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August 26, 2014

Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services
CMS-1612-P
Box 8013
7500 Security Blvd.
Baltimore, MD 21244-8013

RE: CMS-1612-P Medicare Program; Payment Policies Under the Physician Fee Schedule (PFS) and Other Revisions to Part B for CY 2015

Dear Administrator Tavenner,

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) published in the *Federal Register* on July 11, 2014. The following comments will 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 separate comment letters.

Summary of Comments

- **Physician Compare**
  - The AANS and CNS are extremely concerned about the aggressive timeline over which CMS plans to publicly report physician performance data. Two years is an insufficient amount of time to evaluate the accuracy, relevancy, and meaningfulness of publicly reported group practice data and to apply lessons learned to individual level data.
  - We support giving specialty societies the option to publicly report their measures via their own websites linked to Physician Compare so long as the measures are grounded in evidence, developed by relevant clinical experts, and have been adequately vetted.
  - CMS should not publicly report composite scores until it has further studied the accuracy and relevance of calculating composite scores.
  - While we value patient experience data for internal quality improvement purposes, we oppose the public reporting of CAHPS or other patient experience survey data due to the subjectivity of these surveys, potential perverse incentives to keep the patient satisfied, and the cost of administering the surveys.
  - The AANS and CNS urge CMS to use consistent benchmarking across its programs to promote consistency and minimize confusion. We oppose arbitrary thresholds, such as star ratings, which

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often result in inappropriate distinctions between physicians whose performance is not statistically different. At least initially, we urge CMS to recognize personal improvement rather than the attainment of benchmarks.

- Both quality and cost data should not be used for accountability purposes until CMS can give physicians a fair opportunity to review and correct it. Physicians should be given at least 60 days to review and offer corrections to their data before it is published.

- **Physician Quality Reporting System**

  - The AANS and CNS strongly oppose CMS' proposal to remove over 70 measures, including the many measures relevant to neurosurgeons, especially when 2015 is the first year that the PQRS will transition to an all-penalty program. Removal of these measures, paired with the proposed maintenance of the nine measure reporting requirement, will leave neurosurgeons with very few, if any, relevant measures to report on and will result in reporting non-meaningful measures simply to satisfy reporting requirements. The elimination of the Perioperative measures group is particularly concerning since this is the only set of current PQRS measures that applies broadly across the various neurosurgical subspecialties. At the very least, measures should be phased-out, and specialties given at least a two-year grace period over which they can seek alternative reporting mechanisms.
  - We oppose the requirement to report from a "cross-cutting" measure set, which is largely primary care focused and contradicts the goal of offering physicians enhanced flexibility.
  - The AANS and CNS oppose increasing the size of measures groups. Groups should be defined based on the relevance of measures rather than arbitrary thresholds.
  - While we appreciate CMS' efforts to respond to stakeholder feedback and ease the requirements of Qualified Clinical Data Registries (QCDRs). We continue to believe that many of the existing and newly proposed requirements are unreasonable, including the requirement to report on 50 percent of all applicable patients and the requirements to publicly report, risk-adjust and benchmark data. While these are all important elements of a data registry, they are unrealistic goals for newer registries. Instead, we urge CMS to implement a scaled approach that establishes criteria for moving toward accurate and meaningful public reporting of QCDR performance information over time and with experience. We also urge CMS to clarify current informed consent requirements for registries performing quality improvement activities and to make administrative data widely available to registries in order to achieve more accurate analyses of value.

- **Physician Value-Based Payment Modifier**

  - Physicians may be at risk for losing over ten percent of their Medicare payments in the coming years given the cumulative application of penalties associated with the PQRS, VM, and EHR Incentive Program. We therefore strongly urge CMS to reduce the impact of the VM on new participants, smaller practices, and those without relevant measures by holding them harmless from any penalties, reducing the initial payment penalty, or requiring less stringent reporting requirements during the initial year. This is especially critical for smaller practices and those without relevant quality measures to report.
  - CMS should adopt a mechanism whereby it can use quality (and cost) measure data collected by QCDRs to calculate the VM.
  - We oppose CMS' decision to not apply socioeconomic status adjustments to cost measures under the VM.
  - The AANS and CNS have ongoing concerns about CMS' continued reliance on broad-based cost

measures (such as Total Per Capita Cost measures and the Medicare Spending Per Beneficiary (MSPB) measure) that assess the total amount billed per patient and not the cost of the specific care provided by the individual physician. We instead encourage CMS to move towards more specific episode-based cost measures, in consultation with relevant clinical experts.

- CMS must have mechanisms in place to ensure corrections to both quality and cost data before holding practices accountable for performance.

- **Physician Feedback Program**

  - We encourage CMS to continue to consult relevant specialties to further refine specific episodes of care and to improve the presentation of data in feedback reports.

Physician Compare

Support for Recent Enhancements

The AANS/CNS have long advocated that CMS ensure the accuracy of the underlying Physician Compare demographic database and the website's search functions before adding additional performance data. As such, we greatly appreciate the work that CMS has done to enhance the site over the last year, including:

- The new Intelligent Search Function;
- Using claims data to verify physicians' demographic information;
- Denoting board certified physicians, including an explanation of what that means;
- Providing explanations about each of the federal quality reporting programs; and
- Providing disclaimers stating that these federal programs are voluntary, participation/reporting rates are not reflective of the actual quality of care provided, and failure to participate in any of these programs does not necessarily indicate a lack of commitment to quality improvement.

The AANS and CNS also were very pleased to hear in July about additional enhancements made to the website. This quarterly enhancement specifically addressed one of our ongoing concerns about the search function continuing to include primary care physicians when patients search for specialists. We support the reordering of the search options so that the "search all generalists and group practices" links to the bottom of the search results list; therefore ensuring that the specialties most relevant to the search term appear first. We also appreciate the additional labeling of each section to help further clarify the results list for site users, as well as the decision to refine the "Is this you?" link to provide more actionable information to assist group practices and healthcare professionals in updating their information on the site.

Ongoing Concerns

While the AANS and CNS appreciate these continuous improvements to the Physician Compare website, we would like to use this opportunity to reiterate our ongoing concerns over the speed at which CMS proposes to publicly report performance data. In this rule, CMS proposes to move up the date by which it would publicly report on 20 PQRS individual measures collected through a registry, EHR, or claims from late 2015 to early 2015 and to report on 2013 data rather than 2014. CMS also proposes to publicly report all 2015 PQRS measures for individual eligible professionals (EPs) by late 2016 based on 2015 data.

This aggressive timeline is extremely problematic. CMS is only first releasing performance data to the public in 2014, and only on a very limited basis and for a very selective population (i.e., five Diabetes Mellitus and Coronary Artery Disease measures collected via the Web Interface for group practices with

a minimum sample size of 25 patients and Shared Savings Program ACOs). It is highly improbable that CMS can gather sufficient information on the success or failure of this initial roll-out, apply appropriate adjustments to methodologies and reporting formats based on lessons learned, and accurately report on the performance of ***all*** physicians by 2016.

Ongoing improvements to the Physician Compare website and its underlying database will be increasingly critical as CMS transitions from reporting on physician participation rates to reporting on physician performance. Before expanding publicly reported data, we urge CMS to evaluate carefully to what extent patients and physicians are visiting the Physician Compare website and using the information presented for healthcare decision-making. It also is critical that the agency continues to work with the physician community to ensure the accuracy of the site and that the information presented is meaningful and actionable for both patients and physicians. Transparency is essential, and CMS will need to balance the benefits of public disclosure with the risks of information overload. 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.

One specific ongoing concern with the current website that CMS has not yet addressed is the need for a statement clarifying that the majority of the current measures included in the GPRO Web Interface set are primary care-focused and not reportable by specialty practices. Since the Web Interface requires group practices to report on the entire set of measures, most specialty practices cannot use this reporting mechanism, and therefore should not be viewed in a negative light for this decision.

Overall, if the purpose of Physician Compare is to educate the public about their healthcare treatment options, then CMS has to proceed much more cautiously to minimize substantial risks to patient health and physician reputations. CMS should first carefully evaluate the accuracy and utility of publicly reporting data on larger practices before moving to individual physicians. Inaccurate presentations of such data can lead to serious unintended consequences for both patients and physicians, including greater confusion and mistrust among both parties.

Publicly Reporting Specialty Measures via Physician Compare

The AANS and CNS support CMS' suggestion to include specialty society measures on Physician Compare, to link Physician Compare to specialty society websites that publish non-PQRS measures, or both. We appreciate the flexibility that this option would offer in terms of allowing professional societies to select those measures that are most relevant to their specialty.

Although CMS does not offer specific details related to this proposal, we would urge the agency to adopt minimum standards that ensure that specialty society measures are supported by scientific evidence, developed by relevant clinical experts, and have been adequately vetted. It is critical that this alternative mechanism for public reporting only apply to measures developed by specialty societies and trusted by the physician community; not measures developed by private payers or other stakeholders for which the level of physician involvement is unclear. If this proposal is finalized, we also urge CMS to include a disclaimer on the Physician Compare website informing the public of the limitations of the PQRS measure set and how in certain cases, specialty-selected measures may offer patients more relevant and meaningful information.

Publicly Reporting Composite Scores

CMS also proposes to calculate and post composite scores for select measures groups in 2016 based on 2015 data. While none of the measures groups is directly relevant to our members, we again caution against this aggressive timeline. CMS should not publicly report composite scores until it has further

studied the accuracy and relevance of calculating composite scores. As part of this testing process, CMS could share composite scores with physicians confidentially through the Quality and Resource Use Feedback Reports (QRURs) and request feedback from physicians.

Public Reporting of Clinician Group (CG) Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey Data

In this rule, CMS proposes to further incorporate CG-CAHPS survey measures into its federal quality initiatives. In late 2014, CMS will publicly report on CAHPS performance reported by groups of 100 or more. By 2015, the agency will report on CAHPS performance for groups of 25 or more and in 2016, it will report on performance for groups of two or more. While reporting the CAHPS measures would remain optional for groups with 2-99 EPs for the 2014 and 2015 reporting years, CMS proposes that beginning with the 2016 reporting period (i.e., the 2018 PQRS payment adjustment), group practices with 25 or more EPs participating in the GPRO would be required to report on these measures and would also be responsible for the cost of using a certified vendor to collect the CAHPS survey measures.

Organized neurosurgery remains opposed to CMS moving forward with publicly reporting CG-CAHPS or any CAHPS surveys and using patient experience measures for accountability purposes. Patient experience measures are often subjective in nature, capture non-clinical elements of care that are not always under the direct control of the physician (e.g., physician wait times in a hospital setting), and may result in perverse incentives that reward inappropriate or even harmful care (e.g., over-prescribing of pain medications to keep the patient satisfied). Furthermore, response rates on these surveys are typically low and, based on feedback we have received from providers, patient compliance is often difficult to obtain.

The CAHPS is also extremely costly to implement and burdensome on a practice, especially for small private practices. Furthermore, the collection of CAHPS data may also lead to survey fatigue by patients since CMS requires this in both the Medicare Shared Savings and Inpatient Quality Reporting programs. Patients do not know the difference between a CG-CAHPS survey, Surgical-CAHPS and a Hospital-CAHPS survey.

It is also inappropriate to require a surgical practice to institute CG-CAHPS in their practice because the questions are not relevant to surgeons. If CMS insists on moving forward with CAHPS, the Surgical-CAHPS (S-CAHPS) is at least a more appropriate way to measure patient experience data. However, CMS should take into consideration that many practices already collect patient experience data in formats other than the CAHPS survey (e.g., Press-Gainey). Indeed, the American Board of Medical Specialties (ABMS) is considering recognizing multiple different patient experience surveys for the purpose of satisfying Maintenance of Certification (MOC) requirements. CMS should, therefore, recognize and provide credit to practices that use alternative formats to collect patient experience data.

If CMS must move forward with its proposal to hold physicians accountable for patient satisfaction survey measures, physicians should only be held accountable for whether or not they have provided patients with a patient experience survey. Physicians should not be held accountable for completed collection rates, which are outside of the control of the physician, or actual survey results, which also may be due to factors outside of their control and may vary based on cultural and regional differences. If CMS insists on making this information available to the public, then it should, at the very least, refrain from tying physician payments to performance on these measures for the reasons stated above.

Benchmarks

CMS also proposes to develop and publicly report on benchmarks in 2016 for 2015 PQRS GPRO data (calculated based on 2014 data) using a methodology that is similar to that used under the Medicare

Shared Savings Program (MSSP). Benchmarks would be established for each percentile. A group practice would earn quality points on a sliding scale based on performance: performance below the 30th percentile for a measure would receive zero points; performance at or above the 90th percentile would earn the maximum points available. CMS proposes to apply a similar process to individual measures in the future, but offers no details.

While the AANS and CNS appreciate that CMS intends to provide patients with more easily interpretable performance data, the details regarding this benchmarking methodology are vague and confusing. For example, it is not clear whether this is the same benchmarking methodology that CMS uses for the Value-Based Payment Modifier and Quality and Resource Use Reports (QRURs). If not, we urge CMS to use consistent benchmarking across its programs to promote consistency and minimize confusion. It is also not clear whether this benchmarking methodology would rely on the 5-star rating system currently used to display performance data for 66 group practices and 141 Accountable Care Organizations (ACO) on Physician Compare. Again, the AANS and CNS recognize the need to present data in a more consumer-friendly manner to aid healthcare decision-making. However, we caution against 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 result in inappropriate distinctions between physicians whose performance is not statistically different. Furthermore, there continues to be important gaps in what is measurable. Currently, available data is simply not sophisticated enough to be "watered-down" effectively through use of a star-rating system.

Rather than set arbitrary benchmarks, at least initially, we encourage CMS to focus public recognition on improvement in physician performance over time rather than on attainment of specific thresholds (or at least a combination of both). Such an approach would reduce the administrative complexity of calculating meaningful benchmarks and ensure fair comparisons between physicians treating similar patient populations, while still providing patients with useful information about a physician's quality. Over time, CMS could work with physician experts to develop and test benchmarks and relative rating scales for potential implementation in future years, which could be shared confidentially with physicians through QRURs in the interim.

Preview Period and Appeals Process

The AANS and CNS appreciate the proposed policy that only measures that meet the sample size of at least 20 patients and are statistically valid and reliable can be reported on Physician Compare. We believe, however, other safeguards are needed to ensure the accuracy of publicly reported data. For one, physicians should be given at least 60 days to review and offer corrections to their data before it is published, rather than the proposed 30-day period. QRURs distributed to date have been challenging to access and confusing to interpret. Many physicians will be seeing this data for the first time over the next year and will need more than 30 days to access it, carefully evaluate it, identify errors or inconsistencies, and gather the evidence to refute any perceived misrepresentations.

We also believe it is critical that CMS adopt a formal appeals process. Without one, physicians will only be able to request changes in measure display and not accuracy. In the Value Modifier section of this rule, CMS proposes to expand its informal inquiry process starting with the 2015 payment adjustment period to establish an initial corrections process that would allow limited corrections to be made to cost measure determinations. However, CMS notes that it is not operationally feasible to evaluate quality measures data errors by that time. It is not clear if this corrections process would apply simply to VM determinations or also to the public reporting of data. Regardless, performance data should not be used for accountability purposes — whether payment penalties or public reporting — until physicians are given the opportunity to review and appeal it and until CMS has the capability to evaluate and correct calculation errors related to both quality and cost measures.

Physician Quality Reporting System

Proposed Changes to Reporting Requirements/Measures

CMS proposes to increase the requirements for satisfactory PQRS reporting in 2015 so as to avoid a two percent penalty in 2017. CMS will maintain the requirement that physicians report on at least nine measures covering three National Quality Strategy (NQS) domains for at least 50 percent of applicable Medicare Part B patients. However, CMS proposes that two of those measures will now have to come from a list of 18 "cross-cutting" measures.

Penalties

The nine measure reporting requirement, in general, remains a challenge for many specialties, and we are disappointed to see that CMS is proposing to maintain this requirement given other proposed and statutory changes that will simultaneously impose additional reporting burdens on physicians. For one, 2015 is the first year that the PQRS will transition to an all-penalty program. It is unfair to hold all physicians to such a high standard in the very first year that penalties replace incentive payments. There are still a substantial number of physicians who have not yet participated in the PQRS — not because of a lack of interest in quality improvement, but because of a lack of time and resources to devote to reporting measures that are of little relevance to their practice. Holding physicians to such a high standard in the very first year that this program is mandatory, seems inconsistent with previously adopted CMS policies, which included less stringent requirements for those trying to avoid the penalty versus those trying to earn an incentive.

Proposed Removal of Measures

CMS' decision to maintain the nine measures across three NQS domains requirement is even more unrealistic given the agency's simultaneous proposal to remove an unprecedented number of measures from the PQRS. Many of these measures are the only measures currently available to neurosurgeons. We are specifically opposed to CMS' proposal to remove the Perioperative measures set; the Back Pain measures set; the Ischemic Vascular Disease measure set; the Stroke and Stroke Rehabilitation measures; and the Epilepsy measures. Removal of these measures will leave neurosurgeons with very few, if any, relevant measures to report. Those that do manage to report on nine measures would be forced to select peripherally relevant measures simply for the sake of satisfying the reporting requirement and not because they are truly relevant to their patients.

The elimination of the Perioperative measures group is particularly concerning since this is the only set of current PQRS measures that applies broadly across the various neurosurgical subspecialties. Because of the universal application of this measures set in neurosurgery, we have woven it into our National Neurosurgery Quality and Outcomes Database (N^2QOD), which has been a "qualified PQRS registry" for the past two years. If CMS eliminates the Perioperative measures set, we will no longer qualify as a PQRS registry and our members may be left with few, if any, options for reporting.

If CMS' true goal is quality improvement, the agency should adopt a process by which it gradually phases out measures proposed for removal (with the exception of measures shown to cause harm). Should CMS finalize these proposed changes, they will not be announced until late 2014, leaving physicians with very little time to prepare for alternative reporting mechanisms for 2015 and leaving specialty societies with even less time to develop alternative measures. We strongly recommend that CMS provide at least a two-year grace period during which measures proposed for removal would remain in the program. This transition period would give physicians more time to identify alternative reporting mechanisms, while also giving specialty societies more time to develop additional measures or

consider alternative reporting mechanisms, such as the Qualified Clinical Data Registry (QCDR) option. As noted earlier, this grace period is particularly important now that the PQRS is a penalty program.

Another reason to retain measures proposed for removal is to ensure that performance on a measure is truly high and remains high. Many of the measures are being proposed for removal because they have topped out in terms of performance. As such, CMS believes they no longer reveal meaningful distinctions regarding quality. It is not necessarily a bad thing to let the public know that performance on a specific aspect of care is high across-the-board and that they can be confident that just about any provider they select will offer equally high quality care. Current provider rating systems disproportionately focus on the "bad seeds" and rely on consumer scare tactics. A more balanced approach that highlights the positive aspects of quality could enhance patient-physician trust and result in higher quality healthcare. We also take issue with CMS' statement that it would consider re-instituting a measure if performance declines subsequent to the measure being removed from the PQRS. It is unclear how this would be done since once CMS stops collecting this data it has no way of tracking performance or knowing if performance has declined.

Neurosurgery is fully supportive of moving towards more robust measures, such as those that evaluate patient outcomes and appropriate use of services. However, CMS must recognize that it takes an enormous amount of time and resources to develop these more valuable measures. Thus, while this work is being done, CMS should not limit the measures or reporting options available to specialists. Maximum flexibility is especially critical in the first year of all the PQRS becoming a penalty-only program.

Proposed Changes to Measures Groups

Once again, CMS proposes to modify the definition of measures groups to indicate that a measures group must consist of at least six measures. Given the upcoming mandatory penalties and CMS' previously finalized decision to limit the reporting of measures groups to qualified registries and not claims, we oppose this proposal. There is no evidence to support expanding measures groups and setting an arbitrary requirement may result in the addition of non-relevant measures simply for the sake of satisfying the reporting requirement.

Cross-Cutting Measures Proposal

In terms of the cross-cutting measure requirement, we are disappointed by CMS' proposal to move towards a core set of broadly applicable measures at a time when CMS seemed to be moving toward more flexibility. Flexibility is key to encouraging not only physician participation in the PQRS, but meaningful participation that leads to true quality improvement in patient care. Boxing physicians in with arbitrary reporting requirements will breed further frustration with the program. The current set of proposed cross-cutting measures is almost entirely primary care-focused and of very little relevance to surgical specialists. If CMS is wedded to a core measure set strategy, it should at least offer distinct cross-cutting measure sets for surgical and non-surgical specialties. The Perioperative measures set is, for example, a set of measures that would be appropriate for a cross-cutting measures requirement for surgery.

Qualified Clinical Data Registries (QCDRs)

As organized neurosurgery outlined in detail in our comments to CMS last year, we are currently developing tools to help neurosurgeons adopt and incorporate systems of learning into their practice, which will improve the quality of care, provider workflow, patient safety and efficiency. Our national clinical registry, the National Neurosurgery Quality and Outcomes Database (N^2QOD), is one way in which we are working to capture this information and adopt systems that will improve the value of our

services. The N^2QOD 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.

The N^2QOD is the nation's largest cooperative spine registry, and it currently has two clinical data collection modules in operation — one covers lumbar spine, the other cervical spine. The registry analyzes 30-day surgical morbidity and improvements in pain, disability, quality of life and return to work at 3-month and one-year intervals. Overall, 53 sites, in 29 states are participating in N^2QOD, with additional contracted sites in various stages of activation and due diligence. Of the participating sites, 45 percent are academic medical centers, and the remaining 55 percent are in private practice. Three-quarters are in urban settings and roughly half of the participants practice in groups of three to eight surgeons. Nearly one-third of the sites represent groups with more than eight practicing neurosurgeons. In addition to the lumbar and cervical spine modules, the N^2QOD is developing the additional clinical modules:

- Lumbar Deformity
- Cerebrovascular
- Tumor
- Stereotactic Radiosurgery
- Neurosurgery Essentials

Since the PQRS currently lacks a sufficient number of meaningful measures for surgeons, maintaining flexibility in the PQRS program is critical for successful participation. As such, the AANS and CNS strongly supports the QCDR reporting mechanism and the flexibility it grants specialties in terms of recognizing measures that are most relevant to their practice and allowing them to make use of data they may already be collecting for other purposes.

We also appreciate that for 2015, CMS has proposed some modifications that would ease the requirements of this reporting mechanism and provide additional flexibility. These include:

- increasing the number of non-PQRS measures that QCDRs can include from 20 to 30;
- extending the deadline by which QCDRs must submit quality measure data to CMS to March 31 of the year following the reporting period;
- permitting QCDRs to use an external organization for data collection/data transmission; and
- recognizing entities that have broken off from a larger organization for purposes of QCDR qualification.

However, we continue to have serious concerns about other existing requirements and new proposals that seem to place an unreasonable burden on QCDRs and may limit the extent to which entities can take advantage of this reporting option. In fact, it is because of these outstanding concerns that the N^2QOD has not yet applied to become a QCDR and cannot yet offer its members the benefits of this reporting mechanism. The QCDR requirements also seem to continue to adhere to a one-size-fits-all approach by assuming that all registries have the same capabilities and goals, which ignores the unique value of individual registries. This is clearly the opposite of what Congress intended when it authorized this alternative reporting mechanism.

Our concerns regarding existing and newly proposed QCDR requirements are listed below:

- **Proposed Reporting Criteria for Satisfactory Participation in a QCDR for 2015.** Individual physicians participating in a QCDR in 2015 would have to report on at least nine measures covering at least three of the NQS domains for 50 percent of ***all*** applicable patients in order to satisfy PQRS requirements and avoid the 2017 penalty. CMS proposes to add to this, a requirement that

individuals report on at least three outcomes or at least two outcomes measures and one of the following:

- *Resource use measure*: "a measure that is a comparable measure of actual dollars or standardized units of resources applied to the care given to a specific population or event, such as a specific diagnosis, procedure, or type of medical encounter."
- *Patient experience of care measure*: "a measure of person- or family-reported experiences (outcomes) of being engaged as active members of the health care team and in collaborative partnerships with providers and provider organizations."
- *Efficiency/appropriate use measure*: "a measure of the appropriate use of health care services (such as diagnostics or therapeutics) based upon evidence-based guidelines of care, or for which the potential for harm exceeds the possible benefits of care."

One of our most significant concerns regarding QCDRs continues to be the requirement that participants report on measures 50 percent of the time for *all applicable patients* — both Medicare and non-Medicare. Neurosurgery believes that CMS needs to develop a more reasonable methodology for assessing quality. A 50 percent requirement forces physicians to report on their entire patient population, which is more than the traditional PQRS reporting method requires. It should be sufficient for physicians to satisfy QCDR reporting requirements by reporting on a statistically valid sample of patients. If CMS insists on this 50 percent requirement, every time we want to enhance our registry (e.g., by expanding the information captured or diagnoses covered), the federal reporting burden will increase for our members. Furthermore, high volume physicians will have a greater reporting burden due to the amount of information needed for longitudinal quality improvement. For example, a busy spine surgeon may have 200 cases on which to report, as compared with a neurosurgeon whose spine practice is limited and may only have 20 cases on which to report. We strongly urge CMS to provide more flexibility here by recognizing QCDRs that demonstrate a mechanism by which they can provide CMS with data on a statistically valid sample of patients.

While the AANS and CNS appreciate that the QCDR mechanism provides specialties with the flexibility to choose its own measures, we also remain concerned about the requirement that QCDRs meet an artificial number of measures (i.e., nine measures). Rather than focusing on a fixed number of quality measures, as is the case with the current meaningless quality improvement programs, CMS should be moving to a more flexible program that evaluates quality based on what is relevant for individual specialties and their patient population. Instead of developing some standard numeric calculation for evaluating physician quality reporting, CMS should establish broad criteria for compliance. The specialties themselves can then design their clinical registries to meet these criteria, but in a manner that is relevant to them and their patients. It is vital that CMS keep in mind the ultimate goal: improving the quality and value of care delivered to Medicare beneficiaries. Electronic health records, clinical data registries and other efforts are merely tools to reach this desired end point. Therefore, we urge the agency to refrain from requiring an arbitrary number of measures for federal quality reporting program compliance purposes.

In addition, we continue to have concerns about CMS' required measure format. CMS proposes to maintain the requirement that a QCDR measure include the following:

- Denominator data, which must describe the population eligible to be evaluated by the measures (i.e., age, condition, setting, and timeframe when applicable).
- Numerator data, which must detail the quality clinical action expected that satisfies the condition(s) and is the focus of the measurement for each patient, procedure, or other unit of measurement established by the denominator.
- Denominator exceptions and exclusions, where appropriate.

Registries do not typically capture variables in a PQRS measure format. Placing N^2QOD's variables/measures into CMS' traditional numerator/denominator measure format will not only hinder growth, but also alter the information we are capturing. The N^2QOD measures quality through validated protocols supported by evidence. CMS must keep in mind that flexibility is necessary to encourage innovation and the development of novel approaches to achieve healthcare quality and value over time.

It also takes a significant amount of time to develop detailed measure specifications in CMS' traditional PQRS measure specification format. Capturing data through a registry allows for the collection and tracking of data across care settings and disease states, to wit: inpatient and/or outpatient; acute episode or chronic disease; surgical versus nonsurgical interventions; and resource intensive versus relatively inexpensive therapies. Quality measurement must move beyond single episodes or "snapshots" of care, which focus solely on clinicians and individual patients, to a learning system with a broad focus.

- **Public Reporting of QCDR Data.** Another significant concern is the proposed requirement that QCDRs publicly report data. We appreciate that CMS clarifies in this rule that QCDRs would only be required to publicly report on data related to measures reported for purposes of PQRS. Last year we raised concerns about potentially having to report the details of all measures and data elements within the registry, which seemed extraordinarily burdensome, excessive, and simply inappropriate. We are also pleased that CMS proposes to defer to QCDRs the method used to publicly report its data (e.g., it would be sufficient for a QCDR to publicly report performance rates of EPs through board or specialty websites, performance or feedback reports, listserv dashboards or announcements, or in another manner, such as via Physician Compare). We also support allowing QCDRs to determine whether to report performance results at the individual or aggregate level. As we stated last year, group level reporting will help ensure that physicians who are low volume providers are not unfairly penalized under this reporting mechanism.

  Nevertheless, we still remain concerned about the proposed requirement to publicly report performance data by April 31 (we assume this is actually April 30, since no such date exists) of the year following the reporting period. The necessary processes and safeguards required to make public reporting meaningful for physicians, patients and the public requires time, resources and careful consideration. Many specialty society registries are relatively new to this and still working to develop these critical processes. While they may be collecting valuable data on quality and outcomes, this data must be collected over time before quality variables most likely to determine patient outcomes can be defined and meaningful performance benchmarks can be developed. Furthermore, registry participants need the opportunity to familiarize themselves with registry reporting and to make improvements based on feedback. The practical and economic burdens of physician participation in a registry, particularly in the early stages, are significant.

  As an alternative, we urge CMS to implement a scaled approach that establishes criteria for moving toward accurate and meaningful public reporting of QCDR performance information over time and with experience. This would allow specialties in various stages of registry development to take advantage of the QCDR reporting mechanism in a meaningful manner and provide for the necessary processes and safeguards to ensure that consumers receive accurate and reliable information.

- **QCDR Benchmarking.** It is still not clear whether benchmarking would be required at the individual level. We oppose making this a requirement. As stated above, QCDRs should have the flexibility to use the benchmarking methodology that is most appropriate for its participants and patients. Group practice level benchmarking provides a more complete and reliable assessment, as individual data is often insufficient to make quantifiable and valid assessments.

- **QCDR Risk Adjustments.** CMS does not propose any changes to the existing requirement that QCDR's demonstrate a plan to risk-adjust collected quality measures data intended for transmission to CMS, where appropriate, and that this information be integrated with the complete measure specifications. While this requirement appears to offer QCDRs flexibility, we have not yet seen results from the first year of the program to determine the extent to which varying methodologies are acceptable. The N^2QOD's quarterly reports include risk-adjustment information, but we continue to caution against rigid requirements because of the additional data collection burdens it places on individual practitioners. Individual specialties should be able to determine their own standards for meaningful risk-adjustment.

- **Other QCDR-related Topics Not Addressed.** As previously noted, the AANS and CNS are fully supportive of efforts to improve the quality of care that neurosurgeons deliver to their patients. We believe that prospective, systematic tracking of practice patterns and patient outcomes will allow neurosurgeons to improve the quality, efficiency and, ultimately, the value of care. To ensure the success of these efforts, it is imperative that the federal government removes unnecessary regulatory barriers.

  - ***Informed Consent Requirements for Registries Performing Quality Improvement Activities.*** One area in particular that has somewhat hindered our progress are the current regulations for informed consent. While many healthcare providers have embraced registries, which are designed to improve the quality and value of care, the interpretation of current federal regulations — particularly the Privacy and Common Rules — by various institutional review boards (IRBs) has created significant impediments to accomplishing these goals. Because the standards surrounding research and the protection of human subjects are more developed and specific than those for quality improvement, the latter efforts are often subject to research standards in an effort to ensure the protection of patients. As such, if IRBs are unsure of the relationship between federal guidelines and quality efforts, there appears to be a bias towards classifying certain quality programs as "research," which requires informed consent.

    As clinical registries rely on serial evaluation of patient outcomes, the requirement for informed consent undermines quality improvement efforts and compromises the validity of data assessments. Patient consent forms are usually lengthy, confusing, and intimidating. They are typically written in highly, and often unnecessarily, technical terms that may cause mistrust among patients and often discourage consent. The result is difficulty achieving serial enrollment, selection bias and tracking of non-representative populations, which produces data that may be of little value.

    Various investigators have noted that the requirement for informed consent can introduce significant selection bias into quality analyses. This problem was also highlighted in the recent Agency for Healthcare Research and Quality's (AHRQ), "Registries for Evaluating Patient Outcomes: A User's Guide." Simply put, when the requirement for informed consent exists, patients who are willing to give consent often comprise a non-representative subset of the population of interest.

    Therefore, we strongly urge CMS to:

    1) Work with the Office of Human Research Protections (OHRP) and Office of Civil Rights (OCR) to issue guidance that the Common Rule does not apply to the collection and analysis of identifiable patient information for quality improvement purposes, where the entities collecting and analyzing the data (such as clinicians and a corresponding clinical data registry) are engaged in standard patient care and are in compliance with all

applicable HIPAA requirements. Because the HIPAA Privacy and Security Rules provide the same or greater protection for patient data as the Common Rule, there is no need to apply the Common Rule for data collection activities where HIPAA compliant policies, procedures, and waivers are already in place.

2) Include explicit language in federal guidance to allow for a clear differentiation between "human subjects research" and the processes related to the essential prospective analyses that will be required to advance our national quality care objectives. In particular, the generation of new knowledge should be recognized as an expected and desired outcome of healthcare quality improvement projects; the processes related to the generation of such knowledge should therefore be exempt from a requirement for informed consent (assuming that all HIPAA related regulations are adhered to in the course of clinical data collection and analysis).

The AANS, CNS and several other medical specialty societies have repeatedly met with or have been in communication with representatives from the OCR and OHRP. We were encouraged by those discussions and the recognition by senior officials of this problem and the need for regulatory clarifications. However, little action has been taken to date. A gentle nudge from CMS to these offices to address this issue would be timely and would help establish this vital guidance.

- ***Availability of Administrative Data.*** Clearly, clinical data registries are a significant tool for advancing the concept of quality. However, our nation is also striving to achieve value in healthcare, which can be defined as patient outcomes divided by total cost per patient over time. Unfortunately, clinical data registries will not reach their full potential of addressing the value conundrum, unless we can combine clinical information with cost data and death information from the Social Security Administration.

  The issue of linking robust clinical data with resource utilization data, such as Medicare or private payer claims information, is an essential part of any program that attempts to improve the quality and efficiency in healthcare. Linking clinical data with resource utilization data will provide a mechanism to risk-adjust both clinical outcomes and resource utilization, thereby allowing us to better assess the value of care provided by neurosurgeons. The AANS and CNS, therefore, urge CMS to make MEDPAR data available on a regular basis to qualified registries.

  In addition to providing Medicare claims data, it would also be enormously beneficial for registries to have access to the state-reported death data, which is part of the Social Security Death Master File (SSDMF). While we are sensitive to restricting access to the SSDMF so as to "protect" those listed in the file from identity theft, the AANS and CNS believe that these legitimate privacy concerns can be addressed, while also providing qualified registries with access to SSDMF data. Linking clinical registries to the SSDMF allows for the verification of "life status" of patients who otherwise would be lost for follow-up after their treatment, and this longitudinal survival data is vital in assessing the long-term efficacy of many treatments provided by neurosurgeons.

Physician Value-Based Payment Modifier

The AANS and CNS understand that the Affordable Care Act (ACA) requires that CMS phase in the value modifier (VM) over a three-year period beginning in 2015, and that it applies to all physicians by 2017. We continue to believe, however, that implementing this program at such a rapid pace leaves CMS and the public with very little time to evaluate the results of earlier years of implementation and practically no time to make changes to the program based on lessons learned. The VM is yet another regulatory requirement that will only compound the burden that practicing physicians already face and

further erode the physician-patient relationship if carried out too aggressively. In fact, if the proposals set forth in this rule are finalized, physicians may be at risk for losing over ten percent of their Medicare payments in the coming years given the cumulative application of penalties associated with the PQRS, VM, and EHR Incentive Program.

Proposed Increase in Penalties

In this rule, CMS proposes to not only apply the VM to all physicians in 2017, but to double the penalty to four percent. Although group practices with 2-10 EPs and solo practitioners would be held harmless from downward *performance-based* payment adjustments in 2017, they are still at risk for a *non-participation penalty* that is two times as large as the penalty initially applied to larger practices (10-99 EPs) and four times as large as the penalties initially applied to the largest of practices (100+ EPs).

This rapid application of penalties is extremely concerning given the fact that the VM is tied to PQRS reporting, and CMS is simultaneously proposing to remove just about every measure relevant to neurosurgery from the PQRS. Furthermore, smaller practices and individual practitioners face greater challenges participating in federal quality reporting programs. They do not have the resources that large practices have to dedicate to federal quality reporting compliance and will be disproportionately affected by penalties, which, for smaller practices, could impact both quality and patient access to care.

We urge CMS to use its existing authority to ease new participants, smaller practices, and those without relevant measures into the program by either holding them completely harmless from participation ***and*** performance-based penalties, reducing the initial payment penalty, or requiring less stringent reporting requirements during the initial year. For instance, in addition to holding smaller groups and individuals harmless from performance-based downward adjustments during their initial year, CMS also could subject them to a lower penalty for non-participation (e.g. -1 or -2 percent, rather than -4 percent). In the second year, when these groups are no longer held harmless from downward performance-based adjustments, CMS could subject them to lower initial performance-based penalties, such as -1 or -2 percent. Physicians who do not have relevant measures to report (as would be the case for most neurosurgeons and other surgical specialties if CMS finalizes its proposal to remove the Perioperative measures) should be held harmless from VM penalties, in general.

A more gradual roll out of the penalties is also critical in terms of giving CMS more time to evaluate and make improvements to the program. There is much that CMS and the public still need to learn about the validity of cost measures, the accuracy of patient attribution and risk adjustment methodologies, the reliability of composite scores, the significance of benchmarks, and the overall value of performance data to both physicians and patients.

As we discussed earlier in regards to public reporting, we also support cost and quality performance scoring strategies that recognize and reward year-to-year improvements in performance scores, as CMS is proposing for Medicare Shared Savings Program ACOs.

Quality Measures

CMS proposes to continue to base the VM largely on PQRS measures, as well as other acute and chronic care prevention measures that have very little to do with our specialty. We reiterate our concerns about CMS' proposal to remove most, if not all, of the current measures relevant to neurosurgeons. Penalties for both the PQRS and VM are additive, and the lack of relevant measures next year could mean an automatic six percent payment penalty for our members. Imposing these penalties under this circumstance is unfair and unacceptable.

We also encourage CMS to adopt a mechanism whereby it can use quality (and cost) measure data

collected by QCDRs to calculate the VM. CMS claims it does not have the technical capacity to do this yet and that as an alternative, it would automatically consider physicians who satisfy PQRS requirements using a QCDR to be "average quality" for purposes of the VM calculation. We support an initial grace period of one or two years during which QCDRs can collect baseline data, develop benchmarks, and even tweak or remove measures that are found to be unreliable or otherwise flawed for accountability purposes. During this grace period, QCDR participants should be held completely harmless from the quality tiering approach and its associated penalties rather than being deemed "average quality." Under CMS' proposal, QCDR participants characterized as "average quality" could still be subject to a 2 percent penalty if also found to be "high cost." It is not fair to arbitrarily classify physicians as "average quality," and potentially subject them to penalties, when they may be doing very well on measures that are actually more meaningful and relevant than traditional PQRS measures. Looking forward, CMS should work with the QCDRs to develop a mechanism by which quality performance data can be used for payment purposes.

In regards to CAHPS measures, we appreciate that CMS proposes to make the reporting of such measures in 2015 for purposes of the 2017 VM optional for groups with two or more EPs. However, CMS' other proposals related to CAHPS measure reporting seem to indicate the agency's desire to make patient experience measures a required component of federal quality initiatives in the future, including the VM and Physician Compare. As noted earlier, due to the perverse incentives that may result from patient satisfaction measurement and other concerns, we urge CMS to focus on evidence-based, physician-driven clinical quality measures for accountability purposes and to retain patient experience measures for internal quality improvement purposes only.

Cost Measures

We oppose CMS' decision to not 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.

We also have ongoing concerns about CMS' continued reliance on broad-based cost measures (such as Total Per Capita Cost measures and the Medicare Spending Per Beneficiary (MSPB) measure), which assess the total amount billed per patient and not the cost of the specific care provided by the individual physician. While tracking costs (and quality) across the care continuum is important for developing policies to improve our care delivery system, these general assessments are not appropriate for individual physician accountability since they incorrectly assume that physicians have control over the care plan and treatment decisions of other physicians who also treated the patient over the reporting year.

We encourage CMS to move towards more specific episode-based cost measures, in consultation with relevant clinical experts. In doing so, it must ensure that only cost measures that can be paired with relevant quality measures are used for VM calculations and public reporting.

Data Review and Informal Inquiry Process

The AANS and CNS appreciate CMS' efforts to expand the informal inquiry process in regards to performance calculations. Under current policy, a group of physicians is simply given the option to contact CMS after receiving its annual Physician Feedback Report to inquire about the report and the calculation of the VM. In this rule, CMS proposes a more formal process for groups to request a

correction of a perceived error. We also support giving groups until at least February 2015 to request a correction for the 2015 payment adjustment. The extra month provides more time for physicians to analyze their data, but also aligns with the PQRS informal review process.

CMS notes that it would re-compute a group's cost composite and readjust its performance tier accordingly if the agency determines it made an error in the cost calculation for 2015. However, CMS claims it is not technically feasible to do the same for quality composite errors in 2015 and would instead classify a TIN as "average quality" in those cases. We are concerned about CMS proposing to hold practices accountable for performance without a mechanism in place to ensure corrections to that data. It seems inappropriate to deem a group "average quality" simply because CMS cannot correct its own errors, especially if an "average quality" rating could potentially lead to penalties.

For the 2016 and 2017 payment adjustments, CMS proposes to establish a 30-day period that would start after the release of the QRURs for the applicable reporting period for a group or individual to request a correction of a perceived error related to the VM calculation. By 2016, CMS claims it would be able to re-compute a TIN's quality composite. The AANS and CNS urge CMS to instead adopt a ***60-day*** period for physicians to request a correction. Physicians have reported difficulty accessing the QRURs. Since many are still unfamiliar with both theses reports and the VM, they will need more time to sift through this complex set of data and to really understand what they are looking at, let alone identify potential errors.

Physician Feedback Program

We remind CMS of the importance of continuing to evaluate and refine the annual QRURs in an iterative, ongoing manner, working closely with specialty societies. The accuracy, format, and usability of these reports will be increasingly important as the reports include critical information about how physician payments will be affected under the VM and how quality and cost determinations are translated into such payment adjustments.

CMS also discusses its ongoing work related to the development of episode groupers for purposes of evaluating resource use. The 2012 Supplemental QRURs include 26 condition and procedural episode types, including lumbar spine fusion/re-fusion. Given our aforementioned concerns about the inappropriateness of Total Per Capita cost measures and the MSPB measure, we are pleased to hear that CMS is progressing in its work to develop more clearly defined episodes of care. This should minimize attribution issues and concerns about physicians being held accountable for care outside of their control. Organized neurosurgery supports the lumbar fusion episode as currently specified. We specifically support the 30-day timeframe and encourage CMS to focus on as short a time period, and as focused of an episode, as possible. This will ensure that the episode captures the most relevant information and minimizes the risk of surgeons being held accountable for care decisions outside of their control.

We encourage CMS to continue to consult relevant specialties to further refine these episodes, especially now that physicians have access to this data through QRURs. As noted earlier, is important that CMS not use episodes for accountability purposes until it can marry these resource use measures with relevant quality measures — whether from the PQRS set or more homegrown measures developed through specialty societies and collected via QCDRs.

Concluding Remarks

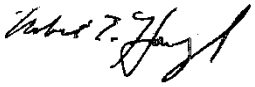
Overall, it is critical for CMS to recognize that medicine, as a whole, is in the relatively early stages of developing the infrastructure necessary to embed *meaningful* quality improvement programs — particularly those involving clinical data registries — into daily practice. With few exceptions, healthcare

stakeholders have yet to develop tools and programs that unequivocally produce improvements in the cost and therapeutic effectiveness of care. Thus, the process for implementing the use of registries, for example, will likely evolve over time and CMS programs should recognize the need for adjustments in requirements over time.

Physicians should be rewarded for participating in registries that are collecting longitudinal data and moving quality measurement beyond process measures. However, we cannot develop meaningful measures within neurosurgery until we have adequate data. Therefore, we continue to push for phased recognition. In the first phase, physician group practices should simply be rewarded for the design and implementation of comprehensive, national quality programs. Individual physicians should be recognized for participation in these programs and for their contributions to aggregate data sets that will allow for the determination of critical benchmarks of care. In later stages, when quality programs have matured, and these efforts have become embedded within the fabric of daily practice, it may be more appropriate to publicly recognize physicians in some comparative fashion, but we are not yet there.

The AANS and CNS appreciate the opportunity to provide feedback on the 2015 MPFS proposed rule. If you have any additional questions or need additional information, please contact us.

Sincerely,



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