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August 26, 2014

Ms. Marilyn Tavenner
Administrator

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

Submitted electronically: <http://regulations.gov>

RE: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015; file code CMS-1612-P

Dear Administrator Tavenner:

The American Academy of Neurology (AAN) is the premier national medical specialty society for neurology representing more than 27,000 neurologists and clinical neuroscience professionals. It is dedicated to promoting the highest quality patient-centered neurologic care. A neurologist is a physician with specialized training in diagnosing, treating, and managing disorders of the brain and nervous system such as Alzheimer's disease, stroke, epilepsy, Parkinson's disease, migraine, multiple sclerosis, and brain injury. The AAN has reviewed the Centers for Medicare & Medicaid Services' (CMS) Proposed Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2015 [CMS-1612-P] and respectfully offers comments related to these topics for your consideration:

- **Improving the Valuation and Coding of the Global Package**
- **Process for Valuing New, Revised and Potentially Misvalued Codes**
- **Chronic Care Management (CCM)**
- **Reports of Payments or Other Transfers of Value to Covered Recipients**
- **Physician Payment, Efficiency and Quality Improvements-Physician Quality Reporting System**
- **Electronic Health Record Incentive Program**

Improving the Valuation and Coding of the Global Package

As part of the potentially misvalued codes initiative, CMS is proposing to transition all 10-day and 90-global surgical codes to 0-day codes by 2018. **The AAN enthusiastically supports this proposal.** We believe that transitioning all 10-day and 90-day global codes to 0-day codes will not only increase the accuracy of payment under the fee schedule but will also eliminate disparities between the payment for E/M services in global periods and those furnished individually. For instance, often the post-procedure care performed by others in the changing systems of care is offered as an example of the need for change. Another major aspect is the institutions that care for those with more severe disease and co-morbidities. Current global payments do not accurately recognize the care delivered. [Our longstanding position](#) is supported by the Office of Inspector General (OIG). In 2005 and 2012, the OIG published reports concluding that the RVUs for the global surgical package are too high because they include the work of E/M services that are not typically furnished within the global period for the reviewed procedures. The number of post-operative visits is now determined largely from a RUC survey of about 30 or more surgeons. As noted by the OIG findings, that method often does not meet the requirements of an evolving resource-based payment system.

In this proposed rule, CMS seeks input on the best approach to achieve this transition, including the timing of changes, the means for revaluation, and the most effective and least burdensome means to collect objective, representative data regarding the actual number of visits currently furnished in the post-operative global periods. The AAN believes that the resource-based physician payment mechanism most accurately values the physician's time, work intensity, and practice expense. Unfortunately, the global payment methodology has removed CMS' ability to audit the accuracy of Harvard or RUC valuation for services with a global period. As procedures change over time, so do the frequency and intensity of post-operative visits. In addition, there is no documentation requirement for post-operative visits, so CMS cannot audit the actual frequency or intensity even if data were reported. Furthermore, CMS cannot track those instances when post-operative follow-up is provided by a different physician or in a different geographic location.

The AAN supports CMS' proposed timeframe to transition 10-day global codes and 90-day global codes to 0-day codes by 2017 and 2018, respectively. We recommend that CMS establish auditable documentation requirements for inpatient and outpatient post-operative visits of varying time and intensity, since the cost of documentation, in time and practice expense, is a direct part of the resource use to provide the service. Post-operative visit notes might follow the same documentation as for E/M visits, but simpler requirements may be adequate. We recommend further that CMS establish G-codes for three levels of post-operative visits furnished by the original surgeon or another surgeon with the same board certification, as well as a second set of three level G codes for post-operative visits furnished by another provider. CMS should also develop methods to fairly measure the duration of E/M times through which a large sample of surgeons might report the number and intensity of post-operative visits. Finally, we recommend that CMS track E/M services provided to surgical patients within the global period, by a different physician, for the same or similar diagnosis, to begin to understand what portion of post-operative visits may be billed outside of the global period.

Most large health systems and ACOs are likely to require detailed information of this type, including the number and type of post-operative visits by provider, because those data will inform payment rates to each physician. Now that mature IT can capture and store data on individual services more easily than in the past, this further supports our position that the global payment system might be outdated, and a resource-based payment system might better pay for services individually as medically necessary and as provided.

Process for Valuing New, Revised and Potentially Misvalued Codes

Currently, changes for new, revised, and potentially misvalued codes are announced first in the final rule in November and implemented on January 1. Neurologists were directly impacted in November 2012 when the interim final values assigned to nerve conduction studies (NCS) and needle electromyography (EMG) received significant reductions in payment as a result of the potentially misvalued code initiative in the 2013 Medicare Physician Fee Schedule (MPFS) final rule. Some services for NCS and EMG experienced cuts of more than 50 percent. Unfortunately, we were unaware that CMS was considering changes in the payment rates of this magnitude and had no opportunity to comment before these values were finalized. Not only were these cuts devastating, but the timing left neurologists scrambling to prepare their practice for the changes.

In an effort to respond to the call for greater transparency in the valuation process for new, revised and potentially misvalued codes, CMS is proposing to publish the values of these codes in the Proposed Rule rather than in the Interim Final Rule in the 2016 Medicare Physician Payment Schedule. **The AAN strongly supports greater transparency and the opportunity to impact proposed payment reductions, however we have concerns about CMS' proposed timeline.** Unfortunately, the 2016 implementation date is premature, as it would have a serious impact on the development of new technology and new code bundles which are already underway for the Current Procedural Terminology (*CPT*[®]) 2016 code set. The cycle for the *CPT* 2016 code set began with code change applications for the May 2014 *CPT* Editorial Panel Meeting submitted by February 14, 2014 and will conclude on February 7, 2015. We believe that it would be highly inappropriate for CMS to implement this proposal in the November 1, 2014 Final Rule because the *CPT* Editorial process for the 2016 cycle will already be nearly complete by that date, and requiring publication in a proposed rule next summer will delay their implementation in Medicare by another year. If CMS were to announce a 2017 implementation date on November 1, 2014, it would provide appropriate notification to those submitting code change applications by the first *CPT* 2017 deadline of February 13, 2015. **Therefore, we strongly urge CMS to begin implementing the new timeline and procedures for the *CPT* 2017 cycle and the 2017 Medicare Physician Payment Schedule.**

In order to accommodate the publication of proposed valuation of new, revised and potentially misvalued services, CMS proposes to require that all RUC recommendations be submitted by January 15 of each year. For 2016, this would mean that the May 2014 *CPT*/September RUC meeting would be the only opportunity for the medical community to offer description and recommended valuation of new technology and code bundles, since the RUC will not have the opportunity to consider codes from the October *CPT* Editorial Panel meeting until January 29, 2015.

In addition, this proposal would extend the time required to generate a code/relative value to 22 to 30 months for each subsequent CPT code set cycle at a time when CMS, the CPT Editorial Panel and the RUC are being asked to reduce the amount of time needed to accommodate changes.

The AAN has reviewed and supports the American Medical Association's (AMA) proposal to expedite the review process for new, revised and potentially misvalued services. We understand that this proposal would retain the current meeting infrastructure for both CPT and the RUC, while shifting the workflow to accommodate the review of commonly performed services to the May CPT/October RUC and October CPT/January RUC meetings. Under the AMA's proposal, the February CPT meeting would predominantly address editorial changes, clinical lab payment schedule services, and new technology services, with expected low volume. The April RUC meeting would replace the formerly lighter September RUC meeting agenda and would be utilized to review the low volume new technology services and discuss methodological and process issues. We believe that CMS should be able to publish consideration of the low volume new technology codes in the Final Rule as interim values, as these changes would have minimal impact on the other services on the Medicare Physician Payment Schedule. Under this alternative, the AMA would submit RUC recommendations to CMS within one month of each meeting (each November and February for new, revised and potentially misvalued; and each May for low volume new technology).

We strongly urge CMS to adopt the AMA proposal for modifications in CPT/RUC workflow to accommodate publication in the Proposed Rule, while ensuring that new technology may be described and valued in an efficient and timely manner.

Lastly, CMS is proposing to eliminate the Refinement Panel process currently utilized by the Agency to consider comments on interim relative values. The Refinement Panel is considered by stakeholders to be an appeals process. The complete elimination of the Refinement Panel indicates that CMS will no longer seek the independent advice of contractor medical officers and practicing physicians and will solely rely on Agency staff to determine if interim relative values are appropriate. The AAN recognizes the importance of the Refinement Panel because our NCS and EMG codes went through this process last summer. **In the spirit of transparency and fairness, we respectfully recommend that if CMS eliminates the Refinement Panel, they consider creating an appeals process that would allow organizations to continue to comment on interim relative values.**

Chronic Care Management (CCM)

The AAN expresses its gratitude to CMS for its support of CCM services not only for primary care physicians, but also for specialists who spend a majority of their time coordinating care. Neurologists treat, and are often the principal care providers for, patients with complex chronic diseases of the brain and nervous system. We believe our shared goal is to recognize the non face-to-face and undervalued services of chronic care management, and we appreciate the support of CMS.

We support the Agency's decision to abandon most of the standards outlined in the 2014 MPFS proposed rule. It is our position that these standards were too restrictive and would have prevented practices that provide CCM services from qualifying for payment. We also thank CMS for revising the requirement for "incident to" services by no longer requiring CCM services be furnished under direct physician supervision or by a person directly employed by the practitioner or practice. We understand that this is intended to make it

easier for providers to delegate care management to their practice staff. We also commend the Agency for removing the restriction that services provided by clinical staff under general supervision may be counted only if they are provided outside of the practice's normal business hours. This change will allow clinical staff time to be counted at any point during which CCM services are provided.

We are, however, concerned that the Agency is requiring providers who furnish CCM services to utilize a certified electronic health record (EHR) system or other health information exchange platform that meets meaningful use requirements in order to provide all members of a patient's care team with 24/7 access to the patient's records. While we certainly see the value in leveraging a practice's EHR capability, the potential practice standard under discussion appears to suggest that all of the EHRs used by the various providers who are involved in a beneficiary's care must be interoperable. If so, then we are concerned that this standard could limit access to CCM services because complete interoperability is not yet attainable for many physicians. The AAN suggests that given the rapid change in the healthcare delivery system currently underway, the requirements and standards for these services should also encourage practices to increase these services to those with chronic disorders. As such, we do not believe that any requirements for EHR or EHR capability should be tied to or related to meaningful use. In addition, many of the meaningful use requirements do not apply to CCM and would disqualify many practices that are currently providing the care.

The AAN is also disappointed that CMS is proposing a payment rate of \$43.67 for the G code. The scope of services required in order to bill CCM simply cannot be performed for the proposed payment amount. The AAN, along with other medical societies, has been working with CMS for the past three years on implementing this service in the Medicare fee-for-service program. We urge CMS to consider the coalition's alternative recommendation in its letter dated September 2, 2014.

Reports of Payments or Other Transfers of Value to Covered Recipients

The AAN urges CMS to retain the existing exclusion for accredited and certified continuing medical education ("CME") under the Open Payments program for two reasons:

1. The existing exclusion was included in the final rule as recognition by CMS that providers of accredited and certified CME strictly adhere to established firewalls that protect against inappropriate commercial influence, as opposed to promotional educational offerings by applicable manufacturers; and
2. There is significant misinterpretation by applicable manufacturers as to what constitutes a reportable "indirect payment. As a consequence, there will be unnecessary reporting of non-reportable indirect payments for accredited and certified CME in conflict with the intent of CMS to exclude accredited and certified CME from reporting.

Importance of CME Exclusion

The AAN recommends that CMS maintain the exclusion detailed at §403.904(g)(1). In this subsection, CMS created a clear and valuable exclusion from reporting requirements for compensation of faculty at, and tuition subsidies of attendees/faculty associated with, accredited or certified CME programs. The medical education community in the US has put in place an effective firewall to keep CME independent, through strict universal adherence to

the Standards for Commercial Support: Standards to Ensure Independence in CME Activities, promulgated by the Accreditation Council for Continuing Medical Education (ACCME). These Standards have been adopted by all three CME credit systems in the US: the American Academy of Family Physicians, the American Medical Association, and the American Osteopathic Association.

The AAN understands that CMS' intent may be to simplify the Open Payments rule and to protect the government from pressure to add to a list of continuing education accreditors and standards, when it is not the government's role to adjudicate such requests. Should CMS wish to consider other accreditors or other equivalent standards, an extant mechanism exists to do so. An inter-professional coalition of accreditors of continuing education in the health professions called, Joint Accreditation, has been convened since 2009 and is a collaboration of ACCME, the Accreditation Council for Pharmacy Education, and the American Nurses Credentialing Center. This is the function of professional self-regulation, and does not require additional governmental regulation.

A core tenet of accredited or certified CME activities is the independence and scientific and clinical integrity of the planning process. Under the Standards, applicable manufacturer supporters cannot exert influence and do not have a role in planning content nor selecting faculty in accredited CME. Additionally, direct compensation from manufacturers to physicians for serving as faculty or speaker is prohibited in the accredited CME setting. Similarly, manufacturers do not identify covered recipients who should receive tuition subsidies; those decisions are left to the accredited CME provider. These central features of accredited CME could be significantly undermined if manufacturers were forced to report faculty or speaker payments or tuition subsidies for attendees and faculty through Open Payments, as though the payments were transfers of value designated for specific covered recipients. The discussion in the final rule notes CMS' intention to separate accredited or certified CE programs from other education and speaking engagements.

Removing the exclusion and relying on the indirect payments provision would open the door for manufacturers to misinterpret the law to require reporting of CME payments in circumstances that would not otherwise meet the requirements for indirect transfers of value. This will discourage physician participation as faculty and attendees of such events, and undermine the value of accredited or certified CME that is already designed to be free of manufacturer influence.

Manufacturer Misinterpretation of the Indirect Payments Standard

The AAN recognizes that CMS' proposed revisions to the Open Payments rule intends that manufacturers' contributions to accredited and certified CME programs would remain non-reportable "indirect payments." However, the AAN strongly recommends that CMS keep the present exclusion because we've experienced significant misinterpretation of the "indirect payments" standard in the rule. While CMS in 403.904(i)(1) refers back to the definition of an indirect payment or transfer in 403.902, in interpreting the rule, manufacturers often do not. Section 403.902 makes clear that indirect payments or transfers of value made by an applicable manufacturer to a third party are only reportable if the applicable manufacturer "requires, instructs, directs, or otherwise causes the third party to provide the payment or transfer of value, in whole or in part, to a covered recipient(s)." Many manufacturers have taken an extremely conservative approach to the indirect payment language of the rule, often

applying only the knowledge standard without considering whether the manufacturer required, instructed, or directed an indirect transfer to occur. Indeed, in some cases, manufacturers are reporting payments made through grants that are indisputably unrestricted (in the sense the manufacturer did not require, instruct, direct, or otherwise cause the third party to provide the payment to a covered recipient) if they become aware of the identity of physicians who may have indirectly benefitted from such grants within the time frame set forth in 403.904(i)(1). This results in significant administrative burden and over-reporting of indirect payments by third parties, including accredited CME providers. To prevent burdensome over-reporting, the CME exemption should remain in effect.

The clear, direct guidance of the CME exclusion has been a valuable provision of the final rule because it prevents unnecessary reporting. Given the overly conservative compliance environment that AAN has experienced, we believe that some manufacturers will interpret the elimination of a specific CME exclusion in the Open Payments rule as an indication that CME faculty and attendees should be reported as recipients of indirect payments or transfers of value in circumstances where manufacturers learn the identity of those individuals within the time frame set out in 403.904(i)(1), even where the circumstances do not meet the causation requirement in 403.902. The cost of confusion around indirect payments is already high. Additional reporting of CME could lead to a chilling effect on attendance at accredited and certified CME programs, and reluctance of highly-qualified faculty to participate for fear of being reported and giving the appearance of a relationship with a manufacturer where none actually exists. Further doubt or lack of clarity about the reportability of CME could result in these unintended consequences.

To provide additional clarity, the AAN urges CMS not only to retain the specific exclusion for accredited CME but also to bring the language from the preamble stating that where the CME provider has full discretion over the speakers, the payments are outside of the scope into the final rule. Specifically, we recommend that CMS spell out in the revised rule that where a manufacturer “does not either select or pay the covered recipient speaker directly, or provide the continuing education provider with a distinct, identifiable set of covered recipients to be considered as speakers for the continuing education program, CMS will consider those payments to be excluded from reporting under § 403.904(i)(1).” (Proposed Rule 40384). As we have noted, this change would bring much needed clarity to the compliance environment as it reinforces the basic premise of the indirect transfers rule—i.e., that applicable manufacturer payments or transfers of value to third parties are not reportable if the manufacturer *does not require, instruct, direct or otherwise cause* the payments to be made a specific physician or teaching hospital.

Alternative Approach

If CMS chooses to rescind the current exclusion, the AAN urges CMS to consider the AMA recommendation in its letter dated August 5, 2014, as an alternative. This recommendation would slightly modify the proposal to add the language that the exemption applies under section 403.904(g)(1)(i) when an applicable manufacturer provides funding to a CME provider, but does not select or pay the covered recipient speaker/faculty or attendees directly, or provide the CME provider with a distinct, identifiable set of covered recipients to be considered as speakers/faculty or attendees for the CME program. The agency can include the guidance in the preamble that the foregoing is achieved where the industry donor is unaware of the speakers/faculty and other participants before committing to fund the activity

under section 403.904(g)(1)(i). To allow CME providers time to ensure that their processes comply with the modified exemption, we urge CMS to make this change effective six months after the final rule is issued.

Additional Considerations

The AAN also supports AMA's recommendation (see August 14, 2014, letter) that CMS expand the exclusion for education materials that directly benefit patients to include medical textbooks, journal reprints, and supplements for the reasons articulated by the AMA. The AAN also shares AMA's concerns, and supports their recommendations, regarding the physician registration process and the current timeline for the reasons articulated by the AMA.

Physician Payment, Efficiency and Quality Improvements- Physician Quality Reporting System (PQRS)

The AAN commends CMS for proposing to retain the dementia, Parkinson's disease and counseling for women of childbearing potential with epilepsy measures in the PQRS program. We also thank the Agency for proposing to adopt the patient care preference measure for Amyotrophic Lateral Sclerosis (ALS). We are, however, concerned that CMS is proposing to remove the Stroke and Stroke Rehabilitation measure set from PQRS. Stroke is the fourth leading cause of death in the United States and is a major cause of disability. Neurologists have particular expertise in the treatment of stroke and often represent the first line of treatment for stroke patients. **We disagree with the Agency's proposal to remove these measures from PQRS.** If CMS were to eliminate these measures from the PQRS program, it could severely impact neurologists' ability to report on quality measures and improve the quality of care their patients receive for stroke.

CMS recommends removal because this measure set represents a clinical concept that is currently included within the inpatient standard of care to improve the quality of life for patients diagnosed with ischemic or intracranial stroke when clinically indicated. We respectfully request that before removing these measures CMS confirm whether it has data to support its conclusion that the measure set represents a clinical concept that is currently included within the inpatient standard of care. If the data are not sufficient to support this conclusion, we request that CMS keep this measure set in the 2015 PQRS program and beyond until such data become available. It is important for CMS to continually consider additional measures that allow for greater participation in the program by more specialties.

The AAN applauds CMS' intent to align the PQRS and Electronic Health Record incentive programs by increasing the PQRS reporting requirement to nine measures. We realize that this will ultimately maximize the number of physicians participating in multiple programs through better coordination. However, in order to be considered a successfully reporting provider in 2015, CMS is proposing that for physicians who see at least one Medicare patient, of the nine individual measures reported at least two must be cross-cutting measures. The addition of two cross-cutting measures may be a significant reporting burden to physicians who are already struggling to meet the current requirements.

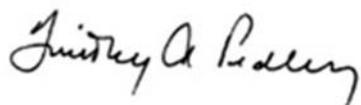
Electronic Health Record (EHR) Incentive Program

In response to feedback from physicians and other stakeholders, CMS proposes to no longer require EHR products be recertified to the most recent version of the electronic specifications

for clinical quality measures. The AAN supports this proposal because it allows flexibility by recognizing some of the challenges physicians encounter in attaining meaningful use. However, the AAN believes that until there are more specialty specific measures available for reporting in the EHR Incentive Program, CMS should continue to allow physicians to attest for the EHR incentive program.

The AAN appreciates the opportunity to provide comments on this proposed rule. Should you have questions about our comments or require further information, please contact Ms. Daneen Grooms, Manager of Regulatory Affairs, at dgrooms@aan.com or (202) 525-2018.

Sincerely,

A handwritten signature in cursive script that reads "Timothy A. Pedley".

Timothy A. Pedley MD, FAAN
President, American Academy of Neurology