AMERICAN ASOCIATION OF NEUROLOGICAL SURGEONS

KATHLEEN T. CRAIG, Executive Director 5550 Meadowbrook Drive Rolling Meadows, IL 60008 Phone: 888-566-AANS Fax: 847-378-0600 info@aans.org

President
ALEX B. VALADKA, MD
Richmond, Virginia





CONGRESS OF NEUROLOGICAL SURGEONS

REGINA SHUPAK, CEO 10 North Martingale Road, Suite 190 Schaumburg, IL 60173 Phone: 877-517-1CNS FAX: 847-240-0804 info@1CNS.org

President
ASHWINI D. SHARAN, MD
Philadelphia, Pennsylvania

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Seema Verma, MPH, Administrator Centers for Medicare & Medicaid Services U.S. Department of Health and Human Services 200 Independence Avenue, SW Washington, DC 20201

Submitted electronically via Regulations.gov

SUBJECT: CY 2018 Updates to the Quality Payment Program (CMS-5522-FC)

Dear Administrator Verma:

On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), representing more than 4,000 neurosurgeons in the United States, we appreciate the opportunity to provide additional feedback on the 2018 Quality Payment Program (QPP) final rule with comment period. As we stated previously, the AANS and CNS recognize that implementing the Medicare Access and CHIP Reauthorization Act (MACRA) is a challenging task. As such, we appreciate that in the final rule, CMS commits to the following critical strategic objectives:

- Enhancing clinician experience through flexible and transparent program design and interactions with easy-to-use program tools;
- Promoting program understanding and maximizing participation through customized communication, education, outreach and support that meet the needs of the diversity of physician practices and patients, especially the unique needs of small practices;
- Improving data and information sharing on program performance to provide accurate, timely, and actionable feedback to clinicians and other stakeholders;
- Delivering information technology system capabilities that meet the needs of users for data submission, reporting, and improvement and are seamless, efficient and valuable on the front and back-end: and
- Ensuring operation excellence in program implementation and ongoing development.

Still, the AANS and CNS remain deeply concerned by CMS' efforts to advance Merit-based Incentive Payment System (MIPS) policies in the absence of making more concrete progress on each of these foundational strategic objectives. Below, we discuss some of our ongoing concerns with existing and newly finalized MIPS policies for 2018, and why they fail to advance the above objectives.

Ongoing Program Complexity

The AANS and CNS continue to have overarching concerns about the complexity of the QPP and the failure of MIPS to produce a more streamlined quality reporting structure that focuses on more meaningful measurement, rather than reporting simply for the sake of compliance. We request that CMS continue to work to meet the following unrealized goals:

Washington, DC 20005

E-mail: korrico@neurosurgerv.org

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- A reporting system that is streamlined, simple, and not so confusing so as to
 discourage meaningful engagement. Policies adopted for 2018 such as inconsistent
 performance periods across the four performance categories, higher data completeness
 thresholds, and modified scoring rules make the program extremely challenging for
 clinicians to understand and adhere to from year to year.
- A flexible approach to measurement that recognizes the diversity of medical practice and allows clinicians to demonstrate their commitment to higher quality care based on their unique setting, specialty, and/or patient population. Although MIPS offers more flexibility than Medicare's legacy quality programs, base requirements associated with each performance category with which clinicians must comply with to qualify for an incentive payment remain. Although a clinician can avoid a penalty in 2020 by satisfying only a single performance category in 2018, CMS has stated its intent to raise the bar in the third year of the program. As such, we expect clinicians to have less flexibility over the selection of categories and measures over time.

The Advancing Care Information (ACI) category is particularly problematic because it continues to focus on electronic health record (EHR) functionality, rather than harnessing clinical data to advance the quality of patient care. We continue to urge CMS to take more concrete steps to move beyond what is still mostly a one-size-fits-all approach to measurement under this category. To realize the full power of data and the potential of information exchange, this category needs to be less prescriptive and recognize alternative pathways to indeed *advance care information*. This should include recognition of clinicians who invest in clinical data registries to collect data and use these tools to improve patient care, which could have a more positive impact on patient outcomes and overall quality than the current ACI metrics.

Finally, we remind CMS that the Qualified Clinical Data Registry (QCDR) mechanism was intended to offer a more streamlined process for clinicians to test more relevant, specialty-specific measures in a more timely and practical manner. However, as we describe below, the annual QCDR self-nomination process has become so rife with problems that specialties are beginning to consider whether it is even worth the investment.

- A scoring system that is transparent and simple enough to understand, but also
 clinically accurate. Many details about the new Eligible Measures Applicability (EMA)
 process, and to what extent it will protect clinicians with fewer than six applicable measures,
 are still unclear. The separate, complex reporting and scoring rules tied to each performance
 category also results in a program that is even more complicated than legacy programs.
- Reporting and performance thresholds that are realistically achievable and that drive
 actual improvements in quality, rather than arbitrary compliance. We recognize that
 CMS would like to see clinicians reporting all data on all patients, but the infrastructure is not
 yet in place to allow clinicians to easily do that without expending a significant amount of
 resources and diverting attention away from patient care. Until there is better data
 interoperability, more standardized data collection tools, and better incentives for compliance,
 CMS should not raise the bar on reporting requirements.

The Need for Enhanced Transparency

As outlined below, there are multiple areas of program implementation where CMS has been less than transparent. We request that CMS improve these processes going forward to ensure more clinically-informed policies and to enhance clinician trust in the program:

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- We appreciate that CMS sought specialty feedback on its draft MIPS Specialty Measure Sets for 2018. However, CMS seemed to ignore the input that the AANS and CNS provided on the neurosurgical measure set in early 2017, opting to include three additional measures (developed by MN Community Measurement) in the final set that were neither included in our recommended set nor ever presented to us for consideration. In the future, not only should CMS rely on clinically relevant input when making these decisions, but the agency should also make available to the public its rationale for these final decisions.
- As mentioned above, it is still not entirely clear how the EMA data validation process will affect scoring under MIPS (e.g., could it result in clinicians being eligible to receive a maximum quality category score based on less than six measures?) or how CMS will evaluate quality measures that are not tied to any EMA clinical clusters. Under the Physician Quality Reporting System (PQRS), the Measure Applicability Validation (MAV) process was conducted in a black box. We strongly urge CMS to not only offer more specific and timely and guidance on how the EMA process will work under MIPS, but to also provide clinicians with clear explanations about how the EMA process was applied to their data and how and why CMS arrived at specific determinations.
- As discussed below, CMS' QCDR measure evaluation process remains arbitrary and disjointed and could also greatly benefit from greater transparency and improved standards.

Qualified Clinical Data Registries (QCDR)

In the 2018 QPP final rule, CMS states:

We...would like to note we have been working to implement process improvements and develop additional standardization for the 2018 performance period self-nomination and QCDR measure review, in which consistent feedback is communicated to vendors, additional time is given to vendors to respond to requests for information, and more detailed rationales are provided for rejected QCDR measures. Furthermore, through our review, we intend to communicate the timeframe in which a decision reexamination can be requested should we reject QCDR measures. In order to improve predictability and avoid delays or misunderstandings, we have made updates to the self-nomination form to outline all of the information needed during the review process.

Furthermore, we intend to assign specific personnel to communicate self-nomination and QCDR decisions as appropriate and will continue to use our internal decision tracker to track all decisions made on QCDRs and their QCDR measures, as we did during the review of 2017 self-nominations and QCDR measures. We appreciate that commenters provided recommendations to standardize a process and timeframe for self-nomination review and will take them into consideration for future policies. We are currently working through such efforts to standardize the process and timelines to the best of our ability.

Organized neurosurgery, through our membership in the Physician Clinical Registry Coalition (PCRC), communicated concerns about this process to CMS earlier in the year through conference calls and comment letters. While we were initially encouraged by these discussions and the above language in the 2018 rule, our personal experience with the 2018 QCDR self-nomination process demonstrated CMS' failure to carry out the very process it committed to in the rule. As a reminder, organized neurosurgery is involved in two separate QCDRs — the Quality Outcomes Database (QOD) and the Spine Quality Outcomes Database (SQOD). The QOD offers surgical spine measures, while the SQOD, which we operate in collaboration with the American Academy of

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Physical Medicine and Rehabilitation (AAPM&R), focuses on non-surgical spine care. For both the QOD and SQOD, the 2018 self-nomination process proved to be incredibly frustrating and disappointing.

Unfortunately, few of the issues that CMS promised to address in the 2018 QPP final rule have actually been resolved. For example, very little about this year's process was consistent, predictable, or standardized. We also found that very few of the timeframes were reasonable — calls with CMS and the contractors were limited to 30 minutes, which was simply not enough time to discuss all of the measures under consideration. Furthermore, we were often given less than 24 hours to respond to CMS with modifications or additional information. Most of the rationales provided for rejected measures were vague and relied on boilerplate language, which gave the impression that they were blanket responses without much thought or consideration for the clinical context. CMS' frequent decision to reject measures that it considers "standards of care" seemed arbitrary and were not backed by any data or clear rationale for how CMS reached its conclusion. We also found ourselves working with numerous contractors, who sent conflicting approvals, denials and requests related to the same measure. We would have a phone call with CMS and the contractors to discuss one measure, and then just a couple of hours later, we would receive a notice about another measure which could have been flagged and discussed on the earlier call. There also is no formal process through which CMS reaches its determinations (and if there is, it lacks transparency). These decisions seem to take place in a black box and appear to be in the hands of a single CMS staff person.

The AANS and CNS recognize that CMS and its contractors are faced with the difficult task of vetting an increasing number of QCDR vendor applications and an even higher number of quality measures. We also appreciate the flexibility provided to date regarding QCDR measures and realize that bypassing the traditional pre-rulemaking and formal rulemaking process will require some tradeoffs. However, there still needs to be a basic level of transparency, standardization, predictability, and organization. We also remind CMS about the implications of its decision to reject measures. CMS often reminds QCDRs that they may continue to use rejected measures for internal data collection and quality improvement purposes. However, this statement fails to recognize the multiple obstacles that continue to stand in the way of more robust registry participation. Without incentives, such as those created by federal reporting mandates, it is challenging to get clinicians to report this data since doing so takes time and resources away from direct patient care.

While the AANS and CNS very much appreciate that CMS finalized its decision to adopt a more streamlined self-nomination process in 2019 for QCDRs in good standing, we remind CMS of the critical need to direct more resources to improve the QCDR measure vetting process. Improvements should focus on the following areas:

- The need for a more transparent and more predictable process for working with specialty societies to vet QCDR quality measures and to provide more consistent feedback. For example, CMS could assign a single coordinator for each QCDR and create an official database containing decisions on measures to ensure there are no conflicting messages. This process also should include more reasonable and structured timelines for an initial review period, an appeals process and a final review.
- We recognize that the rushed timelines and disjointed, piece-meal responses are a result of CMS trying to provide vendors with information as early as possible so that they have an opportunity to respond before the close of the self-nomination period. We reiterate our request for CMS to adopt a multi-year QCDR measure approval process for vendors in good standing and measures for which there is no significant change in the evidence. CMS has voiced concern that this policy would limit QCDRs from adjusting measures in

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response to annual changes in MIPS reporting requirements. However, we do not see the two as mutually exclusive. We believe that under a multi-year measure approval process, QCDRs could still be given the option to update their measures on an annual basis. Those that choose to do so would have to accept the fact that the measures would have to go through the annual review process (which presumably would be more streamlined by then). However, those that wish to avoid that process can leave their measures intact. The AANS and CNS believe that a multi-year approval process would not only free up CMS resources and lead to a more expedited and streamlined review process, but also give measures a chance to prove themselves, lessen clinician burden by providing consistency from year to year, and allow for the calculation of more reliable benchmarks.

- While we support the use of methodologically rigorous measures, we appreciate the role of QCDRs to serve as a more rapid test-bed for nascent and innovative measures. We urge CMS to preserve the Congressional intent of QCDRs by allowing QCDR measures to be used as soon as possible, even if they are still undergoing testing since adequate test data often cannot be collected until a measure is in use and there are real incentives to use it. This is particularly important for engaging specialists like neurosurgeons, who lack a sufficient number of relevant measures in the traditional MIPS set.
- While we fully appreciate CMS' desire to eliminate needless overlap between existing measures and support harmonization where appropriate, we firmly believe that excessive consolidation of QCDR measures threatens to undermine the usefulness of the QCDR mechanism which was designed, in large part, to recognize the complexities inherent in subspecialty care. Indeed, the agency's drive towards consolidation and harmonization threatens to revert to the one-size-fits-all approach to quality reporting, which we believe directly violates the statute and Congress' goal of promoting specialty-specific quality measures.

In summary, the AANS and CNS call on CMS to implement a transparent, predictable multi-year measure approval process with clear and reasonable timelines and clinically relevant standards that allow for a more meaningful review of QCDR measures. We strongly oppose requiring QCDR measures to be evaluated through the existing process used to vet traditional MIPS measures. Doing so would cause unnecessary delays in the testing of more innovative measures and filling critical specialty gaps in measures, all of which the QCDR mechanism was intended to address. We look forward to having an open dialogue with CMS as it continues to consider ways to improve this process going forward.

Group Reporting

CMS seeks comment on additional ways to define a group, not solely based on a tax identification number (TIN). We reiterate our request for CMS to adopt policies that permit a portion of a group practice, such as members of a specific specialty in a large multi-specialty practice, to participate in MIPS as a separate subgroup using a new identifier. We would be happy to work with CMS to discuss ways to allow for these carve-outs while minimizing administrative complexity.

Hospital-Based Clinicians

The AANS and CNS appreciate the reporting accommodations provided to hospital-based clinicians under MIPS — namely, an automatic exception from the ACI category of MIPS. However, we oppose CMS' current requirement that 100 percent of a group practice's clinicians must be considered hospital-based for the group, as a whole, to get hospital-based status. Ideally, we would like to see CMS adopt a policy whereby the group would be exempt from the ACI

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category if a simple majority of the group's clinicians meet the definition of hospital-based as individuals (or at the most, 75 percent). This would be more reflective of the realities of clinical practice and more consistent with the definition CMS uses under its facility-based measures scoring policy, which it finalized for 2019. Under this policy, CMS defines a facility-based group as a group in which 75 percent or more of the MIPS eligible clinician NPIs billing under the group's TIN meet the definition of hospital-based as individuals.

We also request that CMS adopt consistent thresholds across the program as much as possible and that it does not change them from year to year. This will ensure that the rules are easy to follow, spur engagement in the program, and ensure that clinician time is not unnecessarily diverted away from patient care.

Cost Performance Category

The AANS and CNS strongly oppose CMS' decision to weight the cost performance category at 10 percent for the 2018 MIPS performance year. What makes this decision even more concerning is CMS' decision to rely on the cost measures used under the Value-Based Payment Modifier, which organized medicine has voiced strong reservations about for many years now. We appreciate that CMS is trying to minimize the impact of transitioning to year three of MIPS when CMS is required to weight the category at 30 percent. However, as we have stated multiple times in the past, the Total Per Capita Cost (TPCC) measure and the Medicare Spending Per Beneficiary (MSPB) measure are highly flawed measures that are inappropriate for evaluating the resource use of specialty physicians. Both measures hold clinicians responsible for total Part A and B expenditures, including costs that the physician had no control over and that may even have occurred before the physician ever saw the patient. As a result, the measures are largely irrelevant to many physicians and completely inapplicable to others. The MSPB measure also fails to adjust for physician specialty or type of service despite the fact that CMS previously determined that specialty adjustment is an important factor in evaluating cost. The TPCC also was never endorsed by the National Quality Forum, which questioned the measure's validity and its method of attributing costs. As a result, these measures serve little purpose other than to confuse clinicians and their patients.

The AANS and CNS are working with its medical and surgical colleagues to pursue legislation that would extend MACRA's two-year cost transition period to at least five years. In the interim, we support CMS maintaining a weight of zero for the cost category of MIPS in 2018. We also support CMS' ongoing work to develop more focused, episode-based cost measures. Our members have been involved in that work and look forward to working with CMS to further refine these measures. Nevertheless, even the episode-based cost measures should not be used for accountability purposes until CMS has had a reasonable opportunity to refine the risk adjustment and attribution methodologies, to thoroughly test the measures, and to allow the public to carefully review the test data and comment on the measures through future rulemaking. The recent field-testing of these measures was rushed, led to a lot of confusion, and did not provide enough time for clinicians to provide meaningful feedback.

As additional cost measures are developed, it also is essential that CMS not implement them until CMS has had an opportunity to test the new patient relationship categories and codes and clinicians have had a chance to become comfortable using them since these codes are intended to improve current attribution challenges. As CMS continues this work, we encourage the agency to award bonuses to clinicians who agree to pilot test episode-based measures and/or patient relationship categories.

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Physician Compare

Recognizing the MACRA statute requires increased public reporting on the Physician Compare website, we want to continue to work with CMS to ensure information is accurate, not misleading, and presented in a format that consumers can understand and use appropriately. However, we question to what extent clinicians and consumers are relying on this data for medical decision-making and urge CMS to provide the public with data on the actual use and impact of the site. We also have concerns about the complexity of the preview period. Some of our most engaged members reported challenges accessing the preview data — particularly, data related to all the individual clinicians in a group practice. Group practice administrators that secured the proper permission to access all of the group's PQRS data via the feedback reports were not able to do the same for the Physician Compare preview period. Instead, they were told that they would have to set up 50 separate accounts! This complexity is not only absurd but unnecessary. As CMS continues to address regulatory burden and clinician hardships, we strongly urge it to reconsider senseless policies that make it challenging for clinicians to review their performance data before it is used for accountability.

Conclusion

While the AANS and CNS appreciate CMS' attempt to ease clinicians into the QPP, the underlying structure of the program remains unnecessarily complicated and still focuses more on satisfying arbitrary requirements rather than genuine quality improvement. We strongly urge CMS to maintain policies for a minimum number of years to minimize confusion and allow for more accurate evaluations of the program. We also recommend that CMS continue to work to consolidate and streamline the four categories of MIPS and to provide greater flexibilities that will make the program more relevant to a range of clinician types and specialties.

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

Sincerely,

Alex B. Valadka, MD, President

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American Association of Neurological Surgeons

Ashwini D. Sharan, MD, President Congress of Neurological Surgeons

Contact

Rachel Groman, MPH

Vice President, Clinical Affairs and Quality Improvement

Hart Health Strategies

Phone: 202-729-9979 ext. 104 Email: rgroman@hhs.com