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June 25, 2013

Ms. Marilyn B. Tavenner, Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1599-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) 2014 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

- **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 meets the "substantial clinical improvement criterion" set forth by CMS.

Other Proposed Decisions and Changes to the IPPS for Operating Costs

- **Hospital Readmission Reduction Program.** Until adequate guidelines exist and the associated measures can be risk-adjusted, CMS should not move forward with an expansion of the program.
 - CMS 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.
 - AHRQ PSI-90 should not be added to the Hospital VBP because the measure includes PSI-15.
 - Neurosurgery does not support a Medicare Spending per Beneficiary measure until measure specifications are developed, risk-adjustment is included and evidence shows there is a demonstrated linkage of spending to outcomes or some other quality metric.

- **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.
 - Neurosurgery has concerns with including the AHRQ PSI-6 (Iatrogenic pneumothorax rate) measure included in the Hospital Acquired Condition Reduction program due to the lack of exclusions for emergency situations.
 - 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.
- **Admission and Medical Review Criteria for 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**

- Neurosurgery does not support a Hospital-Wide All-Cause Unplanned Readmission measure due to inadequate risk-adjustment.
- 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 Stroke Mortality Rate and Hospital 30-day, All-Cause Readmission Rate Following Stroke.
- Neurosurgery urges 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

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. 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.

Other Proposed Decisions and Changes to the IPPS for Operating Costs

Hospital Readmission Reduction Program

At the current time, the Hospital Readmission Reduction program is limited to three conditions: acute myocardial infarction, heart failure, and pneumonia, but CMS proposes to expand the list of conditions and procedures for this program to include patients admitted for an acute exacerbation of chronic obstructive pulmonary disease and elective total hip arthroplasty and total knee arthroplasty and possibly other diseases in future rulemaking. The AANS and CNS object to CMS' proposed expansion of the Hospital Readmission Reduction Program due to inadequate evidence supporting the conditions. Until adequate guidelines and the associated measures can be risk-adjusted, CMS should not move forward with an expansion of the 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. CMS 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.

Hospital Value-Based Purchasing Program

Fiscal Year 2013 was the first year of payment adjustments under the Hospital Value-Based Purchasing (VBP) program, which was established by the Affordable Care Act (ACA). CMS will base each hospital's VBP percentage on its Total Performance Score for a specified performance period. For FY 2014, the amount of money increases to 1.25 percent of the hospital's base-operating Diagnosis Related Group (DRG) payments.

- **FY 2015 VBP Program Measures.** In FY 2013 IPPS final rule, CMS finalized the addition of three new measures to the Hospital VBP program. Neurosurgery voiced its concern on some of the measures last year and once again, we reiterate our ongoing concerns.
 - **AHRQ PSI-90.** For FY 2015, CMS has added AHRQ PSI-90, a patient safety composite measure to the program. The AANS and CNS do not believe, however, that it should be included in the Hospital VBP program. The measure 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. In addition, the AHRQ PSI-90 composite is difficult to narrow down to identify specific cases, where this type of event occurs. Therefore, it does not actually lead to quality improvement since the surgeon or institution cannot determine the problem. In its 2012 report, the Measure Application Partnership (MAP) recommended that this measure not be included in the Hospital VBP program.
 - **Medicare Spending per Beneficiary.** Beginning in FY 2015, CMS will include a Medicare Spending per Beneficiary measure to the Hospital VBP program. The proposed measure is inclusive of all Part A and Part B payment from three days prior to a hospital readmission through 30 days post discharge, with a minimal amount of exclusions. Neurosurgery has concerns with the measure because it is not currently NQF-endorsed and measure specifications have not been developed or released in the public domain. We cannot support such a measure until measure specifications are developed, risk-adjusted and evidence shows there is a demonstrated linkage of spending to outcomes or some other quality metric. If measure specifications are ever fully developed, we urge CMS to ensure that the measure includes clearly stated reporting

requirements, an analysis of unintended consequences, is tested in various environments, and is endorsed by NQF or some other third-party.

- **FY 2017 Hospital VBP Program Measures**

- MRSA and *C. difficile*. CMS intends to adopt the Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia and the *Clostridium difficile* (*C. difficile*) standardized infection ratio measures in the Hospital VBP for FY 2017. At the current time, measures specifications have not been provided for this measure. Without more information on the measure and its exclusions, it is difficult to provide feedback and comments on whether this measure is appropriate for the Hospital VBP.

If CMS moves forward with the measure, 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*.

In regards to MRSA, it will be important for CMS to differentiate community-acquired from healthcare-associated strains. Many patients enter the hospital already colonized, as well as for *C. difficile*. For *C. difficile*, some patients may contract *C. difficile* after receiving a single dose of appropriate pre-operative antibiotic. In addition, for *C. difficile*, data should be broken down by the number of surgical patients in the hospital and the type of operations.

- HAC Reduction Program. Due to the ACA, CMS is required to implement a HAC payment adjustment beginning in FY 2015. For the FY 2015 HAC Payment Reduction Program, CMS proposes to adopt eight measures, clustered into two domains. Our comments address proposed Domain 1, a proposed Alternate Domain 1 and a proposed Domain 2.

Proposed Domain 1:

- AHRQ PSI-3 (Pressure Ulcer Rate). If CMS includes this measure in the HAC Reduction Program, the measure should incorporate an exclusion for nascent pressure ulcers that are undetectable at admission, but often present soon afterwards. Often, patients are coming from a skilled nursing facility or are elderly and have been admitted after being sick for several days. Due to their state, the patients may not have been moving and developed a pressure-related injury to their back or extremity. The tissue takes several days to diminish so the patient can develop a decubitus ulcer two or three days after being admitted from an injury that was actually present on admission (POA). Therefore, if CMS includes the measure in the HAC Reduction Program the specifications should exclude patients with occult injury that is detectable within a few days of admission.
- AHRQ PSI-5 (Foreign object left in body). It is reasonable to include this measure in the HAC Reduction Program. However, the measure definition should clearly exclude hardware placed in the body, or other devices intentionally left, even temporarily, in the body.
- AHRQ PSI-6 (Iatrogenic pneumothorax rate). Neurosurgery has concerns with inclusion of this measure within the HAC Reduction Program. It is worthy to track iatrogenic

pneumothorax for quality improvement purposes, but there needs to be exclusions for lines placed under emergency conditions. Often a surgeon has no choice but to puncture a lung to gain access to the central venous when performing CPR or trauma resuscitation.

- AHRQ PSI-12 (Postoperative PE/DVT rate). The AANS and CNS are concerned with the inclusion of PSI-12 in the HAC Reduction Program due to the small number of exclusions and the risk adjustment criteria, which will lead to potential unintended consequences with the use of this measure. For example, the measure will tag every LE thrombophlebitis; whether or not it is clinically significant and in-turn produce useless data that will not result in quality improvement.

Patients with a diagnosis of cancer, brain tumors or trauma should be excluded. 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. In addition, the measure includes not otherwise specified (NOS) codes, which includes superficial thrombosis and this is not appropriate to measure. Because there are predictors of DVT that are outside of the control of the facility and the physician, the facility should not be penalized as a result.

- PSI-15 (Accidental puncture and laceration rate). We are concerned about the inclusion of PSI-15 in the HAC Reduction Program because there is a lack of coding guidelines for accidental puncture. As we mentioned previously in the Hospital VBP section, there is ambiguity as to what constitutes an “accident”, and coding for accidental puncture is non-uniform.

Proposed Alternate Domain 1:

- AHRQ PSI-90. We do not support the use of AHRQ PSI-90 in the HAC Reduction Program. As mentioned above, we do not support the use of PSI-15, Accidental puncture or laceration, which is included in the AHRQ PSI-90 composite.

Proposed Domain 2:

- MRSA and C. difficile. CMS intends to adopt the Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia and the *Clostridium difficile* (*C. difficile*) standardized infection ratio measures in the HAC Reduction Program. As mentioned above, we urge CMS to provide the measure specifications for these measures. It is difficult to provide detailed feedback on the usefulness and appropriateness of the measures without detailed specifications. Community acquired MRSA is increasingly common, and many patients are entering the hospital already colonized. Therefore, any specifications that are developed needs to include an exclusion for community acquired MRSA.

Admission and Medical Review Criteria for Hospital Inpatient Services

AANS and CNS support a clear definition for inpatient designation. However, we agree with the American College of Surgeons on a number of issues regarding this significant revision to Medicare policy. Some concerns are highlighted below:

- **Exceptions for Inpatient Admissions Requiring Fewer than Two Midnights.** We appreciate the fact that CMS has stated that the key factor in the inpatient designation is the physician's documentation in the patient's record justifying the medical necessity for inpatient admission, regardless of actual length of stay. A physician may need to order and review tests before determining the admission status of a patient. The patient may require a level of care not available in the outpatient observation area. A hospital stay spanning less than two midnights could theoretically be as long as 47 hours. Therefore, an exception that allows for flexibility and is based on the physician documentation of the medical necessity for admission is essential.
- **Starting Point for Inpatient Designation.** The inpatient designation should begin at the time the physician writes the order, even if there is a delay in locating an available bed. In the case where a patient is in the hospital as an outpatient for observation and then is admitted, the observation period should be included to meet the "two midnight" criteria for the stay to be considered as an inpatient. This is important for a number of reasons, including for the patient to meet requirements for length of stay before eligibility for skilled nursing facility services.
- **Financial Consequences for Patients.** The complexity of facility designation is often unclear to patients, and in some cases, they may stay in the same bed when they change from outpatient to inpatient status. However, a patient's payment liability can be very different and prolonged observation status may result in a significantly higher payment for the patient. We urge CMS to explore policy options to hold patients harmless for site of service changes that are largely beyond their control, perhaps by capping the Part B outpatient co-pay at the inpatient deductible level.
- **Physician Work and Site of Service Designation.** Finally we oppose medical review that would deny medical necessity of corresponding physician services when payment for Part A inpatient payment is disallowed because the more acute setting was determined medically unnecessary. Regardless of the designation of the facility, the intensity of the physician services is typically the same. The AANS and CNS continue to oppose the CMS contention that physician services are less intense if a procedure is performed in the outpatient setting more than 50 percent of the time.

Proposed Quality Data Reporting Requirements

- **Hospital Inpatient Quality Reporting Program.** The Hospital Inpatient Quality Reporting (IQR) program requires hospitals to meet specific quality reporting requirements to receive the full market basket update for that year. Hospitals that do not meet the requirements will receive a two percentage point reduction in that year's inpatient hospital payment update factor.
 - Hospital-Wide All-Cause Unplanned Readmission. CMS finalized the Hospital-wide All-cause Unplanned Readmission Measure (HWR) for FY 2015. The AANS and CNS have voiced our concerns with this measure 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 In addition, the MAP Pre-rulemaking Report for 2013 highlighted that their recommendation for support of this measure was dependent on NQF endorsement. It is our understanding that this measure is still undergoing updates and in-turn has not received NQF endorsement.

- Stroke Measures. For the FY 2016 IQR program, CMS proposes to include the following two stroke outcome measures:
 - Hospital 30-day, All-Cause Risk-Standardized Rate of Mortality Following an Admission for Acute Ischemic Stroke (Stroke Mortality) Measure; and
 - Hospital 30-day, All-Cause Risk-Standardized Rate of Readmission Following Acute Ischemic Stroke (Stroke Readmission) Measure.

CMS states it plans to adopt both measures, even though the measures are not endorsed by the NQF, and are not recommended by the Measures Application Partnership (MAP). We urge CMS to reconsider its proposal for inclusion of the two measures in IQR until they can be properly constructed.

- 30-day Stroke Mortality Measure. In terms of the 30-day 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 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, that 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. We 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, prior to implementation in the IQR.

Furthermore, Yale CORE/CMS (measure steward) voluntarily withdrew this measure from NQF consideration. We do not understand why CMS would propose adopting this measure after voluntarily withdrawing the measure from NQF consideration, when the measure

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

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.

developer said that it “withdrew this measure in order to reevaluate their approach to risk adjustment.”

- 30-day Stroke Readmission Measure. With regards to the proposed stroke readmission measure, there is a growing body of evidence which suggest 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 does not account for the fact that patients who die post discharge cannot be re-hospitalized.

It appears that the concerns voiced by the NQF technical advisory panel were not considered by CMS. CMS should not adopt measures that NQF — because of substantial concerns — declined to endorse. The NQF stroke technical advisory panel specifically stated that, among other things, there was a lack of information regarding the extent to which hospital level factors influence readmission rates, and noted concerns related to the risk-adjustment strategy, the importance of readmissions, and the potential for unintended consequences. While we acknowledge that some measures have been adopted by CMS without NQF endorsement, using its exception authority, we do not believe it is appropriate to use this authority in the case of outcome measures. The potential benefit and harms that can be created through the implementation of outcomes measures bears higher scrutiny. In the case of outcome measures, it is incumbent on CMS to ensure that the measures will not result in potential harm. By ensuring outcome measures are consensus based with expert panel input and endorsement by organization’s such as NQF lends validity and legitimacy to the measures.

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 proposed 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, if implemented. 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. The potential posting of data for these two measures on the *Hospital Compare* website requires a great need for validity. Currently, all outcomes measures that are reported on *Hospital Compare* are NQF endorsed. Both of these measures would likely be candidates for inclusion on the *Hospital Compare* website.

Thus, we urge CMS not to adopt these measures for inclusion in the FY 2016 IQR. CMS should not adopt measures that have the potential to cause unintended harm, and should instead work

to ensure that any stroke outcome measures used by the program are properly developed, tested, and risk-adjusted.

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,



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