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

President
H. HUNT BATJER, MD
Dallas, Texas

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

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

June 16, 2015

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

Subject: Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Policy Changes and FY 2016 Rates Proposed Rule

Dear Mr. Slavitt,

On behalf of more than 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 CMS hospital inpatient prospective payment system proposed rule.

PAYMENT PROVISIONS

Add-on Payments for New Services and Technologies

Responsive Neurostimulator (RNS) System

The AANS and CNS are pleased to see that CMS proposes to grant new technology add-on payment for the responsive neurostimulator (RNS) system. The technology 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 for the last two years. A significant number of epilepsy patients, possibly over a third of these individuals, will not find adequate 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. We believe for those patients RNS offers substantial clinical improvement, and we support CMS' plan to grant a new technology add-on payment for RNS.

QUALITY PROVISIONS

Hospital Inpatient Quality Reporting (IQR) Program

Lumbar Spine Fusion/Re-Fusion Clinical Episode-Based Payment measure

CMS proposes to add eight new measures to the Hospital IQR Program starting with the FY 2018 payment determination and subsequent years, including a claims-based Lumbar Spine Fusion/Re-Fusion Clinical Episode-Based Payment measure.

WASHINGTON OFFICE
KATIE O. ORRICO, *Director*
725 Fifteenth Street, NW, Suite 500 Washington, DC 20005
Phone: 202-628-2072 Fax: 202-628-5264 E-mail: korrico@neurosurgery.org

This episode-based measure targets Medicare A and B spending for non-cervical spine fusion and re-fusion procedures. The approach focuses on a set of grouped payments, triggered by a given inpatient stay where a procedure is performed, looking back three days prior to admission, and forward 30 days after time of discharge.

CMS refers readers to a report produced by Acumen LLC proposing a methodology for developing hospital-based episode measures (available at: http://go.cms.gov/1GEQxED). The spine fusion and re-fusion episode-based spending measure, as defined by Acumen and based upon 2012 Medicare data, have the highest average episode payments, the smallest number of episodes, and the highest episode and facility variations, as represented by episode and facility payment standard deviations. This is assumed to mean that there is considerable opportunity for improving the efficiency of care by decreasing variation in episode payments and by identifying outliers. Here, an outlier is assumed to connote a less efficient, higher cost provider.

In the 2016 IPPS proposed rule, CMS notes, especially with regard to outpatient costs, that, "These clinically related post-discharge costs are an indicator of the quality of care provided during the hospitalization." We counter, however, that this difference could, in fact, reflect acuity of care and need for post-operative rehabilitation. Patients presenting to a tertiary care facility with a spinal cord injury who require post-operative inpatient rehabilitation, and hence have higher post-discharge 30-day cost of care, do not necessarily imply poor or inefficient inpatient care during the patient's initial treatment episode.

Furthermore, the variability in facility spending may partially reflect patient variation and variation in referral base. Tertiary facilities, featuring more extensive or reconstructive procedures, will have higher inpatient and post-operative needs. Hence, variations in expenditure may reflect practice patterns and not inefficiencies of care.

Unfortunately, the measures are also based on identifying patients from administrative datasets and rely on a very broad set of MS-DRG and ICD-9 procedure codes. Unusually, the measure opts out staged spine procedures, but incorporates combined anterior and posterior spine procedures done at the same setting.

The Acumen report acknowledges limitations in use of administrative data and notes that opportunities for bias may be mitigated by applying a rigorous approach to identifying inputs for a given model. The approach here, however, is just the opposite: a wide variety of spine fusion and re-fusion MS-DRGs are incorporated into the model, capturing a broad array of spine procedures that should not be held to the same standards. For example, single-level fusions performed upon patients without comorbidities for degenerative disease (MS-DRG 460) are considered equal to a multi-level reconstructive procedure performed for epidural cord compression from a pathologic fracture presenting in a patient with systemic malignancy and with significant comorbidities (MS-DRG 456). We request that CMS consider the variety of spine MS-DRG and CPT codes described in Appendix A of the Acumen document in contrast to the much more focused list of hip and knee replacement codes. The wide variety of codes incorporated in the measure likely drives the wide variation in spending. This wide variety in trigger codes will also produce a broad spectrum of unrelated patient episodes being assessed by the model.

Furthermore, the list of inclusionary CPT codes seems disconnected from the intended focus of this measure. Erroneously, it encompasses nearly the entirety of spine surgery, including a number of *cervical* codes despite the fact that this measure is supposed to focus only on the *lumbar* spine.

As noted earlier, these measures also fail to acknowledge variation that results from complex care requiring more extensive reconstructive procedures. They also do not account for the impact of referral patterns and level of acuity of care. More extensive, reconstructive procedures may be referred in many environments to tertiary facilities. Tertiary care facilities may be inappropriately penalized by this approach, appearing more inefficient due to their patients' need for more extensive reconstructive

procedures and/or post-operative rehabilitation. When developing episode-based payment measures, we urge CMS to more carefully consider the fact that patient variability will drive choice of operative approaches.

Finally, we remind CMS that earlier in the year, the Measures Application Partnership (MAP) *conditionally* supported this measure pending National Quality Forum (NQF) endorsement. The NQF has not yet been reviewed by the NQF's Cost and Resource Use panel. While we do not always agree that NQF endorsement is necessary, socioeconomic status (SES) has been recently recognized by NQF as a potential significant driver of health care expenditures and the NQF's Cost and Resource panel now mandate that measure developers offer adjustment strategies to account for patient SES. This measure, in its current form, is silent on the impact that SES has on medical expenditures and would likely not be endorsed by the NQF in its current form.

Given the complexity of this and other episode-based spending measures, we oppose use of this measure for accountability until a careful and transparent analysis has been conducted and the full range of clinical and potential patient factors are considered and adjusted for. Alternatively, a more restricted, granular approach to choosing model inputs, perhaps by restricting the episodes based on CPT coding (i.e. looking at single level fusions for degenerative disease in isolation), could address these issues and provide more robust and accurate data.

Overall, the AANS and CNS believe that the Lumbar Spine Fusion/Re-Fusion Clinical Episode-Based Payment measure will not, in its current form, provide a meaningful assessment of differing facility and physician efficiencies in spine care. Clinical factors surrounding lumbar spinal fusion are significantly different and more complex than other procedures for which episode-based spending measures are being developed. We strongly urge CMS to continue to work with organized neurosurgery and other spine care experts to refine and test the lumbar spine fusion measure so that it more appropriately targets varying patient and clinical circumstances prior to it being used for accountability.

Hospital Value-Based Purchasing (VBP) Program

AHRQ PSI-12 (Perioperative Pulmonary Embolism (PE) or Deep Vein Thrombosis (DVT) Rate)

Organized neurosurgery reiterates concerns we have raised in the past regarding PSI-12. This measure, which is included in the PSI-90 composite, includes a small number of exclusions and relies on 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, which could lead to useless data that will have little impact on quality). 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 and other traumatic cases 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.

AHRQ PSI-15 (Accidental Puncture or Laceration)

The AANS and CNS also have ongoing concerns with PSI-15, a measure also included in the PSI-90 composite. We appreciate CMS' reference to the American Hospital Association Coding Clinic guidance on PSI-15 in the FY 2014 IPPS final rule, but we believe that coding for accidental puncture is still non-uniform due to lack of clarity as to what constitutes an "accident." Often punctures or lacerations are incorrectly coded as "accidental" when the puncture or laceration was part of the surgery. We request

that CMS provide more precise guidance regarding the correct coding of PSI-15 to minimize confusion and improve the accuracy of this measure.

Expanding the Efficiency and Cost Reduction Domain

Similar to last year, CMS also seeks comment on expanding the Efficiency and Cost Reduction domain of the Hospital VBP to include a more robust measure set. This may include measures that *supplement* the Medicare Spending Per Beneficiary (MSPB) measure with more condition and/or treatment specific episode measures. CMS encourages comment on efficiency and cost reduction measures already included in the Hospital IQR Program or proposed in this rule.

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 continue to support a shift to more granular episode-based payment measures *in place of* (rather than in addition to) 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 eventually 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. We also request that CMS address the issues we outlined above regarding the lumbar fusion episode-based payment measure. Furthermore, we urge CMS to thoroughly test and carefully evaluate the use of all episode-based payment measures first through the Hospital IQR, and in a confidential manner where performance results are not publicly reported, before using tying hospital payment to performance on these measures.

Hospital Readmissions Reduction Program

The AANS and CNS continue to urge CMS to develop a more comprehensive risk adjustment methodology to more accurately account for the multiple factors that may contribute to a readmission. Hospital readmissions can be related to many factors, such as pre-existing chronic conditions, SES, and patient non-compliance with discharge plans. Providers should not be held accountable for these factors, which are largely (if not entirely) outside of their control. Inadequate risk adjustments that do not account for these factors could result in unfair penalties for hospitals that care for the highest acuity Medicare patients. This could create a perverse incentive for hospitals to avoid these patients and pose a serious threat to care access for patients.

Hospital Acquired Condition (HAC) Reduction Program

See our aforementioned concerns about AHRQ PSI-12 (Perioperative Pulmonary Embolism (PE) or Deep Vein Thrombosis (DVT) Rate) and PSI-15 (Accidental Puncture or Laceration), both of which are included in the HAC Reduction Program.

Expanding the Bundled Payment for Care Improvement Initiative

The Center for Medicare and Medicaid Innovation (CMMI) is currently testing four models of bundled payments as part of the Bundled Payments for Care Improvement (BPCI) initiative. By law, the BPCI initiative must be evaluated before it can be expanded. In the 2016 IPPS rule, CMS is not yet proposing an expansion or any changes to the program, but is seeking public comment on a potential expansion to guide future policymaking.

The AANS and CNS strongly urge CMS to thoroughly and carefully evaluate the feasibility and effectiveness of the program among a variety of care settings prior to proposing an expansion. More specific recommendations include:

- In the event of an expansion, the AANS and CNS urge CMS to maintain voluntary participation. We oppose any expansion under which participation would be compulsory and question whether CMS even has the statutory authority to mandate such a fundamental change in payment policy.
- We advise CMS not to specify a single episode length that applies across all episodes. Instead, CMS should make this determination on a case-by-case basis. For some MS-DRGs, a 30-day episode may be appropriate, while others may require a 60-day, 90-day or even longer episode.
- We remind CMS of the ongoing importance of consulting clinical experts when developing episodes that serve as the basis for bundled payments.
- Similarly, CMS must ensure that the selection of measures used to capture quality and cost are closely tied to the scope of the bundle.
- Finally, it is key that CMS enact policies to ensure that organizations participating in the BPCI have access to enough historical and real-time data to accurately assess the risk that will be assumed by entering into a bundled payment agreement. These data should come from sources across the continuum of care (i.e. including post-acute care data sources) and should be derived not only from claims, but from EHRs and clinical data registries (making interoperability of such data sources critical).

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 feel free to contact us.

Sincerely,

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

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

Staff Contact for Payment Provisions
Catherine Jeakle Hill
Senior Manager, Regulatory Affairs
AANS/CNS Washington Office
725 15th Street, NW, Suite 500
Washington, DC 20005
Phone: 202-446-2026
E-mail: chill@neurosurgery.org

Staff Contact for Quality Provisions
Rachel Groman, MPH
Vice President, Clinical Affairs and Quality Improvement
Hart Health Strategies
Phone: 202-729-9979 ext. 104
Email: rgroman@hhs.com