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September 1, 2014

Ms. Marilyn B. Tavenner, Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1612-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20001

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2015; CMS-1612-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 payment provisions of the above referenced Centers for Medicare and Medicaid Services' (CMS) 2015 Medicare Physician Fee Schedule (MPFS) Notice of Proposed Rulemaking (NPRM). We have submitted comments related to the quality and Open Payment proposals in separate comment letters.

Summary of Comments

- **Resource-Based Relative Value Units (RBRVS) for Practice Expense (PE)**
  - The AANS and CNS agree with the CMS proposal regarding Stereotactic Radiosurgery (SRS) treatment delivery and believe CPT Codes 77372 and 77373 should be used by CMS for these services.
- **Validating RVUs of Potentially Misvalued Codes**
  - The AANS and CNS continue to have a number of concerns regarding contracts with the Urban Institute and the RAND Corporation undertaken by CMS to gather data to review. We urge transparency and adequate public comment in this process.
  - We do not agree with the need to review the work of the Neurostimulator Implantation (CPT codes 64553 and 64555) in addition to the Practice Expense (PE), but understand that the codes have been referred to the RUC. The AANS and CNS will participate in the RUC process for these codes.
- **Improving the Valuation and Coding of the Global Services Package**
  - The AANS and CNS urge CMS not to eliminate the 010- and 090-day global periods. We believe the goals of the agency to assure correct valuation of these services can be met

without scrapping the long standing and well understood practice of the global services package.

- **Professional Liability Insurance (PLI) Relative Value Units (RVUs)**
  - We agree with the CMS methodology for establishing the risk factor for neurosurgery.
  - The AANS and CNS support the RUC proposal that CMS update PLI yearly rather than every five years.
  - We support the RUC efforts to determine the correct specialty risk factor for low volume codes.
- **Change to Publish Proposed Values in the July NPRM**
  - The AANS and CNS would like the proposed 2016 Medicare Physician Fee Schedule to include as many of the proposed code values as possible, while not disrupting the CPT/RUC schedule.
  - We support the inclusion of proposed values in proposed Medicare Physician Fee Schedule notices for 2017 and beyond. We believe the agency can work within the CPT and RUC processes to achieve this goal.
  - The AANS and CNS oppose the development of G-codes to use as temporary codes in 2016.
  - The AANS and CNS support a continued appeal and review process similar to the refinement process.
- **Medicare Private Contracting/Opt-out**. The AANS and CNS are long-time proponents of private contracting for Medicare patients and support the ability of physicians to opt-out of the program without the requirement to file an affidavit every two years to remain in an opt-out status.

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

Stereotactic Radiosurgery (SRS)

Based on comments that CMS received in response to the 2014 Medicare Physician Fee Schedule final rule, CMS proposes to eliminate separate codes for robotic versus non-robotic linac-based SRS delivery services that were previously reported with HCPCS G-codes. In the 2014 final rule, CMS had asked whether PE RVUs for the codes should be reviewed. The AANS and CNS agreed that SRS and Stereotactic Body Radiotherapy (SBRT) delivery services are appropriately captured with CPT codes 77372 and 77373, and the RUC review of the PE was appropriate. Therefore, we are pleased to see that CMS has concluded that the direct PE inputs for CPT codes 77372 and 77373 reflect the typical resource inputs involved in furnishing an SRS service, and that the agency plans to recognize only the CPT codes for payment of SRS services, deleting the G-codes used to report robotic delivery of SRS.

Validating RVUs of Potentially Misvalued Codes

CMS Contracts to Validate RUVs

We are keenly aware that CMS is required by Congress to develop a process for validating the RVUs under the Medicare Physician Fee Schedule and have entered into contracts with outside entities as part of efforts to comply — including 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. However, this process has largely been opaque. We are therefore requesting that CMS provide for for greater

transparency, including an opportunity for public comment, prior to the agency adopting any of the outside contractors recommendations. Based on past activities of the Urban Institute, we are concerned about a potential for bias — particular in favor of primary care and against specialty medicine — and and ask that CMS be vigilant in providing the specialty physicians that will be affected by these studies a voice in the analysis of data provided by the contractors. Recently, the Urban Institute issued a preliminary report citing many difficulties encountered with the study. We are therefore concerned that the data provided to CMS will be very limited and based on only a few sites. We fail to see how this will be superior to, or appropriate for, a review of RUC-approved values. A thoughtful and thorough review of the clinical expertise of physicians involved in the "research" conducted by the contractors is essential in establishing creditability for the studies.

Neurostimulator Implantation — CPT codes 64553 and 64555

CMS reported that a stakeholder raised questions regarding whether the practice expense RVUs for CPT codes 64553 (Percutaneous implantation of neurostimulator electrode array; cranial nerve) and 64555 (Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)) are appropriate when furnished in the nonfacility setting. CMS has referred the issue to the RUC. We believe that the PE inputs for the non-facility use of this code can be reviewed without a resurvey of the work of the code.

Improving the Valuation of the Global Surgical Package

Eliminating 10- and 90-Day Global Packages

The AANS and CNS oppose the elimination of the 10- and 90-day global packages and believe any attempt to finalize a schedule for such a plan is completely inappropriate. We believe the subject deserves far more review and discussion before implementation is contemplated. The unintended consequences are potentially much more far-reaching than were the major practice expense methodology changes imposed a few years ago, and those changes were a very long time in the making and involved years of stakeholder input. We believe the goal of ensuring that services with global periods are accurately valued can be achieved without completely overhauling the existing payment structure, which could lead to disaggregation and fragmentation of patient care and is completely contrary to current trends toward bundling. We fully support the comments submitted by the American College of Surgeons, generally agree with the comments submitted by the AMA RUC, and would highlight the following concerns:

- **Flaws in the OIG Reports.** To the extent the genesis of the CMS proposal to eliminate surgical global packages was the HHS Office of Inspector General (OIG) audits of evaluation and management (E/M) work in the global surgical period, we believe it is important to emphasis that the OIG reports are flawed in many ways. The number of claims for each individual service reviewed is low and the reports review the number, not the level, of visits. Of particular concern for neurosurgery is the fact that only one spine procedure was reviewed in the 2012 HHS OIG report on musculoskeletal procedures -- and that was dropped in the final analysis because of concerns about overlapping global periods for codes sometimes reported together. Global surgical services are based on the typical patient and any individual case could include more or fewer visits. We note the possibility that E/M work is under-reported in the patient record, precisely because the codes are not separately reportable. The issues of concern raised in the OIG reports do not justify completely abandoning the 10- and 90-day global surgical policy, which can be addressed through the RUC process and with improved education about the importance of accurately documenting that the visits have taken place.

- **Post-operative work not captured by E/M Codes.** In addition to visit services, there are many other post-operative care services included in 10- and 90-day global packages including dressing changes, local incision care, removal of operative packs, removal of cutaneous sutures, staples, lines, wires, tubes, drains, casts, and splints, insertion, irrigation and removal of urinary catheters, routine peripheral intravenous lines, and changes and removal of tracheostomy tubes.

- **Practice expense.** The PE for the E/M work in the surgical global package is more resource-intense than separately-reported E/M services. E/M services performed following surgery often include additional, justifiably more expensive, supplies and equipment and may include additional clinical staff time relative to separately-billed E/M services. The RUC thoroughly evaluates the clinical staff time and the typical patient condition and type of services performed when recommending direct PE values. In addition, the indirect PE payment is dependent on specialty and is generally and appropriately higher for surgical specialists and this is reflected in the E/M visits included in the surgical packages.

- **Professional liability insurance expense**. The work RVUs of the proxy E/M services contained in the 10- and 90-day global packages are appropriately included in the professional liability insurance (PLI) expense calculation because the liability cost of a service should reflect the specialties performing it. Under the CMS proposal to eliminate global periods, E/M work would not be linked to the risk of the original service, would be diluted by the wide mix of all specialties performing E/M, and would not take into account the greater relative risk for the visits of a surgical patient.

- **Officevisit level.** On average, global surgical packages have lower levels of office and hospital visits relative to separately-reported E/M visits. The median E/M visit in the global period is 99212, while the median separately-reportable office visit is above a 99213. The same is true for hospital visits. This is a factor that CMS should consider when assessing the impact of any proposal to unbundle visits.

- **Administrative burden**. The CMS proposal to eliminate global periods would create a huge and unnecessary burden for all stakeholders — patients, providers, and payors. Patients would be responsible for paying for each post-op visit separately, disadvantaging those who require more visits. Providers would be subjected to submitting additional claims and the Medicare Administrative Contractors (MACs) would have to process and pay them. In addition, there is no way to know how private payors would choose to treat global periods, creating potential confusion and processing delays.

- **Multiple surgery, bilateral surgery, co-surgeon policies.** Included among the many existing payment structures are those that reduce surgical bundled fees under certain circumstances in which multiple procedures or multiple physicians are involved in the care of the same patient. These policies are in place to account for overlap in resources, including those for E/M services. In addition, modifiers exist to account for a situation in which the post-op care is not provided by the operating surgeon, rarely if ever a situation for a neurosurgical patient.

- **RUC review of 10- and 90-day globals.** The RUC has begun to review 10- and 90-day global periods through the Relativity Assessment Workgroup (RAW). Recently, RUC-reviewed codes are clearer in terms of E/M work and we believe the RUC is the appropriate venue to address the valuation of the global surgical package. At the request of CMS, the RUC is in the process of examining high volume and high expenditure codes that have not been previously reviewed. We believe that this review by the RUC is the most effective method of addressing the issue. We maintain that improved education and RUC review of high expenditure codes that have not been

previously reviewed will adequately address concerns about the appropriate valuation of global surgical services.

Global Surgical Package Comment Summary

The vast scope of the CMS proposal to eliminate global surgical packages presents significant disruption and disservice to all stakeholders. CMS is overburdened with numerous statutorily required work and we fervently believe that the wholesale dismantling of the 10- and 90-day global surgery bundle would neither result in savings to Medicare, nor would it be implemented in a way that would rationally justify its undertaking. The RUC has provided numerous suggestions for sources of outside data to consider in identifying issues of concern in the global packages. CMS can achieve its goals of more accurate valuation in the global surgical packages without forsaking a practice that emphasizes integration and continuity of care.

Professional Liability Insurance (PLI)

CMS reviews, and if necessary, adjusts malpractice (MP) RVUs every five years. For 2015, the agency conducted the third comprehensive review, proposing new malpractice RVUs for all services. The proposed resource-based MP RVUs are based on updated professional liability insurance premiums. We have the following specific comments on PLI:

Proposed Crosswalk for Neurosurgery PLI update

According to CMS, premium data for neurosurgery were only available from 24 states; therefore the agency did not have sufficient data to calculate a national average premium amount for neurosurgery for purposes of updating the malpractice RVUs. As a proxy, CMS used blended data for neurology (surgical) and neurosurgery, claiming premiums are similar. We agree that this crosswalk is more appropriate than merely cross-walking neurosurgery to neurology.

PLI Five Year Review

Over the last ten years, the RUC and CMS have moved away from a five year review for work and PE and have update work and PE on an on-going basis. The RUC has proposed to do the same with PLI RVUs. As the specialty with the highest professional liability insurance premiums, neurosurgery supports moving from a five year review to a yearly update. Updating the PLI RVUs annually would allow the most current PLI premium information to be used, increasing the accuracy and reliability of PLI payments.

PLI Determination for Low Volume Codes

The issue of valuing PLI RVUs for volume codes has long been a concern for neurosurgery. We are pleased that CMS is proposing to use the risk factor of the dominant specialty in determining the PLI RUVs for most services performed fewer than 100 times per year based on the 2013 Medicare claims data. However, some code are so rarely performed or have no Medicare volume for a particular year that the dominant specialty may not accurately the risk. The RUC has asked specialties to review these codes and has provided a list to CMS. We agree that it is appropriate for the PLI of these codes to be considered on a case by case basis.

Change to Publish Proposed Values in the July NPRM

Timing of Publication of Proposed Values

The AANS and CNS support a system under which CMS provides greater transparency and timely notice of its plans to establish or change the values of services provided under the Medicare

Physician Fee Schedule. We also note, that many members of Congress share our views and have raised this issue with the agency. We appreciate the agency's willingness to consider altering the schedule and process by which it publishes proposed values, but as always, the devil is in the details. We therefore provide several comments for your consideration:

- **Calendar year 2016**. Clearly changing the current policy to publish proposed values in July 2015 presents a unique situation. The AANS and CNS would like the proposed 2016 Medicare Physician Fee Schedule to include as many of the proposed code values as possible, while not disrupting the CPT/RUC schedule. We believe that CMS could review and include a significant number of RUC-reviewed values without imposing a January 15, 2014 deadline for receiving data from the RUC. We ask the agency to exercise flexibility in calendar year 2016 by publishing as many proposed values as early as possible to give specialties advanced notice, particularly if the proposed values differ from the RUC-recommended values.

- **Calendar year 2017 and beyond**. The AANS and CNS support the inclusion of proposed values in the proposed Medicare Physician Fee Schedule notices from 2017 and beyond. We urge CMS to work with the RUC to establish a timeline that allows physicians earlier notice of changes in valuation. We support the comments included in the Aug. 13, 2014 letter submitted to CMS by the AMA and 70 specialty societies.

- **G-codes**. The AANS and CNS oppose the development of G-codes to use as temporary codes in 2016. This proposal would cause unnecessary confusion and significant additional work.

Refinement Process and Need for Review and Appeal

The AANS and CNS support a continued "appeal" and review process similar to the refinement process of old. In the 2011 Medicare Physician Fee Schedule final rule, CMS agreed to make the refinement process more transparent. However, CMS did not fulfill its promise. In fact, CMS went on to essentially gut the process, rendering it meaningless. We felt at that time, and continue to believe now, that CMS was changing a process that had been a useful check and balance for twenty years.

While we realize the August 2011 refinement panels were problematic because of the large volume of specialties objecting to the "site of service" screen reductions, we believe that CMS threw the baby out with the bathwater when the agency limited the process to only to those specialties that had information not presented at the RUC. In many instances, there is no additional information to provide to a refinement panel because all available data has been presented to the RUC. However refinement also allows specialties to analyze and challenge to CMS rationale for changing RUC-proposed values, which the specialty does not see until the final rule. Sometimes the CMS discussion in the proposed rule includes little rationale or is based on erroneous information and specialties can use the refinement process to present these concerns to a panel of Carrier Medical Directors and physician colleagues from other specialty societies who can take a fresh look at the RUC and CMS rationales.

Over the years, organized neurosurgery participated in refinement panels, and while full RUC values were not restored in every case, the review was reasonable and sometimes forged a middle-ground value somewhere between the RUC and CMS recommendations. If the agency decides to eliminate the refinement process, we ask that an alternative review and appeal process be developed. The AANS and CNS stand ready to help develop such a process.

Private Contracting/Opt-out

The AANS and CNS are long-time proponents of private contracting for Medicare patients and support the ability of physicians to opt-out of the program without the requirement to file an affidavit

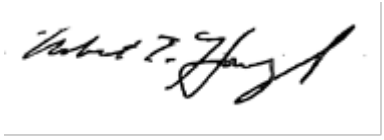
every two years to remain in an opt-out status. We support CMS' clarification that the physicians who have validly opted-out of the Medicare program are nevertheless still permitted to write orders and referrals for Medicare beneficiaries. This will assist beneficiaries in receiving the care they need. We fully support a policy that would create a safe-harbor period physicians to remain opted-out of the Medicare program, without penalty or possibility of recoupment, when they have mistakenly not reaffirmed their intention opt-out. The current requirement — that every physician who opts-out of Medicare must re-file an affidavit every two years in order to maintain his or her opt-out status — is unnecessary and seems completely illogical. No other government program comes to mind, where one has to file a legal document in order to continue not to participate. Most important, this creates an unnecessary burden for these physicians to needlessly submit documentation every two years, and has the potential to catch some physicians unaware, at great peril. Failing to submit such documentation may expose physicians to significant penalties. After the two-year minimum that is required by law, the opt-out period should be effective indefinitely, unless and until the physician chooses to terminate his or her opt-out status**.**

Concluding Remarks

The AANS and CNS appreciate the opportunity to comment on the reimbursement provisions of the proposed 2015 Medicare Physician Fee Schedule. As always, we recognize the hard work and expertise of the many individuals involved in Medicare policy. We urge the agency to consider the ever increasing burden that it places on physicians and other stakeholders involved in Medicare payment policy, and request that CMS reconsider the many proposals that are causing significant disruption for little or no potential gain.

If you have any questions or need additional information, please contact us.

Sincerely,



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