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December 19, 2016

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

Subject: Merit-based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models: Final Rule with Comment Period (CMS-5517-FC)

Dear Administrator Slavitt:

On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), representing over 4,000 neurosurgeons in the United States, we appreciate the opportunity to provide additional feedback on the new Medicare Quality Payment Program (QPP) outlined in above referenced final rule published in the *Federal Register* in October. The AANS and CNS recognize that implementing the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) is a challenging task. And while we greatly appreciate the agency's decision to adopt a transition year that allows increased flexibility and minimizes administrative complexity, we still have serious concerns about the underlying policies driving this program and the impact some of these policies will have on practicing physicians following the 2017 transition year.

GENERAL COMMENTS

The AANS and CNS appreciate that the Centers for Medicare & Medicaid Services (CMS) adopted a strategy whereby physicians will have the flexibility to participate in the Merit-based Incentive Payment System (MIPS) during the 2017 performance year at a pace that best matches the readiness of their practices. Those who contribute minimal effort will still be protected from penalties, while those who feel prepared to report more robustly will have the opportunity to be recognized for their investment and to earn larger bonus payments. This includes reporting measures and activities for as little as 90 days or as long as the calendar year. We also appreciate that CMS recognized the limitations of current physician resource use measures by assigning a weight of zero to the cost category and by not holding physicians accountable for these metrics during the initial year of MIPS. Furthermore, we appreciate that per our suggestions, CMS:

- 1) Lowered the data completeness criteria for reporting on quality measures;
- 2) Removed the requirement to report on a cross-cutting measure;
- 3) Lowered the performance thresholds for both the advancing care information (ACI) and the clinical practice improvement activities (IA) categories;
- 4) Expanded the definition of hospital-based physician for purposes of being exempt from the ACI category; and
- 5) Raised the low-volume threshold, which will appropriately exempt more physicians from MIPS.

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While the AANS and CNS thank CMS for adopting these modified policies and moving in the direction of increased flexibility and reduced burden, we are concerned about the temporary nature of many of these policies and the rapid pace at which the reporting burden and complexity will increase after the transition year. In the final rule, CMS clearly states its intent to rapidly ramp up requirements beyond the transition year, including longer performance periods and higher performance thresholds to avoid a negative payment adjustment, starting as early as 2018. **We strongly urge CMS to extend the 2017 transition year policies, including the zeroing out of the cost category, through at least 2018.** This will allow clinicians to familiarize themselves with the new reporting requirements, better assess the most relevant participation options for their practice, and better understand the complex scoring methodologies and performance benchmarks against which they will be scored. Extending the transition period would also give CMS more time to work with specialty societies to:

- 1) Refine cost measures and to develop additional quality measures;
- 2) Refine MIPS performance analytics, including risk-adjustment and attribution, and scoring methodologies; and
- 3) Further streamline the requirements of each performance category, which remain disjointed and continue to reflect the siloed nature of current quality reporting programs.

As CMS considers our request to extend its 2017 transition year policies to 2018, we remind the agency of the time and cost associated with the following activities:

- Determining reporting options and strategies for maximizing one's total performance score;
- Reporting via claims or contracting with a third party entity, such as a qualified clinical data registry (QCDR), for data submission;
- Adopting and implementing certified electronic health record (EHR) technology;
- Determining whether a clinician is required to participate in MIPS, is a qualifying participant (QP) in an advanced APM, or is a partial QP, as well as the time and cost it would take to determine what requirements are associated with each; and
- Reading educational materials and participating in educational sessions regarding all of these new requirements.

Depending on the size of the practice, neurosurgeons spend a range of \$185,000 to \$385,000, with an average cost of \$285,000, to comply with Medicare's current quality programs. The specialty societies themselves also devote enormous resources to this effort. The AANS has spent well over one million dollars on its clinical data registries, and ongoing costs for staff time, upkeep and data analysis continue. The costs associated with developing quality measures and/or alternative payment models, which can be as high as \$250,000, are simply prohibitive for many small specialties — particularly if there is no guarantee that CMS will even use them. We request that CMS account for these costs when determining policies for 2018 and beyond.

To engage physicians effectively going forward, and to make meaningful progress on raising the bar on quality, CMS still needs to work to achieve the following critical aspects of MIPS:

- A reporting system that is truly streamlined and not overly burdensome;
- A flexible approach to measurement that recognizes the diversity of medicine and allows clinicians to demonstrate their commitment to higher quality care based on their unique practice, specialty, and/or patient population;
- A scoring system that is transparent and simple enough to understand, but also clinically accurate;
- Reporting and performance thresholds that are realistically achievable and do not result in reporting merely for the sake of reporting;

- A short enough measurement/feedback/payment cycle so that MIPS produces more actionable data for both physicians and patients and so CMS can make more timely modifications to the program as necessary.

In the sections below, the AANS and CNS offer feedback on more specific aspects of the final rule that are either still open for comment or that we believe were not adequately addressed in the rule.

SPECIFIC CONCERNS

Quality Performance Category

❖ Data Completeness Criteria.

- **The AANS and CNS continue to oppose the requirement for QCDRs to report on non-Medicare patients.** At least for the first few years of this new quality payment program, CMS should require reporting on no more than 50 percent of applicable Medicare patients across all measures and reporting mechanisms. If CMS must capture data across payers, it should only require a statistically valid sample of patients, such as 20 consecutive patients.
- **The AANS and CNS also strongly encourage CMS to allow physicians to receive a combined score through multiple data submission methods within a performance category in order to provide maximum flexibility.**

❖ Quality Measures

- We remind CMS of the urgency of allocating MACRA-authorized funding toward closing the gap on specialty-focused measures. To date, there has been little transparency in regards to how CMS intends to allocate this funding and whether it has begun the process of determining how to do so. Regardless of how this funding is distributed, measure development must be evidence-based and led by relevant clinical experts.

The AANS and CNS support specialty-specific measure sets and continue to recommend that CMS consider expanding measure sets so that they are also condition or treatment specific. The construction of specialty/condition/treatment measure sets must be transparent and must be done in consultation with relevant specialty societies and clinical experts. For example, in neurosurgery, relevant measure sets could focus on stroke and lumbar spine surgery. In our comments on the proposed rule, we requested that CMS include a neurosurgery/spine set that includes the measures listed below:

- PQRS 021: Perioperative care: Selection of Prophylactic Antibiotic
- PQRS 022: Perioperative care: Discontinuation of Prophylactic Antibiotic
- PQRS 023: Perioperative care: Venous Thromboembolism (VTE) Prophylaxis
- PQRS 130: Documentation of Current Medications in the Medical Record
- NQF 1789: Hospital-Wide All-Cause Unplanned Readmission Measure

We were disappointed that CMS failed to acknowledge our request or provide an explanation as to why it chose some sets over others.

- While we understand the agency's desire to eliminate needless overlap between existing measures, **we strongly believe that excessive consolidation of qualified clinical data registry (QCDR) measures threatens to undermine the usefulness of the QCDR mechanism which was designed, in large part, to recognize the complexities inherent in subspecialty care.**

- **CMS must closely track whether the number of high priority measures available to specialists in the traditional MIPS measure set is equal to the number available to non-specialists over time, and to make adjustments accordingly if they are not.** These evaluations should also help to inform investments in measure development.
- We appreciate that CMS did not finalize the calculation of the two administrative claims ambulatory sensitive measures (acute and chronic composite measures of AHRQ PQIs) due to public concerns about the need for more work to be done around risk-adjustment. However, we question why CMS has elected to continue to calculate and provide informational feedback on the AHRQ PQI measures when they have proven to be of little value in their current state. This extraneous information will simply confuse physicians and make them more mistrustful of the program.

The AANS and CNS were also disappointed to learn of the agency's decision to maintain the all-cause readmission measure for groups of 16 or more who meet a case volume of 200 cases. While we appreciate that CMS has opted not to apply this measure to smaller practices, we remind the agency that it is under no statutory obligation to use these types of claims-derived, global/population-based measures under MIPS. We do not dispute the important role of population-focused quality initiatives but believe that the IA category is a better tool for accomplishing this goal.

- Finally, **we encourage CMS to adopt a general policy of maintaining measures in MIPS for a minimum number of years** (e.g. at least three years, unless there is a change in evidence) to limit scenarios where CMS does not have historical data on the same exact measure to set a benchmark or otherwise evaluate performance. Minimizing changes to measures and measure sets will also make it easier for physicians to plan ahead in regards to reporting strategies.

❖ **Topped Out Measures**

- In regards to topped out measures, we appreciate that CMS decided not to remove these measures or to score them differently in the first year of MIPS. CMS discusses various options for how to address topped out measures beyond the first year of MIPS, including:
 - Potentially removing measures that have been topped out for at least two years;
 - Limiting the maximum number of performance points a topped out measure can earn; or
 - Applying a flat percentage when building benchmarks for topped out measures so that physicians are scored on their percentage of their performance rate and not on a decile distribution.

We strongly recommend that CMS maintain topped out measures for at least three years. As CMS knows, specialists have found it challenging to identify relevant measures, and the rapid and potentially premature removal of topped out measures could compound this problem. The clock should start with the first year of MIPS (i.e., 2017) so CMS can accurately evaluate a measure's topped out status based on the current program rather than a previous quality reporting program (i.e., PQRS) driven by different rules and incentives. It is currently difficult to know whether certain measures appear to be topped out simply because they are being reported on by the nation's top performers only, which might represent a very small portion of the total applicable population. As more physicians participate in MIPS, we might see a broader universe of physicians begin to report on these measures, which could alter the measure's topped out status.

- **It also is critical that CMS identify in proposed rulemaking measures that it considers topped out so that the public has an opportunity to provide meaningful feedback on why performance might appear that way and why the measure should be maintained.**

❖ **Virtual Groups**

- We urge CMS to begin piloting this alternative reporting mechanism as soon as possible.
- CMS should develop minimum standards to ensure that the members of a virtual group are caring for a similar population, are responsible for decisions that could impact the group as a whole, or otherwise have a mutual interest in quality improvement.
- CMS should not limit the number or size of virtual groups, adopt prescriptive geographic standards or limit the reporting mechanisms available to these groups, as long as they can satisfy minimum criteria.

Cost Category

- ❖ While we very much appreciate CMS' decision not to hold physicians accountable for cost measures during the first year of MIPS, **we strongly recommend that CMS weight the cost category at zero percent for the 2018 performance year as well.** Most, if not all, of the episode-based cost measures currently under development, are still not ready for prime time and require additional work. Furthermore, CMS still needs to finalize, implement, and test the patient relationship categories and codes authorized under MACRA to improve the way costs are attributed to physicians. These categories and codes are still under development and will only first be reported by physicians starting on January 1, 2018. Physicians should not be held accountable for episode-based cost measures until these codes have been piloted and until CMS has first provided confidential feedback to physicians on how the codes will be tied to episode-based cost measures and used to attribute costs to physicians more accurately.
- ❖ **The AANS and CNS oppose the agency's ongoing reliance on existing value-based payment modifier (VM) measures, such as the Medicare spending per beneficiary (MSPB) and total per capita cost measures.** As we have noted multiple times in the past, these flawed and meaningless measures are inappropriate for physician-level accountability, result in confusion and should be replaced rather than supplemented by episode-based cost measures. As CMS continues to work with specialties to refine episode-based cost measures and the patient relationship codes, it should continue to assign the MIPS cost category a weight of zero rather than rely on imperfect measures in the interim.
- ❖ **CMS should not rely on profiling measures that have suboptimal reliability scores since doing so will very likely misrepresent physician performance.** For example, CMS considers a reliability score of 0.4 an acceptable threshold for the episode-based cost measures. In this instance, for those physicians whose performance score yields a reliability result of 0.4, there is a 60 percent chance that this score is inaccurate and true performance could be higher or lower. We believe that measures with such low reliability results should not be considered acceptable by CMS for public reporting or for determining payment adjustments.

Advancing Care Information Category

- ❖ **We continue to remind CMS of the foundational work that still needs to be completed to enhance functional interoperability between vendors and among vendors and registries** to ensure incentives for "meaningful use" of health information technology result in improved health care and not another meaningless regulatory burden on physicians.

- ❖ While we appreciate that CMS reduced the reporting/performance thresholds for many of the measures under this category, this category still relies on a rigid structure that fails to provide physicians with flexibility to demonstrate meaningful use in a manner that is most relevant to their practices. **The meaningful use stage 3 framework of measures and objectives should be offered as an option, but not a requirement, along with alternative pathways to demonstrate meaningful use (e.g., participation in a QCDR).**
- ❖ **CMS should offer clinicians the broadest selection of measures to choose from for purposes of both the base and performance score, but should not require the use of any single measure to receive a score in this category.** As finalized, physicians must at least satisfy the base requirements to receive a score in this category, which mirrors the all-or-nothing approach from which CMS has purportedly moved away.
- ❖ We support the agency's decision to finalize a 90-day reporting period for both 2017 and 2018 under this category.

Clinical Practice Improvement Activities Category

- ❖ We thank CMS for reducing the number of activities that a physician must attest to in 2017 to score the maximum number of points under this category. However, **we continue to oppose preferential weighting of activities and the non-transparent manner through which CMS selects activities to include in the inventory and makes determinations regarding weights.**
- ❖ **CMS must ensure that specialists have the same opportunity as non-specialists to choose activities that reflect their practice and to earn the maximum score.**
- ❖ If CMS insists on differential weighting, **MOC Part IV activities and all registry-related activities should fall under the "high category."** We would be happy to arrange a meeting to demonstrate in more detail the amount of work both of these activities entail to justify this request.
- ❖ **The AANS and CNS also continue to urge CMS to refer to registry use more broadly, rather than restricting activities to "QCDR" use only.** Many quality registries are in use by physicians, even though these may not have received official QCDR status for one reason or another.
- ❖ Similar to the way in which CMS approached QCDR reporting under this performance category, **the various and resource-intensive components of MOC should be treated as separate activities rather than CMS only recognizing MOC Part IV.**
- ❖ **We are also very concerned about the arbitrary process through which CMS has selected activities for the IA inventory.** Under MACRA, CMS is required to collaborate with stakeholders to identify this inventory, which we interpret to mean more than just comments through rulemaking that got largely ignored. We appreciate that CMS intends to adopt a more formal nomination process in the future, but remind CMS that it needs to adhere to a more standardized and transparent process when vetting activities. When recommended activities are not accepted, CMS must provide a clear rationale that is more informative than a simple "thank you for your comments" or "we will take these recommendations into consideration in the future." The AANS and CNS recommended several important activities in our proposed rule comments that were disregarded by CMS. In the few instances where CMS acknowledged our request, it provided little to no rationale for why the activity was not included in the final inventory.
- ❖ **We continue to urge CMS to include the following activities in the IA inventory. If the agency fails to adopt our suggestions, we request that CMS engage us in a discussion to identify the reasons that these activities are not included on an updated the list:**

- Participating in a regular morbidity and mortality (M&M) conferences;
 - Continuing medical education (CME) activities;
 - Providing emergency room call coverage; and
 - Participating in other self-assessment/ongoing learning activities, such as the CNS program SANS — Self-Assessment in Neurological Surgery (<https://www.cns.org/education/browse-type/sans>)
- ❖ The AANS and CNS support the agency's decision to finalize a 90-day performance period for this category for both 2017 and 2018.
- ❖ **It is critical that CMS issue additional guidance, as soon as possible, on how to comply with activities.** While physicians should have the flexibility to determine whether activities they are engaged in fall under a particular definition, the current definitions are too broad and vague for physicians to understand what specific activities would count for the 2017 performance year and the level at which they need to be engaged in each particular activity.

Scoring and Performance Standards

- ❖ **The AANS and CNS continue to believe that setting historical performance standards based on non-MIPS programs (e.g., PQRS, VM and electronic health record meaningful use) is a potential source of bias and should not be used as a means for penalizing physicians** since these programs operated under different authority, different rules, and different incentive structures.
- ❖ **We continue to support specialty adjustments for quality measures to ensure that performance comparisons are applied to groups with similar characteristics.** For example, a neurosurgeon reporting on a perioperative measure should only be compared to other surgeons performing a similar procedure. While a surgeon performing spine surgery should not be compared to a surgeon performing a cholecystectomy, there are also instances where it would be inappropriate to hold all spine surgeons to the same benchmarks since performance on perioperative measures might differ depending on the type and complexity of the spine procedure.
- ❖ **Increase opportunities for bonus points.**
- **We request that CMS reward physicians with bonus points for utilizing registries and not mandate end-to-end electronic reporting.** Registries have the ability to provide more timely and actionable information back to physicians and are important components in measuring quality. While some registries support end-to-end electronic reporting, many registries still rely on both automated and manual data entry. Most EHRs cannot support all the necessary data elements needed for advanced quality measures or analytics, and therefore registries still support a hybrid approach to data collection.
 - We also remain concerned that due to data blocking actions by some EHR vendors, many physicians will miss out on the EHR-registry bonus points. Data blocking routinely occurs through EHR vendors levying excessive fees to connect a physician's EHR to a registry, or the vendors citing technical limitations or outright refusing to connect to a registry. While ONC has created a number of certification criteria addressing quality measurement, at this time, there are no methods available for physicians to incentivize or persuade EHR vendors to develop reasonable solutions to registry interoperability. **CMS must work with medical societies and vendors to identify ways to continue to reward physicians for registry participation and develop a process to limit registry blocking in the near term.**
- ❖ While we appreciate that CMS offers physicians an automatic three out of 10 possible points when they report measures that do not have sufficient benchmark data, we reiterate our earlier suggestion

that CMS instead assign a null value for these measures. In other words, CMS should recalibrate the denominator used to calculate the total quality score rather than limit the number of performance points tied to the measure. **In general, a physician should not be at a scoring disadvantage for selecting an infrequently reported measure.** If anything, CMS should incentivize the reporting of these measures so the agency can establish a benchmark as soon as possible.

Alternative Payment Models

- ❖ The AANS and CNS are concerned that there are still a very limited number of advanced APMs available to specialists. In the final rule, CMS estimates that, at most, 8 percent of eligible clinicians will qualify for the advanced APM incentive payment, which means that more physicians will be forced to participate in MIPS than was anticipated by MACRA. **We strongly urge CMS to work closely with specialties to expand the number and type of advanced APMs so that specialists have broader participation options and can qualify for the APM track.**

CONCLUSION

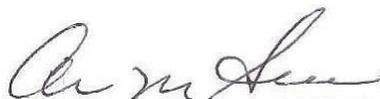
While the AANS and CNS are very grateful for the concessions made by CMS to reduce burden during the 2017 transition year to MIPS, we still believe the underlying structure of the program is overly complex. Transition year policies must be expanded through at least 2018, and substantial changes made after that to further consolidate and streamline the four categories of MIPS and to make the program more relevant to a range of provider types. Without these changes, CMS will disenfranchise physicians and discourage them from participating in the QPP.

Thank you for considering our ongoing feedback. We look forward to working with the agency as it continues to refine the rules for this new program. In the meantime, if you have any questions or need additional information, please do not hesitate to contact us.

Sincerely,



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