September 4, 2018

Ms. Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
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 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program [CMS-1693-P]

Dear Administrator Verma:

The American Academy of Neurology (AAN) is the world’s largest neurology specialty society representing more than 34,000 neurologists and clinical neuroscience professionals. The AAN 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. These disorders affect one in six people and include conditions such as multiple sclerosis (MS), Alzheimer’s disease, Parkinson’s disease, stroke, migraine, epilepsy, traumatic brain injury, ALS, and spinal muscular atrophy.

**Evaluation & Management (E/M) Visits**

The AAN appreciates that the Centers for Medicare & Medicaid Services (CMS) has recognized the problems with the current documentation guidelines. While we support efforts to reduce administrative burden, the approach outlined by CMS in this proposed rule threatens to uniquely impact neurologists and their patients who often have complex conditions. We are very concerned this will result in decreased patient access and quality of care for patients with critical and complex neurologic diseases.

Specifically, the proposal would result in the same payment amount, irrespective of the duration of the visit, for visits from 5 minutes up to at least 46 minutes. This creates an incentive for hospitals and health systems employing neurologists to reduce the scheduled time for all visits to 5-10 minutes and to address only one medical problem per visit. This would reduce the quality of care, especially for patients with multiple illnesses,
functional limitations, and those who rely on caregivers to manage their illnesses. There would also be an increased burden on patients as they will need to return to the neurologist for multiple visits, resulting in more copayments and costs associated with time and travel. Additional travel burden is especially problematic for patients living in rural areas who travel long distances for office visits, along with patients who have profound impairment of mobility and other deficits.

We also caution that, to the extent other payers do not change their coding requirements, implementing the CMS proposal in 2019 would increase complexity and confusion. Additionally, the current proposal from CMS may not reduce documentation in many cases, and instead would just change the documentation format. If patients are to receive the best care, patients need meticulous documentation of their illnesses for accurate diagnosis, treatment, follow-up, for future referrals to other doctors, as a baseline if they are admitted to the hospital, and if other insurances do not accept the CMS standards. Furthermore, neurologists wishing to comply with the Quality Payment Program need to document significant details of their patient encounters in order to meet the new quality standards promulgated from CMS.

The AAN is also concerned about the method through which this proposal was released. For years, the AAN has been an active partner with CMS and other stakeholders on ways to reduce documentation burdens on physicians. However, no group was consulted on this proposal’s specific framework before it was published. This change in physician payment is too important for CMS to move forward with such a limited time for feedback and analysis. Specialty societies like the AAN also need sufficient time to educate their members about the codes and options for documentation, so a proposal moving forward with a January 1, 2019 implementation date is neither feasible nor appropriate. We request CMS reconsider their rule as currently written and engage in consultation directly with specialty societies, including the AAN, on future proposals.

**E/M Proposals**

In the proposed rule, CMS proposes to allow practitioners to rely on MDM (Medical Decision-Making) in its current form to document their visit and the agency is soliciting public comment on whether and how guidelines for MDM might be changed in subsequent years.

The AAN recommends that CMS use time as the basis for E/M coding, as detailed below. If CMS were to choose MDM to determine the complexity of E/M coding, the AAN recommends that providers determine MDM based on closest analogy using a limited number of vignettes written by the professional societies and then agreed upon by the societies and CMS. We recommend that CMS adopt a number of simple vignettes based on current MDM tables in the documentation guidelines.

Current E/M Guidelines require that the provider and auditor determine the level of MDM by matching each patient encounter to vignettes of accepted complexity. The Guidelines further offer enumerable criteria that require complexity of MDM to be determined by the highest two of three factors:
1. Number of diagnoses or management options.
2. Amount and/or complexity of data to be reviewed.
3. Risk of complications, morbidity, and/or mortality.

If MDM becomes the basis for E/M complexity, the AAN recommends that MDM be entirely determined by complexity matching to accepted vignettes, and that the full formal table be used only when the clinician cannot determine MDM by analogy to similar cases.

We further recommend that CMS adopt vignettes based on current documentation tables that would allow ready analogy to almost all E/M visits. For the current four levels of physician visits we think such vignettes might include:

**Straightforward complexity**
1. One self-limited or minor problem.
2. Post-operative visit after minor surgery, without complication.

**Low Complexity:**
1. One stable chronic illness plus over-the-counter drugs or physical/occupational therapy.
2. Post-operative visit without complication.

**Moderate complexity:**
1. Two or more stable chronic illnesses, even if well controlled.
2. One chronic illness with mild exacerbation, progression, or side effects of treatment plus prescription drug management.
3. Post-operative visit with complication.

**High complexity:**
1. Four or more chronic illnesses, even if well controlled.
2. One serious acute illness or injury plus drug therapy requiring intensive monitoring for toxicity.
3. Four or more prescription drugs.
4. Post-operative visit with complication requiring intensive monitoring for progression.

Continuing, CMS is soliciting comment on what the total time should be for payment of the single, new rate for E/M visits levels 2 through 5. However, the AAN strongly urges CMS not to adopt a single code for all E/M services. Adoption of a single rate would incentivize a fundamental change to a physician’s focus during an office visit. The **physician’s focus now is, “How can I best help this patient today?”** If a single code is adopted for all E/M services, the provider focus becomes, **“What is the single best thing I can do for this patient today?”**

If a single code is adopted, CMS calculates the typical time for proposed new payment for E/M visit levels 2 through 5 would be 31 minutes for an established patient and 38 minutes for a new patient. If CMS were to adopt a single payment amount for visit levels 2-5, the AAN estimates that the average visit time will be much shorter, and that current data are not reliable to predict the times for future E/M visits. Our estimate is that the median visit time
will be the same as for a current level 2 visit: 10 minutes for an established patient and 20 minutes for a new visit.

Typical times in the PFS are as follows:

<table>
<thead>
<tr>
<th>New Patient Visit</th>
<th>Typical Time (minutes)</th>
<th>Required Medical Decision Making</th>
</tr>
</thead>
<tbody>
<tr>
<td>99201</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>99202</td>
<td>20</td>
<td>Straightforward</td>
</tr>
<tr>
<td>99203</td>
<td>30</td>
<td>Low Complexity</td>
</tr>
<tr>
<td>99204</td>
<td>45</td>
<td>Moderate Complexity</td>
</tr>
<tr>
<td>99205</td>
<td>60</td>
<td>High Complexity</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Established Patient Visit</th>
<th>Typical Time (minutes)</th>
<th>MDM</th>
</tr>
</thead>
<tbody>
<tr>
<td>99211</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>99212</td>
<td>10</td>
<td>Straightforward</td>
</tr>
<tr>
<td>99213</td>
<td>15</td>
<td>Low Complexity</td>
</tr>
<tr>
<td>99214</td>
<td>25</td>
<td>Moderate Complexity</td>
</tr>
<tr>
<td>99215</td>
<td>40</td>
<td>High Complexity</td>
</tr>
</tbody>
</table>

CMS further offered several proposals. One alternate proposal is to require documentation that the typical time for the CPT code that is reported (which is also the typical time listed in the AMA’s CPT codebook for that code) was spent face-to-face by the billing practitioner with the patient. The AAN supports this alternate proposal for billing by time, however we offer several comments:

1. We recommend that E/M coding be based on total time, rather than face-to-face time. When E/M guidelines and CPT codes were developed, there was a clearer distinction among services that occurred during the visit or in the preservice or postservice time. Those activities are now flexible. For example, many physicians have completed the visit documentation when the encounter is completed. Additionally, physician estimate of face-to-face time is subject to interpretation and manipulation, whereas physician estimate of total time is more objective.

2. Using time as the major factor in encounter coding, we suggest that the physician simply attest that the typical time has been met, rather than recording each minute spent over several days on the encounter.

3. In any system that distinguishes more than one code for E/M services, CMS needs an audit tool. Using time to determine coding, auditors need only add up the reported visit times for a day or week and compare that to office schedules. Since 50-60% of E&M time is now attributed to preservice or postservice work, some extra time should be allowed beyond scheduled patient visits. Any systematic, large, and sustained discrepancy would draw added scrutiny. Current technology could also be programmed to audit time spent inside a patient’s encounter.
4. Prolonged service codes now are rarely used but should remain available to clinicians caring for the most complex patients.

5. We support the proposed GPRO1 code for prolonged visits of 30 minutes, because the current code 99354, requiring prolonged services of 60 minutes, is not adequate for many prolonged services performed by neurologists and by other specialists caring for complex patients.

CMS additionally requests public feedback on the use of time as a framework for documentation of office/outpatient E/M visits, and whether we should adopt any of these approaches or specify other requirements with respect to the proposed option for documentation using time. To address this question, the AAN first wishes to make clear that we support CMS’s use of time as the basis for E/M coding.

Since the inception of the RBRVS, time has been the single most important factor in the Medicare Physician Fee Schedule. This is highlighted most recently in the June 2018 MedPAC Report to Congress. MedPAC finds that about 80% of the variation in the work values that determine provider payment is based on the time of service regardless of whether it be E/M, imaging, major procedures, other procedures or tests.1

Until value-based care is implemented, Medicare pays for provider best efforts as estimated largely by time. Medicare uses CPT codes as a reasonable estimate of provider time during E/M services, and Medicare uses documentation requirements to audit the CPT codes and time. Medicare now proposes to pay the same fee for E/M visits whether 5-46 minutes in duration, reversing 25 years of E/M payment policy and putting into question its commitment to using time as a fundamental unit of physician work for all medical services. We do not believe the patients or physicians can adjust to this change without ramifications significantly impacting patient care of all Medicare beneficiaries, with a disproportionate impact on the sickest.

We recommend that CMS use the current method for calculating the threshold time to bill for a prolonged service code; that is, when the time of a visit exceeds the typical time for a level 5 visit, plus 16 minutes for a 30-minute prolonged visit, or 31 minutes for a 60-minute prolonged visit.

CMS is further soliciting comment on whether Medicare should use or adopt any aspects of other E/M documentation systems that may be in use among practitioners. The AAN believes audit tools are no longer useful for enforcement, since electronic health records (EHRs) now prompt providers to copy, paste, or insert information needed to code each visit to the highest level of complexity. The EHR can be programmed to meet the requirements of any current audit tool, including documentation of MDM. We do worry that current EHR versions will not be ready in time to implement the proposed CMS standards by 2019. However, we do

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agree with CMS that the current Documentation Guidelines are outdated, and new approaches to payment are needed.

The agency states its primary goal is to reduce administrative burden so that the practitioner can focus on the patient. As a result, CMS is interested in comments as to whether the E/M proposals would support and further this goal. To address this question, the AAN notes it agrees with CMS that its proposals to reduce documentation will reduce administrative burden to some degree. However, we point out that the provider still needs to create complex documentation to meet the needs of best patient care and Quality Payment Program goals, for example. The provider also needs to record pertinent information for treatment authorization, to inform prior and subsequent treating physicians, to record the intent and effect of therapy, and to demonstrate that care meets expert standards.

CMS is also seeking comment on whether there may be ways to implement a similar provision for any aspects of MDM, or for new patients, such as when prior data is available to the billing practitioner through an interoperable EHR or other data exchange.

Prior medical history is important to patient care, and we agree with CMS that providers should refer to it. The provider should copy, update, correct, and re-interpret historical information as indicated. Review of medical records may be time-consuming for complex patients; but provider time reviewing medical history should be included in time-based billing, and not in MDM.

CMS is also requesting comments on the new HCPCS code GCG0X (Visit complexity inherent to evaluation and management associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, cardiology, or interventional pain management-centered care).

In response, the AAN is pleased that CMS recognizes that neurologic patients generally present with complex diseases. We also recognize that other specialties care for a majority of complex patients, and some of those specialties do not appear on the list above. Further, many practitioners within any specialty provide care for the most complex patients within that specialty, and every provider cares for some complex patients. We applaud CMS’s intent to recognize and reward physicians who care for complex patients, but we think that paying for physician services based on time is a better way to incentivize all providers to care for the patients who are most ill and in need of the care of a neurologist.

Furthermore, the AAN also wishes to comment on the multiple procedure reduction proposals. We believe this proposal should not be implemented. First, the medical community has worked for several years to remove any overlap in the physician work and practice expense of visits and same day procedures. Second, we are very concerned this proposal will result in patients being asked to return on a different day for minor procedures. This could also reduce the quality of care and increase copayments for patients.

The agency is additionally soliciting stakeholder feedback as to whether the provision should be eliminated that limits payment for two E/M office visits billed by a physician (or physician of the same specialty from the same group practice) for the same beneficial on the
same date of service. The AAN supports the elimination of the provision, as the Medicare population of patients treated by neurologists often have more than one complex condition along with cognitive and/or mobility issues. As such, the patients are often treated by more than one physician and frequent visits are difficult given the nature of their conditions.

Continuing, given the very small number of postoperative visits reported using CPT code 99024 during 10-day global periods, CMS is seeking comments as to whether it might be reasonable to assume that many visits included in the valuation of the 10-day global packages are not being furnished, or whether there are alternative explanations for what could be a significant level of underreporting of postoperative visits. The AAN notes that it is CMS policy to pay for care that is actually furnished, yet CMS data and anecdotal reports indicate that CMS often pays for 10-day global visits that are not performed. E&M visits that are included in the valuation of these services may be unnecessary for some patients, may be performed after the 10-day window, or may be done by providers who did not perform the primary procedure. We recommend that CMS re-establish fair payment by eliminating the 10-day global period for all procedures and paying separately for each E&M visit. As independent services, procedures could be re-valued using a reverse building block method until thorough revaluation is completed.

CMS is also interested in stakeholder input on the best number of E/M visit levels and how to best achieve a balance between number of visit levels and simpler, updated documentation rules. The agency is seeking input as to whether these two aspects of its proposals together can reduce burden and ensure accurate payment across the broad range of E/M visits, including those for complex and high need beneficiaries.

The AAN recommends that 5 levels are the minimum number needed to distinguish among E/M services. Collapsing to fewer levels will not adequately recognize physician services to complex patients. As noted above, we recommend that the provider be required to attest to a minimum service duration for each E/M service.

Advantages for the provider:
- There would be no requirement to meet every bullet point.
- There is no need to time each visit to the minute.
- Compensation for complex services is attained when warranted.

For CMS:
- The information in the service note should be adequate to support the time attestation.
- Office schedules may be audited to assure that the combined service times for a day are reasonably close to total attested service times.
- Provider time, the provider’s principal resource, is a critical component of valuation and a check on potential fraudulent overbilling.
- This system extends the current mechanism of the Physician Fee Schedule that values the variation in work values for medical services about 80% based on time according to MedPAC.

For the patient:
- Physician time is maintained as an essential element for all E/M services.
The provider spends most time on the most critical aspects of care.

**Codes**

As part of the proposed rule making process CMS reviews new and revised CPT codes that were recently reviewed by the AMA Relative Value Update Scale Update Committee (RUC) and are scheduled to be effective January of the following calendar year. The agency may accept those recommendations (including physician work relative value units or RVUs) or take further reductions or implement increases. The AAN was involved in the review process for several codes scheduled for implementation in January 2019 for which CMS did not accept the RUC recommended RVUs. Below is a summary of those recommendations and the AAN’s response to the proposed reductions:

(54) **Home Sleep Apnea testing (CPT Codes 95800, 95801, 95806)**

<table>
<thead>
<tr>
<th>Code</th>
<th>Long Descriptor</th>
<th>Current work RVU</th>
<th>CMS Proposed work RVU</th>
<th>RUC Recommended work RVU</th>
</tr>
</thead>
<tbody>
<tr>
<td>95800</td>
<td>Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (e.g., by airflow or peripheral arterial tone), and sleep time</td>
<td>1.05</td>
<td>0.85</td>
<td>1.00</td>
</tr>
<tr>
<td>95801</td>
<td>Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and / respiratory analysis (e.g., by airflow or peripheral arterial tone)</td>
<td>1.00</td>
<td>0.85</td>
<td>1.00</td>
</tr>
<tr>
<td>95806</td>
<td>Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (e.g., thoracoabdominal movement)</td>
<td>1.25</td>
<td>0.93</td>
<td>1.08</td>
</tr>
</tbody>
</table>

For both CPT codes 95800 and 95801 the RUC recommended a work RVU of 1.00 (currently 1.05 and 1.00, respectively), with 6 minutes of pre-service, 15 minutes intra-service and 10 minutes immediate post-service time. For 95806, currently at an RVU of 1.25, the RUC recommended a work RVU of 1.08, which was below the 25th percentile of 1.15, with 6 minutes of pre-service, 15 minutes of intra-service (reduced by 10 minutes based on survey data), and 10 minutes post-service time.

CMS highlighted the fact that they did not intend to imply that the decrease in time, as reflected by the survey values, should equate to a linear decrease in the valuation of work RVUs. However, this seems to be the approach taken, as the proposed rule suggests that a 5% reduction in the work RVUs for 95800 and 95801, and the 14% reduction in work RVUs...
for 95806, were insufficient based on the amount that surveyed work times decreased. Modifications to work RVUs should be based on empirical evidence, gathered through the survey process, which take into consideration the amount of time required to provide a service as well as the complexity/intensity of each service. Additional information can be gleaned from the comparison of RVUs to those assigned to codes with similar technical and professional components. We believe the RUC recommended work RVUs correctly captured the current relativity between the procedures in the code family. During the last survey, these diagnostic tests were fairly new, accounting for the higher pre-, intra- and post-service times. Since then sleep medicine professionals have become more efficient at performing these procedures, justifying a slight decrease in the times, however, it must be noted that home sleep apnea tests have not fundamentally changed and require the same amount of effort.

The rationale for the CMS recommendations stems from two crosswalk codes, 93281 and 93260. It is unclear why CMS chose these two codes, which are not at all similar to the home sleep apnea test codes and are cardiovascular implantable recording device codes, not diagnostic studies. It is noteworthy that 95800, 95801, and 95806 are all sleep apnea diagnostic service codes which include recording, interpretation, and report of these sleep studies. The reference codes used by the RUC to develop the recommendations provided to CMS were similar to the three sleep codes and included similar components. For 95800 and 95801 the RUC used reference codes 95805(multiple sleep latency or maintenance of wakefulness testing, recording, analysis and interpretation of physiological measures of sleep during multiple trials to assess sleepiness) and 95907 (nerve conduction studies; 1-2 studies). The RUC used a magnitude estimation crosswalk to 95819 (Electroencephalogram (EEG); including recording awake and asleep) to support an RVU of 1.08 for 95806, as this is a similar service. Again, 93281 and 93260 do not include physician diagnosis and thus are not the same complexity/intensity as the home sleep apnea testing codes.

The AAN urges CMS to accept a work RVU of 1.00 for CPT code 95800, 1.00 for CPT code 9581, and 1.08 for CPT code 95806. These recommendations are based on physician survey data and were developed using crosswalk and reference codes that are similar to the home sleep apnea testing codes and endorsed by physician experience.

(55) Neurostimulator Services (CPT codes 95970, 95X83, 95X84, 95X85, and 95X86)
<table>
<thead>
<tr>
<th>Code</th>
<th>Long Descriptor</th>
<th>CMS Proposed work RVU</th>
<th>RUC Recommended work RVU</th>
</tr>
</thead>
<tbody>
<tr>
<td>95X83</td>
<td>Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve neurostimulator pulse generator/transmitter, without programming</td>
<td>NEW 0.73</td>
<td>0.95</td>
</tr>
<tr>
<td>95X84</td>
<td>95X84 Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional</td>
<td>NEW 0.97</td>
<td>1.19</td>
</tr>
<tr>
<td>95X85</td>
<td>Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional</td>
<td>NEW 0.91</td>
<td>1.25</td>
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</table>
For CPT code 95970, the RUC recommended a work RVU of 0.45 and 3 minutes pre-service, 7 minutes intra-service and 5 minutes post-service time. CMS disagrees with the RUC’s recommendation because they do not believe that maintaining the work RVU, given a decrease of four minutes in total time, is appropriate. CMS is comparing accurate survey time to Harvard time, which holds zero validity for comparison. Additionally, the survey pre-service time was reduced, which accounts for this service being reported with an Evaluation and Management (E/M) service. The previous Harvard time most likely did not take this into account.

The RUC compared 95970 to the top key reference service 62368 *Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming* (work RVU = 0.67 and 27 minutes total time). CMS notes that the reference CPT codes
chosen by the survey respondents have much higher intra-service and total times than CPT code 95970, and also have higher work RVUs, making them poor comparisons. The survey respondents chose these reference services as a comparison, not recommending direct crosswalks. The respondents and the RUC agreed that CPT code 95970 requires less physician time and work and thus valued it lower than the reference codes. To clarify, the survey respondents choose a similar service from a list of 10-20 services and not all are going to match up with the exact same time. Additionally, the respondents then indicate the time, work, intensity and complexity differences and relativity between these services. Services are examined based on clinical relativity of all measures compared to other services.

CMS recommends that 95970 be directly crosswalked to CPT code 95930 Visual evoked potential (VEP) checkerboard or flash testing, central nervous system except glaucoma, with interpretation and report (work RVU = 0.35, 10 minutes intra-service time and 14 minutes total time. CPT code 95930 is when the physician reviews and interprets ophthalmological results of brain electrical activity measurements. CPT code 95970 requires more physician work and is more intense because the physician performing the electronic analysis of the implanted neurostimulator pulse generator/transmitter (e.g., contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) and documenting the diagnostic analysis, including the battery state, current program settings, and impedances of electrodes, as well as any event logs from the programming equipment and patient device interrogation. The AAN urges CMS to accept a work RVU of 0.45 for CPT code 95970.

95X83

For CPT code 95X83, the RUC recommended a work RVU of 0.95 and 3 minutes pre-service, 11 minutes intra-service and 10 minutes post-service time. CMS noted that this new code does not exactly replace the deleted CPT code 95974 (work RVU = 3.00 and 30 minutes pre-time, 60 minutes intra-service time and 20 minutes post-service time). The description of the work involved in furnishing CPT code 95X83 differs from that of the deleted CPT code in a few important ways, notably that the time parameter has been removed so that the CPT code no longer describes the first hour of programming. In addition, the new CPT code refers to simple rather than complex programming. Yet, CMS is still comparing the physician work and time of these two services. The physician work and times should be different, and CMS should not compare these two vastly different services.

CMS states that the top key reference service 95816 Electroencephalogram (EEG); including recording awake and drowsy (work RVU = 1.08, 15 minutes intra-service time and 26 minutes total time) is not an appropriate crosswalk. Again, the survey respondents are not recommending 95X83 be cross walked to 95816, but notes that CPT code 95816 was chosen to assess the relativity and to establish a work RVU and physician time recommendation. Clearly, services performed by the same providers, intra-service time differences of 4 minutes, total time differences of 2 minutes, overall intensity and complexity measures indicated as 60% identical and 40% somewhat more for the key reference code, all support the RUC recommended work RVU of 0.95 and physician time relative to another similar service.
CMS recommends 95X83 be crosswalked to CPT code 76641 *Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; complete* (work RVU = 0.73 and 12 minutes of intra-service time and 22 minutes of total time). CPT code 76641 is not a good crosswalk because although the physician time may be similar, CPT code 95X83 requires more physician work to interact with the patient and make programming adjustments to multiple parameters which result in real time changes in patient behavior; including but not limited to speech, breathing patterns, heart rate, and seizure activity. Side effects and risks of parameter adjustments are significant, and considerations must be weighed carefully, including identifying the correct parameter to manipulate. The identification of and adjustment of the correct parameter(s) requires considerable decision-making effort and concern for patient safety. **The AAN urges CMS to accept a work RVU of 0.95 for CPT code 95X83.**

**95X84**

CMS states that the RUC compared CPT code 95X84 with deleted CPT code 95975 *Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode electability, output modulation, cycling, impedance and patient compliance measurements); complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour* (work RVU = 1.70, ZZZ global period and 30 minutes total time). The RUC recommendation did not compare 95X84 to deleted code 95975. The RUC recommended the survey 25th percentile work RVU of 1.19. The specialty societies reduced the pre-service time, which accounts for this service being reported with an E/M service. The RUC recommended 3 minutes pre-service, 17 minutes intra-service and 10 minutes post-service time. The specialty societies indicated and the RUC agreed that the 10 minutes required for the post-time include reviewing all the parameters, documenting final program measurements and any other relevant clinical information obtained during the programming session, reducing side effects and making treatment adjustments. The physician will also address patient and family questions about planned therapy and re-educate the patient and family on the use of the patient device.

The RUC noted that the top two key reference services were disparate compared to this service. Therefore, as a better reference, the RUC compared 95X84 to MPC codes 99308 *Subsequent nursing facility care, per day, for the evaluation and management of a patient* (work RVU = 1.16, 15 minutes of intra-service time and 31 minutes total time) and 12013 *Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 2.6 cm to 5.0 cm* (work RVU = 1.22, 15 minutes of intra-service time and 27 minutes total time), which support the recommended work RVU as the survey code involves somewhat more intra-service and total time and a comparable amount of physician work. For additional support, the RUC referenced code 93975 *Duplex scan of arterial inflow and venous outflow of abdominal, pelvic, scrotal contents and/or retroperitoneal organs; complete study* (work RVU = 1.16, 20 minutes of intra-service time and 30 minutes total time) and 67810 *Incisional biopsy of eyelid skin including lid margin* (work RVU = 1.18, 13 minutes of intra-service time and 27 minutes total time). Thus, the survey 25th percentile
work RVU appropriately places CPT code 95X84 relative to the top key reference service and other similar services.

CMS is proposing to use a reverse building block in developing the work RVU for 95X84. CMS is proposing a work RVU of 0.97 for CPT code 95X84 without the use of survey data or direct crosswalking to another similar code. CMS is taking the difference in work RVUs from the RUC recommended values of 0.24. The AAN recommends that CMS use valid survey data to develop work RVUs as was demonstrated with this code. **The AAN recommends a work RVU of 1.19 for CPT code 95X84.**

**95X85**

For CPT code 95X85, CMS states that the RUC’s recommendation of 1.25 work RVUs is based on codes 12013 Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 2.6 cm to 5.0 cm (work RVU = 1.22, intra-service time of 15 minutes and 27 minutes total time) and 70470 Computed tomography, head or brain; without contrast material, followed by contrast material(s) and further sections (work RVU = 1.27, 15 minutes of intra-service time and 25 minutes total time). The RUC based its recommendation on the survey 25th percentile work RVU of 1.25. Then to support the valid survey data the RUC referenced similar services from the Multi-Specialty Points of Comparison (MPC) list. The RUC recommended 3 minutes pre-service, 15 minutes intra-service and 10 minutes post-service time for CPT code 95X85, which tight in relativity for physician work and time to CPT codes 12013 and 70470.

CMS is comparing CPT code 95X85 which describes the first 15 minutes to the deleted CPT code 95978 which described the first hour. CPT code 95978 could still be reported for the first hour as long as it was over 31 minutes. Therefore, comparing the old coding structure to the new coding structure is not straightforward based on comparing the time in the descriptor and actual time to what will be reported now. The RUC examined this family of services and the RUC recommended values are work neutral, even when assuming 95X85 may be reported once and 95X86 reported three times.

CMS examines the use of a reverse building block in developing the work RVU for 95X85. CMS is proposing a work RVU of 0.91 for CPT code 95X85 by directly crosswalking CPT Code 95X85 to CPT code 93886 Transcranial Doppler study of the intracranial arteries; complete study (work RVU = 0.91, intraservice time of 17 minutes, and with total time 27 minutes). Although, CPT code 95X85 requires similar physician time as 93886, 95X85 is more intense and complex and requires more physician work because it entails programming adjustments to multiple parameters which result in real time patient behavior. This includes monitoring for changes in the patient’s speech, mobility, strength, voice, and ADLs, (as they can be assessed on an immediate basis). Side effects and risks of parameter adjustments are significant, and considerations must be weighed carefully to consider the benefits of clinical improvement without minimal negative side effects. The service includes observations based on adjustment made, a review of the results and further adjustments as needed. **The AAN urges CMS to accept a work RVU of 1.25 for CPT 95X85.**

**95X86**
For CPT code 95X86, CMS states that the RUC’s recommendation of 1.00 work RVUs is based on the key reference service CPT code 64645 Chemodenervation of one extremity; each additional extremity, 5 or more muscles (List separately in addition to code for primary procedure) (work RVU = 1.39 and 15 minutes of intra-service time). The RUC based its recommendation on the survey 25th percentile work RVU of 1.00. Then to support the valid survey data the RUC indicates that the survey respondents chose 64645 as the key reference service for comparison for what they thought was the most similar services. The RUC noted that the survey respondents indicated the surveyed code is more intense and complex to perform but CPT code 64645 requires more technical skill. Therefore, CPT code 64645 appropriately requires slightly more work than 95X86.

CMS is proposing a work RVU of 0.80 for CPT code 95X86, which is a random calculation using building block and the incremental difference between 95X85 and 95X86, followed by CMS choosing an RVU in between these calculations of 0.75 and 0.82. CMS then indicates that a work RVU of 0.80 is supported by crosswalking 95X86 to 51797 Voiding pressure studies, intra-abdominal (i.e., rectal, gastric, intraperitoneal) (work RVU = 0.80 and 15 minutes intra-service/total time). The RUC recommends that CMS use valid survey data and review the actual relativity for all elements (physician work, time, intensity and complexity) when developing the work RVU for services and not place everything in a box by calculating increments and then pick a code to mirror the calculation.

CPT code 51797 is not a good crosswalk for CPT code 95X86. CPT code 95X86 require more physician work to perform programming adjustments to multiple parameters which result in real time patient behavior. This includes monitoring for changes in the patient’s speech, mobility, strength, voice, and ADLs, (as they can be assessed on an immediate basis). Side effects and risks of parameter adjustments are significant, and considerations must be weighed carefully to consider the benefits of clinical improvement without minimal negative side effects. The service includes observations based on adjustment made, a review of the results and further adjustments as needed. The AAN urges CMS to accept a work RVU of 1.00 for CPT code 95X86.

Furthermore, the RUC unanimously passed the work RVUs for all services in this family and the AAN urges CMS to accept the RUC recommended values based on the rationale provided above.

(57) Electrocnocography (CPT code 96X00)

<table>
<thead>
<tr>
<th>Code</th>
<th>Long Descriptor</th>
<th>Current work RVU</th>
<th>CMS Proposed work RVU</th>
<th>RUC Recommended work RVU</th>
</tr>
</thead>
<tbody>
<tr>
<td>96X00</td>
<td>Electrocnocogram from an implanted brain neurostimulator pulse generator/transmitter, including recording, with interpretation and report, up to 30 days</td>
<td>NEW</td>
<td>1.98</td>
<td>2.30</td>
</tr>
</tbody>
</table>
CMS is proposing a work RVU of 1.98 based on a direct crosswalk to the top reference, CPT code 95957 Digital analysis of electroencephalogram (EEG) (e.g., for epileptic spike analysis) (work RVU = 1.98). CMS states that they agree with the survey respondents that this is a correct valuation for 96X00. However, the survey respondents chose 95957 as reference service not as a direct crosswalk. The survey respondents pick from a list of 10-20 services to use as a comparison and then recommend a work RVU based on the intensity, complexity and physician time required to perform the surveyed code. The median survey work RVU was actually 2.97, much higher than the key reference service. The respondents specifically indicated that CPT code 96X00 is more intense and complex than CPT code 95957 on all measures (mental effort/judgment, technical still/physical effort and psychological stress), which justifies the higher work value. Therefore, CMS crosswalking the work RVU to the key reference service and suggesting that what the survey respondents indicated is completely false. **AAN urges CMS to accept the valid surveyed 25th percentile work RVU of 2.30 for CPT code 96X00.**

**Part B Drugs and Wholesale Acquisition Cost (WAC)-based Payments**

The AAN is concerned about proposals that suggest physicians are responsible for the rising cost of prescription drugs. We support concepts that increase transparency and believe that the current health care system includes perverse incentives that favor high cost medications. We are concerned that the proposed reductions to Part B reimbursement serve as yet another perverse incentive for manufacturers to increase list prices as they attempt to promote new products that may be reimbursed at lower rates than existing drugs. This would be in direct opposition to CMS goals to lower costs and introduces unnecessary nonclinical incentives at the point of prescribing.

The AAN agrees that greater parity between ASP-based acquisition costs and WAC-based payments for Part B drugs is a preferable outcome for physicians as it adds predictability and administrative simplicity. However, we disagree with the premise that a reduction in payments to physicians will solve the problem of exponential drug price growth in Part B drugs and that changes in payments to physicians will effect meaningful change for patients facing unaffordable drug costs. Further, overhead costs to administer Part B drugs are a substantial consideration for many neurologists in small practices and they may face financial losses with any WAC-based payment reductions. If physicians are unable to offer Part B drugs due to reduced payment rates, patients will suffer.

CMS cites MedPAC recommendations to support the proposal to reduce WAC-based payments. We encourage CMS to consider additional statements from MedPAC that note, “setting a drug’s WAC is ultimately controlled by the manufacturer.” Further MedPAC analysis finds that, “growth in Medicare’s ASP payment rates for individual drugs is driven by manufacturer pricing policies.” Based on this information, from 2016 to 2017 manufacturer pricing policies increased the ASP of 9 of the 20 high-expenditure drugs by 5 percent or more, and 4 of the 20 high-expenditure drugs by 10 percent or more. Between 2010 and 2017, 17 products with at least $5 million in spending saw an ASP increase of 100 percent or more.

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MedPAC offers two approaches for limiting ASP increases to inflation: a manufacturer rebate and a limit on provider payment rates. Manufacturers are responsible for the unsustainable price increases in Part B drugs and the growing costs of medications for patients. It is concerning that this proposal focuses on physician payment rates when data clearly demonstrates manufacturer pricing as the source of the problem. The AAN urges CMS to consider changes at the manufacturer level, including greater transparency requirements and financial liabilities for manufacturers when a drug price rises higher than an inflation benchmark.

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 of the appropriate use criteria (AUC) program to 2020. 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 proposes a delay in implementation of the AUC program until testing has been completed, results are published, and a public comment period is established.
- 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.
- 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 related to if the Provider-led entity (PLE) which the provider relies on to obtain AUC, becomes unavailable.
- The AAN also requests that CMS clarify how the modifier would work and if it would be added to the E/M code.
- The AAN also recommends a more graduated schedule of implementation for the eight clinical conditions due to varied evidence on the overutilization for each condition.
- 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.

- The AUC program will increase the time burden for physicians when caring for the patient. The impact of AUC in conjunction with the potential new E/M code proposal creates a further burden that would detract from the care of the patient unless time-based billing is maintained.

Additionally, the AAN thanks CMS for continued incorporation of AUC as a high-impact Improvement Activity under the Merit-based Incentive Payment System (MIPS). The AAN supports expanding the definition of applicable settings to include independent diagnostic testing facilities.

**Mobile Stroke**

The AAN supports the proposed addition of a mobile stroke unit (MSU) as a permissible originating site for acute stroke telehealth services, in accordance with the Bipartisan Budget Act of 2018. To provide critical patient care, mobile stroke units must be able benefit from the expertise of neurologists via telemedicine to help in diagnosis and determination of appropriate treatment. The AAN believes that CMS’s definition of a mobile stroke unit is well aligned with the statutory requirements.

The AAN supports the proposed inclusion of a new modifier that would be used to identify acute stroke telehealth services. The AAN has previously emphasized the importance of including the pre-hospital phase in the stroke bundle. This approach will provide flexibility in the future as new stroke treatments are developed by allowing practitioners to determine clinical appropriateness of the use of the modifier. Furthermore, this approach provides flexibility by allowing providers to determine the appropriateness of using the modifier with codes from the existing telehealth list. The AAN believes that the G0508 and G0509 codes that are currently on the telehealth list are sufficient for the furnishing of a neuro-consult service by a neurologist to an MSU. The AAN also recommends further study of potential telehealth reimbursement for CT scan and tPA administration on a mobile stroke unit. Ongoing clinical trials related to administration of tPA on an MSU have yielded promising results and developing evidence may warrant inclusion of additional codes and reimbursement pathways for use of a CT scan and administration of tPA on an MSU in future fee schedules.

CMS also requested feedback on additional appropriate originating sites for telehealth services for the diagnosis, evaluation or treatment of an acute stroke. The AAN recommends studying the evidence basis for potential inclusion of skilled nursing facilities as an appropriate originating site for tele-stroke services.

**Recognizing Communication Technology-Based Services**
The AAN is encouraged by CMS’s commitment to recognizing and expanding communication technology-based services. CMS’s interpretation of Medicare Telehealth Services will expand access to communication technology-based services by limiting the range of telehealth services that are subject to originating site requirements. The AAN supports the creation of new codes for virtual check-ins, interprofessional internet consultation, and remote evaluation of pre-recorded patient information. The AAN requests clarification on a specific time frame for when these new telehealth services would be deemed to have resulted in an office visit as the proposed rule is open-ended and unclear. Without a specific timeframe, it is possible that any E/M in-person service that results after a virtual check-in or remote evaluation of pre-recorded patient information could result in bundling of the telehealth code, regardless of whether the E/M service was related to the telehealth service.

While the new communication technology-based services codes represent needed progress towards the incorporation of new technology into the modern practice of medicine, the AAN is concerned with the projected 0.2% decrease in the base rate that will offset the inclusion of these new codes.

The AAN believes that the establishment of a virtual check-in code that allows for audio-only telephone virtual check-ins represents a positive move towards expanding access to care for the Medicare population, especially Medicare beneficiaries who are not highly tech-savvy. Audio-only telephone is one of several tools that neurologists utilize to communicate with patients. Other methods of communication to furnish check-in services include the patient portal through an EMR and video communication technology.

The AAN also believes that a frequency limitation on telehealth services is only appropriate if it is consistent with frequency limitations on other outpatient E&M type services. The AAN does not believe that it is necessary for CMS require physicians to note verbal consent for each virtual check-in service and instead it may be less burdensome for patients to consent to virtual check-in services one time when establishing care with a practice. Furthermore, the AAN believes that clinicians could best document the medical necessity of a virtual check-in service either by documenting time spent in care or through a standard attestation that the necessary services could be comprehensively provided through the chosen telehealth format for the virtual check-in.

The creation of new codes for “store and forward” video and image technology will significantly impact the practice of neurologists who will be reimbursed for reviewing videos from patients and utilizing medical decision making to evaluate symptoms including abnormal movements and tremor. Although these new codes represent a step in the right direction, CMS’s proposal to limit reimbursement for remote evaluation of pre-recorded patient information to established patients can limit patient access to needed neurology services, especially for patients without a usual source of care. It is important to note that all states currently allow new patient relationships to be established via telemedicine. There are cases, such as the evaluation of tremor or abnormal movements, where it would be clinically appropriate for a new patient to receive a remote evaluation of pre-recorded “store and forward” patient information. Therefore, the AAN requests that evaluation of pre-recorded
video by a neurologist be included on a list of communication technology-based services that are deemed appropriate for a new patient.

**RFI on Price Transparency: Improving Beneficiary Access to Providers and Supplier Charge Information**

The AAN supports CMS’s goal of increasing price transparency and patient understanding of their out-of-pocket costs. Although CMS’s goal is laudable the AAN is concerned that a requirement for providers to furnish patients with information on what Medicare pays for a particular service would be overly burdensome. A recent survey conducted by University of Utah Health and NEJM Catalyst showed that 86% of surveyed physicians lacked the training they would need to discuss the cost considerations affecting their patients.\(^3\) Given this lack of readiness, requiring physicians to provide cost information to patients would necessitate time-consuming and costly physician training on how to accurately assess potential out-of-pocket costs for individual physician services.

This requirement would also decrease the time physicians could spend on patient care as physicians would be constrained by the need to participate in training to accurately assess costs and burdened with the need to consistently stay apprised of specific changes in service costs. Furthermore, physicians would be required to use office time providing patients with cost information that could otherwise be used to provide patient care. The AAN is also concerned with the need for accuracy when communicating cost information and the potential impact that inaccurate information could have on physician-patient trust. The AAN is unsure that physicians will be able to accurately assess patient out-of-pocket information, as the University of Utah Health and NEJM Catalyst survey also indicated that 78% of physicians believe that the tools to estimate patient out-of-pocket costs are unavailable.\(^4\)

Given the importance of accuracy in communicating cost information to patients, the AAN is also concerned that requiring providers to provide patients with cost information could lead to future rulemaking related to consequences for inaccurate provision of cost information.

**Quality Payment Program (QPP)**

As year three of the Quality Payment Program (QPP) begins, it should be noted that physicians still lack critical knowledge about how exactly the program operates. Results of a recent survey indicate that sixty percent of physicians report not being at all or only slightly familiar with MACRA and its requirements.\(^5\) Only 8 percent of surveyed physicians reported being very familiar with MACRA.\(^6\) This knowledge gap represents a significant challenge for the majority of physicians who fundamentally lack the knowledge needed to successfully participate in the QPP. Continuing education of physicians is necessary to increase provider understanding of the requirements of the QPP. Compounding a lack of understanding is the


\(^4\) Id.


\(^6\) Id.
fact that many physicians reject the value proposition of MACRA. Nearly a quarter of surveyed physicians indicated that they believe that the incentives present in the MACRA program will actually reduce the value of care.\(^7\) Although these physicians are in the minority, their beliefs indicate a need for further incorporation of physician perspectives into the QPP.

It is also important to note that the QPP is uniquely burdensome on small and solo practitioners. This is acknowledged by the United States Government Accountability Office.\(^8\) Challenges related to selecting a functional EHR system are particularly problematic for small and solo practitioners as they have fewer resources and less ability to share costs across providers.\(^9\) Small and solo practices also must face unique challenges when managing cost measures since they see fewer patients and are far more exposed to the risk of performing poorly on cost measures due to a small number of extremely high cost patients. Additionally, financial and staff resource constraints can be especially problematic for small and solo practices when complying with the QPP due to the resources required to select, track and report on measures. Finally, small and solo practices are especially challenged by annual updates to the QPP and struggle to keep up to date with changing program requirements. These challenges have historically manifested in terms of comparatively poor performance in legacy quality programs and these challenges will likely persist in year three of the QPP as they have not yet been sufficiently addressed.

**Merit-Based Incentive Payment System (MIPS)**

We believe raising the proposed overall MIPS score to 30 is too large of an increase. 15 is a more reasonable composite score to avoid a negative payment adjustment. Doubling the threshold while many physicians still are unaware of MIPS is not a wise move. Such a high threshold is a continued regulatory burden on physicians and fosters distrust between the medical community and CMS. We further disagree that the exceptional performance threshold should be raised from 70 to 80 points. It should remain at 70 points and possibly be lowered.

**Low-Volume Threshold**

The AAN supports the expanded definition of the low-volume threshold as it will benefit small and solo neurology practices. We ask CMS to maintain the current thresholds in the future as the agency updates the QPP. This would further benefit practices as they make investments and considerations regarding future participation in the QPP.

**Virtual Groups**

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\(^7\) Id.


\(^9\) Id.
The AAN supports a web-based system for election to a virtual group. This is a helpful example of reducing regulatory burdens as it should be easier for physicians to join virtual groups with a web interface.

Additionally, we remain pleased that CMS has implemented virtual groups into the QPP. However, we still believe CMS should provide additional resources for small and solo practices to help determine if a virtual group is best for their practice. These groups will be especially helpful for rural neurologists who can structure the group to leverage expertise and help patients.

The AAN still encourages CMS to issue safe harbors for these virtual groups to address potential fraud and abuse claims. We also believe there should be bonus points under MIPS as an incentive to join virtual groups. This is particularly important in the first few years virtual groups are created. Our worry is that some neurologists may not join a group because they do not want to be locked into an entire performance year with a potentially unreliable partner. Because there will be administrative and operational challenges, such as identifying reliable partners, aggregating and sharing data, and coordinating workflow across multiple physicians, entering into one of these groups therefore deserves consideration by CMS for some level of bonus points under MIPS.

Complex Patients

The AAN strongly agrees with the need for a bonus point when a clinician cares for a complex patient. However, as we have previously noted, the AAN is concerned that the HCC mechanism works for primary care providers, but not specialists. A patient with a disorder such as advanced multiple systems atrophy or ALS, may be highly complex, but might have a lower HCC score than a 60-year-old patient with cardiovascular conditions. There are large concerns that HCC valuations are inadequate, or at least is an unsubstantiated approach with respect to measuring individual clinicians and specialists caring for complex diseases and it is poorly explained by CMS. The AAN supports further delay of any financial reimbursement impact on providers until there is clarification that the work of providers caring for complex patients is adequately captured by the CMS methodology in this area.

Small Group Bonus

The AAN strongly agrees with the CMS proposal to add a new bonus for small practices. However, we believe it should be applied to the composite score and not applied to just one category of MIPS. Additionally, we believe groups larger than 15 clinicians could be considered a “small practice.” We also continue to call upon CMS to include rural areas in this bonus opportunity as well.

Promoting Interoperability

The AAN supports CMS’s proposal to streamline and simplify the scoring of the Promoting Interoperability category. The proposed scoring methodology reduces clinician burden by eliminating confusing base and performance category scores in favor of scoring at the individual measure level, with relevant measure performance exclusions. The AAN supports the overall reduction of measures in this category through the elimination of burdensome
measures. Although the AAN supports this specific proposal to streamline and simplify the category, the AAN cautions CMS against further implementation of major category overhauls. Significant changes, even those intended to reduce physician reporting burden, can increase burden when they require yet another round of provider and staff education to understand how to maximize performance under a redesigned category scoring methodology. Small and solo practice providers in particular have indicated that substantial category changes are significant burdens for their practices.10

The AAN opposes requiring eligible clinicians to use 2015 CEHRT in Year 3 of MIPS. The AAN believes the 2015 CEHRT requirement should be pushed back to 2020 to provide clinicians with sufficient transition time to meet the 2015 CEHRT standard and avoid disruptions to patient care. CMS also ought to consider strategies to mitigate limited availability of software that meets the 2015 CEHRT standard, as well as strategies to offset costs associated with implementation of 2015 CEHRT, especially for small and solo practices who have fewer resources to leverage and less ability to share costs across providers. Additionally, small and solo practice providers have indicated that EHR vendors have historically been slow to provide updates to meet technology certification requirements to small and solo practices.11

The AAN strongly agrees with the decision to offer a hardship exception for small practices under the Promoting Interoperability category. CMS specifically states that qualification for this exception will be determined by “overwhelming barriers” preventing a MIPS eligible clinician from complying with the ACI category. The AAN disagrees with the use of the word “overwhelming” in determining this qualification. CMS should clarify what constitutes an overwhelming barrier and recommends more precise language to define when this standard will be applied. Without further clarity, it is possible that the application of the “overwhelming” standard could be overly burdensome.

The AAN supports the proposed exclusions for the Query of PDMP and Verify Opioid Treatment Agreement measures and believes it is appropriate for MIPS eligible clinicians to be excluded from these measures beginning in the 2020 reporting period if they are unable to report on the measure in accordance with applicable state law. The AAN also supports the exclusion for the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure and appreciates CMS’s acknowledgement that there are often time-related challenges associated with a health IT vendor implementing measures on a short timeline for a given performance year. The AAN also supports the continuation of exclusions from previous rulemaking for the Public Health and Clinical Data Exchange measures.

The security risk analysis measure has historically been challenging for physicians. The AAN does not support the proposal for annual reporting of this measure to be required to achieve any score in the Promoting Interoperability category. To overcome the burdensome nature of this measure, clinicians need additional support and resources to aid in their

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11 Id.
understanding of how to conduct a security risk analysis that is compliant with CMS’s standards.

**Improvement Activities**

The AAN believes practices should be able to complete Improvement Activities lasting 90 days even if performance spans over two performance periods. We believe CMS could require practices to complete at least 45 consecutive days during each of two consecutive periods to equal a total of at least 90 days. This is a lower burden on clinicians and will further encourage participation in this component of MIPS.

For small practices, CMS should phase in Improvement Activities over a multi-year period. In the future, CMS should have sufficient data to establish a baseline for each Improvement Activity and after that point, it will be appropriate to consider increasing the requirements. However, we strongly support the reduced reporting requirements for small practices in this area.

The AAN wishes to support the additional criterion for nominating improvement activities. We further note that aligning with public health emergencies is important for patient care. Clarification is requested as to whether a public health emergency is required to be listed in order for an activity to be considered. Additionally, we would like to know if activities related to emergencies will be removed when the public health emergency has been resolved. Generally, the AAN supports the Improvement Activities proposed by CMS for the MIPS CY 2019 Performance Period and Future Years. We do recommend Financial Navigation Program, Care Coordination/Relationship Centered Communication, and Patient Safety and Practice Assessment be considered high-level weighted activities.

Furthermore, regarding the Financial Navigation Program activity, the AAN notes this may only be feasible in larger practices with access to data on cost of care. Additionally, for Care Coordination/Relationship Centered Communication, it proposes clinicians complete an 8-hour training and then states this does not “require substantial time or effort.” While this is easier than implementing a new practice workflow, it still seems burdensome. We applaud the focus on communication but worry that clinicians will have to purchase the course at additional expense.

As we wrote last year, we thank CMS for including qualified continuing medical education (CME) in the proposed rule, although we believe CME should be weighted in a bifurcated manner with more substantial CMEs potentially counting as a higher weighted Improvement Activity.

We believe qualified CME can improve beneficiary outcomes, lead to practice improvement, can be performed by providers of all types, is feasible to implement, can be validated by CMS, and is evidence-based. Additionally, many believe legacy CMS programs such as the Physician Quality Reporting System (PQRS), Meaningful Use, and Value Modifier would have achieved significantly greater success had physicians received the education and training on these topics that certified CME provides.
CME has long been recognized as a means by which physicians demonstrate engagement in continued professional development. This encourages physicians to develop and maintain the knowledge, skills, and practice performance that leads to optimal patient outcomes. Lifelong learning, assessment, and improvement are integrally related. Learning is a necessary component of the change process that results in meaningful, sustained clinical performance improvement. Without this professional development, the measurement of adherence to quality metrics and use of health information technology are insufficient to produce clinical performance improvement.

Additionally, physicians have a professional responsibility to keep up-to-date through CME and there is a preexisting infrastructure to record participation in CME activities. Currently 45 states plus the District of Columbia require participation in CME to maintain licensure.\textsuperscript{12} CME is a familiar activity for physicians and giving credit for participation in CME related to quality improvement will reduce the regulatory burden on physicians as they can receive CME credit and QPP-related points at the same time.

Furthermore, mechanisms already in place ensure that accredited/certified CME activities are designed to address clinicians’ practice-relevant learning needs and practice gaps. The programs are also measured to evaluate the educational and clinical impact of the activity. Finally, they are planned and provided independent from commercial influence or other biases.

\textbf{Quality}

\textbf{Topped out status}

The AAN does not support the proposal to remove extremely topped out measures (those with an average mean performance within the 98\textsuperscript{th} to 100\textsuperscript{th} percentile range) in the next rulemaking cycle regardless of whether or not it is in the previously proposed four-year lifecycle to retirement. The AAN notes measure developers should have more time to respond to information that a measure has topped out to confirm if the measure remains relevant to care. For example, if in year 1 to year 2 average mean performance goes from 50\% to 98\% the measure developer should have time to investigate data for accuracy. Additionally, more time should be allowed to assess if there are meaningful areas to address in the identified topped out measure such as care disparities that may affect at risk populations. Unintended consequences may occur through such a rapid change in measure reporting and CMS should allow time for these consequences to be studied with subject matter experts and patients.

The AAN has similar concerns regarding the rapid retirement of topped out QCDR measures. The QCDR platform although innovative, also has time limitations and restrictions that CMS must be cognizant of prior to removal of measures. Removing measures without notice, will pose a burden to providers who must identify new measures to report on. Providers often build EHR templates for data collection, and the process of generating a new template for measure collection may take months if not years. Further the QCDR must work with their

\textsuperscript{12} My CME, “State License CME/CE Requirements for Physicians, Nurse Practitioners, and Physician Assistants”. Available at: http://www.mycme.com/state-licensing-cmece-requirements/section/3858/.
vendor to implement new measures to replace those that are topped out, review new measure
data collection for accuracy, assess unintended consequences, and monitor for validity and
reliability. This process takes many months. Coordination with CMS must also occur for new
measures to be implemented ensuring measures meet CMS program needs. As a result,
advance notice should be given regarding measures that are to be retired allowing providers
time to adapt and QCDRs to implement new measures to replace those topped out.

Replacing process measures with outcome measures

The AAN agrees that outcome measures are valuable to the clinical process and to patients
and caregivers. It should be noted there are specialties such as neurology where meaningful
outcomes in a calendar year are difficult to measure when the disease status is degenerative,
results in increased co-morbidities, and is terminal with limited treatment options such as
disease-modifying therapies. Given the lack of improvement in neurologic diseases, CMS
should support process measures for more time to establish ways to convert process to
meaningful outcomes.

Retirement of process measures

The AAN does not support the planned retirement of non-high priority process measures.
The criteria outlined are broad and give leeway to CMS without meaningful opportunity to
engage the measure developer and/or steward.

Classification of measures proposal

The AAN does not support the proposal to implement a classification of value to measure
system. The QPP is a complex system. An additional layer of complexity is not needed and
would result in unnecessary confusion. As noted above outcome measures cannot be
consistently implemented across specialties and as a result such a classification system would
unfairly disadvantage some specialties with limited treatment options for terminal diseases.

Measures to be added

The AAN supports the inclusion of QPP 0418 Preventive Care and Screening: Screening for
Clinical Depression and Follow-up Plan. The AAN notes that comorbid depression is a
frequent concern for patients with neurologic conditions. The AAN requests that CMS
consider adding the following additional measures to the Neurology Specialty Measurement
Set (B.16): QPP 0710 Depression Remission at Twelve Months. The AAN notes that
comorbid depression is a frequent concern for patients with neurologic conditions.

Measure removal

The AAN does not support the removal of the following measures from the Neurology
Specialty Measurement Set (B.16):

- QPP 386 ALS Patient Care Preferences: CMS suggests adoption of Measure 46: Care
  Plan. The AAN notes patients with ALS are often younger than Measure 46
denominator age 65. Most people develop ALS between the ages of 40-75 years, and
there are cases of individuals diagnosed when 20-30 years. The average life expectancy of a patient diagnosed with ALS is 2-5 years. For this reason, a separate measure applying to all patients with a diagnosis of ALS is clinically indicated. Use of this process measure leads to improved end-of-life care for patients with ALS.

- **QPP 276 Sleep Apnea: Assessment of Sleep Symptoms:** CMS suggests adoption of Measure 277: Severity Assessment at Initial Diagnosis. Measure 277 focuses on care provided to patients with a diagnosis of obstructive sleep apnea. The AAN notes many patients with neurologic disorders experience sleep disturbances and disorders other than obstructive sleep apnea. These symptoms include hypersomnia, Restless Legs Syndrome, parasomnias and REM sleep disorders. Removing 276 would result in limited reporting options for neurologists specializing in sleep care, therefore the AAN opposes this change.

- **QPP 154 and 155:** The AAN does not believe a seamless transition to a composite measure can be achieved under the timeline proposed. The technical implementation of the measure would be a massive burden on QCDRs and eligible clinicians. Additionally, there are benefits to maintaining the separate measures to identify performance variance versus an overall composite score. The AAN would support a trial period of collection of QPP 318 to confirm that measure data is able to be collected as a composite without unintended consequences or extreme burden.

**Qualified clinical data registries (QCDR)**

CMS is looking to update the definition of QCDR. The definition suggests that QCDRs must have clinical expertise in medicine and quality measure development. This is because CMS is finding that technology companies were applying to become QCDRs despite lacking quality measurement expertise. The AAN suggests that instead of doing this, CMS develops a separate definition for those QCDRs which are being put forth by a technology company solely as a for profit entity as opposed to those which are managed by a specialty society.

Starting in performance period 2019, QCDR measures will need to be “licensed” to CMS for general use by all QCDRs in order to be accepted. While we understand that CMS would like for QCDR measures to be available for more widespread use by all QCDRs who have gone through CMS's self-nomination process we do not agree that this is the solution to the problems that have arisen in the past. There is no way to ensure that measures are being implemented uniformly in the current QPP system, widespread use of QCDR measures will not yield better data or better benchmarks if we as measure stewards have no way of controlling how the QCDR measures are being implemented. The only way we will agree to this is if CMS proposes a way to require a standard data dictionary be used for all QCDR measures.

Continuing, the AAN requests a definition of minimal changes regarding the simplified self-nomination process starting for the 2019 MIPS performance period. At this time, QCDRs in good standing with minimal changes can attest to those items which have not changed and submit their changes during the self-nomination period.

For the 2020 performance year, QCDR application process will be moved to 2019 July 1-Sept 1 and will include a streamlined application process and full process. We agree with the
movement of this timeline however CMS will need to provide specifications around data requests to support measures. A September 1 timeline provides very little time for a registry to collect data for a measure to show its worth for the program.

**Benchmarking**

QCDRs should be able to provide data about averages in the registry and number of providers participating to set benchmarks. This could be submitted during the submission period (March/April) so that the benchmark is current. Additionally, benchmarking data for QCDR measures, not just MIPS measures, should be published before submission. Without this data, practices have no way of knowing which measures will perform well in the program or have any idea of how many points they will receive.

**Meaningful Measures**

For the 2019 MIPS performance period, CMS is proposing updates to the meaningful measures initiative. The plan adds 4 patient reported outcome measures. The American Academy of Neurology supports this and suggests approving a global and tailorable product that measure the physical, mental, and social health for adults and children, such as the PROMIS measures. Regarding CMS's plan to remove 34 quality measures, the AAN cautions that if providers have gravitated to the measure it could be because it provided them with meaningful information and presented little burden. The AAN recommends an informed and objective approach to removing measures from the programs.

**Cost**

We continue to have concerns regarding the cost methodology that CMS will be using in 2018 and going forward. It will be challenging to appropriately link physicians to each episode group. While we appreciate that CMS is gradually increasing the Cost Category to allow clinicians to develop experience with cost measures, we feel that the episode-based cost measures are too new, the availability of other cost measures is still limited for specialists like neurologists, and the category weight should be maintained at 10 percent of the overall MIPS score. Extensive education and resources from CMS are still required to ensure that clinicians better understand this area of MIPS.

**Episode-Based Cost Measures**

The AAN is particularly concerned about the implementation of the episode-based cost measures, which were first developed and tested in 2017. AAN members participated in the development of the Intracranial Hemorrhage or Cerebral Infarction episode-based cost measures, and we appreciate that CMS and its contractor, Acumen LLC. has been inclusive of physician voices throughout the measure development process. However, these measures are not yet ready for full implementation and use in MIPS.

The National Quality Forum (NQF)-convened Measure Applications Partnership (MAP) only conditionally supported implementation of episode-based cost measures conditioned on their receiving NQF endorsement in the future. CMS intends to submit the measures to NQF
for endorsement in the future. NQF uses rigorous criteria to assess a measure for endorsement:
- Important to measure and report;
- Scientifically acceptable;
- Useable and relevant; and
- Feasible to collect.

NQF endorsement would indicate the episode-based cost measures are safe, efficient, effective, and patient-centered. The AAN urges CMS not to implement episode-based cost measures until this endorsement has been secured.

Additionally, the AAN contends that the small case minimums and low reliability of episode-based cost measures indicates that these measures are not yet ready for full implementation and use in MIPS.

When CMS uses measures and methods that are validated for large populations, and applies them to individual providers, the results may not be valid. For example, if the cost score for a single neurologist is based on a small number of admissions for cerebral infarction or hemorrhage, the neurologist’s attributed costs will depend more on the characteristics of those few patients—hemorrhages versus ischemic infarcts, small versus large infarcts—than on the clinician’s decisions. In addition, neurologists and other physicians have not mastered the complex diagnostic coding criteria for stroke, so it is even more difficult to compare one group of patients to another. There is little reliable information about which treatments may reduce cost as measured by this process. In short, the data CMS provides to physicians will not be actionable until a lot more information is available. Implementation of these novel, largely untested, and potentially unreliable, measures could further add to cynicism and distrust between physicians and the policymakers behind future updates to the QPP.

Measurement Periods

While the AAN does not support using the episode-based cost measures to assess performance, we urge CMS to analyze these measures every year, to allow more regular input to refine the measures.

The cost measures and methodology are all new. They are based on expert opinion and not on a history of prior successful cost measures. We do not know, for example, what categories of cost separate the putative high or low-cost providers. We do not know whether there will be enough patients per NPI or TIN to get statistically valid results.

Therefore, we estimate that it will be at least 3 cycles of data release, analysis and refinement before the cost measure might accurately categorize providers. CMS and its contractors will depend on expert feedback from providers to refine these measures. Any delay in analysis of results will prolong the time it will take to get an accurate measure and actionable information.

Attribution by TIN for Inpatient Episode-based Cost Measures
Attribution is a critical part of the episode-based cost measures, but, because these measures are novel and untested, there is no good evidence that current methods are accurate. We understand that each inpatient episode is to be attributed at the TIN level. This would allow for more cases than attribution at the TIN/NPI level. Attribution by TIN, rather than TIN/NPI, should allow better statistical analysis of the cost measure, which should help CMS and the medical societies to improve the methodology with annual iterations of the cost measure.

The principal attribution method is particularly limited in these situations:

- Members of a single practice may rotate to perform hospital visits, and in that case attribution by TIN is likely to be more accurate, and more actionable, than attribution by NPI.
- Attribution may be difficult particularly for a short inpatient stay. For a 2-day visit, for example, the patient may have daily visits from a hospitalist and from each of 2 specialists. In that case a secondary method needs to be used to determine which of the 3 providers will be attributed the admission.

The AAN believes that the treating physician or hospital should be able to designate attribution as a patient relationship code. This would allow the team to decide among themselves the most appropriate attribution, rather than leaving it to statistics.

### Clinician Feedback

The AAN agrees with CMS’s current proposal that “clinicians would have received feedback on cost measures at several points prior to the cost performance category counting as part of the final score.” However, as we indicated in our previously prepared feedback to Acumen LLC. on the field test reports released in Fall 2017, the AAN would like to see significant improvement to the feedback reports and the delivery of these reports to ensure physician feedback is timely and actionable.

The AAN finds the Field Test Reports to be complex. We recommend that the release of future cost reports be accompanied by further information to help providers understand the reports and to advise physicians how they might reduce cost. Additionally, accessing the CMS Enterprise and Identity Management (EIDM) portal to retrieve and view reports has been difficult for clinicians, even while using the guidance provided by CMS. During field testing, AAN members required lengthy telephonic assistance from CMS in order to gain access to EIDM. The AAN recommends that CMS consider alternate methods of distribution for the reports, or, if use of the EIDM is required, that CMS significantly improve the usability for the site. For example, CMS could consider removing the requirement that clinicians undergo a credit report check to verify the account.

### Use of Existing Cost Measures

The AAN continues to have concern that the broader Medicare Spending Per Beneficiary and Total Per Capita Cost measures have a poor record of identifying efficient physicians and practices. For example, 96 percent of physician practices were scored as “average cost” using
similar measures in the 2016 Value-Based Payment Modifier program. Given that the MIPS measures will apply to smaller practices, as well as specialties whose discretionary services are not yet captured by well-developed episode definitions, clinicians can generally expect average scores, which offers little motivation to change.

**Risk Adjustment and Attribution**

As stated in previous comment letters, the AAN is concerned that risk adjustment and attribution methods have not been adequately developed for MIPS cost measures.

- HCC scores, while validated as cost predictors for large groups of patients, are not valid when applied to a small number of patients with a specific disorder, when attributed to a single clinician.
- There is, as of now, no validated method to adjust for social risk factors. The AAN agrees with CMS that upcoming trials are likely to be informative, but it would be surprising if a definitive method were achieved in this first attempt.
- Patient/clinician attribution rules have not been tested to date. It will be difficult for the clinician who admits a patient to influence all costs over the next 90-180 days unless the patient and clinician maintain a therapeutic relationship throughout the episode.

Finally, we encourage CMS to continue to educate providers on the new cost methodology as it is developed. Clinicians need to be aware that they may be attributed acute hospital care costs such as patient transportation, hospital overhead charges, some concurrent care during the acute episode, and skilled nursing facility charges. The AAN recognizes that CMS will refine episodes of care and related cost inputs over several years, and the AAN also recognizes that it may take several more years until clinicians might affect those costs.

**Feedback from CMS**

Where appropriate, CMS should aim to display feedback and performance measurement information in graphic form with additional details displayed elsewhere. Detailed information should be provided in feedback reports, including the ability to see high-level, overall performance information, as well as detailed tables with individual patient information. CMS must continually consult with stakeholders to ensure displayed data is relevant, meaningful, and understood by the intended audience.

Feedback reports should be accessible to physicians, practice administrators, and related officials. The log-in process for accessing reports must be simple and user-friendly. There have been ongoing problems with accessing reports due to the overly complicated log-in process and cumbersome password requirements which reset at very short intervals, ultimately limiting access to these reports. CMS should make more staff available to help physicians and administrators interpret the reports. The CMS Help Desk is not sufficient.

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13 CMS Website, “Physician groups receive upward, neutral, or downward adjustments to their Medicare payments in 2016 based on their performance on quality and cost efficiency measures”. Available at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/2016-VM-Overview-PDF-Memo.pdf.
Finally, CMS must provide a fair and transparent process for providers to appeal findings in feedback reports and should lengthen the appeals process to at least 90 days.

Summary Reports

The AAN believes CMS should generate a summary report of all measures across the MIPS domains per specialty and TIN size. This should include the “success” of each measure assessed. This level of transparency would help evaluate the value of the QPP program and methodologies. However, we are uncertain if this information is currently available or will be made available in the coming performance years.

Physician Compare

As a general matter, the AAN believes physicians should be able to review information before it becomes public. There should also be a mechanism to challenge and provide evidence that corrects CMS data. We are concerned that patients often do not understand the data used to judge physicians. Therefore, context must be provided so patients better understand what they are evaluating.

Advanced Alternative Payment Models (A-APMs)

The AAN supports the move to value-based payment (VBP) and Advanced Alternative Payment Models (Advanced APMs). Since 2012, the AAN has convened a group of dedicated experts to monitor new payment and delivery models with an eye toward communicating to neurologists how they can meaningfully participate. CMS has indicated that Advanced APMs will remain a priority for the foreseeable future, but to-date there have been no models approved that address the patients and services for which neurologists are responsible.

The AAN commends CMS for many of the policies included in the NPRM that harmonize the Medicare Advanced APM and Other Payer Advanced APM pathways, simplify qualified participant determination processes, and allow more existing payment arrangements to meet statutory requirements for Another Payer Advanced APMs.

However, the Advanced APM pathway currently favors just a handful of existing APM models that meet CMS’s strict financial risk standards to qualify as Advanced APMs. We appreciate that CMS is working to establish more APMs, but CMS’s process for creating and implementing new APMs, especially those that would qualify as Advanced APMs, has been slow, and we are concerned that this pace will lead to implementation of new models only after qualifying participants no longer receive the 5 percent incentive to participate in Advanced APMs.

Similarly, although the AAN appreciates the ongoing flexibility that CMS has introduced into the financial risk requirement for Advanced APMs, we strongly believe that CMS should permit APM Entities to take on less financial risk to qualify as an Advanced APM Entity. For example, we believe that certain models with one-sided risk should be eligible to be Advanced APMs.
Many of our neurologist members have expressed that the APM requirements are intimidating. In particular, small and rural neurology practices may not be able to participate at all; they may not be equipped to take on the necessary financial risk, and could incur prohibitively expensive administrative, technological, and start-up costs. Over the course of CMS’ implementation of the Advanced APM pathway, such costs will only increase for small and rural practices as the Advanced APM requirements become more stringent.

Despite these concerns neurologists want to be full participants in the evolution to value based payments. We understand that Medicare’s initial AAPMs were directed towards primary care and towards large provider groups. But it is time for CMS to encourage new models for specialists to participate more fully in integrated value-based care.

Finally, the AAN generally supports the purpose and goals of the Physician-Focused Payment Model Technical Advisory Committee (PTAC), which was created to “provide comments and recommendations to the Secretary . . . on physician-focused payment models.” However, we were discouraged that the Department of Health and Human Services (HHS) recently rejected all models that were recommended by the PTAC for implementation or testing despite the models having met all criteria established in previous rulemaking. Moreover, in light of the rejections, we were disappointed that the PTAC criteria were not addressed in this NPRM.

Below we discuss each of these recommendations in more detail.

**Neurologists Lack APM Options**

Neurologists are eager to participate in value-based care, but we have no substantive APM options. At present, the only CMMI initiative targeted directly at the services neurologists provide is the recently announced voluntary Bundled Payment for Care Improvement – Advanced (BPCI-A). The model is comprised of a single retrospective bundled payment with prospective price-setting. The model includes 29 inpatient episodes and 3 outpatient (but surgically oriented) episodes among which are episodes for acute ischemic stroke and intracranial hemorrhage. This is not a very useful path for neurologists, because we are usually consultants rather than primary admitting physicians in these cases, and because most costs are determined by hospital and skilled nursing facility charges and by the cost of transport between care facilities.

Neurologists often act as primary (or “principal”) care physicians for patients with complex neurologic conditions, such as ALS, epilepsy, traumatic brain injury, Parkinson’s disease, or neurodevelopmental/intellectual disabilities. Neurologists should have the opportunity to participate in the American medical system as it evolves toward value-based care through Advanced APMs and MIPS APMs. This is critically important to encourage specialists to join APMs, since few practices with accept the costs of participation without an opportunity to participate in the bonus payments.

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14 Social Security Act (SSA) § 1868(c)(1)(D).
To that end, the AAN asks CMS to focus additional resources on the development of specialty-specific APMs this year, since the Advanced APM Incentive Bonus is only available until payment year 2024. We would be pleased to partner with CMS on the development of APMs specifically targeting complex neurologic conditions or more general APMs for specialist integration into multi-disciplinary care teams.

**CMS Should Finalize a More Flexible Financial Risk Criterion for Advanced APMs**

The AAN urges CMS to decrease the amount of risk an APM must bear in order to qualify as an Advanced APM. The MACRA defines an “eligible APM entity” (i.e. an Advanced APM) as an entity that participates in an APM that (1) requires participants to use certified EHR technology, (2) provides for payment based on quality measures that are comparable to MIPS, and (3) “bears financial risk for monetary losses under the APM that are in excess of a nominal amount,” or is a medical home expanded under CMMI. The statute does not define “financial risk for monetary losses” or “excess of a nominal amount.” In this comment, we focus on the third criterion in the definition of an “Advanced APM.”

In the CY2017 Quality Payment Program Final Rule (CY2017 Final Rule), CMS finalized that an APM bears financial risk in excess of a “nominal amount” if the amount the APM Entity potentially owes CMS or forgoes is equal to at least either (1) 8% of the average estimated total Medicare Part A and Part B revenue of [providers and suppliers in] participating APM Entities for Qualifying APM Participant (QP) Performance Periods in 2017 and 2018 (the revenue-based standard) or (2) 3% of the expected expenditures for which an APM is responsible under the APM for all QP Performance Periods (the benchmark-based standard). In the CY 2018 Quality Payment Program Final Rule (CY2018 Final Rule) rule, CMS also finalized to add a revenue-based standard that Other Payer Advanced APMs can use to meet the nominal risk standard; this standard, which CMS proposed would mirror the generally applicable 8% revenue-based standard, would be an additional way that Other Payer APMs could meet the nominal risk standard. In this NPRM, CMS proposed maintaining the generally applicable revenue-based nominal standard amount at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for QP Performance Periods 2021 through 2024. Our below recommendation is relevant to both the generally applicable financial risk standard and the Other Payer APM financial risk standard.

While the AAN was pleased that CMS proposed a consistent revenue-based standard through 2024, we strongly recommend that CMS finalize a lower revenue-based nominal amount standard, particularly for small and rural practices. CMS itself has recognized that the proposed revenue-based nominal risk standard was derived, in part, on the statutorily mandated 5 percent Advanced APM incentive bonus. Therefore, it seems reasonable that CMS finalize a financial risk standard as least as low as the applicable percentage for the

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15 SSA § 1833(z).

16 In the CY2017 Final Rule, to determine whether an Other Payer APM meets the financial risk standard, CMS finalized a test that involves three measures of risk: marginal risk, minimum loss ratio, and total risk. See 81 Fed. Reg. at 77426.

17 American Medical Association, APM Briefing, oral statement of Gregory Woods (July 17, 2017).
bonus a qualified participant would receive based on his or her participation in an Advanced APM. Even a small decrease in the percent of estimated total Medicare Part A and Part B revenue could represent a very large percentage of a provider’s revenue and most, if not all, of their operating margin. This is particularly true for small or rural entities for whom Medicare patients make up a large portion of the practice. Neurologists who are part of small groups or solo practices want to participate in an APM and meet the requirements to be a QP. To facilitate such participation, the AAN strongly recommends that CMS reduce the amount of revenue-based financial risk an APM entity must bear to meet the requirements of an Advanced APM.

In general, we encourage CMS to broaden its definition of risk and consider the preparation costs, implementation costs, and opportunity costs (such as missing out on a MIPS bonus) as risks that could qualify an Advanced APM.

**APMs with One-Sided Risk Should be Eligible to be Advanced APMs**

As finalized in the CY2017 Final Rule, CMS continues its policy that APMs with only one-sided risk do not meet the Advanced APM requirements. However, CMS continues to promote its one-sided risk accountable care organizations and other APMs as sufficient to meet CMS’s value-based policy goals. Moreover, many physicians, even those in APMs, are reluctant to assume full downside risk. Therefore, the AAN continues to encourage CMS to consider the operational and investment costs associated with implementing a one-sided risk model as sufficient “nominal risk” to meet the Advanced APM financial risk standard.

Current low levels of clinician participation in two-sided risk models should demonstrate to CMS that it should expand flexibility regarding Advanced APM requirements for bearing downside risk. At the same time that CMS reviews the generally applicable and Other Payer revenue-based financial risk standards, the AAN recommends that CMS develop a financial risk standard that allows one-sided financial risk to meet Advanced APM requirements.

If the agency continues to consider one-sided models as not including enough risk, the AAN believes CMS could soften the transition to two-sided risk by allowing entities to qualify as an Advanced APM if the entity creates a contractual relationship that transitions the entity to bear downside risk component within a set period of time. For example, CMS could allow an entity to qualify as an Advanced APM if it implements a five-year contract requiring two years of one-sided risk followed by three years of two-sided risk. The AAN fears the requirement that entities be in two-sided risk models will create cynicism among clinicians and irreparable harm to CMS’s goals within the physician community. Additionally, permitting entities to implement transition years with respect to financial risk would align with CMS’s policy to make it easier for clinicians to meet the requirements of the QPP. The AAN supports a phased-in approach.

**AAN Supports the Proposal to Simplify Other Payer Advanced APM Determinations**

In the CY 2018 Final Rule, CMS finalized that Other Payer APM determinations would be in effect for only one year at a time. The AAN is pleased that CMS carefully regarded
stakeholder feedback that indicated that this process is burdensome because payment arrangements for other payers are often implemented through multi-year contracts.

The AAN supports the proposal to allow a payer, APM entity, or eligible clinician to submit multi-year arrangements of up to five years, which would require updates only on any changes to the payment arrangement that are relevant to the Other Payer Advanced APM criteria for each successive year. The AAN agrees that a 5-year interval is a reasonable timeframe to require such a full submission using the Payer Initiated Process or Eligible Clinician Initiated Process and that this will simplify the APM determination process and likely result in more Other Payer Advanced APMs.

**AAN Supports the Proposal to Make QP Determinations under the All-Payer Combination Option at the TIN-Level**

In the CY 2018 Final Rule, CMS finalized that an eligible clinician may request a QP determination at the eligible clinician level and that an APM Entity may request a QP determination at the APM Entity Level. In the event that CMS received a request from an individual eligible clinician and separately from an APM Entity, CMS would make a determination at both levels, and the eligible clinician could become a QP on the basis of either of the two determinations.\(^\text{18}\) The AAN is pleased that CMS considered stakeholder input that supported a third alternative for QP determinations under the All-Payer Combination Option.

The AAN supports the proposal to add a third alternative to allow QP determinations at the TIN level when all clinicians who have assigned billing rights to the TIN are included in a single APM entity.

**Physician-Focused Payment Models**

As mentioned above, the AAN strongly supports the PTAC’s mission to make recommendations to CMS regarding physician-focused payment models (PFPMs). As finalized in the CY2017 Final Rule, a PFPM is “an Alternative Payment Model (1) in which Medicare is a payer; (2) in which eligible clinicians that are eligible professionals as defined in section 1848(k)(3)(B) of the Act are participants and play a core role in implementing the APM’s payment methodology; and (3) which targets the quality and cost of services that eligible professionals participating in the Alternative Payment Model provide, order, or can significantly influence.”\(^\text{19}\) However, the AAN requests clarification from HHS about expectations for these models.

**The AAN Supports a Broader Definition of PFPM**

The AAN supports CMS’s proposal to broaden the definition of a PFPM to include payment arrangements that involve Medicaid or CHIP as a payer. As noted above, the current

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18 82 FR 53881
19 42 C.F.R. § 414.1465(a).
The definition of “PFPM” requires that Medicare be a payer.\(^{20}\) Under CMS’s proposal, a PFPM could include a payment arrangement in which Medicaid and/or CHIP is a payer, if Medicare is also a payer. Broadening the definition of a PFPM would allow stakeholders, like neurologists, to propose models that include populations beyond the Medicare population, such as Medicaid-only populations.

We support this proposal as a mechanism for CMS to provide value-based care to larger patient populations and to increase the potential APM options available to neurologists.

**CMS Should Commit to Test All PFPMs Recommended by the PTAC**

As stated previously in the CY2017 Final Rule, CMS continues to believe it is not in a position to test all models on which the PTAC will make comments and recommendations. Additionally, CMS states that it cannot speak to how long it would take a state to implement a PFPM, including one with Medicaid or CHIP as a payor. The AAN recommends that CMS should be committed to implement all PFPMs recommended by the PTAC. Without this commitment by CMS, physicians and medical societies cannot commit the resources needed to develop PFPMs. PTAC uses criteria finalized by CMS after public notice and comment. PTAC followed those criteria in making its recommendations. It appears to us that CMS has in fact sunk the PTAC process, and we simply do not see a way forward to develop new PFPMs that might be acceptable to CMS.

**The PTAC PFPM Review Criteria Should be Reviewed and Clarified**

In accordance with SSA § 1868(c), CMS established criteria for physician-focused payment models, including models for specialist physicians. Of the criteria finalized, no criterion is specialty-specific. Therefore, the AAN strongly recommends that CMS propose criteria that would apply to specialists, including neurologists. Congress intended for specialists to have sufficient APM and Advanced APM options; but at this time, there are few. The AAN would be pleased to propose specialty-specific PFPM review criteria.

In particular, the AAN strongly recommends that CMS specify in regulation that specialty-specific PFPMs meet the “scope” criterion requirements. We also recommend that CMS clarify that one goal of the “scope” criterion is to encourage the submission of specialty-specific PFPM proposals to signal CMS’ willingness to review and implement those proposals.

The AAN developed a process of extensive research and expert consensus that resulted in neurology-specific care models for headache and epilepsy. In October 2017, the AAN submitted the headache APM for consideration. We are hesitant to develop these models more completely, or to prepare further care pathways, until CMS better explains the criteria for PFPMs it would implement. The AAN urges CMS to articulate their vision for the PFPMs and for the role of PTAC so that this valuable avenue for physician innovation can blossom.

\(^{20}\) 42 C.F.R. § 414.1465(a)(1).
The PTAC Should Provide Technical Assistance

There are still major gaps in knowledge surrounding payment methodologies, especially with regards to risk adjustment to ensure adequate payment and prevent physicians from cherry picking patients. Moreover, physicians have limited access to meaningful, nationally representative Medicare claims data, which prevents accurate cost estimates.

PTAC currently provides a limited number of data tables and other resources for use by stakeholders and potential proposal submitters. These are insufficient because in order to adequately produce evidence for proposed models, there must be a data file that can be manipulated in order to compare condition-specific costs across different types of providers. Currently, the PTAC only offers data with associated costs on a few conditions. A data file, preferably in the form of a CSV document, that includes data fields for patient demographic information, diagnosis codes, procedural codes, associated costs, and physician specialty are imperative for organizations to support the proposed models. Moreover, this data must be a representative sample of the patient population. The free 5% Medicare files are not representative of the population and organizations are forced to use less robust data files in order to address data needs. The data expectations of the PTAC in proposed models do not align with the reality of freely available data. Providing a condensed and statistically representative data file for organizations to use in support of their models is imperative to the success of these proposals.

PTAC is well-positioned to provide physicians with necessary access to data and technical assistance in developing their PFPMs. However, PTAC has previously stated that the “PTAC has been advised that it may not provide technical assistance.”

The AAN does not understand the basis of this policy—the PTAC is not prohibited by statute from providing technical assistance—and urges PTAC to establish a technical assistance mechanism to benefit the PTAC and entities submitting PFPMs. Access to technical assistance throughout the proposal development process would ensure that PFPMs meet the criteria for PTAC recommendation and, ultimately, CMS adoption.

The AAN recommends that the PTAC implement both a process to provide technical assistance to entities submitting PFPM proposals to ensure that the necessary supporting evidence is provided and a process to request technical assistance from those who have already submitted PFPM proposals. Such technical assistance would aid CMS in gathering the evidence needed to evaluate a PFPM proposal and, simultaneously, offer entities a vehicle to ensure that submitted proposals contain sufficient evidence to aid the PTAC’s review process.

The AAN was encouraged by recent policies enabled by the Bipartisan Budget Act of 2018 (BBA of 2018), which included, among many other changes, a mechanism for PTAC to provide feedback to submitters. In fact, the AAN decided to delay proposal review in order to benefit from the additional insight afforded by the BBA. However, when the AAN received the promised feedback on its October 2017 proposal, we discovered that it was ambiguous, largely disregarded previously provided details, and was ultimately unhelpful for purposes of resubmitting the proposal to feedback. The AAN urges CMS to work with PTAC to improve this process.
Conclusion

We greatly appreciate this opportunity to express the views of the AAN in response to the proposed rule. The AAN strongly urges CMS to consider our suggested improvements to the proposed rule so that the final rule may further reduce regulatory hassles on neurologists and promote the care of their patients.

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

Sincerely,

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