September 6, 2013

Ms. Marilyn B. Tavenner. Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1600-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014

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 above referenced Notice of Proposed Rulemaking (NPRM) published in the Federal Register on July 19, 2013. The following comments focus on a variety of non-quality related topics. Our comments regarding the new Qualified Clinical Data Registry (QCDR) requirements, Physician Compare, other PQRS program topics, and the Value-Based Payment Modifier Program have been submitted in separate comment letters.

SUMMARY OF COMMENTS

• Resource-Based Relative Value Units (RBRVS) for Practice Expense (PE)
  – Stereotactic Radiosurgery (SRS). The AANS and CNS agree with the CMS proposal regarding SRS treatment delivery, and believe the recent RUC reviewed PE data for CPT Codes 77372 and 77373 should be used by CMS.
  – Non-facility PE Cap. Neurosurgery supports the withdrawal, or at a minimum, a delay, the CMS proposal to cap PE in the non-facility setting at the Medicare Hospital Outpatient Prospective Payment System (OPPS) rate.

• Validating RVUs of Potentially Misvalued Codes
  – The AANS and CNS have a number of concerns and recommendations regarding recent contracts undertaken by CMS to gather data to review. We urge transparency and adequate public comment in this process.

• Medicare Economic Index (MEI)
  – Neurosurgery appreciates the effort undertaken by CMS to rebase the MEI, but we urge CMS to revisit the physician productivity assumptions.
• Complex Chronic Care Management (CCCM) Services
  − The AANS and CNS support measures that would improve coordination of care for Medicare patients with multiple co-morbidities, but we urge CMS to consider criteria that are verifiable and permit any specialist that meets the requirement to report the new codes.

• Overpayment Look-back Period
  − The AANS and CNS recommend that CMS maintain a three year look-back period for overpayments and not extend the period to five years.

• Medicare Coverage of Items and Services in FDA Investigational Device Exemption Studies
  − Neurosurgery supports Medicare payment for services provided under an FDA IDE approved clinical trial and are uncertain of the impact of the CMS proposal to establish a centralized review process for approval. We urge CMS to provide greater detail on the proposal, and show evidence of a need to change the current policy.

DETAILED COMMENTS

Resource-Based Relative Value Units (RBRVS) for Practice Expense (PE)

• Stereotactic Radiosurgery (SRS). The AANS and CNS agree with the CMS suggestion to eliminate separate codes for robotic versus non-robotic linac-based SRS delivery services, which were previously reported with HCPCS G-codes. We agree that SRS and Stereotactic Body Radiotherapy (SBRT) delivery services are appropriately captured with CPT codes 77372 and 77373. In the proposed rule, CMS asked whether the PE RVUs for the codes should be reviewed. The RUC PE subcommittee reviewed the codes in January and April of this year, and the proposed values have been submitted to CMS for use in the 2014 MPFS. As part of this review of direct PE inputs, all technologies (including robotic functionality) were included. In addition, equipment invoices for all these technologies were included with the RUC’s submission to CMS. The price for the SRS system, CMS equipment code ER083, is the result of weighting six different treatment systems. As such, the direct PE inputs used to develop PE RVUs for CPT codes 77372 and 77373 are as accurate as currently possible and reflect the typical resources used when furnishing these services in the non-facility setting. The AANS and CNS therefore support the deletion of the G-codes and encourage CMS to accept the RUC-approved PE recommendations.

• OPPS/ASC Cap for Non-Facility PE. The AANS and CNS add our concerns to those expressed by the American College of Surgeons (ACS) and the American Medical Association (AMA)/Specialty Society Relative Value Update Committee (RUC) regarding the CMS proposal to cap payment rates for 211 physician services at Hospital Outpatient Prospective Payment System (OPPS) or ambulatory surgical center (ASC) rates when these procedures are performed in the non-facility setting. While we support practice expense and facility payments that fairly compensate physicians and do not create inappropriate site-of-service incentives, we question whether CMS has provided enough data to evaluate their proposal for the 211 services. We recommend that CMS withdraw the proposal, conduct additional study, and provide more information on the specialty impact of the proposal.

Validating RVUs of Potentially Misvalued Codes

We are keenly aware that CMS is required by Congress to develop a process for validating the RVUs under the MPFS, to that end the agency has entered into two contracts with outside entities as part of
this mandate — one contract with the Urban Institute to develop time estimates and work validation, and a second contract with the RAND Corporation to build a validation model to predict work RVUs and individual components of work RVUs, time and intensity. We would echo the detailed comments provided by the ACS and ask for greater transparency and an opportunity for public comment on these efforts. Based on past activities of the Urban Institute, we are concerned about a potential for bias and ask that CMS be vigilant in providing specialty physicians that will be affected directly by study recommendations a voice in the analysis of data provided by the contracts. A thoughtful and thorough review of the clinical expertise of physicians involved in the “research” conducted by the contractors is essential in establishing credibility for the studies.

**Medicare Economic Index (MEI)**

The AANS and CNS support rebasing the MEI; however we ask CMS to reconsider its assumptions about physician productivity. The productivity assumptions for physicians are twice that used for the hospital outpatient department and ambulatory surgery centers. While we understand that these are two different calculations, it is hard to imagine that individual physicians would have twice the capability of increasing productivity than would facilities.

**Complex Chronic Care Management Services**

CMS proposes to establish a separate payment under the MPFS for complex chronic care management (CCCM) and begin paying for these services in 2015. The AANS and CNS agree that Medicare beneficiaries are likely to suffer from multiple co-morbidities and improved coordination is needed for this vulnerable population. In this proposed rule, CMS offers a detailed set of policies relating to CCCM services over and above the recently implemented payment for transitional care management services (TCM). For the new service to be meaningful, efficient, and effective, CMS must be able to ensure that physicians reporting the CCCM services are truly able to educate patients and caregivers, as well as coordinate care among all service providers — especially for their patients in high level hospital settings whose health status may changes hourly. Critical illness and hospitalization for an elderly patient and their family members can be bewildering and frightening, as a parade of clinical personal examine the patient and care can seem completely uncoordinated. In these cases, the primary care physician may not even see the patient each day may or may not be effectively coordinating care.

The value of the new CCCM services rests on the CMS ability to identity objective criteria for assessing improved coordination. We therefore urge CMS to review the comments provided by the ACS, and we agree that CMS should delay implementation to develop standards, through public rulemaking, related to physician office capability to perform these CCCM services. In addition, we urge CMS to allow any specialist who meets the requirements to report the new services. Elderly patients with co-morbidities may have a condition that requires most of their healthcare to be provided by a specialist whose office potentially could be the patient’s “medical home” more so than a primary care physician.

**Collection of Overpayments**

The AANS and CNS strongly oppose the longer five-year look back period for “without fault” overpayments. Extending this time period requires physicians to be subject to audits, recovery initiatives, and other burdens for an additional two years, even if they inadvertently or unknowingly receiving such overpayments. As we, the AMA, and the ACS stated in comments to CMS’ proposed rule on Returning and Reporting Overpayments, CMS should maintain a three-year look back period to encourage consistency and avoid confusion with existing CMS overpayment initiatives.
Medicare Coverage of Items and Services in FDA Investigational Device Exemption

CMS proposes to establish new criteria governing coverage of the costs and routine items and services in Category A and B Investigational Device Exemption (IDE) studies and trials. The AANS and CNS support Medicare payment for services provided under an FDA IDE approved clinical trial, but we are uncertain of the impact of the CMS proposal to establish a centralized review process for approval. We therefore urge CMS to provide greater detail about the proposal, and provide evidence as to why the current policy needs to be changed. We are concerned that this policy will create additional bureaucracy that will lead to significant barriers and/or delays in access to care. We ask CMS to provide greater details on its plan to centralize standards for determining Medicare coverage in clinical trials and to issue a public notice with opportunity for public comment. Similarly, CMS should follow an equally transparent process that will provide for stakeholder feedback for individual determinations, should a centralized process be implemented.

CONCLUDING REMARKS

Thank you for the opportunity to comment. The AANS and CNS commend the many dedicated and knowledgeable employees at CMS who work under increasing demands, and we appreciate the agency’s efforts to reach out to physician specialty societies. As such, we urge CMS not to expand its administrative reach beyond that required by statute. Given limited resources, new initiatives should be thoroughly justified, transparent, and permit extensive public review. We appreciate your consideration of our remarks.

Sincerely,

William T. Couldwell, MD PHD, President
American Association of Neurological Surgeons

Ali R. Rezai, MD, President
Congress of Neurological Surgeons

Staff Contact:
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