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June 27, 2016

Andy 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

Subject: 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 (CMS-5517-P)

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 comment on the above-referenced proposed Medicare physician fee schedule rule implementing the new Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APM) quality payment programs. The AANS and CNS recognize the complexity of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), and we appreciate the agency's efforts to develop a new payment system that provides physicians with greater flexibility while at the same time minimizing the reporting burden.

We remind CMS that organized neurosurgery continues to develop tools to help neurosurgeons adopt and incorporate systems of learning into their practice to improve quality of care, provider workflow, patient safety and efficiency. Our national clinical registry, the <u>Quality and Outcomes Database</u> (QOD) — which was approved by CMS as a Qualified Clinical Data Registry (QCDR) for the past two years — is one way in which we are working to capture this information and adopt systems that will improve the value of our services. The QOD allows for prospective, systematic tracking of practice patterns and patient outcomes that will allow neurosurgeons to improve the quality, efficiency and, ultimately, the value of care.

Overall, we believe that MACRA presents an unprecedented opportunity to fix the currently broken and burdensome Medicare quality programs, which have little meaningful impact on quality and have been extremely disruptive to physician practices. We urge CMS to seize this moment and make substantial changes to the proposed rule to ensure that the new quality payment program:

- Sharpens its focus on paying for what works;
- Reduces the time physicians and their offices spend on paperwork;
- Makes health care technology a tool, not an industry; and
- Applies an open process that reduces the gulf between how policies are made in Washington and front-line patient care.

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Furthermore, it is essential that the program accomplish the following:

- Be patient-centered, not only in the focus of the program but in the agency's approach to everything, so that we can promote the highest quality and most coordinated care for beneficiaries with the least disruption to the physicians and other clinicians who are treating them;
- Allow practices the flexibility to drive how they use the program as much as possible so that it supports the unique needs of their patients and allow adjustments as time goes on;
- Focus on the unique concerns of small practices as well as rural practices and practices in underserved areas; and
- Simplify wherever and whenever possible so that we can reduce the noise from the signal and give physicians time back to spend with patients.

With these principles in mind, we offer the following overarching principles that are critical to the success of MACRA implementation:

Phased Approach and Reasonable Transition Period

The timeline proposed for implementation of this major physician payment overhaul is overly ambitious and is one of the most concerning aspects of the proposed rule. We strongly urge CMS to adopt a phased approach that includes sufficient time for both clinician education, as well as the collection of updated data on which to set benchmarks. At a minimum, the initial **performance period should begin no earlier than July 1, 2017, but ideally not until January 1, 2018**. MACRA does not require CMS to implement MIPS payment adjustments until 2019, and it is critical that the initial transition to this new system is as seamless and as undisruptive to clinical practice as possible. Participation in the first few years should serve as an on-ramp to more robust reporting in the future.

Such a gradual implementation of the new MIPS system would allow for physician education and engagement and would also foster superior compliance with the goals of the system. Using the initial performance period(s) for physician education and data collection, while minimizing any downward payment adjustments, will allow for adequate time for educating practitioners about the new system. In addition, gathering a year to 18 months of baseline data will provide a much more rigorous foundation for future payment modifications based on MIPS performance in later years.

Minimize Reporting Burden

A March 2016 *Health Affairs* study found that each year, physician practices in four common specialties spend, on average, 785 hours per physician and more than \$15.4 billion complying with quality measure reporting. The authors concluded that while much is to be gained from quality measurement, the current system is unnecessarily costly, and greater effort is needed to standardize measures and make them easier to report.

Thus, as stated above, a key goal should be to gather the most reliable and relevant data, while at the same time keeping the data collection and reporting burdens as low as possible. The intent of MACRA was to consolidate and streamline current reporting mandates, yet the CMS proposal continues to perpetuate the existing siloed approach to quality reporting. CMS needs to take a more holistic approach than that which is reflected in the proposed rule. For example, participation in a QCDR should automatically satisfy multiple MIPS categories, including quality, advancing care information (ACI) and clinical practice improvement activities (CPIA). Quality

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measures also must have a more direct link to resource use measures to evaluate overall value more meaningfully,

Ensure Equal Opportunities for All Clinicians

Throughout the rule, CMS offers incentives for clinicians to invest and focus on certain measures and activities that meet high priority policy goals. However, most of these incentives seem to favor primary care physicians over specialists. It is critical that all clinicians have an equal opportunity to demonstrate quality and value in a meaningful way that limits penalties and maximizes payment incentives.

Education and Technical Assistance Key to Success

The proposed rule says little about how CMS plans to assist the public with making sense of this complicated program. The task of distilling all of this information is gargantuan and one that professional societies cannot do alone. CMS must invest more heavily in easy to access educational tools and other interactive resources. Technical assistance must be accessible, responsive, and well-informed.

Investment in Measure Gaps Must Occur Expeditiously

For many specialties, the most significant barrier to meaningful participation in current programs is an ongoing lack of relevant quality and resource measures. The AANS and CNS believe CMS must quickly allocate MACRA-authorized funding and work in close collaboration with specialties to close these measure gaps. As part of this effort, CMS must accelerate the development of better resource use measures and methodologies to replace the severely flawed set of cost measures now used to calculate the Value-Based Payment Modifier (VM). Until such time, clinicians should not be held accountable for resource use.

Flexibility will Ensure More Meaningful Engagement

Flexibility and autonomy over measure selection, reporting mechanisms, and participation options will foster innovation, trust and meaningful engagement across medicine. Numerous participation approaches should provide the opportunity to maximize scoring potential. To account for varying practice circumstances and various levels of physician control over infrastructure and care decisions, CMS should not mandate participation in any single reporting option or require the reporting of any particular measures.

CMS Must Monitor the Regulatory Burden of These New Programs

Over both the short and long term, the AANS and CNS believe it is vital that CMS carefully monitor the regulatory burden of these new policies on practicing physicians to ensure that compliance does not breed frustration, meaningless engagement or otherwise interfere with direct patient care.

In the pages that follow, the AANS and CNS offer more detailed feedback on a number of specific proposals included in the proposed rule.

EXECUTIVE SUMMARY OF DETAILED COMMENTS

✤ Performance Start Date

- The AANS and CNS strongly urge CMS to establish the initial transition period beginning no earlier than July 1, 2017, but ideally not until January 1, 2018.
- CMS should adopt concurrent policies that further minimize the reporting burden in the initial years of MIPS so that performance thresholds are low enough to ensure that most clinicians receive no adjustment or as little of an adjustment as possible during this transition.
- CMS should exercise its discretionary authority and give physicians' credit for "participation" rather than "performance" in the initial performance period(s).
- Performance-Payment Period Gap. The AANS and CNS strongly urge CMS to make every effort to reduce the gap between the performance period and the payment year and to provide performance feedback in as real-time as possible. Two years is simply too long.

Application of the Payment Adjustment

- Organized neurosurgery does not favor using non-MIPS historical data to set performance thresholds for the first year or two of the MIPS program.
- CMS should use its discretionary authority to minimize downward payment adjustments during the initial year or two of the quality payment program.
- Regarding the targeted review process, the AANS and CNS recommend that CMS gives clinicians as much time as possible to submit these requests since it will take time to understand the adjustments and clinicians will simultaneously be working to comply with the subsequent performance period. In addition, we strongly urge CMS to give clinicians at least 60 days to respond to these requests.

✤ Group vs. Individual Participation

- Before we can meaningfully comment on the newly expanded group reporting option, CMS must provide more details on how the agency intends to evaluate group performance in each category.
- In general, organized neurosurgery wants to make sure that by expanding the group reporting option, CMS preserves the intent of this mechanism, which is to reduce the participation burden that could be experienced by larger groups.
- Regarding resource use, if the intent of the alternative proposed policy is to ensure that individuals within a group using the group reporting option are not held accountable for cases attributed to the group, as a whole, and only to cases for which they have direct control over, then we very much support that proposal. However, we request that CMS clarify its intent here.

Virtual Groups

- 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.
- The AANS and CNS also believe that CMS should not limit the number or size of virtual groups, adopt prescriptive geographic standards or limit the reporting mechanisms available to these groups, so long as they can satisfy the minimum criteria.

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Low-Volume Threshold

- The AANS and CNS recommend raising the MIPS low-volume exclusion threshold to \$30,000 in Medicare allowed charges <u>or</u> fewer than 100 unique Medicare patients seen by the physician.
- We also oppose CMS' decision to hold both individuals and groups to the same low-volume threshold.

Data Completeness Criteria

- The AANS and CNS strongly oppose the agency's proposal to increase the reporting thresholds to 80 or 90 percent depending on the reporting mechanism.
- The AANS and CNS continue to oppose the requirement for QCDRs to report on non-Medicare patients.
- CMS should require reporting on no more than 50 percent of applicable Medicare patients

 at least for the first several years of the new quality payment program across all measures and reporting mechanisms. Preferably, however, the AANS and CNS strongly urge CMS to consider adopting a 20 patient threshold consistently across all measures and reporting mechanisms. If CMS is concerned about gaming or patient selection, it could require that clinicians report on 20 consecutive patients.

Measures

- We remind CMS of the urgency of allocating MACRA-authorized funding toward closing the gap on specialty-focused measures. Furthermore, it is essential that measure development is evidence-based and led by relevant clinical experts.
- CMS should not limit the scoring potential of specialists that CMS has expressly identified as having less than six measures.
- In addition to specialty-specific measure sets, we recommend that CMS consider measure sets that are condition or treatment specific. In neurosurgery, for example, this could include measure sets for stroke and/or lumbar spine surgery.
- We propose that a neurosurgery and/or spine measures set could include:
 - 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
- The AANS and CNS believe the proposed bonus system for high priority measures is premature. If the agency moves forward with this plan, for non-MIPS measures reported through QCDRs, the AANS and CNS strongly urge CMS to give QCDRs the authority to determine how best to classify which measures are high priority during the measure review process.
- We also request that CMS 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 primary care physicians and to make adjustments accordingly if they are not.
- The AANS and CNS are concerned about the agency's plans to increase the requirements for reporting outcome measures through future rulemaking.
- Bonus Point for CEHRT/Registries. Anyone using a QCDR should be eligible for a bonus point, regardless of whether they directly transfer data from a federally certified EHR into their registry. Concurrently, CMS must do whatever possible to insist that EHR vendors embrace interoperability.

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> Global/Population-Based Measures. Since CMS is not actually required to use these measures, and since the agency already proposes to include multiple CPIAs that would sufficiently target population health, we do not believe CMS should continue to use these measures for accountability.

* Topped Out Measures.

- The AANS and CNS support the agency's decision not to remove topped out measures at this time.
- If in the future CMS moves forward with plans to remove topped out measures, the AANS and CNS request 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. Physicians also need time to adjust their reporting options, so it is essential that CMS keep topped out measures in the program for at least three years to allow for an appropriate transition period and to allow measure developers and other stakeholders to submit new measures with the current Call for measures timeframe.
- We further recommend that all MIPS quality measures be considered in "pilot" mode for the first two years they are included in MIPS, rigorously evaluated for validity and accuracy during this pilot mode, and maintained for at least five years following to ensure sufficient benchmark data and accommodate more robust evaluation of topped out performance.
- Finally, we encourage CMS to adopt a broader policy of maintaining measures in MIPS for a minimum number of years (e.g. at least five years) to limit scenarios where CMS does not have historical data on the same exact measure to set a benchmark or otherwise evaluate performance.

✤ CAHPS for MIPS

- The AANS and CNS request that CMS add other patient experience measures to the MIPS measure set, such as the Surgical CAHPS (S-CAHPS). We also recommend that CMS give more credit to those who opt to administer a CAHPS survey (whether primary care or specialty-focused).
- We also ask CMS to consider incorporating CAHPS under CPIA rather than quality due to the subjective nature of these measures.
- Finally, regardless if patient satisfaction remains as a component of quality or is moved to CPIA, it is important to keep this option open to get credit for alternate forms of patient satisfaction methods. Many neurosurgeons use patient satisfaction surveys, but not the CAHPS instrument, so we urge CMS to be flexible on this point.
- Facility-Level Measures. The AANS and CNS support CMS taking advantage of facility-level measures in the future provided clinicians maintain the freedom to make this election and choose the appropriate attribution facility.

Scoring Quality

- The AANS and CNS support the agency's proposal that clinicians would not receive zero points if the required measure is submitted but is unable to be scored, such as not meeting the required case minimum.
- We recommend that CMS also consider specialty adjustments to 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 neurosurgeons reporting that measure.

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Resource Use

- The AANS and CNS oppose the agency's decision to maintain and expand the Medicare Spending Per Beneficiary (MSPB) and Total Per Capita Cost measures. However, if CMS ultimately maintains the MSPB measure, we request that it also maintain the higher case minimum, as well as the specialty adjustment until it has better data on which to base potential modifications.
- For the initial year or two, we request that CMS seriously consider using its authority
 under MACRA to re-weight the resource use category to zero and to distribute the excess
 weight to the CPIA and quality categories. CMS could also work with affected physicians
 and professional societies to determine the most appropriate strategy for redistributing
 excess weight across MIPS categories.
- The lumbar fusion episode of care as defined in the MIPS architecture has an overly broad definition and will incorporate a wide variety of surgical procedures. We, therefore, ask that CMS internally harmonize their episode definitions with regard to lumbar fusion, and that CMS delay implementation of the lumbar fusion episode in the MIPS resource use scoring until data is available from use of the episode in the IPPS system.

Advancing Care Information

- CMS must first focus its efforts on increasing the functional interoperability between vendors and among vendors and registries to ensure meaningful use is a program that improves healthcare, and not another meaningless regulatory burden on providers.
- The AANS and CNS do not believe the current set of objectives and measures which still reflect the same set of inflexible Modified Stage 2 and Stage 3 objectives — are an appropriate way to measure meaningful use across clinicians. We urge CMS to consider a different approach for this category that provides true flexibility by offering the current set of measures as an option, but not a requirement, and offering alternative pathways to demonstrate meaningful use (e.g., through the use of a QCDR). It is not appropriate to assign performance scores in the ACI performance category until CMS has identified more appropriate metrics, adopted a more flexible reporting approach, and more thoroughly addressed interoperability.
- 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.
- If CMS insists on measuring performance, we recommend it adopt the following approach:
 For the first year, require clinicians to only report numerator/denominator data (i.e., no performance score).
 - In year two or three (or when feasible), use year one as the benchmark for performance. Benchmarks should incorporate a methodology to distinguish between practice size/makeup to ensure those with less capabilities and resources are not at a disadvantage.
 - Alter the distribution of weights (e.g. make the base score, which is only based on reporting and not performance, 80 percent of the total score for small practices specialists, rather than 50 percent).
- We strongly oppose CMS holding clinicians accountable to a full year of performance and request that CMS maintain the 90-day reporting period.
- The AANS and CNS support CMS using its authority to reweight this performance category to zero for hardship exemptions that previously existed under the EHR Incentive Program, as well as for those eligible clinicians that were not previously able to participate in the EHR Incentive Program. However, with respect to the proposed definition of a

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hospital-based MIPS eligible clinician, the threshold for a hospital-based MIPS eligible clinician should be lowered to the majority of one's covered professional services in an inpatient hospital or emergency room setting.

Clinical Practice Improvement Activities

- CMS should eliminate preferential weighting of CPIA elements and each CPIA element could be weighted at 15 points, making achievement of a higher score feasible for surgeons. If preferential weighting remains, then CMS must move MOC Part IV activities into the "high" weight category.
- Similar to the way in which CMS is approaching QCDR reporting in the CPIA category, the list of MOC components could be treated as separate activities. This will allow clinicians who demonstrate participation in all aspects of MOC to be able to attend to each of those different MOC related activities to achieve a higher cumulative CPIA score beyond the currently proposed 10 points. This is appropriate because of the intensity of MOC, including its emphasis on the use of clinical data registries to report cases under Part IV.
- The AANS and CNS support the 90-day performance period.
- CMS must ensure that specialists have the same opportunity as non-specialists to select activities that reflect their practice and to earn the maximum score.
- CMS should give more weight to the QCDR-related activities on the list.
- The AANS and CNS also request that CMS refer to registry use more broadly, rather than restricting these activities to "QCDR" use only.
- Other CPIA activities should be added the current list. These include:
 - Participating in a regular **morbidity and mortality** (M&M) conferences.
 - Continuing medical education (CME) activities.
 - Providing emergency room call coverage.
 - Participating in other self-assessment/ongoing learning activities, such as the CNS program SANS — Self-Assessment in Neurological Surgery.

Scoring and Performance Standards

- In situations where CMS does not have benchmark data (e.g., first year measures), CMS should assign a null value toward the total quality score (i.e., rather than a zero, which would impact their overall performance score).
- The AANS and CNS believe that setting historical performance standards on non-MIPS programs (e.g., PQRS) is a potential source of bias and should not be used as a means to apply downwards modification on CMS reimbursement. We, therefore, recommend that CMS use the initial year or two to educate physicians regarding performance standards through the physician/groups feedback reports, but minimize payment adjustments until the system is established and the learning curve surmounted.
- The AANS and CNS support the overall concept of evaluating both achievement and improvement. However, we urge CMS to further investigate the feasibility of its proposed approaches and factors that might impede application of each strategy. And while supporting the concept of rewarding both achievement of thresholds and year over year improvement, we would suggest that CMS not commit to a single approach to incorporating improvement into MIPS scoring.

Third Party Data Submissions

• If HIT vendors are going to be allowed to serve in an equal capacity to registries and QCDRs under MIPS, they should be held to the same standards.

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• The expanded role of HIT under MIPS should not create a situation where HIT vendors start to enter the business of quality measure development since there are currently no safeguards to ensure that such work would be informed by relevant clinical input.

* Feedback Reports

- Since CMS' feedback reports are confidential and intended to assist clinicians with tracking their performance and managing deficiencies throughout the reporting period, the AANS and CNS urge CMS to include as much data as possible in their reports.
- The AANS and CNS very much support the use of interactive dashboards that provide data to clinicians in as real a time as possible, but at the very least, on a quarterly basis. It is critical that feedback meaningfully guide improvements in practice.
- The AANS and CNS support the proposal that QCDRs and other intermediaries would be expected to provide feedback to participants only on the quality performance category.
- The AANS and CNS propose two options for reporting. A basic report covering the data elements immediately relevant to physician reimbursement and performance:
 - The performance threshold for the present reporting period;
 - Where the physicians stands with regard to his or her performance; and
 - The potential payment adjustments and a roadmap of how the clinician can improve to avoid any penalties and earn bonus payments.

For physicians or practices that want more granular information, there should be an option to obtain a richer dataset.

Burden Estimates

- 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 quality programs. The specialty societies themselves also are devoting 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.
- In general, we request that CMS provide estimates that include:
 - The time and cost associated with reading educational materials and participating in educational sessions regarding the new MIPS requirements;
 - The time and cost associated with determining reporting options available to clinicians and groups under MIPS and strategies for maximizing one's CPS; and
 - The time and cost associated with determining whether an eligible 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.
- For the quality performance category, we urge CMS to provide estimates that include:
 - The time and cost associated with reviewing the measures list and determining whether an eligible clinician should use a specialty measure set, measures in the general quality MIPS set, or measures offered by a third party vendor (such as a QCDR);
 - The time and cost associated reviewing which measures are high priority, which are cross-cutting, and which have been deemed topped out since this impacts a clinician's score;

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- The time and cost associated with reviewing benchmarks for the quality performance category; and
- The time and cost associated with the proposed increased reporting thresholds.
- For the **resource use performance category**, we urge CMS to provide estimates that include:
 - The time and cost associated with understanding whether and how measures in this category apply to physicians and how physicians are attributed patients and held accountable under these measures; and
 - The time and cost associated with learning how these measures are applied to clinicians not previously impacted by the VM.
- For the **ACI performance category**, we urge CMS to provide estimates that include the following:
 - The time and cost associated with understanding the requirements for this performance category for eligible clinicians not previously participating in the EHR Incentive Program; and
 - The time and cost associated with applying for a hardship under this category, if applicable.

DETAILED COMMENTS

PAYMENT ADJUSTMENTS

Performance Start Date

CMS proposes CY2017 as the performance period for the first MIPS payment adjustment in 2019, which would necessitate MIPS eligible clinician to be ready on Jan. 1, 2017. We remind CMS that MACRA does not require the agency to adopt an initial performance period that begins on Jan. 1, 2017, nor does it require CMS to rely on a calendar year performance period. The statute only states the following:

(4) PERFORMANCE PERIOD.—The Secretary shall establish a performance period (or periods) for a year (beginning with 2019). Such performance period (or periods) shall begin and end prior to the beginning of such year and be as close as possible to such year. In this subsection, such performance period (or periods) for a year shall be referred to as the performance period for the year.

The proposed MIPS timeline for the initial performance year is problematic for multiple reasons. Most importantly, a Jan. 1, 2017, start date erroneously assumes that clinicians, and the professional societies and administrative staff that support them, have the capacity to make sense of this incredibly complex overhaul in a span of two months. Although CMS proposes to preserve some elements of current quality programs, the proposed scoring methodology for both the individual performance categories, as well as the overall Composite Performance Score (CPS), are incredibly complex. The proposed rule also significantly expands reporting requirements, mechanisms and options available to clinicians. While we welcome this flexibility, those affected by all of these new regulations will need sufficient time to understand which options are most feasible and meaningful for their practice, and how to maximize their CPS and minimize potential penalties. The changes proposed for MIPS are significant enough that clinicians that have historically relied on one reporting mechanism might now want to consider alternative participation options, which further contributes to the learning curve. Similarly, CPIA and some aspects of ACI are novel and will require new reporting procedures. Finally, as discussed in more detail below, this aggressive timeline precludes the accumulation of MIPS-related data that are needed to set accurate and actionable performance benchmarks.

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AANS/CNS Comments. The AANS and CNS strongly urge CMS to establish the initial transition period beginning no earlier than July 1, 2017, but ideally not until January 1, 2018. Furthermore, CMS should adopt a more phased approach to implementation that provides adequate time for practicing clinicians and their support staff to familiarize themselves with these new complex payment requirements and for the agency and third-party vendors to conduct outreach and education. Phasing in the new payment program rules over a year to 18-month period would allow CMS to build a sufficient foundation of data on which to set meaningful and fair benchmarks for future program years. A phased approach would also provide CMS with the opportunity to learn from any initial glitches or other unintended consequences.

As discussed elsewhere in this letter, gradual implementation of this program should include a variety of strategies. For example, **CMS should adopt concurrent policies that further** minimize the reporting burden in the initial years of MIPS so that performance thresholds are low enough to ensure that most clinicians receive no adjustment or as little of an adjustment as possible during this transition.

Finally, to the extent possible, **CMS should exercise its discretion authority and give physicians' credit for "participation" rather than "performance" in the initial performance period(s)**. This would allow the agency to develop more reliable baseline threshold data for future program years and would minimize the initial downward payment adjustments in the early years.

Performance-Payment Period Gap

The AANS and CNS also continue to have concerns about the lag between the performance period and payment adjustment since it results in reported data that are not necessarily actionable for quality improvement among clinicians or for timely healthcare decision-making among patients. A two-year gap also forces CMS to truncate development of policies and hinders timely modifications to the program.

✤ AANS/CNS Comments. In accordance with MACRA, we strongly urge CMS to make every effort to reduce the gap between the performance period and the payment year and to provide performance feedback in as real-time as possible. Two years is simply too long.

Application of the Payment Adjustment

MACRA defines the applicable percent for each year as follows:

- For 2019, four percent;
- For 2020, five percent;
- For 2021, seven percent; and
- For 2022 and subsequent years, nine percent.

The final MIPS payment adjustments would be determined by the distribution of CPS across MIPS eligible clinicians and the performance threshold. A clinician's MIPS CPS will be expressed as a number between 1 and 100, as opposed to the more generic performance quadrants (or tiers) used under the VM. For each performance year, CMS will set an overall "performance threshold" number of points. A clinician earning a CPS at that threshold would receive zero adjustment to their Medicare Part B payments. Each incremental point earned above the threshold would result in progressively higher incentive payments while each point below the threshold would result in a proportional penalty until a

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floor is reached. This linear scoring approach means that very few clinicians will experience a zero payment adjustment under MIPS and every CPS point translates directly into higher or lower reimbursement. This contrasts with the current VM methodology, under which a vast majority of clinicians end up with a zero payment adjustment (98 percent in 2016).

Section 1848(q)(6)(D)(i) of the Act requires the performance threshold in year three and beyond to be equal to the mean or median of CPS from a prior period. For the initial two payment years (2019 and 2020), CMS has more discretion over the threshold. For the 2019 MIPS payment year, CMS proposes to set the performance threshold at a level where approximately half of the eligible clinicians would be below the performance threshold and half would be above the performance threshold. CMS also considered setting the performance threshold to ensure a minimum number of points are earned before a clinician can receive a positive adjustment factor. CMS will finalize a methodology for determining the performance threshold in the final rule and intends to publish the performance threshold on the CMS website prior to the performance period.

To establish the overall performance threshold against which clinicians' 2017 CPS will be compared for purposes of determining 2019 MIPS payment adjustment, CMS proposes to model 2014 and 2015 Part B allowed charges, PQRS data submissions, QRUR and sQRUR feedback data and Medicare and Medicaid EHR Incentive Program data to inform where the performance threshold should be since it will not yet have historical MIPS data. CMS would use this data to estimate the impact of the quality and resource use scoring proposals. It would also use the EHR Incentive Program information to determine which MIPS eligible clinicians are likely to receive points for the advancing care information performance category. Since CMS lacks historical data for the CPIA performance category, it would apply some sensitivity analyses to help determine the performance threshold.

CMS also proposes to adopt a targeted review process under MIPS wherein a clinician may request that the agency review the calculation of the MIPS adjustment factor applicable for a given year. All requests for targeted review would be submitted by July 31 after the close of the data submission period or by a later date that CMS specifies in guidance. As part of this proposal, if CMS or its contractors request additional information from the clinician, the supporting information must be received from the MIPS eligible within 10 calendar days of the request. Non-responsiveness to the request for additional information will result in the closure of that targeted review request, although another review request may be submitted if the targeted review submission deadline has not passed.

AANS/CNS Comments. While the payment adjustment formula is set in law, because every point now counts and payments will be affected much more than they were in the past, it is even more critical that all physicians have an equal opportunity to achieve the maximum amount of points in a meaningful manner across all four performance categories.

Organized neurosurgery does not favor using non-MIPS historical data to set performance thresholds for the first year or two of the MIPS program. Any effort to "guesstimate" a performance threshold in the new MIPS architecture is a poor approach. Thresholds should be developed based on the performance of physicians and physician practices in the MIPS system. Arbitrarily choosing thresholds for this new, complex system without experience concerning its implementation is prone to significant bias and, concerning population health and database modeling, bad science. To the extent possible, CMS should use its discretion authority to minimize downward payment adjustments during the initial year or two of the quality payment program, particularly if the performance threshold is based on non-MIPS historical data and the comparison with the new values will be inexact. Andy Slavitt AANS/CNS MACRA Comments (CMS-5517-P) June 27, 2016 Page 13 of 38

With regard to targeted review process, the AANS and CNS recommend that CMS gives clinicians as much time as possible to submit these requests since it will take time to understand the adjustments and clinicians will simultaneously be working to comply with the subsequent performance period. In addition, we strongly urge CMS to give clinicians at least 60 days to respond to these requests. Ten days does not account for the time it takes to process such a request, understand exactly what actions need to be taken and gather any supporting evidence required by CMS. It also leaves very little room for error, such as the request or response getting lost in the mail (or being sent to the wrong email address).

IDENTIFYING MIPS ELIGIBLE CLINICIANS

Group vs. Individual Participation

Currently, under the PQRS for individual reporting, CMS uses a combination of TIN and NPI to assess eligibility and participation, while under the PQRS Group Reporting Option (GPRO), eligibility and participation are assessed at the TIN level. Under the Medicare EHR Incentive Program, CMS currently uses the NPI to assess eligibility and participation, while under the VM, performance and payment adjustments are assessed at the TIN level.

Recognizing the various ways an eligible clinician may engage in quality improvement, CMS proposes to use multiple identifiers that allow clinicians to be measured as an individual or collectively through a group's performance under MIPS. However, the same identifier would have to be used for all four MIPS performance categories. In other words, a clinician cannot report as an individual for some aspects of MIPS and as a group for others. More specifically, for *performance of an individual*, CMS proposes to use a combination of billing TIN/NPI to assess an individual clinician. Similar to PQRS, each unique TIN/NPI combination would be considered a different MIPS eligible clinician, and MIPS performance would be assessed separately for each TIN under which an individual bills. To assess *performance of a group*, CMS proposes to use a group's billing TIN to identify a group, an approach used for both PQRS and the VM. CMS believes the use of the TIN can significantly reduce the participation burden that could be experienced by large groups. It also allows practices to submit performance data one time for their group and develop systems to improve performance.

Although CMS proposes the use of multiple identifiers for participation and performance, it proposes to use a single identifier, TIN/NPI, for applying the payment adjustment, regardless of how the clinician is assessed. Specifically, if the clinician is identified for performance only using the TIN, CMS proposes to use the TIN/NPI when applying the overall MIPS payment adjustment. However, in this situation, CMS would apply the group Composite Performance Score (CPS) to all the TIN/NPI combinations that bill under that TIN during the performance period.

Unfortunately, the rule is vague regarding how CMS plans to evaluate group performance for each of the four performance categories and whether CMS will evaluate each individual within the group and somehow roll that into a composite group score or whether CMS will truly look at the group's performance, as a whole (e.g., did the group, as a whole, report on 6 measures for 90 percent <u>of the group's</u> applicable patients). While it might be feasible (although not necessarily always fair) for CMS to evaluate group level performance for quality and resource use and then apply that score to everyone in the TIN regardless of whether all individuals in the group contributed to the score, that strategy does not necessarily translate to the new ACI or CPIA categories, since these categories rely on individual attestation.

The only category that CMS seems to address this issue more specifically is in regards to resource use, where CMS proposes to evaluate performance at the individual and group levels (versus the VM, where

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resource use has historically been attributed at the group level). For clinicians who opt for individual reporting, CMS would attribute resource use measures using TIN/NPI rather than TIN. This would allow them to be measured based on cases that are specific to their practice, rather than being measured on all the cases attributed to the group TIN, which is a policy we appreciate. For clinicians that choose to have their performance assessed as a group, CMS proposes to attribute resource use measures at the TIN level.

As an alternative proposal, CMS seeks comment on whether clinicians who choose to have their performance assessed as a group should first be attributed at the individual TIN/NPI level and then have all cases assigned to that individual attributed to the group under which they bill. This alternative would apply one consistent methodology to both groups and individuals. For example, CMS assigns the Medicare Spending Per Beneficiary (MSPB) measure based on the plurality of claims for Medicare Part B services rendered during an inpatient hospitalization. The agency's primary proposal would determine "plurality of claims" separately for individuals and groups. For individuals, it would assign the MSPB measure using the "plurality of claims" by TIN/NPI, but for groups it would determine the "plurality of claims" by TIN/NPI for both groups and individuals. However, for individuals, only the MSPB measure attributed to the TIN/NPI would be evaluated, while for groups the MSPB measure attributed to any TIN/NPI billing under the TIN would be evaluated

AANS/CNS Comments. Organized neurosurgery appreciates that CMS is offering more flexibility by expanding the performance categories available under the group practice reporting option. Ongoing reliance on the TIN/NPI for payment purposes is also important since it allows CMS to calculate performance for multiple unique TIN/NPI combinations (i.e., those who practice under more than one TIN), which enables greater accountability for individual clinicians beyond what might be achieved when using the TIN, alone, as an identifier. It also provides a safeguard for clinicians who might try to change their identifier simply to avoid payment penalties.

Before we can meaningfully comment on the newly expanded group reporting option, however, CMS must provide more details on how the agency intends to evaluate group performance in each category. For ACI and CPIA, does CMS plan to look at the performance of each individual and then roll that up into one score for the TIN? And if so, how would CMS calculate that composite score? For the CPIA category, for example, would the group as a whole have to demonstrate that it achieved 60 points and if so, does that mean that if one or two individuals in the group performed activities worth 60 points, the entire group would get the full score for the CPIA category?

The ACI category is even more confusing because it relies on a mix of reporting and performance. Again, would CMS look at the reporting and performance rates of each individual within the TIN and then somehow roll that up into an overall TIN score? Also, how would CMS treat individual members of the group that normally would receive a hardship exception or have their ACI performance reweighted to zero? In general, organized neurosurgery wants to make sure that by expanding the group reporting option, CMS preserves the intent of this mechanism, which is to reduce the participation burden that could be experienced by larger groups.

Regarding resource use, if the intent is to ensure that individuals within a group using the group reporting option are not held accountable for cases attributed to the group, as a whole, and only to cases for which they have direct control over, then we very much support the alternative proposal. However, we request that CMS clarify its intent here.

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Virtual Groups

After weighing multiple factors, CMS determined that implementation of virtual groups for the 2017 performance period is not feasible, but aims to implement a web-based registration system for 2018. While we understand this decision, we were disappointed by the lack of detail regarding this future proposal since this would have been an excellent opportunity for CMS to solicit input on a range of more specific potential strategies.

AANS/CNS Comments. We reiterate our belief that 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. The unifying feature might be as broad as a similar specialty (with a specialty-sponsored registry being the source of data), a clinical service line or a geographic area.

At the same time, **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 the minimum criteria.** Such limitations would be arbitrary, would ignore the unique and diverse needs of virtual groups, and could impede collaborations that might benefit from this option.

Since virtual groups might cross settings, geographic regions, specialties and patient populations (including those with varying degrees of risk), it is also critical that all of these factors are accounted for when measuring the performance of such groups. Recognizing the unique nature and composition of each virtual group, we also recommend that CMS not pit virtual groups against each other when measuring performance, and instead look at annual self-improvement (at least initially).

Overall, we recommend that CMS work to operationalize the virtual group option since it better recognizes the realities of modern day medical practice than the current system. This includes the facts that: a) physicians often work for multiple organizations at the same time; b) those in smaller or independent practice do not have the resources, negotiating power, or overall influence over more comprehensive care decisions that larger group practices and systems have; and c) the multi-specialty makeup of many groups makes performance assessment challenging and often results in performance scores that do not reflect the quality of all of the individuals in that group.

Low-Volume Threshold

CMS proposes a low-volume threshold under which clinicians would be excluded from MIPS. CMS proposes to define those who do not exceed the low-volume threshold as an individual clinician or group who, during the performance period, has Medicare billing charges less than or equal to \$10,000 and provides care for 100 or fewer Part B-enrolled Medicare beneficiaries. CMS claims that this strategy aims to retain as MIPS eligible clinicians those who are treating relatively few beneficiaries, but engage in resource intensive specialties, as well as those treating many beneficiaries with relatively low-priced services.

AANS/CNS Comments. As currently proposed, this policy significantly disadvantages neurosurgeons and other procedural specialists, as well as those in solo and small practices, due to the low dollar threshold. For example, one or two major adult spine deformity surgeries could easily exceed \$10,000, and the neurosurgeon would be subject to MIPS even if he or she only sees one or two Medicare patients. Additionally, some pediatric neurosurgeons have pediatric Andy Slavitt AANS/CNS MACRA Comments (CMS-5517-P) June 27, 2016 Page 16 of 38

patients with cerebral palsy or spina bifida that they continue to treat into adulthood. These patients might be on Social Security/disability or otherwise eligible for Medicare, which puts the pediatric neurosurgeon in Medicare for this limited purpose. While he or she might fall under the proposed patient threshold, the few unique procedures that are done to follow this limited population of patients are typically costly and would exceed the \$10,000 threshold.

To mitigate the adverse effects, the AANS and CNS recommend raising the MIPS low-volume exclusion threshold to \$30,000 in Medicare allowed charges <u>or</u> fewer than 100 unique Medicare patients seen by the physician. We also oppose CMS' decision to hold both individuals and groups to the same low-volume threshold. Under this proposal, it would be much more difficult for a group practice to be excluded from MIPS and it could result in situations where a single individual who does not necessarily represent the practice patterns of an overall practice disqualifies that group from the exemption.

PERFORMANCE CATEGORY MEASURES AND REPORTING MECHANISMS

Quality

- Data Completeness Criteria. For claims, qualified registry, QCDR and EHR reporting, CMS proposes to reduce the number of measures that physicians must report from nine to six. Additionally, physicians will no longer need to report measures that span three National Quality Strategy domains. Under each of these reporting mechanisms, individual MIPS eligible clinicians and groups would have to report at least six measures, including one cross-cutting measure and at least one outcome measure, or if an outcome measure is not available, report another high priority measure (i.e., appropriate use, patient safety, efficiency, patient experience and care coordination measures). If fewer than six measures apply, then the clinician or group is expected to report on each measure that is applicable. For claims, each measure would have to be reported for 80 percent of all applicable Medicare patients (versus the current requirement of 50 percent under PQRS). For QCDRs, qualified registries and EHRs, each measure would have to be reported for 90 percent of all applicable Medicare <u>and</u> non-Medicare patients (versus the current requirement of 50 percent).
 - AANS/CNS Comments. The AANS and CNS strongly oppose the agency's proposal to increase the reporting thresholds to 80 or 90 percent depending on the reporting mechanism. This proposal disregards the fact that reliable data is achievable at much lower sample sizes, which can be collected without imposing such an unreasonable and impractical reporting burden on clinicians. Furthermore, this significant reporting burden leaves clinicians and third-party data submission vendors with very little room for error. While the AANS and CNS appreciate the agency's proposal to reduce the number of quality measures required for reporting, as well as the elimination of the NQS domain requirement, the impact of these accommodations on a clinician's overall reporting burden will be negligible if CMS simultaneously adopts policies substantially raising the measure reporting threshold.

Overall, the proposal to raise the reporting thresholds runs counter to the agency's goal of simplifying reporting, especially in light of the fact that clinicians also now have to report on CPIAs, which was not a requirement of the past. It also contradicts MACRA's goal of supporting the use of registries by creating a disincentive for clinicians to enter that market. The "90 percent of all applicable patients" requirement could pose a particularly large burden for hospital-based clinicians, who often face barriers gaining access hospital

data, as well as clinicians who practice at multiple sites since not all sites might be enrolled in a registry. Furthermore, the AANS and CNS continue to oppose the requirement for QCDRs to report on non-Medicare patients.

We remind CMS about its historical decision-making related to reporting thresholds. When CMS first required eligible professionals (EPs) using the gualified registry under PQRS to report on at least 80 percent of patients, EPs were only required to report on three measures. When CMS subsequently decided to increase this requirement to nine measures in the 2014 PFS final rule (78 FR 74459-74461), CMS lowered the reporting threshold to 50 percent of patients to compensate for the increased reporting threshold. While CMS is proposing to reduce the number of measures required for reporting under MIPS to six, the reporting burden is still considerably higher than when the 80 percent PQRS threshold. Also, CMS is now proposing that clinicians and groups report on a cross-cutting measure, as well as an outcome or high priority measure. Furthermore, we note that many of the measures used to complete the 80 percent reporting threshold in the past had a much lower bar than the more robust measure set currently proposed. Over the past few years, CMS has removed many topped out measures and proposes in this rule to limit further the diversity of cross-cutting measures, which will make it even harder for neurosurgeons and other specialists to comply with these higher reporting thresholds. CMS should require reporting on no more than 50 percent of applicable Medicare patients — at least for the first several years of the new quality payment program.

Preferably, however, the AANS and CNS strongly urge CMS to consider adopting a 20 patient threshold consistently across all measures and reporting mechanisms. We remind CMS of its long-standing reliance on a 20 patient minimum sample as a reliable threshold for many aspects of the PQRS and VM. CMS has historically permitted the reporting of only 20 patients for EPs using measures groups. We are disappointed by the agency's decision to retire measures groups under MIPS since this policy will further restrict what are already very limited reporting options available to specialists. We are especially concerned by this decision because the agency itself noted at a recent AMA-hosted meeting that they have long had evidence that 20 patient sample for many quality and cost measures. CMS also has relied on a 20 patient sample for many quality and cost measures used under the VM and proposes to continue to do so under MIPS, noting that a minimum of 20 cases results in moderate to high reliability. We believe that 20 patients would provide a reliable snapshot of practice. If CMS is concerned about gaming or patient selection, it could require that clinicians report on 20 consecutive patients.

CMS claims its proposal to increase the reporting thresholds will ensure a more accurate assessment and avoid any selection bias that may exist under current requirements. We respectfully question whether CMS has evaluated whether selection bias is even a problem. If it is, we request that the agency establish this fact before making such a drastic change in policy — which will at worst result in many clinicians receiving unfair penalties, and at best result in clinicians cherry picking low-bar measures that are relatively easy to report, but have little impact on quality.

Finally, CMS could adopt a process where the reporting sample is determined on a measure-by-measure basis. This approach works well for QCDRs, which must determine performance thresholds (along with validation and risk-adjustment mechanisms) during the self-nomination process.

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• **Measures.** In general, CMS must continue to address measurement gaps and improve the existing set of MIPS measures. The biggest remaining barrier to meaningful and successful participation in quality programs among specialists is an insufficient set of relevant measures from which to choose. While QCDRs have allowed for the development of more diverse measures, this reporting mechanism is not yet accessible to everyone.

Clinicians and groups may select their quality measures from either a list of all MIPS Measures or a set of specialty specific measures. Some specialty-specific measure sets include additional measure sets defined at the subspecialty level. CMS defines QCDR measures as "non-MIPS measures" (i.e., not a part of the MIPS quality measure set). If a QCDR wants to use a non-MIPS measure for inclusion in the MIPS program for reporting, CMS requires that these measures go through a rigorous CMS approval process during the QCDR self-nomination period.

CMS designed the specialty-specific measure sets to address concerns that the quality measure selection process can be confusing (e.g., under PQRS, EPs were asked to review close to 300 measures to find applicable measures for their specialty). The specialty measure sets contain measures that are all also available through the traditional MIPS measure list. While there is no requirement to report on a specialty set, CMS proposes special accommodations in situations where a specialty set includes less than six measures. Clinicians and groups reporting on such sets would only have to report on the measures in the set, as well as a cross-cutting measure.

CMS also proposes scoring adjustments to create incentives for clinicians to submit certain high priority measures (i.e., outcome, appropriate use, patient safety, efficiency, patient experience and care coordination measures) and to allow these measures to have more impact on the total quality performance category score. Specifically, CMS proposes to provide two bonus points for each outcome and patient experience measure and <u>one bonus point</u> for other high priority measures reported in addition to the one outcome/high priority measure that would already be required under the proposed quality reporting criteria.

AANS/CNS Comments. We remind CMS of the urgency of allocating MACRAauthorized funding toward closing the gap on specialty-focused measures. We also remind CMS of the importance of ensuring that measure development is evidence-based and led by relevant clinical experts. Over time, it is also critical that CMS closely monitor the availability of measures for specialists versus those used by primary care providers and track whether lower scores are the result of a lack of available measures a particular specialty.

The AANS and CNS appreciate that the agency's specialty set policy was intended to address the fact that very specialized clinicians may only have one or two applicable measures. However, the rule is unclear about how CMS would score clinicians in this situation. CMS should not limit the scoring potential of specialists that CMS has expressly identified as having less than six measures. These clinicians should have as equal an opportunity to earn the maximum amount of performance points in the quality category as clinicians with six available measures — in other words, do not score the missing measure values as zero or require these specialists to report on additional, non-relevant measures simply for the sake of filling a gap in the numbers.

We also recommend that instead of speaking of "specialty measure sets," CMS should recreate the tables so that they list "specialty measure sets by reporting option." Many of the sets include a mix of measures that are only available via specific

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reporting mechanisms. Since clinicians can only choose one reporting mechanism per performance category, it might be impossible for a clinician to report on all measures in a set (e.g., a clinician using claims to report measures in a set will not be able to report measures in a set categorized as registry-only).

In addition to specialty-specific measure sets, we recommend that CMS consider measure sets that are condition or treatment specific. In neurosurgery, for example, this could include measure sets for stroke and/or lumbar spine surgery.

We propose that a neurosurgery and/or spine measures set could include:

- 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

With regard to high priority measures, the AANS and CNS understand the rationale of assigning more weight to outcomes measures. However, we remain concerned about the paucity of such measures available for neurosurgeons and other specialists. In addition, we are very concerned that current risk adjustment and attribution methodologies are lacking. Thus, until such time as these issues are addressed, **the proposed bonus system for high priority measures is premature.** If the agency moves forward with this plan, for non-MIPS measures reported through QCDRs, **the AANS and CNS strongly urge CMS to give QCDRs the authority to determine how best to classify which measures are high priority during the measure review process.**

We also request that CMS 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 primary care physicians and to make adjustments accordingly if they are not. While QCDR measures could help close this gap, this reporting option is not yet available to all specialists for a variety of reasons, and many will continue to rely on the traditional MIPS measure set.

While we very much appreciate that CMS recognizes the value and importance of outcome and other high priority measures, the AANS and CNS are concerned about the agency's plans to increase the requirements for reporting outcome measures through future rulemaking. We remind the agency that certain types of measures might be more appropriate for certain specialties and practice settings than others. For instance, process measures that are evidenced-based can be integral to improved outcomes and in some specialties, this foundational step must first be addressed before they can move on to outcomes. Furthermore, individual clinicians do not have direct influence over which measures are developed and available to meet the needs of their patient population. There are also many infrastructure challenges that may prevent the development or incorporation of appropriate outcome measures into CMS programs, which must be accounted for. These could include problems with capturing patientreported or experience of care measures in the EHR, as well as interoperability issues that interfere with the exchange of needed information, and the inability to do longitudinal tracking due to the lack of uniform patient identifiers. CMS should maintain flexibility by not requiring the use of any particular type of measure.

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- **Bonus Point for CEHRT/Registries.** CMS proposes to allow one bonus point under the quality performance category score for each reported measure up to the cap described, if a clinician meets the requirements for "end-to-end electronic reporting." This would be accomplished when:
 - The clinician uses CEHRT to record the measure's demographic and clinical data elements in conformance to the standards relevant for the measure and submission pathway, including but not necessarily limited to the standards included in the CEHRT definition;
 - The clinician exports and transmits measure data electronically to a third party using relevant standards or directly to CMS using a submission method as defined at §414.1325; and
 - The third party intermediary (for example, a QCDR) uses automated software to aggregate measure data, calculate measures, perform any filtering of measurement data, and submit the data electronically to CMS using a submission method.
 - AANS/CNS Comments. We are concerned that this bonus structure is linked to CEHRT since many QCDRs do not have the ability to obtain data from CEHRT in the manner specified by the federal government. Furthermore, data standards are lacking, which restricts the amount and the quality of data that can be seamlessly pulled into a registry from CEHRT. If CMS is serious about carrying out the Congressional intent of MACRA and incentivize registry use, anyone using a QCDR should be eligible for a bonus point, regardless of whether they directly transfer from a federally certified EHR into their registry. The many impediments to data transfer are due to the unwillingness of EHR vendors to adopt interoperability. Without interoperability in this realm, achieving that point for QCDRs is not feasible. CMS must do whatever possible to insist that EHR vendors embrace interoperability.
- Global/Population-Based Measures. Section 1848(q)(2)(C)(iii) of MACRA provides that CMS may use global measures such as global outcome measures and population-based measures for purposes of the quality performance category. Using this authority, CMS proposes to automatically incorporate the following population-based measures into a clinician or group's total quality performance score, as applicable. These measures would contribute to a clinician or group's overall quality performance category score in addition to the six measures discussed above:
 - All-cause readmissions
 - AHRQ acute preventive quality indicator composite (bacterial pneumonia, UTI, dehydration)
 - AHRQ chronic preventive quality indicator composite (COPD, HF, DM)

These administrative claims-based measures are currently used under the VM and do not require the clinician to submit any data to CMS. They are intended to identify areas where good outpatient care can potentially prevent the need for hospitalization or for which early intervention can prevent complications or more severe disease. CMS has determined these measures to be reliable with a minimum case size of 20 (200 for the all-cause readmission). The agency also intends to incorporate a clinical risk adjustment as soon as feasible to the PQI composites, which suggests they are currently *not* risk-adjusted.

AANS/CNS Comments. To date, CMS has provided little to no evidence that these measures are having a beneficial impact on quality. Although these measures do not impose any additional reporting burden on clinicians, they are calculated automatically Andy Slavitt AANS/CNS MACRA Comments (CMS-5517-P) June 27, 2016 Page 21 of 38

> and behind a "black-box." This results in confusion among clinicians and frustration over their lack of control over the selection of clinically appropriate measures for purposes of accountability. Since CMS is not actually required to use these measures, and since the agency already proposes to include multiple CPIAs that would sufficiently target population health, we do not believe CMS should continue to use these measures for accountability.

• **Topped Out Measures**. Using 2014 PQRS quality reported data measures, CMS modeled the proposed benchmark methodology and identified that approximately one-half of the measures proposed under the quality performance category are topped out. The agency's proposal recognizes the challenge of determining whether a measure is truly topped out or if only excellent performers are choosing to report the measure. By maintaining these measures in MIPS, CMS and QCDRs can track performance over time and clinicians who might not have reported them in the past continue to have the opportunity to do so.

At the same time, CMS does not believe that clinicians electing to report topped out process measures should be able to receive the same maximum score as clinicians electing to report preferred measures, such as outcome measures. Therefore, CMS proposes to limit the maximum number of points a topped out measure can achieve based on how clustered the scores are. CMS would notify clinicians about which measures are topped out when benchmarks are published.

AANS/CNS Comments. The AANS and CNS support the agency's decision not to remove topped out measures at this time. We appreciate that CMS acknowledges that removing such a large volume of measures would make it difficult for some specialties to have enough applicable measures to report. To keep things administratively simple in the initial years of MIPS, we recommend that CMS not differentiate between topped out and non-topped out measures since it adds another level of complexity to an already complex program. As expressed throughout this comment letter, we also take issue with CMS making policy decisions that are based on data collected before MIPS since measures sets, reporting options and overall incentives for participation were different.

If in the future CMS moves forward with plans to remove topped out measures, the AANS and CNS request that CMS identify in proposed rulemaking — or other appropriate mechanism — measures that it considers topped out so that the public has an opportunity to provide meaningful feedback on why performance might appear that way. Physicians also need time to adjust their reporting options, so it is essential that CMS keep topped out measures in the program for at least three years to allow for an appropriate transition period and to allow measure developers and other stakeholders to submit new measures with the current Call for Measures timeframe.

We further recommend that all MIPS quality measures be considered in "pilot" mode for the first two years they are included in MIPS, rigorously evaluated for validity and accuracy during this pilot mode, and maintained for at least five years following to ensure sufficient benchmark data and accommodate more robust evaluation of topped out performance.

Finally, we encourage CMS to adopt a broader policy of maintaining measures in

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MIPS for a minimum number of years (e.g. at least five years) to limit scenarios where CMS does not have historical data on the same exact measure to set a benchmark or otherwise evaluate performance.

- CAHPS for MIPS. CMS proposes to allow registered groups of two or more MIPS eligible clinicians to voluntarily elect to participate in the CAHPS for MIPS survey. Although CMS is not requiring groups to participate in the CAHPS for MIPS survey, it proposes a scoring incentive (i.e., bonus points) for those groups who do report via the CAHPS for MIPS survey. While CMS proposes an overall policy of giving more credit for high priority measures, including patient experience measures, there do not appear to be any other patient experience measures in the MIPS measure set other than the CAHPS for MIPS, which gives primary care practices and those to whom the survey is more applicable a scoring advantage over specialists.
 - AANS/CNS Comments. We appreciate the proposal to allow registered groups of two or more MIPS eligible clinicians to elect voluntarily to participate in the CAHPS for MIPS survey. This is a welcome departure from the current policy of requiring CAHPS for PQRS among larger groups. To create a more equal opportunity for all clinicians to earn the maximum score in the quality category, we request that CMS add other patient experience measures to the MIPS measure set, such as the Surgical CAHPS (S-CAHPS).

We also recommend that CMS give more credit to those who opt to administer a CAHPS survey (whether primary care or specialty-focused). Under CMS' proposal, the CAHPS for MIPS survey would count as only one cross-cutting and/or a patient experience measure, and the group would be required to submit at least five other measures through one other data submission mechanisms. In the past, CMS has counted the CAHPS for PQRS survey as three measures covering one NQS domain. Given the cost and burden of administering CAHPS surveys, we believe any CAHPS measure should count as three measures, including one cross-cutting and a patient experience measure. One approach that CMS also should consider would be to incorporate CAHPS under CPIA rather than quality due to the subjective nature of these measures.

Regardless if patient satisfaction remains as a component of quality or is moved to CPIA, **it is important to keep this option open to get credit for alternate forms of patient satisfaction methods**. Many neurosurgeons use patient satisfaction surveys, but not the CAHPS instrument, so we urge CMS to be flexible on this point.

- Facility-Level Measures. MACRA provides CMS with the authority to adopt measures used for non-physician payment systems such as inpatient hospital measures for purposes of the quality and resource use performance categories. However, CMS may not use measures for hospital outpatient departments, except in the case of items and services furnished by emergency physicians, radiologists and anesthesiologists. Although CMS acknowledged RFI comments received related to this proposal, the agency is not proposing this as an option for the first year of MIPS because there are several operational considerations that must be addressed before this approach can be implemented.
 - ✤ <u>AANS/CNS Comments</u>. The AANS and CNS support CMS taking advantage of facility-level measures in the future provided clinicians maintain the freedom to make this election and choose the appropriate attribution facility. Given the

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implications for payment and public reporting, this process must not be automatic and should remain in the control of the clinician.

Scoring Quality

For the quality and resource use performance categories, all measures would be converted to a 10-point scoring system. CMS proposes to assign 1-10 points to each measure based on how a clinician's performance compares to benchmarks. Benchmarks would be determined based on performance on measures in the baseline period, which would be broken down into performance deciles. A clinician's actual measure performance during the performance period would then be evaluated to determine the number of points that should be assigned based on where the actual measure performance falls within these baseline period benchmarks. Measures must have the required case minimum to be scored, which CMS proposes as 20 cases (except for the all-cause admission measure). If a clinician fails to submit a measure required under the quality performance category criteria, he or she would receive zero points for that measure. If a measure does not have baseline period information (e.g., new measures or update measures specifications) then CMS would determine the array of benchmarks based on performance period.

For the quality category, CMS proposes to use measure-specific benchmarks. All MIPS eligible clinicians — regardless of whether they report as an individual or group, and regardless of specialty — that submit data using the same submission mechanism would be included in the same benchmark. CMS proposes to unify the calculation of the benchmark by using the same approach as the VM of weighting the performance rate of each clinician and group submitting data on the quality measure by the number of beneficiaries used to calculate the performance rate so that group performance is weighted appropriately.

AANS/CNS Comments. The AANS and CNS support the agency's proposal that clinicians would not receive zero points if the required measure is submitted but is unable to be scored, such as not meeting the required case minimum. As noted earlier, we urge CMS to adopt the same methodology for first-year measures and measures that lack a historical benchmark.

Additionally, similar to the VM, we recommend that CMS also consider specialty adjustments to quality measures to ensure that performance comparisons are applied to groups with similar characteristics. These calculations should be very clear and highly transparent, so that physicians can understand them and be successful in MIPS. For example, a neurosurgeon reporting on a perioperative measure should only be compared to other neurosurgeons reporting that measure.

Resource Use

To calculate a clinician or group's score under the resource use category, CMS proposes 41 new episode-based cost measures, in addition to maintaining most of the controversial cost measures used under the VM, including the Medicare Spending Per Beneficiary (MSPB) measure and the total Per Capita Cost measure. CMS proposes not to maintain the Total Per Capita Cost measures for the four condition-specific groups (COPD, CHF, CAD, and DM).

* AANS/CNS Comments.

• Existing VM Measures. The AANS and CNS have long critiqued the relevancy of the

resource use measures used to date under the VM. Not only do they tend to hold clinicians accountable for costs that are outside their direct control, but they are calculated in a less than transparent manner, making it difficult for clinicians to understand why and how they are being evaluated. This results in confusing data that provides very little meaningful guidance about how an individual clinician can improve the value of their patients' care. These measures were intended for facility-level accountability and should remain as such.

We are further disappointed by CMS' proposal to make other changes that would further weaken the MSPB measure. For instance, CMS proposes to lower the case minimum requirement for the MSPB measure from 125 to 20, which means that more clinicians could be held accountable for this flawed measure than in the past. Furthermore, CMS proposes to remove the specialty adjustment from the MSPB measure since it is unclear as to whether the current adjustment improves the accounting for case-mix differences for acute care patients. The MSPB measure, in general, is a relatively new addition to the VM. and the specialty adjustment was only first added to the measure in 2016. This is much too short of a time to accurately determine that the adjustment is not effective. Overall, we very much oppose the agency's decision to maintain and expand the MSPB and Total Per Capita Cost measures. However, if CMS ultimately maintains the MSPB measure, we request that it also maintain the higher case minimum, as well as the specialty adjustment until it has better data on which to base potential modifications. Doing so would also ensure that the measure aligns with the methodologies used to calculate the Total Per Capita Cost measure and minimize the overall complexity of MIPS.

• Episode-Based Resource Use Measures. It is absolutely critical that CMS stop pouring resources into the aforementioned measures and instead accelerate efforts to develop more specific episode-based cost measures, to refine existing ones, and to test alternative types of resource use measures. We appreciate all of the work CMS and its contractors have done on this front to date and are pleased that over 40 episode-based measures are now available. However, even with these more focused episode-based cost measures, there is still a lot of work that needs to be done in regards to fine tuning risk-adjustment and attribution methodologies so they accurately and comprehensively account for the multiple factors that contribute to the overall cost of caring for a patient.

CMS also needs to devote resources to figuring out how to better account for less overt things that contribute to the overall value of care, such as return to work. Similarly, upfront investments in care (e.g., surgery, medical devices) might accrue long-term savings in regards to better outcomes and avoided costs elsewhere in the health system. Finally, a major problem with the current VM program is its flawed definition of value. The cost measures that CMS uses to calculate value have absolutely nothing to do with what CMS is measuring on the quality side, which results in a flawed value equation. Ultimately, appropriateness of care (which accounts for both quality and spending) should be the goal, rather than measuring raw cost data in isolation.

We appreciate that under MACRA, CMS is required to develop patient condition groups that better describe the patient's clinical history, as well as patient relationship categories and codes that define and distinguish the relationship and responsibility of a physician with a patient at the time of furnishing an item or service. These codes should help to better compare similar patients and to more accurately conduct analyses of resource use. However, the comment period for the agency's first effort to collect substantive feedback on these categories and codes does not close until August 2017 and clinicians are not even required to begin reporting these codes on claims until 2018.

We also remind CMS that some of the episode-based cost measures being proposed in this rule have not yet been included in Quality and Resource Use Reports (QRURs), which means that the public might not have had a sufficient opportunity to evaluate how they could affect payments. Furthermore, we suspect that very few physicians had an opportunity to analyze those episodes that did appear in the QRURs due to report access issues and simply not understanding how to evaluate them.

CMS has the authority to re-weight a MIPS category in situations where there are insufficient measures. As we noted earlier, the existing VM measures are of little value to clinicians and simply serve to confuse the public. Since CMS has not yet had the opportunity to develop and implement more granular patient condition groups and patient relationship categories, and clinicians have not yet had the opportunity to provide thoughtful feedback on existing episode groups being proposed in this rule, for the initial year or two, we request that CMS seriously consider using its authority under MACRA to re-weight the resource use category to zero and to distribute the excess weight to the CPIA and quality categories. CMS could also work with affected physicians and professional societies to determine the most appropriate strategy for redistributing excess weight across MIPS categories.

Should CMS choose to proceed with resource use and care episodes in MIPS scoring, we would note that the lumbar fusion episode of care as defined in the MIPS architecture has an overly broad definition and will incorporate a wide variety of surgical procedures. This will produce a denominator of patients that is so heterogeneous that any variation based upon physician performance will be lost. Restricting the episode to a smaller set of procedures and specifying diagnoses reduces this opportunity for bias. This approach is in action at present in the CMS Inpatient Prospective Payment System (IPPS) for 2017. We would ask that CMS internally harmonize their episode definitions with regard to lumbar fusion, and that CMS delay implementation of the lumbar fusion episode in the MIPS resource use scoring until data is available from use of the episode in the IPPS system.

As currently proposed, CMS would not allow clinicians to receive credit in the resource use category for measures collected via QCDRs or available for MIPS quality reporting (e.g., appropriate use measures). Until CMS has made further progress on its own work to refine resource use measures, the agency should consider broadening its interpretation of what could count in this category, consider appropriate applications of facility-level measures and allow QCDRs to submit what they believe are appropriate resource use measures for approval.

Advancing Care Information

- * AANS/CNS Comments.
 - **General Concerns.** Our biggest concern with this category is its complexity, and the agency's assertion that it has abandoned the all-or-nothing approach that has long plagued meaningful use under the EHR Incentive Program. To realize the full potential of EHRs, the requirements need to be less prescriptive to allow clinicians to be creative in applying technology to their unique clinical workflows and patient needs. Clinicians also

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should not be penalized for actions they cannot control. Clinicians should not be required to report on any single measure in this category and if they are, CMS must ensure that it is one that clinicians are able to attest to without relying on the actions of other individuals (patients, technology, or other providers). Overall, CMS must first focus its efforts on increasing the functional interoperability between vendors and among vendors and registries to ensure meaningful use is a program that improves healthcare, and not another meaningless regulatory burden on providers.

Objectives, Measures, and Scoring Approach. The AANS and CNS appreciate the agency's effort to offer flexibility by breaking this category into a base and performance score and opting not to maintain the previously established thresholds for each measure. However, our view of the proposed changes, as a whole, is that the program would still rely largely on the same set of inflexible Modified Stage 2 and Stage 3 objectives and measures as it does today, which provide clinicians with very little choice to demonstrate meaningful use in a way that is most relevant to their practice. We do not believe the current set of objectives and measures are an appropriate way to measure meaningful use across clinicians. We urge CMS to consider a different approach for this category that provides true flexibility by offering the current set of measures as an option, but not a requirement, and offering alternative pathways to demonstrate meaningful use (e.g., through the use of a QCDR). It also is not appropriate to assign performance scores in the ACI performance category until CMS has identified more appropriate metrics, adopted a more flexible reporting approach, and more thoroughly addressed interoperability.

CMS also discusses whether or not to remove the Clinical Decision Support and Computerized Provider Order Entry objectives and measures from the proposed set of measures. The agency also proposes to require, at a minimum, that all clinicians meet the Protect Patient Health Information objective and measure in order to earn any score within the ACI performance category. **Ideally, CMS should offer clinicians the broadest selection of measures to choose from for purposes of both the base and performance score, but should not** <u>require</u> the use of any single measure to receive a score in this category.

CMS also proposes that clinicians must meet the Protect Patient Health Information objective and its associated measure in order to earn any score within the ACI performance category. This measure requires clinicians to secure electronic protected health information, created or maintained by the certified EHR technology, through the implementation of appropriate technical, administrative, and physical safeguards. Failure to satisfy this measure would result in a base score of zero, as well as a performance score of zero and an ACI performance category score of zero. For the reasons stated above, as well as the fact that many of our members continue to have obstacles with this measure, we strongly oppose CMS' decision to require the Protect Patient Health Information measure.

In regards to agency's claim that it has abandoned the all-or-nothing scoring approach, we remind CMS that in order to earn the base score for this category (which makes up 50 percent of the total score), a clinician must successfully submit data (i.e., have at least one patient in the numerator) for every existing objective and measure regardless of whether it is relevant to his/her practice. If a clinician fails to satisfy the reporting requirement for any one of these, he or she cannot earn any points toward the base score or the performance score and would automatically receive a zero in the ACI category. We

question how this is different from CMS' traditional all-or-nothing approach. Also, for those who satisfy the base score requirements, CMS dictates which specific subset of these measures would be evaluated for the performance portion of the score, which further limits flexibility and leaves specialists with no control over determining how best to demonstrate meaningful use.

Regarding the performance score specifically, instead of relying on measure thresholds finalized for Stage 3, CMS proposes to calculate performance score based on how many of a clinician's total patients achieve the measure (e.g., for Patient Access, a clinician's performance score would be based on what percentage of all of his/her patients seen over the performance year received timely access to view their health info online, etc.). This strategy not only sets an unnecessarily high bar, but it creates a huge advantage for larger practices that are technically advanced. We remind CMS that there is a very low chance that any clinician would achieve a 100 percent performance score since very few clinicians can currently hit the 50 percent mark.

If CMS insists on measuring performance, we recommend it adopt the following approach:

- For the first year, require clinicians to only report numerator/denominator data (i.e., no performance score).
- In year two or three (or when feasible), use year one as the benchmark for performance. Benchmarks should incorporate a methodology to distinguish between practice size/makeup to ensure those with less capabilities and resources are not at a disadvantage. Rather than its current proposal to evaluate performance using 100 percent of a physician's patients, CMS should instead focus on a majority of a physician's patients — allowing physicians the opportunity to earn the maximum points for each measure when they report on at least 50 percent of their patients.
- Alter the distribution of weights (e.g. make the base score, which is only based on reporting and not performance, 80 percent of the total score for small practices and specialists, rather than 50 percent).

We also would like to point out that the bar required for scoring points under the ACI performance category is higher than the proposed requirement for eligible clinicians in advanced APMs to use CEHRT. Specifically, CMS proposes that an Advanced APM must require at least 50 percent of eligible clinicians who are enrolled in Medicare to use the CEHRT functions (as outlined in the proposed CEHRT definition) "to document and communicate clinical care with patients and other health care professionals." There is no indication that a QP in an advanced APM would be required to meet any specific objectives and measures used under the EHR Incentive Program. Ideally, we would encourage CMS to adopt a similar approach for clinicians and groups in the ACI performance category rather than the more specific proposals discussed earlier.

ACI Performance Period. CMS proposes that the performance period for the ACI performance category would be one full calendar year. CMS would no longer offer a separate 90-day performance period for demonstrating meaningful use. We strongly oppose CMS holding clinicians accountable to a full year of performance and request that CMS maintain the 90-day reporting period. Clinicians will need time to understand the scoring methodology proposed for this category, as well as the MIPS program overall. Providing a grace period is especially critical during the first year of this

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program. We also remind CMS that a 90-day period would be consistent with CMS' proposal that clinicians engage in CPIAs for at least 90 days.

- Hardship Exemptions. Under the EHR Incentive Program, hospital-based EPs and EPs facing a significant hardship were exempted from being a meaningful EHR user. CMS notes that, under MIPS, these hardship exemptions do not apply to the ACI performance category. As an alternative to exempting these clinicians, CMS is proposing to assign a weight of zero to the ACI performance category for purposes of calculating a MIPS CPS for the following clinicians:
 - Hospital-based MIPS eligible clinicians who furnish 90 percent or more of covered professional services in inpatient hospital or emergency room settings in the year preceding the performance period;
 - MIPS eligible clinicians facing a significant hardship; or
 - Clinicians previously not eligible to participate in the Medicare/Medicaid EHR Incentive Programs

The AANS and CNS support CMS using its authority to reweight this performance category to zero for hardship exemptions that previously existed under the EHR Incentive Program, as well as for those eligible clinicians that were not previously able to participate in the EHR Incentive Program. However, with respect to the proposed definition of a hospital-based MIPS eligible clinician, we believe the 90 percent threshold is too high. The threshold for a hospital-based MIPS eligible clinician should be lowered to the majority (or more than 50 percent) of one's covered professional services in an inpatient hospital or emergency room setting.

As noted earlier, in scenarios where a clinician receives a zero percent weight under the ACI category, we believe that CMS should shift the weight to the CPIA and quality.

Clinical Practice Improvement Activities

CMS proposes an inventory of over 90 activities that fall into multiple mandated subcategories. Activities are designated as either medium-weight (10 points) or high-weight (20 points).

<u>AANS/CNS Comments</u>. Organized neurosurgery is unsure as to the goal of having weighted CPIA activities. We also find that most, if not all, of the high-weighted CPIA activity categories are not available to procedural physicians, limiting the ability of these physicians to achieve a competitive CPIA score. For example, many Population Management activities in the CPIA system are not relevant to surgeons and would not be routine in their practices. **Eliminating preferential weighting of CPIA elements would correct some of this concern. Each CPIA element could be weighted at 15 points, making achievement of a higher score feasible for surgeons.**

If CMS choses to maintain the present scoring structure, **we would strongly suggest that MOC Part IV be moved to a high-weight category.** Implementation of MOC programs has been an ongoing effort of many surgical and non-surgical specialty societies. Similar to the way in which CMS is approaching QCDR reporting in the CPIA category, the list of MOC components could be treated as separate activities. This will allow clinicians who demonstrate participation in all aspects of MOC to be able to attend to each of those different MOC related activities to achieve a higher cumulative CPIA score beyond the currently proposed 10 points. This is appropriate because of the intensity of MOC, including its emphasis on the use of clinical data registries to report cases under Part IV. Recognition of the importance of MOC should be incorporated into, and highly valued, in the CPIA system.

In general, the AANS and CNS appreciate that no specific subcategory or activity would be mandatory and that clinicians would have a broad choice of activities to choose from. We do not believe that clinicians should be held accountable for performance in this category now or in the future due to the technical complexity of calculating such performance and the lack of experience collecting this type of data. Furthermore, **we support the 90-day performance period**. We are pleased this would provide clinicians with the flexibility to perform activities over any 90 days rather than imposing a minimum hour requirement or a requirement to engage in an activity over the entire year.

We also appreciate that CMS proposes what sounds like a relatively simple attestation process for reporting data on CPIAs and that, for the first year, all clinicians or third party entities that submit on behalf of a clinician would only have to designate a yes/no response for activities on the CPIA Inventory. We request that CMS maintain this reporting structure for at least the first few years of MIPS to account for the increased reporting burden that clinicians will face under MIPS overall. We also request that when CMS restructures its attestation website, they provide clear instructions on exactly what the screens will display or prompt for. Many neurosurgical practices currently find it challenging to navigate the meaningful use attestation website and often contact our Washington office for step-by-step instructions and screenshots. We encourage CMS to re-instate its "test" submission process, which allowed clinicians to see how they scored before signing off on a final submission. Clinicians also should not have to click on an answer for more than 90 activities since this would be very time-consuming. It should be easy for clinicians to identify and select only the activities that he/she is going to attest "yes" to.

Although the proposed inventory of more than 90 activities is diverse, the AANS and CNS are concerned that there are few activities designated as "high-weighted activities" and of the few that are proposed, most are primary care-centric. We encourage CMS to ensure that specialists have the same opportunity as non-specialists to select activities that reflect their practice and to earn the maximum score. There must be opportunities for CPIA reporting that are available to all physicians. The present measures are far too concentrated on primary care.

In regards to specific activities, we are grateful that CMS proposes multiple QCDR-related activities under this performance category and that the proposal would enable clinicians working with a QCDR to meet the criteria for multiple CPIAs at once. However, we request that CMS consider giving more weight to the QCDR-related activities on the list. Currently, all but one of these activities is classified as "medium-weight." We remind CMS of the significant time and resources that a clinician must invest when participating in a registry. This includes implementation of the data collection tool into the flow of practice, gathering and maintaining data use agreements and other legal or administrative documentation, ongoing data entry, and the tracking of performance over time. Most practices must hire a full-time employee simply to manage these tasks. Registries also capture much richer data than are captured via claims, which means more work for the clinician and his/her staff, but also means that the clinician has the opportunity to perform much more robust analytics.

We also request that CMS refer to registry use more broadly, rather than restricting these activities to "QCDR" use only. Many clinicians participate meaningfully in registries that are not yet QCDRs, but still require significant investments and result in valuable data. These efforts should be recognized. Currently, only one of the CPIAs refers to registries more broadly. Finally, we very much support the agency's proposal to, in future years, allow QCDRs to define specific

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CPIAs for specialty clinicians through the already-established QCDR approval process for measures and activities. We urge CMS to adopt this policy as soon as feasible.

Other CPIA activities should be added the current list. These include:

- Participating in a regular **morbidity and mortality** (M&M) conference is a valuable "best practice" means of ongoing learning and continued practice improvement and would fit within the Patient Safety and Practice Assessment category.
- **Continuing medical education** (CME) activities in addition to MOC should also be recognized, also as an aspect of Patient Safety and Practice Assessment.
- Providing **emergency room call coverage** is another opportunity for surgeons to contribute to population health and also expands access to care.
- Participating in other self-assessment/ongoing learning activities. Neurosurgeons
 participating in the CNS program SANS <u>Self-Assessment in Neurological Surgery</u> —
 should be afforded credit as an approved CPIA. SANS is an interactive educational
 curriculum designed to help neurosurgeons reinforce current practice patterns and
 recognize knowledge gaps. The program includes an extensive bank of peer-reviewed
 questions and offers a comprehensive review of clinical applications across neurosurgical
 specialties, as well as several non-clinical core competencies, to help neurosurgeons
 assess their strongest areas of neurosurgical knowledge and identify areas for further
 study and growth.

SCORING AND PERFORMANCE STANDARDS

Proposed performance standards for each performance category were discussed in more detail earlier in this document, but generally include the following:

- For **Quality**: Measure benchmarks to assign points, plus bonus points.
- For **Resource Use**: Measure benchmarks to assign points only on measures that meet minimum case attribution.
- For **CPIA**: Based on participation in activities that align with the patient-centered medical home. The number of points from reported activities compared against a static highest potential score of 60 points.
- For ACI: Based on participation (base score) and performance (performance score). Base score is achieved by meeting the Protect Patient Health Information objective and reporting the numerator (of at least one) and denominator or yes/no statement as applicable (only a yes statement would qualify for credit under the base score) for each required measure. Performance score relies on a decile scale for additional achievement on measures above the base score requirements.

CMS claims that MIPS would generally not rely on the "all-or-nothing" approach used under the PQRS or the EHR Incentive Program since the MIPS methodology would incrementally score measures and activities so long as they meet certain standards (e.g., required case minimums to ensure validity and reliability), and performance at any level would receive points towards the performance category scores.

• <u>AANS/CNS Comments</u>. While we appreciate CMS' intent to give clinicians the opportunity to earn points for effort, this strategy does not necessarily protect clinicians from penalties since MIPS, as a whole, is budget neutral and there must always be losers to finance the winners. Stated differently, the linear scoring approach above and below the CPS threshold means that "performance at any level" might not to be sufficient to avoid a penalty.

Baseline Period/Benchmarks

CMS intends to adopt baseline periods that are as close as possible in duration to the performance period. For each MIPS payment year, CMS proposes that the baseline period would be two years prior to the performance period for the MIPS payment year. Therefore, for the first MIPS payment year (CY 2019 payment adjustments), for the quality performance category, CMS proposes that the baseline period would be calendar year 2015 which is two years prior to the proposed calendar year 2017 performance period. CMS proposes some exceptions to this rule. For example, for new quality measures, CMS would set the benchmarks using performance in the *performance period*. For resource use, CMS also proposes to set the benchmarks using performance in the performance period and not the baseline period. In these situations, CMS would not be able to determine the benchmark until *after* the performance period.

• <u>AANS/CNS Comments</u>. The AANS and CNS appreciate that CMS would make available to clinicians, in advance of the performance period, the performance standard and scoring methodologies. However, CMS notes that it will provide the actual performance standards *only when possible*. Given MIPS' heavy emphasis on pay-for-performance, it is more critical than ever that clinicians know ahead of time precisely what benchmark they are working towards. If CMS cannot provide this information to clinicians prior to the start of the performance year, it should not hold a clinician accountable for the measure. In situations where CMS does not have benchmark data (e.g., first year measures), CMS should assign a null value toward the total quality score (i.e., rather than a zero, which would impact their overall performance score). This strategy will allow clinicians to receive credit for the effort of reporting the measure and incentivize the collection of data that can eventually serve as a baseline for future performance benchmarks.

Although we support polices that allow CMS to provide clinicians with actual performance standards prior to the performance period, we strongly advise CMS' against the use of 2015 data to set the 2017 benchmark since MIPS did not even exist at that time and the programs that were in existence relied on a different set of measures and reporting mechanisms, and in some cases, applied to different populations. CMS should not set benchmarks or hold clinicians accountable for performance until it has established an adequate foundation of MIPS data. Overall, we urge CMS to minimize the gap between the baseline and the performance period. We recognize that it takes time for CMS to process all of these data, but remind the agency that under the VM, benchmarks for each quality measure are based on the performance of groups nationwide in the <u>year prior to</u> the performance year (e.g., 2013 benchmarks for the 2014 performance year).

Incorporating Improvement

Section 1848(q)(3)(B) of the Act requires the Secretary, in establishing performance standards for measures and activities for the four MIPS performance categories, to consider historical performance standards, improvement, and the opportunity for continued improvement. Section 1848(q)(5)(D) of the Act lays out the requirements for incorporating performance improvement into the MIPS scoring methodology beginning with the second MIPS performance period, if data sufficient to measure improvement is available. Section 1848(q)(5)(D)(ii) of the Act also provides that achievement may be weighted higher than improvement. CMS seeks feedback on the following three options for measuring improvement in the future:

<u>Option 1 — Approach similar to Hospital VBP</u>: CMS would assign from 1-10 points for achievement (i.e., compared to benchmark performance scores for each applicable measures) and from 1-9 points

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for improvement (i.e., compared to the clinician's own previous performance during a baseline period for each measure). CMS would then compare the achievement and improvement scores for each measure and only use whichever is greater, but only those clinicians with the top achievement would be able to receive the maximum number of points. If a clinician's practice was not open during the baseline period, but was open during the performance period, points would be awarded based on achievement only for that performance period.

<u>Option 2 — Approach similar to Shared Savings Program</u>: Clinicians would receive a certain number of bonus points for the quality performance category for improvement, although the total points received for the performance may not exceed the maximum total points for the performance category in the absence of the quality improvement points. CMS would score individual measures and determine the corresponding number of points that may be earned based on the clinician's performance. Bonus points would be awarded based on a clinician's net improvement in measures within the quality performance category, which would be calculated by determining the total number of significantly improved measures and subtracting the total number of significantly declined measures. Up to four bonus points would be awarded based on a comparison of the clinician's net improvement in performance on the measures to the total number of individual measures in the quality performance category. When bonus points are added to points earned for the quality measures in the quality performance category, the total points received for the quality performance category to the total points received for the quality performance category. The total points received for the quality performance category may not exceed the maximum total points for the performance category in the absence of the quality improvement points.

<u>Option 3 — Approach similar to Medicare Advantage 5-star rating methodology</u>: CMS would identify an overall "improvement measure score" by comparing the underlying numeric data for measures from the prior year with the data from measures for the performance period. To obtain an "improvement measure score" clinicians would need to have data for both years in at least half of the required measures for the quality performance category. The numerator for the overall "improvement measure" would be the net improvement, which is a sum of the number of significantly improved measures minus the number of significantly declined measures. The denominator is the number of measures eligible for improvement. CMS recognizes that high performing clinicians may have less room for improvement and consequently may have lower scores on the overall "improvement measure". Therefore, similar to CMS' 5-star rating methodology for health plans, CMS would calculate a clinician's score with the "improvement measure" and without, and use the best score.

AANS/CNS Comments. The AANS and CNS support the overall concept of evaluating both achievement and improvement. However, we urge CMS to further investigate the feasibility of its proposed approaches and factors that might impede application of each strategy. We remind CMS that in the physician world, thousands of group practices operate in a fluid environment of recruitment, acquisition, expansion and reduction. If a particular group improves one year but the payment adjustment is applied two years later, the clinicians or groups responsible for positive results may no longer be part of the group and may never see any reward for their achievements. Conversely, those who achieved success somewhere else and then moved to a group with low performance two years earlier will be penalized instead of rewarded for their efforts. Therefore, while supporting the concept of rewarding both achievement of thresholds and year over year improvement, we would suggest that CMS not commit to a single approach to incorporating improvement into MIPS scoring. This choice should be made after an adequate sample of physician and practice behavior is available for modelling.

CPS Performance Category Weights

In accordance with Section 1848(q)(5)(E)(i) of the Act, CMS proposes to assign the following weights to

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each performance category:

- Quality: 50 percent for the 2019 payment year; 45 percent for the 2020 payment year
- Resource use: 10 percent for the 2019 payment year; 15 percent for the 2020 payment year
- Advance Care Information: 25 percent for the 2019 and 2020 payment years
- Clinical Practice Improvement Activities: 15 percent for the 2019 and 2020 payment years

In situations where certain clinicians might not receive a performance score in the quality, resource use, or ACI performance categories, CMS proposes that it would use the authority under section 1848(q)(5)(F) of the Act to assign a weight of zero to the performance category and redistribute the weight for that category(ies). More specifically, CMS offers the following proposals:

- If a clinician has fewer than three scored quality measures (either submitted measures or measures calculated from administrative claims data) for a performance period, it would consider the clinician not to have a sufficient number of measures available for the 2019 MIPS payment year quality category and would lower the weight of the quality category as such:
 - If a clinician has only two scored measures, CMS proposes to reduce the weight of the quality category by one-fifth (e.g., from 50 percent to 40 percent in year one) and redistribute the weight proportionately to the other categories,
 - If a clinician has only one scored quality measure, then CMS proposes to reduce the weight of the quality category by two-fifths (e.g., from 50 percent to 30 percent in year one) and redistribute the weight proportionately to the other categories.
- For clinicians who have fewer than three scored measures in the quality category score, then CMS proposes to reassign the weights for any other performance categories without scores proportionately to the other performance categories for which the clinician has received a score.
- If the clinician does not receive a resource use or ACI score and has at least three scored measures in the quality category, CMS proposes to reassign the weights of the categories without a score to the quality performance category.
 - CMS proposes an alternative that would not reassign all the weight to the quality performance category, but rather reassigns the weight proportionately to each of the other categories.
- For the CPIA category, CMS does not propose any scenario where a clinician would not receive a CPIA performance category score.

CMS also proposes that if a clinician receives a score for only one performance category, it would assign the clinician a CPS equal to the performance threshold, which means the clinician would receive a MIPS adjustment factor of zero percent for the year.

• <u>AANS/CNS Comments</u>. It is challenging to recommend an appropriate strategy for re-weighting categories without knowing the final set of measures, activities and reporting criteria for the first year of MIPS. For example, as currently proposed, the CPIA list is currently very primary care-centric. CMS would need to expand its proposed inventory of activities so that it includes more specialty-focused activities before we would feel comfortable requesting that all excess weight be redistributed to this category. **Overall, we urge CMS to work with affected physicians and professional societies to determine the most appropriate strategy for redistributing excess weight across MIPS categories rather than setting a blanket policy that applies across medicine. Depending on the rules finalized for the first year of MIPS, in some instances it might**

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be more appropriate to proportionality redistribute category weights, while at other times it may be more appropriate to place the full weight in one category.

THIRD PARTY DATA SUBMISSIONS

CMS proposes that MIPS data may be submitted by third party intermediaries on behalf of a MIPS eligible clinician or group by: (1) a qualified registry; (2) a QCDR; (3) a health IT vendor; or (4) a CMS-approved survey vendor. Registries, QCDRs and HIT vendors may choose to collect and report data to CMS for the quality, ACI and CPIA components of MIPS so long as they meet all the requirements designated by CMS as a condition of their qualification or approval to participate in MIPS as a third party intermediary.

 <u>AANS/CNS Comments</u>. We strongly urge CMS to preserve this flexibility. CMS should never require these entities, including QCDRs, to report across all categories. There already are sufficient market incentives built in to the program to encourage these entities to report across as many categories as possible. CMS should also not require QCDRs to report on cross-cutting measures since it creates additional barriers for the use of QCDRs and contradicts the intent of the QCDR mechanism to provide the entities the flexibility to select measures that are most relevant to their participants.

In this section, CMS proposes detailed requirements for qualified registries and QCDRs, but the requirements proposed for HIT vendors are less extensive. We realize that federally certified HIT vendors are also responsible for complying with federal criteria issued by the Office of the National Coordinator. However, without seeing a comprehensive list of those additional requirements vis-à-vis the requirements being proposed for registries, it is difficult to assess whether HIT vendors are being held to an equal standard. As currently proposed, it appears that HIT vendors, unlike QCDRs and qualified registries, would not have to provide regular feedback reports to participants, do not have to describe the method they use to accurately calculate performance across MIPS categories, do not have to explain any sort of validation strategy. If HIT vendors are going to be allowed to serve in an equal capacity to registries and QCDRs under MIPS, they should be held to the same standards. We also request that CMS carefully consider the implications of giving HIT vendors too much authority in this space. If they are allowed to capture and report data across MIPS categories, this might create a further disincentive to achieve meaningful interoperability.

Similarly, we are concerned about CMS' proposal that an entity that uses an external organization for purposes of data collection, calculation, or transmission may meet the definition of a QCDR provided the entity has a signed, written agreement that specifically details the relationship and responsibilities of the entity with the external organization effective as of September 1 the year prior to the year for which the entity seeks to become a QCDR. We assume CMS is trying, through this provision, to address the situation where a clinician-led professional organization may need to partner with a database vendor or other similar entity to meet the QCDR requirements. However, we are concerned that the language of this provision is so broad that it would allow HIT vendors and other commercial entities to become QCDRs without any participation of clinician-led professional organizations that are focused on quality improvement relating to specific medical procedures, conditions, or diseases. We request that CMS clarify that QCDRs that involve multiple organizations must be led and controlled by clinician-led professional organizations do not particular types of medical procedures, conditions, or diseases. This language should not

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adversely affect HIT vendors, which have numerous other ways in which they can submit MIPS data to CMS on behalf of eligible clinicians.

Regarding public reporting requirements, QCDRs have historically been given a choice to either publicly report its participants' quality measure data on its own website and provide a link to those data to CMS to include on Physician Compare or to provide the data to CMS to consider for public reporting on Physician Compare. CMS does not appear to discuss this requirement in the rule, but we strongly support CMS maintaining its current policy of giving QCDRs a choice regarding public reporting strategies. Across all aspects of measurement, QCDRs should have the flexibility to choose what is best for its participants.

FEEDBACK REPORTS

Under MACRA, CMS is required, at a minimum, to provide clinicians with timely (e.g., quarterly) confidential feedback on their performance under the quality and resource use performance categories beginning July 1, 2017. CMS has discretion to provide such feedback regarding the CPIA and ACI performance categories. With this authority, CMS proposes to initially include in the feedback reports information on quality and resource use only. CMS will distribute the first performance feedback reports by July 1, 2017. As this is prior to CMS having received any MIPS data, CMS proposes to initially provide feedback using historical data set (e.g., CY2015 or CY2016 data) as a baseline, as available and applicable. Within these performance categories, CMS proposes to use fields similar to those currently available in the QRURs. As technically feasible, CMS plans to provide data fields such as the CPS and each of the four performance categories in future performance feedback once MIPS data becomes available. In addition, it plans to explore the possibility of including the MIPS adjustment factor in future feedback reports.

CMS proposes to initially make performance feedback available using a CMS designated system, such as a web-based portal and if technically feasible perhaps an interactive dashboard. Given the agency's decision to rely on historic data, CMS proposes to provide feedback on an annual basis, at a minimum for the first year. As the program evolves, and CMS can operationally assess/analyze the MIPS data, it may consider in future years providing performance feedback on a more frequent basis, such as quarterly.

CMS also proposes to leverage additional mechanisms such as HIT vendors, registries, and QCDRs to help disseminate data/information contained in the performance feedback to clinicians, where applicable. At this time, CMS believes that these third-party intermediaries will only be able to provide information on the quality performance category for MIPS in regard to performance feedback.

AANS/CNS Comments. Since CMS' feedback reports are confidential and intended to assist clinicians with tracking their performance and managing deficiencies throughout the reporting period, the AANS and CNS urge CMS to include as much data as possible in their reports. In general, we believe that the more data that is shared with clinicians the better so long as it is presented in an easy to understand format. The previous QRUR reports offered summary data, but little in depth for individual EPs. Even when CMS tried to provide more specific drill-down tables, it was still challenging for clinicians to make sense of the data. At the same time, the more recent Supplemental QRURs featured tremendous amounts of information about individual episodes, but offered limited aggregation of data into a usable format. For example, it was not clear from reviewing the sQRURs where a given clinician could intervene to decrease costs. While we recognize that too much information can confuse and overwhelm a clinician and strongly urge CMS to continue to work with clinical stakeholder to make reports

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more user-friendly, we still believe that clinicians should have the opportunity to access as much data about their ongoing performance as possible if they so choose.

To balance the need for full transparency with the need for meaningful and actionable formats, CMS should make those portions of the data that it has not yet figured out how best to present (e.g., data about Advancing Care Information performance to date) as supplemental materials (e.g. appendices) so that it does not detract from the main report. CMS also should include clear disclaimers about the limitations of these data, how it might not yet accurately represent final performance in a category, and how CMS is working with stakeholders to address how best to present these data.

The AANS and CNS very much support the use of interactive dashboards that provide data to clinicians in as real a time as possible, but at the very least, on a quarterly basis. It is critical that feedback meaningfully guide improvements in practice.

We remind CMS of the ongoing challenges that clinicians and practices continue to face when trying to access these reports. While we appreciate the agency's efforts to keep these reports secure and confidential, this process should not result in the diversion of valuable time away from direct patient care. Furthermore, the current requirement that only allows an "authorized group practice representative" to access these reports often restricts an individual clinician's ability to directly access his/her own report. We believe that the clinicians who are being evaluated in these reports should each have the independent ability to access to their own reports.

The AANS and CNS support the proposal that QCDRs and other intermediaries would be expected to provide feedback to participants only on the quality performance category. We strongly urge CMS to coordinate with these intermediaries as MIPS evolves to determine whether additional feedback on the other performance categories is feasible in the future.

We would like to suggest two options for reporting. There should be a basic report covering the data elements immediately relevant to physician reimbursement and performance:

- The performance threshold for the present reporting period;
- Where the physicians stands with regard to his or her performance; and
- The potential payment adjustments and a roadmap of how the clinician can improve to avoid any penalties and earn bonus payments.

A basic report providing just the scoring for the four MIPS elements and projected performance and thresholds would be of utility to all physicians. For physicians or practices that want more granular information, there should be an option to obtain a richer dataset, reviewing each of the elements of each MIPS component, down to the success or failure of individual PQRS reporting, a patient-by-patient assessment of resource use, etc. This will prevent inundating practices with data that they do not have the capacity to process.

Overall, we urge CMS to continue to work with stakeholders to improve the usability of these reports and to ensure that clinicians are able to access their feedback. As part of this strategy, we support CMS using its authority under MACRA not only to provide feedback, but to also <u>receive</u> feedback from clinicians (e.g., if they are experiencing issues accessing their data, technical questions about their data, etc.). We recommend that CMS link this resource to the CMS designated feedback system so that clinicians do not have to log in to multiple portals.

Finally, we remind the agency that all the fixes in the world will not make inherently flawed

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measures more comprehensible or meaningful. A large part of improving these reports will be improving the underlying measures and methodologies used to calculate performance.

BURDEN ESTIMATES

The AANS and CNS are concerned about the limitations of basing burden estimates on existing quality program rules and participation patterns. Such an approach does not accurately account for the significant changes proposed under MIPS, including an especially complex scoring methodology, and it results in an overly conservative estimate of burden.

In an assessment of the costs associated with these programs, and depending on the size of the practice, neurosurgeons spend a range of \$185,000 to \$385,000, with an average cost of \$285,000! This includes the costs of research, development, testing, training/education modules, CMS and other education webinars, implementation/maintenance meetings, time spent on attestation, and ongoing maintenance. The administrative staff now spend a good deal of time generating the continuity of care document, care summaries and closing all loops associated with these programs. Additionally, the nurses and other clinical staff spend up to five minutes per office encounter gathering information on measures to record in the EHR. Managers then spend weekly time reviewing scoring reports and following up on any outstanding issues. These costs do not even begin to address the full magnitude of expenses related to complying with Medicare's quality programs. The specialty societies themselves also are devoting 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 has high as \$250,000, are simply prohibitive for many small specialties—particularly if there is no guarantee that CMS will even use them.

CMS must do something to address these cost burdens, but at the very least, the agency should better understand these costs and provide accurate and detailed information about the significant compliance burden. To that end, **in general**, we request that CMS provide estimates that include:

- The time and cost associated with reading educational materials and participating in educational sessions regarding the new MIPS requirements;
- The time and cost associated with determining reporting options available to clinicians and groups under MIPS and strategies for maximizing one's CPS; and
- The time and cost associated with determining whether an eligible 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.

For the quality performance category, we urge CMS to provide estimates that include:

- The time and cost associated with reviewing the measures list and determining whether an eligible clinician should use a specialty measure set, measures in the general quality MIPS set, or measures offered by a third party vendor (such as a QCDR);
- The time and cost associated reviewing which measures are high priority, which are crosscutting, and which have been deemed topped out since this impacts a clinician's score;
- The time and cost associated with reviewing benchmarks for the quality performance category; and
- The time and cost associated with the proposed increased reporting thresholds.

For the **resource use performance category**, we urge CMS to provide estimates that include:

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- The time and cost associated with understanding whether and how measures in this category apply to physicians and how physicians are attributed patients and held accountable under these measures; and
- The time and cost associated with learning how these measures are applied to clinicians not previously impacted by the VM.

For the ACI performance category, we urge CMS to provide estimates that include the following:

- The time and cost associated with understanding the requirements for this performance category for eligible clinicians not previously participating in the EHR Incentive Program; and
- The time and cost associated with applying for a hardship under this category, if applicable.

CONCLUSION

The AANS and CNS recognize the enormity of the task to overhaul the Medicare physician payment system. Nevertheless, it is essential that the CMS establish the programmatic building blocks that will ensure the quality payment program's success into the future. The current proposal is overly complex and if substantial changes, including those outlined above, are not made, we fear that physicians won't embrace this new payment system. Clearly, that is not an outcome CMS wants, so we hope you are open to making the necessary adjustments to enfranchise, rather than disenfranchise, physicians.

Thank you for considering our comments. We look forward to working with the agency as you continue to refine the rules for this new program. In the meantime, if you have any questions or need additional information, please don't hesitate to contact us.

Sincerely,

Frederich A. Bergs

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