive the incentives due them.

**State-based Medical Homes**

A number of state-based Patient Centered Medical Home (PCMH) models currently underway[1] include multi-payer programs. These state-based models currently do not qualify for A-APMs under the proposed rule. In the spirit of the objectives of the Qualified Private Payer (QPP) program, and the future goal of including multi-payer claims data in the QPP pathways, the state-based models should be actively considered for A-APM qualification, thereby incentivizing physicians to participate in these models.

**Definition of Total Risk**

The proposed rule states that to qualify as an A-APM, the total risk borne by the APM entity (i.e., the maximum amount of losses possible) under the A-APM track must be at least 4 percent of the APM spending target. Since clinicians will not have access to information on the percentage of the APM's spending on other providers (such as

[1]National Academy for State Health Policy "Medical Homes & Patient- Centered Care Maps." Available at: http://www.nashp.org/medical-homes-map/

hospitals, post-acute care providers, skilled nursing facilities) and other resources, clinician practices will not know the amount of potential losses at the end of the year. Moreover, as discussed above, clinicians do not have any, or have extremely limited, control over costs and resource use by other partners within an A-APM. Thus, SIS urges CMS to reconsider the definition of nominal total risk to a lower percent of spending.

In conclusion, SIS appreciates the stated goal of moving to value-based payments in Medicare and commends CMS on the proposed rule, which is mostly in line with the complicated tasks of the MACRA statute. We are thankful for the opportunity to comment on some of the proposals, as above, and look forward to engaging with CMS in this transformation of our healthcare delivery system.

If we may answer any questions or provide any assistance, please feel free to contact Belinda Duszynski, the Spine Intervention Society's Senior Director of Policy and Practice at bduszynski@spinalinjection.org.

Sincerely,

John MacVicar, MB ChB
President
Spine Intervention Society