September 16, 2019

Ms. Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

RE: Medicare Program; CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations [CMS-1715-P]

Dear Administrator Verma:

The American Academy of Neurology (AAN) is the world’s largest neurology specialty society representing more than 36,000 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.

**Long-Term EEG Monitoring**

Although the AAN appreciates that the Centers for Medicare & Medicaid Services (CMS) accepted the RUC recommendations for codes 95X18, 95X19, 95X20, 95X21, 95X22, and 95X23, we are greatly disappointed CMS did not accept the RUC recommendations for professional component codes 95X14, 95X15, 95X16, and 95X17 and urge CMS to accept the RUC recommended wRVUs for these codes in the final rule.

While 10 professional component (PC) codes were established to replace the four existing long-term EEG monitoring services (95950, 95951, 95953, and 95956), the AAN asserts the PC code set should be viewed as two distinct
subsets when considering rank order for the family, as they represent two distinct patient populations. When viewing the family of codes in this manner, the RUC recommended wRVUs do not create a rank order anomaly for the family and recognizes both the time and intensity of the physician services and typical patients.

95X14 – 95X17 are typically facility-based services, provided to hospital inpatients, and outpatients (observation stays and clinical services). For these services, the physician has access to data in real-time and can make medical decisions related to further testing or treatment options during the course of the study. This subset of codes is provided to patients because of the severity of their disease state. The physician work is more complex and intense as the typical patients are undergoing pre-surgical evaluations and/or being withdrawn from anti-seizure medications to induce seizures.

95X18 – 95X23 will be provided to patients primarily tested in their homes. The physician does not access the data until the conclusion of the study, at the end of two, three, or four or more days. These studies, which allow for the monitoring of patients in their homes and during their usual daily routines, play an important role in the diagnosis of patients with epilepsy.

95X17

For CPT Code 95X17, CMS disagrees with the RUC recommended work RVU of 3.86 and proposes a work RVU of 3.50 based on the survey 25th percentile. CMS references one of the predecessor codes for this family, CPT Code 95956, in the rationale for reducing the RVU of 95X17. Specifically, the Agency states the “prior valuation of CPT code 95956 does not support the RUC-recommended work RVU of 3.86 for CPT code 95X17, but does support the proposed work RVU of 3.50 at the slightly lower newly surveyed work times. We also note that at the recommended work RVU of 3.86, the intensity of CPT code 95X17 was anomalously high in comparison to the rest of the family, the second-highest intensity as compared to the other professional component codes. We have no reason to believe that the 24 hour EEG monitoring done with video as described in CPT code 95X17 would be notably more intense than the other codes in the same family.” We think that it would be appropriate to consider CPT Code 95951 as the most accurate predecessor code for 95X17 as it includes both EEG and video recording for each 24 hours, as does 95X17, whereas 95956 does not include video recording. CMS appreciates the difference in physician work when video is recorded, and we request that the Agency look directly to 95951 as the single predecessor code for 95X17.

The RUC’s recommendation was based on a direct work value crosswalk to top key reference code 99223 Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components… (work RVU= 3.86, intra-service time of 55 minutes, total time of 90 minutes) which CMS criticized, writing “… the 15 minutes of additional total time in CPT code 99223 result in a higher work valuation that overstates the work RVU of CPT code 95X17.” This statement seems to assert that all crosswalks must have near identical work intensity instead of simply involving the same overall amount of physician work. As crosswalks with near identical times do not always exist, which was the case for this service, it sometimes necessitates selecting a crosswalk with somewhat disparate...
total time which has a different level of work intensity though the same overall amount of work. Although the reference code involves more total time, the survey code is a more intense service to perform given the intensity involved in making an appropriate reading/diagnosis prior to the typical patient’s pre-surgical evaluation for neurosurgery.

More specifically, the typical patient is a candidate for epilepsy surgery and the long-term EEG physician report will inform the neurosurgeon on whether epilepsy surgery is appropriate, as well as specifically what type of procedure (and in most cases which part of the brain to disconnect or remove), which reflects an EEG study with a particularly high level of intensity. This pre-surgical evaluation often includes the withdrawal of anti-seizure medications to invoke seizures and identify the seizure focus (requiring detailed review as this is the principal determinant for the site for surgical brain resection). Typical patients requiring this procedure have failed multiple anti-convulsant therapies and are some of the most complex patients seen in neurologic care. Additionally, the CPT code 95951 was used in inpatient monitoring centers of varying levels including NAEC Level 4 centers. These centers are also performing continuous, surgical placed, intracranial EEG with video. In addition to the intensity mentioned above with medication withdrawal, there is added risk and a significantly increased cognitive load compared to non-surgical patients. The same 95951 code was used in these cases with a significantly higher cognitive and workload. The proposed rule does not capture this level of effort and work. The proposed rule will likely result in an unintended disincentive to this essential patient service. CMS’ proposed alternate value actually assigns the survey code a slightly lower intensity than the RUC’s crosswalk code.

As part of the Agency’s rationale for not accepting the RUC recommendation, it wrote: “We have no reason to believe that the 24 hour EEG monitoring done with video as described in CPT code 95X17 would be notably more intense than the other codes in the same family.” However, two paragraphs earlier in the Proposed Rule, CMS inconsistently cited the opposite rationale as part of its reason for rejecting the RUC recommendation for 95X16. Also, and importantly, it seems that the Agency failed to account for the typical, highly complex patient for this service as described above. When looking at this sub-set of four codes that entail daily review by the physician (95X14 – 95X17) the RUC recommended RVU of 3.86 is not anomalously high for 95X17, but rather reflects the increased amount of intensity associated with the review of a pre-surgical patient’s EEG recording.

As stated above, the RUC recommendation was based on an appropriate crosswalk. In addition, it was agreed upon following a careful review of all underlying clinical attributes of the procedure. The AAN urges CMS to accept a work RVU of 3.86 for CPT code 95X17.  

95X16

For CPT Code 95X16, CMS disagrees with the RUC recommended work RVU of 3.00 and proposes a work RVU of 2.60 based on a direct work RVU crosswalk to CPT code 99219 Initial observation care, per day, for the evaluation and management of a patient, which requires these 3 key components... (work RVU= 2.60, intra-service time of 40 minutes, total time of 64.5 minutes). CMS’ selected crosswalk is inappropriate as observation care involves relatively less intensity than the typical long-term EEG described by the survey code.
Although both services involve identical intra-service time and similar total time, the survey code is a more intense service performed on a sicker patient population. **The typical patient for 96X16 is a patient with an intracerebral hemorrhage being evaluated for potential epileptic seizures, whereas the typical patient for 99219 is a patient that could be admitted for observation for an allergic reaction to a bee sting following a separately reported emergency department visit.**

The RUC recommendation was based on the 25th percentile work RVU from robust survey results and careful review of all underlying clinical attributes of the procedure. The RUC strongly supported its recommendation with favorable comparison to top key reference code 99223 *Initial hospital care, per day, for the evaluation and management of a patient, ...* (work RVU = 3.86, intra-service time of 55, total time of 90 minutes) and CPT code 44405 *Colonoscopy through stoma; with transendoscopic balloon dilation* (work RVU = 3.23, intra-service time of 38 minutes, total time of 72 minutes). **The AAN urges CMS to accept a work RVU of 3.00 for CPT code 95X16.**

95X15

For CPT Code 95X15, CMS disagrees with the RUC recommended work RVU of 2.50 and proposes a work RVU of 2.35 by adding the increment between the RUC recommendations for 95X14 and 95X15 to the CMS proposed value for 95X14. As CMS’ rationale for rejecting the RUC recommendation for 95X14 is flawed, as described below, it should not be used as the basis to derive a new value for 95X15.

The Agency did not explicitly indicate why it disagrees with the RUC recommendation, although it did provide one reference code to support the alternate value, 99310 *Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components* (work RVU = 2.35, intra-service time of 35 minutes, total time of 70 minutes). As CMS acknowledges, this is a lower intensity service. This service is a very poor comparator as it is typically performed by a non-physician and involves highly disparate work. Even though there are few XXX-global comparator codes with similar times and values to draw from, this service was intentionally not referenced in the RUC’s recommendation for that reason.

The RUC recommendation was based on the 25th percentile work RVU from robust survey results and careful review of all underlying clinical attributes of the procedure. The RUC strongly supported its recommendation with favorable comparison to CPT code 75573 *Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology in the setting of congenital heart disease (including 3D image postprocessing, assessment of LV cardiac function, RV structure and function and evaluation of venous structures, if performed)* (work RVU = 2.55, intra-service time of 30 minutes, total time of 60 minutes). **The AAN urges CMS to accept a work RVU of 2.50 for CPT code 95X15.**

95X14

For CPT Code 95X14, CMS disagrees with the RUC recommended work RVU of 2.00 and proposes a work RVU of 1.85 based on a direct work RVU crosswalk to CPT code 93314
Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); image acquisition, interpretation and report only (work RVU = 1.85, intra-service time of 30 minutes, total time of 50 minutes). The work value the RUC had recommended for this crosswalk code in 2014 was 2.80; when CMS finalized a value much lower than that code’s RUC-recommended value, they concurrently accepted the RUC intra-service time greatly reducing the code’s derived intensity. We feel that CMS’ crosswalk code is an inappropriate reference point in general for this or any other service under review.

The RUC recommendation was based on the 25th percentile work RVU from robust survey results and careful review of all underlying clinical attributes of the procedure. The RUC strongly supported its recommendation with favorable comparison to CPT code 74178 Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by contrast material(s) and further sections in one or both body regions (work RVU = 2.01, intra-service time of 30 minutes, total time of 40 minutes). The AAN urges CMS to accept a work RVU of 2.00 for CPT code 95X14.

We cannot understate the critical value and consequent physician intensity associated with monitoring for seizures. Unquestionably, missed seizure activity, or predilection towards seizure activity as found on an EEG can not only impact a patient’s life, but save the patient’s life, as well as other’s lives, such as in the case of driving considerations. For these reasons and others noted, the AAN strongly requests CMS reconsider the work RVU values.

Practice Expense

Based on a valid practice expense (PE) survey the RUC recommended direct practice expense inputs consistent with the median survey time data for certain clinical staff time activities, especially for those clinical activities in which no time standard is established as typical for all services within the RBRVS. Although the RUC understands that conducting a survey is not standard for RUC direct practice expense recommendations, the CMS rationale for proposing the 25th percentile for some clinical labor times inputs is flawed. CMS wrote:

“This was in contrast to the typical process for recommended direct PE inputs, where the inputs are usually based on either standard times or carried over from reference codes. We believe that when surveys are used to recommended direct PE inputs, we must apply a similar process of scrutiny to that used in assessing the work RVUs that are recommended based on a survey methodology.”

Although PE surveys are not atypical, generally the RUC reviews direct practice expense recommendations developed by a physician expert panel. This expert panel utilizes knowledge of the service and considers standard times and reference code times. The RUC does not disagree with CMS’ assertion that similar scrutiny should be applied to assessing both physician work and practice expense; however, the RUC reminds CMS that the 25th percentile clinical labor times are a completely different measure than the 25th percentile physician work RVU. The RUC does not make recommendations on the PE RVUs which would be the equivalent of the work RVUs, rather the RUC makes recommendations on direct practice expense inputs only. These inputs are part of a complex formula with many
factors including indirect practice expense data and the physician work RVU as part of the “bottom up methodology” that CMS uses to determine the final PE RVU. Further, the median survey times for physician work are what is recommended by the RUC, not the 25th percentile survey times. The survey 25th percentile physician work RVU is what CMS is referring to when the agency states in the NPRM that “…over the past decade the AMA RUC has increasingly chosen to recommend the survey 25th percentile work RVU over the survey median value…”, so using the rationale that CMS has provided, the factors that should be compared are the survey medians for physician time and clinical labor time. Because the RUC routinely recommends survey median physician time and it is generally accepted by CMS that is even more reason that the survey median times of 13 minutes for clinical activity CA011, Provide education/obtain consent and 10 for clinical activity CA035, Review home care instructions, and coordinate visits/prescriptions are justified for CPT code 95X01.

For the 10 professional component procedures, CPT codes 95X14-95X23, CMS is proposing to refine the equipment time for the ambulatory EEG review station (EQ016) equipment, citing the use of the ambulatory EEG review station as analogous in these procedures to the use of the professional PACS workstation (ED053) in other procedures, and the equipment times for these 10 procedures should match the CMS standard equipment time formula for the professional PACS workstation. CMS is proposing an equipment time for the ambulatory EEG review station equal to half the preservice work time (rounded up) plus the intraservice work time for CPT codes 95X14 through 95X23. We disagree with this calculation for the EQ016 equipment time for 95X14-95X23. The EEG review station (EQ016) equipment is used during the providers’ post-service work period and should be included in the practice expense inputs for all the professional component codes. The use is as follows: Often the referring physician (e.g.: intensive care unit physician, hospitalist) calls the physician providing the service to ask urgent questions about the recording. The providing physician will pull up the record on an EEG review station and go over the questions and provide responses with the inquiring physician. This is similar to when a physician asks a radiologist about an MRI or CT report, and the radiologist opens the Radiology review station to view the images while discussing with the referring physician the questions and answers.

Furthermore, the AAN disagrees with several of the refinements CMS is proposing to the practice expense inputs for the technical component codes 95X02 – 95X13.

CMS is proposing to refine the clinical labor time for the “Coordinate post-procedure services” (CA038) activity from either 11 to 5 minutes or from 22 to 10 minutes as appropriate for the CPT code in question. The CMS rationale is that many of the tasks detailed here are administrative in nature consisting of forms of data entry, and therefore, would be considered types of indirect PE. The agency also notes that when CPT code 95812 (Electroencephalogram (EEG) extended monitoring; 41-60 minutes) was recently reviewed for CY 2017, it finalized the recommended clinical labor time of 2 minutes for “Transfer data to reading station & archive data”, a task which they believe to be highly similar. Due to the longer duration of the procedures in CPT codes 95X02-95X13, CMS is proposing clinical labor times of 5 minutes and 10 minutes for the CA038 activity for these CPT codes.
We disagree with this rationale to arrive at a recommendation for CA038 activity minutes. CMS referred to a clinical labor time of 2 minutes for “Transfer data to reading station & archive data” for CPT code 95812 (Electroencephalogram (EEG) extended monitoring; 41-60 minutes) as “a task which we believe to be highly similar.” Code 95812, however, is for a 41-60-minute study (routine), and the codes in question are for long term EEG monitoring. Archiving data includes selecting the relevant EEG and video data to be archived (generally from prior technologist or MD annotations and review of the video-EEG report). This process takes approximately 2 minutes for the first hour (as noted for the 95812 study) and 1 minute per additional hour of recording. Therefore 11 minutes for a 2-12 hour study is more accurate for the time required for transfer and archiving. The video component of these reports is critical in the characterization of events and determination of the locus of patient’s neurologic issues and is necessary for optimized outcomes and therapeutic interventions.

CMS is proposing to refine the ambulatory EEG review station (EQ016) equipment time for the continuous monitoring technical component codes 95X04, 95X07, 95X10, and 95X13. The recommended equipment time for the ambulatory EEG review station was equal to four times the “Perform procedure/service” clinical labor time plus a small amount of extra prep time. CMS did not agree that it would be typical to assign this much equipment time, as it is our understanding that one ambulatory EEG review station can be hooked up to as many as four monitors at a time for continuous monitoring. Therefore, we do not believe that each monitor would require its own review station, and that the equipment time should not be equal to four times the clinical labor of the “Perform procedure/service” activity. We disagree with this rationale to arrive at a recommendation for EQ016 equipment time for 95X04, 95X07, 95X10, and 95X13. It is not typical for a review station to be hooked up to four monitors, but rather two or three. As such it would be more appropriate to assign EQ016 minutes by multiplying CA021 clinical labor time two or three times plus prep time, rather than the times proposed by CMS. It should be noted that the methodology used to arrive at the determination was not included in the proposed rule.

Payment for Evaluation and Management (E/M) Visits

The AAN applauds CMS for accounting for feedback from the physician community and withdrawing its proposal to collapse the levels of E/M coding. The AAN vehemently opposed CMS’ proposal to collapse the levels of E/M coding and appreciates that the agency responded to our advocacy by issuing a significantly improved alternative proposal. The AAN was deeply involved in the AMA CPT/RUC process to develop the proposed alternative and concurs with CMS that the proposal will produce a simplified and more intuitive system of E/M coding that is more consistent with the current practice of medicine.

The AAN supports CMS’ proposal to implement the CPT/RUC proposal, with modification. Specifically:

- The AAN supports separate payment for each of the outpatient E/M levels for new and established patients, 99202-99205 and 99211-99215. The AAN believes that this proposal contains the minimum number of levels needed to distinguish among E/M services. Collapsing to fewer levels would not have adequately recognized physician
services for complex patients. The AAN believes the proposed payment levels for these codes are adequate and notes that the AAN participated in the RUC process that was used to determine these payment levels.

- The AAN supports payment for the new prolonged visit add-on code 99XXX that can be paid for each additional 15-minute increment of service. We agree that the GPRO1 code should be eliminated. The AAN appreciates that a prolonged service add-on code is included in CMS’ proposal. The current code, 99354, for the first hour of prolonged services, is not adequate for many prolonged services performed by neurologists and by other specialists caring for complex patients. Although prolonged service codes are rarely used, the AAN believes they should remain available to clinicians who care for the most complex patients. The AAN also supports that this code can be used to account for multiple 15-minute increments of additional time.

- CMS proposes add-on code GPC1X for “Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient’s single, serious, or complex chronic condition.”
  - The AAN supports payment for the revised GPC1X add-on code that accounts for the complexity of non-procedural specialized medical care. The AAN was pleased to see in the previous rulemaking cycle that CMS recognized that neurologic patients generally present with complex diseases. We applaud CMS’ intent to recognize and reward physicians who care for complex patients, regardless of specialty, with the inclusion of the GPC1X add-on code in the current proposal. The AAN concurs with CMS’ rationale that there are different pre-visit resource costs associated with non-procedural specialized medical care and is grateful that this code is not restricted by specialty or to primary care practitioners.
  - CMS will need to give clear guidance to the physician community about the correct use for add-on code GPC1X. Examining the CPT vignettes, a level 3 service is for a patient with “a stable chronic illness or acute uncomplicated injury.” The vignette for a level 4 service is a patient with “a progressing illness or acute injury that requires medical management or potential surgical treatment,” and the vignette for a level 5 service is a patient with “a chronic illness in a severe exacerbation that poses a threat to life or bodily function or an acute illness/injury that poses a threat to life or bodily function.” Based on these vignettes, patients with level 3 service do not qualify as having a “single, serious or complex, chronic problem.” Patients with levels 4 and 5 services may qualify under the proposed description. We suggest that the add-on code be used for visits with medical decision making that meets the CPT requirements for a level 4 or 5 new or established patient visit and also the definition embedded in code GPC1X.
  - Correct coding for GPC1X will require further guidance from CMS. The AAN suggests that CMS publish a list of clinical situations that meet the definition of a “single, serious or complex, chronic problem,” and a list of clinical situations that do not meet the definition. The medical community is
familiar with using clinical analogy for coding, as similar clinical guidelines were embedded in the 1995 and 1997 coding guidelines.

- CMS requests comments regarding the valuation of code GPC1X. CMS proposes to value code GPC1X at 0.33 RVU and 11 minutes of time. The AAN supports the CMS proposed values for GCP1X. There are few precedents in the fee schedule for valuing work intensity, and CMS’s proposed crosswalk is rational, though inexact. **These are reasonable values for added complexity and time for patients who meet MDM for codes 99204, 99205, 99214 and 99215, but not for codes with lower MDM complexity.**
  - MedPAC in its 2018 report to Congress¹ (page 74) found that the value of most physician services was based about 80% on the physician time, while intensity accounted for about 21-23% of service value among all specialties. Proposed values for codes 99204, 99205, 99214 and 99215 are in the range 1.92-3.5 RVUs. At about 20% of total value, an estimated (imputed) value for the work intensity in these codes is 0.38-0.7 RVU. Adding 0.33 RVU for a more complex patient is a reasonable increase in value for the increased work intensity.
  - The proposed total time for code 99204 is 60 minutes. Adding 11 minutes of time to this code, the typical total time is still less than the proposed total time for code 99205, 85 minutes. Similarly, the proposed total time for code 99214 is 49 minutes. Adding 11 minutes of time to this code, the typical total time is still less than the proposed total time for code 99215, 70 minutes.

- The AAN supports implementation of the CPT framework under which documentation of history and examination must support the complexity of medical decision making, but specific bullet points are no longer required. The AAN believes that this framework will reduce the documentation burden on providers and allow them to conduct examinations and obtain histories as clinically appropriate. The AAN concurs with CMS that this system is simpler and more intuitive. It allows medical care to be driven by the clinical judgment of providers, rather than cumbersome and sometimes irrelevant bullets.

- The AAN supports the proposal to adopt RUC-recommended work RVUs. Since E/M is, in fact, the basis for all subsequent diagnostic testing and therapy, we suggest that E/M services are still undervalued in a value-based medical care system. We note that the higher-level office visits are defined by higher complexity of medical decision making, but RUC recommends no increase in wRVU/minute as the MDM complexity increases. Although the higher-level visits are, therefore, relatively undervalued, we believe that the RUC data, based on extensive surveys, are the values most acceptable to most of the medical community.

- The AAN supports the decision to exclude office visits bundled into the global surgery package from the increase applied to outpatient E/M services. The AAN believes it would be inappropriate for CMS to revalue global surgery packages while they are currently examining data related to global surgery valuations. The AAN urges CMS to carefully consider the findings from RAND related to the disparity

between expected and observed post-operative visits. We note that Rand, OIG, and other reports support the conclusion that CMS is now paying for many postprocedural visits that do not actually occur. Any investigation of the global billing periods will have limitations, but we are not aware of any independent data that support the number of postprocedural visits indicated in RUC surveys and in current CMS global periods.

Separately identifiable office/outpatient E/M visits furnished in conjunction with a global procedure are different from other typical outpatient visits. The complexity of medical decision making is similar for pre-procedure outpatient visits and for typical office visits to nonprocedural providers. On the other hand, the medical decision making for the typical post-procedure outpatient visit typically is less complex. The post-procedure visit usually is concerned with a well-defined problem; and, by definition, the provider has taken a medical history and examined the patient a short time before the visit in the global period. Practice expense may differ for post-procedure visits, some of which require supplies such as suture removal kits and dressings. The resources required for postprocedural visits in the global period differ from resources needed for the typical office visit, and we agree with CMS that these visits should be independently of typical office E/M visits. It is of the utmost importance that the valuation of global packages actually reflects the work being done and that the values are supported by data. The AAN recommends that CMS establish G codes for 3-5 levels of post-procedural visits performed within a 10- or 90-day period after surgery, and that CMS request RUC to recommend values for those services.

The AAN supports using time as the basis for E/M coding but has concerns about using medical decision making (MDM) as one of the primary factors used to determine E/M levels. Since the inception of the RBRVS, time has been the single most important factor in the Medicare Physician Fee Schedule. As noted previously, this is highlighted in the June 2018 MedPAC Report to Congress. MedPAC found 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. Until value-based care is implemented, Medicare essentially pays for provider best efforts as estimated largely by time. Additionally, time-based coding is easier to audit than MDM.

Furthermore, the AAN is concerned that the MDM levels fail to account for the complexity of neurologic conditions. The AAN is concerned that under the current proposal, efficient neurologists treating highly complex patients may have difficulty attaining the highest-level E/M visit based on MDM alone. Neurodegeneration, acute vascular events and intractable seizures are every bit as complex, with the same life-death-profound disability as myocardial infarction and surgical decisions and must be valued as such.

CMS acknowledges that stakeholders have argued for using time as the primary determinant of E/M levels and wrote “some stakeholders suggested that only time should be used to select the service level because time is easy to audit, simple to document, and better accounts for patient complexity, in comparison to the CPT Editorial Panel revised MDM interpretive guidance. These stakeholders stated that the implementation of the CPT Editorial Panel revised MDM interpretive guidance will result in the likely increase in the selection of levels

2 Id.
4 and 5, relative to current typical coding patterns. They suggested that to more accurately distinguish varying levels of patient complexity, either the visit levels should be recalibrated so that levels 4 and 5 no longer represent the most often billed visit, or a sixth level should be added.” CMS does not offer a rationale for rejecting this argument. The AAN concurs with these arguments and requests further clarification from CMS as to why the agency chose to allow the use of MDM as one determinant of E/M levels.

The AAN is concerned with CMS proposing to remove equipment item ED021 (computer, desktop, with monitor), because in CMS’ view it is included in the overhead costs. The AAN believes ED021 represents a practice expense and recommends that it be resurveyed.

CMS is requesting comment on how to address discrepancies in the RUC recommended times for office E/M visits. All of the RUC-recommended times for office E/M visits, are for intraservice activities. Because any part of the E/M visit may be done face-to-face, total time is the best indication of provider resource use for the office E/M codes. This is similar to “floor time” for inpatient services. Provider time reviewing medical records, and preparing a chart note, is counted as floor time toward determination of the level of inpatient E/M visit. RUC surveyed, separately, the amount of time spent 3 days prior to a visit, on the day of visit, and during the seven days after a visit; RUC also surveyed the total visit time. RUC reported the median of each value; the sums of the 3 service-period medians did not equal the median of the total time. Had the RUC reported mean, or average times, then the sums of the three medians would more likely equal the total time estimate. The separate surveys of services in the three time periods support the total time recommendation, but RUC did not provide data upon which to determine preservice, intraservice, and postservice times. We are not aware of codes for which partial intraservice times have been used for RUC valuation or for CMS rate setting.

Additionally, CMS requested feedback regarding the appropriate interpretation of the CPT reporting instructions for CPT codes 99358 and 99359. CMS notes that these codes may potentially overlap with the proposed 99XXX code. The AAN notes that the descriptor and guidelines clearly state that 99XXX should be utilized for the extended time on the date of encounter and that 99358 and 99359 are not to be reported for this time. CMS states that CPT codes 99358 and 99359 may need to be redefined, resurveyed, and revalued. The AAN concurs with CMS’ assessment and recommends that CMS refer this issue to CPT for further refinement.

Continuing, CMS requested feedback regarding whether it would be appropriate to reexamine the value of services, other than the global surgical codes that are closely tied to the E/M values. It has not been RUC or CMS policy to review the values of services when changing the value of other services that may have been used as key references, and we do not recommend that CMS needs to alter the values of codes related to E/M services. Specifically, codes that include office E/M as part of comprehensive care do not need revaluation because of their inclusion of an E/M code: transitional care management services (CPT codes 99495, 99496); cognitive impairment assessment and care planning (CPT code 99483); certain ESRD monthly services (CPT codes 90951 through 90961); the Initial Preventive Physical Exam (G0438) and the Annual Wellness Visit (G0439). It may be

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3 84 Fed. Reg. at 40673.
reasonable to re-value other E/M codes, but we consider that it is not reasonable simply to raise their value to maintain a value in proportion to office E/M codes. The patient presentation, nature of presenting problem, and social/environmental influences on physician work are different for E/M visits performed in the home, for ophthalmology visits, and for psychoanalysis.

The AAN appreciates CMS’ attention to this issue and to the importance of input from the physician community throughout this process. The AAN was deeply troubled by the lack of physician input prior to the release of the proposed collapse of the E/M levels in the previous rulemaking cycle. The AAN appreciates CMS’ willingness to consider stakeholder feedback, once widespread opposition to the proposal became apparent. If CMS contemplates any further revisions to the outpatient E/M codes, we urge the agency to consult with relevant specialty groups, including the AAN, to better understand any potential negative consequences of a change, prior to releasing a proposal.

**Care Management Codes**

**Transitional Care Management Services**

The AAN supports CMS’ proposal to revise the billing requirements for transitional care management (TCM) services by allowing TCM codes to be billed concurrently with the 14 proposed codes. The AAN believes that TCM services are in the interests of the patient but are underutilized in part due to insufficient reimbursement and substantial administrative burden. The AAN believes that this change can effectively promote the use of TCM services and will be beneficial for the complex patients that need services related to the proposed 14 codes. The AAN believes that this proposed change will benefit neurologists and neurology patients in relation to the transitional care services that neurologists provide, including medication acquisition and follow-up for adherence.

Additionally, the AAN believes that 99491 should be added to the list of 14 codes that are proposed to be allowed to be billed concurrently with TCM. Patients with chronic diseases can have ongoing issues unrelated to a discharge requiring TCM billing. For example, a patient being treated for dementia may be admitted for a new stroke. Once discharged the patient may have new issues related to the discharge and management of the stroke, while still having ongoing chronic issues related to dementia that are not inherently covered by stroke care management. Both conditions will need care simultaneously and these types of situations are very common in patients with neurologic and neurodegenerative disease. Even if the admission was related to a patient’s chronic condition, however, it is important to follow the TCM care for a variety of reasons including to assure that no medications were changed inappropriately and to review caregiver and family concerns. This care may not replace the ongoing management of a patient’s baseline issues. The AAN also urges CMS to ensure that the frequency of usage of these codes is not limited for patients within a given time period, as patients may present with multiple chronic problems that requires the care of multiple specialists. For instance, a patient with multiple sclerosis (MS) may require seizure management and urinary incontinence management during a “flare” of the disease based on the location of their inflammation.
The AAN does not believe that overlap with TCM depends on practitioner type. Neurology patients often have prior evaluations or treatment trials before their first evaluation by a neurologist. These more complicated patients also may be more likely to seek second opinions. Complex patients can have extensive records and imaging studies that require review before or after face-to-face visits. This work is not duplicative of an E/M face-to-face visit which should focus on clarifying questions from the record, performing a physical examination, discussing next steps, and educating the patient on their condition or treatment expectations. It is important to note that this could occur following a hospital discharge, for a new patient, or for one with a chronic condition. It is possible a practice might include an advanced practice provider to review and summarize the records, prior to a physician seeing the patient in the visit, which results in different practitioners billing for patient care. This example may represent a better workflow for an office. Multiple team members in a group provide different types of services including care plan oversight and chronic care management in the context of a change in health status indicated by a need for TCM. To support clinical practice transformation, it would be inappropriate for overlap to depend on practitioner type.

**Chronic Care Management**

The AAN supports CMS’ proposal to separate existing coding for chronic care management into codes that account for the initial 20 minutes of clinical staff time and each additional 20 minutes thereafter. If more time is expended providing CCM, consequentially, more resources are utilized. The AAN believes that the additional time should be accounted for and reimbursed. The AAN notes that there should be limited use of the add-on to maintain the distinction between complex and non-complex CCM, as patients requiring multiple uses of the add-on are highly likely to require moderate to high medical-decision-making, which would necessitate use of the complex CCM code.

**Complex Chronic Care Management**

The AAN supports the elimination of the substantial care plan requirement because it is redundant and may be unnecessary for appropriate care. The AAN supports the proposed revision of the CCM typical care plan language. The AAN believes this change will aid in adoption of the complex CCM code, reduce documentation burden, and promote coordination of care with outside resources, practitioners, and providers. The AAN requests clarification on whether CMS requires a certain number of the elements of the “typical care plan” to be completed for a care plan to be considered valid according to the requirements for complex chronic care management.

**Principal Care Management**

The AAN strongly supports the creation of separate coding and payment for principal care management services. Establishment of separate coding will aid neurology practices that could utilize PCM codes to support their ancillary staff and care coordinators, particularly those with a large portion of patients with disabling autoimmune disorders. Caring for these patients requires coordination of trials of various immunomodulatory treatments to prevent further decline. PCM codes would also benefit the treatment of medication-refractory
epilepsy, when staff coordinate presurgical non-invasive testing, inpatient hospitalizations in an epilepsy monitoring unit, and help to collate outside records for decision making. Separate PCM coding and payment also mitigates some concerns related to placing specialists in competition with referring providers. PCM codes would allow neurologists to focus on one neurological issue without having to be involved with care coordination for other health issues unrelated to their specialty.

One challenge that the AAN believes warrants CMS’ attention is that providers can have difficulty recognizing which patients will utilize the service, so that providers can obtain their consent and enroll them pre-emptively. This is especially problematic if this occurs with a new patient visit, in which a vast amount of information is collected, reviewed, shared, and explained. Explaining PCM and obtaining consent for PCM would likely be time-consuming and burdensome. Enrollment and assent are clearly delineated requirements in the CM codes, but the AAN believes that CMS should consider allowing use of the PCM code when it is documented that the patient has utilized 30 minutes of clinical staff time for PCM services.

The AAN believes that to prevent care fragmentation and service duplication, CMS should not allow PCM codes to be used for the same indication by different providers in a given time period. The AAN does believe that it would be appropriate for PCM to be used by multiple specialists for different indications within a given time period to promote patient health and decrease preventable admissions.

The AAN supports the creation of an add-on code to account for the additional resources and time spent on PCM services each month beyond the 30 minutes per patient per month threshold.

**Communication Technology-Based Services**

The AAN’s appreciates CMS’ efforts to reduce unnecessarily burdensome and duplicative consents for communication technology-based services. The AAN supports allowing clinicians to obtain advanced consent for these services. The AAN does not believe that it is necessary for CMS to require physicians to note verbal consent for each service and instead the AAN recommends that consent should be obtained at the time of initiating care with a practice. Standardized language for the consent would be appreciated and would benefit patients who see multiple providers and likely would sign multiple consents. Additionally, in the case of using codes 99446 – 99452 (inter-professional telephone/internet/EHR assessment and management services provided by consultative physician), the AAN believes that the burden of obtaining prior consent should fall on the requesting provider only. If the consulting physician providing a medical opinion in their area of expertise has never seen the patient, they should not be held accountable for having this prior consent.

Furthermore, the AAN believes that clinicians could best document the medical necessity of a virtual check-in service (HCPCS code G2012) 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.
**Open Payments**

The proposed rule aims to require additional payment information for device and drug manufacturers through an expanded Open Payments program updated to include additional required reporting information from practitioners.

**Covered Recipients**

CMS is proposing to codify the provisions in the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) Act regarding Open Payments. The SUPPORT Act expanded the definition of covered recipients from physicians and teaching hospitals to include physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives.

The AAN appreciates CMS’ proposal to expand the definition of covered recipients to include the aforementioned mid-level practitioners in an effort to increase overall transparency and recommends that CMS considers the potential increased burden these reporting updates may have on the expanded group of covered recipients going forward.

**Device Identifier**

CMS proposes that the device identifier (DI) component of the universal device identifier (UDI) assigned to a device, if any, should be incorporated into Open Payments reporting that applicable manufacturers or applicable group purchasing organizations (GPOs) are required to provide. CMS is not proposing that a full UDI should be required. CMS believes this requirement would substantially support enhancement of the quality of the Open Payments data as the identifiers can be used to validate submitted device information.

The AAN appreciates this effort by CMS as it would also improve the usefulness of Open Payments data to the public by providing more precise information about the medical supplies and devices associated with a transaction.

**“Nature of payment” categories**

To clarify the types of payments or transfers of value made by applicable manufactures and GPOs to covered recipients, CMS is proposing to revise the “nature of payment” categories by consolidating the accredited/certified and unaccredited/non-certified continuing education program categories and by adding the following three additional categories: debt forgiveness, long-term medical supply or device loans, and acquisitions. These new categories would apply to future reported payments and not require updating of previously reported payments or relevant transfers of value.

The AAN agrees that this proposal would allow applicable manufacturers to be more precise in reporting the nature of payments and transfers of value and aid in avoiding incorrect categorization of payments that are often of significant value.
Provisions Affecting Advanced Practice Providers

Physician Supervision for Physician Assistant Services

The AAN supports CMS’ proposal to simplify the physician assistant (PA) supervision requirement to provide that the statutory physician supervision requirement for PA services would be met when a PA furnishes their services in accordance with state law and state scope of practice rules for PAs in the state in which the services are furnished, with medical direction and appropriate supervision as provided by law in the state in which the services are performed. The AAN concurs with CMS that it is appropriate that in the absence of state law governing physician supervision of PA services, that supporting documentation in the medical record related to the PA’s approach to working with physicians in furnishing their services should be required. The AAN believes this approach will reduce burden by harmonizing CMS and state requirements.

Review and Verification of Medical Record Documentation

The AAN supports CMS’ efforts to reduce mandatory duplicative medical record documentation requirements. The AAN supports CMS extending its documentation burden relief proposals to non-physician practitioners that would allow them to review and verify, rather than re-document, information in the medical record that was recorded by physicians, residents, nurses, students or other members of the team. Re-documentation requirements are burdensome on APPs and take time away from necessary patient care.

Medicare Enrollment Revocation Proposal

CMS is proposing to add a new subsection to 42 C.F.R. § 424.535(a) and to 42 C.F.R. § 424.530(a), which lists the reasons that CMS may revoke a currently enrolled provider or supplier’s Medicare billing privileges or deny a provider or supplier’s enrollment in Medicare.4 CMS proposes that a provider or supplier may be denied enrollment or have enrollment revoked if

“[H]e or she has been subject to prior action from a state oversight board, federal or state health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm.”5

The AAN strongly disagrees with this proposal for six primary reasons. First, CMS does not have the statutory authority to finalize the proposal. Second, the proposal is vague and unenforceable. Third, this proposal imposes harsh sanctions on providers for potentially minor violations. Fourth, the proposal would negatively affect Medicare beneficiaries’ access to care. Fifth, the proposal would have a chilling effect on physician self-reporting to medical boards and on medical boards’ willingness to discipline physicians. Six, this proposal does not adequately codify in regulations the proposed leniency toward minor violations.

4 84 Fed. Reg. at 40723.
5 Id.
The statutory authority that CMS relies on to support its proposal are the provisions at SSA §§ 1102, 1871, and 1866(j)(1)(A). SSA §§ 1102 and 1871 are general rule-making provisions in the Social Security Act. Specifically, Section 1102(a) authorizes the HHS Secretary to issue regulations that are “not inconsistent with [the SSA]” and that are “necessary to the efficient administration of [the Secretary’s] functions” [under the SSA]. SSA § 1871(a) authorizes the Secretary to prescribe regulations “necessary to carry out the administration of [the Medicare program].” Neither of these general rulemaking authorities can be construed to provide the authority to CMS to revoke a currently enrolled provider or supplier’s Medicare billing privileges or deny a provider or supplier’s enrollment in Medicare if the provider has been subject to an IRO determination or administrative action taken by a state oversight board, a federal or state health care program, or other healthcare-related governmental program. CMS’ proposal is not “necessary” to run the Medicare program at all, let alone efficiently. In fact, as described in more detail below, the proposal could interrupt the provision of care to Medicare beneficiaries and lead to a more inefficient Medicare program. Therefore, CMS is not authorized to finalize its proposal under the authority granted by either SSA § 1102 or SSA § 1871.

SSA § 1866(j)(1)(A) states that:

The Secretary shall establish by regulation a process for the enrollment of providers of services and suppliers under [Title 18 of the SSA]. Such process shall include screening of providers and suppliers in accordance with [the paragraph on provider screening], a provisional period of enhanced oversight in accordance with [the paragraph on provider screening], disclosure requirements in accordance with [the paragraph on increased disclosure requirements], the imposition of temporary enrollment moratoria in accordance with [the paragraph on a temporary moratorium on enrollment of new providers], and the establishment of compliance programs in accordance with [the paragraph on compliance programs].

This statutory section permits CMS to implement enrollment processes—not revocation processes. Specifically, the statute does not include any language related to revoking enrollment or denying enrollment. It speaks solely to regulating the process of enrollment that includes screening and a period of enhanced oversight. It contains no authority allowing CMS to deny enrollment at all, let alone, based on an IRO determination or administrative action taken by a state oversight board, a federal or state health care program, or other healthcare-related governmental program. SSA § 1866(j)(1)(A) uses the phrase “process for the enrollment of providers,” but relates only to enrollment and not to revocation. Therefore, the statutory authority that CMS cites for its proposal does not relate in any way to its authority to deny or revoke a provider’s Medicare enrollment after the provider has already been enrolled in the Program. In other words, this statute does not provide CMS with the authority to implement its proposal to deny or revoke a provider’s Medicare enrollment based on an IRO determination or administrative action taken by a state oversight board, a federal or state health care program, or other healthcare-related governmental program.

6 SSA § 1102(a).
7 SSA § 1871.
8 SSA § 1866(j)(1)(A).
Similarly, the statute describes that the “process for the enrollment of providers” in Medicare “shall include screening of providers.” SSA § 1871(j)(2) describes the provider screening, specifically stating that the screening “shall include a licensure check” and “may . . . include (I) a criminal background check; (II) fingerprinting; (III) unscheduled and unannounced site visits, including pre-enrollment site visits; (IV) database checks (including such checks across States); and (V) such other screening as the Secretary determines appropriate [based on the risk of fraud, waste, and abuse].”  

9 There is no authority to deny or revoke enrollment based on a finding of “patient harm.” As described in additional detail below, CMS’ proposal would not limit Medicare fraud and abuse and might increase Program inefficiency. Additionally, the enumerated list of screening procedures does not specifically describe a process through which CMS may take action based upon any IRO determination or state or federal agency action. Therefore, CMS is not authorized by the statute to finalize, or enforce, its proposal to deny a provider’s Medicare enrollment based on an IRO determination or administrative action taken by a state oversight board, a federal or state health care program, or other healthcare-related governmental program that is related to “patient harm.”

In addition to believing that CMS does not have the statutory authority to implement its proposal, the AAN strongly believes that an administrative action against a provider for minor violations does not warrant the disproportional punishment of denying or revoking Medicare enrollment. CMS proposes to codify the authority to take administrative action against a physician or other eligible professional based solely on an IRO determination or administrative action taken by a state oversight board, a federal or state health care program, or other healthcare-related governmental program. However, IRO determinations or administrative actions may be minor, and may not be relevant to a provider’s participation in Medicare. In cases of minor violations, the punishment CMS could impose far outweighs the scope and gravity of the alleged violation.

Furthermore, the proposal does not include any criteria or process by which CMS would determine when it would deny or revoke enrollment, which raises the potential for arbitrary decisions. For example, physicians with similar actions taken against them could be treated differently—one could continue to be enrolled and the other could have her enrollment revoked. In addition, state practice of medicine statutes vary considerably, as do the standards by which Boards of Medicine review physician behavior. Treating all “offenses” as being the same is completely inappropriate. Therefore, the AAN believes CMS should not impose disproportionately harsh punishment based solely on an administrative action taken by a state oversight board, a federal or state health care program, or other healthcare-related governmental program.

The proposal could also impede access of beneficiaries to healthcare. In 2017 alone, the Federation of State Medical Boards reports that over four thousand physicians were subject to state medical board actions. 10 The Federation of State Medical Boards also reported that 989 physicians were disciplined by a “reprimand,” defined as a “warning or letter of

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9 SSA § 1866(j)(2)(B).
These statistics demonstrate that CMS’ proposal has the potential to affect the Medicare enrollment of thousands of physicians across the U.S., which in turn could affect beneficiary access to medical care. Each time CMS revokes a provider’s Medicare enrollment, that provider’s patients will be forced to find alternative care. The AAN recommends that CMS withdraw its proposal and rely only on current Medicare enrollment revocation authority in an effort to ensure ongoing beneficiary access to necessary medical care.

The proposal could have a chilling effect on physician self-reporting behavior such as drug abuse or alcoholism to medical boards and create a disincentive for medical boards to discipline physicians for violations of State medical practice acts because of the potential effect on Medicare enrollment. As described by the AMA Journal of Ethics, “state medical boards are the agencies that license medical doctors, investigate complaints, discipline physicians who violate the medical practice act, and refer physicians for evaluation and rehabilitation when appropriate.” The AAN is concerned that State medical boards will refrain from disciplining physicians for minor violations if the medical boards know that the consequence of a minor violation could be revocation of the provider’s Medicare enrollment.

Furthermore, the proper venue for taking disciplinary action against physicians are the state boards of medicine because the proper punishment for physicians who are found to have violated the law is to take action against the provider’s license. We urge CMS to withdraw its proposal so as not to deter State medical board disciplinary actions and referrals for rehabilitation that may be warranted but that would not rise to the seriousness that would justify Medicare enrollment revocation. With respect to physician self-reporting, the AAN is concerned that CMS’ proposal will have a chilling effect on physician self-reporting to State medical boards. Many State medical boards require physician self-reporting of certain specific occurrences, and an OIG white paper noted that even in the late 1980s, there was “increased use of self-reporting requirements on license renewal forms” which “provides boards with increased opportunities to initiate cases.” The AAN cautions CMS that physicians may self-report with less frequency if a consequence of such self-reporting could be revocation of the provider’s Medicare enrollment.

Furthermore, CMS states in its proposal that it should not be “assumed” that “a very modest sanction would automatically result in revocation or denial action.” However, the text of the proposed regulation does not codify this statement, but instead only lists the factors CMS proposes to consider when making a revocation or denial decision. The AAN strongly believes that physicians should not be required to rely only on an informal statement that a modest sanction would not automatically result in a revocation or denial action. A preamble statement does not provide sufficient certainty or comfort to a provider when the potential consequence of a minor violation is revocation of Medicare enrollment. It also creates the potential for arbitrary decisions to be made. Lastly, we note that the proposal does not

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11 Id. at 21.
13 See e.g., Cal. Bus. & Prof. Code §§ 801.01(b)(2), 802.1, 2240, and 2021; D.C. Code §§ 3-1205.13a, 7-161; and 22 Tex. Admin. Code § 180.7(f). Many other states have self-reporting requirements in place.
14 OIG, State Medical Boards and Medical Discipline OEI-01-89-00560, at 98 (August 1990).
15 84 Fed. Reg. at 40723.
describe who will make these decisions. Will it be a CMS contractor or CMS itself? Will physician review of the case be included? As written, the proposal provides no safeguards against arbitrary decisions made on the basis of an insufficient record. CMS should withdraw this proposal.

**Quality Payment Program: Merit-based Incentive Payment System (MIPS)**

As year four of the Quality Payment Program (QPP) begins, it should be noted that physicians still lack critical knowledge about how exactly the QPP operates. According to a recent survey, only 8 percent of surveyed physicians reported being very familiar with MACRA. This knowledge gap represents an important 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 so that providers can successfully participate as the performance thresholds are increased going forward. Lack of physician understanding and the complexity of the QPP are significant contributors to the administrative burdens imposed on physicians. A recent MGMA survey indicated that compliance with the QPP represents the most significant administrative burden facing physician practices, with 80% of those surveyed calling the QPP either very or extremely burdensome. It also should be noted that many physicians reject the value proposition of the QPP. Nearly a quarter of surveyed physicians indicated that they believe that the incentives present in the QPP will actually reduce the value of care. Although the survey data indicates that 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 particularly challenging for small and solo practitioners. This is acknowledged by the United States Government Accountability Office and supported by the variation in performance scores between small and large practices. Challenges related to selecting a functional EHR system are particularly problematic for small and solo practitioners as they have fewer resources and less capacity to share costs across providers. Small and solo practices also face unique challenges when managing cost measures because they see fewer patients and are far more exposed to the risk

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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.

Without additional education and support services, the impact of increasing administrative and financial pressure by CMS through the QPP on solo and small practices will contribute to the demise of these practices, incentivizing physicians to enter into employment in hospitals or healthcare systems, withdraw from Medicare participation, or experience substantial hardship.

**Performance Threshold**

2017 final MIPS performance data indicates that there is a large disparity in performance scores between large and small practices, with clinicians in large practices achieving an average performance score of 74.37, whereas clinicians in small practices achieved an average performance score of 43.46. The AAN is highly skeptical that this large disparity in performance is an accurate reflection of a real difference in the quality and value of care delivered by large practices as compared to small practices. Instead, the AAN believes that this difference is more likely explained by the variation in resources, time, and expertise that large practices are able to devote to MIPS compliance and performance, as compared to small practices. In the absence of substantial evidence indicating that small practices deliver lower value care when compared to large practices, the AAN believes that this disparity in performance is inappropriate and likely reflective of systematic bias within the MIPS program.

The AAN believes that there are fundamental issues with MIPS scoring if performance differences are attributable to practice size, rather than the value of the care delivered by individual practices. As performance scores are directly tied to reimbursement, these fundamental issues with MIPS scoring are likely to result in unfairly reduced payments to small practices. For the 2020 performance year, CMS is proposing a performance threshold of 45 points to avoid a negative payment adjustment. Although the AAN concurs with CMS that performance scores are likely to increase as clinicians become more familiar with MIPS requirements, the most recent available data indicates that the average large practice is well above the proposed threshold with a score of 74.37, while the average small practice is below the 45-point threshold with an average score of 43.46. This is compounded by the fact that under CMS’ own projections, average 2017 performance scores would have been lower if they had been calculated according to the 2019 performance year methodology.

CMS is also proposing a 60 point threshold for the 2021 performance year, which will be even more difficult for small practices to meet, magnifying the payment impact of the current performance disparity. Based on this data, unless small practices substantially improve their

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23 84 Fed. Reg. at 40802.
MIPS performance year-over-year, the AAN believes that the average small practice will be unfairly penalized while the average large practice will be rewarded. To address the fundamental unfairness of rewarding the average large practice while penalizing the average small practice, the AAN recommends that CMS explore options that would address performance differences between small and large practices. These measures may include:

- Delaying any increase in the performance threshold and the exceptional performance threshold until the differential in performance between small and large practices is sufficiently addressed.
- Additional bonus points to eliminate the substantial gap in average performance between small and large practices.
- Differential performance thresholds and exceptional performance thresholds for small and large practices based on the average performance of practices of varying sizes.
- Additional resources and funding to help small practices succeed in MIPS.
- Ensuring that measure changes in future updates to the QPP are not uniquely burdensome for small practices.
- Exempting small practices from MIPS penalties until the differential in performance between small and large practices is sufficiently addressed.
- Continuing the low-volume threshold exclusion and examining potential changes to the low-volume threshold that would exclude additional small practices from a negative payment adjustment.

**Exceptional Performance Threshold**

Given the data laid out above, indicating a disparity in performance between large and small practices, the AAN does not believe that it would be appropriate to increase the exceptional performance threshold, as proposed by CMS. The current exceptional performance threshold is already far above the average performance level of small practices. Increasing it above the current level may represent a significant challenge for small practices. Given the present performance disparities, the AAN is concerned that exceptional performance bonuses will be disproportionately awarded to large practices if the threshold is increased.

**Complex Patient Bonus**

The AAN supports the continuation of the complex patient bonus. The AAN concurs with CMS’ rationale that there is a need for a bonus to protect access to complex care by ensuring that clinicians who care for complex patients are not at a potential disadvantage in terms of MIPS performance. The AAN concurs with CMS’ assessment that more data is needed based on future years of MIPS performance to more fully understand how patient complexity impacts MIPS performance. If CMS were to consider any further revisions to the complex patient bonus, we urge the agency to consult with relevant specialty groups, including the AAN, to better understand any potential issues, prior to releasing a proposal.

**Reweighting**

The AAN appreciates CMS’ proposal to allow for reweighting of performance categories in cases in which MIPS data is compromised due to circumstances outside of the control of
clinicians or their agents. The AAN concurs with CMS that clinicians should not be penalized for circumstances that are outside their control, but requests additional clarity from CMS on how they will determine whether a circumstance is outside of the control of clinicians, aside from whether clinicians knew or had reason to know of a particular issue, if clinicians or their agent attempted to correct the issue, and whether the issue caused data to be inaccurate or unusable. Illustrative examples would be useful to better understand this policy.

**Low Volume Threshold**

The AAN appreciates that CMS did not propose any changes that would diminish clinicians’ abilities to qualify for the low-volume threshold. The AAN believes the low-volume threshold is critical to ensuring that clinicians who do not treat large numbers of Medicare patients are not unfairly penalized or forced to undergo costly changes to comply with the QPP. However, the AAN supports CMS allowing physicians who do not meet low volume thresholds to still voluntarily participate, allowing them the opportunity to benefit from a potential bonus. Although the AAN supports current CMS policy in relation to the low-volume threshold, the AAN notes that some have argued that the low-volume threshold decreases MIPS participation and artificially inflates average MIPS performance scores. Although these concerns may have some basis in the available data, the AAN does not support changes to the low-volume threshold and instead encourages CMS to work to ensure that MIPS performance adjustments accurately reflect real differentials in value delivered by MIPS-eligible clinicians.

**Qualified Clinical Data Registries (QCDRs)**

The AAN has several recommendations based on the policies proposed by CMS. We support efforts of quality improvement related to the QCDR, but we suggest more clarity and specificity be added to the quality improvement services requirement. Similar to the requirement of providing feedback to clinicians at least four times per year, the quality improvement requirement needs a minimum threshold. A minimum requirement would be sharing links to the quality improvement education website or a QCDR platform with trending performance graphs.

We disagree with CMS on the proposal to give greater preference to QCDR measures that have a benchmark. Many providers do not submit measures without a benchmark because of the lower points allowed for non-benchmarked measures. Providers have been encouraged to submit more than six measures for MIPS so that the data can be used for establishing benchmarks. Providers are not agreeable to submitting measures that may have lower performance because of the possible negative impact with Physician Compare reporting. QCDR measures without benchmarks are still used in MIPS submission and should be allowed to remain available for MIPS reporting.

Regarding linking QCDR measures to Cost measures, Improvement Activities, or MVPs, we believe that would place an additional burden on QCDRs. Not all measures have a clear link to an approved improvement activity or Cost measure. QCDR measures need to have the
option to be excluded from MVP and still be utilized for MIPS submission without lessening the available scoring value.

Furthermore, QCDR measures must be fully developed with testing results. There are different levels of testing and requiring NQF testing is both burdensome and expensive. Currently, it costs the AAN approximately $25,000 per measure and there are likely measure developers without the funds to support this requirement. Additionally, QCDRs perform measure testing based on performance scores and chart audits after the measure is implemented into the registry. Measure implementation involves confirmation that a measure is valid. Requiring measure testing prior to measure implementation is not the standard. Also, not all MIPS measures have had NQF validity assessments. This is ultimately an additional unfair burden on QCDRs.

Finally, the AAN believes there are problems in collecting data to determine if a QCDR measure reflects an important clinical concept. A measure is not approved for use if public comments reveal that a quality measure would be a burden or not clinically important. Providers also have a choice as to which measures to report, so if a measure is not used in MIPS reporting, it does not indicate the measure is not clinically important.

**RFI on MIPS Value Pathways (MVPs)**

The AAN appreciates CMS’ acknowledgement of the confusing and burdensome reporting requirements MIPS eligible clinicians (ECs) are required to report each year and is interested in contributing to its efforts to address these challenges. At its highest level, we understand CMS’ intention to merge the siloed MIPS components of Quality, Cost, Improvement Activities and Promoting Interoperability into MIPS Value Pathways (MVPs) to more accurately reflect the workflow clinicians experience when delivering care to patients. However, we are concerned that the concept will accomplish little more than MIPS in its current state and in its effort to transition clinicians into APMs.

We also believe developing and implementing MVPs by 2021 is not feasible. We caution CMS to carefully consider the potential implications that a complete overhaul of the MIPS program would have not only on clinicians participating in MIPS but on those administrative, support, and technical staff that are responsible for implementing yet another program with a new set of requirements by 2021. If CMS moves forward with the MVP framework in 2021 or later, we implore CMS to provide robust transition materials and support to stakeholders to ensure a smooth transition from MIPS to MVPs and then into APMs.

As experts in the specialty of neurology, we appreciate CMS’ willingness to work with the AAN in developing MVPs that are meaningful to neurologists and other neurology advanced practice providers. The AAN believes that specialty societies are the most appropriate venue for MVP development. The AAN looks forward to continued conversation and collaboration with CMS regarding the development of MVPs for neurologists and neurology advanced practice providers to meaningfully report and participate in value-based care reporting programs. Some key considerations related to the MVP Request for Information are detailed below.
CMS should allow more than one MVP per specialty.

The development of MVPs solely based on specialty would have significant negative consequences for those specialties in which there is wide variation in terms of condition and practice across providers. MVPs should be constructed around conditions, with only providers who treat a minimum number of patients with a given condition qualifying to participate in the condition-specific MVP. For example, many neurologists specialize in a specific neurological condition such as epilepsy, multiple sclerosis, stroke or dementia, each requiring measurement of quality and cost for clinical actions specific to the condition on which they focus. Although a general neurology MVP may be appropriate for some neurologists, others still will only be able to participate meaningfully if condition-specific MVPs are also developed. Therefore, we do not support developing just one MVP per specialty, as this would leave many clinicians in neurology without a meaningful pathway to participate and be scored on clinical actions pertinent to their practice. It should also be noted that such a limitation on MVPs per specialty may limit patient access to specialists trained in treating specific neurologic conditions such as epilepsy, movement disorders, multiple sclerosis, and others.

Although we recognize CMS’ concern with allowing a potentially unwieldy number of MVPs to be developed, we are concerned that even a few neurology-specific MVPs would leave many of our members without an opportunity to meaningfully participate. The AAN believes that for these clinicians, traditional MIPS reporting should remain even beyond the first year of MVP implementation. The AAN also notes that CMS should consider allowing the use of cross cutting measures, that any specialist, not just neurologists, could use.

CMS should work with specialty societies familiar with the conditions for which MVPs are developed to set appropriate patient thresholds for participation in a given MVP.

AAN urges CMS to be flexible in assigning MVPs for diverse specialties.

A hybrid approach between CMS-assigned and self-assigned MVPs could be an appropriate method to ensure clinicians are presented with the most applicable and appropriate MVPs for reporting. Given that an increasing number of neurologists focus on a specific condition within neurology, CMS could determine the selection of MVPs that apply to an eligible clinician based on specialty designation and from there, the eligible clinician could choose the most applicable, condition-specific MVP within neurology. CMS should work with specialty societies individually to understand the unique characteristics of a given specialty and its conditions and take this into consideration when developing and approving MVPs. We strongly urge CMS to consider how best to address specialties with a variety of condition-specific specialists like neurology.

CMS must commit to developing complexity and risk adjustments for specialties that treat patients with complex comorbidities and negative long-term outcomes.

CMS should consider the varying complexity of specialties and conditions when scoring and comparing MVPs. Specialty societies, including the AAN, continue to struggle to develop meaningful outcome metrics for patient populations in a calendar year when long-term
Disease outcomes are often, very complex, negative and terminal. For example, if there were to be an MVP related to stroke, it is likely that performance outcomes and scores for this MVP would be very different from performance outcomes and scores for an MVP related to neuromuscular disorders. It is imperative that CMS appropriately address the disparities in patient populations and mix when scoring and comparing condition and/or specialty specific MVPs.

**AAN strongly urges CMS against requiring participants to use a specific collection type for reporting MVPs.**

The administrative and technical undertaking of implementing a data collection type requires substantial time and capital for a practice and can be especially time-consuming and expensive for small and rural practices with limited resources. Offering only one collection type for MVPs would lead to significant barriers to participation and reporting in the new framework and is at odds with the stated goals of MVPs, which includes increasing access, reducing silos and transitioning into APMs. Allowing one collection type would preclude those not already using the selected collection type from participating and force them adapt to the collection type, likely with great expense. For example, if CMS were to require all MVP participants to only report eCQMs, a significant proportion of eligible clinicians would be unable to report, especially those practices without the technological infrastructure and capability to support eCQMs. However, CMS should continue to promote the QCDR reporting mechanism and the reporting of QCDR measures which are more adept at filling measure gaps in specialties where some providers may have few measures that apply to their practice. Further, QCDR measures can more swiftly address gaps in care than MIPS and other measures that must go through the several year approval process that CMS currently employs.

**CMS should clarify its intention and process for linking Quality measures with Cost measures in MVPs.**

AAN appreciates CMS’ efforts to more closely align Quality measures, Cost measures and Improvement Activities to more accurately reflect the overlap such measures and activities have in clinical workflow. We are, however, concerned about the feasibility of tying every Quality measure to a Cost measure or Improvement Activity and are concerned this may devalue or distort measure intent, and further could have significant unintended consequences because clinicians will be doubly scored on their performance.

Although we understand that theoretically, each clinical action captured in a Quality measure would have a cost associated with it downstream, requiring each Quality measure be tied to a Cost measure seems infeasible and unrealistic. Additionally, the scoring methodology for Quality measures and Cost measures are very different and would require considerable revision or cross-walking for clinicians and practices to understand how the methodologies align. The AAN recommends CMS develop robust educational materials and offerings for clinicians participating in MVPs to understand the ways in which the newly connected Quality and Cost measures would be scored.
It should also be noted that cost changes may not be reflected immediately. Extra efforts to diagnose the cause of seizures may lower costs in the future years through reduced hospitalizations and emergency department visits. Widely accepted process measures need not be tied into costs, which can be poor short-term outcome measures in some cases. An illustrative example of a process measure that reduces costs over the long term is adding an antiplatelet agent after stroke, which reduces recurrent cardiovascular risk over years.

If CMS intends to connect each quality measure to one or both global cost measures, Total Spending Per Beneficiary and/or Total Per Capita Cost, they should clarify this in the future or should indicate the process for correlating Cost measures with Quality measures used in MVPs moving forward.

Although the AAN recognizes the importance of outcome and patient reported measures, we are concerned again, about the lack of appropriate and feasible patient reported and other outcome measures in neurology. Although some neurological conditions lend themselves to meaningful outcome and patient-reported outcomes measures, others, such as dementia measures, may not. CMS should be cautious when emphasizing patient-reported and other outcome measures when they may not be appropriate and offer alternatives for MVPs where outcome measures are not available.

**CMS should offer accommodations for small practices participating in MVPs.**

We know from the first years of MIPS that small practices on average, have lower performance scores and, anecdotally, cite more difficulty in meeting reporting requirements compared to larger groups. Additionally, the costs associated with implementing the processes and technological infrastructure to meet program requirements are significant, especially for small practices. We strongly urge CMS to consider implementing safeguards for small practices expected to participate in MVPs, given the disproportionate strain transitioning and updating their practice for another regulatory program over a short period of time has on such practices. CMS should consider developing a separate, lower performance threshold for small practices, under whatever scoring methodology is adapted for MVPs.

Further, CMS should consider the implications using the Promoting Interoperability component as the foundation of MVPs will have on practices unable to participate in this MIPS component or small practices that have considerable barriers to meeting the objectives of the Promoting Interoperability component. Although most neurologists do use electronic health records (EHRs), anecdotally, a significant number of practices, small and large, have communicated to us that there are significant barriers to interoperability with primary care practitioners (PCPs) and other referring clinician practices that don’t have compatible software, resulting in prohibitive costs associated with establishing and maintaining interoperability between the practices.

AAN has also learned of other issues that practices have encountered working with EHR vendors, including a small practice whose EHR vendor discontinued its relationship because the vendor was not interested in allocating time and resources to such a small practice, leaving the practice to find and implement a new EHR. These examples are meant to
highlight the problematic and inconsistent relationships practices have with EHR vendors, and other practices with which they must establish interoperability at great cost. We urge CMS to be realistic about all, and especially small, practices’ capability to fully transition to a program whose foundation relies on the assumption that Promoting Interoperability objectives can be met consistently, feasibly and affordably, an assumption we know not to be guaranteed in practice. Until regulations are finalized requiring effective interoperability amongst EHRs or through appropriate application programming interfaces (APIs), the AAN strongly discourages CMS to place any such information technology burdens on clinicians.

**CMS should consider the unique challenges of multispecialty groups participating in MVPs.**

AAN does not support restricting multispecialty groups from reporting on only one MVP, however, we do believe CMS must put forth extensive guidance and set reasonable thresholds for MVP participation, especially for multispecialty groups that provide varying types of care, often to different patient populations. CMS should consider imposing a cap on how many MVPs a multispecialty group can report and provide guidance on how an overall performance score would be calculated when multiple MVPs are involved. CMS should also consider use of cross-cutting measures.

**Concerns regarding administrative claims-based quality measures focusing on population health.**

We are concerned that administrative claims data may be old and not conducive to true quality improvement. For clinicians to be engaged in quality improvement, data should be able to be reviewed on an ongoing basis allowing for timely intervention implementation to drive meaningful change in practice.

Additionally, the AAN notes that CMS has delayed integration of the most recently proposed measure, “All-cause unplanned admission for patients with multiple chronic conditions,” until the 2021 performance period. Creation of such a set may take longer than anticipated.

**QCDRs can be important to MVP.**

We believe combining MIPS measures together but not including QCDR measures would lessen the importance of QCDRs. We recommend integrating QCDR measures into this plan.

Providers submit MIPS data through a QCDR so that they have access to specialty specific QCDR measures that are not available under the MIPS measures. Although we support the integration of QCDR measures into the MVP, not all QCDR measures align with cost measures or improvement activities. QCDR measures need to have the option to be excluded from MVP and yet still be utilized for MIPS.

**A standalone RFI examining the MVP framework in more granular detail would be helpful**
The AAN encourages CMS to issue a standalone RFI on the MVP framework prior to developing and issuing a proposal. The AAN is aware of frameworks that are already in use that meet CMS’ stated goals for MVPs. These frameworks are validated and have data indicating that they increase quality while reducing costs. The AAN believes a change to MIPS of this magnitude warrants continued engagement between the agency and relevant stakeholders and believes that CMS will need additional feedback as the MVP framework is developed and clarified.

**Promoting Interoperability**

The AAN appreciates CMS’ efforts to further streamline and simplify the Promoting Interoperability category to reduce reporting burden on clinicians. Additionally, the AAN appreciates that CMS is not proposing to substantially revise the proposed scoring methodology and notes that major overhauls of individual categories can be burdensome on providers due to the need for provider and staff education to understand how to maximize performance under a redesigned category scoring methodology.

The AAN supports the proposal to align the proposed EHR reporting period in CY 2021 with the hospital Medicare Promoting Interoperability program and supports a continuous 90-day reporting period, rather than the full-year reporting period used in other MIPS categories.

The AAN appreciates CMS’ efforts to revise burdensome measures and supports CMS’ proposal to revise the “Query of Prescription Drug Monitoring Program (PDMP)” measure by removing the numerator and denominator and instead requiring a yes/no response. The AAN concurs with CMS that this change is needed to account for varying degrees of state PDMP development and integration. The AAN believes this will reduce clinician burden as providers will not need to manually track numerator and denominator inputs, in cases in which PDMP and EHR integration is not fully realized. The AAN notes that providers would benefit from a requirement for states to allow PDMP data to be integrated into the EHR. Currently, this is not required in every state. Providers in some states can connect out from the EHR to the PDMP, but cannot bring data back in. This creates additional work for the provider who then has to attest and document what they found. This additional step not only can lead to errors with significant patient safety implications, but also creates additional work and administrative burden for the physician.

The AAN also appreciates CMS’ clarification of the “Support Electronic Referral Loops by Receiving and Incorporating Health Information Measure” exclusion criteria to ensure that clinicians understand their potential eligibility for this exclusion. Although the AAN appreciates the clarification, the AAN is concerned that this exclusion may now be more difficult to attain.

The AAN also appreciates CMS’ proposal to reduce clinician burden by exempting groups and virtual groups from reporting on the Promoting Interoperability category if more than 75 percent of the NPIs billing under the group’s TIN or virtual group’s TINs meet the definition of a hospital-based individual MIPS eligible clinician. The AAN believes this proposal will reduce reporting burden for neuro-hospitalists.
Request for Information on a Metric to Improve Efficiency of Providers within EHRs

The AAN believes that efforts to measure efficiency must be carefully weighed against the potential burdens that measurement efforts would place on providers. The AAN notes that EHR systems have inconsistent capabilities and is concerned with the potential for reporting burdens being placed on those who use EHR systems that lack the capability to measure provider efficiency. Additionally, being measured on efficiency could be counter-productive if doing so results in additional administrative burdens that diminish provider efficiency. The AAN recommends that for larger groups and institutions, CMS could consider an attestation statement that would indicate whether those providers have a system to assess and improve provider efficiency in the EHR. Additionally, CMS could encourage voluntary reporting to better understand the landscape of what capabilities are available and what sites are measuring, with possible inclusion of a metric for self-perception of efficiency by providers. The AAN notes that many EHR systems measure provider efficiency. Useful, measurable, and automated outcomes include time spent in the EHR outside of clinic hours, average time in in-basket, orders that require additional text entry or modification from defaults, and number of screen changes needed to complete a task.

The most fundamental problem hindering providers’ ability to achieve greater efficiency is ever increasing documentation and regulatory requirements. Providers cannot become more efficient if the burden for documentation and meeting measures is placed primarily on physicians. Efficiency is hindered by current required metrics and the inability of some EHR systems to accurately capture physician practice. This ultimately requires extra clicks, sometimes hundreds or thousands a day, to prove that a physician is doing what they say they are doing. These burdens are compounded by necessary EHR updates. Leveraging the EHR to improve quality and drive value must be weighed against growing administrative burdens and the detrimental impact that these requirements have on provider efficiency. It is also important to note that these requirements can negatively impact interoperability and lead to an inability to discretely reconcile data. Additionally, the design of certain EHR features and functionalities can create issues, as non-user-friendly design can have negative impacts on utilization.

Continuing, the AAN believes that increasing the efficiency of provider interactions with technology systems should start with the basics. This can include the promotion of public recommendations for EHR usability and safety including the SAFER guides and the AHRQ usability toolkit. The AAN believes that adoption and use of these strategies should be completely optional. Category bonus points could penalize smaller providers who may not be able to easily afford or implement these capabilities because they would achieve lower scores than larger systems. Smaller providers would therefore achieve lower payment adjustments or be subject to penalties. CMS could potentially explore a way to acknowledge technologically advanced organizations that support provider efficiency outside of the Promoting Interoperability category. CMS could also consider incentivizing collaboration between more advanced institutions and smaller practices.

Administrative processes that can benefit from more efficient electronic workflows include prior authorizations for medications, step therapy protocols, non-Medicare prior authorizations for imaging, documentation requirements for E&M billing, automated quality
reporting including integrations with registries, hospital discharge, pre-certifications, and transitions to care. It is important to note that CMS cannot measure or reward providers for their uptake of more efficient electronic workflows until these workflows exist in the real world and are implemented without increasing burdens or costs on providers. Addressing the burdens associated with prior authorizations in particular can benefit from automatic inflow of information into the EHR from the patient’s insurance, giving guidance on what is needed to fulfill the prior authorization requirements. Federal guidelines are needed on the standardization and bilateral exchange of clinical data related to complying with prior authorizations. The AAN supports the proposal contained in the Office of the National Coordinator’s “Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs” to support pilots for standardized electronic ordering of services and to coordinate efforts to advance new standard approaches supporting prior authorization.

Further, given CMS’ interest towards “patients over paperwork,” and CMS’ recognition of the need to improve EHR efficiencies, the AAN continues to strongly request CMS further delay appropriate use criteria due to the additional administrative burden.

The AAN applauds CMS for raising issues associated with successfully incentivizing efficiency but notes that CMS’ focus should be on vendors, rather than on providers. Although it is important to note that increasing requirements on vendors could dampen innovation, the AAN believes that CMS should focus on encouraging enhanced user interface development and testing, click reduction, usability, and features that promote interoperability and efficiency. This can be done as a requirement under the ONC Health IT Certification program.

**Request for Information on the Provider to Patient Exchange Objective**

Although making patient health information available immediately may be feasible, the AAN is concerned with the practical implications of this idea. The AAN is concerned that, given that laboratory results can be returned intermittently over several days, patients may be overwhelmed by excess notifications, which could cause patients to miss critical information. This would run counter to the goal of promoting transparency for patients as it would result in patients understanding less about their health and test results. Additionally, it must be noted that it would be inappropriate and potentially harmful for patients to immediately receive the results of certain genetic tests, such as the test for Huntington’s disease. The AAN appreciated ONC’s proposal to include an exception to the data blocking prohibition for data sharing that would cause harm and wants to ensure that implementation of the patient exchange objective accounts for the need for this exception.

The AAN has concerns with the language used to describe an alternative to the provider to patient exchange objective. Specifically, the AAN is concerned with the use of the term “all data stored in health systems” and suggests that disclosure of secure messages would be required. The AAN believes this term should be changed to “legal medical record.” Additionally, the AAN questions if this alternative measure will be effective as many practices struggle with feature and functionality limitations that they have with both the native EHR application and the 3rd party patient-facing systems with which they interface. In the long term, the AAN believes that for many practices, this requirement would cause
financial and operational burden in cases where current systems do not support access to or sharing of the complete electronic health data contained in the EHR. Finally, the patient exchange objective may result in decreased involvement or complete removal of the appropriate clinician in communication of healthcare information resulting in distress or even harm to patients.

If this certification criterion is finalized and implemented, the AAN believes this measure should be included as a bonus measure, based on attestation of capability, to reduce provider burden. The AAN believes that long term, technical burdens exist related to ensuring capability for transfer. There are also significant security concerns and potential burdens on patients due to the need for patients to request and be able to receive data.

The AAN believes that the data elements that would be of most use to health care providers to share in a standardized electronic format, if complete records are not available, are items that are typically present in a continuity of care document. These include medications, allergies, problem lists, surgical histories, family histories, as well as test results including labs, radiology, and pathology results. Additional useful elements include operative notes, discharge summaries, consult notes, immunizations, patient instructions, and after visit summaries.

The AAN supports inclusion of a health IT activity to promote engagement in health information exchange across the care continuum. Electronic exchange of information with these community partners would be beneficial for both treating physicians and the community staff. The AAN cautions CMS that this could be complex to implement given variability in systems, EHRs, and resources in a given community.

The AAN believes that CMS’ criteria for identifying high priority health IT activities should be to identify activities that will truly promote interoperability. The AAN also agrees with CMS’ focus on provider efficiency and data exchange across the care continuum. Additionally, CMS could consider the impact of new clinical decision support tools on provider burden.

CMS also should consider putting some of the onus for interoperability and innovation on the health IT vendors themselves, rather than the end users of health IT systems. The treating physician’s office can only work within the confines of their system’s capabilities. EHR vendors should be encouraged to work towards easier interoperability and information sharing, while providing information to end users in usable, legible formats. CMS could consider a requirement for vendors to work directly with major health information exchanges to ensure compatibility.

**Request for Information on Patient Generated Health Data (PGHD)**

The AAN believes there are specific use cases within neurology for using patient generated health data as part of treatment and care coordination. These could include pre visit questionnaires for epilepsy history and migraine history, CPAP compliance reports, loop monitor recordings, and reporting of blood pressure and pulse measurements for patients with autonomic neuropathy and orthostatic hypotension.
The AAN does not believe that providers should be expected to collect information from patients outside of scheduled appointments. Under the current reimbursement structure, this may impose significant additional burden on providers. The AAN also has concerns with potential additional liability associated with abnormal patient generated health data that arrives outside of normal business hours. The AAN believes that these risks would need to be appropriately managed and could be addressed through stops in questionnaires directing patients to seek immediate attention if they report certain concerning developments. Additionally, patients should be made aware that their data may not be reviewed until their appointment and that they should not expect an immediate response from their physician based on the submission of data.

**Request for Information on Activities that Promote the Safety of the EHR**

The AAN believes that points for review of the SAFER guides may be more appropriate in the improvement activities category, rather than in the promoting interoperability category. Review of these guides could be an ideal improvement activity for large organizations with dedicated IT teams, however this may not be practical for small or solo practitioners. CMS could also consider awarding bonus points for participation in other quality activities to leverage existing programs that promote the safety of the EHR.

**Cost**

The AAN supports the inclusion of attribution methodology in measure specifications moving forward.

Cost measure methodology has remained opaque to many clinicians participating in MIPS over the past years and it is unclear how and if cost measures are attributed to certain specialty clinicians. We appreciate CMS’ shift to be more transparent about how cost measures are attributed at both the individual and group levels.

**We request additional guidance on how the TPCC and MSPB Clinician measure methodology will affect specialties that coordinate with primary care.**

Although we understand that the revised methodology to the Total Per Capita Cost (TPCC) and Medicare Spending Per Beneficiary Clinician (MSPB Clinician) measures more clearly delineate how attribution affects primary care providers, it is still unclear as to how the proposed changes to the attribution methodology for the TPCC measure would apply to specialties that bill E/M services and follow ups for patients with chronic conditions. Similarly, it is unclear how the proposed attribution methodology for the MSPB Clinician measure captures team-based care, which can include neurologists. CMS should clarify how this attribution methodology relates to primary care adjacent specialties like neurology who coordinate care with primary care physicians.

**As stated in previous comment letters, the AAN continues to be concerned that risk adjustment and attribution methods have not been adequately developed for MIPS cost measures.**
As the Cost component weight continues to increase, we request more education for clinicians that treat complex patient populations, including how this complexity is considered when calculating cost performance. For example, a neurologist subspecializing in multiple sclerosis will likely have very high inpatient costs compared to other neurologists even if treating a relatively small patient population with multiple sclerosis. We request clear, accessible guidance for clinicians who want to understand their cost performance and how it may be impacted by a small population of complex patients. 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. As part of CMS’ educational efforts, we also strongly believe CMS should provide a clear rationale to providers as to why providers’ reimbursements are tied to factors that are perceived as being out of their control. Examples of case studies to clarify how providers mitigate the cost component would be helpful to all stakeholders.

**CMS should explore opportunities to incorporate more clinicians in already developed cost measures.**

In an effort to include more clinicians in cost measure calculations, we suggest that CMS consider alternative cost measurement methods that may lead to meaningful attribution without developing an unwieldy number of cost measures. For example, within an episode-based cost measure, neurologists could be held accountable for the neurologic-associated costs borne in an episode, such as neurology-related E/M services, testing, medications and other therapies, but not the rest of the entire episode, as the episode is not necessarily measuring a neurological condition. Receiving data related to an episode in which neurology is consulted or considered is valuable and informative, even if not central to the episode. CMS’ shift towards tying Quality measures to Cost measures is a significant undertaking requiring considerable time and resources. CMS should consider repurposing current measures to incorporate more clinicians that play a role in an episode – not by attributing the entire episode to an individual clinician or TIN who bills a certain percentage of Medicare Part B claims, but by appropriately attributing certain aspects of an episode to the specialists who bear the costs and more accurately capturing the nuance and delineation of a given episode of care across providers.

**The AAN requests detailed information on Cost component performance, including by specialty.**

Without robust, specialty-specific Cost component data, it is difficult for clinicians and practices to understand their Cost performance and difficult for specialty societies and other stakeholders to understand how to best educate membership on how to improve said performance. The AAN would gain more perspective on how to best educate our membership on the complex Cost component if CMS shared more information related to the neurology specialty such as: number of neurologists and neurology APPs attributed in the Cost component, the measures in which they are attributed, the range of performance scores in the Cost component, and the range in dollar amount of episode costs.
**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. We strongly support the reduced reporting requirements for small practices in this area.

CMS intends to remove several Improvement Activities related to QCDRs which will be combined. Although we do not oppose this move, we hope CMS will closely monitor this change. We are concerned the removal of multiple QCDR-related Improvement Activities could lower participation in QCDRs.

We are supportive of the modifications listed to seven existing Improvement Activities. Additionally, we support the addition of two new activities. We specifically support the activity, “Tracking of clinician’s relationship and responsibility for a patient by reporting MACRA patient relationship codes,” and appreciate that it can be accessed through attestation. We believe this is another opportunity for QPP participants to receive credit across multiple MIPS domains.

We agree with the new factors for considering removal of an Improvement Activity as listed in the proposed rule. We also agree with CMS on the section related to ending the study on Improvement Activities and measures. We, however, also believe this is something CMS should be continuously evaluating, especially as the MIPS program progresses and requirements become more stringent.

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. 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.

**Quality Component**

The AAN supports collection of additional narrative data and the use of patient and care partner reported data. The AAN also supports a pilot on the collection of patient experience data at an individual clinician level. The AAN hopes the pilot would evaluate if appropriate risk stratification or risk adjustment should be completed on individual level data. The AAN believes that such data, if collected, should be benchmarked for each specialty and not reported across care. For example, performance rates for psychiatry, neurology, and geriatric providers may be different than providers treating patients without cognitive impairments. Risk adjustment for cognitive impairment may also address these concerns. Collection of this data at an individual level will help drive quality improvement. The AAN agrees that expansion of collection methods to include email and web-based surveys should occur.

The AAN also agrees that use of QCDRs and EHR reporting methods will increase data completeness. Many small and solo practitioners, however, would be burdened by such a high data threshold. The current average data completeness rate supplied by CMS for small practices is 74.76% and average rate for individual eligible clinicians is 76.14%. Given these rates, increasing the requirement to 80% is premature, especially given the requirement that all payer data be provided. Many solo and small practices continue to abstract data for use in a QCDR or have not shifted from claims data. Additional performance years should occur prior to increasing the data threshold beyond 70%.

The AAN believes the lack of current cost measures prevents the implementation of a requirement on measure stewards to link measures to existing and related measures. We have no objections to the proposal that realigns MIPS quality measure update cycles with that of the eCQM update progress. We also agree with the delay of the “All-cause unplanned admission for patients with multiple chronic conditions” until the 2021 performance period.

Regarding quality measure removal, the AAN does not support the removal of MIPS #131 Pain Assessment and Follow-up. The statement that this measure may have the unintended
consequence of encouraging excessive prescribing greatly overstates the complex situation that led to the opioid crisis in the US. The AAN believes that measure should be maintained given the large population (approximately 100 million) of Americans who live with chronic pain. The measure focuses on appropriate follow-up, which is not limited to medication use. Additionally, the expansion of the measure to include patients with severe incapacities including those with dementia is needed for neurology. A separate measure maintained by the AAN and APA specifically addressing pain for patients with dementia could be retired given this measure’s proposed expansion to include those who are non-verbal.

The AAN does not support the removal of MIPS #282 Dementia Functional Status Assessment. The proposed duplicative measure #182 focuses on use of physical therapy tools and as such is not applicable to this patient population. The AAN evaluated integration of #182 into the AAN’s QCDR in 2020 and felt given the restrictive slate of available tools, that it could not be broadly used by neurology clinicians. The AAN and APA remain committed to measure harmonization and expanded the denominator to include physical therapy and occupational therapy as a result.

We also do not support the removal of MIPS #288 Dementia Education and Support of Caregivers for Patients with Dementia. CMS has indicated there is overlap with the safety concern screening and follow-up for patients with dementia measure. The measure numerators, however, are substantially different, warranting use of both measures in MIPS. The safety measure is intended to ensure appropriate follow-up was taken to remove and address patient concerns that may lead to unintended injury of patients and caregivers. The education measure is intended to address the unique mental health and burdens faced by caregivers for patients with dementia who are more at risk for their own mental health issues as a result of caring for patients.

We do not support removal of #371 Depression utilization of the PHQ-9 tool. There is agreement that patient reported outcome data is important and meaningful to both clinicians and patients. Removal of #371 would disincentivize providers from collecting PHQ-9 data. Earlier adopters of the measure are now reporting outcome data and have time to improve scores for patients. Allowing clinicians to continue to report on 371 allows clinicians to integrate patient reported outcome data incrementally, driving improvement over time that might not be demonstrable in first year performance of an outcome measure.

CMS is also proposing to increase the data completeness threshold for extremely topped out quality measures that are retained in the program due to limited availability of other measures. We agree with this proposal. The AAN does not support rapid removal of extremely topped out measures and supports comments made by stakeholders that measures tend to appear to be topped out due to clinicians’ ability to select measures they perform well on. Data CMS receives is not representative of clinician performance across the country. The AAN suggest CMS evaluate and incentivize eligible clinicians to provide QCDR data to assist in establishing composite benchmark data of reporting rates between data submitted via QCDR and other forms. It is noted that QCDRs may have access to performance rate data for individuals who are opting not to report the measure as they have an additional six measures that have higher performance rates. Potential incentives could be offered in the
form of bonus reporting points for providing data on such low performance measures and could be used to demonstrate average performance rates that are not topped out.

Furthermore, CMS proposes to remove MIPS quality measures that do not meet case minimums and reporting volumes required for benchmarking after being in the program for two consecutive calendar years. We do not support the implementation of this proposal as it may unfairly impact specialty clinicians. We suggest CMS encourage innovation and incentives to report on such measures. As CMS moves towards a smaller measurement set there is a risk of a potential unintended consequence that in the near future few measures would be available to specialists.

Currently, many eligible clinicians are using broad measures, in part due to working in large systems where it is easier for a system to collect and report on six measures that are broadly applicable, as compared to multiple measures for each specialty. These measures include medication reconciliation, care plan, tobacco cessation, and falls measures, which have received topped out status. As these measures are retired from CMS’ programs in the coming years, clinicians will need to begin reporting alternate measures. Without access to these measures there is a likelihood that specialists will lack meaningful measures for their populations. Potential incentives should be used to increase reporting on these novel measures to determine benchmarks rather than dropping the measures from the program. Anecdotally, clinicians have reported a desire to use specialty measures that would be more meaningful to their practice but are prevented from doing so given the burden to collect data in a large system with competing data needs.

Regarding determining which factors should be considered in the delaying of the removal of measures, the AAN encourages CMS to consider several. These include the time the measure has been available in a QCDR, the number of QCDRs that integrated the measure or are requesting to implement in the performance year, the opportunity to collect meaningful data after specification changes have been integrated into MIPS, the lack of available measures for a subspecialty, and for process measures, and the demonstrated link between collection and improved outcomes.

On the proposal to remove quality measures from the program if the measure steward refuses to enter into a user agreement with CMS, we wish to reiterate our opinion from the prior year. We oppose this because measures are expensive to develop, they are our property, and there are technical aspects CMS is not in a position to implement. We encourage CMS to reach out to measure stewards to better understand why user agreements may not be entered into. Measure development and testing is expensive and burdensome. To arbitrarily prevent use of the measure without consideration of all circumstances unfairly impacts clinicians’ ability to drive quality improvement through use of the measure.

On a potential opioid overuse measure, we believe the measure’s use of a daily dosage of 90 morphine milligram equivalents prevents broad use for neurology, and as such, there is limited impact on neurological practice. Therefore, it would not be implemented or considered for use in our QCDR. However, the AAN agrees that data elements for medication start and end dates and times are not accurate given inconsistent medication
documentation practices by clinicians, and such results should be compared over time to chart reviews to determine reliability and validity.

Finally, we request CMS update its list of stewards for dementia management measures. The AAN is joined by the American Psychiatric Association as a co-steward of the dementia management measures.

**Quality Payment Program: Advanced Alternative Payment Models (Advanced APMs)**

The AAN continues to support the move towards value-based payment and Advanced Alternative Payment Models (Advanced APMs), however we remain concerned about the lack of approved models that address the patients and services for which neurologists are responsible. Although CMS suggests that implementing MVPs based on specialty or condition will help transition clinicians from MIPS and into Advanced APMs, the process for such a transition is unclear. We request not only extensive education on the process of developing and implementing MVPs, but also detailed information on how clinicians are expected to transition from an MVP into an Advanced APM. We are concerned that focusing on upending MIPS and implementing the MVP framework, without laying out a feasible, detailed, and linear pathway into Advanced APMs early in the MVP process, would be a detriment to clinicians and stakeholders who dedicate time and resources to the QPP. CMS should not implement the MVP framework with the intended goal to transition clinicians into Advanced APMs without clearly directing them on how to do so.

Neurologists are eager to participate in value-based care but have no substantive APM options. At present, the only CMMI initiative targeted at the services neurologists provide is the voluntary Bundled Payment for Care Improvement – Advanced (BPCI-A). The model includes many inpatient episodes and only a few surgically oriented outpatient episodes including episodes for acute ischemic stroke and intracranial hemorrhage. This is not a very useful path for neurologists, as they 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, often chronic neurologic conditions, such as ALS, epilepsy, traumatic brain injury, Parkinson’s disease, or neurodevelopmental/intellectual disabilities that are not captured in the BPCI-A model.

Although the MVP proposal may offer a short-term solution, neurologists should have the opportunity to participate in the American healthcare 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 will accept the costs of participation without an opportunity to participate in the bonus payments. The AAN welcomes the opportunity to collaborate with CMS on the development of APMs specifically targeting complex neurologic conditions, more general APMs for specialist integration into multidisciplinary care teams, and MVPs addressing neurological conditions as a viable pathway to transition neurologists into APMs in the future.
The AAN appreciates CMS’ continued efforts to align options for clinicians participating in Other Payer APM entities.

We support the proposed definition of the Aligned Other Payer Multi-Payer Medical Home Model, as we believe this parallels the current Medical Home Model definition already used in the APM track and offers more opportunity for participation in the Advanced APM track of the QPP. The AAN also supports the proposed changes to use the average marginal risk rate across all possible levels of actual expenditures for Other Payer Advanced APMs and its effort protect clinicians from massive losses and align with CMS Advanced APMs.

CMS should provide detailed participation and performance data for specialists in APMs.

Although we believe publishing data for both MIPS and APMs is imperative, to date, CMS has not shared sufficient data on APMs, calling into question the processes and opportunities currently offered in the APM track. CMS continues to emphasize the need to transition clinicians into APMs. However, without offering data to support the claim, it is difficult to understand and promote the incentives for participation in APMs to our members. We hope that CMS will provide clinicians and other stakeholders like the AAN with data on Advanced APMs, MIPS APMs and Other Payer Advanced APMs including detailed participation and performance results, including by specialty. Again, we believe that providing stakeholders with a rich dataset that can offer an overview of the landscape of participation in value-based care models will help with understanding the breadth and opportunity that adaption of these models provides.

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.

The 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 for 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.
The PTAC is well-positioned to provide physicians with necessary access to data and technical assistance in developing payment models. However, the 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 the PTAC to establish a technical assistance mechanism to benefit the PTAC and entities submitting payment models. Access to technical assistance throughout the proposal development process would ensure that payment models meet the criteria for PTAC recommendation and, ultimately, CMS adoption as an Advanced APM.

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

Additionally, the AAN is concerned with the process of submitting models to the PTAC. This process can be confusing and burdensome and should be clarified. Additionally, the AAN is concerned with the lack of any model that was recommended by the PTAC being implemented by CMS as an approved Advanced APM. The apparent futility of submitting a model through the PTAC for implementation by CMS is a substantial disincentive to costly and time-consuming model development.

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 comments so that the final rule further reduces regulatory and documentation burdens on neurologists and promotes the highest quality patient-centered neurologic care.

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,

James C. Stevens, MD, FAAN
President, American Academy of Neurology