August 21, 2017

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

Re: CMS-5522-P
Medicare Program, CY 2018 Updates to the Quality Program; Proposed Rule

Dear Administrator Veerma:

On behalf of the members of the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM), we appreciate the opportunity to provide comments in response to the Notice of Proposed Rulemaking for the updates to the Quality Payment Program (QPP) for 2018. We appreciate the outreach by the Centers for Medicare & Medicaid Services (CMS) to the physician community during this comment period and we hope that this open dialogue will continue in order to ensure the successful and effective implementation of the QPP.

The AANEM is comprised of nearly 4000 neurologists, physical medicine and rehabilitation (PMR) physicians, technologists, and other collaborators interested in neuromuscular diseases. Our physician members diagnose and treat patients with disorders of the muscle and nerve, such as carpal tunnel syndrome, cervical and lumbar radiculopathies, Guillain-Barre syndrome, Lou Gehrig’s disease (ALS), diabetic and other forms of peripheral neuropathy, myasthenia gravis and muscular dystrophy. Many of these are considered rare disorders, e.g., myasthenia gravis.

Many of our physicians subspecialize in neuromuscular medicine, electrodiagnostic medicine, or neurophysiology. These physicians see a very select subset of patients and, in some cases (such as for electrodiagnostic testing), only see the patient once for an electrodiagnostic evaluation with the follow-up care being provided by the referring physician. As a result, our members have found it nearly impossible to find meaningful quality measures under Medicare’s past value-based/quality programs that relate to their care of their patients. These difficulties have continued with the first year of the QPP in 2017. Due to the lack of follow-up performed by our physicians and the general trend away from process measures to outcome-based measures, there seems to be no good pathway for our members to meet the QPP standards. Additionally, many of our members have had trouble finding any APMs that work in their specialized practices. For these reasons and more, we have carefully reviewed the proposed rule and made specific suggestions for modifications that we believe will improve the new proposed payment programs for eligible clinicians, patient care, and CMS.
We were impressed that many of the changes in the 2018 proposed rule show CMS’ willingness to listen to and work with the physician community. However, we do have serious concerns over the implementation of the program and certain aspects of the program’s design. First, as was the case with 2017, we are very concerned about the extremely short timeframe between the publication and the implementation of the final rule. We respectfully request that, in the future, CMS allow a minimum of 6 months between the release and implementation of the final rule in order to allow the eligible clinicians enough time to learn about the new requirements and to make the necessary changes to their practices to bring them into compliance with the new rule. We also believe that this extra time will be helpful for vendors, registries, and others to update their systems to ensure they are in compliance with the new program requirements.

The following paragraphs contain comments related to specific sections of the proposed rule. Occasionally, specific page numbers of the proposed rule are cited – these page numbers are based on the PDF version available at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-13010.pdf.

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

**General Comments**

**Consideration for Small Practices:** We commend CMS’s efforts in this proposed rule to ease the burden on small practices. We support the proposed rule’s increase in the low volume threshold for participation in MIPS for eligible clinicians to $90,000 or 200+ Medicare patients. We would also support allowing physicians who do not meet the low volume threshold to participate in MIPS. There are many clinicians who have already invested significant resources in order to comply with the requirements for MIPS and they should be permitted to opt-in to the payment program. We urge CMS to notify individuals and groups as soon as possible that they qualify for the low-volume threshold exemption.

We also support the additional flexibilities directed specifically at small practices, including: the addition of the significant hardship exemption for the Advancing Care Information (ACI) category, the automatic 5 bonus points added to the MIPS composite score, the creation of a website for technical assistance and continuing to award small practices a floor of 3 points for each measure submitted that doesn’t meet the case minimum or doesn’t have a benchmark.

With regards to the small practice exception from the ACI category, we do have some concerns about the application requirements. The proposed rule states that eligible clinicians seeking this exception must submit an application and, in the application, must “demonstrate in the application that there are overwhelming barriers that prevent the MIPS eligible clinician from complying with the requirements for the advancing care information performance category.” (p. 220). There is no definition in the proposed rule of what may constitute “overwhelming barriers” that would qualify the providers for the exception. We are especially concerned about the word “overwhelming” and we would respectively
request CMS provide detailed guidance on the application of this standard. Also, we believe that by requiring small practice clinicians to fill out an application this may unnecessarily undermine the intent of the exception which is to help ease the administrative burden on these practices. Instead, we encourage CMS to consider an automatic exception from the ACI category for small practices (with the ability to “opt-in”). If an automatic exception is not feasible, then we urge CMS to make the application as simple and straightforward as possible.

**Complex Patient Bonus:** We support CMS’ effort to account for the increased burden and difficulty clinicians who treat medically complex and vulnerable patients face by providing bonus points to be added to the overall MIPS composite score. Many of our physicians treat patients with complex neuromuscular disorders and we appreciate CMS’ recognition of the impact that may have on their QPP scores. However, we have concerns about the proposed use of the Hierarchical Condition Category (HCC) mechanism in the valuation of complexity. The HCC mechanism could work well for primary care providers but it may not work well for specialists who see patients with a single but complex disease. It is also our understanding that HCC scores are only validated for large groups of patients and it is unclear that they are valid for small groups of patients with a single disorder when attributed to a single clinician.

**Virtual Groups:** We support CMS’ efforts to develop alternative paths for MIPS participation, including the introduction of virtual groups as an option. Virtual groups may be a good option for eligible clinicians with limited resources or limited experience with past quality reporting programs. However, we do not agree with CMS’ proposal to limit this option to practices with 10 or fewer providers. Elsewhere in the proposed rule, small practices are defined as those with 15 or fewer providers. In order to avoid unnecessary confusion, we suggest that practices with 15 or fewer providers be eligible for participation in a virtual group.

We also do not agree with CMS’ proposal that a virtual group with 16 or more eligible clinicians would not be eligible for the small practice accommodations, even if all of the tax identification numbers (TINs) involved would otherwise qualify as a small practice. The formation of these groups will involve substantial administrative burdens for these small practices and they should not lose the accommodations they would otherwise be entitled to.

We encourage CMS to simplify and streamline the contract and application process as much as possible to encourage participation. The proposed rule suggests opening the application process for the 2018 performance year sometime in September 2017 (prior to the publication of the final rule) and requiring eligible clinicians to make the election by December 1, 2017. Given the lack of a final rule, clear details about the requirements, and the fact that this is a new option, we would suggest that CMS consider extending the election timeframe by three (3) months (new deadline of March 1, 2018) and conduct extensive outreach to eligible clinicians to educate them about this option and provide them time to reach out to potential collaborators. We also urge CMS to use this time to engage additional stakeholders, such as EHR or other technology vendors, in the development of
and participation in this concept.

**Submission Mechanisms:** We appreciate CMS’ proposal to allow clinicians to use multiple reporting mechanisms within the quality, ACI and IA performance categories.

**Performance Threshold:** While we understand CMS’ need to increase the performance threshold (set at 3 for the 2017 performance year), we believe that moving the threshold up to 15 is too drastic. Despite our best efforts to provide education, many of our members still have very little understanding of how the QPP works. We believe increasing the threshold by a smaller increment, such as two-fold so it would be 6 points, is more appropriate and acknowledges that clinicians still face a steep learning curve.

**Inclusion of Part B Drugs and Other Items:** We oppose CMS’ proposal to include Part B drugs and other items, such as durable medical equipment, in any MIPS calculations. First, the inclusion of Part B drug costs or other items creates an inconsistency between participation in MIPS versus Advanced APMs (where eligible clinicians’ bonus is calculated solely on “covered professional services”). This has the potential to disadvantage clinicians who are unable to participate in the QPP via the APM track. In addition, such a policy would also unfairly impact some specialties who deal with Part B drugs and other items, which are often very costly. Medicare has already applied a 2% sequestration adjustment to clinicians’ Part B drug reimbursement, which brings Medicare’s drug payment rate down to an Average Sales Price (ASP) plus 4.3%. If Part B drug costs are also subject to a MIPS adjustment, it may become untenable for clinicians to provide these needed drugs and services to Medicare patients. This could lead to site of service shifts from the physician’s office to the hospital outpatient setting, which would potentially create access problems for Medicare patients. Finally, CMS acknowledges in this proposed rules that there are likely to be problems administering this policy consistently. For these reasons, we respectfully request that CMS not include Part B drugs or other services in MIPS calculations.

**Feedback Reports:** Given the complexity of the MIPS scoring calculations and clinicians’ continued lack of familiarity with the program, we urge CMS to provide clinicians with more timely feedback on their overall performance so that they may make adjustments to their practices and so that they can ensure the information is accurate. Release of such information on at least a quarterly basis would be the most beneficial. This is especially important as CMS has proposed posting MIPS performance scores on the Physician Compare website. Furthermore, access to such reports must be simple and user-friendly. The reports must also be in easy-to-understand format. We also urge CMS to extend the time to request for a targeted review from 60 to 90 days after a clinician is notified of their MIPS performance scores.

**Reweighting MIPS Performance Categories:** MACRA allows a fair amount of latitude for the Secretary to reweight MIPS categories if there are not sufficient measures or activities applicable to a participant. However, the proposed rule focuses primarily on shifting any missing category into the weight of the quality performance category. Given that the quality category is already worth 60%, we believe this puts too much emphasis on
this particular category, essentially negating the remaining categories. Instead, we suggest that CMS work with affected physicians and physician organizations to determine the best method of reweighting to accommodate the unique needs of various practices.

Improvement Activities (IA) Category

We commend CMS for holding the required timeframe for the performance of relevant activities in the IA category at 90 days. We also support CMS’ proposal to maintain the automatic doubling of the IA score for small and rural practices, as well as those practicing in Health Professional Shortage Areas (HPSA). We also agree with the proposal to remove the requirement of eligible clinicians to self-identify in order to qualify for this scoring standard. We support any effort to reduce the administrative burden on eligible clinicians, particularly those with more limited resources. Relatedly, we also appreciate CMS retaining the attestation submission option for improvement activities.

One concern that we have heard from other groups is that CMS has not provided explanations when an improvement activity suggestion is submitted but not accepted. It would be helpful if CMS could provide a detailed explanation as to why the particular activity didn’t qualify as an “improvement activity” under MIPS. We would also appreciate further explanation of what activities qualify under specific, approved IAs. For example, for activity IA_PSPA_XX – Patient Safety and Practice Assessment – Completion of an Accredited Safety or Quality Improvement Program, we would like clarification as to what constitutes an “Accredited” program – are there requirements for who the accrediting body is? We have an electrodiagnostic (EDX) laboratory accreditation program that we believe meets all of the requirements of this measure but we are unclear as to whether the AANEM qualifies as an accrediting body.

Cost Category

We support the proposal to maintain a weight of zero for the cost performance category. We also urge CMS to work with Congress to amend the statutory mandate requiring the cost category to count for 30% of the composite score for the 2019 performance period, instead providing for a gradual ramping up by 10% each year (10% for performance year 2019, 20% in 2020 and then 30% in 2021+).

We are very concerned about the accurate attribution of costs to providers, noting that the patient condition and patient relationship codes have not been sufficiently tested. Furthermore, we also have concerns that the risk adjustment is not as robust as it should be. We recommend that CMS conduct further testing, perhaps in the form of pilot projects, of these measures. We also urge CMS provide more frequent cost information to eligible clinicians, ideally on a monthly or at least a quarterly basis to assist them in better understanding this category and allow them to adjust their practices as necessary. Access to more frequent information will also make it easier for eligible clinicians to catch potential attribution or other errors and work with CMS to correct them.
We also have concerns about CMS calculating improvement scores when there remains serious issues with the baseline cost scoring methodology, as discussed above. We suggest CMS wait to add in improvement scoring until the baseline scoring methodology is studied and found to be accurate. Furthermore, for the 2018 performance year, CMS proposes using only the Medicare Spending Per Beneficiary (MSPB) measure and the total per capita cost measure for improvement. These measures are not available to many specialists, particularly those in small practices. Therefore, we urge CMS to at least hold off on scoring improvement for specialists until better cost measures can be found for these clinicians.

Quality Performance Category

There continues to be a lack of meaningful measures for many specialties and, in particular, subspecialties like electrodiagnostic and neuromuscular medicine. We have been contacted by a large number of our members noting that they can’t find any applicable measures and, instead, are expending significant time and energy asking patients questions and documenting responses to generic questions that have no relevance to that physician’s treatment of the patient. While most of our members are able to find 6 measures that they can report on, these measures are not measuring the quality of care they are providing their patients. For example, a common measure our neuromuscular and electrodiagnostic physicians report on is body mass index (BMI) screening. For a patient coming in with suspected carpal tunnel, this measure has no relevance. Furthermore, the BMI measure requires the development of a follow-up plan but many of our physicians will never see the patient again after performing the diagnostic testing so, again, this measure doesn’t assess our physician’s care for the patient.

Another problem with the use of more generic quality measures is that many have been identified by CMS as “topped out” and are proposed to be worth a maximum of 6 (versus 10) points for 2018 and slated to likely be removed within the next couple of years (p. 781). We encourage CMS to consider retaining these measures for physicians who do not have other available measures and we also urge CMS to remove the 6 point cap on these measures for physicians that are not primary care physicians.

In addition to the dearth of quality measures available for our members, there is also a significant lack of “outcome” measures available. While there are outcome measures available in the general specialty sets for neurology and physical medicine and rehabilitation, few if any of these measures apply to our subspecialized members. Although our members can report on another “high priority” measure if an outcome measure isn’t available, we have concerns over CMS’ expressed preference for the development of “outcome” (over “process”) measures. AANEM is in the process of developing quality measures, all such measures are “process” in nature. Again, due to the unique situation of our physicians they often see a patient only once for diagnostic purposes. It is unlikely we will be able to develop meaningful “outcome” measures for these situations. Therefore, we propose that CMS work directly with subspecialist physicians and organizations that represent these physicians to create meaningful sub-specialty measure sets, such as
measures for common conditions like carpal tunnel syndrome or more complex, but less common, conditions like ALS. As CMS is no doubt aware, the creation of new measures is very time and resource-intensive so we would request that CMS provide these groups of physicians and the organizations that represent them with additional financial and administrative support in the development and testing of such measures.

Advancing Care Information (ACI) Category

We appreciate and support the proposal to allow the use of 2014 CEHRT for performance year 2018. Many of our sub-specialized clinicians, especially those in smaller practices, use smaller vendors whose products are better tailored to their specific needs and these vendors are less likely to offer 2015 CEHRT.

We are also pleased to see that CMS will continue the 90-day reporting for the ACI category for 2018. We encourage CMS to consider making the 90-day reporting period for the ACI category permanent. A 90-day reporting period allows clinicians to test out new technologies throughout the year.

As noted earlier in our letter, we also support CMS’ proposed exception from the ACI performance category for small practices. We would also urge CMS to extend this exception to rural practices, as they often face the same barriers, such as fewer resources or lack of access to technology or expertise, as small practices.

Alternative Payment Models (APMs)

At the present time, there are very few APMs and even fewer Advanced APMs that neuromuscular/electrodiagnostic physicians would be able to utilize. While we are currently in the early stages of researching the development of an APM that may be applicable, we note that such an endeavor is extremely resource-intensive, especially for a smaller organization, such as AANEM. Therefore, we respectfully request that CMS provide additional resources targeting specialists and subspecialists with no current APM options to aid in the development of new APMs. The incentive bonus offered for APM participation is only available until the 2024 payment year so we urge CMS to help these groups to ensure that these providers have the opportunity to receive the bonus.

Advanced APMs

We appreciate CMS’ efforts to encourage participation in Advanced APMs. CMS seeks comment on whether a different, potentially lower, revenue-based nominal amount standard be created for small and rural practices. We support the creation of such a standard for these practices as they are less able to withstand the financial risk involved with an APM as larger or more urban practices who have access to far greater resources, financially and professionally.
MIPS APMs

We appreciate CMS’ proposal to allow for at least some incentives for participants in APMs that do not qualify as Advanced APMs. We support CMS’ proposal to add a fourth snapshot date for “full TIN” MIPS APMs to include the addition of MIPS APM clinicians. There are several reasons that a MIPS eligible clinician may join a MIPS APM during the last quarter of the year, such as relocation, and we believe CMS should continue to encourage participation in APMs by extending the snapshot date to include these clinicians.

Conclusion

We thank you for your consideration of our recommendations. We hope that this letter will serve as part of a continuing and collaborative discussion with CMS as the regulations are finalized and implemented. We would welcome meeting with CMS to answer questions related to any of our suggestions.

Sincerely,

William S. Pease, MD, AANEM President