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August 25, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

RE: Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts [CMS-1770-P]

Dear Administrator Brooks-LaSure,

The American Academy of Neurology (AAN) is the world's largest neurology specialty society representing more than 38,000 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 (AD), Parkinson's disease, stroke, migraine, epilepsy, traumatic brain injury, ALS, and spinal muscular atrophy.

Table of Contents

Conversion Factor and Passive Devaluation

The AAN is deeply concerned with the impact of the 4.42% decrease to the conversion factor projected to occur if all policies in the 2023 Medicare Physician Fee Schedule (MPFS) proposed rule are implemented. The AAN understands that the agency cannot waive budget neutrality requirements without modification of existing legislation. The AAN also understands that the Centers for Medicare and Medicaid Services (CMS) cannot unilaterally add additional funds into the MPFS. The AAN is highly supportive of requests to Congress to waive budget neutrality and to appropriate necessary additional funds into the MPFS that will offset the impacts of the expiration of temporary relief measures. The AAN is also supportive of efforts to mitigate the detrimental financial impacts of statutory PAYGO requirements and the expiration of funding for alternative payment model (APM) incentive payments. Additionally, the AAN calls on Congress to provide a positive update, based on medical inflation, to the Medicare conversion factor in 2023 and in all future years to counterbalance the detrimental impacts of inflation on patient access to care and the stability of neurology practices serving all communities.

Furthermore, the AAN is concerned with the structural impacts of passive devaluation on all services in the MPFS, particularly on the evaluation and management (E/M) codes. As MedPAC has noted, because "the fee schedule is budget neutral, ambulatory E/M services become underpriced through a process of passive devaluation."[1] The impacts of passive devaluation are substantial, as they accumulate over time. Purely due to budget neutrality requirements and the introduction of additional relative value units (RVUs) into the 2023 MPFS, all services that aren't directly updated in the MPFS are subject to a 1.55% reduction in payment.[2] E/M services are uniquely vulnerable to the impacts of passive devaluation due to structural constraints under the process by which the relative values of code sets are updated. The AAN urges CMS to work with Congress to ensure that cognitive work maintains its appropriate value.

II. B. Determination of PE RVUs

Strategies for Improving Global Surgical Package Valuation

[1] "Rebalancing Medicare's Physician Fee Schedule toward Ambulatory Evaluation and Management Services." Report to the Congress: Medicare and the Health Care Delivery System, Medicare Payment Advisory Commission, June 2018, https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun18_ch3_medpacreport_sec.pdf.
[2] Table 136, 87 Fed. Reg. at 46386.

The AAN is pleased that CMS is prioritizing the development of strategies for improving global surgical package valuation. The AAN has long believed, in alignment with the findings of the various RAND studies[3], the current valuations are deeply flawed and based on the inaccurate valuations of post-operative E/M visits contained in a high proportion of global packages. Specifically, the finding, "according to claims-based data, the reported number of E/M visits matched the expected number (included for purposes of PFS valuation) for only 4 percent of reviewed 10-day global packages and 38 percent of reviewed 90-day global packages" [4] demands CMS consideration of alternative valuation methodologies to address the disparities between the observed and predicted values for the global packages. The AAN believes that it is of the utmost importance to assure the valuation of the global packages accurately reflects the work being done and that the values are supported by data. The AAN understands the complexity of making changes to these packages, as well as the constraints placed on CMS by the Medicare Access and CHIP Reauthorization Act of 2015, and therefore aims to provide recommendations that will protect Medicare program integrity without being unnecessarily disruptive to existing practice patterns.

The AAN does not believe the disparity between expected and observed post-operative E/M visits in the 10 and 90-day global packages are the result of any significant changes in the post-operative healthcare landscape. It is customary for the surgeon that performs a procedure to follow-up with every patient to confirm good wound healing, absence of infection, and return to expected level of function, before transferring the care of the patient to other providers. The AAN believes that there is a strong basis for CMS' hypothesis that these post-operative visits are not being performed because the physician who performed the surgical procedure has performed the necessary tasks to ensure expected recovery before determining additional office visits are not necessary. CMS requested comment on whether changes in practice patterns may account for the observed disparity in post-operative visits. The AAN does not believe that an increase in utilization of non-face-to-face codes for transitional care management services has or will occur as many components of these codes (patient education, laboratory review, referrals to community resources, etc.) are performed by qualified staff, but not the surgeon or other QHP. It is possible that the observed discrepancy is due to improvements in comprehensive discharge planning. It is also possible that some of the visits contained in a global package may be performed by a provider other than the provider who performed the procedure. However, the AAN believes that regardless of whether the disparity between observed and predicted post-operative visits is a result of more comprehensive discharge planning, or any other cause, CMS should not continue to value the global packages based on visits that are not being performed by the billing provider.

The AAN is confident that the data and analyses contained in the RAND reports represent the best available data and believes that the survey methodology, whatever its limitations, is no different from the limitations of the Relative Value Scale Update Committee (RUC)

[3] "Global Surgery Data Collection." CMS, Centers for Medicare and Medicaid Services, 1 Dec. 2021, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Global-Surgery-Data-Collection-.

[4] Kranz, Ashley M., Teague Ruder, Ateev Mehrotra, and Andrew W. Mulcahy, Claims-Based Reporting of Post-Operative Visits for Procedures with 10- or 90-Day Global Periods: Final Report. Santa Monica, CA: RAND Corporation, 2019. https://www.rand.org/pubs/research_reports/RR2846.html

survey used to assess all other Healthcare Common Procedure Coding System (HCPCS) codes. Any investigation of the global billing periods will have limitations, but the AAN is not aware of any independent data supporting the number of post-procedural visits indicated in RUC surveys and in current CMS global packages. The AAN is in agreement with CMS' assessment in the 2020 MPFS final rule that the current body of evidence "suggests that the values for E/M services typically furnished in global surgery periods are overstated in the current valuations for global surgery codes."[5] The AAN believes that, in the absence of compelling evidence that these post-operative visits are being performed, CMS should rely on the data from the RAND reports when considering changes to these global packages.

The AAN believes that due to the impacts on program integrity and required budget neutrality, this issue is of great importance, and action should be taken swiftly. In the proposed rule, CMS asks whether or how recent changes in coding and valuation of separately billable E/M services may have impacted global packages and whether global packages, and especially those with 10 and 90-day global periods, continue to serve a purpose when physicians could otherwise bill separately, not only for the post-operative E/M visits they furnish, but also for aspects of post-operative care management they furnish to patients. The AAN agrees that the ability to bill separately for the post-operative E/M visits actually occurring would resolve any potential disparity between expected and realized post-operative visits. However, the AAN shares CMS' concern for the potential disruption that would be caused by drastically changing or eliminating all of the 10 and 90-day global packages abruptly, especially in the context of the ongoing Covid-19 Public Health Emergency (PHE). That is why the AAN is recommending that CMS transition all 10-day global packages to 0-day global packages, allowing for the relevant post-operative visits that are occurring to be billed separately. This approach would allow CMS to address those packages that have demonstrated the most egregious discrepancy between predicted and observed visits while allowing CMS the opportunity to apply any lessons learned to future policy changes impacting the 90-day global packages.

While this change would impact neurology practices who currently submit claims for specific 10-day global packages, the AAN believes that the overall impact would be positive for physicians performing the allotted post-operative visits, due to the increased valuation of E/M codes in previous rulemaking. This approach will hold harmless physicians performing the allocated post-operative visits while allowing CMS to evaluate the true frequency and cost of these visits. Using this information, CMS will be able to better determine what additional changes need to be made to certain 90-day global packages that have exhibited a significant discrepancy between observed and expected visits.

The AAN recognizes that CMS declined to increase the values of the global packages proportionally to the increase in values for the office/outpatient E/M codes. The AAN believes this was an appropriate decision at the time, given the likely inflated values of the existing packages. Once a 10-day global package is transitioned to a 0-day global package, it may be appropriate for subsequent post-operative E/M visits to be valued in accordance with the updates that went into effect in 2021. For some post-operative visits, the practice cost associated with those visits may even be higher than those associated with office/outpatient visits. To more precisely account for variations in practice cost, the AAN recommends that

[5] 84 Fed. Reg. at 62858.

CMS establish G codes for several levels of post-procedural visits performed within a 10-day period after surgery. For cases in which a global package is not transitioned to a 0-day global, the AAN does not support increasing the value of the package based on the 2021 update to E/M coding and payment until CMS has accurately determined the quantity and intensity of post-operative visits in each package.

II. D. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

The AAN strongly supports policies that ease unnecessary restrictions on telehealth services, support long-term sustainability of care delivery, and promote high-quality, patient-centered care. We note the evidence supports the effectiveness of telehealth in inpatient and outpatient settings, for both the acute evaluation and routine assessment across general neurologic and multiple neurologic subspecialties.[6] The AAN appreciates CMS' attention to the need to prioritize policy changes that promote sustainable care delivery both during and after the Covid-19 PHE, in accordance with relevant statute.

AAN members and their patients rapidly adopted telehealth in response to the PHE. There is consensus among our members that adoption of telehealth and continued use over more than two years has yielded numerous benefits for patient care. Throughout the PHE, the expanded availability of telehealth services and additional administrative flexibilities implemented by HHS have allowed AAN members to mitigate infection risk and continue to provide care to patients who otherwise would have missed critical appointments with serious potential consequences. These consequences include the risk of neurologic deterioration. For example, access to telehealth services has allowed many patients with seizure disorders to safely manage their medications and thus avoid life-threatening seizures. Successful models of care include the use of telehealth to augment capacity in areas where there is a shortage of providers or other barriers to access and include the use of both audio/video and audio-only services, as appropriate. The available literature demonstrates that benefits for neurology patients associated with expanded access to telehealth services include:[7]

- Improved access to expert neurologic evaluation and enhanced comfort, convenience, and safety, particularly for patients with limited mobility due to their medical condition or need for home medical support equipment.
- Reduced travel time and decreased time away from work or other essential activities for patients and care partners.
- Reduced patient costs, including fuel costs, associated with traveling for an in-person visit.
- Increased care partner and provider participation during a visit and reduced caregiver stress.
- Better assessment of social determinants of health, including the patient's home environment.
- Early intervention prior to a scheduled office visit, based on continuous assessment of neurologic disease progression and treatment efficacy.

[6] Hatcher-Martin, Jaime M., et al. "American Academy of Neurology Telehealth Position Statement." Neurology, Wolters Kluwer Health, Inc. on Behalf of the American Academy of Neurology, 17 Aug. 2021, https://n.neurology.org/content/97/7/334.
[7] Id.

- Protection of patients and providers from infectious disease exposure and reduction in the use of personal protective equipment.

Requests to Add Services to the Medicare Telehealth Services List for CY 2023
Telephone E/M Services

Telephone E/M Services

CMS has received requests to temporarily add Telephone E/M visit codes, Current Procedural Terminology (CPT) codes 99441, 99442, and 99443, to the Medicare Telehealth Services List on a Category 3 basis. CMS has already established separate coding and payment for audio-only E/M services for the duration of the PHE. Under the Consolidated Appropriations Act (CAA), coverage and payment for these services has been extended for 151 days following the termination of the PHE. The AAN strongly supports the decision to extend coverage for audio-only services beyond the termination of the PHE.

In the proposed rule, CMS states that the agency does not believe it would be appropriate for the Telephone E/M codes to remain on the Medicare Telehealth list after the end of the PHE and the 151-day post-PHE extension period because outside the circumstances of the PHE, "the telephone E/M services would not be analogous to in-person care; nor would they be a substitute for a face-to-face encounter."[8] CMS interprets the relevant statute to require "telehealth services be so analogous to in-person care such that the telehealth service is essentially a substitute for a face-to-face encounter."[9] As such, CMS will assign Telephone E/M visit codes (CPT codes 99441, 99442, and 99443) a bundled status after the end of the PHE and the 151-day extension period.

The AAN urges CMS to reconsider the decision to assign the Telephone E/M codes a bundled status and strongly supports permanent coverage and adequate reimbursement for 99441-99443. There is a substantial proportion of the neurology patient community that simply do not and will likely never have access to computers, or who cannot operate computers or mobile devices that have video and audio capability. Additionally, many neurology patients cannot afford broadband access or robust cellular data plans that would allow audio/video encounters to take place. For many neurology patients, especially the elderly or those with even early dementia and those with adverse social determinants of health, including limited access to broadband because of location or expense, audio-only services have been a successful model of care delivery. Recent data indicates that usage of varying telehealth modalities is correlated with demographic factors including age, race, education, and income.[10] The AAN believes a decision to decline to provide permanent coverage and adequate reimbursement for audio-only services is likely to contribute to health disparities and inequities in access to care while magnifying challenges associated with accessing these services during a natural disaster. Coverage of audio-only services may also yield long-term benefits to the Medicare program and Medicare beneficiaries as audio-only

[8] 87 Fed. Reg. at 45891.
[9] Id.
[10] Karimi, Madjid, et al. "National Survey Trends in Telehealth Use in 2021: Disparities in Utilization and Audio vs. Video Services." ASPE Office of Health Policy, Department of Health and Human Services, Feb. 2022, https://www.aspe.hhs.gov/reports/hps-analysis-telehealth-use-2021.

services can be used for triage, continuity of care, medication refills, and necessary check-ins.

The AAN believes that in a certain subset of cases, the visit for a neurology patient may primarily involve verbal interaction between the patient and provider and that visualization may not always be critical to the provision of a particular E/M service. In these cases, the AAN believes that such a visit would be analogous to in-person care. Additionally, for patients unable to operate computers or other devices that have video and audio capability, the patient's only other option would be an in-person visit. The AAN believes that as clinically appropriate, an audio-only encounter could serve as a substitute to a face-to-face encounter for those patients for which audio-video telehealth is not a feasible option.

While audio-only service may not always be appropriate for all clinical encounters, the AAN believes that there are specific applicable use cases within neurology for which the spectrum of audio-only service would be appropriate, including stroke. CMS currently provides coverage and payment for communication-technology-based services (CTBS), including brief virtual check-ins (G2012 and G2252). There are clinical circumstances when a neurologist can use audio-only technology while providing stroke care, but this service is likely to be significantly more intense than a virtual check-in. Beneficiary access to these critical services is dependent on adequate reimbursement. Absent permanent coverage and payment for the Telephone E/M codes, as an alternative, CMS could consider increasing reimbursement for higher intensity CTBS and creating additional higher level G codes, to reflect differences in the care provided.

Neurostimulator Pulse Generator/Transmitter

The AAN supports CMS' decision to temporarily add CPT codes 95970, 95983, and 95984 to the Medicare Telehealth list on a Category 3 basis to allow for additional evidence to be developed and for relevant questions regarding patient safety and quality of care to be addressed. The AAN is aware that there is technology allowing for two-way communication via a virtual clinic platform, which permits a neurologist to program and/or reprogram the deep brain stimulator in real-time and examine the patient. This has improved access to care in areas of the country with a shortage of movement disorder specialists.

The AAN agrees with CMS' determination that the full scope of service elements described by CPT codes 95976 and 95977 cannot currently be furnished via two-way, audio-video communication technology. The AAN urges the agency to reconsider as evidence develops regarding the ability to furnish these services as telehealth services.

Emotional/Behavior Assessment, Psychological, or Neuropsychological Testing and Evaluation Services Other Services Proposed for Addition to the Medicare Telehealth Services List

The AAN applauds CMS' decision to add 97151-97158, 0362T, and 0373T to the Medicare Telehealth List on a Category 3 basis. The AAN concurs with CMS that there is likely a clinical benefit when furnished via telehealth. While the AAN appreciates the agency's concern that an audio-video telehealth visit may not fully capture certain environmental cues,

the AAN believes that the decision as to the appropriateness of care should be determined by the provider without financial disincentives between in-person and telehealth care.

There are significant benefits to being able to provide these services via telehealth. Patients with dementia or other cognitive or psychological impairments may require the assistance of additional parties during a visit. Providing these services remotely can allow for conferencing in other people, including family, significant others, and other providers, which can provide substantial benefits. This is not always the case for in-person visits, as caregivers and other family members may not be able to take time off from work or travel to the appointments. Virtual visits allow for the provider, the patient, and important family members to be in separate locations while still being able to participate in the visit. Additionally, psychiatric patients often have social anxiety issues, leading to limitations on leaving safe places like their home, facility, or family, and remote visits are important ways to ensure these patients maintain access to care.

Other Services Proposed for Addition to the Medicare Telehealth Services List – Prolonged Service Codes

CMS is proposing to permanently add the prolonged service codes GXXX1-GXXX3, established in conjunction with new coding and payment policies for inpatient E/M services, to the Medicare Telehealth list on a Category 1 basis. These codes would replace 99356-99357, which are currently on the telehealth list. The AAN strongly supports permanently adding GXXX1-GXXX3 to the Medicare telehealth list and believes doing so is essential to maintaining consistency with the new coding and payment structure for inpatient E/M services. The AAN requests clarification on the usage of these new codes because some base codes that should allow for a prolonged service code to be added are not currently approved to be on the Medicare Telehealth list.

Services Proposed for Removal from the Medicare Telehealth Services List After 151 Days Following the End of the PHE

The AAN urges CMS to reconsider its proposal to include CPT codes 99221-99223 and 99234-99236 on the list of codes that will be removed from the Medicare Telehealth Services list after the 151-day extension period following the end of the PHE. Although the admitting physician ought to be on-site, these codes can be used for consultations, during which the consulting physician need not be physically present.

Implementation of Telehealth Provisions of the Consolidation Appropriations Acts, 2021 and 2022

CMS is implementing provisions of the CAA that extend certain Medicare telehealth flexibilities adopted during the PHE for 151 days after the end of the PHE. The AAN strongly supports the implementation of these provisions. These flexibilities have been critical for clinicians who have adapted to rapidly changing circumstances in order to maintain access to high-quality care for patients who may have otherwise had their care compromised. Critical flexibilities extended by the CAA that are supported by the AAN include:

- Expansion of the scope of permissible telehealth originating sites to include any site in the United States where the beneficiary is located at the time of the telehealth service, including an individual's home, for a 151-day period beginning on the first day after the end of the PHE for COVID-19
- Allowing for payment of an originating site facility fee to an originating site with respect to those telehealth services furnished during the 151-day period if the originating site is one that meets pre-existing geographic and originating site restrictions
- Consistent with existing waivers, continuation of coverage and payment of telehealth services included on the Medicare Telehealth Services List as of the March 15, 2022, date of enactment that are furnished via an audio-only telecommunications system during the 151-day period beginning on the first day after the end of the PHE for COVID-19.

The AAN strongly supports policies that assist patients with access to telehealth services regardless of location. This necessarily requires continued coverage for telehealth services and equitable provider reimbursement. Telehealth, including audio-only encounters, has been a lifeline connecting neurology patients with neurology providers. The choice to use telehealth technology is determined by the needs of the patient, the ability to access and use the technology, and the clinical problem to be addressed. Patients and caregivers alike have benefitted from expanded access to telehealth services both before and during the PHE. Patients report that access to care has improved, and that in many instances, telehealth services are more convenient and comfortable, while providing more confidentiality. Benefits accrue for outpatient and inpatient populations and apply to new and established patients requiring physician services and other services such as physical therapy and speech and language therapy.

The expansion of telehealth services for the Medicare population has been particularly beneficial for patients with cognitive and mobility impairments. AAN members report that being able to complete appointments at home has increased patient satisfaction. For example, many patients with dementia, a condition that affects more than 1 in 10 adults over age 65,[11] cannot attend in-person clinical visits due to behavioral symptoms such as anxiety, agitation, apathy, or mobility limitations that come with advanced disease. These patients often are cared for by a spouse, who often has physical limitations, or children that live distantly, that could interfere with the patient's ability to travel for an office visit. The ability to complete telehealth visits eliminates the barrier of coming into a doctor's office to be seen. The ability to conference-in additional family members without their needing to take extended time away from work or other commitments to attend appointments has improved care coordination for this vulnerable population. Telehealth services can approximate some of the benefits of physician house calls which patients appreciated during the last century and seeing patients in their own home environment may offer further insight on their clinical care, including fall risks.

[11] "Alzheimer's Disease Facts and Figures." Alzheimer's Disease and Dementia, Alzheimer's Association, 2022, https://www.alz.org/alzheimers-dementia/facts-figures.

The AAN strongly urges CMS to implement the provisions of the CAA and consider any additional administrative actions that can promote stability and patient access to telehealth services both during and following the termination of the PHE.

Modifier and POS Policy

CMS is proposing to update policies associated with the use of modifiers and POS codes to account for the use of telehealth services accurately, both during the PHE and following the 151-day extension of certain policies under the CAA. The AAN supports the proposed changes and believes it is appropriate to revert to existing policy after the 151-day extension period has elapsed.

Expiration of PHE Flexibilities for Direct Supervision Requirements

The AAN supports permanently modifying direct supervision requirements so that direct supervision can be performed via real-time interactive audio/video technology for a subset of services, namely E/M services. Virtual supervision, when appropriately utilized, can be an excellent way to maximize supervised team-based care across a more distributed geography. Providers have demonstrated throughout the PHE that this flexibility has allowed them to expand access without compromising patient care. The AAN believes that, in cases in which supervision is provided via interactive telecommunications technology, supervision should be robustly documented to ensure that patients are safely receiving clinically appropriate care from members of the care team.

II. E. Valuation of Specific Codes

Cognitive Assessment & Care Plan Services (99483)

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommended work RVU
99483	Assessment of and care planning for a patient with cognitive impairment, requiring an independent historian, in the office or other outpatient, home or domiciliary or rest home, with all of the following required elements: Cognition-focused evaluation including a pertinent history and examination, Medical decision making of moderate or high complexity, Functional assessment (eg, basic and instrumental activities of daily living), including decision-making capacity, Use of standardized instruments for staging of dementia (eg, functional assessment staging test [FAST], clinical dementia rating [CDR]), Medication reconciliation and review for high-risk medications, Evaluation for neuropsychiatric and behavioral symptoms, including depression, including use of	3.84	3.50

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommended work RVU
	standardized screening instrument(s), Evaluation of safety (eg, home), including motor vehicle operation, Identification of caregiver(s), caregiver knowledge, caregiver needs, social supports, and the willingness of caregiver to take on caregiving tasks, Development, updating or revision, or review of an Advance Care Plan, Creation of a written care plan, including initial plans to address any neuropsychiatric symptoms, neuro-cognitive symptoms, functional limitations, and referral to community resources as needed (eg, rehabilitation services, adult day programs, support groups) shared with the patient and/or caregiver with initial education and support. Typically, 50 minutes are spent face-to-face with the patient and/or family or caregiver.		

Following the review of the office/outpatient E/M visits for Calendar Year (CY) 2021, CMS identified services for which the values are closely tied to the values of the outpatient E/M codes. The agency noted that due to the increase in value for E/M services that "the current work RVU for CPT code 99483 would have a lower work RVU than a new patient level 5 office/outpatient E/M visit, which would create a rank order anomaly between the two codes."[12] To avoid 99483 having a lower work RVU than the highest valued office/outpatient E/M visit, the agency proposed to increase this code's work RVUs from 3.44 to 3.80. CMS noted that 99483 "includes an evaluation of a patient's cognitive functioning and requires collecting pertinent history and current cognitive status, all of which require medical decision-making of moderate or high complexity."[13]

In February 2021, the CPT Editorial Panel revised 99483 to replace "50 minutes" from its descriptor with a revised time value determined by the RUC survey to align with the principles underlying the office/outpatient E/M codes. The 2023 descriptor time for CPT code 99483 will be 60 minutes typical time instead of 50 minutes typical time. The RUC recommended a revised work RVU of 3.50, which CMS disagrees with, citing their continued belief that this service is appropriately valued greater than the analogous EM visit code 99205. The agency is proposing to instead increase the RVU from 3.80 to 3.84 to account for the increase in physician time. **The AAN supports this change and urges CMS to finalize its recommended value of 3.84 for 99483.**

Neuromuscular Ultrasound (76881, 76882, 76XX0)

[12] 85 Fed. Reg. at 50127.
[13] 87 Fed. Reg. at 46001.

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommended work RVU
76881	Ultrasound, complete joint (ie, joint space and peri-articular soft-tissue structures), real-time with image documentation	0.54	0.90
76882	Ultrasound, limited, joint or focal evaluation of other nonvascular extremity structure(s) (eg, joint space, peri-articular tendon[s], muscle[s], nerve[s], other soft-tissue structure[s], or soft-tissue mass[es]), real-time with image documentation	0.59	0.69
76XX0	Ultrasound, nerve(s) and accompanying structures throughout their entire anatomic course in one extremity, comprehensive, including real-time cine imaging with image documentation, per extremity	0.99	1.21

76881

CMS disagrees with the RUC's work RVU recommendation of 0.90 for CPT code 76881 which represents the survey 25th percentile. CMS also disagrees on whether there is overlap in pre-service and post-service work between the E/M visit and CPT code 76881 and proposes 0 minutes for the pre-service and post-service time rather than the RUC-recommended 5 minutes of pre-service and post-service time. CMS proposes a work RVU of 0.54 using the reverse building block methodology "based on the removal of the 5 minutes of pre-service and post-service time, with a long-standing intensity of 0.0224 (10 minutes * 0.0224 work/minute = 0.224 work RVUs)."[14] **The AAN is of the same opinion as the RUC and does not agree with any suggested approach that uses reverse building block methodology to systematically reduce work RVUs for services.** We believe that reverse building block methodology, or any other purely formulaic approach, should not be used as the primary methodology to value services. It is inappropriate as magnitude estimation has been used to establish work RVUs for services since the publication of the first Medicare Physician Payment Schedule in 1992.

CMS asserts that the "proposed work RVU accounts for the 0.224 work RVU decrease as a result of the removal of pre-service and post-service time and the increase of 5 minutes of intra-service time, while maintaining the current intra-service work per unit of time (IWPUT) of 0.027, as there was no discussed change in the work intensity."[15] The RUC discussed that the change in intra-service time and intensity related partially to the change to rheumatologists performing the scanning of the current patient population. Ultrasound technology has evolved immensely since the code was valued in 2010, including proliferation of high-frequency ultrasound probes dedicated to musculoskeletal imaging, with the ability to produce images with higher fidelity and more detail. The complete ultrasound

[14] 87 Fed. Reg. at 45923.
[15] Id.

code is increasingly used to evaluate for a greater range of complex musculoskeletal injuries and has replaced magnetic resonance imaging (MRI) as the first line investigation for many pathologies. Further, ultrasound can be used to troubleshoot difficult cases that are inconclusive on either clinical evaluation or other imaging modalities, which supports a change in overall physician time and work intensity. For the typical patient with gradual onset, activity limiting ankle pain requires a detailed examination to provide optimal patient care.

There are over 20 codes in the RUC database with an XXX global period and 20 minutes intra-service time and 5 minutes pre- and post-service time, and all of these codes have work RVUs that are 2-3 times higher than the CMS proposed 0.54. These values align with the median survey value for CPT code 76881, yet the RUC recommends the survey 25th percentile. The RUC compares CPT code 76881 with comparator code 93975 *Duplex scan of arterial inflow and venous outflow of abdominal, pelvic, scrotal contents and/or retroperitoneal organs; complete study* (work RVU = 1.16, 20 minutes intra-service time and 30 minutes total time) noting that the times are identical, yet the RVU is higher than the RUC recommendation of 0.90 because the vascular ultrasound code requires evaluation of a larger anatomic area compared to CPT code 76881 and includes the additional work of performing duplex color and spectral Doppler ultrasound imaging in addition to the standard grey-scale and cine ultrasound imaging.

Moreover, the methodology employed by CMS has resulted in a work RVU for CPT code 76881 that is less than the proposed work RVU for CPT code 76882. This is inappropriate considering that 76881 describes the physician work involved in a complete evaluation of a specific joint in an extremity, while 76882 represents a limited evaluation of a joint or focal evaluation of a structure(s) in an extremity other than a joint (e.g., soft-tissue mass, fluid collection, or nerve[s]). CPT code 76881 requires ultrasound examination of all the following joint elements: joint space (e.g., effusion), peri-articular soft-tissue structures that surround the joint (i.e., muscles, tendons, other soft-tissue structures), and any identifiable abnormality. In some circumstances, additional evaluations such as dynamic imaging or stress maneuvers may be performed as part of the complete evaluation. CPT code 76882 does not assess all the elements included in 76881 and 76882 should have a lower work value. The Agency's proposal to assign 0.54 work RVUs to 76881 and 0.59 to 76882 creates a rank order anomaly.

The AAN disagrees with CMS utilizing reverse building block methodology for valuing services and strongly recommends a work RVU of 0.90 as supported by the survey. The CMS recommended work value falls far below the survey 25th percentile and below the current value. **The AAN urges CMS to accept a work RVU of 0.90 for CPT code 76881.**

76882

CMS disagrees with the RUC's work RVU recommendation of 0.69 for CPT code 76882, which represents the survey 25th percentile. However, CMS agrees with the RUC that 15 minutes of intra-service time is warranted. The Agency proposes a work RVU of 0.59 using the reverse building block methodology "to account for the 4-minute increase in intra-service

time and the maintenance of the current IWPUT of 0.024."[16] CMS notes there was no information indicating a change in intensity, the RUC notes that similarly with the complete ultrasound code, for the limited joint code, ultrasound technology has evolved immensely since the code was valued in 2010, including proliferation of high-frequency ultrasound probes dedicated to musculoskeletal imaging, with the ability to produce images with higher fidelity and more detail. For the typical patient, the limited joint ultrasound code is used to evaluate patients with acute injury and triage for urgent surgical intervention or conservative physical therapy. The improved level of detail by current ultrasound technology allows for physicians to perform this work with ultrasound rather than advanced imaging to optimize patient outcomes but also results in an overall increased intensity based on the number and quality of images to obtain and review for medical decision-making.

The AAN does not agree with any suggested approach that uses reverse building block methodology to systematically reduce work RVUs for services. We believe that any mathematical or computational methodology used to value physician work is not appropriate. The RUC's established valuation process is based on specialty society survey data and its use of magnitude estimation is the only methodology that should be used in assigning physician work values to individual services, as the MPFS is a relative system and maintaining appropriate relativity between the services is vital in valuing physician work. CMS states that by proposing work RVUs that maintain the current IWPUTs, it is maintaining relativity within the neuromuscular ultrasound family. We disagree, and believe that a rank order anomaly is created by the CMS methodology that has resulted in a work RVU for CPT code 76881 less than the proposed work RVU for CPT code 76882, as stated above. This flawed intensity argument relies on anchoring to incorrect IWPUT values established based on previous assumptions and ignores the rigorous values obtained from physician survey data and approved by accepted RUC methodology.

CMS disregards the input of 100 physicians by proposing to base the work RVU of code 76882 using reverse building block methodology. The AAN disagrees with the use of reverse building block methodology and concurs with the RUC recommendation that CPT code 76882 should be valued based on the survey 25th percentile. **The AAN urges CMS to accept a work RVU of 0.69 for CPT code 76882.**

76XX0

For CPT code 76XX0, CMS disagrees with the RUC-recommended work RVU of 1.21 and states that the RUC "arrived at a recommended work RVU of 1.21 by comparing the pre-, intra-, and post-service times to those of CPT code 76881, which CMS is proposing to modify due to overlapping work in the pre- and post-service time with E/M visits."[17] The RUC reviewed the survey results from 66 physicians and determined that the survey 25th percentile work RVU of 1.21 appropriately accounts for the work involved in this service. CMS then employs reverse building block methodology to propose a work RVU of 0.99 for CPT code 76XX0. This computation is based on the proposed work RVU of 0.54 for CPT code 76881 with proposed times of 20 minutes intra-service time and 0 minutes pre- and post-service time and the times of 25 minutes intra-service time and 7 minutes pre- and post-

[16] Id.
[17] 87 Fed. Reg. at 45924.

service time for CPT code 76XX0. The AAN agrees with the RUC reiteration of its belief that any mathematical or computational methodology used to value physician work is inappropriate. The RUC's established valuation process is based on specialty society survey data and its use of magnitude estimation is the only methodology that is appropriate when assigning physician work values to individual services as the MPFS is a relative system and maintaining appropriate relativity between the services is vital in valuing physician work.

The RUC compares CPT code 76XX0 with comparator code 70553 *Magnetic resonance (eg, proton) imaging, brain (including brain stem); without contrast material, followed by contrast material(s) and further sequences* (work RVU = 2.29, 25 minutes intra-service time and 37 minutes total time) and notes that the intra-service and post-service times are the same yet there is more complex physician work involved with 70553, an MRI of the brain, thus it is appropriately valued higher than 76XX0. The physician is typically evaluating a significantly greater number of images for CPT code 70553, which requires localization across both pre- and post-contrast sequences to evaluate for a greater range of pathology, potentially involved adjacent structures, and a wider range of differential diagnostic considerations. CPT code 76XX0 is used for complex cases that are a diagnostic dilemma. This may include differentiating between distinct types of peripheral neuropathy, such as multifocal motor neuropathy with conduction block, chronic inflammatory demyelinating polyneuropathy, acute inflammatory demyelinating polyneuropathy, length-dependent peripheral neuropathy, and hereditary neuropathy with tendency to pressure palsies. This procedure involves measuring the cross-sectional area of a nerve at multiple different sites throughout the length of an entire limb, calculating ratios, checking vascularity, evaluating echo intensity of affected muscles, determining patterns of peripheral nerve involvement, and saving cine loops. It includes scanning at least two joints and the limb in between, above and below those joints, so it is more than three times as much physician work as a limited limb ultrasound.

The AAN disagrees with the use of reverse building block methodology and concurs with the RUC recommendation that CPT code 76XX0 should be valued based on the survey 25th percentile. **The AAN urges CMS to accept a work RVU of 1.21 for CPT code 76XX0.**

Chronic Pain Management and Treatment (CPM) Bundles (HCPCS GYYY1, and GYYY2)

Code	Long Descriptor	CMS Proposed work RVU
GYYY1	Chronic pain management and treatment, monthly bundle including, diagnosis; assessment and monitoring; administration of a validated pain rating scale or tool; the development, implementation, revision, and maintenance of a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes; overall treatment management; facilitation and coordination of any necessary behavioral health treatment; medication management; pain and health literacy counseling; any necessary chronic pain related crisis care; and ongoing communication and care coordination	1.45

Code	Long Descriptor	CMS Proposed work RVU
	between relevant practitioners furnishing care (e.g. physical therapy and occupational therapy, and community-based care), as appropriate. Required initial face-to-face visit at least 30 minutes provided by a physician or other qualified health professional; first 30 minutes personally provided by physician or other qualified health care professional, per calendar month. (When using GYYY1 30 minutes must be met or exceeded.)	
GYYY2	Each additional 15 minutes of chronic pain management and treatment by a physician or other qualified health care professional, per calendar month (List separately in addition to code for GYYY1). (When using GYYY2, 15 minutes must be met or exceeded.)	0.5

CMS is proposing to create separate coding and payment for chronic pain management and treatment (CPM) services beginning January 1, 2023. While the AAN agrees with CMS that the proposed CPM bundles, HCPCS GYYY1 and GYYY2, address a gap in current coding and payment policies, the AAN is concerned that as proposed, the bundles may disincentivize the provision of CPM services to the most complex patients. Currently, many neurologists who provide comprehensive pain management care, for safety purposes must use office/outpatient E/M codes on a monthly basis when billing for the services that are described in the bundle. The CPM bundles cannot be billed on the same day that CPT codes 99202-99215 are provided, and the time used in reporting CPM services may not represent time spent in any other reported service, including the existing chronic care management and principal care management. The AAN is concerned that clinicians billing for CPM services would face a substantial decrease in work RVUs generated, relative to the current reimbursement received when billing the outpatient E/M codes monthly. As such, it remains unclear to the AAN as to the circumstances under which the CPM bundles would be billed. Additionally, the AAN requests clarification regarding how interventional pain specialists can bill for procedures in months in which they bill for the CPM bundles.

The AAN supports CMS' proposed inclusion of "administration of a validated pain assessment rating scale or tool"[18] as an element of the proposed CPM services. There are a number of appropriate and validated pain assessment rating scales and tools that could be utilized in providing this service. As such, the AAN supports the development of a repository or list of applicable tools to be made available to clinicians delivering CPM services.

CMS is requesting comment on whether the proposed CPM bundles have components that do not necessarily require face-to-face interaction with the billing practitioner. The AAN believes that there are components of the bundles that do not necessarily require face-to-face interaction with the billing practitioner. Relevant components include administration of questions relating to the timing of the last dose of pain medication taken, the improvement observed by the patient while taking medication, patient social determinants of health, and any recent history with drug-related crime. The AAN also believes that facilitation and

[18] 87 Fed. Reg. at 45935.

coordination of any necessary behavioral health treatment and pain and health literacy counseling also do not require face-to-face interaction with the billing practitioner.

CMS is requesting comments on whether components furnished incident-to the services of the billing provider could be appropriately furnished under the general supervision of the billing practitioner. The AAN believes it is reasonable to allow certain components to be furnished under general supervision.

CMS is requesting comment regarding what care coordination may occur between relevant practitioners furnishing services, such as complementary and integrative care, and on the community-based element included in the descriptors for proposed GYYY1 and GYYY2. Care coordination may include prescribing of durable medical equipment and the treatment of comorbid mental health conditions.

II. F. Evaluation and Management (E/M) Visits

The AAN remains highly supportive of the new coding and reimbursement policies and supports the agency's proposal to adopt the revised CPT E/M Guidelines for Other E/M visits and to adopt the general CPT framework for Other E/M visits, such that practitioner time or MDM would be used to select the E/M visit level. The AAN was intensely involved in the American Medical Association (AMA) CPT/RUC process to develop the new structure and concurs with CMS that it will produce a simplified and more intuitive system of E/M coding which is more consistent with the current practice of medicine. The AAN urges CMS to implement the new structure as proposed. We encourage the agency to adopt the RUC recommendations for work RVUs and times for the entire code set. In support of this goal, the AAN offers the following comments.

Prolonged Services for Hospital Inpatient or Observation Care

Effective January 1, 2023, the CPT Editorial panel will implement code 993X0 (*Prolonged inpatient or observation evaluation and management service(s) time with or without direct patient contact beyond the required time of the primary service when the primary service level has been selected using total time, each 15 minutes of total time)* to replace deleted prolonged service codes 99356 and 99357. CMS proposes not to adopt 993X0 citing the agency's belief that the billing instructions for CPT code 993X0 will lead to administrative complexity, potentially duplicative payments, and limit the agency's ability to determine how much time was spent with the patient using claims data. Instead, CMS is proposing to create a single G-code, GXXX1 *(Prolonged hospital inpatient or observation care evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact)* as the agency disagrees with the CPT instructions regarding the point in time at which the prolonged code should apply. The AAN is concerned that the addition of the G-code will lead to confusion among practitioners and prove to be disruptive when medical specialty societies educate members about the correct coding for prolonged services. We encourage CMS to adopt code 993X0 as approved by the CPT Editorial Panel.

Split (or Shared) Visits

AAN members, including more than 1,900 advanced practice providers, referred to in the proposed rule as "non-physician practitioners (NPPs)" practice as part of physician-led care teams. To ensure timely access to high-quality care, many elements of a patient visit are performed by NPP members of the care team rather than the physician. The AAN concurs with CMS that, given recent updates to policies relating to E/M billing, as well as the rapidly changing medical workforce, alterations must be made to keep up with new models of care delivery as well as the collaborative role that NPPs play in neurologic care.

Although the AAN appreciates CMS proposing to delay implementation of the previously finalized policy used to determine the substantive portion of a split (or shared visit) until 2024, the AAN is highly concerned with the changes finalized in the 2022 MPFS redefining the "substantive portion" of a split (or shared) visit. These changes would amend the definition of "substantive portion" for the purposes of determining who may bill for a split (or shared) visit to mean "more than half of the total time spent by the physician and NPP performing the split (or shared) visit."[19]

The AAN believes this new definition is not aligned with changes already implemented for outpatient E/M services and changes that are proposed to be implemented in 2023 for inpatient E/M services. Allowing practitioners to select visit level based on either time or medical decision-making (MDM) is a critical element of the new policies governing billing for E/M services. The AAN believes that establishing a different paradigm for determining which practitioner may bill for split (or shared) E/M visits will be overly burdensome and confusing for practitioners and is not aligned with the actual workflow that has safely developed over time within these care teams. The AAN believes that it is most appropriate to select the billing practitioner based on either time or MDM and that doing so would be consistent with recent changes to E/M billing.

In the 2022 MPFS final rule, CMS justified its decision only to allow the practitioner responsible for more than half of the total time of the visit to bill for the visit, by stating "no key or critical portion of MDM is identified by CPT. Therefore, we do not see how MDM (or its critical portion, or other component part) can be attributed to only one of the practitioners."[20] The AAN has previously submitted comments noting that we believe that the simplest way to resolve this issue is through coordinated attestations from both the physician and the NPP as to who provided the MDM.[21] CMS has a long history of auditing E/M services by examining the elements of documentation in the medical record that support appropriate billing. Given that written attestation by physicians has been accepted by CMS in the past, there would not be a need for any new auditing process. The AAN sees no reason why CMS would be unable to continue to use these same program integrity levers to audit split (or shared) visits billed based on MDM attested to by all providers involved in the specific visit.

[19] 86 Fed. Reg. at 65153.
[20] Id.
[21] See AAN comments found at: https://www.aan.com/siteassets/home-page/policy-and-guidelines/advocacy/final-aan-split-shared-letter.pdf

Prohibiting the determination of the substantive portion of a split (or shared) visit by any method other than the majority of total time spent performing the visit does not reflect the practice patterns of physician-led care teams. In cases in which the NPP's MDM determines the level of care that the patient receives during a split (or shared) visit, the AAN believes it would be appropriate for the NPP to bill for that visit. Conversely, in cases in which the physician performs the cognitive work that determines the level of care delivered to the patient, the physician should be allowed to bill for the visit regardless of which practitioner performed more than half of the total time of the visit.

The AAN notes that the proposed 2023 policy, allowing the substantive portion to be determined based on history, exam, or MDM, in addition to time, is not in alignment with other changes proposed to be made effective in 2023. Although this proposal is not ideal, it is highly preferable to requirements that limit the determination to the majority of time only. As such, the AAN urges CMS to ensure that providers are adequately educated regarding this temporary transitional policy and its interaction with other new policies impacting coding and payment for E/M services. To minimize the potentially disruptive impacts of the transitional policy, the AAN strongly urges CMS to work with the physician community to expeditiously develop a permanent policy that allows for the substantive portion of a split (or shared) visit to be determined on the basis of either time or MDM.

The AAN is now aware of the intention of the joint RUC and CPT E/M workgroup to address clarification and definition requirements related to the substantive portion of the visit. The AAN is highly supportive of these efforts and urges the agency to ensure that the updated definition of substantive portion is accounted for in future rulemaking, so that the clinician whose MDM is determining the plan of care may be permitted to bill for the visit.

II. I. Non-Face-to-Face/Remote Therapeutic Monitoring (RTM) Services

CMS has heard concerns related to the clinical labor in the direct practice expense for the two remote therapeutic monitoring (RTM) treatment management codes, CPT codes 98980 and 98981. In response to these concerns, CMS is proposing to create four new HCPCS G codes with one pair of codes aimed at increasing patient access to remote therapeutic monitoring services and the second pair aimed at reducing physician and NPP supervisory burden and to make 98980 and 98981 non-payable. The AAN supports these changes and believes they will expand access to RTM services to more patients by allowing a larger number of non-physician qualified health professionals to bill RTM services, while reducing the burden on supervising physicians.

CMS is also soliciting feedback on the development of a generic device code for RTM. The AAN believes it is necessary to expand RTM to include products used for neurological and other organ systems. The AAN strongly supports the development of a generic device code and believes there is a need to broaden the array of devices for which there is coverage for remote monitoring services. The AAN notes that there are Food and Drug Administration (FDA) approved products used to monitor neurologic conditions including epilepsy, essential tremor, concussion, traumatic brain injury, bradykinesia, dyskinesia, and Parkinson's disease that could fall under the generic device code. Several of the products used to monitor neurologic conditions are not associated with a billable code. The AAN requests clarification

regarding how best to communicate data to CMS that is collected by specialty societies relating to relevant products that could qualify for a future generic code.

II. K. Proposal to Allow Audiologists to Furnish Certain Diagnostic Tests Without a Physician Order

CMS is proposing a limited exception to the order requirement for diagnostic hearing testing services furnished by audiologists in order to broaden patient access to these services. As proposed, this exception will remove the order requirement under certain circumstances for certain audiology services furnished personally by an audiologist for non-acute hearing conditions. Under current regulations, diagnostic tests must be ordered by the physician or NPP treating the beneficiary who will use the results to manage the beneficiary's care.

The AAN opposes this proposal and urges the agency to reconsider. We recognize the positive impact audiologists and specifically hearing amplification can have on the cognitive, vestibular, and mental health of beneficiaries. This impact is optimized when audiologists work in coordination and under the direction of a physician.[22] The AAN believes that an order should be necessary for vestibular testing, balance testing, and audiograms. The AAN concurs with CMS' concern regarding "patient safety if Medicare beneficiaries seek hearing and balance services directly from audiologists without the involvement of a treating physician or practitioner."[23]

The AAN strongly believes that vestibular testing should only be performed with a physician's order for multiple reasons, including the risk of patient harm because of delayed diagnosis of a potentially life-threatening condition. The AAN has serious concerns regarding allowing audiologists to independently perform and bill for balance assessments, given the importance of these assessments and the evidence suggesting there is "inadequate training and knowledge of audiologists on fall risk factors and measures."[24] Continuing, the AAN believes that a physician needs to be involved in interpreting an audiogram due to the potential association of test results with tumors. Furthermore, the AAN is concerned with a lack of sufficient training for audiologists when interpreting an audiogram and notes that allowing audiologists to provide them independently may increase error rates and result in delayed patient care due to misdiagnosis. The AAN also believes that routine audiometry for non-acute hearing loss without an order poses a risk of overuse and may not result in envisioned cost savings.

II. M. Rebasing and Revising the Medicare Economic Index (MEI)

CMS explores at length in the preamble a plan for revising and rebasing the Medicare Economic Index (MEI). In creating the MEI, CMS establishes the weights placed on the several different components of input costs of physician services. CMS then uses these MEI

[22] Távora-Vieira, Dayse, et al. "Extended Scope of Practice Audiology in the Ent Outpatient Clinic – a Pilot Study." International Journal of Audiology, vol. 61, no. 1, 2021, pp. 29–33., https://doi.org/10.1080/14992027.2021.1900610.
[23] 87 Fed. Reg. at 46031.
[24] Van Rie, Kayla J., et al. "Professional Guidelines and Reported Practice of Audiologists Performing Fall Risk Assessment With Older Adults: A Systematic Review." American Journal of Audiology, vol. 31, no. 1, 2022, pp. 243–260., https://doi.org/10.1044/2021_aja-21-00148.

cost weights in the Geographic Practice Cost Index (GPCI). CMS tracks changes in each component of the index using a set of input price proxies, and the change in each component is then multiplied by that component's cost weight in determining the overall change in the GPCI. In short, the cost weights determine the relative importance assigned to changes in the various input costs.[25] As a result, a rebasing/revision of the MEI can have redistributive effects across various services and hence across specialties and geographies. As the changes CMS contemplates are extensive and are estimated to have substantial effects, CMS does not propose to make any changes in this year's rulemaking cycle but invites comments on its suggested approach for possible action in a future year. The AAN appreciates CMS' caution prior to implementing a potentially disruptive change. This caution is particularly warranted given the ongoing Covid-19 PHE and uncertainty about the Medicare conversion factor.

CMS' principal proposed change would be to use 2017 data derived predominantly from the U.S. Census Bureau's Services Annual Survey (SAS) to replace the AMA's Physician Practice Information Survey (PPIS). The PPIS, last conducted in 2007 and 2008, captured data from 2006 and the sample was limited to self-employed physicians. The proposed new data source is more than a decade more current and represents all types of physician practice ownership.[26]

CMS estimates the effects of the proposed change on cost weights would be to reduce the weight on physician compensation by 3.6 percentage points (from 50.9 percent to 47.3 percent), an effect that CMS attributes to secular changes from 2006 to 2017 in the relative cost of these services and to the more inclusive data on physician ownership. The weight on practice expenses would increase by 3.6 percentage points, mirroring the reduction in the weight on physician compensation. Within the practice expense category, the weight on non-physician compensation would rise by just over eight percentage points and the weight on other practice expenses would fall by about 8.5 percentage points.[27] CMS estimates of the effects by specialty show a range of substantial increases or decreases. To mitigate these effects, CMS proposes to phase in the changes over a four-year period. In general, reductions are more pronounced for facility versus non-facility practices.

The AAN supports efforts to improve the accuracy of data used in rate calculations, which should help to ensure that all physicians are paid more appropriately for their services. Accordingly, replacing a data source over ten years old with a high-quality data source that is more recent, given the pace of technical change in delivery of physician services, appears in general desirable. However, the AAN is aware of several potential methodological flaws that give us pause in recommending implementing this change based on these data. The proposed changes in the category weights are primarily derived from the United States Census Bureau's 2017 Service Annual Survey (SAS) for the "Offices of Physicians" industry, which was not designed with the purpose of updating the MEI. Seven percent of the revenue for "Offices of Physicians" on the 2017 SAS was from non-patient care sources (e.g., grants, investment income) and any expenses associated with these sources cannot be excluded. Additionally, since the SAS for "Offices of Physicians" collects payroll and benefits for all staff combined, CMS is proposing to use a series of complex estimates and assumptions to

[25] 87 Fed. Reg. at 46041.
[26] 87 Fed. Reg. at 46043-46044.
[27] Table 30, 87 Fed. Reg. at 46043.

determine the relative distribution of salaries. These assumptions and estimates are particularly skewed when accounting for practice owners and are likely to significantly underestimate the compensation for practice owners.

The AAN is aware that the AMA is engaged in a methodologically sophisticated effort to update and improve the PPIS 2006 data. The goal of this effort is to ensure consistency and reliability in physician payment when updating the MEI. In support of this effort, the AMA has engaged leading researchers to assist in designing data collection procedures that recognize the complex operational realities of modern physician practices, by, for instance, identifying the best respondents in large practices and creating collection instruments that are likely to yield meaningful results. We understand the AMA's comment letter in response to the MPFS proposed rule will provide a detailed description of its efforts.

Even though it appears that the data from the AMA's new survey may not be available for use until the CY 2025 rulemaking cycle, the quality of the new survey's data may exceed or supplement that of the primary data source proposed by CMS. The data captured will be from 2022, which will be much more up to date than 2017 SAS data. Accordingly, we think it would be worthwhile to wait so that the new data can be considered for rebasing/revising the cost weights. If, alternatively, CMS were to adopt the SAS data for CY 2024, moving to the AMA's new data source thereafter (should that appear desirable once the data can be evaluated) would run the risk of creating even more instability in payment rates, by "yo-yoing" payment rates as one data source succeeded another and was in turn succeeded by a third. Therefore, the AAN strongly recommends that CMS not pursue its proposals to use the SAS data, and instead wait until the AMA survey data is available and then proceed with updating the MEI after considering both data sources.

That said, the AAN endorses the principle of regular and frequent updates in the future to help ensure that payment rates reflect the current underlying realities of work, practice expenses, and malpractice insurance to the greatest extent possible without sacrificing accuracy. If updates in the cost weights were introduced every three to five years and then phased in, the size of any attendant changes in payment rates in a given year would be reduced and the possibility of disruptive effects on physician practices would be minimized. The AAN supports the development of a mechanism to update these data on a more frequent basis. Further, we urge CMS, as it introduces further changes in the data sources and inputs for the MPFS, including not only changes in cost weights but also supply and equipment pricing and clinical staff wage rates, to coordinate introduction and phase-in of these changes to smooth impacts and avoid abrupt and potentially disruptive effects.

Additionally, the AAN requests clarification regarding the projected impacts of the proposed changes. We note inconsistencies across the projections contained in Table 148[28] as opposed to Table 139. [29] Column D of Table 148 claims that the projected impact listed in that column is the same as that listed in Table 139, but the AAN notes that the total impact on neurology in Table 148 Column D is listed as 0%, whereas the total impact in Table 139 is listed as -1%. The AAN also requests clarification regarding the estimated conversion factors listed on Table 148 and notes that none of the conversion factors listed are consistent with the

[28] 87 Fed. Reg. at 46420.
[29] 87 Fed. Reg. at 46390.

proposed conversion factor listed on Table 136 "Calculation of the CY 2023 PFS Conversion Factor."[30]

III. A. Requiring Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts

CMS is proposing new rules to more accurately account for discarded amounts of single-dose container or single-use package drugs, and which require refunds for discarded product that exceeds 10% of the total allowed charge. The AAN shares CMS' concern regarding excessive waste of Part B drugs. Specifically, CMS is proposing rulemaking relating to identifying the quantity of drug being discarded, a definition of which drugs are subject to refunds and exclusions, when and how often CMS will communicate with manufacturers, the development of a new refund calculation methodology, a dispute resolution process, and enforcement provisions. The AAN supports efforts to dissuade wastage based on manufacturer packaging decisions and to mitigate the various factors that influence of wastage of Part B drugs. Beyond requiring rebates, such efforts may include support or encouragement of safe and appropriate use of multi-use vials or vial sizes that provide greater flexibility to reduce wastage.

The AAN is concerned that in response to this proposal, manufacturers may raise the price of certain drugs to compensate for the cost of any refund payments. The AAN urges CMS to ensure that implementation is closely monitored, and appropriate action is taken to dissuade any manufacturer from compensating for lost revenue with a price increase.

Discarded Amounts

CMS is proposing to amend current policy relating to the use of modifiers on claims for Part B drugs. Under current policy, on claim forms, the amount of drug administered is billed on one line and discarded amounts are billed on a separate line using the JW modifier. There is currently no additional modifier required to confirm if there is no drug discarded. To more precisely identify the amount of waste, CMS proposes the addition of the JZ modifier to be applied if there is no discarded drug from a single-use container or single-dose drug. CMS believes this will mitigate the confusion that currently exists when the JW modifier is left off a claim, which can be due to either there being no discarded drug, or the JW modifier being incorrectly left off the claim.

While the AAN is supportive of CMS' goal of more accurately accounting for systematic wastage of Part B drugs due to packaging decisions made by the manufacturer, the AAN is concerned that this proposal could result in a significant increase in claim denials and appeals. Providers already use and are familiar with the JW modifier and implementation of the JZ modifier is likely to require significant educational efforts to ensure compliance. The AAN strongly supports CMS requiring manufacturers to provide refunds for wastage, but not at the expense of potential increases in claim denials and audits on providers. It is also worth noting that there is a possibility that the wastage of a drug paid for by the manufacturer via a rebate may simply be passed along to the patient in the form of a price increase.

[30] 87 Fed. Reg. at 46386.

Refundable single-dose container or single-use package drug

CMS proposes the definition of "refundable single-dose container or single-use package drug" would apply to drugs paid under Medicare Part B and are described as being supplied in a "'single-dose' container or 'single-use' package based on FDA-approved labeling or product information."[31] CMS also proposes to add a new definition of "refundable single-dose container or single-use package drug," which would be defined to mean "a single source drug or biological or a biosimilar biological product for which payment is made under this part and that is furnished from a single-dose container or single-use package based on FDA-approved labeling or product information, except as otherwise specified."[32] In alignment with authorizing statute, CMS is proposing a number of exclusions and clarifies that for a drug to meet the definition of a product that would be subject to a refund, all national drug codes assigned to the drug's billing and payment code must be single-dose containers or single-use packages. Under the proposed approach to exclusions, radiopharmaceuticals or imaging agents, drugs that require filtration during the drug preparation process, and drugs approved on or after the date of enactment of the Infrastructure Act (that is, November 15, 2021) for which payment under Part B has been made for fewer than 18 months would be excluded. The AAN supports the definitions and exclusions as proposed.

The AAN requests that CMS examine the implications of these proposals on products commonly used in neurology. The AAN believes that there are several products commonly utilized by neurologists that are currently packaged in a manner that drives significant wastage. For example, onabotulinumtoxinA (Botox) comes in vial sizes of 50 units, 100 units, and 200 units. Dosage recommendations for indications for which Botox may be used range from 10 units for hemifacial spasm to 155 units for migraine.[33] Neurology indications often require individual flexibility in dosing for each patient at each visit. The AAN supports strategies to encourage provision of more flexible options for dosing in single-use packaging. Therefore, the AAN also urges CMS to provide guidance to the FDA to encourage, or in some cases require, manufacturers to develop and implement new medication dosing and packaging that would limit the need for discarded drugs from single-dose containers or single-use packages.

III. E. Removal of Selected National Coverage Determinations

In May of 2020 the AAN was a part of a collaborative request with the American Clinical Neurophysiology Society (ACNS) and the National Association of Epilepsy Centers (NAEC) to remove National Coverage Determination (NCD) 160.22 Ambulatory EEG Monitoring and allow coverage to be determined by local Medicare contractors.[34] We would like to thank the agency for including the NCD for consideration in the proposed rule and notes that the rationale for doing so is fully in alignment with recommendations submitted by the AAN,

[31] 87 Fed. Reg. at 46058.
[32] 87 Fed. Reg. at 46059.
[33] Botox prescribing information found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/103000s5236lbl.pdf
[34] See AAN, ACNS, and NAEC comments found at: https://www.aan.com/siteassets/home-page/policy-and-guidelines/advocacy/letter-to-cms-to-remove-ncd-160.22-ambulatory-eeg-monitoring_final.pdf

ACNS, and NAEC. In the case of NCD 160.22, with an effective date of June 12, 1984, the AAN supports the action to remove the NCD, as proposed, allowing for coverage to be determined by the Medicare Administrative Contractors.

III. G. Medicare Shared Savings Program

Increasing Participation in Accountable Care Models in Underserved Communities by Providing an Option for Advance Investment Payments to Certain ACOs

Building on the evaluation of the Accountable Care Organization (ACO) Investment Model, CMS is proposing to make advance shared savings payments, referred to in the rule as advance investment payments (AIPs), to certain ACOs participating in the Shared Savings Program. The goal of this proposal is to support ACOs in providing accountable care for underserved beneficiaries.

The AAN notes that ACOs are one of the few APMs that are currently available for neurologist participation. The AAN firmly believes that neurologists should have the opportunity to participate in the transition of the healthcare system towards value-based care through Advanced APMs and Merit-based Incentive Payment System (MIPS) APMs. As such, the AAN believes it is critical to support ACOs and to ensure that ACOs can provide care to all Medicare beneficiaries. The AAN believes that targeted advanced payments, based on beneficiary risk profile, are an appropriate way to ease up-front costs for inexperienced, low-revenue ACOs and to support ACOs in providing accountable care for underserved beneficiaries. The AAN supports CMS' proposal that AIPs must be used to improve the quality and efficiency of items and services furnished to beneficiaries by investing in increased staffing, health care infrastructure, and the provision of accountable care for underserved beneficiaries, which may include addressing social determinants of health.

Smoothing the Transition to Performance-Based Risk

The AAN strongly supports CMS' proposals to allow certain ACOs more time under a one-sided model and more flexibility in transitioning to higher levels of risk and potential reward by modifying the participation options available under the Medicare Shared Savings Program (MSSP). When changes were proposed in 2018 to the MSSP to redesign the existing MSSP tracks and limit access to one-sided risk ACOs, the AAN expressed concern that changes would limit program participation.[35] Since changes were finalized, the AAN's predictions have come to fruition, necessitating a substantial change in policy.

The AAN supports CMS' goal to "provide ACOs with a more gradual on-ramp to taking on two-sided risk and to allow them the flexibility they need to best ensure their readiness to take on two-sided risk."[36] ACOs need enough time to optimize processes in the early stages of their development and should not be expected to prematurely take on downside risk before they are ready. Furthermore, prematurely assuming downside risk can be especially problematic for providers in rural areas and safety-net organizations, for whom patients are generally more vulnerable and harder to effectively manage. As such, the AAN strongly

[35] See AAN comments found at: https://downloads.regulations.gov/CMS-2018-0101-0081/attachment_1.pdf
[36] 87 Fed. Reg. at 46117.

supports CMS' proposal to allow an ACO that enters the BASIC track's glide path at Level A and is currently at Level A to elect to remain in Level A for all subsequent performance years of the agreement period, for agreement periods beginning on or after January 1, 2024. The AAN concurs with CMS that this proposal is likely to encourage more ACOs to form and join the program, as well as encourage currently participating ACOs to remain in the program.

Proposal to Remove the Limitation on the Number of Agreement Periods an ACO can Participate in Level E of the BASIC Track

The AAN supports CMS' proposal to allow ACOs to participate indefinitely under the BASIC track, Level E, or the ENHANCED track. The AAN concurs with CMS that it is in the best interest of Medicare beneficiaries to allow ACOs to continue participating under the highest level of the BASIC track indefinitely, rather than risk a significant number of experienced and successful ACOS terminating their participation in the program. ACOs that reach Level E of the BASIC track qualify as Advanced APMs and given limited opportunities for neurologists to meaningfully participate in APMs, it is critical that ACOs who have achieved Advanced APM status are not effectively forced out of the program due to burdensome compliance requirements and the need to take on greater financial risk.

III. L. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD Plan (Section 2003 of the SUPPORT Act)

Proposed Changes to Exceptions –- Cases Where Prescribers Issue Only a Small Number of Part D Prescriptions

CMS is proposing to modify the small prescriber exception for the Electronic Prescribing for Controlled Substances (EPCS) program so that the exception more directly aligns the timeframes of data used to evaluate prescribing patterns with the year in which an exception is applied. Specifically, CMS is proposing to use same year data to evaluate whether a clinician meets the criteria for the small prescriber exception. As such, "neither CMS nor an individual prescriber will be able to determine until after the evaluation year whether or not the individual prescriber qualifies as a 'small prescriber' unless the prescriber tracks the number of Medicare Part D controlled substance prescriptions the prescriber issues during the evaluation year."[37] The AAN is concerned that this proposal will create significant uncertainty for providers who frequently are close to the threshold in a given year for eligibility for the small prescriber exception. These providers may not be able to utilize the exception in a given year, since they are unlikely to be able to predict with sufficient precision whether they will meet or exceed the exception threshold. A provider who expects to receive the exception because they have received the exception in past years may not also be adequately equipped to meet EPCS program requirements in a year in which their prescribing volume unexpectedly increases to exceed the threshold. The AAN believes the current methodology for determining the exception provides prescribers with much-needed clarity and urges CMS to refrain from finalizing its proposed modifications to this exception.

[37] 87 Fed. Reg. at 46239.

Penalties

CMS is soliciting feedback to ensure that penalties do not place too much of a burden on prescribers, to avoid the unintended consequence of incentivizing prescribers to stop prescribing controlled substances to Part D beneficiaries. The AAN agrees that this is a critical consideration as the agency moves forward with developing penalties to go into effect no sooner than January 1, 2025. The AAN urges the agency to consider the need to appropriately balance reporting burden and any disincentives placed on relatively low volume prescribers, with the need to sufficiently dissuade potential high-volume violators.

IV. Updates to the Quality Payment Program

Transforming MIPS: MVP Strategy

The AAN appreciates CMS' continued efforts to make quality measurement through the MIPS program more meaningful to clinicians through the establishment of MIPS Value Pathways (MVPs). However, we remain concerned that the new framework will present many of the same issues that MIPS currently suffers from, while also creating additional challenges within many specialty or condition-specific pathways that will be difficult to manage and compare for both CMS and stakeholders developing MVPs. We believe that ideally MVPs would be aimed towards addressing the fundamental issues within the current MIPS program, but the proposals included in this rule do not appear to make participation, reporting and scoring more streamlined, nor do they demonstrate the clear advantages of MVPs over MIPS in driving quality of care or containing costs. The AAN looks forward to continuing our collaborative relationship with CMS during future MVP development; however, we do have concerns that MVPs will accomplish little more than MIPS in its current state and in its efforts to transition clinicians into alternative payment models (APMs). To date, the value that MIPS has yielded for neurology in terms of cost containment and quality improvement, is not clear.

The AAN has engaged with CMS on the development of all three MVPs proposed to be launched in 2023 that are relevant to neurology (Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes, Optimal Care for Patients with Episodic Neurological Conditions, and Supportive Care for Neurodegenerative Conditions). The AAN is grateful for the transparency, collaboration, and regard for the AAN's expertise that CMS demonstrated throughout this process. The AAN is interested in learning more from CMS regarding next steps for these and other neurology MVPs and looks forward to continued collaboration with CMS on MVPs that include condition-specific cost measures and quality measures that allow for meaningful participation in MVPs.

The AAN finds these MVPs, as proposed, to be an amenable starting point for MVPs in neurology, as they capture various common neurological conditions and divide them into episodic and chronic categories. Please note, some neurological conditions are progressive, with episodic flareups, such as relapsing remitting multiple sclerosis and myasthenia gravis and might not fit into the MVPs as currently delineated. Additionally, there are monophasic or single episode conditions such as Guillain-Barre, meningitis, and other neurologic illnesses that would not fit into these current categories. The AAN hopes that as additional

quality measures related to these and other conditions are tested and deemed eligible for use in the Quality Payment Program, that neurology MVPs will adapt to be more reflective of the diversity of neurological conditions that neurologists and neurology providers treat, and additional MVPs will be developed to capture these differences.

In addition to the MVP previously finalized, the AAN supports the inclusion of the two additional neurology MVPs (Optimal Care for Patients with Episodic Neurological Conditions and Supportive Care for Neurodegenerative Conditions) for use in CY2023 but notes that if adoption by neurology providers is the intention, developing neurology MVPs relevant to the outpatient setting must be prioritized. Clinician uptake of the two newly proposed MVPs relevant to neurology will be limited without access to a meaningful cost measure. The MSPB cost measure will not be applicable to neurologists who work in solo or small practices focused on outpatient care. MVPs for these clinicians must include outpatient-relevant cost measures. Specialty societies, like the AAN, lack the resources to develop meaningful cost measures as there is a lack of access to Medicare cost data that would allow for development of episodic cost measures. Without meaningful cost measures, it is not likely many clinicians will begin to adopt MVPs. CMS must dedicate funds to the rapid development of meaningful cost measures to ensure the success of MVPs prior to sunsetting MIPS. Participating providers, and the organizations that support them, will also need time to understand and educate clinicians on the new MVPs and determine how to best utilize these pathways. Given that this rule will be finalized approximately two months before January 1, 2023, there will be substantial challenges associated with developing and disseminating the necessary education so that providers are prepared to meaningfully participate in the newly proposed models in such a condensed timeframe.

Additionally, the AAN requests further guidance on whether there will be incentives for providers to report MVPs. Given the ongoing stresses that COVID-19 and workforce shortages have put on the healthcare system, as well as the potential burden of implementing multiple MVPs in clinical settings, we believe that there is little appetite among providers to voluntarily participate in MVPs without having first demonstrated the value of MVPs or offering incentives to participate in the early years of the framework. There is also a significant concern that MVP participants may perform worse and be subject to either a negative payment adjustment or a lesser positive payment adjustment than MIPS-eligible clinicians who do not participate in an MVP. We recommend, in order to increase participation and to improve measures based on real world evidence of their use, that clinicians who participate in MVPs should either be held harmless from receiving a negative performance adjustment for a designated transition period or be given an incentive within the first few years of implementation. To address the burdens associated with reporting MVPs, the AAN recommends that CMS consider ways to work with the Office of the National Coordinator (ONC) to promote the integration of reporting through existing electronic health record (EHR) technology. It would be highly beneficial to providers if MVP requirements could be integrated through existing EHR technology to identify visits that fit MVP criteria and facilitate relevant measure reporting.

The AAN is supportive of the proposal to initiate a comment period when soliciting feedback from stakeholders, such as the AAN, during the development process of these MVPs by posting model drafts online. However, we believe CMS should consider a 60-day comment

period in order to maximize stakeholder input. The AAN requests clarification regarding whether CMS will still reach out to relevant stakeholders when considering development of an MVP that will impact a particular specialty or set of specialties, or if it will be the responsibility of specialty societies to monitor for and respond to open notices for comment. Additionally, will CMS consider feedback received outside of the comment period or will feedback only be accepted during the comment period?

MVP Development and Reporting Requirements

Feedback on Measures Contained in Neurology-Relevant MVPs

The AAN has previously submitted extensive feedback to CMS on the neurology-relevant MVPs that are proposed to be made available in 2023. A summary of the AAN's final recommendations on the various measures contained in the Quality, Improvement Activities, and Cost MIPS performance categories for each MVP is below.

Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP

Quality Performance Category

Quality Measures (9 Quality Measures Total)	**AAN Feedback**
Q047: Advance Care Plan (Medicare Part B Claims, MIPS CQM) High Priority	We understand the rationale for inclusion of this measure within the MVP.
Q187: Stroke and Stroke Rehabilitation: Thrombolytic Therapy (Collection Type: MIPS CQMs Specifications)	We agree with the inclusion of this measure within the MVP.
Q236: Controlling High Blood Pressure (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications)	We agree with the inclusion of this measure within the MVP.
Q326: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy (Collection Type: MIPS CQMs Specifications)	We recommend removing this measure given recent suppression of performance rates for CY 2022 and past concerns that it has topped out.
Q344: Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) (Collection Type: MIPS CQMs Specifications)	We recommend removing this measure as it is outside the scope of neurologists.
Q409: Clinical Outcome Post Endovascular Stroke Treatment (Collection Type: MIPS CQMs Specifications)	We agree with the inclusion of this measure within the MVP.
Q413: Door to Puncture Time for Endovascular Stroke Treatment (Collection Type: MIPS CQMs Specifications)	We agree with the inclusion of this measure within the MVP.
Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Collection Type: eCQM Specifications, MIPS CQMs Specifications)	We agree with the inclusion of this measure within the MVP.

Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) (Collection Type: MIPS CQMs Specifications)	We recommend removing as the measure specifications target performance to primary care provider or cardiologist. Further, all or none measures are unlikely to be adopted given complexity and burden, which hinders the ability to generate meaningful quality improvement data.

Improvement Activity Performance Category

Improvement Activities (9 Improvement Activities Total)	**AAN Feedback**
IA_BE_1: Use of certified EHR to capture patient reported outcomes (Medium)	We agree with the inclusion of this improvement activity in this MVP.
IA_BE_4: Engagement of patients through implementation of improvements in patient portal (Medium weight)	We agree with the inclusion of this improvement activity in this MVP.
IA_BE_24: Financial Navigation Program (Medium)	We agree with the inclusion of this improvement activity in this MVP.
IA_CC_2: Implementation of improvements that contribute to more timely communication of test results (Medium)	We agree with the inclusion of this improvement activity in this MVP.
IA_CC_13: Practice improvements for bilateral exchange of patient information (Medium)	We agree with the inclusion of this improvement activity in this MVP.
IA_CC_17: Patient Navigator Program (High)	We agree with the inclusion of this improvement activity in this MVP.
IA_PCMH: Implementation of Patient-Centered Medical Home model	We agree with the inclusion of this improvement activity in this MVP.
IA_PM_13: Chronic care and preventative care management for empaneled patients (Medium)	We agree with the inclusion of this improvement activity in this MVP.
IA_PM_15: Implementation of episodic care management practice improvements (Medium)	We agree with the inclusion of this improvement activity in this MVP.

Cost Performance Category

Cost Measure(s)	**AAN Feedback**
Intracranial Hemorrhage or Cerebral Infarction	We understand the rationale for including this cost measure in the MVP.

Optimal Clinical Support for Patients with Episodic Neurological Conditions MVP

Quality Performance Category

Quality Measures (10 Quality Measures Total 4 MIPS Quality Measures & 6 QCDR Measures)	**AAN Feedback**
Q047: Advance Care Plan (Medicare Part B Claims, MIPS CQM) High Priority	We agree with the inclusion of this measure within the MVP.
Q130: Documentation of Current Medications in the Medical Record (Medicare Part B Claims, MIPS CQM, eCQM)	We agree with the inclusion of this measure within the MVP.
Q268: Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy (MIPS CQM)	We agree with the inclusion of this measure within the MVP.
Q419: Overuse of Imaging for the Evaluation of Primary Headache (MIPS CQM) High Priority	We agree with the inclusion of this measure within the MVP.
AAN5: Medication Prescribed for Acute Migraine Attack (QCDR)	We agree with the inclusion of this measure within the MVP.
AAN22: Quality of Life Outcome for Patients with Neurologic Conditions (QCDR) High Priority, Outcome	We agree with the inclusion of this measure within the MVP.
AAN29: Comprehensive Epilepsy Care Center Referral or Discussion for Patients with Epilepsy (QCDR)	We agree with the inclusion of this measure within the MVP.
AAN30: Migraine Preventive Therapy Management (QCDR)	We agree with the inclusion of this measure within the MVP.
AAN31: Acute Treatment Prescribed for Cluster Headache (QCDR)	We agree with the inclusion of this measure within the MVP.
AAN32: Preventive Treatment Prescribed for Cluster Headache (QCDR)	We agree with the inclusion of this measure within the MVP.

Improvement Activity Performance Category

Improvement Activities (14 Improvement Activities Total)	**Feedback**
IA_AHE_3: Promote Use of Patient-Reported Outcome Tools (High weight)	We agree with the inclusion of this improvement activity in this MVP.
IA_BE_4: Engagement of patients through implementation of improvements in patient portal (Medium weight)	We agree with the inclusion of this improvement activity in this MVP.
IA_BE_16: Promote Self-management in Usual Care (Medium weight)	We agree with the inclusion of this improvement activity in this MVP.
IA_BE_24: Financial Navigation Program (Medium weight)	We agree with the inclusion of this improvement activity in this MVP.
IA_BMH_4: Depression screening (Medium weight)	We agree with the inclusion of this improvement activity in this MVP.

IA_BMH_8: Electronic Health Record Enhancements for BH data capture (Medium weight)	We agree with the inclusion of this improvement activity in this MVP.
IA_CC_1: Implementation of use of specialist reports back to referring clinician or group to close referral loop (Medium weight)	We agree with the inclusion of this improvement activity in this MVP.
IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High weight)	We agree with the inclusion of this improvement activity in this MVP.
IA_EPA_2: Use of telehealth services that expand practice access (Medium weight)	We agree with the inclusion of this improvement activity in this MVP.
IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation	We agree with the inclusion of this improvement activity in this MVP.
IA_PM_11: Regular review practices in place on targeted patient population needs (Medium weight)	We agree with the inclusion of this improvement activity in this MVP.
IA_PM_16: Implementation of medication management practice improvements (Medium weight)	We agree with the inclusion of this improvement activity in this MVP.
IA_PM_21: Advance Care Planning (Medium weight)	We agree with the inclusion of this improvement activity in this MVP.
IA_PSPA_21: Implementation of fall screening and assessment programs (Medium weight)	We understand the rationale for inclusion of this improvement activity in this MVP.

Cost Performance Category

Cost Measure(s)	**Feedback**
Medicare Spending Per Beneficiary (MSPB) Clinician	We understand the rationale for including this cost measure in the MVP.

Supportive Care for Neurodegenerative Conditions

Quality Performance Category

Quality Measures (13 Quality Measures Total 10 MIPS Quality Measures & 3 QCDR Measures)	**Feedback**
Q047: Advance Care Plan (Medicare Part B Claims, MIPS CQM) High Priority	We agree with the inclusion of this measure within the MVP.
Q238: Use of High-Risk Medications in Older Adults (eCQM, MIPS CQM) High Priority	We agree with the inclusion of this measure within the MVP.
Q281: Dementia: Cognitive Assessment (eCQM)	We agree with the inclusion of this measure within the MVP.

Q282: Dementia: Functional Status Assessment (MIPS CQM)	We agree with the inclusion of this measure within the MVP.
Q286: Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia (MIPS CQM) High Priority	We agree with the inclusion of this measure within the MVP.
Q288: Dementia: Education and Support of Caregivers for Patients with Dementia (MIPS CQM) High Priority	We agree with the inclusion of this measure within the MVP.
Q290: Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease (MIPS CQM)	We agree with the inclusion of this measure within the MVP.
Q291: Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease (MIPS CQM)	We agree with the inclusion of this measure within the MVP.
Q293: Rehabilitative Therapy Referral for Patients with Parkinson's Disease (MIPS CQM) High Priority	We agree with the inclusion of this measure within the MVP.
Q386: Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences (MIPS CQM) High Priority	We agree with the inclusion of this measure within the MVP.
AAN9: Querying About Symptoms of Autonomic Dysfunction for Patients with Parkinson's Disease (QCDR)	We agree with the inclusion of this measure within the MVP.
AAN22: Quality of Life Outcome for Patients with Neurologic Conditions (QCDR) High Priority, Outcome	We agree with the inclusion of this measure within the MVP.
AAN34: Patient reported falls and plan of care (QCDR) High Priority, Outcome	We agree with the inclusion of this measure within the MVP.

Improvement Activity Performance Category

Improvement Activities (14 Improvement Activities Total)	**Feedback**
IA_AHE_3: Promote Use of Patient-Reported Outcome Tools (High weight)	We agree with the inclusion of this improvement activity in this MVP.
IA_BE_4: Engagement of patients through implementation of improvements in patient portal (Medium weight)	We agree with the inclusion of this improvement activity in this MVP.
IA_BE_16: Promote Self-management in Usual Care (Medium weight)	We agree with the inclusion of this improvement activity in this MVP.
IA_BE_24: Financial Navigation Program (Medium weight)	We agree with the inclusion of this improvement activity in this MVP.
IA_BMH_4: Depression screening (Medium weight)	We agree with the inclusion of this improvement activity in this MVP.
IA_BMH_8: Electronic Health Record Enhancements for BH data capture (Medium weight)	We agree with the inclusion of this improvement activity in this MVP.

IA_CC_1: Implementation of use of specialist reports back to referring clinician or group to close referral loop (Medium weight)	We agree with the inclusion of this improvement activity in this MVP.
IA_EPA_2: Use of telehealth services that expand practice access (Medium weight)	We agree with the inclusion of this improvement activity in this MVP.
IA_EPA_2: Use of telehealth services that expand practice access (Medium weight)	We agree with the inclusion of this improvement activity in this MVP.
IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation	We agree with the inclusion of this improvement activity in this MVP.
IA_PM_11: Regular review practices in place on targeted patient population needs (Medium weight)	We agree with the inclusion of this improvement activity in this MVP.
IA_PM_16: Implementation of medication management practice improvements (Medium weight)	We agree with the inclusion of this improvement activity in this MVP.
IA_PM_21: Advance Care Planning (Medium weight)	We agree with the inclusion of this improvement activity in this MVP.
IA_PSPA_21: Implementation of fall screening and assessment programs (Medium weight)	We agree with the inclusion of this improvement activity in this MVP.

Cost Performance Category

Cost Measure(s)	**Response**
Medicare Spending Per Beneficiary (MSPB) Clinician	We understand the rationale for including this cost measure in the MVP.

APM Performance Pathway

APP Reporting Options

CMS is clarifying regulatory text to make it clear that subgroup reporting under the APM performance pathway (APP) is not allowed under current rules. CMS notes that there is potential ambiguity in the current regulation that was not intended by the agency. Although this clarification is not intended to represent a change in policy, CMS indicates that there may be scenarios in which a group may have an interest in reporting for the APP through subgroups.

If CMS were to consider allowing APP reporting through subgroups, the AAN strongly urges the agency to ensure that this is a voluntary option. While we understand that subgroups may more meaningfully measure clinicians in select circumstances, we are concerned about the administrative burden of maintaining and reporting for subgroups within a multispecialty practice. The AAN believes that subgroup reporting could quickly become unwieldy for groups to maintain if multiple subgroups are formed within its TIN, which would be at odds

with CMS' goal to develop more streamlined and less burdensome reporting options. In addition, nuanced requirements and changes between group and subgroup reporting are confusing and may be onerous for groups to track and maintain. Given the existing ambiguity that is being corrected by CMS, the AAN strongly urges that the agency use caution before implementing any further requirements or options that may create additional regulatory burden or ambiguity.

MIPS Performance Category Scoring

Quality Performance Category

Quality Data Submission Criteria

CMS is proposing to amend the definition of the term high priority measure to include health equity measures. Specifically, starting in the CY 2023 performance period, CMS will update the term high priority measure to mean "an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, opioid, or health equity-related quality measure."[38] The AAN supports this updated definition and believes addressing persistent inequities in health care outcomes existing in the United States, including among Medicare patients, ought to be prioritized by CMS policy.

Screening for Social Drivers of Health Proposed Measure

CMS believes it is important to delineate between key terms used to describe health-related social needs, including social determinants of health, social risk factors, and drivers of health (DOH). CMS has adopted DOH to capture more holistically "related concepts while minimizing potential misinterpretation and/or negative connotation."[39] CMS is proposing the adoption of an evidence-based DOH measure, which would enable systematic collection of DOH data. The AAN agrees with the CMS effort to raise awareness of DOH for patients and healthcare teams. "Screening for Social Drivers of Health" (food insecurity, housing instability, transportation problems, utility difficulties, and interpersonal safety), may help the healthcare team understand potential barriers to better patient health outcomes.

The AAN believes that CMS must recognize that DOH and inequities in health reach far beyond the control of a medical team and are rooted in societal policies impacting equity in education, housing, and income. The AAN firmly believes that healthcare providers and teams must never be accountable for and paid based on the amelioration of patients' DOH. The AAN has significant concerns about a quality measure to assess clinician referrals to community-based services to address DOH, including:

1) attribution (which provider is accountable)
2) risk adjustment (what risk factors affect the likelihood of better or worse outcomes in patients)
3) unintended consequences (refusal to see or dropping patients)

[38] 87 Fed. Reg. at 46277.
[39] 87 Fed. Reg. at 46280.

4) the impact on an already stressed and underfunded social service system
5) the likelihood that this is a checkbox measure not reflective of meaningful engagement in community-based services
6) potential competition with chronic condition management, assessment of acute symptoms, medication reconciliation, assessment and management of treatment side effects, and creation of treatment plans.

Measures such as this are more appropriate for Federally Qualified Health Centers (FQHCs), given that FQHCs are provided financial resources to address DOH including access to care, affordable medication, and funding for hiring staff that will connect patients with external resources (e.g., food banks, shelters for the homeless and domestic violence survivors). If CMS wants private and public health organizations to measure equity, they should consider allowing these organizations to apply for the same grants made accessible to FQHCs.

MIPS Quality Performance Category Health Equity Request for Information

To facilitate efforts to reduce health inequities, CMS is considering the development of broadly applicable health equity measures for potential use within traditional MIPS and MVPs. In support of this effort, CMS is soliciting comments to better understand the type and structure of health equity measures that would be appropriate for implementation in MIPS.

The AAN wholeheartedly agrees that there is an opportunity to improve data collection of race and ethnicity data. Improved data collection on these variables will lead to better risk adjustment strategies, provide the necessary data to assess disparities in health, and ideally lead to a decrease in inequities in health outcomes. In 2022, the AAN used its Axon Registry® to explore the availability of race and ethnicity data. Low levels of data in these fields resulted in an AAN position paper encouraging neurology practices to collect demographic data in a patient-centered and standardized way. The AAN supports a common tool with coded questions and standardized data elements to collect these data. The AAN believes this tool should be required for certification of electronic health record systems. Without requiring implementation of standardized data fields for race, ethnicity, preferred language, gender identity, and sexual orientation across EHR vendors, adoption will be variable.

Developing Quality Measures that Address Amputation Avoidance in Diabetic Patients Request for Information

CMS is exploring the development of a process quality measure, as well as a composite measure, for inclusion in MIPS, designed to reduce the risk of lower extremity amputation among patients with diabetes. The AAN appreciates CMS raising awareness of the concerns and challenges faced by patients with painful diabetic neuropathy. The AAN believes measurement of neuropathic pain is important and in 2022 released a measurement set that includes three measures.[40] The three measures are:

[40] Full specifications available at: https://www.aan.com/siteassets/home-page/policy-and-guidelines/quality/quality-measures/polyneuropathy-measures.pdf

1. Avoidance of opioid medications for patients with diabetic neuropathy,
2. Pain assessment and follow-up for patients with diabetic neuropathy
3. Reduction of pain for patients with polyneuropathy.

The reduction of pain for people with polyneuropathy measure is an outcome measure focusing on a broader population of patients. The denominator assures there is a significant population of individuals who are included and addresses care for patients that have painful neuropathy beyond those diagnosed with diabetes.

The AAN believes that development of a composite measure is premature, and the proposed composite measure is unlikely to be meaningful for clinicians. The individual components of the composite measure are more reflective of team-based care and not individual clinician performance.

Scoring administrative claims measures in the quality performance category using performance period benchmarks

CMS is proposing to amend the benchmarking policy to score administrative claims measures in the quality performance category using a benchmark calculated from performance period data. The AAN supports this proposal. Practices are already dependent on CMS for these data and without a feedback loop on performance, the ability to use the data for quality improvement is reduced. The calendar year proposed allows for the implementation of quality improvement efforts.

Improvement Activities Performance Category

CMS is proposing to update the improvement activities performance category through the inclusion of four new improvement activities, modification of five existing activities, and removal of five existing activities from the inventory. The AAN supports the updates to the improvement activities inventory.

Cost Performance Category Score

Improvement Scoring Methodology

In the CY 2018 Quality Payment Program final rule, CMS established policies related to measuring improvement in the cost performance category at the measure level, an improvement scoring methodology for the cost performance category, and a formula for calculating the cost performance category percent score to include both achievement and improvement. These policies were subsequently delayed due to provisions of the Bipartisan Budget Act of 2018, which disallowed CMS from accounting for cost improvement until the 2022 performance year (PY 2022). Although the agency failed to address cost improvement in rulemaking prior to PY 2022, it is the agency's view that it is "necessary to comply with the requirement of section 1848(q)(5)(D) of the Act that we take in to account the improvement of the MIPS eligible clinician when scoring the cost performance category"[41] starting in PY 2022. Although the AAN understands that the agency may not have flexibility

[41] 87 Fed. Reg. at 46316.

due to the statute, the AAN is deeply concerned by a mid-year change in scoring methodology that will not be finalized until November of the same performance year. The AAN strongly urges the agency to ensure appropriate diligence in future rulemaking so that such a significant oversight does not occur again.

To implement this statutory requirement, CMS believes that it would be appropriate to begin gradually with a maximum cost improvement score of 1 percentage point. The AAN supports gradual implementation of this requirement and urges transparency from CMS on how the improvement scoring methodology has impacted both clinicians' scores within the cost performance category and the overall payment adjustment that clinicians receive under MIPS.

Promoting Interoperability Performance Category

Changes to the Query of Prescription Drug Monitoring Program (PDMP) Measure under the Electronic Prescribing Objective

Beginning with the 2023 performance period, CMS is proposing to require the previously optional Query of PDMP measure for MIPS eligible clinicians participating in the Promoting Interoperability (PI) performance category. The AAN believes that this is reasonable once every state has an operational PDMP. The AAN does note that there are variations across states and at least one state is still working to make its PDMP operational. For prescribers who see patients that may have sought or received care in a different state, accessing PDMP information across state lines can be a challenge. Some states have now begun to charge for access to the interface between the EHR and the PDMP, representing additional expense associated with complying with this measure. The AAN also notes that there continue to be challenges for patients who have received care through the Veterans Administration.

The AAN supports the proposed measure description: "For at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a PDMP for prescription drug history."[42] The AAN believes that given existing state requirements, this requirement balances CMS' interest in promoting PDMP engagement with the need to minimize compliance burden. CMS is inviting public comment on whether to expand this measure to include Schedule V or other drugs with potential for abuse. The AAN does not support expanding the description of this measure to include schedule V or other drugs and notes that such a requirement may be overly burdensome and take time away from patient care.

CMS is also proposing two exclusions for this measure beginning with the performance period in CY 2023: "(1) Any MIPS eligible clinician who is unable to electronically prescribe Schedule II opioids and Schedule III and IV drugs in accordance with applicable law during the performance period, and (2) Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period."[43] The AAN supports the

[42] 87 Fed. Reg. at 46289.
[43] Id.

proposed measure exclusions and believes they reasonably balance the need to prevent inappropriate prescribing with potential cost and administrative burdens.

CMS is requesting comment regarding what information returned from the PDMP query would be clinically significant. The AAN believes that the most significant information includes the name of the drug(s) prescribed, including strength and quantity, as well as information relating to the prescribing physician. AAN members note that when querying the PDMP that there have been instances in which they have only received the first two letters of the first and last name of the prescribing physician, which can make conversation with the patient difficult. Additionally, pharmacy information would be helpful.

Modifications to the Public Health and Clinical Data Exchange Objective

The AAN supports CMS' increased emphasis on promoting public health and clinical data exchange. This need is heightened by the ongoing Covid-19 PHE, as well as the growing body of evidence demonstrating the link between post-acute sequelae of SARS-CoV-2 infection, commonly referred to as "Long Covid" or "PASC." According to one study, one-third of patients diagnosed with COVID-19 developed psychiatric or neurologic disorders within six months, including depression, anxiety, stroke, and dementia.[44] In that same study, researchers who evaluated more than 230,000 electronic health records, which includes anonymous data from 81 million patients primarily in the US, found that among COVID-19 patients admitted to an intensive care unit, the incidence of developing a psychiatric or neurologic disorder rose to 46 percent.[45] EHR data reporting to public health and clinical data registries present a critical opportunity to better understand and respond to PASC. Without proper information sharing, patients could suffer devastating consequences and misdiagnoses. Additionally, understanding the core causes of PASC will make it easier for providers to identify patients who are more at risk of developing chronic symptoms, while allowing for the provision of early interventions.

The AAN also believes that public health reporting is growing to be increasingly important for conditions beyond infectious disease, including Parkinson's disease and multiple sclerosis, as well as for post-vaccine surveillance for Guillan-Barre syndrome. The AAN strongly supports taking the steps needed to improve the capture of this information.

Although the AAN is supportive of CMS' broader goal, the AAN is concerned with CMS' proposal to modify the threshold for active engagement under the Public Health and Clinical Data Registry Reporting Objective. CMS is specifically proposing to consolidate pre-production and validation into a single stage to demonstrate active engagement. The AAN urges CMS to reconsider this proposal and notes that we support the measure as currently structured, with separate stages for pre-production and validation. This is necessary so that practices have adequate time to negotiate and test new and changing technical integration policies that are often needed to bring up reporting to the production stage. The AAN also urges CMS to allow for necessary flexibility in the timeline before a practice must advance to each stage in the cycle to demonstrate active engagement.

[44] Bender, Eve. "6 Months after COVID-19 Infection, 1 in 3 Develop a Psychiatric or Neurologic Diagnosis." Neurology Today, vol. 21, no. 11, 2021, https://doi.org/10.1097/01.nt.0000755768.68019.f5.
[45] Id.

Health Information Exchange Objective: Proposed Addition of an Alternative Measure for Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA)

CMS is proposing to add an additional measure through which a MIPS eligible clinician could earn full credit for the Health Information Exchange (HIE) Objective by connecting to an entity that connects to a Qualified Health Information Network (QHIN) or connecting directly to a QHIN. The AAN supports the addition of this measure as an option under the existing HIE objective. The AAN strongly supports efforts to build alignment across vendors and exchanges to promote interoperable data exchange across the healthcare system and believes that this measure will aid in the transition towards a healthcare system that is better equipped to accurately exchange information. The AAN notes that these efforts must appropriately account for potential burdens being placed on providers and appreciates that this measure is one of several options available to achieve full credit under the HIE objective.

Patient Access to Health Information Measure – Request for Information

CMS is seeking feedback regarding how to further promote equitable patient access to and use of their health information without adding unnecessary burden on MIPS-eligible clinicians or
groups. Below are the AAN's comments to CMS' various inquiries.

- Would allowing patients to add information to their records be useful in promoting patient access and utilization? Are there other incentives that would promote patient access?

The AAN believes that allowing patients to add information to their records would be beneficial and consistent with existing information blocking regulations. The current information blocking prohibition defines information blocking as "a practice by an actor, except as required by law or specified in an information blocking exception, that is likely to interfere with the access, exchange, or use of electronic health information (EHI)."[46] The AAN's understanding of the current regulations is that "use" of EHI includes the ability to read and write and is also bidirectional.[47] The AAN requests clarification regarding whether there is ambiguity in the statute and regulations surrounding whether patients writing into their own health record implicates the existing information blocking regulations. The AAN believes there are likely to be significant benefits associated with allowing patients to self-report certain health maintenance activities performed elsewhere, including immunizations and other preventive services like mammograms.

- Are there potential unintended consequences in allowing patients to add information to their records? What could be done to mitigate any potential unintended consequences?

[46] "Information Blocking." HealthIT.gov, Office of the National Coordinator for Health IT, 27 July 2022, https://www.healthit.gov/topic/information-blocking.
[47] "Part 1 - What Is Information Blocking?" American Medical Association, Jan. 2021, https://www.ama-assn.org/system/files/2021-01/information-blocking-part-1.pdf.

The AAN urges CMS to consider the potential volume at which a subset of patients may add information to the existing record. Physicians may need to allocate time to reviewing updated records, which may take time away from directly serving patients and it is possible that this time will not be reimbursed. CMS could consider the appropriateness of reimbursing physicians for the time spent reviewing patient-reported updates when the review is conducted outside the time that would be counted towards the total service time for an E/M visit. The AAN also requests clarification regarding how the time involved in the provider's review of information that the patient adds to the record interacts with the care management codes.

Additionally, a high frequency of updates without sufficient context may confuse providers who will have to navigate an increasingly noisy chart. There may also be difficulties associated with reconciling new information and ensuring that all available information is up to date and accurate. CMS should consider working with ONC on strategies to ensure that when patient updates are made, that the chart is still clear and understandable to providers. One possible solution would be to segregate patient updates in a separate section of the chart into discrete USCDI elements within the EHR so there is clear tracking of provenance until the provider can review any updates and records can be reconciled.

- Recent studies have raised concerns about the presence of racial bias and stigmatizing language within EHRs that could lead to unintended consequences if patients were to obtain disparaging notes regarding their medical care. What policy, implementation strategies, or other considerations are necessary to address existing racial bias or other biases and prevent use of stigmatizing language?

The AAN is deeply concerned with the use of stigmatizing language in the health record but believes that inclusion of stigmatizing language in the EHR is ultimately a provider professionalism and education issue. It is likely infeasible to implement policies that dictate or modify the language that providers use within the EHR. The AAN encourages CMS to explore opportunities to offer educational opportunities to providers, so that providers can better understand the existing regulatory environment surrounding patient access to health records and the impacts that stigmatizing language can have on the patient-provider relationship and quality of care. CMS could also consider the appropriateness of incentives surrounding education on these critical topics.

- What are the most common barriers to patient access and use of their health information that have been observed?

The AAN believes that access to reliable high-speed internet is one of the most significant barriers preventing patients from accessing their health information. The AAN strongly supports the Biden Administration working across relevant agencies and with Congress and the states to develop necessary infrastructure for high-speed broadband internet in rural and otherwise underserved communities.

- Do you believe the API and app ecosystem are at the point where it would be beneficial to revisit adding a measure of patient access to their health information

which assesses clinicians on the degree to which their patients actively access their health information?

The AAN believes that the API and app ecosystem is still maturing and that providers are still adapting to the rapidly changing environment. We do not believe that a measure of patient access to health information that assesses clinicians on the degree to which patients actively access health information is appropriate currently. The AAN is also concerned with the potential burdens associated with collecting data for and reporting on this measure, as well as the potential that performance on this measure may be dictated by factors outside of the provider's control, including patient technological literacy and internet access.

MIPS Payment Adjustments

The AAN supports CMS' proposal to maintain the performance threshold at 75 points. The PHE has made it difficult for many practices, and small practices especially, to prioritize MIPS performance and reporting. Historically, small practices have struggled significantly to meet the performance threshold compared to larger group practices and clinicians that have a more robust infrastructure in place for data collection and reporting. While maintaining the 75-point threshold, the AAN recommends that CMS explore the appropriateness of establishing a separate MIPS performance threshold for small practices as well as any additional bonus points or considerations to ensure that small practices are not unfairly penalized.

Third Party Intermediaries General Requirements

QCDR Measure Self-Nomination Requirements

As part of the qualified clinical data registry (QCDR) measure self-nomination process, CMS requires the nominating QCDR to publicly post QCDR measure specifications and provide CMS with a link to where this information is posted no later than 15 calendar days following CMS approval. To avoid confusion relating to this requirement, CMS is proposing to "revise the language such that entities must publicly post measure specifications no later than 15 calendar days following CMS's posting of approved QCDR measure specifications on a CMS website and that QCDRs need to confirm that the measure specifications they post align with the measure specifications posted by CMS."[48] CMS is also proposing for a QCDR measure, that "the entity must submit for CMS approval measure specifications including the Name/title of measure, National Quality Forum (NQF) number (if NQF-endorsed), descriptions of the denominator, numerator, and when applicable, denominator exceptions, denominator exclusions, risk adjustment variables, and risk adjustment algorithms."[49] CMS is also proposing to require that "no later than 15 calendar days following CMS posting of all approved specifications for a QCDR measure, the entity must publicly post the CMS-approved measure specifications for the QCDR measure (including the CMS-assigned QCDR measure ID) and provide CMS with a link to where this information is posted."[50] The AAN believes that these clarifications are necessary and appreciates CMS providing them.

[48] 87 Fed. Reg. at 46324.
[49] Id.
[50] 87 Fed. Reg. at 46324.

QCDR Measure Approval Criteria

CMS is proposing to revise QCDR measure approval requirements by delaying the requirement for a QCDR measure to be fully developed and tested with complete testing results at the clinician level until the CY 2024 performance year. The AAN supports the proposed delay of measure testing requirements and believes it is necessary given the ongoing impacts of the Covid-19 PHE. Measure developers need clear guidance and non-conflicting requirements on reliability and validity testing thresholds. Documents citing the National Quality Forum and recent experiences relating to measures reviewed by the Measures Application Partnership only exacerbate the confusion.

Request for Information on Value of Adding CME Accreditation Organizations as Third-Party Intermediaries

CMS is considering whether national continuing medical education (CME) accreditation organizations that provide certification of CME could serve as a new type of third-party intermediary to submit data for clinicians seeking improvement activities performance category credit for the completion of certain improvement activities. The AAN requests clarification regarding the origin of this idea as well as why CMS believes it has the potential to reduce clinician burden. The AAN believes that QCDRs are well positioned to collect information relating to the completion of improvement activities and does not believe that creating an additional class of third-party intermediary is necessary.

Public Reporting on the Compare Tools hosted by HHS

Telehealth Indicator

To improve patient access to telehealth services, CMS is proposing to add a telehealth indicator to Physician Compare profile pages as technically feasible. The AAN supports the addition of this indicator and concurs with CMS that "adding an indicator to clinician and group profile pages would clarify for website users which clinicians offer telehealth services."[51] Additionally, the AAN supports CMS' clarification that the proposed indicator would "include a statement on the profile page caveating, in a user-friendly way based on consumer testing, that the clinician or group only provides some, not all, services via telehealth."[52] The AAN believes this is necessary so that patients do not expect that all services would be provided via telehealth, regardless of appropriateness. The AAN also believes it would be appropriate to include an acknowledgment that individual patient access to telehealth services may be restricted due to limitations relating to interstate licensure.

Publicly Reporting Utilization Data on Profile Pages

CMS is proposing to update the Physician Compare program to publicly report service-specific utilization data on patient-facing clinician profile pages. CMS believes doing so would provide patients with more useful data than what is currently available and allow for more granular clinician searches so that patients would not only be able to find specific types

[51] 87 Fed. Reg. at 46329.
[52] 87 Fed. Reg. at 46330.

of clinicians, but also those clinicians who have performed specific types of procedures. The AAN supports this proposal and believes that it would be useful for patients to be able to search for comparative data on the frequency and volume of certain types of procedures performed when selecting a physician.

Although the AAN is supportive of this proposal, the data that is proposed to be used is likely to be a major limiting factor on the intended utility of providing service-specific information. The data may be too confusing for patients to understand even with a disclaimer stating that listed information only includes Medicare data and therefore may not be reflective of the physician's actual volume of the specified procedure. The AAN is also concerned with the use of a 12-month lookback period to develop the data that will be displayed. The AAN believes that there is a risk of unfairly disadvantaging physicians who do a particular procedure relatively infrequently, but nevertheless have expertise based on years in practice. There are a variety of reasons why a physician may not have conducted a specific procedure for a Medicare patient during a given 12-month period, despite their willingness and ability to provide a particular service. The AAN believes a longer lookback period may be appropriate, along with allowing physicians to update and correct the services and other information listed on their profiles. The AAN also believes that using data from Medicare Advantage and Medicaid may provide a more accurate and robust data set.

Incorporating Health Equity into Public Reporting Request for Information

CMS is considering including additional information on Compare profile pages, including "whether the clinician or group has language services available, speaks other languages besides English, and whether they accept insurance outside of traditional Medicare Fee-for-Service, such as Medicaid, Medigap, Medicare Advantage, and other commercial insurance."[53] The AAN offers the following responses to CMS' request for information:

- Should we publicly report available language (including sign language) services on a clinician's Compare tool profile pages? If so, what data sources are available?

The AAN notes that although medical interpreters must be provided for patients with limited English proficiency by law, language information may be helpful for patients when looking for a physician with the ability to communicate in the patient's native language. The AAN believes this has the potential to make care more accessible to patients while reducing costs associated with translator services. Although this information is likely to be useful, the AAN is not aware of a central resource that comprehensively provides language information and is concerned with the potential establishment of additional reporting requirements. Additionally, the AAN requests clarification regarding how CMS will determine whether a particular language ought to be listed and whether there will be a requirement for a provider to be a certified translator, prior to having a particular language listed. The AAN also believes that CMS should consider the need for providers to make updates to practice pages based on staff turnover.

[53] 87 Fed. Reg. at 46331.

- Should we publicly report information through the Compare tool on whether clinicians and groups accept other insurance outside of traditional Medicare Fee-for-Service, such as Medigap, and Medicare Advantage; Medicaid; and commercial insurance for non-Medicare eligible patients, including through the healthcare exchanges. If so, what data sources are available for this information?

While the AAN believes it would be useful for patients to be provided with more comprehensive information regarding which insurance providers and groups accept, the AAN is concerned about the lack of availability of a comprehensive data source, as well as the potential administrative burdens that would be placed on providers that are associated with reporting and updating such information. The AAN does note that under the No Surprises Act (NSA) provisions of the CAA, health plans must maintain a provider directory that includes pertinent information relating to providers and groups participating in the plan.[54] Provider directories maintained by health plans under the NSA could potentially serve as a data source that could be used to provide more comprehensive insurance information without creating additional reporting burdens for providers.

Overview of the Advanced Alternative Payment Model Incentive

The AAN continues to support the move towards value-based payment and Advanced Alternative Payment Models (Advanced APMs). The AAN is highly concerned that following PY 2022, there is no further statutory authority for a 5 percent APM incentive payment for eligible clinicians who become qualifying participants (QPs). The AAN understands that CMS has no authority to continue making these payments absent congressional action. Neurologists have largely been excluded from APM incentive payments due to the paucity of approved models that address the patients and services for which neurologists are responsible. As such, APM incentive payments have not served their supposed function for neurologists, as the transition to APMs has not been driven by incentives but rather a lack of opportunity to participate.

CMS is clearly interested in developing MVPs for neurology, given the three that are proposed to be made available in 2023, but these MVPs do not serve as an on-ramp to APMs, when there are so few meaningful opportunities for neurologists to participate in APMs. The AAN strongly urges CMS to work to develop APM participation opportunities that are relevant to neurologists and neurology patients. Furthermore, the AAN urges CMS to work with Congress and relevant stakeholders, including the AAN, so that clinicians that have not had the opportunity to benefit from incentive payments are given the opportunity to benefit from incentive payments while transitioning to APMs.

Starting in performance year 2024, statute requires the creation and application of two different conversion factors depending on whether a clinician achieves QP status. By statute, QPs will receive an annual, compounding 0.75% update to the conversion factor, while non-QPs will receive an annual compounding 0.25% update to the conversion factor. As noted by

[54] "The No Surprises Act's Continuity of Care, Provider Directory, and Public Disclosure Requirements." Centers for Medicare and Medicaid Services, Center for Consumer Information & Insurance Oversight, https://www.cms.gov/files/document/a274577-1b-training-2nsa-disclosure-continuity-care-directoriesfinal-508.pdf.

CMS, in performance year 2023 (PY 2023), statute does not provide for any positive financial incentives for eligible clinicians who achieve QP status. Clinicians who achieve QP status in PY 2023 and onwards will not be subject to any MIPS performance adjustments, whether they be positive or negative.

As noted in Figure 5, *PFS Conversion Factors vs. Maximum MIPS Payment Adjustments*[55], the differential conversion factors, when combined with MIPS performance adjustments, may lead to a significant divergence in payments for QPs when compared to non-QPs. Surprisingly, in the initial years of the differential conversion factors, CMS notes that the QP conversion factor may not provide sufficient incentive for clinicians to transition out of MIPS and into APMs, since the maximum expected payment adjustment under MIPS, will exceed payments received by QPs under the APM conversion factor. While the AAN generally concurs with this point, it is important to note that CMS' analysis is based on non-QPs potentially being able to achieve the theoretical maximum MIPS payment adjustment of 7%. Although 7% may represent the theoretical maximum, historical data indicates that the highest performing MIPS-eligible clinicians have received a positive payment adjustment of approximately 1.8% in recent years and that no clinician has been able to receive the maximum theoretical positive payment adjustment.[5657] The AAN sees no reason that this trend would cease to continue. Once one accounts for historical data, it appears likely that the disincentive to participating in APMs will likely exist for a far shorter length of time than that projected by CMS. If historical trends are maintained, QPs can expect to receive reimbursement at a higher level than non-QPs who receive the highest MIPS payment adjustment during the fourth payment year following policy implementation, rather than the thirteen years projected by CMS.[58]

The AAN does concur with CMS that during the four years in which high-performing MIPS clinicians can reasonably expect to receive a modestly higher payment adjustment under MIPS than under APMs, that the differential may pose a significant disincentive to achieving QP status. This disincentive may be mitigated by the possible shift of eligible clinicians into MIPS and out of APMs. As noted by CMS "the average MIPS final score for MIPS eligible clinicians who were participants in MIPS APMs in 2020 was 96.24 points while the average MIPS final score for all other MIPS eligible clinicians was 84.42 points."[59] Given that those shifting from APMs to MIPS will likely be disproportionately those who score very highly and would receive a positive payment adjustment, it is likely that this trend "would result in a corresponding reduction in the average and maximum positive MIPS payment adjustment."[60] As such, the length of time in which a high-performing clinician may rationally choose to strategically select to perform in MIPS may be even shorter than four years, given a substantial enough reduction in the observed maximum MIPS performance adjustment.

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[55] 87 Fed. Reg. at 46333.
[56] Quality Payment Program Participation in 2019: Results at-a-Glance. Centers for Medicare and Medicaid Services, Oct. 2020, https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1190/QPP%202019%20Participation%20Results%20Infographic.pdf.
[57] Quality Payment Program Participation in 2020: Results at-a-Glance. Centers for Medicare and Medicaid Services, Feb. 2022, https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1783/QPP%202020%20Participation%20Results%20Infographic.pdf
[58] American Academy of Neurology Analysis
[59] 87 Fed. Reg. at 46334.
[60] Id.

Furthermore, this perverse incentive may be mitigated by model-specific opportunities to benefit from shared savings and to receive waivers that grant practices additional flexibilities to coordinate care and engage beneficiaries in innovative ways.

CMS has requested feedback on whether the combined impact of existing incentives, including the potential for shared savings, a 0.75% conversion factor update, and exemption from MIPS reporting requirements are sufficient to promote participation in advanced APMs. The AAN notes that the current incentive structure was crafted before key events that have greatly impacted the long-term financial stability of physician practices and the healthcare system at large. Practices are still working to address substantial hardships, including staffing shortages, increased labor costs, and supply chain issues, stemming from the Covid-19 PHE. These hardships have been compounded by the combined impacts of high inflation and a lack of meaningful annual payment increases within the MPFS. While the AAN believes that many clinicians would prefer the incentive structure within the APM track, as compared to MIPS, we believe neither option is likely to be sufficient to keep pace with inflation or to offset the detrimental financial impacts of the PHE. The AAN understands that CMS is limited by statute but believes that the payment system needs to be reformed to support the transition to value-based care. The AAN strongly believes that CMS should work with Congress and relevant stakeholders, including the AAN, to provide financial stability through a baseline positive annual update that is reflective of medical inflation, while promoting meaningful models and incentives that are impactful and tailored to different specialties, including neurology.

In addition to working with Congress and relevant stakeholders to maintain bonus payments and develop meaningful incentives over the long term, to strengthen APM participation, the AAN urges CMS to prioritize efforts to develop meaningful participation opportunities in APMs for neurologists and to provide clear guidance to stakeholders. CMS should also provide detailed participation and performance data for specialists within APMs, including data on Advanced APMs, MIPS APMs, and Other Payer Advanced APMs. The AAN believes that providing stakeholders with a comprehensive 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 adoption of these models provides. Clinicians would also benefit from additional education on available APMs and how to determine whether participating in a particular model is appropriate for a particular clinician.

Requests for Information

Continuing to Advance to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs—Request for Information

Potential Future Definition of Digital Quality Measures (dQMs)

CMS is proposing to revise the potential future definition of a dQM so that it is defined as "a quality measure, organized as self-contained measure specification and code package, that uses one or more sources of health information that is captured and can be transmitted

electronically via interoperable systems."[61] The AAN supports the revised definition for a digital quality measure. CMS and ONC have established comprehensive strategies to ensure advanced standardization and interoperability across all EHR platforms.

CMS is also seeking feedback on potential considerations or challenges relating to non-EHR data sources. The AAN is concerned about standardization of non-EHRs data sources. There are no clear guidelines on how non-EHR data will be standardized or harmonized with EHR data in a meaningful way. For example, how will the quality of the data be assessed? CMS and ONC should consider providing data requirements, a list of data elements, and acceptable data formats and terminologies from non-EHRs data sources that can be used in developing digital quality measures.

Advancing the Trusted Exchange Framework and Common Agreement (TEFCA) – Request for Information

CMS is soliciting feedback in support of advancing the development of the Trusted Exchange Framework and Common Agreement (TEFCA). The goals for TEFCA are as follows[62]:

- Establish a universal policy and technical floor for nationwide interoperability.
- Simplify connectivity for organizations to securely exchange information to improve patient care, enhance the welfare of populations, and generate health care value.
- Enable individuals to gather their health care information

The AAN is highly supportive of this effort and provides the following feedback on the specific areas of inquiry raised by CMS.

- What are the most important use cases for different groups that could be enabled through widespread information exchange under TEFCA? What key benefits would be associated with effectively implementing these use cases, such as improved care coordination, reduced burden, or greater efficiency in care delivery?

The AAN supports the important use cases for health information exchange under TEFCA, including enhanced syndromic surveillance, streamlined public reporting, and improved access to population health data that will help in emergency preparedness responses. The AAN believes that more work needs to be done to support interoperable exchange. Utilizing TEFCA to build on the existing infrastructure of health information exchange has great potential, but in practice, the information that is currently being exchanged is often either limited or may contain excessive information that is difficult to go through when searching for relevant information. The main benefit for providers that could be achieved through widespread information exchange under TEFCA is the ability to exchange comprehensive and accurate, reader-friendly versions of patient information, particularly between disparate EHRs.

[61] 87 Fed. Reg. at 46259.
[62] Tripathi, Micky, and Mariann Yeager. "3...2...1...TEFCA Is Go for Launch." Health IT Buzz, Office of the National Coordinator for Health Information Technology, 18 Jan. 2022, https://www.healthit.gov/buzz-blog/interoperability/321tefca-is-go-for-launch.

Additionally, CMS states that the agency is "considering future opportunities to encourage information exchange under TEFCA for payment and operations activities such as submission of clinical documentation to support claims adjudication and prior authorization processes."[63] The AAN strongly encourages CMS to work with ONC to address prior authorization (PA) burden. Physicians in the United States complete an average of 41 PA requests every week, taking an average of 13 hours to process.[64] PA is one of the most time consuming and expensive administrative requirements preventing physicians from spending more time with patients. Over 90% of clinicians reported that PA requirements have a negative impact on patient clinical outcomes and 82% of clinicians reported that issues associated with PA can lead to patients abandoning a recommended course of treatment.[65] Burdens associated with PA are often cited as a top concern among AAN members. Our members have expressed frustration with existing electronic prior authorization (ePA) systems relating to inaccurate or inadequate population of information from the EHR to the relevant form and payer. The AAN believes that TEFCA implementation presents a unique opportunity to build on existing infrastructure to improve the accuracy and usefulness of ePA processes.

- What concerns do commenters have about enabling exchange under TEFCA?

Facilitating increased exchange of data across providers and EHR systems can yield numerous benefits to patients and providers, but this is only possible if the information is presented in a usable and actionable format to the end user. When providers receive out-of-date information from the HIE on patients, such as old medication or problem lists, relying on the out-of-date information has the potential to create as unsafe a situation as if the provider did not have the information at all. When implementing TEFCA, it will be critical to ensure that information exchange is accurate, timely, and comprehensive. Information exchange ought not to overwhelm providers and must be presented in a manner that does not increase burdens and is user-friendly. Appropriate incentives for engaging real-world providers and patients in assessing burdens and usability of interfaces exchanging and presenting information for reconciliation should be encouraged.

Additionally, the AAN has concerns relating to practices that meet the criteria for a hardship exception and subsequent reweighting of the MIPS PI performance category, due to lacking the resources needed to have certified EHR technology (CEHRT). CMS should consider the appropriateness of any additional actions to incentivize and support practices without the resources to adopt 2015 CEHRT.

Appropriate Use Criteria

The AAN applauds CMS' July 7 announcement that for the Appropriate Use Criteria (AUC) program the "payment penalty phase will not begin January 1, 2023 even if the PHE for COVID-19 ends in 2022. Until further notice, the educational and operations testing period

[63] 87 Fed. Reg. at 46263.
[64] "2021 AMA Prior Authorization (PA) Physician Survey." American Medical Association, 2022, https://www.ama-assn.org/system/files/prior-authorization-survey.pdf
[65] Id.

will continue. CMS is unable to forecast when the payment penalty phase will begin."[66] The AAN appreciates CMS' continued recognition of the impact that the ongoing PHE has had on providers' ability to participate in the current AUC educational and operations testing period. Due to the PHE, providers are unlikely to have gained the experience they will need to fully participate in the AUC program after the education and testing period has ended. The AAN believes that indefinitely delaying this program is necessary because further implementation of this program is likely to have significant detrimental impacts on timely patient access to care, which is already hindered by the ongoing PHE.

Beyond implementing an indefinite delay, CMS should consider whether the standalone AUC program is necessary or if programmatic requirements have become redundant due to provider participation in the Quality Payment Program. Additionally, if CMS were to consider reinstating a compliance deadline, wherein the payment penalty phase would be implemented, the AAN strongly urges the agency to gather feedback from impacted specialties, including the AAN, prior to establishing the timeline.

Conclusion

Thank you for the opportunity to comment on the 2023 MPFS proposed rule. The AAN urges CMS to carefully consider our recommendations to ensure that Medicare payment policies adequately compensate for cognitive care, support patient access to necessary health services, and promote the highest quality patient-centered neurologic care, while protecting program integrity. Please contact Matt Kerschner, the AAN's Director, Regulatory Affairs at mkerschner@aan.com, or Max Linder, the AAN's Government Relations Manager at mlinder@aan.com with any questions or requests for additional information.

Sincerely,

Orly Avitzur, MD, MBA, FAAN
President, American Academy of Neurology

[66] "Outreach and Education." Appropriate Use Criteria, Centers for Medicare and Medicaid Services, 7 July 2022, https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/OandE.