August 21, 2017

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 314G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program [CMS-1676-P]

Dear Administrator Verma:

The American Academy of Neurology (AAN) is the premier national medical specialty society representing more than 32,000 neurologists and clinical neuroscience professionals and 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 (MS), and brain injury.

The AAN appreciates CMS’ effort in this proposed rule to reduce regulatory hassle through the Request for Information and changes to the Appropriate Use Criteria program, Physician Quality Reporting System, Meaningful Use, and the Value Modifier. However, it is critical that CMS continue a dialogue with specialty societies like the AAN as it moves forward in the reevaluation of E/M guidelines. We offer a number of options CMS can take to further reduce regulatory burdens on neurologists across the country and emphasize the need to carefully reconsider the E/M documentation standards.

1. Appropriate Use Criteria (AUC)

The AAN appreciates the opportunity to provide further comments on this important issue to neurologists. We agree and support the delay of implementation to 2019. Further education from CMS for providers including the “town hall” approach is very much needed. Many providers are completely unaware of this upcoming requirement. We also suggest several other ideas for CMS to consider in the final rule:
The AAN requests clarification on functionality, specifically related to warning issues and the potential impediment to provider workflow. The AAN asks for a standard on how the functionality works and there should be more public comment on this particular issue.

As noted in the recent proposed Quality Payment Program (QPP) rule, we agree CMS should support the incorporation of AUC as a high-impact Improvement Activity under the Merit-based Incentive Payment System (MIPS).

Regarding outliers, CMS should further elaborate on its formal notification process for providers deemed to be outliers. Formal warning with an appropriate period of time to change behavior prior to being subjected to prior authorization is reasonable. We are especially concerned for specialized and tertiary care centers with a significant population of complex patients, in that they may be unfairly identified as outliers, even though imaging is often appropriate.

The AAN recommends adding language to the hardship exception if the Provider-led entity (PLE), or the vendor which provider relies on to obtain AUC, becomes unavailable.

The AAN also believes that having separate G-codes for every qualified Clinical Decision Support Mechanisms (CDSM) is unwieldy and represents a burden on the coding provider. Additionally, a possible lag time exists for the approval of CDSM and new G-codes.

For the Value Modifier, CMS took a staged approach in which the large centers were measured first, then medium practices, then small practices. For an intervention this big, we recommend a similar staged approach so that larger medical practices that have resources to figure this out go first, and small and solo practices have more time to adjust. Moving from nothing to implementing an intervention for eight clinical areas is a large step. The AAN believes it would make more sense to implement this process in a way such that one priority clinical area of the clinician’s choosing is selected. This would help prove that the policy can work, and then expand the number of clinical areas, similar to the way quality measures in the Physician Quality Reporting System (PQRS) were implemented.

2. E/M Guidelines

The American Academy of Neurology applauds CMS’ ongoing appreciation and effort to reform E/M documentation guidelines last revised in 1997. We offer two different levels of comment:

First, the AAN supports CMS’ effort to reconfigure necessary documentation for reimbursement, with CMS’ focus towards measuring quality and cost and eliminating antiquated and unnecessary documentation requirements.

To this end, the AAN would ask that CMS consider a policy such that for any new reporting requirement, or expected electronic health record (EHR) click, that may be expected of providers, a different requirement, or EHR click be eliminated.

As practices continue to work towards a paperless system, patients are now partners within their EHRs such that they may be required to administer more than 20 clicks to document
“yes” or “no” with respect to just the Review of Systems. This creates the potential of “click fatigue” for patients which may affect their answers on more important questions and also slows the patient intake for providers, resulting in inefficiencies during the visit. The AAN agrees with CMS that if the history and physical exam are documented and generally consistent with complexity of MDM, there is no longer a need to maintain such detailed specifications for what must be performed and documented. Elimination of Review of Systems would be a beginning step in the right direction to diminish hospital, provider, and patient burden.

Further, the AAN supports CMS consider re-allocating some of its resources from auditing elements of history and examination to expansion of its efforts to collect process and outcome data through natural language, as well as ongoing improvements to understand disease burden; develop better process and outcome measures that reflect disease entities, their severity, comorbidities, and management; and their impact on activities of daily living. The AAN also strongly recommends that CMS continue to provide payments based on time coding as an alternative payment choice as well. In most fields of medicine, time spent with a patient and/or family discussing a diagnosis, its management, and prognosis is a critical and necessary role to ensure our patients are treated humanely, with respect and dignity.

While the AAN is encouraged by voice recognition and natural language processing, we do not yet believe it has reached a level of technical competence for most practices. Further, we do not believe EHRs are presently user-centric enough to leverage work flow efficiencies. Continuing, we encourage CMS to work closely with the Office of the National Coordinator for Health Information Technology to require certified EHRs to be able to seamlessly communicate with each other, requiring standardized mapping technology across the industry. The AAN also requests that information exchange require a simple user-friendly approach to implement.

Second, we agree with CMS that the vital components of E/M services have evolved, the processes of visit documentation have changed, and current documentation guidelines place unnecessary burdens on clinicians. We also agree that the level of service should optimally be determined by the complexity of Medical Decision Making (MDM) or the amount of time for each encounter.

We recommend:

- CMS should continue to accept current CPT E/M visit definitions.
- CMS should maintain the existing four levels of History and four levels of Examination: Problem Focused, Expanded Problem Focused, Detailed, and Comprehensive.
- CMS should rule that the necessary components for each level of History and Examination are those components that support the level of MDM. The “key components” for each level, as defined in the 1995 and 1997 Documentation Guidelines are guidelines (as stated in the titles of those documents), and acceptable documentation within each level does not require each of the “key components.”
- Providers and auditors should first assure that the level of MDM justifies the level of each E/M visit and then should assure that the documented components of History and Examination are sufficient to support the clinical action.
• CMS should promulgate simplified MDM audit guidelines for use by clinicians, coders, and auditors.

We also support CMS consideration to expand the possible number of E/M codes. In recent years CPT and CMS have approved new codes for E/M, such as codes for transitional care management and chronic care management. We believe that CMS should consider a separate set of E/M codes for use in the post-operative period, since those visits have different considerations regarding history, examination, and MDM.

Finally, we support E/M codes for non-face-to-face synchronous and asynchronous care for those illnesses where it is safe to do so, which could improve patient care by increasing provider availability and efficiency, as well as reduce costs to the patient and medical system by moving the care outside of the facility.

3. Request for Information on CMS Flexibilities and Efficiencies

The AAN thanks CMS for the opportunity to provide ideas regarding flexibilities and efficiencies. We believe there are several opportunities for CMS to issue regulations and policies that will simplify rules and policies for beneficiaries, clinicians, providers, physicians, and suppliers.

Appropriate Use Criteria (AUC)
Although this may change given the proposed rule, the AUC mandate for physicians ordering diagnostic imaging services is scheduled to go into effect on January 1, 2018. There is some uncertainty around the readiness of the infrastructure to implement AUC. Further, the lengthy AUC documentation requirements will amount to more time away from patients. As such, the AAN recommends CMS delay the start date of AUC until at least 2019 and simplify the phase-in requirements. Hardship exemptions should also be expanded.

EHR Vendor Data Blocking & Interoperability
EHR vendors continue to engage in data-blocking activities. This runs contrary to the goals of interoperability and the requirements physicians face under the Quality Payment Program.

The AAN recommends CMS work with the Office of the National Coordinator for Health Information Technology (ONC) to implement a vendor data-blocking attestation requirement as part of all current and future health information technology certification editions. ONC should also prioritize and ensure interoperability solutions are scalable and can be replicated with minimal cost, time, and effort.

Other suggestions related to EHR technology include:

• Establish a standard for interoperability for every EHR vendor. Mandate one click access to all EHR data. The technology is already available, and we all need this Medicare, providers, and patients.
• Mandate universal consent forms for patients to allow access to their data. At present individual institutions may require separate and different forms for information sharing. For example, the patient or treating physician may need to download, print, and then sign multiple consents to access records from multiple separate institutions or departments.

• Mandate full natural language processing be integrated with the EHR.

• Incentivize specialist providers to report specialty-specific quality measures, rather than generic measures. General measures now may be performed by primary care or other providers, but reported by specialists when performed a second time, or when the primary care providers are in the same group. Specialist practice quality can be better ranked if specialists report specialty quality measures.

• Mandate the following electronic standards as a later target:
  o Require wireless connectivity capability and device integration with seamless incorporation into flowsheets and other documentation.
  o Require default functionality to capture specialty-specific quality data.
  o Require improved documentation capabilities that allow information to be entered only once and then used to populate registries, discharge summaries, integrated handoff tools, and other forms.
  o Provide the regulatory framework for all EHRs to exchange data.

• The portability of EHRs must be made easier for physicians to analyze relevant data and avoid the concerns of an audit.

Auditing of E/M
As we previously mentioned, the AAN recommends CMS simplify the audit process for E/M visits by stopping any audit of the history and physical exam, limiting the audit to Medical Decision Making (MDM); and further that CMS promulgate simplified audit guidelines for MDM to improve the consistency of audits across multiple auditors and practice settings.

Program Integrity
Physicians face significant pre-payment and post-payment scrutiny from a variety of government entities and contractors. The volume of reviews and types of reviewers is confusing, adds unwarranted physician burden and unnecessary costs, and disrupts and distracts from delivering care. Further, some contractors are auditing and attempting to recoup against services that Medicare does not require or are not adhering to CMS requirements surrounding the approval of Local Coverage Determinations (LCD).

The AAN recommends CMS develop a single transparent, consistent, and fair review process to reduce administrative burden and consider ways to avoid situations that lead to reviews in the first place. Additionally, HHS should eliminate all duplicate reviews by different federal government reviewers.

Recovery Audit Contractors (RACs)
RAC audits continue to be a source of great frustration for physicians. As such, the AAN recommends CMS reevaluate the contingency fee structure for RAC auditors and implement financial penalties for RACs who make errors. RACs should be required to reimburse physicians for all costs incurred when physicians win on appeal. Finally, RAC audits should be reviewed by a practicing physician of the same specialty or subspecialty and in the same jurisdiction.

Medicare Advantage Risk Adjustment Scores
MA plans can receive increased payment from CMS depending on the health status of plan enrollees. This leads to frequent requests for medical records from physician practices, which is time-consuming and generally uncompensated. Often these requests are duplicative and unclear as to whether they are audit-related or not. Notably, physicians do not receive any additional compensation from MA plans that have higher risk adjustment scores.

The AAN recommends CMS accept physician attestations to support MA beneficiaries’ diagnoses instead of requiring documentation from medical records. Once beneficiaries have been diagnosed with a permanent condition (e.g., multiple sclerosis), documentation of this diagnosis should only be required once. Communication to the physician office regarding medical record request should be clear and standardized.

Prior Authorization and Utilization Management
Prior authorization (PA) is a process used by payers to determine coverage for a prescribed procedure, service, or medication. US physicians compete an average of 37 prior authorization requests every week, taking an average of 16 hours to process.

The AAN recommends CMS simplify PA requirements in Medicare Advantage (MA) and Medicare Part D plans, including the use of the National Council for Prescription Drug Program electronic PA transactions, disclosure of Part D and MA drugs subject to coverage restrictions to be searchable in electronic health record systems, and requiring that “peer-to-peer” reviews are done by physicians in the same specialty as the ordering physician. Ideally, PA should not be required for drugs that are the standard treatment for the patient’s condition and/or have been previously approved for treatment of an ongoing/chronic condition.

Certification and Documentation
Medicare documentation requirements delay care, create hassle, and are often redundant. The AAN recommends CMS standardize forms and eliminate the requirements for physicians to annual recertification of patient conditions for permanent chronic conditions. The more generic, the better.

Non-Narcotic Treatments
As a specialty of medicine that assumes a large role in neural modulation and thus pain management, the AAN has extensive expertise in non-narcotic management of pain disorders. As a result, we would encourage a partnership with CMS to develop pilot program to attempt to curb narcotic use. One subspecialty area that could be considered is headache medicine. Either through an APM or direct pilot program, the AAN can work with CMS to expand on non-narcotic approaches to healthcare. In the same area, the Academy would request CMS look closer at patient populations that respond to safe, non-narcotic treatments
that are standard of care across the country. Specifically, the AAN would ask CMS to look closer at cluster headache and consider use of oxygen therapy as a covered treatment as it is standard of care in substitution for narcotics and other illicit substances.

**Prescription Drug Monitoring Programs**
As CMS is aware, there is a growing number of states that have developed prescription drug monitoring programs (PDMPs). PDMPs are inherently valuable to better monitor patient use of narcotic prescriptions. However, it creates another burden on providers as they are now required to log into systems separate from their EHRs. This burden further decreases provider efficiency and/or decreases necessary time spent with patients. While the AAN understands this program is outside the scope of CMS, the AAN nonetheless encourages CMS to support federal efforts to innovate in ways that will integrate PDMPs within current EHRs. Additionally, neurologists are concerned with that confusion created by PDMPs when patients fill prescriptions across some state lines.

These rules are especially burdensome for neurologists because one class of medications that must be surveyed are the benzodiazepines, used to treat epilepsy, a common neurological disorder. Furthermore, the provider already monitors their prescription authorizations, thus the places the burden of being a detective of other provider’s prescribing practices on the provider, a skill set that goes beyond the provider’s training. As these medications are dispensed by pharmacies that can be seamlessly integrated with state or federal PDMPs, placing the burden of this task on the pharmacies under the direct control of pharmacy board procedures seems to be the safest approach.

4. **Physician Quality Reporting System (PQRS) Criteria for the 2018 Payment Adjustment**

In this rule, CMS proposes to modify the requirements for successful reporting under the 2018 PQRS payment adjustment without collecting any additional data for the 2016 reporting period. The AAN thanks CMS for offering this proposal. We agree with CMS’ intent for individual eligible professionals (EPs) and groups to be assessed for the 2018 PQRS payment adjustment using reporting criteria that are “simpler, more understandable, and more consistent with the beginning of the [Merit-based Incentive Payment System] MIPS.” We agree the proposed changes would result in fewer individual EPs and groups being subject to the PQRS payment reduction.

Specifically, we agree with the proposed PQRS modifications to reduce the number of required measures from 9 measures across 3 National Quality Strategy (NQS) domains to 6 measures with no domain requirement (consistent with the MIPS transition year). We agree with the elimination of the requirement that individual EPs and group practices reporting via QCDR report an outcome or “high priority” measure. We further agree that CMS should eliminate the requirement that individual EPs and group practices reporting via a claims or qualified registry report a cross-cutting measure.

5. **Value-Based Payment Modifier (VM)**
CMS proposes to modify the VM policies for the 2018 payment adjustment. The proposals would result in fewer EPs and groups receiving a negative VM adjustment, and because the VM is budget neutral, the size of the positive adjustments made to high performers would therefore also be reduced. The AAN believes CMS’ proposals appropriately balance the interests of high and low-performing groups and solo practitioners. The AAN also agrees the proposed policies would provide a better transition from the last year of the VM to the first year of MIPS (2019).

Specifically, the AAN agrees with the CMS proposal that certain groups and solo practitioners would be held harmless from downward adjustments under quality tiering for 2018. We further agree with the proposed category of groups and solo practitioners seeing a reduction from -4 percent to -2 percent for groups with 10 or more EPs and at least one physician, and from -2 percent to -1 percent for groups and solo practitioners with between 2 and 9 EPs, physician solo practitioners, and for groups and solo practitioners consisting only of non-physician EPs. Finally, the AAN agrees with CMS’ proposed changes aimed at aligning the upward adjustment for groups of 10 or more with those previously finalized for groups with 2 to 9 EPs and solo practitioners and for non-physician groups and solo practitioners.

6. Medicare EHR Incentive Program

The AAN agrees with CMS’ proposal to modify requirements for EPs and groups who choose to electronically report clinical quality measures (CQMs) through the PQRS Portal for purposes of the Medicare EHR Incentive Program for the 2016 reporting period. Specifically, instead of reporting at least 9 CQMs covering 3 domains, the requirement would be for reporting 6 CQMs with no domain requirement. This would align the reporting requirement for the Medicare EHR Incentive Program with the proposed modified requirement for the 2016 PQRS reporting period as well as the QPP transition year requirement.

Conclusion

The AAN again thanks CMS for the opportunity to comment on this proposed Fee Schedule rule. We appreciate CMS’ commitment to reducing regulatory hassle through the Request for Information and changes to the AUC program, PQRS, Meaningful Use, and the Value Modifier. We ask, however, that CMS continue a robust dialogue with specialty societies like the AAN as it moves forward in the reevaluation of E/M guidelines.

If you have any questions regarding this letter, please contact Daniel Spirn, Regulatory Counsel for the AAN, at dspirn@aan.com or (202) 525-2018.

Sincerely,

Ralph L. Sacco, MD, MS, FAHA, FAAN
President, American Academy of Neurology