June 27, 2016

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models; Proposed Rule (CMS-5517-P)

Dear Acting Administrator Slavitt:

The American Society of Nuclear Cardiology (ASNC) appreciates the opportunity to respond to the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models; Proposed Rule (CMS-5517-P). ASNC appreciates CMS' commitment to streamlining quality reporting and efforts to make the transition to the Merit-based Incentive Payment System as seamless as possible.

ASNC is a 4,500 member professional medical society, which provides a variety of continuing medical education programs related to nuclear cardiology and cardiovascular computed tomography, develops standards and guidelines for training and practice, promotes accreditation and certification within the nuclear cardiology field, and advocates for furthering research and excellence in nuclear cardiology and cardiovascular computed tomography.

CMS delineates an alternative pathway in MIPS for non-patient facing physicians. Non-patient facing physicians are defined as "an individual MIPS eligible clinician or group that bills 25 or fewer patient-facing encounters during a performance period, such as general office visits, outpatient visit, and surgical procedure codes." CMS recognizes in the rule that there are a number of "hybrid" physicians, such as nuclear cardiologists, who may spend much of their time engaged in a non-patient facing activity but who also see and care for patients. The current definition is so stringent that it would not account for physicians who are in this "hybrid" arena. We ask CMS to consider an alternative pathway for physicians who may see patients but spend a significant portion of their time and clinical expertise engaged in a non-patient facing activity. Until such time, we urge CMS to adopt the recommendations offered below which we believe will make it easier for nuclear cardiologists to successfully participate in MIPS. We believe this

is critically important because at this time there are no alternative payment models (APMs) that are well-suited for nuclear cardiologists, making MIPS the exclusive pathway for nuclear cardiologists for the immediate future.

Additionally, we urge CMS to allow more suitable reporting period for MIPS in 2017. A full calendar year requirement can create significant administrative burden for practices and limit innovation while not improving the validity of the data, particularly in categories where measures are not automatically calculated by CMS. Eligible clinicians should be able to select a shorter reporting period or use the full calendar year (with an optional look-back to January 1 in 2017) if they believe it is more appropriate for their practice.

Furthermore, while we appreciate that there is some accommodation available for eligible clinicians in solo and small practices in the proposed rule, CMS should also provide additional exceptions and lower thresholds throughout the proposed rule for eligible clinicians, most notably for eligible clinicians in small practices.

QUALITY AND SCORING

ASNC is pleased that CMS recognizes how essential measure specificity and integrity is to robust quality measurement. In addition, we are encouraged that CMS integrated the use of qualified clinical data registries (QCDRs) into many of the merit-based incentive (MIPS) performance categories and we hope to continue a collaborative process to ensure that compelling quality information can continue to be gathered and utilized by CMS to improve patient care.

We appreciate that CMS is proposing a Quality performance category that offers greater flexibility and simplicity to eligible clinicians compared to PQRS. Specifically, ASNC supports that CMS has proposed to:

- lower the number of measures on which eligible clinicians would need to submit quality data;
- abandon the "all or nothing" measure approach, allowing eligible clinicians to get credit for measures reported if performance thresholds are met; and
- eliminate the requirement that eligible clinicians report quality measures covering a specified number of National Quality Strategy domains.

CROSS CUTTING MEASURE —

MACRA encourages the use of QCDR in a number of MIPS performance categories and incorporates modifications to performance categories throughout the program to accommodate participants who reporting using qualified clinical data registries. For example, QCDR measures are not subject to requirements mandating inclusion on an annual final list of quality measures, publication in peer-reviewed journals, or endorsement by a consensus-based entity.

In addition, in the 2014 Physician Fee Schedule CMS stated the importance flexibility in selecting measures because clinical data registries would know best what measures should be reported to achieve the goal of quality of care furnished by their eligible professionals.[1] CMS has proposed requiring eligible clinicians, including those reporting via a QCDR, to report one cross-cutting measure chosen from the list of general quality measures. ASNC believes the requirement to report one cross-cutting measure is counter to the statute's intent to allow providers who report via QCDR the flexibility to select measures that are most relevant to their practice. We urge CMS to remove the requirement that physicians reporting the quality performance category via QCDR must report on one cross-cutting measure.

Importantly, requiring data collection in 2017 for measures not already included in a QCDR presents a myriad of technical challenges. For example, a QCDR's development and any modifications requires partnering with a number of vendors that program code and develop software updates to facilitate reporting. These vendors often require 9-12 months to update data elements which enables physicians reporting to registries to enter new information. In addition to the technical updates, eligible clinicians require adequate time to train practice staff on how to enter new data and new measures must be integrated into the practice workflow.

MEASURE STABILITY AND TOPPED-OUT MEASURES —

The technical aspects of adding measures to a QCDR and adaption of new measures into practice workflow underscores the need for quality measure predictability from year to year. We ask that CMS modify the QCDR self-nomination process to allow measures that have been approved in prior years a period of stability by automatic measure approval for a period of at least three years. This allows our physician members and vendor partners a period of assured measure inclusion.

With regard to CMS' proposal for topped-out measures, CMS has propose to identify "topped out" measures by using a definition similar to the definition used in the Hospital Value-Based Purchasing Program: Truncated Coefficient of Variation *(the 5 percent of MIPS eligible clinicians with the highest scores, and the 5 percent with lowest scores are removed before calculating the Coefficient of Variation)* is less than 0.10 and the 75th and 90th percentiles are within 2 standard errors; or median value for a process measure that is 95 percent or greater.

Using 2014 PQRS quality reported data measures, CMS modeled the proposed benchmark methodology and found that approximately half of the measures proposed under the quality performance category are topped out. **We agree with CMS that it would not be appropriate to remove the topped out measures because it could leave some specialties without sufficient measures to report**, and, as stated above, we believe measure predictability is important from year-to-year.

[1] Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, 42 C.F.R Parts 405, 410, 411, et al.

If CMS identifies a topped-out measure, the measure should remain eligible measure for quality reporting for at least two performance periods and eligible for full credit (10 points). This timeline should give practices time to identify alternative measures, and would provide notice for measure developers if specialty measure gaps need to be filled. It also provides time to accommodate QCDRs that need to incorporate new measures.

We oppose CMS' proposal to limit the maximum number of points a topped out measure can achieve based on how clustered scores are. **Eligible clinicians should get full credit for topped out measures and a phased approach for removing topped out measures from the program should be instituted.**

HIGH PRIORITY MEASURES —

CMS proposes to emphasize, by awarding bonus points, high priority measures defined as outcome, appropriate use, patient safety, efficiency, patient experience and care coordination measures. We support the ability of eligible clinicians to earn greater points for these measures. **ASNC believes that CMS has correctly identified the following measures as high-priority, appropriate use measures that would be eligible for one bonus point.**

PQRS #322 — Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients

PQRS #323 — Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention

PQRS #324 — Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients

PQRS #360 — Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies

QUALITY MEASURE THRESHOLDS —

CMS states in the proposed rule that it is increasing measure data submission thresholds to ensure a more accurate assessment of a MIPS eligible clinician's performance on the quality measures and to avoid any selection bias that may exist under the current PQRS requirements. We believe the proposed requirement that individual MIPS eligible clinicians or groups submitting data on quality measures using QCDRs, qualified registries, or via EHR report on at least 90 percent of patients that meet the measure's denominator criteria, regardless of payer (both Medicare and non-Medicare), for the performance period is too high. Likewise, we believe the 80 percent threshold for submission of measure data using Medicare Part B claims is also too high. **We ask CMS to not finalize its proposal to raise the data submission thresholds beyond the 50 percent threshold currently in place for PQRS.**

Furthermore, PQRS experience does not support raising the threshold from 50 to 80 percent for claims-based reporting. In 2014, more than 286,000 eligible professionals participated in PQRS by using the claims reporting mechanism. According to the CMS PQRS experience report, only 24 percent of eligible professionals successfully submitted data via claims for 4 to 8 measures for 50 percent of eligible instances. The experience report data suggests that the number of required measures should be lower than the proposed six. **ASNC therefore recommends that in addition to lowering the case threshold to 50 percent that CMS also reduce the number of measures required under the Quality performance category from six to four until reporting success rates improve.**

SPECIALTY MEASURE SETS —

CMS is proposing to allow reporting of specialty-specific measure sets to meet the submission criteria for the quality performance category. CMS has proposed a electrophysiology subspecialty measure under the border cardiology measure set. **We request that CMS work with ASNC to establish a similar measure subset for nuclear cardiology.**

RESOURCE USE AND SCORING

We believe Congress understood the challenges with designing measures that accurately capture the resource use of physicians when Congress stipulated that the Resource Use Performance Category should only constitute 10 percent of an eligible clinician's composite score for the first year of MIPS.

If properly selected and designed, measures tied to episodes of care have the potential to increase the relevance, reliability and applicability of resource measures and make physician feedback reports more actionable. However, transparency and physician involvement in the development of these measures and the accompanying methodological decisions are critical.

In response to CMS' previous solicitation of input on episode groups, ASNC encouraged CMS to prioritize episode groups for use in MIPS. To restate, within cardiology ASNC urges CMS to initially focus on discrete invasive procedures for which episode windows and attribution are more easily defined. Candidate procedures include pacemaker/defibrillator implantation, elective single-vessel percutaneous cardiovascular intervention (PCI), "simple" coronary artery bypass graft (CABG) (i.e. no concomitant cardiovascular surgeries), and "simple" valve replacement surgeries (i.e. isolated aortic valve replacement and isolated mitral valve replacement). Chronic cardiovascular conditions, including ischemic heart disease, heart failure, and atrial fibrillation are inherently challenging to episodes groups because resource use is a complex function of multiple patient-level demographics (i.e. age, sex, socioeconomic status) and medical co-morbidities (i.e. hypertension, diabetes, chronic kidney disease). Though important strides have been made in the field of cardiology, we still don't understand all of the factors that confer risk of poor outcomes in our patients, much less how much it should cost to care for complex patients.

Additionally, as ASNC has commented in the past, there is an inherent difficulty of assigning an episode group to physicians, such as nuclear cardiologists, who are rendering diagnostic tests.

While we believe that accurate and appropriate diagnostic testing sets the course of a patient's treatment, and for which the physicians who are ordering and rendering the diagnostic tests should be held responsible, we are very concerned that a patient's downstream costs and outcomes could be misappropriated to the provider rendering the diagnostic test.

Episode-based groups have not been used as a basis for payment under fee-for-service Medicare, and we do not believe that it is prudent to introduce an untested metric at the same time that CMS is rolling out an extraordinarily complex and completely new payment system for physicians' services. We are particularly concerned about the inclusion of completely new episode groups that have never been included in Quality and Resource Use Reports (QRURs), and our concerns are strongest with respect to condition-based episode groups that are triggered by ambulatory care services. These episode groups' triggers may be based on ICD-10 coding, with which physicians are just becoming familiar. For example, in our view, it extremely premature to measure physician resources for ischemic heart disease condition-based episodes, in light of the complexity of the condition and multiplicity of treatment options.

Based on the aforementioned reasons, it is important that CMS begin measuring cardiovascular resource use by using only well-established procedure-based episode groups. At a minimum, for the first year of MIPS, CMS should only include cardiology measure groups that have been included in the QRURs.

When CMS does proceed with assessing physician resource use using episode groups, it should do so exclusively and not also use the current value modifier cost measures. The idea behind the episode groups is to assess physicians for costs they can control based on measures with a high level of patient attribution. Maintaining the value modifier cost measures while also using the episode group measures is unnecessary.

ATTRIBUTION —

For the Medicare spending per beneficiary (MSPB) measure, CMS is proposing to use a minimum 20 case threshold and to eliminate the specialty adjustment. The threshold for the value modifier is currently 125. CMS states that its analysis indicates that after making these and other changes to the MSPB measure's calculations, the MSPB measure will meet he desired 0.4 reliability threshold used in the value modifier for more than 88 percent of all TINs with a 20 case minimum, including solo practitioners. However, this percentage is lower than under CMS' current value modifier policy, which results in virtually all TINs with 125 or more episodes having moderate reliability. We understand that CMS is proposing a case minimum of 20 to increase participation in the measure.

For the CY 2017 payment adjustment, CMS increased the episode minimum for the MSPB measure from 20 to 125. CMS' stated reason for this adjustment was because the 20 episode minimum no longer provided moderate or high reliability after CMS instituted a specialty adjustment for the MSPB measure for the CY 2016 payment adjustment. Therefore, we follow CMS' logic that if it eliminates the specialty adjustment, it can maintain the desired reliability for a majority or practices if it reduces the minimum case threshold to 20.

Once episode groups are adopted for assessing resource use, the MSPB measure should be eliminated from the MIPS program. Until such time, the minimum case threshold for the MSPB measure should not be raised.

ASNC is concerned that the proposed changes to the MSPB measure results in fewer practices meeting the desired reliability threshold than under the current construct of the MSPB measures. We also question CMS' confidence in the reliability of the measure based on the year-to-year editing of the measure. We do not understand how CMS can justify modifications to the MSPB measure designed to increase participation in the measure if it does not ensure the same level of reliability as the current MSPB measure.

QUALITY AND RESOURCE USE REPORTS —

Seven of the 12 proposed cardiovascular episode groups have been previously reported in a QRUR. In theory, for these episode groups, physicians would have been able to begin to assess their performance and potentially begin to take corrective actions, if needed, to improve their resource use relative to their peers. Unfortunately, we know first hand from conversations with ASNC members that they are not accessing their QRURs for a variety of reasons. This is problematic for a program that relies on physicians being able to review their performance and make adjustments in the delivery of care accordingly. ASNC urges CMS to take steps to improve the accessibility of these reports to physicians. Not having access to QRUR information, at an individual physician level or in aggregate, has made it very difficult of ASNC to provide meaningful analysis of current cost measures, as well as the episode groups included in the 2014 QRURs. At a minimum, CMS should aggregate information by specialty so that medical societies can provide a informed assessment of CMS' policies.

CLINICAL PRACTICE IMPROVEMENT ACTIVITIES AND SCORING

ASNC thanks CMS for proposing to structure the CPIA performance category and its associated requirements in a manner that reflects many of the suggestions offered by ASNC and other medical societies. We support that CMS has proposed to:

- provide, at least initially, a broad interpretation of CPIAs;
- allow eligible clinicians the freedom to choose CPIAs, regardless of subcategory domain;
- require that reporting occur through a simple process of a yes/no attestation;
- reduce the participation requirements for small and rural practices; and
- recognize the future role of qualified registries, EHRs, and QCDRs for the submission of data for the CPIA category.

ASNC has reviewed the list of 94 CPIAs and has identified the following as potential CPIAs for ASNC members:

Subcategory	Activity	Weighting

Population Management	Use of QCDR to generate regular feedback reports that summarize local practice patterns and treatment outcomes, including for vulnerable populations	High
Population Management	Participation in a QCDR, clinical data registries, or other registries run by other government agencies such as FDA, or private entities such as a hospital or medical or surgical society. Activity must include use of QCDR data for quality improvement (e.g., comparative analysis across specific patient populations for adverse outcomes after an outpatient surgical procedure and corrective steps to address adverse outcome)	Medium
Care Coordination	Participation in a Qualified Clinical Data Registry, demonstrating performance of activities that promote use of standard practices, tools, and processes for quality improvement	Medium
Patient Safety and Practice Assessment	Use of QCDR data, for ongoing practice assessment and improvements in patient safety	Medium
Patient Safety and Practice Assessment	Use decision support and protocols to manage workflow in the team to meet patient needs	Medium

Patient Safety and Practice Assessment	Measure and improve quality at the practice and panel level that could include one or more of the following: Regularly review measures of quality, utilization, patient satisfaction and other measure that may be useful at the practice level and at the level of the care team or MIPS eligible clinician or group panel; and/ or Use relevant data sources to created benchmarks and goals for performance at the practice level and panel level	Medium

CMS has only weighted 11 activities as "high," which disadvantages specialty practices and diminishes the value of activities that are more specialty-oriented.

We request CMS level the playing field among eligible clinicians by equally weighting all CPIAs in the first year of MIPS and lowering the number of required CPIA, while maintaining the proposed exceptions, including for MIPS groups of 15 or fewer clinicians and groups that participate in an APM and/or a patient-centered medical home submitting in MIPS. We believe, based on the identification of possible CPIAs for nuclear cardiology, that CMS should only require participation in two CPIAs for the first year of MIPS.

Because most nuclear cardiologists will not meet the proposed definition of non-patient facing, we believe that CMS should accommodate physicians who may not have significant face-to-face interaction with patients with the addition of other CPIAs. Accordingly, we strongly urge CMS to give physicians credit for imaging lab accreditation if they provide services in a cardiovascular imaging laboratory that is accredited by the Intersocietal Accreditation Organization (IAC) or equivalent organization.. **Accordingly, we recommend adding an imaging laboratory accreditation component to the following proposed CPIA:**

> Measure and improve quality at the practice and panel level that could include one or more of the following:
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> Regularly review measures of quality, utilization, patient satisfaction and other measure that may be useful at the practice level and at the level of the care team or MIPS eligible clinician or group panel; and/ or
>
> Use relevant data sources to created benchmarks and goals for performance at the practice level and panel level; and/or

[new] **Obtain imaging laboratory accreditation by a deemed accreditation organization that includes elements of patient safety and continuous quality improvement.**

The accreditation process for cardiovascular imaging laboratories is targeted to ensure labs provide high quality. The IAC process of accreditation includes a comprehensive review of the laboratory's organization and each lab must reapply for accreditation every three years. A random site visit and audit are conducted within the three-year period. In addition, a review of the qualifications of a lab's technical staff, physician staff, and medical directors is conducted; the format and content of the reports that it produces are reviewed including a process to ensure that images match reports provided, a thorough analysis of the lab's quality improvement activities, and a host of other critical organizational and operational requirements. Laboratory accreditation (which is voluntary for all hospital laboratories and all office-based laboratories other than those that provide advanced imaging) is precisely the type of clinical quality improvement that Congress envisioned when it enacted this component of MIPS. We also support providing CPIA credit to a physician whose cardiovascular imaging laboratory institutes a process to review the studies it performs against appropriate use criteria. CPIA credit should be made available for physicians who provide services both in laboratories that provide advanced imaging and for physicians who provide services in laboratories that provide other cardiovascular imaging.

ADVANCING CARE INFORMATION AND SCORING

ASNC is grateful that CMS has proposed to structure the ACI performance category in a manner that reflects several concerns that ASNC and others in the physician community have expressed in previous comments to CMS. Namely, we appreciate that CMS is proposing to:

- award partial credit under this category to eligible clinicians who can demonstrate the functionality of their EHR;
- eliminate measure thresholds;
- streamline quality reporting requirements by eliminating quality measures from ACI performance requirements; and
- allow eligible clinicians to use EHR technology certified to either the 2014 or 2015 Edition for the first MIPS performance period.

The proposed requirements for earning points within the ACI performance category eases some of the obstacles that have frustrated so many physicians when attempting to fulfill Meaningful Use requirements, but CMS can and should do more to recognize onboarding efforts among late adopters and MIPS eligible clinicians facing continued challenges in full implementation of certified EHR technology in their practices.

ACI SCORING —

While we commend CMS for its proposals to move away from the "all-or-nothing" scoring approach of the Medicare EHR Incentive Program, the proposed rule retains a pass-fail element in the base ACI score that we urge CMS to reconsider.

CMS proposes that eligible clinicians who successfully submit a numerator and denominator or yes/no statement for each measure of each objective would earn a base score of 50 percent. Failure to meet the submission criteria (numerator/denominator or yes/no statement as applicable) and measure specifications for any measure in any of the objectives would result in an ACI performance category score of zero. For the Public Health and Clinical Data Registry Reporting objective only a yes statement would qualify for credit under the base score. Furthermore, CMS proposes a MIPS eligible clinician must meet the Protect Patient Health Information objective and measure to earn any score within the ACI performance category. **While we believe the Protect Patient Health Information objective and measure is important, failure to adequately meet this measure should not result in a zero ACI score.**

Before CMS proceeds with an ACI scoring methodology that emphasizes performance on objectives and measures that have proved challenging for most physicians, **CMS should revise its proposed scoring so the base score is more heavily weighted than the performance score.**

FUTURE ACI WEIGHTING —

MACRA provides that in any year in which the Secretary estimates that the proportion of eligible professionals who are meaningful EHR users is 75 percent or greater, the Secretary may reduce the applicable percentage weight of the ACI performance category in the MIPS CPS, but not below 15 percent, and increase the weightings of the other performance categories such that the total percentage points of the increase equals the total percentage points of the reduction.

CMS is alternatively proposing to estimate the proportion of physicians who are meaningful EHR users as those physician MIPS eligible clinicians who earn an advancing care information performance category score of 50 percent. CMS should not redistribute weight from the ACI performance category to other categories until CMS can increase the reliability of its attribution and risk adjustment for the other performance categories.

CONCLUSION —

ASNC appreciates your consideration of our comments, and we look forward to future opportunities to provide input as the implementation of MACRA evolves. Should you have questions or require additional information, please contact Georgia Hearn, Senior Specialist, Regulatory Affairs at ghearn@asnc.org.

Sincerely,

Brian Abbott, MD
President, American Society of Nuclear Cardiology