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June 30, 2014

Ms. Marilyn B. Tavenner, Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1607-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SQ
Washington, DC 20001

Re: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year (FY) 2015 Rates; Quality Reporting Requirements for Specific Providers

Dear Ms. Tavenner,

On behalf of 4,000 practicing neurosurgeons in the United States, the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) appreciate the opportunity to comment on the above referenced Centers for Medicare and Medicaid Services' (CMS) hospital inpatient prospective payment system proposed rule.

SUMMARY OF COMMENTS

Proposed Changes to MS-DRG Classifications and Relative Weights

- **Back and Neck Procedures.** The AANS and CNS support the proposal to delete MS-DRGs 490 and 491 and create three new back and neck MS-DRGs to better describe these procedures
- **Add-On Payments for New Services and Technologies.** The Responsive Neurostimulator (RNS) System represents a significant clinical improvement for epilepsy patients who are refractory to medical or surgical treatment, and therefore, the AANS and CNS agree that this new technology meets the "substantial clinical improvement criterion" set forth by CMS.
- **Proposed Medicare Code Editor (MCE) Changes.** The AANS and CNS support the proposal to removed intracranial-extracranial bypass procedures from the non-covered procedure list.

Other Proposed Decisions and Changes to the IPPS for Operating Costs

- **Hospital Readmission Reduction Program.**
 - The AANS and CNS are pleased that CMS has not proposed to add any new measures to the HAC Reduction Program or the HAC/Present on Admission Program.
 - Neurosurgery believes that CMS must exclude readmission for conditions that are related to the original admission.

- The AANS and CNS strongly suggest that CMS take into consideration recommendations in the recent NQF report on Risk Adjustment for Socioeconomic Status or Other Sociodemographic Factors.
- **Hospital-Acquired Conditions (HACs)**
 - The AANS and CNS appreciate CMS' decision not to expand the number of measures used under the program in 2016 and cautions against further expansion in 2017.
- **Hospital Value-Based Purchasing Program**
 - The AANS and CNS do not support the addition of the MRSA and *C. difficile* measure in the program due to the lack of measure specifications.
 - Patients with a diagnosis of cancer, brain tumors or trauma should be excluded from the AHRQ PSI-12 (Postoperative PE/DVT rate) measure because these patients represent a very high-risk group due to their underlying medical condition. Emergent cases and patients with a prior history of PE or DVT should also be excluded.
 - The AANS and CNS have provided details for a number of measures proposed in future years. In particular, we emphasize issues surrounding lumbar spinal fusion, which are significantly different and more complex than other procedures with episode-based cost measures such as hip and knee procedures.
- **Medicare Payment for Graduate Medical Education.** The AANS and CNS continue to support GME funding for the full course of residency. In particular we believe the transfer of residency slots from closed hospitals should not be limited to hospitals that are only increasing primary care and general surgery slots
- **Medicare Payment for Short Hospital Inpatient Services.** The AANS and CNS support clear criteria from CMS for inpatient designation, but we have a number of concerns about the proposal. Most importantly, we emphasize that physician work should be accurately measured and patient financial liability should be appropriately limited, regardless of site of service or how the hospital bed is categorized.

Proposed Quality Data Reporting Requirements

- **Hospital IQR Program**
 - The AANS and CNS support efforts to minimize reporting burden by removing topped out measures from the program.
 - Due to lack of evidence to support the measures, the AANS and CNS urge CMS to reconsider its proposal for including the Hospital 30-day, All-Causes Readmission Measures.
 - The AANS and CNS urge CMS to begin collecting stroke severity in the form of NIHSS and work to revise the Stroke Mortality measure to include adjustment for stroke severity.

DETAILED COMMENTS

Proposed Changes to MS-DRG Classifications and Relative Weights

Changes in MS-DRG Classification

- **Back and Neck Procedures.** CMS is proposing to delete MS-DRGs 490 and 491 and replaced them with the following MS-DRGs:

- Proposed new MS-DRG 518 (back & neck procedures except spinal fusion with MCC or disc device/neurostimulator)
- Proposed new MS-DRG 519 (back & neck procedures except spinal fusion with CC)
- Proposed new MS-DRG 520 (back & neck procedures except spinal fusion without CC/MCC)

The AANS and CNS agree that the analysis presented by CMS seems to indicate that a patient's severity of illness is captured more appropriately with the new MS-DRGs and meets established criteria for creating new MS-DRGs. We hope that the new categories will allow CMS to assess utilization of resources for these services and that the agency will continue to assure that important innovation in device dependent neurosurgical procedures is adequately accounted for and reimbursed appropriately.

Add-on Payments for New Services and Technologies

- **Responsive Neurostimulator (RNS) System.** The AANS and CNS agree that the Responsive Neurostimulator (RNS) System represents a substantial clinical improvement for patients who are medically refractive or not candidates for surgery. We presented these views at the Food and Drug Administration's (FDA) Neurological Devices Advisory Panel on February 22, 2013 and in our comments on the IPPS proposed rule last year. A significant number of epilepsy patients, possibly over a third of these individuals, will not find significant relief from medications. Some of these patients may be helped by traditional surgery, but that carries risk and discomfort to the patient, as with any surgery. The likelihood that people with intractable epilepsy will be helped by a traditional surgery is perhaps less than ten percent, leaving a large portion of patients with either medically or surgically untreatable epilepsy.

Neurostimulation offers hope for these patients, and we believe for those patients, RNS offers substantial clinical improvement and meets the "substantial clinical improvement criterion" set forth by CMS. We support the comments submitted by the American Society for Stereotactic and Functional Neurosurgery (ASSFN) and other stakeholders indicating that the RNS system offers significant clinical improvement over existing options for epilepsy patients, including Medicare patients, and is a reasonable and durable treatment for these patients.

Proposed Medicare Code Editor (MCE) Changes

- **Extracranial-Intracranial (EC-IC) Bypass Surgery.** For FY 2015, CMS is proposing to remove extracranial-intracranial (EC-IC) bypass surgery from the "Noncovered Procedure" edit code list for Version 32.0 of the MCE. This procedure is identified by ICD-9-CM procedure code 39.28 (Extracranial-intracranial (EC-IC) vascular bypass). We agree with CMS that because of the complexity of appropriately classifying the circumstances under which the EC-IC bypass surgery may be considered reasonable and necessary for certain conditions, the Medicare non-covered procedure edit for EC-IC bypass surgery should be removed.

Other Proposed Decisions and Changes to the IPPS for Operating Costs

Hospital Readmission Reduction Program

The AANS and CNS appreciate CMS' decision not to expand the number of measures used under the program in 2016 and cautions against further expansion in 2017. While we understand that excess readmissions can be an indicator of poor quality of care and wasteful spending, we continue to urge CMS to carefully consider the risk-adjustment methodology used for measures in this program. Hospital readmissions for chronic illnesses are often related to pre-existing conditions, education level and socioeconomic status — all which greatly affect outcomes. The outcomes for patients with chronic illnesses vary widely, and hospitals and physicians will be unjustly penalized for readmissions that are

outside of their control. Given these concerns, we strongly recommend that CMS take into consideration the recent NQF report on Risk Adjustment for Socioeconomic Status or Other Sociodemographic Factors, which recommends that measures should be stratified on the basis of relevant sociodemographic factors when used in analyses by providers, policymakers, researchers, and the public.

CMS also must exclude readmission for conditions that are related to the original admission, such as readmission due to ongoing care for patients suffering traumatic injury and requiring staged operative therapies. While this has been a longtime concern of organized neurosurgery, we are encouraged by CMS' work to review and update its Planned Readmission Algorithm. These improvements, based on validated studies, will result in more accurate classifications of planned versus unplanned procedures and conditions.

CMS Proposals Related to Hospital-Acquired Conditions (HACs)

The AANS and CNS appreciate that CMS is not proposing to add any new measures to the HAC Reduction Program or the HAC/Present on Admission Program. Organized neurosurgery has long expressed concerns about these programs, which take an all-or-nothing approach and do not account for situations where HACs occur despite adherence to the best available evidence. As a result, hospitals may be subject to arbitrary penalties due to payer mix, socioeconomic strata of the patient population, degree of patient comorbidity burden, and other factors outside of the control of the facility. Furthermore, the two programs, together, seem to subject hospitals to double jeopardy and their duplicative nature seems to contradict CMS' goal of streamlining federal quality reporting initiatives.

For the HAC Reduction Program, specifically, CMS proposes to use a standardized electronic composite measure of all-cause harm in future years in addition to or in place of claims-based measures assessing HACs. While we appreciate CMS' effort to transition away from claims-based measures and towards more robust sources of data, we caution against all-cause harm composites, which have not yet been fine-tuned or well tested, may exacerbate issues with existing individual HAC measures, and do not provide a level of granularity that is useful or meaningful to consumers.

Hospital Value-Based Purchasing Program

- **Measures Proposed for 2017.** CMS proposes to add the Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia and the *Clostridium difficile* (*C. difficile*) standardized infection ratio measures to the Hospital VBP for FY 2017. As we have noted in the past, it will be important to control for known regional variation in the infection rates. To compare a hospital in an endemic area, to one in a non-endemic area, is a flawed approach and the rates will not be reflective of practice. Hospitals caring for high-risk populations may be unintentionally targeted or incentivized to limit access to care to such high-risk patients. As an alternative, it may be more cost-effective and appropriate to include measures that focus on best practices and guidelines for patients who contract MRSA or *C. difficile*.

For these measures, it also will be important for CMS to differentiate community-acquired from healthcare-associated strains. Many patients enter the hospital already colonized. And while pre/peri-operative antibacterial prophylaxis is an important and appropriate component of surgical site infection prevention, it may be associated with adverse effects, such as *C. difficile* infection. Hospitals should not be penalized for these situations. In addition, for *C. difficile*, data should be broken down by the number of surgical patients in the hospital and the type of operations.

- **Measures Proposed for 2019.** For FY 2019, CMS also proposes to continue use of the Patient Safety for Selected Indicators Composite measure (PSI #90). This measure is currently used in the VBP program. As noted last year, the AANS and CNS do not believe that this composite should be

included in the Hospital VBP program due to serious flaws in its component measures. For example, the composite includes the use of PSI-15, accidental puncture or laceration, which we do not support due to lack of clarity as to what constitutes an “accident” and coding for accidental puncture is not uniform. Often punctures or lacerations are incorrectly coded as “accidental” when the puncture or laceration was part of the surgery. Coding is neither consistent nor reliable when it comes to this measure, which calls into question the validity of this component of the PSI set.

The PSI-90 composite also includes PSI-12 (Postoperative PE/DVT rate), which includes a small number of exclusions and relies on a risk adjustment criteria that could lead to potential unintended consequences (e.g. the measure could tag every LE thrombophlebitis, whether or not it is clinically significant and in-turn produce useless data that will not result in quality improvement). The AANS and CNS believe it is critical that patients with a diagnosis of cancer, brain tumors or trauma should be excluded from this measure. These patients represent a very high-risk group due to their underlying medical condition. Without the trauma exclusion, facilities that treat a large amount of spinal cord injury patients will automatically be adversely affected and will not be able to compete with non-trauma facilities. Emergent cases and patients with a prior history of PE or DVT should also be excluded from this measure. The measure also includes not otherwise specified (NOS) codes. This includes superficial thrombosis, which we do not believe is appropriate to measure and use for accountability purposes since there are predictors of DVT that are outside of the control of the facility.

- **Measures Proposed for Future Years.** For future years of the VBP, CMS proposes to consider shifting to more granular episode-based payment measures in addition to or in place of the Medicare Spending per Beneficiary (MSPB) measure currently used to measure cost. Organized neurosurgery has long opposed the use of the MSPB measure in both inpatient and physician programs due to insufficient granularity. This measure provides very little useful information related to value and relies on poor risk-adjustment and attribution methodologies. Furthermore, there is a general lack of evidence demonstrating a link between overall spending and quality. The AANS and CNS support a shift to more granular episode-based payment measures *in place of* the MSPB measure so long as episode-based measures are evidence-based, adequately risk-adjusted (including for socio-demographic factors, which is currently not a component of the MSPB measure), properly attributable, and well-tested. If CMS does move in this direction, we highly encourage it to reduce the weight of the efficiency domain during initial implementation of these new measures until CMS and providers have adequate experience using them.

In laying out this proposal, CMS notes that under an episode-based cost measure, unlike under the MSPB measure, if a beneficiary is readmitted for a condition that is clinically related to the index admission during the 30 days following discharge from an index admission, that would trigger another separate episode-based cost measure episode (e.g., if a beneficiary were discharged after a hip replacement, then readmitted for a revision 15 days later, the payments associated with the revision would count toward the initial hip replacement/revision episode and would also trigger a new hip replacement/revision episode where the index admission would be that for the revision). We caution against this proposal, which seems to hold the hospital accountable twice for the same thing and ignores the fact that transfers to higher acuity facilities are difficult to attribute. CMS should walk and not leap forward with cost of care measures. It should first start with single, distinct episodes and only after adequate testing consider linking consecutive episodes, if doing so results in meaningful and accurate information for both the patient and provider.

In proposing a shift to episode-based cost measures, CMS identifies specific potential episodes, including **lumbar spine fusion/re-fusion**. Organized neurosurgery has been integrally involved with various efforts to define episodes around spine procedures, including fusion. Since various stakeholders and CMS contractors have worked on these definitions over the years, we question who would be responsible for defining episodes of care for cost measurement purposes and what process

CMS would use to select the most appropriate definition. For example, we previously worked with HCI3 and convinced them to look more carefully at CPT coding and to restrict their initial effort at developing episodes to a tightly defined patient set (i.e., single level fusions and single level laminectomies). We encourage CMS to take the same approach.

The AANS and CNS also would like to remind CMS that while the inclusion of post-acute care costs in an episode may result in the capturing of a much better global appreciation of the cost of care, it may also skew the results due to greater impact of patient comorbidities, case severity, and other factors. The most expensive post-acute care expense is inpatient rehabilitation care, which now gets attributed to the initial facility. While the intent is to provide hospitals with a stronger incentive to efficiently manage post-acute care services, we are concerned that this could be a perverse incentive to not use inpatient rehabilitation services. Furthermore, while the costs of inpatient rehabilitation are realized within the 30-day window of the episode and attributed to the index facility/procedure, the benefits of the inpatient rehabilitation stay may not be realized for months and may be hard to quantify. This could result in unintentional incentives to discharge patients home, with home physical therapy (PT) instead of discharging them to a SNF with inpatient PT. Facilities that deal with a high percentage of patients that need rehabilitation services (e.g., spinal cord injury centers) could face a particularly difficult hurdle.

Other procedures that CMS proposes to apply episode-based cost measures to, such as knee and hip replacement, are much more straightforward. There are only so many ways to do these procedures and the procedures have less variation than what can be done within the lumbar spine. For example, the hip and knee measures each deal with a single joint while at each lumbar level, there are 3 joints: a disc and 2 facets. With 5 lumbar levels, this results in a total of 15 separate joints that are treatable by anterior, posterior, lateral, or any combination of the above. Hence, using a one size fits all MS-DRG trigger is going to result in very poor data. The breadth of treatments within that DRG is just too broad. As anticipated, in CMS' retrospective data the standard deviations in the lumbar fusion cases are higher than in any of the other categories.

Furthermore, the number of CPT codes included in the lumbar spine segment is so extensive that they essentially cover all thoracolumbar spine procedures. This is going to muddy the data. A facility that routinely performs single level fusions in patients that go home post-operative day (POD) 3 is going to be directly compared to a facility that routinely performs osteotomies and 10 level thoracolumbar reconstructive procedures where the patients are in the ICU for 2 days and are discharged to inpatient rehab POD 8, with the inpatient rehab counting against the second facility. Using the present architecture, this VBP metric is more likely to identify facilities that do more complex spine reconstructions, not facilities that provide inefficient or low value care.

Payment for Indirect and Direct Graduate Medical Education (GME) Costs

Neurosurgery is a highly technical and rapidly evolving specialty which is based on neurological principles that require years to acquire and organize into a knowledge base that is necessary for sound surgical decision-making. The development of the technical expertise necessary to perform procedures in a safe and effective fashion also takes years to refine. The AANS and CNS continue to believe that Medicare GME should fully fund the entire length of training required for initial board certification, which in neurosurgery's case is six to seven years. We are concerned about the projected shortage of physicians, both for primary care and specialty care. We believe that policies to redirect funding from specialty to primary care do not take in to consideration the serious consequences of a potential shortage of specialty physicians. Neurosurgical training is unique with a length of post graduate residency training among the longest for any specialty, up to seven years. Neurosurgical subspecialty fellowship training adds an additional one to two years. Medicare's GME contribution does not come close to covering these costs, and therefore much of this expense is borne by the academic departments themselves. While the current ratio of neurosurgeons to population is approximately 1:61,000, by

neurosurgery's account this is likely inadequate -- now and into the future -- when factoring in new neurosurgical treatments, the demand for pediatric, trauma and emergency neurosurgical care, and an aging neurosurgical population. As such, we would like to provide the following comments on CMS proposals for GME.

- **Proposed Changes to the Review and Award Process for Resident Slots under Section 5506 of the ACA.** Section 5506 of the Affordable Care Act (ACA) allows for redistribution of residency slots from closed teaching hospitals. In order to prevent duplication of FTE cap slots, CMS' previous rules allowed those teaching hospitals that absorbed residents from closed hospitals (but had otherwise filled all of their original capped residency slots) to temporarily increase their FTE slots with temporary caps expiring when the displaced residents completed the training program. The ACA also instructed the Secretary to establish a process for a permanent redistribution of those FTE slots when the residents completed the program. In order to avoid duplicating the slots (having a slot from a closed program be held temporarily by a hospital who absorbed a resident and another hospital holding the same slot because it was received through the permanent redistribution process), CMS delayed the permanent redistribution of residency slots from a closed teaching hospital until the resident completed the program.

CMS is now concerned that this process has led to a delay in the permanent distribution, and therefore use of, slots. As such, CMS proposed changes that would allow a hospital to permanently receive a slot from a closed hospital while another hospital holds the slot temporarily in order to complete the training of a resident from a closed hospital. We support this change, which better maintains stability during residency program closures, thereby supporting the continuity of education for the affected residents. It is also important to note that residency closures often adversely impact the care of the most vulnerable populations that the residency programs serve, so we support improved regulations that enable the full utilization of allowed residency slots.

CMS also proposed to revise its ranking criteria for awarding section 5506 slots for closed teaching hospitals. The ACA included provisions that expressed a preference for redistributed residency slots to go to new or expanding primary care or general surgery training programs. CMS' previous regulations on the redistributed slots attempted to address this preference by giving priority to programs seeking to expand only primary care or general surgery programs, but not those seeking to expand primary care or general surgery programs in addition to non-primary care or non-general surgery programs. The current rules do not differentiate programs seeking to expand primary care or general surgery programs in addition to non-primary care or non-general surgery programs from those only seeking to expand non-primary care or non-general surgery programs. We believe this is reasonable and those institutions that are seeking to expand non-primary care or non-general surgery programs should still be able to take advantage of the redistributed slots. CMS is proposing to alter the ranking criteria to award slots only to institutions solely increasing primary care and general surgery residency programs and not programs for other specialties. We do not support these changes because we believe that future Medicare beneficiaries will also need access to other specialties such as neurosurgery. The pipeline to train neurosurgeons is long and policies that support increasing primary care at the expense of specialty care are short-sighted and do a disservice to future Medicare patients.

Medicare Payment for Short Inpatient Stays

CMS is seeking public comment on the issue of an alternative payment methodology for short inpatient hospital stays, specifically, on an appropriate definition of short or low cost inpatient hospital stays. As with the "two midnight" policy, we appreciate CMS' desire to clarify patient stay, but urge CMS to consider the impact on patient out of pocket expenses and the difficulty of predicting the exact post-operative needs of an individual patient. We echo comments submitted by the American College of

Surgeons and other stakeholders in emphasizing the primacy of the physician's clinical judgment in making admission decision about their patients.

In making any changes to the definition of an inpatient stay, CMS must consider the impact on patient care and financial obligations. Time spent as inpatient or an outpatient on observation should continue to count toward the three-day qualifying stay requirement for Medicare Part A coverage in a skilled nursing facility. In addition, CMS should cap the sum of the co-payments for patients who receive observation services at the inpatient deductible. Although the care that patients receive in the inpatient and outpatient setting can often be the same, the difference in the financial impact can be drastic, so we urge CMS to take into account these considerations while examining methodologies to pay for short inpatient stays. No physician has a crystal ball to make exact predictions on patient length of stay and patients who are ready to go home earlier than expected and those who require extra care and observation should not have significant unexpected financial liabilities.

Hospital Inpatient Quality Reporting (IQR) Program

The AANS and CNS appreciate CMS' stated goal of aligning its various quality reporting programs and moving towards collection and reporting of measures data through EHRs to simplify and streamline reporting burden on providers. We also support efforts to minimize reporting burden by removing topped out measures from the program. We encourage CMS to retain topped out measures as voluntary electronic clinical quality measures, where possible, to provide hospitals with more flexible reporting options and to ensure these metrics can still be tracked by those facilities that wish to do so.

Although not addressed in this rule, we reiterate the following concerns about measures included in the IQR Program as part of last year's rulemaking process:

- **Hospital-Wide All-Cause Unplanned Readmission.** CMS previously finalized the Hospital-wide All-cause Unplanned Readmission Measure (HWR) for FY 2015. The AANS and CNS have voiced our concerns with this measure multiple times and continue to not support it. We support improving the care provided in hospitals, but we do not support a HWR measure in the hospital IQR program due to inadequate risk-adjustment.

In its current form, the measure does not appropriately account for socioeconomic factors and resource use of safety net hospitals. The HWR measure is also not aligned with current modeling considerations focused on patient subgroups and their related factors and outcomes. It is generally accepted in most medical disciplines that focused risk adjustment algorithms perform best when applied to focused patient populations.

A recent article regarding risk prediction for hospital readmission published in the *Journal of the American Medical Association (JAMA)* noted that "readmission risk prediction remains a poorly understood and complex endeavor. Indeed, models of patient-level factors such as medical comorbidities, basic demographic data, and clinical variables are much better able to predict mortality than readmission risk."¹

- **Hospital 30-day, All-Cause Risk-Standardized Rate of Mortality Following an Admission for Acute Ischemic Stroke (Stroke Mortality) Measure.** There is compelling scientific evidence that stroke severity, as measured by the National Institutes of Health Stroke Scale (NIHSS), is the single most important determinate of 30-day outcomes for acute ischemic stroke having more discriminatory power than all other variables combined. It is feasible to collect NIHSS in all acute ischemic stroke patients without any missing data at the hospital system and entire community level. This data is

¹ Kansagara et al., Risk Prediction Models for Hospital Readmission, 306 (15) JAMA 1688, 1695 (2011).

routinely and voluntarily reported by hospitals participating in *Get With The Guidelines-Stroke*. Also, training and certification modules are available online and widely used.

It has also well established that risk models based on administrative data or clinical data, which do not include stroke severity, have inferior discrimination, substantial unaccounted for variance, and result in marked misclassification of hospital performance for 30-day mortality. A recently published *JAMA* article demonstrates the importance of including the NIHSS.² In a risk model nearly identical to the proposed stroke mortality measure, the authors showed that 58 percent of the hospitals identified as having “better than” or “worse than” expected risk-standardized mortality would be reclassified to “as expected mortality” if risk-adjustment does not include an adjustment for stroke severity with the NIHSS. Therefore, we continue to urge CMS to begin collecting stroke severity in the form of the NIHSS score and work to revise this measure to include adjustment for stroke severity.

- **Hospital 30-day, All-Cause Risk-Standardized Rate of Readmission Following Acute Ischemic Stroke (Stroke Readmission) Measure.** There is a growing body of evidence that suggests the primary drivers of variation in 30-day readmission rates involve variables that are not included in this model nor captured in administrative claims data, including poor social supports, poverty, and inadequate community resources (all factors that are beyond a hospital’s control). This measure will not be identifying higher or lower quality of care, but will instead reflect unaccounted variability in case mix and other unmeasured factors. The current scheme to impose financial penalties on hospitals with high readmission rates is likely to disproportionately affect “safety-net” hospitals that care for disproportionately larger numbers of poor or minority stroke populations. This measure also does not account for the fact that patients who die post discharge cannot be re-hospitalized.

Last year, we expressed concerns about the NQF Stroke Technical Advisory Panel’s conclusion that there was a lack of information regarding the extent to which hospital level factors influence readmission rates, and concerns related to the risk-adjustment strategy, the importance of readmissions, and the potential for unintended consequences. In the case of outcome measures, it is incumbent on CMS to ensure that the measures will not result in potential harm.

We agree that stroke is a significant health problem and support the creation and implementation of measures that lead to quality improvement. However, it is critical to ensure that such measures are properly constructed and do not result in unintended consequences. Unfortunately, the stroke mortality and readmission measures, because they are not appropriately risk-adjusted, could inaccurately characterize hospital performance and ultimately harm patient care. Currently, there are no peer-reviewed articles or published data to support either of these two measures or to delineate what limitations, if any, were identified through data analysis. As a result, we are concerned that there is no way to substantiate that the measure models will provide adequate discrimination and prevent unintended consequences. For example, the measures may encourage hospitals to select or “cherry pick” stroke patients with mild or moderate strokes, and may discourage hospitals from accepting patients via transfer who have the most severe strokes. This is of particular concern, since hospitals are aware that the resulting mortality and readmissions data will be publicly available on hospital comparison websites, without the benefit of an adequate risk adjustment.

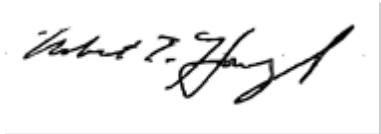
Thus, we again urge CMS to remove these measures from the IQR and, going forward, not adopt measures that have the potential to cause unintended harm. CMS should instead work to ensure that any stroke outcome measures used by the program are properly developed, tested, and risk-adjusted.

² Fonarow et al. Comparison of 30-Day Mortality Models for Profiling Hospital Performance in Acute Ischemic Stroke With versus Without Adjustment for Stroke Severity. *JAMA*. 2012;308(3):257-264. Available at: <http://bit.ly/173kkDD>. Last accessed: August 13, 2012.

CONCLUDING REMARKS

The AANS and CNS appreciate the opportunity to comment on this proposed regulation. We look forward to working with CMS to make improvements to the IPPS program. In the meantime, if you have any questions or need further information, please contact us.

Sincerely,



Robert E. Harbaugh, MD, President
American Association of Neurological Surgeons



Daniel K. Resnick, MD, President
Congress of Neurological Surgeons

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