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NEUROLOGICAL SURGEONS

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April 8, 2013

Marilyn Tavenner, Acting Administrator  
Centers for Medicare & Medicaid Services  
Attention: CMS-3276-NC  
Mail Stop S3-02-01,  
7500 Security Boulevard,  
Baltimore, MD 21244-1850

**Re: Request for Information on the Use of Clinical Quality Measures (CQMs) Reported under the Physician Quality Reporting System (PQRS), the Electronic Health Record (EHR) Incentive Program, and Other Reporting Programs**

Dear Ms. Tavenner,

On behalf of the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS), we appreciate the opportunity to comment on the Center for Medicare & Medicaid Services' (CMS) request for information (RFI) on the *Use of Clinical Quality Measures Reported under the Physician Quality Reporting System (PQRS), the Electronic Health Record (EHR) Incentive Program and Other Reporting Programs*. Organized neurosurgery is encouraged by the agency's efforts to address physician quality measurement reporting and improvement in a manner that is more relevant and meaningful to clinicians and patients.

**Summary of Comments**

- Neurosurgery is currently developing tools to help neurosurgeons adopt and incorporate systems of learning into their practice, which will improve quality of care, provider workflow, patient safety and efficiency. To meet the growing need for tools to measure and promote quality care, we have launched the National Neurosurgery Quality and Outcomes Database (N2QOD). In addition, the American Board of Neurological Surgery is incorporating clinical data collection into its Maintenance of Certification (MOC) program; thus providing a further avenue for ensuring the quality of care provided by neurosurgeons.
- The present mechanisms for reporting quality do not allow CMS to achieve its intended effect of promoting performance improvement. Furthermore, smaller specialties cannot possibly afford the time and expense to develop measures and measures groups using existing approved methodologies. It is therefore essential that CMS establish a process to streamline and align the many existing quality reporting programs and programs in development.
- The AANS and CNS envision a situation in which specialty societies, working within broad guidelines established by CMS for quality improvement activities, would develop specialty specific parameters for acceptable quality improvement projects that could ultimately be used across public and private sector programs, including PQRS, EHR, VBPM, MOC and those established by third party payers and other private sector organizations.

- CMS should establish a process so physicians are able to meet data reporting requirements under Medicare's quality improvement programs (including PQRS, EHR/meaningful use, and VBPM) through their participation in "deemed" quality reporting and measurement activities. Under this concept, CMS would "deem" participation in clinical data registries or other quality improvement programs such as regional quality collaboratives or enhanced maintenance of certification, as meeting CMS' quality data collection and reporting requirements.
- Rigorous national standards need to be adopted to ensure the collection of meaningful and relevant quality data, but a one-sized-fits-all approach will not help us achieve our national quality goals. There needs to be flexibility in quality improvement programs that recognizes the unique needs of various specialty groups and the patients they serve. Such flexibility is also necessary to encourage innovation and the development of novel approaches achieving healthcare quality and value over time.
- Meaningful quality programs take time and resources to mature — iterative development will be necessary to optimize these systems. Therefore, a tiered approach needs to be adopted, that initially rewards process and the development of meaningful quality infrastructures. Physician ranking programs should be de-emphasized, at least in the early stages of these programs.
- Neurosurgery believes that CMS can, and should, play a greater role in facilitating the use of clinical data registries by encouraging the development of standards for sharing/transmitting data between EHRs and registries. Presently, practices are forced to manually enter data into a registry because no streamlined process exists, and because of the proprietary nature of health information technology (HIT) products.
- Legal protections must be implemented to ensure that any performance report or data used for satisfying Medicare's quality programs will not be subject to discovery or admission as evidence in judicial or administrative proceeding without the consent of the physician.
- CMS can, and should, play a greater role in facilitating the use of clinical data registries by encouraging the development of standards for sharing/transmitting data between EHRs and registries.
- CMS needs to 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.

### ***Introductory Comments***

As a specialty, neurosurgery is currently developing tools to help neurosurgeons adopt and incorporate systems of learning into their practice, which will improve quality of care, provider workflow, patient safety and efficiency. However, if CMS continues to move forward with stringent, overly ambitious performance program requirements, the inability of specialists to tailor programs to their practice will hinder widespread adoption. We are therefore hopeful that CMS is now shifting course, and a new registry quality program, which allows for flexibility and for physicians to adopt objectives and measures that enhance and meet the needs of their practice, will result in improved outcomes. To this end, it is essential that CMS consider the input of individual specialty societies as the agency moves towards reforming the Medicare quality programs.

National medical specialty groups have the ability to define minimum standards for adequate participation in specialty-specific (or, when appropriate, multispecialty) performance improvement activities. Using those standards, specialty groups can encourage the development of a variety of quality

improvement programs that meet the needs of various healthcare stakeholders. Approved programs should include large national efforts appropriate for widespread use, along with pilot programs that incorporate potential enhancements in quality methodologies. When possible, specialty groups should foster the development of cooperative programs with stakeholder groups such as private payers to help promote the quality agenda and advance the science of care.

The development of new measures in the present system is complex, costly and time-consuming. Small specialties such as neurological surgery, cannot possibly afford the development costs of multiple measures groups based on the current standards. The arbitrary number of patients required to meet reporting standards does not allow for a statistically valid measurement of individual performance, nor does it promote true measures of risk-adjusted care. CMS must also keep in mind that many specialties are just beginning to develop the infrastructure necessary to embed meaningful quality programs into daily practice. Certain specialties, such as thoracic surgery, have had over 90 percent practitioner participation in comprehensive, nationally coordinated quality projects that have evolved over many years. Only a few specialties have accumulated the necessary data to allow for the development of robust risk-adjusted national benchmarks and the identification of those clinical variables most critical to predicting various outcomes. Therefore, at the present time, most specialty groups are unable to participate in quality programs that specifically focus on many issues of present importance to many stakeholders, such as shared decision-making and appropriate use of medical resources — although we are working towards these goals.

As CMS moves forward to align and refine its physician quality reporting requirements, we strongly recommend that the agency adopt a scaled approach to reporting so specialties that are in different registry development phases are eligible for a number of Medicare physician performance programs, such as PQRS and EHR meaningful use.

### ***Background Information on Neurosurgery's Registry***

The AANS and CNS are fully behind efforts to improve the quality of care that neurosurgeons deliver to our patients and we share with the public a sense of urgency and responsibility to meet the challenges of creating a sustainable healthcare system. To that end, 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. In support of this mission, the AANS in cooperation, with a broad coalition of other neurosurgical societies including the CNS, Society of Neurological Surgeons (SNS), and the American Board of Neurological Surgery (ABNS), created the NeuroPoint Alliance (NPA), a not-for-profit corporation, in 2008. The NPA coordinates a variety of national projects involving the acquisition, analysis, and reporting of clinical data from neurosurgical practice using online technologies. It is designed to meet the quality care and healthcare research needs of individual neurosurgeons and neurosurgical practices, national organizations, healthcare plans, biomedical industry and government agencies.

To provide tools to measure and promote quality care, the NPA collaborated with several national stakeholders to create an unprecedented program: The National Neurosurgery Quality and Outcomes Database (N<sup>2</sup>QOD). The Vanderbilt Institute for Medicine and Public Health (VIMPH) is the N<sup>2</sup>QOD's strategic partner, and the Resource Electronic Data Capture (REDCap™) is the database's software platform. This resource allows any U.S. neurosurgeon, practice group, or hospital system to contribute to and access aggregate quality outcomes data through a centralized, nationally coordinated clinical registry. The N<sup>2</sup>QOD is primarily designed to serve as a continuous national clinical registry for neurosurgical procedures and practice patterns along the lines of the very successful Society of Thoracic Surgeons' database. The primary goals of this registry are to:

- Participating N<sup>2</sup>QOD practice sites collect data related to the care of patients undergoing specified types of neurosurgical procedures at their facilities each week.

- This data is collected from the medical record, pre-and post-operative validated survey assessment procedures and interviews.
- That data is entered into a HIPAA secure, web-based portal (the REDCap™ database) and transmitted to the institution (VIMPH) serving as the registry for analysis
- VIMPH, among other activities, uses this data to 1) establish new national practice benchmarks for the quality of surgical procedures; and 2) provide reports back to the practice sites about the risk-adjusted quality of their services compared to the national benchmarks.
- The NPA is providing oversight for the entire project. Data transfer and data use are governed by Business Associate Agreements between the sites, NPA and VIMPH.

Over the course of last year, the N<sup>2</sup>QOD has been rapidly adopted by a variety of medium and large size practices representing academic and community groups across the country. Currently, N<sup>2</sup>QOD has signed contracts with over 30 practices (54 percent private practice, 45 percent academic practice; 70 percent urban, 30 percent sub-urban/rural; 17 percent 1-4 surgeons, 50 percent 3-8 surgeons, and 33 percent >8 surgeons). This represents nearly 200 surgeons, over 45 hospitals in approximately 25 states. In just ten months, this registry has become the largest cooperative spine registry in the nation, with over 3,000 patients enrolled and over 378,000 variables entered into the database. Ultimately, the registry will encompass all neurosurgical subspecialty areas, and it recently just added a new subspecialty module for cervical spine disorders, with the cerebrovascular disease module poised to come on-line in the near future.

Among many other services, VIMPH provides independent, third-party, continuous quality control for N<sup>2</sup>QOD and will conduct site audits to ensure the validity and reliability of collected data. VIMPH provides registry participants with continuous feedback, including automated weekly missing data reports and quarterly registry performance reports. Approximately 10 percent of the sites are audited. Compliance is extraordinarily high, with only 2.8 percent missing data. Based on the first year of operation, data extraction has been found to be accurate in 56/56 cases and case sampling and patient inclusion is accurate in 97 percent (113/116 audited cases)

In addition to the N<sup>2</sup>QOD project, the NPA also provides the portal for the NeuroLog database system developed by the ABNS. The NPA portal serves as the vehicle for candidate neurosurgeons who are in the process of board certification to submit practice data, or for ABNS Diplomates who are participating in Maintenance of Certification (MOC) to submit key cases required by ABNS. It also provides a tool for those participating in Medicare's PQRS to enter practice cases.

More information about the NPA, its projects and the REDCap™ system is available at: <http://www.neuropoint.org/> and <http://project-redcap.org/>.

### **Answers to CMS' RFI Questions**

With those introductory and background remarks in mind, we will now turn our comments to the specific questions posted by CMS in your RFI announcement.

#### **High Level Questions:**

1. *How are the current reporting requirements for the PQRS and the reporting requirements in 2014 for the EHR Incentive Program similar to the reporting requirements already established for the ABMS boards or to other non-federal quality reporting programs? How are they different? In what ways are these reporting requirements duplicative and can these reporting programs be integrated to reduce reporting burden on eligible professionals?*

Disparate and uncoordinated regional reporting efforts, including those required by private insurers, state licensing boards, individual hospital systems and specialty boards, represents inefficient, and mostly ineffective programs, to promote quality improvement. Truly efficient reporting systems should ideally

combine elements of central coordination (specialty-based), cost effective development of meaningful outcomes measures and alignment with related educational, payment and quality programs. Thus, aligning quality reporting efforts will be essential to reduce practical and economic burdens on individual physicians and physicians groups.

In that regard, organized neurosurgery is examining pilot programs with private payers and purchasers of care to align requirements of our quality improvement programs with evolving private incentive programs. With respect to board certification, the American Board of Neurological Surgery has recently embarked on a program to expand Part IV of Maintenance of Certification (MOC) to help achieve the board's goal of promoting quality care in neurosurgery. This effort, which is consistent with the strategic priorities of the American Board of Medical Specialties (ABMS), will involve the expansion of data collection from practice, and will promote the use of clinical registries and other quality programs. The ABNS will work to align its MOC program with emerging PQRS requirements. The process of Maintenance of Licensure (MOL) is also rapidly being aligned with participation in MOC programs. Finally, the Accreditation Council for Continuing Medical Education (ACCME) is now encouraging the development of CME programs that include participation in approved quality efforts. It is therefore likely that well-designed quality improvement programs in the future could help satisfy continuing medical education needs, private and public payer incentive programs, and in the processes of maintenance of certification and maintenance of licensure.

While the current PQRS and EHR programs are good examples of well-intentioned quality efforts, they have very little relevance to actual patient care. For example, most of the existing measures and measures groups have not been shown to substantively improve the therapeutic or cost-effectiveness of care and are irrelevant to the care of many patients, particularly those cared for by surgical subspecialists. Neurosurgery therefore urges CMS to promote flexibility in its performance program requirements so physicians participating in a specialty clinical data registry receive credit for multiple quality improvement activities. The current reporting requirements for the PQRS and the EHR Incentive Program are not in sync with reporting requirements established by the ABNS. Ideally, neurosurgery would like our members to receive credit for ABNS and other reporting requirements within the PQRS and EHR incentive programs, rather than being required to add another layer of quality measures to neurosurgery's own programs. We envision a situation in which specialty societies, working within broad guidelines established by CMS for quality improvement activities, would develop specialty specific parameters for acceptable quality improvement projects that could ultimately be used across public and private sector programs, including PQRS, EHR, MOC and those established by third party payers and other private sector organizations.

*2. Are there examples of other non-federal programs under which eligible professionals report quality measures data?*

There are several examples of non-federal programs under which physicians report quality measure data. One example that affects neurosurgical practice — in the areas of spine and cancer care — is the Blue Cross Blue Shield Association's (BCBSA) Blue Distinction® program. The program requires the collection of data to establish that a facility or a professional meets select quality and efficiency benchmarks. Another is the National Committee for Quality Assurance's (NCQA) Back Pain Recognition Program.

While neurosurgery has worked with these and other groups to help guide the programmatic parameters and quality reporting requirements, widespread participation remains elusive because the programs are not fully compatible with actual neurosurgical practice. The NCQA program failed to achieve meaningful participation, and was therefore retired in 2012. Likewise, the AANS and CNS have encouraged the BCBSA to recognize N<sup>2</sup>QOD participation as a mechanism to receive Blue Distinction®, but the group has thus far rejected our suggested partnership. CMS recognition of specialty-specific registries and other quality improvement programs should help pave the way for broader adoption in the private sector.

3. *What would be the benefits and shortcomings involved with allowing third party entities to report quality data to CMS on behalf of physicians and other eligible professionals?*

There are a number of benefits for allowing third-party entities to report quality data to CMS on behalf of physicians and other eligible professionals. First, as elaborated on above, it is essential to align and streamline quality measurement initiatives across different public and private programs, and utilizing a third-party entity, such as a clinical registry, will help achieve this goal. Reporting through a third-party could also reduce the measurement reporting burden and would allow reporting to be tailored to the needs of individual physicians and their patients. Capturing data through a registry also 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. Finally, quality measurement must move beyond single episodes or “snapshot” of care which focuses solely on clinicians and individual patients to a learning system with a broad focus. Using third-party registries will provide an opportunity to evaluate the care provided within an entire specialty, as well as at the individual physician level.

But a cautionary tale remains — CMS must recognize that medicine, as a whole, is in the relatively early stages of instituting widespread quality programs. No healthcare stakeholders have, as of yet, developed tools and programs which unequivocally produce improvements in the cost and therapeutic effectiveness of care. Whereas certain specialties such as thoracic surgery have had over 90 percent participation in their nationally coordinated quality projects over many years, other specialties are just now beginning to develop the infrastructure necessary to embed meaningful quality programs into daily practice. Thus, the process for implementing the use of third-party registry reporting will likely evolve over time to allow the profession to make the necessary adjustments.

It is also important to recognize that clinical data collection efforts vary among the specialties. Thus, while CMS may set-up some general parameters for reporting quality data through a third-party, the agency must also recognize specialty specific differences. Examples where this variation occurs include:

- validated quality measures;
- national benchmarks and the identification of key drivers of outcomes and costs;
- rapid-cycle learning;
- creation of methodologies that will allow for the meaningful application of accumulated knowledge for quality improvement; and
- education programs and the advance of clinical science.

Finally, safeguards must be put in place to ensure the accuracy of the data before it is reported to CMS or the public. Third-party entities that are collecting quality (as well as cost) data should be responsible for its appropriate use and disclosure. Each entity should have an established infrastructure for the collection and storage of secure patient-level data and physician performance measurement.

Safeguards should also be incorporated to ensure that the data is valid, comprehensible, and subject to effective methodologies for risk-adjustment and attribution of care. In addition, physicians should have the opportunity for review their data, with a corresponding appeals process, prior to public reporting. Finally, protections should be implemented to ensure that any performance report or data used as a basis for the report will not be subject to discovery or admission as evidence in judicial or administrative proceeding without the consent of the physician.

4. *What entities have the capacity to report quality data similar to those reported under the PQRS, Value-based Payment Modifier, and/or EHR Incentive programs? If these entities were to report such data to CMS, what requirements should we include in the reporting system used by such entities, including requirements to ensure high quality data?*

Registries, such as neurosurgery's N<sup>2</sup>QOD, should be capable of reporting quality data to CMS. However, as the profession redirects its focus from reporting administrative or process measures to reporting clinical outcomes data, we expect that Medicare's quality programs — including the PQRS, VBPM and EHR — will evolve to accommodate this new reporting paradigm. To have maximum confidence in the data, CMS should require registries to comply with a valid data auditing process to ensure completeness and accuracy and provide a basis for risk-adjustment models that appropriately account for patient characteristics. This is particularly important if payment differentials are at stake, as there may be intrinsic pressure to avoid patients with more complex medical conditions and/or limit the reporting of adverse outcomes. Additionally, it is advisable for registries to have trained data abstractors who can review data across all participating sites, thereby increasing the accuracy and reducing data collection errors and bias.

Finally, as stated above, to maximize accurate and high quality data, appropriate legal protections must be put in place — for individual physicians and groups, as well as for the registries.

*5. How should the CMS quality reporting programs change/evolve to reduce reporting burden on eligible professionals, while still receiving robust data on clinical quality?*

CMS should establish a process so physicians are able to meet data reporting requirements under Medicare's quality improvement programs (including PQRS, EHR/meaningful use, and VBPM) through their participation in "deemed" quality reporting and measurement activities. Under this concept, CMS would "deem" participation in clinical data registries or other quality improvement programs such as regional quality collaboratives or enhanced maintenance of certification, as meeting CMS' quality data collection and reporting requirements. Such an approach would recognize the wide variety of meaningful quality improvement activities, and would facilitate a more streamlined and efficient process through single data submission that meets Medicare's quality reporting requirements.

Working with the specialties, CMS should develop guidance and standards for physicians to qualify under the "deemed" status. Once again, it is critical that CMS recognize that most specialties are in the early stages of developing these quality improvement programs and numerous practical considerations stand in the way of rapid and ubiquitous implementation of quality programs. These factors mandate an intelligent, iterative approach to healthcare quality improvement that rewards innovation and recognizes the challenges inherent in the development of meaningful quality programs. The AANS and CNS therefore recommend that CMS adopt some basic standards for deeming quality improvement programs, while at the same time not setting the bar so high during the initial years to avoid excluding activities that may hold promise, but do not yet have an established record of achievement.

Concomitant with the development of these standards, we strongly recommend that CMS work to align the measures and format for reporting under the PQRS, meaningful use, and value-based payment modifier programs. To accomplish this, CMS must do the following: set common program objectives; align the measures; establish a common format for reporting; and test the common "measures" and "reporting format" to see if they can be implemented in an EHR system. CMS must also work to standardize its timelines for reporting to these various programs. Currently, the timelines, as well as the reporting deadlines, vary, which increases measurement burden and confuses physicians who are trying to participate and receive credit across all Medicare quality programs. Furthermore, to meet the PQRS, VBPM and the EHR Incentive program requirements, neurosurgeons must separately report to each of these. Ideally, this problem will be solved if CMS will allow neurosurgeons to receive credit for all these programs by participating in the N<sup>2</sup>QOD (or other clinical data registries).

Finally, while CMS has outlined a general framework of how the PQRS Group Reporting Option (GPRO) and Accountable Care Organization (ACO) quality reporting will align with the EHR Incentive Program, many details still need to be clarified and tailored to meet the needs of specialists. The current alignment

efforts of GPRO and ACO do not work for neurosurgeons due to the fact that virtually all the measures are tailored to primary care practitioners.

### **Reporting Requirements for Entities that Report via a Registry under PQRS or EHR Programs:**

As a general matter, while the AANS and CNS recognize the potential value of electronic health records to improve quality, there are considerable barriers to its widespread adoption, including high cost, lack of functionality (especially for specialists, who required much more tailored EHR systems) and interoperability challenges. In terms of interoperability, problems persist not just between physician practices and hospital systems, but also between EHR systems and clinical data registries. We believe that CMS can, and should, play a greater role in facilitating the use of clinical data registries by encouraging the development of standards for sharing/transmitting data between EHRs and registries. Presently, practices are forced to manually enter data into a registry because no streamlined process exists, and because of the proprietary nature of health information technology (HIT) products. This existing data sharing process is particularly challenging for solo and small practices; thus preventing many from participating in registries. Finally, the manual data entry process requires a full-time or half-time employee, which is an added cost that most practices cannot easily absorb.

Our comments will now focus on the specific questions raised in the RFI.

1. *What types of entities should be eligible to submit quality measures data on behalf of eligible professionals for PQRS and the EHR Incentive Program? Examples might include medical board registries, specialty society registries, regional quality collaboratives or other entities. What qualification requirements should be applicable to such entities?*

The AANS and CNS certainly agree that specialty-sponsored clinical data registries, national medical specialty boards and regional quality improvement cooperatives are well-suited to report quality data. However, we cannot overemphasize that CMS must recognize a *process*, as opposed to an inflexible set of procedures or list of entities, in the early stages of national quality improvement programs. In our own specialty, we estimate that it will take at least three years for neurosurgery to develop a full spectrum of data collection vehicles and relevant quality measures for use across all subspecialty areas. Perhaps most importantly, it will take at least 18 months to two years after the initial roll-out of each new subspecialty module to accumulate enough data to allow for the development of risk-adjusted national benchmarks and the identification of the principal variables that drive neurosurgical outcomes. Furthermore, it will be easier in the early stages of these projects for determinations to be made about the performance of physicians *groups*, as opposed to the performance of individual physicians. This is because meaningful, risk-adjusted, determinations of the relative performance of various physicians cannot be made without the accumulation of a critical volume of provider specific data, which, depending on the frequency of event occurrence associated with the clinical variable in question, can vary from as few as 30 patient encounters to as many as hundreds of patient encounters.

At some point in the future, our efforts to accumulate high quality data related to the care of patients with various medical and surgical disorders will facilitate a variety of essential quality improvement projects, including those related to shared decision-making and the development of appropriate use criteria, along with focused educational and scientific programs. All stakeholders must embrace the reality that our quality objectives can only be achieved by recognizing and rewarding intelligent, long-term, specially directed strategies for achieving quality care, the conspicuous demonstration of those strategies, and objective evidence of growth and evolution along the path of quality improvement.

As mentioned above, we believe that any system that rewards risk-adjusted quality must be fairly constructed and open to outside analysis. Such standards will be essential to allow for the development of programs that truly reward quality, as opposed to penalizing individuals who choose to participate in the care of the sickest patients and most complicated medical conditions. Standards to ensure the veracity of submitted quality data, which necessarily will require programs such as routine data auditing,

will increase stakeholder confidence in the systems, improve physician “buy-in” and prevent certain groups from “gaming the system” by submitting information that does not accurately reflect the conditions and outcomes of care.

2. *What criteria should we require of entities submitting quality measures data to us on behalf of eligible professionals? Examples might include transparency of measures available to EPs, specific frequency of feedback reports, tools to guide improvement efforts for EPs, ability to report aggregate data, agreement to data audits if requested, etc.*

The AANS and CNS recommend that in order to participate in such a system, national registries should adhere to the following aspects of a deemed registry:

- demonstrate improvement in care, including published, peer-reviewed evidence for clinical improvement in care;
- focus on outcomes or processes that are closely linked to outcomes; have the ability to compare care delivered across multiple providers or delivery system (i.e., not a single report from an electronic health record);
- offer the capability for state, regional or national aggregation so that results can assess variations in care and address population health and variability in a comparative manner;
- provide a registry infrastructure that is audited, has demonstrated methodological rigor, reliability and data validity; and
- allow for data sharing agreements between CMS and deemed national medical specialty society registries that will not convey ownership of registry data to CMS, i.e. the specialty registry will retain ownership of reported data.

3. *Should reporting entities be required to publicly post performance data?*

Given the fact that many medical specialties are in the beginning phases of developing meaningful quality improvement programs, we strongly believe it is premature to publicly post performance data. The necessary processes and safeguards required to make public reporting meaningful for physicians, patients and the public requires time, resources and careful consideration. CMS should provide the necessary lead time through a scaled or tiered approach in rulemaking that establishes criteria for moving toward accurate and meaningful public reporting of performance information. Only the acquisition of large amounts of high quality, risk-adjusted, practice data over time will allow specialty groups to develop meaningful benchmarks for quality and also define the quality variables most likely to determine patient outcomes. In addition, the widespread institution of quality programs will initially create disruptions to practice and increase the cost of delivering care. The practical and economic burdens on an individual physician who adopt these methods (particularly in the early stages) must be taken into account.

In the first tier, 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 recognize physicians in some comparative fashion, but we are not yet there.

Furthermore, neurosurgery does not support public rankings of physicians or physician group practices because, in general, it provides little value in either informing the public or promoting the provision of quality care unless they reflect substantial and verifiable differences in quality of care. It is best to consider a system in which the vast majority of providers who are engaged in continuous quality improvement are given a simple, standard quality ranking for the care that they provide. On the extremes of the quality spectrum, individuals and groups that are routinely achieving poor quality of care

or (perhaps more importantly) not engaged in meaningful quality improvement efforts might be assigned a lower quality ranking.

*If* ranking systems are adopted, then the methods used to determine those rankings must be unambiguous and made widely available to all stakeholders. Risk-adjusted standards for individual physicians need to be based on fair and statistically valid measures of performance. In particular, standards must be in place to ensure the accuracy of submitted data. If our mutual goal is truly to improve the quality of care, then medical professionals should be provided access to their rankings before that information is made public. They should also be afforded the opportunity to understand those quality rankings (including the ability to review the data that went into the determination of the rankings) and address any deficiencies in care. If physicians fail to address obvious deficiencies in care, then the public release of information related to that lack of accountability may ultimately be justifiable.

Finally, physicians need to be afforded appropriate legal protections, as any large national quality programs could be subject to errors in the analysis of reporting data. In that regard, physicians should be able to appeal their performance information based on a number of predetermined factors, such as inaccuracies in the data used to determine performance and/or faulty methods of data analysis. It is also important that CMS make clear that these quality reporting programs are in no way creating a new national standard of care for purposes of medical liability.

*4. Should CMS require an entity to submit a yearly self-nomination statement to participate in PQRS?*

Neurosurgery does not recommend that entities be required to submit a yearly self-nomination statement in order to participate in PQRS. Rather, similar to the current processes for qualifying registries under the PQRS program, CMS should only require an initial letter of intent, followed by a completed application. CMS should also consider a three or more year deeming period. By eliminating additional administrative burdens, potential “deemed” entities would be able to focus on the development, testing, and use of methods that strengthen their activities around quality measurement and improvement. Registries should also be able to make updates based on information learned from data collection.

*5. What should be included in the data validation plan for these reporting entities?*

Reporting entities should establish and provide documentation of a data validation plan. Within the plan, entities should have to disclose their standards to ensure the veracity of submitted quality data, as well as their audit plan. The current CMS PQRS Validation Plan Protocol also includes items such as verification of an entity’s tax identification number and its ability to send an accurate QRDA or XML file. The N<sup>2</sup>QOD recently went through this process, and found it more or less reasonable. We also note that each registry may have slightly different processes in place for validating the data, and CMS should therefore recognize the validity of multiple approaches to data validation within an overall validation framework.

*6. If CMS provided a reporting option for PQRS and/or the EHR Incentive Program through such entities, what specification should CMS use to receive the quality data information (for example, Quality Reporting Document Architecture [QRDA] 1 or 3, XML, other)?*

If third party entities are provided a reporting option for PQRS and/or the EHR Incentive Program, they should also be provided clear guidance for what specification standard is required for CMS to receive the quality data information. Additionally, neurosurgery recommends that regardless of which standard is designated to be used for the reporting of quality data information, that the standard be applied across all CMS program, and be consistent with the EHR certification program. Until CMS provides further clarification on its intended use for the submitted information, it is difficult for us to further elaborate on the details.

7. *Should data submission timelines for these reporting entities be modified so that the submission timeframes for these quality reporting programs are aligned? For example, PQRS qualified registries are required to submit quality measures data once, within 2 months following the reporting period. How much time are reporting entities outside of PQRS afforded to submit quality measures data? What challenges do reporting entities face in reporting data according to current timeframes?*

A consistent timeline is ideal and will help promote alignment, but this requirement may force registries to alter their practices. Not all collection entities will be ready for immediate data transmission to CMS. Therefore, neurosurgery urges the adoption of a scaled approach with regard to how and when CMS requires the submission of quality data from “deemed” activities. The timelines also may be highly variable depending on the individual registries. For example, the N<sup>2</sup>QOD is currently evaluating outcomes up to a year following the performance of a surgical procedure. Data is collected throughout that year at various intervals. Individual practice sites are continuously working with our registry partner, VIMPH, to ensure the completeness and accuracy of data. Given the goal of evaluating quality over a period of time, rather than for each individual episode of care at a given point in time, this is a question that will need further consideration to fully examine all the ramifications.

Since not all third-party quality data collection activities will be immediately ready to transmit data to CMS, we recommend that for initial participation, third-party entities/activities not be required to transmit data to CMS. Rather, these “deemed” entities should have, at a minimum, a year or longer (depending on their current infrastructure) to create, develop, and implement sound data collection and transmission processes. Such a transition period is essential as it takes years to collect and analyze data in an accurate, timely and robust fashion. Therefore, it is essential that CMS build in realistic timelines into any “deeming” status program. With time, additional modules can be built. Additionally, physicians should not have to report on their entire patient population to be considered a successful participant in a third-party quality data reporting activity. Rather, a report on a statistically valid sample of patients should be sufficient.

We encourage CMS to establish realistic standards for “deeming” given that not all third-party quality data activities are starting from the same point in their data capture, calculation, and reporting. CMS should focus on building upon and capturing the significant quality improvement efforts already underway by physicians nationally as well as local initiatives.

8. *What oversight should be in place to ensure that data is submitted and calculated properly by entities?*

Reporting entities should establish and provide documentation of an audit plan to ensure the accuracy of data. As mentioned above, CMS should set some general criteria for ensuring the accuracy of data, but should allow some flexibility for each registry to adopt an approach that best fits with its own system. CMS can review this process through the periodic validation plan program. It should be also noted, that CMS has at its disposal the full force and weight of Medicare’s fraud and abuse laws and regulations. Thus, physicians who are attesting to CMS that they are reporting quality data to a data registry or other approved third-party effort, are in essence warranting that they are complying with any requirements set forth by CMS for compliance with these programs. This should be a powerful incentive for physicians to ensure the accuracy of their data. This, coupled with a periodic review of the third-party entity’s data collection plan, should help ensure that the data that is submitted is accurate and calculated properly.

### **Selection of Measures for Registry Reporting under PQRS and EHR Programs for 2014 & Beyond:**

1. *Should CMS require that a certain proportion of submitted measures have particular characteristics such as being NQF-endorsed or outcome based?*

Well-designed quality improvement programs can, and should, encourage innovation and monitor the development of novel approaches to quality improvement. This cannot happen, however, if physicians

are subjected to overly prescriptive and one-size-fits-all requirements. Furthermore, the current measure approval process is cumbersome, expensive and time consuming, and often serves to hinder innovative quality improvement efforts. Thus, neurosurgery is not generally supportive of the NQF having a direct role in determining or endorsing outcomes measures as a prerequisite to CMS recognizing physician registry participation. While we appreciate the role that the NQF is playing in the quality improvement space, the specialties themselves are in the best position to determine appropriate outcomes measures relative to the patient populations they serve.

### **Registry Measures Reporting Criteria:**

Any new reporting policies for the PQRS, VBPM and EHR meaningful use programs should be meaningful and not overly prescriptive. As previously mentioned, there should be a transition period so registries can evolve. Furthermore, registries need to have the flexibility to tailor data collection efforts to the specific patient population that is subject to evaluation and measurement.

- 1. If CMS proposed revised criteria for satisfactory reporting under PQRS and for meeting the CQM component of meaningful use under the EHR Incentive Program, how many measures should an eligible professional be required to report to collect meaningful quality data?*

This very question seems to miss the entire point of these new efforts to redirect Medicare's current quality improvement program. Rather than focusing on a set 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 set broad criteria and a menu of options available for compliance. The specialties themselves can then implement programs such as clinical data registries, enhanced maintenance of certification, continuing medical education and regional quality collaboratives. The number and type of specific measures will necessarily vary depending on the quality improvement program. It is absolutely 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 PQRS and EHR program compliance purposes.

- 2. If CMS were to align reporting criteria with reporting requirements for other non-federal reporting programs, in future years, should the agency propose to require reporting on a different number of measures that what is currently required for the PQRS in 2013 and the EHR Incentive Program under the Stage 2 final rule or should the non-federal reporting programs align with CMS criteria?*

Alignment of quality reporting efforts is essential to reduce practical and economic burdens on individual physicians and physician groups. Neurosurgery strongly advocates that CMS work to identify harmonized reporting criteria within its programs and for the agency to encourage other non-federal programs to do the same. Organized neurosurgery is examining pilot programs with private payers and purchasers of care to align the requirements of our quality improvement programs with evolving private incentive programs. However, as stated above, flexibility is key and we urge CMS to move away from the notion that physicians must comply with a fixed set of measures to satisfy quality improvement requirements.

- 3. For PQRS, should eligible professionals still be required to report quality measures data on a certain percentage of their applicable patients, such as 80 percent, for 2014 and subsequent years? Or, should CMS require that eligible professionals report on a certain minimum number of patients, such as 20, rather than a percentage?*

The AANS and CNS do not support fixed numeric requirements for reporting quality data. We do support, however, using a statistically valid sample size to evaluate neurosurgeon compliance with

Medicare's quality programs. Medicare's current reporting requirements for both the PQRS and EHR programs are arbitrary and have not been shown to substantively improve the therapeutic or cost-effectiveness of care. Furthermore, an arbitrary number of patients required to meet reporting standards does not allow for a statistically valid measurement of individual performance, nor does it promote true measures of risk-adjusted care. Specialty groups need to be given the ability to define minimum standards for adequate participation in specialty-specific (or when appropriate, multi-specialty) performance improvement activities.

Neurosurgery, therefore, strongly urges CMS to avoid the development and implementation of a one-size-fits-all data reporting system. The intention behind section 601(b) of the "American Taxpayer Relief Act" is to provide physicians with greater flexibility to report on and receive credit for their quality improvement activities relevant to their practice and patients.

### **Miscellaneous Issues:**

As noted above, the AANS and CNS are fully behind efforts to improve the quality of care that neurosurgeons deliver to their patients and 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 remove unnecessary regulatory barriers. One area in particular that has somewhat hindered our progress are the current regulations for informed consent.

### ***Informed Consent Requirements for Registries Performing Quality Improvement Activities***

Again, registries are valuable tools that support evidence development, provider performance assessment and comparative effectiveness studies, among other important quality efforts. Unfortunately, while many healthcare providers have embraced these registry efforts, 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." This situation is complicated by a fundamental lack of consistency in local interpretations of Common and Privacy Rules provisions relevant to clinical registries.

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. 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 a requirement for informed consent exists, patients who are willing to give consent often comprise a non-representative subset of the population of interest. Several national groups have now pointed out the extent to which traditional research requirements, such as informed consent, are a significant hindrance to quality improvement efforts.

Clearly, there is a need for regulatory agencies to establish appropriate standards for quality improvement activities that will both adequately protect patients and not unnecessarily burden quality improvement efforts. Until that guidance is forthcoming, it is inevitable that significant variability will persist in the local interpretation of guidelines relevant to clinical quality initiatives. Furthermore, it will be difficult, if not impossible, for clinicians to participate in the full spectrum of quality efforts now mandated by regulatory bodies in the public and private healthcare arenas.

The difficulties posed by a designation of “human subjects research” to quality efforts cannot be overstated. In particular, the requirement for informed consent creates almost insurmountable barriers to the practical implementation of quality efforts. Since clinical registries rely on continuous, prospective collection of data to produce longitudinal evaluations of patient outcomes, unnecessary application of informed consent and other patient authorizations could significantly compromise the validity of data assessments and create significant impediments to generating data of adequate quality to drive practice improvement. 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 end result is difficulty achieving serial enrollment, selection bias and tracking of non-representative populations, which produces data that may be of little value.

The AANS and CNS strongly believe that the regulatory agencies need to establish appropriate standards for quality improvement activities that will both adequately protect patients and not unnecessarily burden quality improvement efforts. Until that guidance is made available, it is inevitable that significant variability in interpreting and applying the Privacy and Common Rules will persist. Furthermore, it will be difficult, if not impossible, for clinicians to participate in the full spectrum of quality efforts now being mandated by regulatory bodies in the public and private healthcare arenas.

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. Therefore, we request that:

- 1) CMS 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.
- 2) That explicit language be included 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).

## **Conclusion**

Quality reporting requirements in neurological surgery are evolving. At the present time, our national quality programs are voluntary in nature. To date, our specialty has developed and implemented comprehensive programs related to the collection and analysis of practice data related to the treatment of patients with cervical and lumbar spine disorders through our national registry, the N<sup>2</sup>QOD. Within the next 6 to 12 months, neurosurgery anticipates that data from these spine related programs will mature sufficiently to allow for the development of national performance benchmarks. In addition, we anticipate the ability to identify the key variables that drive outcomes related to the neurosurgical treatment of most common spine disorders. The N<sup>2</sup>QOD effort will soon expand to other neurosurgical subspecialty areas, such as cerebrovascular, and we hope that these programs will be ready for implementation sometime in 2014. Therefore, a transition period is needed before CMS moves from pay-for-reporting to pay-for-implementation and outcomes.

Neurosurgery believes that CMS should revisit and scrap the current quality improvement programs — including PQRS, EHR and VBPM — and replacement them with a new system for recognizing specialty-based programs through a “deeming” approach. Such a system should allow for the recognition of

quality data reporting activities across all of the Medicare physician performance programs, thereby reducing the regulatory burdens on physicians and moving the program to one that will be more meaningful for patients and physicians alike. In this new paradigm, CMS must recognize that the development and maintenance of quality measurement and improvement tools are not inexpensive endeavors. To date, the financial burden has been absorbed by physicians and their specialty societies, but small specialties such as neurological surgery cannot possibly afford the development costs associated with multiple irrelevant measures and reporting requirements. We therefore encourage CMS to invest in an infrastructure that supports the development and implementation of clinical data registries and other quality improvement tools identified by the profession, rather than putting more resources into ineffective and meaningless quality improvement programs.

The AANS and CNS are committed to working with CMS to improve Medicare's quality improvement programs. Of paramount importance is what we hope is our shared goal to make the programs worthwhile for physicians and meaningful for patients. Thank you for considering our comments. In the meantime, if you need further information or have any questions, please don't hesitate to contact us.

Sincerely,



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