November 16, 2015

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

RE: Request for Information Regarding Implementation of the Merit-based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models [CMS-3321-NC]

Dear Acting Administrator Slavitt:

The American Academy of Neurology (AAN) is the premier national medical specialty society representing more than 28,000 neurologists and clinical neuroscience professionals and is dedicated to promoting the highest quality patient-centered neurologic care. A neurologist is a physician with specialized training in diagnosing, treating, and managing disorders of the brain and nervous system such as Alzheimer’s disease, stroke, epilepsy, Parkinson’s disease, migraine, multiple sclerosis, and brain injury.

The AAN appreciates all actions taken by CMS to consult with stakeholders during the implementation process of MACRA. Regardless of statutory mandates in the legislation, the AAN believes CMS should commit itself to the highest possible level of transparency and consultation with outside organizations. The AAN encourages CMS to continue offering requests for information on a regular basis, separate from all mandated timelines and notice-and-comment rulemaking.

A. The Merit-based Incentive Payment System (MIPS)

The AAN requests CMS work to ensure the implementation of these programs is not more complicated or cumbersome than necessary. MIPS information should be submitted to CMS in a single streamlined manner that considers reducing administrative burdens and complexities, especially on small and rural practices, as a highest priority.

We offer several recommendations for further CMS clarification such as how the agency will attribute patients to the physician via an advanced practice provider and why CMS defines group size differently. For example, groups of 10 or fewer can be a virtual group, but practices of 15 or fewer are
considered “small” and therefore eligible to receive technical assistance dollars. The AAN believes the definitions of terms should be consistent to avoid confusion.

The AAN also believes there is not a need to create another separate identification number for physicians under MIPS. CMS should be able to use some combination of an NPI and/or TIN. Additionally, providers should be expected to update their information in PECOS at least on an annual basis.

We are also concerned about the lack of connection made between data collected for the quality-reporting programs and the resulting clinical practice improvement activities. Quality improvement in health care is a systematic approach to making changes that lead to better patient outcomes and stronger health system performance. It involves the application of Quality Improvement (QI) science, which provides a structure, tools and processes to assess and accelerate implementation and spread of QI practices activities (e.g., evidence-based medicine systematic reviews and guidelines, Total Quality Management and Continuous Quality Improvement, IHI’s plan-do-study-act, Lean, or Six Sigma).

Throughout this RFI, CMS appears to be proposing standalone quality measurement and quality improvement programming that is not rooted in the quality improvement methods and approaches, which have been found to improve quality. CMS could implement programs that would lead to real change and improvement if they devised a program that: (1) used the data collected for quality reporting; (2) encouraged providers to review and interpret these data; (3) provided guidance on relevant and meaningful interventions based on the data and the individual practice needs; (4) supported implementation of interventions that address the key drivers; and (5) re-measured to assess if improvement occurred.

As currently constructed, these programs are standalone with little or no link to the realities of clinical practice. The AAN firmly believes that in order for real change to happen these programs must be grounded in measurement and improvement science. We further believe that CMS must abandon its focus on provider compliance with programs and instead focus on assessing the impact these programs have on quality of care. Finally, there must be a link between the data used for quality reporting and the clinical practice improvement activities.

2. Virtual Groups

Virtual groups should be limited to same specialty only and should not be limited by having to be within a pre-determined geographic distance.

3. Quality Performance Category

   a. Reporting Mechanisms Available for Quality Performance Category

CMS asks if it should maintain all PQRS reporting mechanisms noted above under MIPS.

The mechanism used should depend on the type of data needed. While clinical quality measures are derived best from clinical data, cost and utilization measures usually are constructed from administrative data. Both sources of data should be used to calculate quality
and costs scores. Additionally, the reporting options recognize the varied needs of providers in differing health care settings using differing measures. That said, the level of complexity this produces is untenable in the long-run and as measure developers move towards electronic measures and outcome measures, claims-based reporting is no longer meaningful or practical. Ultimately, the onus for calculating data related to resource use and cost could eventually fall on the shoulders of Medicare and alleviate some of the burden on practices.

The AAN recommends continuing to transition away from claims-based reporting and towards only electronic and registry reporting options for clinical data. This could reinforce the need for interoperability and standards development across health information technologies, including electronic health records and clinical registries.

**If so, what policies should be in place for determining which data should be used to calculate a MIPS EP’s quality score if data are received via multiple methods of submission? What considerations should be made to ensure a patient’s data is not counted multiple times?**

It is highly unlikely that an organization or an individual would choose to report using multiple mechanisms, based purely on the administrative burden it would cause. However, if this question is aimed at determining how CMS can use comparable methodologies for calculation of data across multiple providers, this relates to testing the measures for reliability. Ensuring reliable measures are used will address concerns about the degree to which data collection mechanisms can be depended upon to secure consistent results and meaningful data. To address concerns about patients data counted more than once, CMS could require random sampling. Random sampling is a technique used to reduce the likelihood of bias when collecting samples. In random sampling, each subject is selected entirely by chance and it ensures that the sample chosen will be representative of the larger population that it was drawn from. The results generated by the sample can be accurately projected onto the larger population.

The AAN recommends CMS ensure measures are reliable across reporting methodologies and employ random sampling to alleviate any unnecessary concerns that patients will be counted multiple times.

**Should we maintain the same or similar reporting criteria under MIPS as under the PQRS? What is the appropriate number of measures on which a MIPS EP’s performance should be based?**

There has been tremendous growth in the use of measurement in the health system creating significant areas of overlap or redundancy. The burden of so many measurement activities and requirements can have negative consequences in terms of both inefficiency and excessive spending on measurement. The current criteria requires that eligible professionals (EPs) report on a total of nine clinical quality measure across three of the six National Quality Strategy domains. Data collection, aggregation, and management can be expensive. Any effort to increase the number of measures will require significant financial and personnel investments (e.g., to configure data systems to capture the key data, to collect the data and enter them into the electronic health records, and to update the data systems as measure specifications change over time). In addition, more than likely providers have not
considered using PQRS data for quality improvement purposes. This new element of MIPS will increase the complexity and burden on providers participating in MIPS. It will be imperative for CMS to consider these demands as they determine the appropriate number of measures.

The AAN recommends CMS maintain the current number of required measures as providers transition into the MIPS program and participate in clinical practice improvement activities.

**Should we maintain the policy that measures cover a specified number of National Quality Strategy domains?**

While the aims and domains of the National Quality Strategy (NQS) are laudable, requiring physicians to select measures based on the domain results in an arbitrary selection of measures. Rather, providers ought to be selecting measures based on where they have gaps in care and opportunities for improvement. Framing the selection of measures based on domain misses an opportunity for providers to measure what matters most to their practices.

The AAN recommends removing the requirements for selecting measures based on NQS domain and that the provider’s goals for quality improvement drive their selection of measures.

**Should we require that certain types of measures be reported? For example, should a minimum number of measures be outcomes-based? Should more weight be assigned to outcomes-based measures?**

A balanced set of measurements including process and outcomes are necessary to facilitate and maintain health system improvements. Despite the fact that clinical outcome measures are more difficult to develop and implement, measuring, reporting, and comparing outcomes is an important goal of the MIPS program. Determining the group of relevant outcomes to measure for any medical condition should include measuring intermediate and longer-term outcomes, measuring a timeframe that is long enough to lead to improved outcomes, and sufficient risk adjustment.

The AAN supports the requirement that providers report a minimum number of outcome measures, with the caveats that the outcome measures include intermediate and longer-term outcomes, use measures that are relevant to the patient population treated, employs a timeframe that is long enough to lead to improved outcomes, and outcome measures that allow for risk adjustment.

**Should we require that reporting mechanisms include the ability to stratify the data by demographic characteristics such as race, ethnicity, and gender?**

In order for providers to address health disparities in their practices, they must first know whether disparities exist and whom they affect. The collection of standardized data related to race, ethnicity, preferred language, and gender has likely increased with the implementation of Meaningful Use Stage 2 Requirements. However, data accuracy is key. Although standards for collecting race, ethnicity and language, and gender data have been put forth and MU has made it mandatory for many organizations, the collection of accurate data and
patients’ willingness to provide the data is still an issue. In some cases, it may not be feasible to stratify a metric of interest. Data must be accurate, complete, timely, and consistent.

The AAN supports stratifying data by demographic characteristics, and potentially separating scores by race, ethnicity and language, and gender. However, stratification must be based on reliable and valid data that can lead to the discovery of health care disparities.

**For the CAHPS for PQRS reporting option specifically, should this still be considered as part of the quality performance category or as part of the clinical practice improvement activities performance category? What considerations should be made as we further implement CAHPS for all practice sizes? How can we leverage existing CAHPS reporting by physician groups?**

There are great opportunities to improve clinical practice and patient experience based on the data collected via CAHPS. The question of whether it falls into the data collection or the clinical practice improvement category does not seem as relevant as what the provider does with the information to improve their delivery and patient experience. CMS has identified several potential interventions that improve patient experience (see Section 1848(q)(2)(B)(iii) of the Act). This approach seems overly prescriptive. To ensure buy-in, the appropriate data must be used to identify relevant and meaningful interventions to improve quality. CMS must allow for flexibility in improvements based on the data each practice or provider receives from their patient population.

There is no doubt that small or solo practices will experience administrative and financial burden in administering and reporting on CG-CAHPS. Even though the CAHPS surveys are free, to use them practices must follow a rigorous process. For example, practices must use specific templates and disseminate the survey via phone or mail. All of this has an impact on staff time and practice costs. CMS must acknowledge and address these concerns.

The AAN recommends that any efforts to broaden a CG-CAHPS reporting requirement to smaller practices consider its impact on the financial and administrative burdens associated with implementation. In addition, the AAN cautions CMS that these scores do not reflect a good outcome or a bad outcome for the patient and should not signify whether the care was high quality or poor quality.

**How do we apply the quality performance category to MIPS EPs that are in specialties that may not have enough measures to meet our defined criteria? Should we maintain a Measure-Applicability Verification Process? If we customize the performance requirements for certain types of MIPS EPs, how should we go about identifying the MIPS EPs to whom specific requirements apply?**

The AAN proposes the processes to address the lack of measures on the back end (i.e., MAV) are not necessarily broken, but suggests that an evaluation of and improvement to the processes used to identify and select measures on the front end are likely needed. The lack of measures is likely related to several factors including the limitations of the Measure Application Process, the requirements for measures to come from across National Quality Strategy domains, and the limited ability of the National Quality Forum to keep up with the demand for “endorsed” quality measures in specialty areas.
The AAN suggests that CMS evaluate why there is a “lack of measures” for specialties in order to remedy this problem. CMS must be aware of the unintended consequences of their systems and processes and their impact on the number of measures relevant to all providers in their programs. CMS ought to actively engage specialty societies when identifying measures for inclusion in CMS programming.

**What are the potential barriers to successfully meeting the MIPS quality performance category?**

Often specialists are left reporting on cross cutting measures (e.g., smoking, BMI, medication management) rather than those that are relevant to their patients and their internal quality improvement efforts. Specialty societies are a natural locus for deciding what constitutes good care and CMS should engage societies as they determine measures for programming. The AAN recommends that CMS actively seek out or engage specialty societies as part of the measure selection process. We believe the process could be more transparent and appreciate as many opportunities as possible to provide CMS feedback.

**b. Data accuracy**

**What should CMS require in terms of testing of the qualified registry, QCDR, or direct EHR product, or EHR data submission vendor product? How can testing be enhanced to improve data integrity?**

CMS should implement a testing process that generates 1000 QRDA Level 1 files and submits them to the test platform. Further, using the generated sample of 1000 QRDA Level 1 files for each measure, it should produce a QRDA Level 3 file.

CMS’s testing tool should take the QRDA Level 1 input for each measure and calculate its own Level 3 data. The submitted level 3 files should match the testing tool generated level 3 file. This process will ensure that the quality measure calculation engine and the algorithms that drive the engine are implemented according to CMS’s expectation.

**Should registries and qualified clinical data registries be required to submit data to CMS using certain standards, such as the Quality Reporting Document Architecture (QRDA) standard, which certified EHRs are required to support?**

Yes. The QRDA standard is robust and unless all submitters use the same standard a comparable output cannot be derived.

**Should CMS require that qualified registries, QCDRs, and health IT systems undergo review and qualification by CMS to ensure that CMS’ form and manner are met? For example, CMS uses a specific file format for qualified registry reporting.**

Yes. However, CMS should consolidate all reporting methodologies to use a standard format. The custom XML must be retired.

**What should be involved in the testing to ensure CMS’ form and manner requirements are met?**
CMS’ form and manner requirements need to be clear and structural as well as content validations need to be performed against the requirements.

**What feedback from CMS during testing would be beneficial to these stakeholders?**

Like in any testing process, feedback regarding exact failures and suggested remediation strategies would help. The current testing process provides little insight into the actual failure.

**What thresholds for data integrity should CMS have in place for accuracy, completeness, and reliability of the data?** For example, if a QCDR’s calculated performance rate does not equate to the distinct performance values, such as the numerator exceeding the value of the denominator, should CMS re-calculate the data based on the numerator and denominator values provided?

CMS should require 100% data integrity or reject the submission. The submitter must be able to provide calculated rates that match the underlying distinct performance values. This is a very basic level of validation that all competent submitters must be able to perform.

**Should CMS require MIPS EPs to submit a calculated performance rate (and instead have CMS calculate all rates)?** Alternatively, for example, if a QCDR omits data elements that make validation of the reported data infeasible, should the data be discarded? What threshold of errors in submitted data should be acceptable?

CMS should require MIPS EPs to submit both calculated performance rates and the underlying data. This will provide CMS the ability to verify the submitted performance rates through random checking. If the QCDR omits data elements that make validation of the report data infeasible, the data should be discarded. Submitters must be able to provide absolute accuracy in the data submission.

**If CMS determines that the MIPS EP (participating as an individual EP or as part of a group practice or virtual group) has used a data reporting mechanism that does not meet our data integrity standards, how should CMS assess the MIPS EP when calculating their quality performance category score?** Should there be any consequences for the qualified registry, QCDR or EHR vendor in order to correct future practices? Should the qualified registry, QCDR or EHR vendor be disqualified or unable to participate in future performance periods? What consequences should there be for MIPS EPs?

The AAN believes CMS should not penalize the EP, group practice, or virtual group and give them 12 months to switch to a different vendor. This is similar to what happens to providers if their EHR vendor cannot achieve certification for Meaningful Use.

**4. Resource Use Performance Category**

**How should we incorporate Part D drug costs into MIPS?** How should this be measured and calculated?
Part D costs should be scaled and adjusted to reflect different patient population needs. CMS should consider that higher drug costs may be necessary in some specialty areas to provide the highest quality of treatment.

**How should CMS define peer groups? Benchmarks?**

Some neurologists subspecialize in one area and only see patients in that area (e.g. Multiple sclerosis). Those neurologists currently have no way of letting CMS know that they subspecialize. The AAN implores CMS to support the rapid development of subspecialty codes and/or identification for these individuals so that their resource use could be appropriately compared to true peers in the MIPS program.

**CMS has received stakeholder feedback encouraging us to align resource use measures with clinical quality measures. How could the MIPS methodology, which includes domains for clinical quality and resource use, be designed to achieve such alignment?**

Aligning resource use to quality measures can be problematic as quality care does not necessarily equate to less expensive care and decreased resource use.

5. Clinical Practice Improvement Activities Performance categories

Section 1848(q)(2)(B)(iii) of the Act specifies that the measures and activities for the clinical practice improvement activities performance category must include at least the following subcategories of activities: expanded practice access, population management, care coordination, beneficiary engagement, patient safety and practice assessment, and participation in an APM. The RFI further expands this section to include subcategories: Promoting Health Equity and Continuity, Social and Community Involvement, Achieving Health Equity, emergency preparedness and response, integration of primary care and behavioral health.

While they are laudable areas of improvement, the AAN believes these categories are arbitrary and lack meaning for providers without the relevant data to support their need to improve in these areas. In addition, CMS is likely being too prescriptive in the categories/subcategories and they risk identifying areas that are not relevant to individual providers and practices; especially since there is no association of these categories to practice level data indicating a need for improvement. These concerns further demonstrates to the AAN the need for CMS to evaluate whether these programs are rooted in the science of quality improvement and whether their implementation as proposed will lead to real change.

The AAN recommends CMS reassess the categories and subcategories provided. The AAN encourages CMS to relate the clinical practice improvement activities directly to a quality measure data source (such as CAHPS, cross cutting measures, etc.). Rather than risk what will likely be significant investments in resources and infrastructure with little improvement, the AAN recommends the CPIAs outlined in Section 1848(q)(2)(B)(iii) of the Act are identified and implemented as a result of what the practice’s or provider’s data show, rather than an arbitrary category that may not be relevant to a practice.
Should EPs be required to attest directly to CMS through a registration system, web portal or other means that they have met the required activities and to specify which activities on the list they have met? Or alternatively, should qualified registries, QCDRs, EHRs, or other health IT systems be able to transmit results of the activities to CMS? How often providers should report or attest that they have met the required activities? What information should be reported and what quality checks and/or data validation should occur to ensure successful completion of these activities?

CPIAs should be directly related to the measures used to assess the quality of care in the measure reporting section of MIPS. If this occurs, there would be no need to complicate MIPS by adding measures to assess or attest that quality improvement has occurred.

The AAN encourages CMS to relate the clinical practice improvement activities directly to a quality measure data source (such as CAHPS, cross cutting measures, etc.) rather than institute another set of measures or processes and another bureaucracy to indicate compliance with processes. The AAN further recommends that QCDRs should be considered part of a clinical practice improvement activity as the act of measuring leads to improvements.

Additionally, CMS seeks comment on the following areas of how it should assess performance on the clinical practice improvement activities category. Specifically:

- What threshold or quantity of activities should be established under the clinical practice improvement activities performance category? For example, should performance in this category be based on completion of a specific number of clinical practice improvement activities, or, for some categories, a specific number of hours? If so, what is the minimum number of activities or hours that should be completed? How many activities or hours would be needed to earn the maximum possible score for the clinical practice improvement activities in each performance subcategory?
- Should the threshold or quantity of activities increase over time? Should performance in this category be based on demonstrated availability of specific functions and capabilities?
- How should the various subcategories be weighted? Should each subcategory have equal weight, or should certain subcategories be weighted more than others?

While the AAN believes providers ought to be collecting quality data and using these data to implement QI efforts, it is unlikely that a focus on QI occurs regularly in most practices. CMS must consider that this is a significant culture change and the skills required are not universal. CMS is attempting to be too prescriptive, risking significant backlash and disengagement.

The AAN recommends that the data in the MIPS measurement program should indicate whether improvement has occurred. Arbitrary measures of completion and compliance with the programs are not as useful. CMS should abandon the need to quantify participation in their programs and focus on the impact these programs have on quality.
6. Meaningful Use of Certified EHR Technology Performance Category

Under MIPS, EPs should not be required to fully achieve meaningful use. Providers meeting a significant number of program requirements should not face penalties due to missing a small number of thresholds and/or requirements. Performance levels should be tiered instead of the “all-or-nothing” approach.

10. MIPS Composite Performance Score and Performance Threshold

**What is the case minimum threshold should CMS consider for the different performance categories?**

The AAN recommends providers should be excluded from MIPS penalties if less than 10 percent of their patients are CMS patients that can be attributed to that physician. Additionally, there should be no MIPS-related adjustment if the physician had less than 100 eligible Part B encounters with patients, or if less than 20 patients are attributed to them. MIPS adjustments should be based solely on prospective attribution—the list of patients the provider receives before the measurement year begins—regardless of whether the provider is part of a group that is participating in a higher-risk Medicare Shared Savings Plan. The AAN believes CMS should model its policies with the MIPS low-volume threshold off the thresholds found in other CMS programs like Meaningful Use and the Value-based Payment Modifier. The AAN is also concerned about the extent to which certain subgroups of neurologists like pediatric subspecialists may have sufficiently low Medicare patients, volume, and revenue, such that they are better off excluded from MIPS.

12. Feedback Reports

The AAN believes QRURs should visually look the same and contain the same information. It is confusing to have mid-year QRURs look different. Additionally, all QRURs should clearly show how the physician is performing in each MIPS area on one summary page. Neurologists viewing their QRURs have described the reports as being difficult to relate to; therefore, we propose that future feedback be more tailored to the factors that make up a physician’s score.

B. Alternative Payment Models

1. Information Regarding APMs

The AAN believes physicians, and in particular neurologists, must play a more active role devising CMS policies in this area. Without genuine CMS consultation taking place over an extended period of time, the agency risks a lack of physician investment in the success of proposed programs. Additionally, if further stresses are added to a profession already at its tipping point, there may be well-designed reforms, but insufficient numbers of physicians to provide services, thereby limiting access to care. Medicine is unlike other industry workforces; for every neurologist that retires or leaves clinical practice, it takes 20 years to replace them (post-college 8-10 years of education/training, but also another 10 years of experience to reach the competence level of an experienced neurologist). Thus, there are challenging workforce issues in the future to implement any CMS reforms. If CMS does not
consider future workforce training, there will be insufficient professionals to implement APMs or other reforms.

The AAN also recognizes that health care reforms have led to disproportionate burdens on independent and private practices, hurting these cost-effective sources of health care delivery. “Non-facility” providers, as defined by Medicare, provide an equivalent service for lower cost/reimbursement compared to “facilities” (i.e. hospitals). Thus, any CMS proposal should include strategies to preserve independent and private practices, and not only depend on hospital-driven APM models.

f. Regarding EAPM Entity Requirements

CMS asks what entities should be considered EAPM entities. CMS also asks about criteria to measure quality for these entities.

Alternative payment models include capitation, shared savings, pay-for-performance, bundled payments, episodes of care. These models are often administratively more complex than fee-for-service payment and lead to increases in overhead costs reducing or eliminating any overall cost savings to the health care system. Some require payers to develop new measurement systems. Physicians in these models have also raised concerns that the multiplicity of measures within and across programs could distract practices from making the changes to patient care that are actually the ultimate goal of many payment programs.

Therefore, we propose CMS consider the fundamental goals and structures these entities should contain. They need sufficient flexibility to deliver services in a high quality and efficient way that can adjust care delivery to the needs of individual patients. They must further assure that spending for services covered by payments will be limited to a specific amount and that quality of care will meet or exceed certain standards. The payment system should also hold physicians accountable for some aspects of quality and cost that they can control, but not for services or costs they cannot control or sufficiently influence. It must further determine which patients have the greatest needs for services and adjust for the structural differences in costs for different providers. Ultimately, providers should be compared based on costs and outcomes of care.

Furthermore, physician practices need support and guidance to optimize the quantity and content of physician work under alternative payment models. These programs carry risk of adding more work for overburdened physicians, increasing burnout, especially when the work is perceived to be unrelated to quality patient care. CMS should help guide physician leadership so they can guide practices and health systems in their efforts to succeed in alternative payment models while preserving or enhancing physicians’ professional satisfaction.

Addressing physicians’ concerns about the operational details of alternative payment models could improve their effectiveness. Physicians have complained about program failures including the use of clinical performance measures with unclear validity and the development of financial incentives that physicians do not understand. Each can undermine the effectiveness of alternative payment models. If a program’s specific intent cannot be communicated clearly, this could be a sign that the program should be redesigned.
To succeed in alternative payment models, physician practices need data and resources for data management and analysis. Practices must make substantial data infrastructure investments to manage patient care effectively and monitor the performance measures that make up many alternative payment programs. Although the financial resources necessary to make these investments can come from practices merging with each other and with hospitals, CMS should further incentivize the investment in physician practices’ data management capabilities.

It is also important to standardize components of alternative payment models, especially performance measures that would help physician practices respond constructively. Alignment of payment models with each other will free up the substantial physician practice resources currently spent on many performance measures. This will empower practice leaders with more energy to better devote their attention to the difficult work of making meaningful and beneficial changes to their processes for patient care.1

2. Information Regarding Physician-Focused Payment Models

CMS is interested in the definition of a physician-focused payment model and information on a number of fundamental issues in the development of PFPMs that are specialist models.

Many specialist physicians do not have the expertise or data infrastructure to define and correctly price episodes of care. We encourage CMS to develop supraregional or national APMs that will, in accordance with the Act:

- Require participants to use certified EHR technology.
- Provide for payment for covered professional services based on quality measures comparable to the MIPS quality measures.
- Bear financial risk for monetary losses under the APM that are in excess of a nominal amount.

We envision an independent APM centered on neurologic patients and their disorders that will:

- Define one or more episodes of care for commonly treated disorders.
- Estimate the services and RVUs required to perform each episode of care.
- Develop a data and payment model:
  - Request G codes and/or CPT codes for each episode of care.
  - Request CMS national payment policy and payment amount for each episode of care.
  - Submit service reports and billing statements for these services on behalf of participating physicians.
  - Record registry data for the patients being treated under the APM model.
  - Report registry data to CMS on behalf of participating physicians.
  - Over time refine the defined APM model.

1 http://www.rand.org/content/dam/rand/pubs/research_reports/RR800/RR869/RAND_RR869.pdf
It will be very expensive to establish such an APM. CMS should provide CMMI funding for this type of organization. CMS should also recognize that physician funding of organizational start-up exposes each physician to financial risk for monetary losses that are in excess of a nominal amount.

Patients with chronic conditions have unmet neurological needs. This represents a large economic burden and there is much waste attached to the lack of appropriate transition services. The concept of “lifespan service” for chronic, non-fatal neurological conditions, particular those that begin in pediatric years such as epilepsy, autism, brain injury, and cerebral palsy is of particular importance when defining physician-focused payment models. The AAN believes models that provide lifespan and transition services will be cost-effective and should be supported by CMS.

a. Definition of Physician-focused Payment Models

How should “physician-focused payment model” be defined?

These models should emphasize the improved coordination of services between providers and sites of service, while also bolstering the education and support of caregivers. These services should simultaneously assist in preventing avoidable complications and exacerbations, such as hospitalizations, which should lower long-term costs. The models should be comprehensive and offer additional support services such as caregiver counseling, patient-centered care plan development, and emergency telephone services. They should be structured using complex care management teams. They may provide comprehensive case management, using extensive services and tools to address all aspects of care, and include caregiver support, decision support tools, and care coordination.

b. Criteria for Physician-focused Payment Models

CMS asks what criteria should be used for the assessment of PFPM proposals and additional or different criteria that should be used for assessing PFPMs that are specialist models and criteria that would promote development of new specialist models.

These models should outline specific ways they will improve patient care and result in lower total health care spending. They should identify specific barriers that current payment systems create making it difficult or impossible for physicians to implement these improvements in patient care. They should also identify the changes in payment needed to overcome these payment barriers. Further, they should analyze whether the benefits for patients and the savings for payers and patients are sufficient to justify any costs associated with payment changes. Finally, these models should be designed in a way that removes barriers to improving care so physicians can improve outcomes for patients and achieve savings for payers.
The AAN suggests some examples of quality measures that are both outcomes-based and easily determined, such as: (1) Admission/ED visit rates for MS, epilepsy, migraines, or Parkinson’s; (2) falls (prevented) in a population of people with MS or Parkinson’s, compared to a control group; (3) functional outcome measures (FIM scores; Kurtzke disability scores, etc.) for stroke, Parkinson’s or MS; and (4) the total cost of care for MS or Parkinson’s patients per year. The comparison group should be evaluated with an appropriate matching population.

To address a limited number of diagnoses with smaller numbers of patients, one possibility would be an APM which would include all of the neurologist’s patients seen in year. The measures could still be related to outcomes such as ED visits and admissions last year versus the following year. The outcome measurement of a neurologist’s patients could be completed in several ways: (1) patient-reported outcomes; (2) functional scoring (such as FIM scores); or (3) by surveying the referring providers who could rate the performance of the neurologist.

This idea could be employed by using comparative survey data that rates many aspects of a neurologist’s care by surveying the referring providers based on a statistical sample of all the neurologist’s patients who were referred, and patient-reported outcome surveys for those who were not referred. The scores could have both comparisons with other (non-APM) neurologists’ scores as well as year-to-year improvement for the first year’s low scorers.

c. Required Information on Context of Model Within Delivery System Reform

CMS is considering that proposed PFPMs should primarily be focused on the inclusion of participants in their design who have not had the opportunity to participate in another PFPM with CMS because such a model has not been designed to include their specialty.

The AAN strongly supports this as the primary focus of PFPMs. As noted in an October 2014 report from the Brookings Institution, despite the proliferation of alternative care models addressing the needs of patient populations with dementia, epilepsy, multiple sclerosis, traumatic brain injury, and complex headaches, there are currently no APMs implemented with a specific focus on complex chronic neurologic conditions.²

d. Required Information on Model Design

CMS is interested in the definition of target populations, how the population differs from the non-target population and the number of Medicare beneficiaries that would be affected by the model. How would the model impact quality and efficiency of care, whether the model would provide payment for covered professional deserves based on quality measures, specific proposed quality measures, among other specific inquires.

Neurologic conditions are typically chronic and usually of life-long duration. Unfortunately, some neurologic diseases are progressive and incurable costing billions of dollars in medical

expenses and lost productivity. It is therefore important to develop neurology-specific alternative payment models that target conditions such as epilepsy, stroke, dementia (including Alzheimer’s), neuropathy, chronic headache, traumatic brain injury, and chronic, non-fatal lifespan disorders such as autism, intellectual disabilities, ADHD and neuropsychiatric disorders. As brain research progresses, many neuropsychiatric disorders will be shown as being true neurologic disorders and diseases, including genetic variations, connectome abnormalities, inflammatory disorders, metabolic/mitochondrial disorders, and more. Many of the disorders outlined as chronic neurological disorders have co-morbid neuropsychiatric syndromes. If not addressed by neurologists, then care becomes more fragmented, leading to increased costs and worse outcomes.

Epilepsy is surprisingly common, but it is often poorly understood and misdiagnosed which can lead to considerable variations in treatment. Epilepsy usually begins in childhood and many military service veterans are also developing an acquired form of epilepsy from their service. In total, over two million Americans are living with epilepsy. About 30 percent have medically refractory seizures and require care coordination and collaboration with specialized multidisciplinary centers. The deficits in quality of life due to epilepsy and its treatment are comparable to conditions such as diabetes, heart disease and depression.

Four percent of Medicare beneficiaries have had a stroke and the prevalence of stroke is expected to rise by more than 20 percent by 2030. In 2005, stroke patients cost Medicare $31 billion. Approximately 11 percent of Medicare beneficiaries have been diagnosed with Alzheimer’s disease/dementia and the number of elderly with dementia is expected nearly to triple by 2050.

Parkinson’s disease, amyotrophic lateral sclerosis (ALS) and multiple sclerosis (MS) are less prevalent neurologic disorders but should be included as target health conditions. For instance, approximately 630,000 Americans had Parkinson’s disease in 2010, and the diagnosed prevalence is likely to double by 2040. The total economic burden of Parkinson’s disease exceeded $14 billion in 2010. This is $8.1 billion higher than would be expected for a similar population without this neurological disorder.

ALS, also known as Lou Gehrig’s disease, is a disease of motor neurons that is rapidly progressive and fatal. It is estimated that as many as 30,000 Americans have ALS at any given time, and about 5,600 new cases are reported each year.

Multiple sclerosis (MS), an inflammatory disease in which the insulating covering of nerve cells in the brain and spinal cord are damaged, affects roughly 400,000 Americans. MS symptoms include difficulty walking, loss of vision, incoordination, and fatigue. The annual economic impact in the US to care for the population of MS patients is $10 billion.

The numbers of autism spectrum disorders are staggering (more than 1:100 children), and will lead to increased expenses as they transition to adult life and are no longer provided funding from school districts. This is not only a neurological disorder, but also extends into other organ systems with common co-morbidities affecting general systemic health. ADHD and neuropsychiatric disorders are also increasing with significant associated costs.
Given that these are chronic conditions, it should be expected that episodes are likely to be prolonged due to the gradual worsening of the illness. This is particularly true for dementia, ALS, Parkinson’s disease, and MS.

Proposals should emphasize care coordination and be factored into payment. Screening and diagnostic tools may be required for Alzheimer’s disease/dementia episodes of care and could be included as part of a beneficiary’s annual wellness visit. Patient and family education regarding medication compliance and lifestyle management to prevent recurrent seizures is also important, along with ancillary support services like counseling.

These models should also take into consideration the accountability for medication prescribed. Physicians are responsible for assuring that patients are prescribed correct medication and, for medications to be effective, compliance with the prescribed regimen is important. We believe that prescribed medications should be factored into a payment model, and that pharmacists could be included as part of the care team to monitor medication compliance and side-effects. Each patient is unique, and some may respond better to a brand name medication than an approved generic. For example, in the case of epilepsy or multiple sclerosis, patients may have better outcomes on newer, more effective drugs. It is clear that many newer medications have fewer interactions, improve tolerability, and are logistically easier to use, such as the administration of the medication once per day as opposed to several times. However, physicians should not be held accountable for the unreasonably high cost of medications that are often best for an individual patient’s condition. The appropriateness of a medication should be emphasized because this decision is controlled by the physician.

CMS should also take into account that drug therapy is but one aspect of a complete treatment regimen. APMs need to account for the delivery of services not classically considered “medical” but that ameliorate medical/neurological conditions, often through biological mechanisms. For example, creative arts therapies (music, art, dance/movement) have been shown to improve Parkinson, stroke, Alzheimer’s, and can lead to a lessening of the drug burden, leading to overall cost-effectiveness. Such therapies can be incorporated into medical homes, along with more classic physical, occupational, and speech therapies.

To achieve maximum success and buy-in of a complex medical management model, the responsibility for the patient should be assigned to the physician who has the requisite expertise and/or manages the plurality of care for that condition—irrespective of specialty designation. Neurologists are often the principal care providers for Medicare beneficiaries with neurologic conditions and are typically referred the most complex cases by other providers. It is essential that payment models focusing on neurologic conditions include neurologists.

As principal care providers, neurologists are involved in all stages of the patient’s care and coordination of care. Noting this, the AAN published a paper describing a new model of providing specialty health care for patients with neurologic diseases in the “neighborhood” of the patient-centered medical home.3 The new model must also account for the time and effort required of the physician to manage and coordinate all of the communication and care associated with treating these patients. CMS should also consider “specialty care medical

3 http://cp.neurology.org/content/3/2/134.full.pdf+html
homes” where the neurologist is the principal care provider and not just a neighbor of the primary care physician. Similarly, CMS should consider general neurologists who see all types of neurology patients—including patients that after an evaluation do not ultimately possess a neurologic condition—in any proposal for the practice of neurology.

C. Technical Assistance to Small Practices and Practices in Health Professional Shortage Areas

CMS asks what it should consider when organizing a program of technical assistance to support clinical practices as they prepare for effective participation in the MIPS and APMs. CMS also asked what existing educational and assistance efforts might be examples of “best in class” performance in spreading the tools and resources needed for small practices and practices in HPSAs? What evidence and evaluation results support these efforts?

The AAN believes CMS should model its assistance programs off existing CMS Quality Improvement Organizations (QIOs) by using their existing infrastructure, resources, and methods. If necessary, the QIOs should commit to expanding their scope of work to include specialty practices.

For years, CMS has relied upon QIOs to improve the quality of health care for Medicare beneficiaries. The restructured QIO Program aims to maximize learning and collaboration in improving care, enhancing flexibility, support the spread of effective new practices and models of care, helping to achieve the priorities of the National Quality Strategy and goals of the CMS Quality Strategy, and in the delivery of program value to beneficiaries, patients, and taxpayers.

Changes include separating case review from quality improvement, extending the contract period of performance from three to five years, removing requirements to restrict QIO activity to a single entity in each state, and opening contractor consideration to a broad range of entities to perform the work. One group of QIOs handle complaints while another provides technical assistance to support providers and suppliers. QIOs are designed to transform practices by employing lean methodologies, assist with value based purchasing programs, and develop innovative approaches to quality improvement. Additionally, CMS is required to publish a Report to Congress each fiscal year outlining the administration, cost, and impact of the QIO Program.4

Recent reports indicate QIOs generated nearly $1 billion in savings and prevented more than 44,000 adverse drug events over a three-year period. Health and Human Services Secretary Sylvia Mathews Burwell in a December 2014 address credited the QIO program for helping to achieve a 17 percent drop in overall harm, or 1.3 million fewer harms and $12 billion in savings.5

For example, CMS highlights the Colorado QIO, which discovered a practice’s modest influenza immunization rates. The QIO linked the practice to the stat adult vaccination registry and now the practice’s electronic health record system is generating more accurate patient reminders. To supplement the health record’s built-in preventive care prompts, the QIO provided the practice with exam room posters and reminder postcards and encouraged follow-up phone calls to patients overdue for preventive services.6

The organization implementing the CMS QIO contract in Minnesota is an example of work with small and rural practices. In this case, the QIO is working to establish or strengthen palliative care programs in rural communities. Since 2008, they have supported 25 rural communities in Minnesota and nationally to build community capacity to offer palliative care services. Rural populations are disproportionately ill, disabled, poor, and older. Rural adults are also more likely than their larger urban counterparts to have a range of chronic conditions.7

The QIO emphasized collaboration, including the creation of a set process and timeline, access to palliative care program development expertise, and external facilitation to help initiate and develop community-based teams. The QIO assists these rural and small communities with program development and in building skills to improve advance care planning, symptom management, communication, and the coordination and delivery of care. The community-based teams identify their goals and resources, and then develop plans for implementation with a focus on current strengths and resources.8

**CMS asks about the most significant clinical challenges and lessons learned related to spreading quality measurement, leveraging CEHRT to make practice improvements, value based payment and APMs in small practices and practices in health shortage areas, and what solutions have been successful in addressing these issues?**

The lack of resources in small practices makes it harder for them to purchase and meaningfully use CEHRT. They lack the highly qualified practice administrators who focus on analyzing data and making business decisions that large practices and institutions possess.

**CMS asks if assistance require multi-year provider technical assistance commitment, or should it be provided on a one-time basis?**

The AAN believes assistance must be a continuous process requiring a multi-year commitment.

**CMS asks if there should be conditions of participation and/or exclusions in the providers eligible to receive such assistance, such as providers participating in delivery system reform initiatives such as the Transforming Clinical Practice Initiative, or having a certain level of need identified?**

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7 [http://www.stratishealth.org/about/history.html](http://www.stratishealth.org/about/history.html)
8 [http://www.stratishealth.org/expertise/longterm/palliative.html](http://www.stratishealth.org/expertise/longterm/palliative.html)
Assistance should be available to any small practices that seek to improve and successfully participate in MIPS or APMs.

D. Conclusion

We greatly appreciate this opportunity to share the views of the AAN in response to the questions raised by CMS. If you have any questions regarding this letter, please contact Daniel Spirn, Regulatory Counsel for the AAN, at dspirn@aan.com or (202) 525-2018.

Sincerely,

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