June 25, 2012

Ms. Marilyn B. Tavenner, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1588-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year (FY) 2013 Rates; CMS–1588–P

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 Centers for Medicare & Medicaid Services’ (CMS) hospital inpatient prospective payment system proposed rule for FY2013. Our comments focus on the quality-related provisions of the proposed rule.

Other Proposed Decisions and Changes to the IPPS for Operating Costs and GME 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 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 can 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 unrelated to the original admission, such as readmission due to traumatic injury.

Proposed Quality Data Reporting Requirements for Specific Providers and Suppliers- Hospital Inpatient Quality Reporting Program

Proposed Removal of 16 Claims-Based Measures

Beginning in FY 2015, CMS proposes to remove eight hospital acquired condition (HAC) measures from the Hospital Inpatient Quality Reporting Program (IQR). Neurosurgery is supportive of this
proposal as it is unnecessary to penalize hospitals twice for the same conditions -- once under the HAC nonpayment policy and a second time under the Hospital IQR program.

**Hospital-wide Readmissions**

CMS proposes to add the Hospital-wide all-cause unplanned readmission measure (HWR) -- NQF #1789 -- to the Hospital IQR program. As noted above, the Hospital IQR program currently includes readmission measures for heart failure, acute myocardial infarction and pneumonia and states that a HWR measure could provide a broader portrait of the quality of care provided in hospitals. We support improving the care provided in hospitals, but neurosurgery does not support a HWR measure in the Hospital IQR program due to the lack of risk adjustment and testing on this measure.

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

CMS must also take into consideration readmission related to trauma, staged procedures or instances outside of the surgeon and institution’s control. CMS needs to ensure that if a patient has “staged” spinal surgery or other staged surgeries, which is necessary for some of the more complex deformity surgeries, that the second surgery is not classified as a “re-admission”. **Private payers who have implemented such programs have inappropriately classified staged surgeries as an unplanned readmission in the past and we urge CMS to properly classify and risk-adjust for such medical care.**

We offer two examples, to further amplify our concerns related to inappropriately classifying readmissions under this program. First is the case where a patient enters the hospital a few days before a scheduled surgery because of an unrelated problem. This problem is addressed and the surgeon subsequently proceeds with the scheduled procedure as planned. In this scenario, we are concerned that CMS’ proposal would pay for the initial procedure, but not reimburse the hospital for the second planned procedure.

Second, consider stage two of a deep brain stimulator (generator and extension cables), which consists of two stages, an electrode array placement in the brain, and a pulse generator with the battery and programming doing the stimulating. The patient comes in with shortness of breath two days after being discharged from electrode implant. The surgeon decides to keep them in another day or two because stage two is already scheduled. Under CMS’ proposal, the second stage would not be reimbursed, including the costly generator. The surgeon will basically be forced to discharge the patient and re-admit a second time for the implant.

If CMS moves forward with the HWR measure, proper risk-adjustment must occur and take into consideration issues and scenarios surrounding readmissions involving staged procedures.

**Proposed Hospital IQR Program Quality Measures for the FY 2016 Payment Determination and Subsequent Years**

**Safe Surgery Checklist**

Beginning in FY 2016, CMS proposes to add a yes/no measure of whether a hospital uses a safe surgery checklist. The checklist is to be used during three periods: prior to administration of
anesthesia, prior to skin incision, and from the closure of incision prior to the patient leaving the operating room. We support the use of a safe surgery checklist, but hospitals and surgeons must have flexibility in terms of implementation. We are wary of any requirement that stipulates when the checklist should be done relative to the procedure or dictates how it is documented. It will be extremely burdensome to now require surgeons to implement the checklist three times. The surgeon could be using the few minutes productively elsewhere. The World Health Organization (WHO) Safe Surgery Checklist describes one time out, not three.\(^1\) The pauses are important but a series of three time outs are disruptive and impracticable.

As advised by our members, all hospitals use a safe surgery checklist but often it is a modified version of the WHO Surgical Safety Checklist. For example, omitting the operating team’s introduction and description roles if all individuals already know each other or have been working together throughout the day, and adding reminders about VTE prophylaxis. The WHO Safe Surgery Checklist Implementation Manual also mentions flexibility with implementation. The Implementation Manual states, “the Checklist can be modified to account for differences among facilities with respect to their processes, the culture of their operating rooms and the degree of familiarity each team member has with each other . . . Each locale is encouraged to reformat, reorder or revise the Checklist to accommodate local practice while ensuring completion of the critical safety steps in an efficient manner.”\(^2\) Therefore, the AANS and CNS recommend that CMS clarifies and ensures that surgeons can implement a modified Safe Surgery Checklist and that they are not mandated to incorporate three “pauses”.

**Hospital Value Based Purchasing Program- Medicare Spending Per Beneficiary Measure**

CMS proposes to incorporate a Medicare Spending per Beneficiary measure into the Hospital Value Based Purchasing Program (VBP). The proposed measure is inclusive of all Part A and Part B payment from three days prior to a hospital admission through 30 days post discharge, with a minimal amount of exclusions. Neurosurgery has concerns with the current measure because it is not endorsed by NQF and the Measures Application Partnership (MAP) recommended against its inclusion in the Hospital VBP. The AANS and CNS, therefore, cannot support such a measure until measure specifications are developed and the measure is risk-adjusted for socioeconomic status, education and co-morbidities. Preliminary developed measure specifications excluded socioeconomic status and education, which greatly plays a role in cost and outcomes. If measure specifications are ever fully developed, we urge CMS to ensure the measure includes clearly stated reporting requirements, an analysis of unintended consequences, tested in various environments and endorsed by NQF.

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

Sincerely,

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