

AMERICAN ASSOCIATION OF
NEUROLOGICAL SURGEONS

THOMAS A. MARSHALL, *Executive Director*
5550 Meadowbrook Drive
Rolling Meadows, IL 60008
Phone: 888-566-AANS
Fax: 847-378-0600
info@aans.org



CONGRESS OF
NEUROLOGICAL SURGEONS

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

President
H. HUNT BATJER, MD
Dallas, Texas

President
NATHAN R. SELDEN, MD, PHD
Portland, Oregon

September 8, 2015

Andy Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1631-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1631-P Medicare Program; Payment Policies Under the Physician Fee Schedule (PFS) and Other Revisions to Part B for CY 2016

Dear Mr. Slavitt,

On behalf of the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS), representing over 4,000 neurosurgeons in the United States, we appreciate the opportunity to comment on the above referenced Notice of Proposed Rulemaking (NPRM). The following comments focus on the Physician Compare website, Physician Quality Reporting System (PQRS), and Value-Based Payment Modifier (VM) Programs. We have submitted comments related to the non-quality proposals in a separate comment letter.

EXECUTIVE SUMMARY

Physician Compare

• **Timeline and Criteria for Reporting Physician Performance Data**

- It is critical that CMS carefully weigh the benefits of public reporting against the risks of information overload and misuse of data and CMS should work with medical specialty societies to ensure that the data are accurate, relevant and meaningful.
- The AANS and CNS oppose CMS' proposal to make certain performance data available through a downloadable raw data file as it could be misused or misinterpreted by consumers, researchers, health plans, or even lawyers.
- Qualified Clinical Data Registries (QCDRs) need ample time to develop a sufficient foundation to analyze and test measures and data for reliability and validity prior to public reporting.
- The AANS and CNS request that CMS extend the 30-day preview period to at least 60 days to allow physicians to review their data prior to it being published in Physician Compare.

• **Benchmarks**

- The AANS and CNS support efforts to make physician performance data more meaningful and understandable for consumers; however we question whether the Achievable Benchmark of Care (ABC™) is a proven methodology for all physicians, regardless of their specialty, practice setting or patient mix. We therefore recommend that CMS only test benchmarking on measures for

WASHINGTON OFFICE
KATIE O. ORRICO, *Director*

725 Fifteenth Street, NW, Suite 500
Phone: 202-628-2072 Fax: 202-628-5264

Washington, DC 20005
E-mail: korricoo@neurosurgery.org

which there is little variability in terms of the targeted patient population and types of physicians reporting the measure prior to widespread adoption of any uniform benchmarking methodology.

- The ABC benchmarking methodology does not align with the methodology used for the Value-Based Payment Modifier (VM) and Quality and Resource Use Reports (QRURs). If CMS insists on using the ABC (or other methodology) we recommend that it be consistently applied across the various quality reporting programs.
- The AANS and CNS reiterate our concerns about the use of star ratings or other methods that oversimplify quality data. Star ratings, in particular, may exaggerate minor performance differences and fail to adequately incorporate risk adjustment factors, thereby resulting in inappropriate distinctions between physicians whose performance is not statistically different.
- Regardless of the benchmarking method adopted for *traditional* PQRS measures, it is essential that CMS continue to allow QCDRs to identify the best mechanism for publicly reporting their own measure data.

- **Publicly Reporting Value Modifier Data**

- The AANS and CNS continue to have serious concerns regarding the measures and methodology used to calculate the VM as the underlying quality and cost measures are insufficiently risk adjusted and have absolutely no direct association with each other, making them a poor proxy for value.
- Because of the shortcomings of the VM, the AANS and CNS oppose CMS' proposal to display a green checkmark to indicate a physician's receipt of an upward payment adjustment under the VM.
- The AANS and CNS strongly oppose the proposal to add the VM quality and cost data to the Physician Compare downloadable database. Until CMS further refines the accuracy and relevance of the "value" calculations, such data will be misleading and result in inappropriate applications.
- The AANS and CNS would support the inclusion of a checkmark or other symbol on a physician or group practice profile page to indicate that an EP is participating in a QCDR.

- **Publicly Reporting Utilization Data**

- The AANS and CNS have concerns about the accuracy, value and potential misuse of utilization data, particularly if made available through a raw data file without any context.

- **Potential Future Policies**

- Neurosurgery strongly recommend that CMS not include downward and neutral VM adjustment information on physician profile pages.
- The AANS and CNS do not believe that the Physician Compare website is an appropriate place to post data regarding financial relationships between drug and device manufacturers. Such information is available on the Open Payments website and is irrelevant to determinations of quality.

Physician Quality Reporting System

- **Proposed Changes to Qualified Clinical Data Registries**

- Neurosurgery supports CMS' proposal to open the QCDR self-nomination period on December 1, rather than the current January 1 date.
- The AANS and CNS oppose the proposal to move up the deadline by which an entity must submit all documents to CMS by January 31 of the reporting year to be considered for QCDR status. Rather, we recommend that entities have until at least March 31 to complete the QCDR application process.

- The AANS and CNS are pleased that MACRA now allows group reporting via a QCDR. We recommend, however, that CMS give QCDRs the flexibility to determine whether group practice reporting is feasible, rather than requiring all QCDRs to provide both group and individual reporting options.
- Neurosurgery remains concerned about the requirement that QCDRs report on 50 percent of *all* applicable patients. The AANS and CNS, therefore, strongly urge CMS to provide more flexibility to QCDRs to demonstrate reporting compliance — for example allowing QCDRs to report on a statistically valid sample of patients.

- **New PQRS Measures Proposed for 2016**

- It was impossible for us to ascertain which, if any, of the proposed PQRS measures were applicable to neurosurgeons. The AANS and CNS, therefore, recommend that CMS publish the detailed measure specifications during the proposed rule comment period to allow stakeholders to more fully analyze the measures.

- **Potential Future Policies**

- Organized neurosurgery supports efforts to stratify data by factors — race, ethnicity, sex, disability status, etc. — that may influence overall quality. However, we recommend that CMS be mindful not to place additional mandates on physicians to report on such data as the additional data collection burdens are significant and such data is not easily extracted from an electronic health record or other source.

Value-Based Payment Modifier

- **Payment Adjustments**

- The AANS and CNS continue to strongly oppose the measures and methodologies on which CMS relies to make “value” determinations. Until CMS has adopted a mechanism to more accurately incorporate quality and cost data that is relevant to specialists, the agency should hold physicians harmless from downward VM payment adjustments.

- **Benchmarks**

- The AANS and CNS request that CMS provide clarification on how it will use QCDR data to calculate performance-based payment adjustments under the VM. We believe that QCDRs should have the flexibility to develop their own performance benchmarks.
- We are concerned that the benchmarking methodology for the VM differs from the ABC method that CMS is proposing for the quality reporting on Physician Compare. To avoid confusion and inappropriate results, we strongly urge CMS to use consistent benchmarking methodologies across the various quality reporting programs.

- **Potential Future Policies**

- The AANS and CNS support efforts to further stratify cost benchmarks so that they accurately capture patient populations with varying risk. It is imperative that CMS apply socioeconomic status adjustments to cost measures under the VM since a large body of evidence demonstrates that factors such as income and insurance status affect many patient outcomes, including readmissions and costs.

Quality and Resource Use Reports

- Neurosurgeons continue to question the usefulness of the QRURs, which need refinement to be more relevant to individual physician practices.

- The AANS and CNS urge CMS to continue to work closely with relevant clinical experts to better define and refine specific episode-based cost measures.

Provisions Related to MACRA

- As it implements MACRA, CMS must avoid the one-size-fits-all approach that currently plagues federal quality programs and limits meaningful participation by specialists.

• Merit-based Incentive Payment System

- The AANS and CNS urge CMS to recognize a diverse set of activities for purposes of the clinical improvement activities portion of the MIPS system. These should include, among others, the following:
 - Serving on-call to the hospital emergency department.
 - Attending and participating as faculty in ACCME-accredited.
 - Fellowship or other advanced clinical training completed within a certain window of a performance year.
 - Physician practice accreditation, such as accreditation achieved by the National Committee on Quality Assurance (NQCA) or other recognized accreditation organizations.
 - Engagement in private quality improvement initiatives, such as those sponsored by health plans and health insurers.
 - Consulting evidence-based clinical practice guidelines or contributing to the development of such guidelines.
- CMS should adopt a clinical improvement activity attestation process that is as simple as possible.

• Alternative Payment Models

- CMS should adopt a broad set of criteria that would be inherent to any APM recognized by the agency so as to provide the flexibility needed for physicians to develop, test and implement APMs that make the most sense for their practices.

COMMENTS

Physician Compare

Timeline and Criteria for Reporting Physician Performance Data

CMS reiterates its goal of reporting quality *performance* data collected from all group practices and individual practitioners via all Physician Quality Reporting System (PQRS) reporting mechanisms — including Qualified Clinical Data Registries or QCDRs — by late 2016, based on 2015 data. As finalized last year, CMS will only make available to the public measures that prove to be:

- Valid, reliable, and accurate upon analysis (discussed in the 2015 rule);
- Deemed statistically comparable;
- Meet a minimum sample size of 20 patients; and
- Are not first year measures.

Even if deemed acceptable for public reporting, CMS will not necessarily post all of this data on a physician or group practice's profile page. CMS' analysis of this data, along with consumer testing and stakeholder feedback, will determine which measures are published on physician profile pages versus a downloadable data file. All physicians would also have a 30-day preview period to view their measure data as they will appear prior to being published.

The AANS and CNS support efforts to provide consumers with an appropriate set of tools to help them become better healthcare decision-makers. We also appreciate CMS' continuous efforts to improve the Physician Compare website and to adopt processes to enhance the accuracy and utility of data. Nevertheless, we remain concerned about the rapid pace at which CMS hopes to accomplish these tasks. As CMS proceeds down this path, it is absolutely critical that it carefully weigh the benefits of public disclosure against the risks of information overload and misuse of data. Releasing too much data too rapidly and without appropriate safeguards could confuse consumers, mislead the public, and even inappropriately harm the reputation of physicians.

We urge CMS to very carefully and thoughtfully evaluate quality measure data to determine whether it is ready for public reporting and in what format. We cannot overemphasize the importance of working with professional societies and their clinical experts throughout this process to ensure not only the accuracy of data, but that it is relevant, meaningful and actionable. Transparency is also critical, particularly as it relates to the manner in which CMS conducts consumer testing and the results of that work. To date, we know very few details about the extent to which this important work has been conducted to date. It is also still unclear to what extent patients and physicians are visiting the Physician Compare website and using the information presented for informed healthcare decision-making. Before CMS posts additional performance data on the website, we recommend that it carefully conduct these studies and share the results with the public.

The AANS and CNS oppose CMS' proposal to make certain performance data available through a downloadable data file. If, after careful evaluation and testing, CMS determines that select data are not suitable for posting on a physician profile page, then CMS should assume they are unsuitable for public release, in general. CMS believes that by making performance data accessible through a raw data file, it can satisfy the public's demand for data while continuing to test ways to most properly present the data. However, we believe that the risks associated with making these raw files available (e.g., the data being misused or misinterpreted by researchers, health plans, or even attorneys) far outweigh any value they would provide to the public. The Physician Compare website is meant to provide consumers with tools to make more informed healthcare decisions. It is not meant to provide "public interest" groups with fodder to issue highly questionable and widely contradictory physician "report cards."

We also question CMS' previous decision to set the minimum sample size for publicly reported data at 20 patients. There are multiple studies that indicate that a sample size smaller than 30 is statistically invalid and prone to misleading conclusions.

As CMS continues to work to determine what measure data is appropriate for public reporting, the AANS and CNS also request that the agency give careful consideration to QCDR data. While we appreciate that CMS will not publicly report on first year measures, we request that CMS consider the unique nature of QCDR measures. This reporting mechanism is still relatively new and one additional year of data (beyond the first year) might not provide a sufficient foundation to analyze and test measures for reliability and validity and to set accurate benchmarks. QCDRs need ample time to gain experience with collecting and reporting data to CMS, resolving any inaccuracies in the data, and conducting test for reliability and validity before requiring QCDRs to publicly report data.

Finally, the AANS and CNS request that CMS extend the 30-day preview period and instead give physicians at least 60 days to preview their data prior to it being published on Physician Compare. This is especially important as CMS transitions to more widespread reporting of *performance* data, which entails more complex analytics that will require more of a physician's time to review and understand. A 60-day preview period would also better account for the flood of information that physicians already face as a result of multiple, competing quality reporting mandates. It is also consistent with the 60-day informal review submission period that CMS offers physicians following the release of Quality and Resource Use Reports (QRURs) for determinations related to the 2016 Value Modifier (VM).

Overall, as CMS expands the amount of performance data posted on the Physician Compare website, explanations regarding the data, descriptions about calculations and benchmarks, and disclaimers will all need to be much more specific than they are now, and will require continuous evaluation and updates based on physician input and consumer testing.

Benchmarks

Based on public feedback and the consideration of a Technical Expert Panel, CMS proposes to apply a measure-level benchmarking methodology known as the Achievable Benchmark of Care (ABC™) to publicly reported PQRS measures. CMS claims this is a well-tested, data driven model that evaluates who the top performers are, and then uses that to set a point of comparison for all of those groups or individual EPs who report the same measure.

CMS also proposes to use this benchmark to assign stars under a Physician Compare one-to-five star rating system. Currently, for select measures reported through the Group Practice Reporting Option or GPRO (Diabetes Mellitus and CAD), CMS displays quality measure scores using stars, where each star represents 20 percentage points. However, these stars simply represent how each group practice performed on a measure (e.g. if a group practice performed the appropriate care process 80% of the time, it receives four fully-filled stars). They are not currently used as a rating or ranking system because they do not benchmark group practices against each other.

The AANS and CNS support efforts to make physician performance data more meaningful and understandable for consumers. However, it is unclear to what extent the ABC benchmarking methodology accounts for the varying circumstances of physicians who report on the same measure. Under the VM, CMS currently applies no adjustments to PQRS quality measures to account for the specialty mix of those reporting the same measure. CMS simply compares performance across any and all physicians who reported on the same measure, regardless of their specialty, practice setting, or patient mix. It is critical that any benchmarking methodology adopted by CMS adequately accounts for these factors in order to ensure apples-to-apples comparisons of physician performance. If stratifying data to this level is not feasible in the early stages of public reporting because of insufficiently small cohorts, then CMS should hold off on benchmarking until it has a more sufficient foundation of data. Until this data is gathered, we recommend that CMS only test benchmarking on measures for which there is little variability in terms of the targeted patient population and the types of physicians reporting the measure (e.g. it would be inappropriate to hold neurosurgeons to the same benchmark as primary care providers for the smoking cessation measure).

One way to avoid the complexities of national benchmarking is to initially focus performance assessments on physician or group practice self-improvement over time. This would give CMS more time to develop and test more complex adjustments that need to be made to data to ensure fair comparisons across physicians.

We are also concerned about what seems to be a lack of consistency in the benchmarking methodologies used across physician quality programs. The ABC benchmarking methodology does not seem to align with the benchmarking methodology that CMS uses for the Value-Based Payment Modifier and Quality and Resource Use Reports (QRURs). We request that CMS adopt consistent methodologies across physician programs, as appropriate, and that it provide clear explanations to the public in instances where it believes these methodologies should differ.

Finally, we reiterate concerns registered last year about the use of star ratings or other arbitrary thresholds. Oversimplification of data can lead to information that is not meaningful and may harm, rather than aid, decision-making. Star ratings, in particular, may exaggerate minor performance differences on measures and fail to adequately incorporate risk adjustment factors, thereby resulting in inappropriate distinctions between physicians whose performance is not statistically different. CMS must

keep in mind that there continues to be important gaps in what is measurable. Currently, most available data is simply not sophisticated enough to be “watered-down” effectively through use of a star-rating system. In cases where a star rating system is used, it is critical that CMS provide a consumer-friendly explanation of what the measures actually mean so that the public can easily interpret the data and use it for informed medical decision-making.

Regardless of what benchmarking approach CMS ultimately adopts for *traditional* PQRS measures, it is also very important that CMS preserve the freedom it has afforded to QCDRs up until this point to determine the best mechanism for publicly reporting its own measure data. Decisions about public reporting, including the most appropriate benchmarking methodology, should remain in the control of QCDRs.

Publicly Reporting Value Modifier Data

As early as late 2017 — based on 2016 data — CMS proposes to include a green check mark on individual and group practice profile pages who received an upward adjustment as a result of the VM. This check mark would indicate that a physician achieved one of the following: higher quality care at a lower cost; higher quality care at an average cost; or average quality care at a lower cost. Currently, CMS uses a green check mark on physician profile pages only to indicate which quality programs a physician satisfied the reporting requirements for.

Organized neurosurgery continues to have many serious concerns regarding the measures and methodology used to calculate the VM. The underlying quality and cost measures are insufficiently risk adjusted and have absolutely no direct association with each other, making them a poor proxy for value. The program’s attribution mechanism is also problematic. As a result of these multiple inherent flaws, physicians often receive a misleading score or are determined by CMS to be “average” due to a lack of relevant measures, an insufficient number of attributed patients, or calculation errors on the part of CMS or a third-party vendor. For all of these reasons, we do not support CMS’ proposal to display a green checkmark to indicate a physician’s receipt of an upward payment adjustment under the VM. We do not believe this program results in accurate conclusions about the overall “value” of a physician and feel that a checkmark tied to program performance would be misleading.

CMS also proposes to add to the Physician Compare downloadable database (but not the individual profile pages) the 2018 VM quality tiers for cost and quality, based on the 2016 data, for group practices and individual EPs. The database would indicate if the group practice or physician is high, low, or average on cost and quality per the VM. CMS also proposes to include a notation of the payment adjustment received based on the cost and quality tiers, and an indication if the individual EP or group practice was eligible but did not report quality measures to CMS. Given our concerns above, the AANS and CNS strongly oppose this proposal. We do not see what value this information would provide the public and believe that it will simply lead to confusion and result in inappropriate applications. Until CMS further refines the accuracy and relevance of its “value” calculations under the VM, including better cost of care measures that are actually tied to what it being measured on the cost side, it should limit the extent to which it shares these “value” determinations with the public. In the interim, we also urge CMS to report quality and cost performance data separately, rather than trying to merge it, since, as we stated earlier, one currently has nothing to do with the other.

The AANS and CNS would, however, support the inclusion of a checkmark or other symbol on a physician or group practice profile page to indicate that an EP is participating in a QCDR. We believe that this is a better indicator of physician quality and overall value than the currently flawed VM score. It also will allow CMS to move in the direction of enhanced transparency and public engagement, while giving QCDRs time to adequately prepare to publicly report performance data in the future.

Since CMS plans to display performance data only for select measures that it believes are ready for public reporting, it is equally important that CMS add language to the Physician Compare site explaining why certain professionals might not yet have performance data that is suitable for public reporting and that this should not be interpreted as a reflection of the quality of the care that they provide. We also recommend that CMS include language on the site explaining the significance of QCDR reporting and how these measures often capture aspects of care that are most relevant to a specialist.

Publicly Reporting Utilization Data

As required by the Medicare Access and CHIP Reauthorization Act (MACRA), CMS also plans to make utilization data available to the public (i.e., counts of services/procedures provided to Medicare beneficiaries and generated from Medicare Part B claims) beginning in 2016. CMS acknowledges these data are less immediately useable in their raw form by the average consumer, so it proposes to add them to the downloadable database versus the consumer-focused physician profile pages. While we appreciate CMS' recognition that these data are not appropriate for the posting on the physician profile pages, we still have concerns about the accuracy, value, and potential misuse of these data if made available through a raw data file.

Potential Future Policies

CMS seeks feedback on potentially including in the future an indicator of downward and neutral adjustments under the VM on physician profile pages. In line with our earlier concerns, we strongly recommend against CMS taking this action. CMS also seeks comment on potentially including Open Payments data on individual EP profile pages on Physician Compare. These data are already publicly available, but CMS feels making them available in this context would help consumers better understand the information.

The AANS and CNS do not believe that the Physician Compare website is an appropriate place to post data regarding the financial relationships between drug and device manufacturers and health care providers. Placing this information alongside quality measure data is misleading and might result in the public misinterpreting Open Payments data as being an indicator of quality. Furthermore, it is irrelevant to determinations of value.

Physician Quality Reporting System

Proposed Changes Related to Qualified Clinical Data Registries (QCDRs)

In this rule, CMS proposes multiple modifications to the requirements for becoming a QCDR.

Self-Nomination Requirements

Organized neurosurgery supports CMS' proposal to open the self-nomination period one month earlier (i.e., December 1). We also appreciate CMS' proposal to require that an entity be in existence as of January 1 of the year for which the entity seeks to become a QCDR rather than the year prior to the application. These proposals are particularly important for newer registries who might need additional time to gather the necessary information prior to submission.

At the same time, we are concerned about CMS' proposal to move up the deadline by which an entity must submit all documents to CMS for purposes of being considered for QCDR status to January 31 of the reporting year. Under current policy, entities have until March 31 to provide CMS with such information. Under this proposal, CMS would require that the entity submit its data validation plan, as well as detailed measure specifications and supporting evidence for all non-PQRS measures it intends to report, by the earlier deadline. Once an entity submits this information, it would not be able to change

it for purposes of qualification (e.g., it cannot later modify the measures specifications the entity submitted). However, CMS could still request supplemental information from the entity after this date.

Neurosurgery's National Neurosurgery Quality and Outcomes Database (N²QOD) became a QCDR for the first time in 2015. This experience shed light on how much time and detailed work is required to complete an application, how many times we needed to reach out to CMS contractors directly for input, and how many times we needed to tweak our application and measures based on that feedback. Based on this experience, and the fact that CMS is also proposing to modify some of the requirements related to submission of an acceptable validation strategy, we request that CMS preserve the March 31 deadline, or at least extend it to the end of February. A later deadline would give entities more time to fine-tune their validation strategies, measures specifications, audit plans, and other safeguards to ensure that they are able to collect and report data accurately and meaningfully. Again, this extra time is especially important for entities that are applying to become a QCDR for the first time.

Group Practice Reporting via QCDR

The AANS and CNS are pleased that MACRA included language requiring CMS to create an option for EPs participating in the Group Practice Reporting Option (GPRO) to report quality measures via a QCDR. In accordance with this mandate, CMS proposes that QCDRs have the ability to submit quality measure data for group practices, in addition to individuals, starting in 2016. QCDRs often offer physicians a much more relevant way of participating in the PQRS, and we support efforts to make this alternative reporting mechanism as widely available as possible. However, we request that CMS give QCDRs the flexibility to determine a) whether group practice-level reporting is even relevant and appropriate for the registry's target population and 2) whether the registry is prepared to collect and report group practice level data to CMS. Group practice-level reporting should be an option for QCDRs and not a mandate.

QCDR Measure Reporting Requirements

Finally, we reiterate our concerns with the requirement that QCDRs report each quality measure for 50 percent of **all** applicable patients (i.e., Medicare and non-Medicare). As we have stated in the past, a sample this large is not always necessary to ensure the validity and reliability of reported data. As evidenced by our own registry, as well as other registries already approved as QCDRs, there are many instances where the integrity of data can be preserved by using a statistically valid sample that represents much less than 50 percent of total patients. We also remind CMS that the requirement to report on 50 percent of all patients is much more onerous than the requirement under traditional PQRS, which only requires reporting on 50 percent of Medicare Part B patients. If the reporting threshold for QCDR measures is too high, it will discourage these entities from enhancing the scope and granularity of their measures. We strongly urge CMS to provide more flexibility to QCDRs that are able to demonstrate an alternative mechanism by which they can provide CMS with data on a statistically valid sample of patients. CMS currently permits EPs to submit a 20 patient sample if reporting PQRS measures groups via registry, which demonstrates its confidence in the suitability of this methodology.

Similarly, the AANS and CNS request that CMS permit QCDRs to report on PQRS and non-PQRS measures groups. This would provide EPs with a greater choice of potentially relevant reporting options. If CMS were to adopt this policy, we believe it should do so in a manner that is consistent with current policy (i.e., requiring EPs to report on a minimum sample of 20 patients).

New PQRS Measures Proposed for 2016

CMS proposes multiple new PQRS measures for 2016 that might apply to neurosurgeons. These potentially include:

- **Chronic Opioid Therapy (COT) Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during COT documented in the medical record [registry only]
- **Clinical Outcome Post-Endovascular Stroke Treatment:** Patients with 90 day mRs score of 0 to 2 post- endovascular stroke intervention [registry only]
- **Documentation of a Health Care Proxy for Patients with Cognitive Impairment:** The percentage of patients with a diagnosis of dementia or a positive result on a standardized tool for assessment of cognitive impairment, with documentation of a designated health care proxy during the measurement period. [registry only]
- **Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during COT documented in the medical record. [registry only]
- **Door to Puncture Time for Endovascular Stroke Treatment:** Door to puncture time less than 2 hours for patients undergoing endovascular stroke treatment. [registry only]
- **Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, SOAAP-R) or patient interview documented at least once during COT in the medical record. [registry only]
- **Extravasation of Contrast Following Contrast- Enhanced Computed Tomography (CT):** Percentage of final reports for patients aged 18 years and older who received intravenous iodinated contrast for a computed tomography (CT) examination who had an extravasation of contrast. [claims, registry]
- **Imaging in Adult Emergency Department (ED) Patients with Minor Head Injury:** Percent of adult patients who presented within 24 hours of a non- penetrating head injury with a Glasgow coma score (GCS) \leq 15 and underwent head CT for trauma in the ED who have a documented indication consistent with guidelines prior to imaging. [claims, registry]
- **Imaging in Pediatric ED Patients Aged 2 through 17 years with Minor Head Injury:** Percent of pediatric patients who presented within 24 hours of a non-penetrating head injury with a Glasgow coma score (GCS) of 14 or 15 and underwent head CT for trauma in the ED who have a documented indication consistent with guidelines (PECARN) prior to imaging [claims, registry]
- **Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened at least once within the last 24 months for unhealthy alcohol use using a systematic screening method AND who received brief counseling if identified as an unhealthy alcohol user [registry, measures group]
- **Cognitive Impairment Assessment Among At-Risk Older Adults:** Percentage of patients age 80 years or older at the start of the measurement period with documentation in the electronic health record at least once during the measurement period of (1) results from a standardized cognitive impairment assessment tool or (2) a patient or informant interview [registry only]
- **Depression Remission at Six Months:** Adult patients age 18 and older with major depression or dysthymia and an initial Patient Health Questionnaire-9 (PHQ-9) score $>$ 9 who demonstrate remission at six months defined as a PHQ-9 score less than 5. This measure applies to both patients with newly diagnosed and existing depression whose current PHQ-9 score indicates a need for treatment. [registry only]
- **Overuse Of Neuroimaging for Patients with Primary Headache And a Normal Neurological Examination:** Percentage of patients with a diagnosis of primary headache disorder whose health-related quality of life (HRQoL) was assessed with a tool(s) during at least two visits during the 12- month measurement period AND whose health related quality of life score stayed the same or improved. [claims, registry]
- **Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques:** Percentage of final reports for patients aged 18 years and older undergoing CT with documentation that one or more of the following dose reduction techniques were used:

Automated exposure control; Adjustment of the mA and/or kV according to patient size; Use of iterative reconstruction technique [claims, registry]

- **Perioperative Anti-platelet Therapy for Patients Undergoing Carotid Endarterectomy:** Percentage of patients undergoing carotid endarterectomy (CEA) who are taking an anti-platelet agent (aspirin or clopidogrel or equivalent such as aggrenox/tiglacor, etc.) within 48 hours prior to surgery and are prescribed this medication at hospital discharge following surgery. [claims, registry]
- **Quality of Life Assessment for Patients with Primary Headache Disorders:** Percentage of patients with a diagnosis of primary headache disorder whose health related quality of life (HRQoL) was assessed with a tool(s) during at least two visits during the 12- month measurement period AND whose health related quality of life score stayed the same or improved [claims, registry]
- **Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of high-risk adult patients aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR adult patients aged ≥ 21 years with a fasting or direct Low-Density Lipoprotein Cholesterol (LDL-C) level ≥ 190 mg/dL; OR patients aged 40- 75 years with a diagnosis of diabetes with a fasting or direct Low-Density Lipoprotein Cholesterol (LDL-C) level of 70-189 mg/dL who were prescribed or are already on statin medication therapy during the measurement period [claims, registry, GPRO Web Interface, measures group]

Unfortunately, it is difficult to know to what extent these are truly relevant to our members without access to the measures' specifications. It is our understanding that measure developers still have another few weeks until they must provide CMS' contractor with their final specifications for 2016. In the future, we recommend that CMS not propose a measure for a future reporting year unless its specifications are available for review. The specific details of a measure very much influence decisions about its appropriateness for inclusion in federal accountability programs.

Potential Future Policies

CMS intends to require the collection of quality data, stratified by race, ethnicity, sex, primary language and disability status, within each of the PQRS reporting mechanisms. CMS seeks comments on facilitators and obstacles to collecting and reporting these attributes. Organized neurosurgery supports efforts to stratify data by factors that may influence overall quality. However, we request that CMS keep in mind the unique limitations of each reporting mechanism, which may make it difficult to collect this information. For example, claims data might not adequately capture the breadth of socio-demographic factors that need to be accounted for. While a clinical data registry has more flexibility to customize its data points, CMS needs to keep in mind the additional data collection burden this might pose for registry participants if the registry cannot easily extract this additional information from an EHR or other source due to lack of interoperability or uniformity of data definitions.

Value-Based Payment Modifier (VM)

Payment Adjustments

The AANS and CNS continue to strongly oppose the measures and methodologies on which CMS relies to make "value" determinations. While we are pleased that CMS is not proposing to raise the ceiling on potential penalties under this program for 2018, we request that it continue to hold smaller group practices and solo practitioners completely harmless from downward performance-based payment adjustments. The current set of quality and cost measures, and the methods those measures rely on to attribute patients to physicians, are often of little relevance to smaller group practices and solo practitioners, who tend to be more specialized and/or focus on a single specialty. In many instances, CMS cannot even apply these measures to smaller groups because of an insufficient sample size of

applicable patients. Until CMS has adopted a mechanism to incorporate quality data that is relevant to specialists (such as data collected via a QCDR) and more accurate and episode-specific cost measures, we believe it should hold physicians harmless from downward performance-based payment adjustments under the VM.

Although we oppose the current set of cost measures, we do appreciate that CMS is proposing to increase the minimum number of attributed episodes needed for CMS to include the Medicare Spending Per Beneficiary measure in a cost composite. We believe this will, at the very least, minimize the inappropriate application of this measure. CMS proposes to increase the minimum from 20 to 100 cases, but we strongly recommend that CMS increase the minimum to 200 cases due to this measure's tendency to hold physician's accountable for care outside of their direct control. A 200 case minimum would also be consistent with the case minimum finalized last year for the all-cause hospital readmissions measure used in the VM's quality composite.

Benchmarks

Although CMS does not propose any specific changes to the benchmarking methodology used to determine physician performance under the VM, it cites the following previously finalized policy: "Once we have historical data from measures submitted via QCDRs, the benchmark for quality of care measures will be the **national mean** for the measure's performance rate during the year prior to the performance period (79 FR 67956)." We request that CMS provide clarification on how it will use QCDR data to calculate performance-based payment adjustments under the VM. Organized neurosurgery was under the impression that QCDRs would have the flexibility to develop their own performance benchmarks so long as the methodology is able to compare the quality of care an EP provides to his or her patients to other EPs performing the same or similar functions. However, the language in the rule seems to indicate that CMS will automatically use a national mean to determine QCDR participant performance.

Adding another layer of complexity to all of this is that CMS is proposing in this rule what appears to be a separate benchmarking methodology (i.e., the ABC methodology) for quality measure reported via Physician Compare. This methodology sets a benchmark that represents the best care provided to the top 10 percent of patients, which appears to be different than the national mean performance on a measure. These are the same measures, yet it appears that they will be benchmarked differently under the VM (and in QRURs) versus when publicly reported on Physician Compare.

We strongly urge CMS to employ consistent benchmarking methodologies across programs, especially programs that rely on the same measures. It is very confusing and inappropriate to analyze the same quality measure data using one method for a physician's confidential QRUR (and for subsequent payment determinations) and using another method for public reports.

Potential Future Policies

In response to public concerns that the CMS-hierarchical condition categories (HCC) Risk Adjustment methodology used in the total per capita cost measures for the VM does not accurately capture the additional costs associated with treating the sickest beneficiaries, CMS is seeking feedback, but not making any proposals at this time, on potential future approaches. One option would be to stratify the cost measure benchmarks so that groups and solo practitioners are compared to other groups and individual practitioners treating beneficiaries with similar risk profiles.

Organized neurosurgery supports efforts to further stratify cost benchmarks so that they accurately capture patient populations with varying risk. However, we remind CMS of the importance of maintaining minimum sample size thresholds to ensure the ongoing validity and utility of the data. We also continue to urge CMS to apply socioeconomic status adjustments to cost measures under the VM.

A large (and growing) body of evidence demonstrates that sociodemographic factors such as income and insurance status affect many patient outcomes, including readmissions and costs. Failing to adjust measures for these factors can lead to substantial unintended consequences, including harm to patients and increased healthcare disparities, by diverting resources away from providers treating large proportions of disadvantaged patients. It also can mislead patients, payers and policymakers by blinding them to important community factors that contribute to worse outcomes.

Quality and Resource Use Reports (QRURs)

While the AANS and CNS appreciate CMS' efforts to refine these reports, to improve their timeliness by issuing them more frequently, and to provide more detailed drill down tables with data on which attribution and performance calculations are based, our members continue to question the usefulness of this tool since the measures remain largely irrelevant to their practice.

We support and have been involved in CMS' ongoing work to define more specific episode-based cost measures and appreciate that CMS has begun to provide physicians with a confidential preview of this data through supplemental QRURs. These measures should more accurately capture care decisions that are in the direct control of the surgeon, and we appreciate that CMS is sharing this data. As CMS works to refine these episodes, we urge the agency to continue to work closely with relevant clinical experts and to keep in mind that certain conditions and procedures (i.e., those with minimal heterogeneity) fit more easily into discrete episodes than others. It is also important that CMS not use episode-based cost measures for accountability purposes until it has identified quality measures that align directly with those cost measures.

Provisions Related to the Medicare Access and CHIP Reauthorization Act

In this rule, CMS seeks preliminary feedback on strategies for implementing both the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) provisions of MACRA. The AANS and CNS remind CMS of the critical importance of recognizing a wide range of activities and payment models that are relevant to physicians in different specialties and practicing in a variety of settings. CMS must avoid the one-size-fits-all approach that currently plagues federal quality programs and limits meaningful participation by specialists. Under current quality programs, physicians based in hospitals or who work in large academic or private systems also have limited control over how they participate in these programs. For example, the hospital administration might decide, on behalf of physicians working in that hospital, to participate in the PQRS as a large group practice. Specialists such as neurosurgeons are often not even aware of these decisions, have no control over the selection of measures for which they are held accountable for, and often do not even see or have access to feedback reports. It is critical that both MIPS and APM programs address this current barrier to participation and provide specialists with more direct control over the selection of meaningful and relevant quality activities and payment/delivery models.

Merit-based Incentive Payment System (MIPS)

MIPS is applicable beginning with payments for items and services furnished on or after January 1, 2019. In this rule CMS seeks input on multiple provisions of the legislation to guide future policymaking.

Low-Volume threshold

CMS is required to select a low-volume threshold to apply for purposes of excluding certain EPs from the definition of a MIPS eligible professional. The low-volume threshold may include one or more or a combination of the following: (1) the minimum number of individuals enrolled under Medicare Part B who are treated by the EP for the performance period involved; (2) the minimum number of items and services furnished to individuals enrolled under Medicare Part B by such professional for such performance period; and (3) the minimum amount of allowed charges billed by such professional under

Medicare Part B for such performance period. CMS seeks comment on what would be an appropriate low-volume threshold for purposes of excluding certain EPs. The agency also seeks comment as to whether it should consider establishing a low-volume threshold using more than one or a combination of factors or, alternatively, whether CMS should focus on establishing a low-volume threshold based on one factor. Low-volume thresholds are currently used in other CMS reporting programs (e.g., EPs and acute care hospitals must meet certain Medicaid patient volume thresholds-- in general, 30 percent for EPs and 10 percent for acute care hospitals) to be eligible for the Medicaid EHR Incentive Program).

While we do not have a specific recommendation at this time, we remind CMS that a universal low volume threshold might not be sufficient for all physicians, and CMS will likely need to adopt multiple distinct thresholds to accommodate a wide range of specialties and practice types. Regardless, physicians who fall under any adopted threshold should still have the opportunity to participate in MIPS if they believe they can provide CMS with meaningful data to qualify for an incentive.

Clinical Practice Improvement Activities

CMS seeks comments on what activities could be classified as clinical practice improvement activities under MIPS. By statute, these activities must fall under at least the following subcategories:

- Expanded practice access, such as same day appointments for urgent needs and after-hours access to clinician advice.
- Population management, such as monitoring health conditions of individuals to provide timely health care interventions or participation in a qualified clinical data registry.
- Care coordination, such as timely communication of test results, timely exchange of clinical information to patients and other providers, and use of remote monitoring or telehealth.
- Beneficiary engagement, such as the establishment of care plans for individuals with complex care needs, beneficiary self-management assessment and training, and using shared decision-making mechanisms.
- Patient safety and practice assessment, such as through use of clinical or surgical checklists and practice assessments related to maintaining certification.
- Participation in an alternative payment model.

The AANS and CNS urge CMS to recognize as diverse a set of activities as possible to reflect the language and intent of the statute. We are especially supportive of CMS using this as an opportunity to recognize the value of clinical data registries and their many applications. In addition to what CMS has already listed as examples, we believe it would be appropriate for CMS to recognize the following:

- Serving on-call to the hospital emergency department.
- Attendance and participation as faculty in ACCME-accredited events (e.g., the AANS and/or CNS Annual Meetings, and other CME offerings).
- Fellowship or other advanced clinical training completed within a certain window of a performance year.
- Physician practice accreditation, such as accreditation achieved by the National Committee on Quality Assurance (NQCA) or other recognized accreditation organizations.
- Engagement in private quality improvement initiatives, such as those sponsored by health plans and health insurers.
- Consulting evidence-based clinical practice guidelines or contributing to the development of such guidelines.

It is critical that CMS adopt a process by which physicians can demonstrate compliance with Clinical Practice Improvement Activities that is as simple as possible. This will not only minimize physician reporting burden, but allow CMS to recognize a broader diversity of activities under this category. We recommend that CMS employ a simple attestation process, potentially through an online form that physicians already submit to CMS (e.g., PECOS).

Alternative Payment Models (APMs)

Regarding APMs, we suggest that CMS consider adopting a broad set of criteria that would be inherent to any APM recognized by the agency. This would provide the flexibility needed for our members to work with other stakeholders to develop and test APMs that make the most sense for their practices. APMs could incorporate elements such as clinician-driven quality measurement, data collection (e.g., through the use of registries), shared decision-making, and patient reported outcomes. Other options, including bundled payments or additional shared-savings models would be appropriate to include in this payment approach. And while we recognize that financial risk will be an element, we urge CMS to take extreme caution and work closely with specialties to ensure cost metrics used are fair, appropriate and risk-adjusted.

The AANS and CNS also request that CMS consider the fact that many surgical specialties have not yet had a chance to develop or test APMs. Much of the work done to date has focused on models that are relevant to primary or non-acute care. This is not necessarily due to specialty lack of interest in these models, but to the fact that our care is often more nuanced and does not neatly fit into existing models (e.g., there have been multiple unsuccessful attempts to appropriately capture spine surgery through a bundle). Another challenge we face is that the more focused the payment model and the more discrete the payment bundle, the more difficult it will be for a physician to meet the revenue threshold for becoming a qualified APM participant. As CMS proceeds with this work, we ask it to keep in mind the unique challenges facing specialties like ours.

CONCLUSION

The AANS and CNS appreciate the opportunity to provide feedback on the 2015 MPFS proposed rule. We look forward to providing more detailed input on MACRA implementation, but in the meantime, if you have any additional questions or need additional information regarding this proposed rule, please contact us.

Sincerely,



H. Hunt Batjer, MD, President
American Association of Neurological Surgeons



Nathan R. Selden, MD, PhD, President
Congress of Neurological Surgeons

Staff Contact:

Rachel Groman, MS
AANS/CNS Washington Office
725 15th Street, NW, Suite 500
Washington, DC 20005
(202) 628-2072
E-mail: rgroman@hhs.com