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September 7, 2023

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

RE: Medicare and Medicaid Programs; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program [CMS-1784-P]

Dear Administrator Brooks-LaSure,

The American Academy of Neurology (AAN) is the world's largest neurology specialty society representing more than 40,000 neurologists, clinical neuroscience professionals, and students. The AAN is dedicated to promoting the highest quality patient-centered neurologic care. A neurologist is a doctor 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 Alzheimer's disease, stroke, migraine, multiple sclerosis, concussion, Parkinson's disease, and epilepsy.

Conversion Factor and Passive Devaluation

The AAN is deeply concerned with the impact of the 3.36% decrease to the conversion factor projected to occur if all policies in the 2024 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. Additionally, the AAN calls on Congress to provide a permanent positive update, based on medical inflation, to the 2024 MPFS 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.

II. B. Determination of PE RVUs

As part of the 2024 MPFS, CMS announced further postponement of updated Medicare Economic Index (MEI) weights, which have long been viewed as a measure of practice cost inflation and a mechanism to determine the proportion of payments attributed to physician earnings and practice costs. The MEI weights that are the basis for current CMS rate setting were based on data obtained from the American Medical Association's (AMA) Physician Practice Information Survey, last conducted in 2007/2008. In 2023, CMS finalized policy to rebase the MEI using a methodology based primarily on a subset of data from the 2017 US Census Bureau's Service Annual Survey. However, the agency noted the intention to postpone implementation of the proposed MEI changes to allow for public comment in response to the significant redistributive impact for physician payments. While the AAN recognizes the critical need for updated input data to accurately reflect the current economic environment for practices, the AAN is pleased CMS intends to further delay implementation to allow for additional data collection being facilitated by the American Medical Association. We encourage the agency to consider all data sets when implementing future MEI updates to ensure that updates reflect the most accurate data from the entire house of medicine.

The AAN endorses the principle of regular and frequent updates 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. This is particularly salient given the projected substantial increase in demand for neurologic care and current inadequacy of the neurologic workforce. This has substantial impacts on practice costs, including costs associated with recruitment and retention of providers. 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.

II. D. Payment for Medicare Telehealth Services Under Section 1834(m) of the Social Security Act (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. AAN members and their patients rapidly adopted telehealth in response to the COVID-19 Public Health Emergency (PHE). There is consensus among our members that the rapid adoption of telehealth and continued use over more than three years, in response to the COVID-19 pandemic, has yielded numerous benefits for patient care. The AAN notes substantial cost savings for patients receiving virtual care associated with time off from work, childcare, and transportation costs. We note the increasing body of evidence supporting diagnostic concordance between telehealth and in-person evaluations in both inpatient and outpatient settings for acute evaluation and routine assessment of various

neurologic conditions.[1][2][3][4][5] 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. The AAN appreciates CMS' attention to promoting telehealth as a necessary modality of care both during and after the COVID-19 PHE.

Implementation of Provisions of the CAA, 2023

CMS is proposing to implement provisions of the Consolidated Appropriations Act, 2023 (CAA, 2023) that extend many of the Medicare telehealth flexibilities adopted during the PHE through December 31, 2024. The AAN strongly supports implementing these flexibilities as they remain critical to maintaining access to high-quality care for neurology patients who may otherwise have their care compromised. Critical flexibilities extended by the CAA, 2023 that the AAN supports include:

- Expansion of permissible telehealth geographic and 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.
- Allowing for payment of an originating site facility fee to an originating site with respect to those telehealth services if the originating site is one that meets pre-existing geographic and originating site restrictions.
- Continuation of coverage and payment of an expanded set of services included on the Medicare Telehealth Services List, including reimbursement of permissible audio-only services.

The AAN strongly supports policies that promote access to high-quality telehealth services regardless of patient location. The expansion of telehealth services has been particularly beneficial for Medicare beneficiaries with cognitive and mobility impairments. For example, many patients with Alzheimer's disease and related disorders, which affects more than 1 in 9 adults over age 65,[6] face difficulties attending in-person clinical visits due to behavioral symptoms such as anxiety, agitation, apathy, or mobility limitations that come with advanced disease. Telehealth services are also essential for epilepsy patients who may not be permitted to drive due to recent seizure activity. The inability for epilepsy patients to receive care

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[1] McCormick, Robert, et al. "Teleneurology Comprehensive Inpatient Consultations Expedite Access to Care and Decreases Hospital Length of Stay." The Neurohospitalist, U.S. National Library of Medicine, July 2021, www.ncbi.nlm.nih.gov/pmc/articles/PMC8182406/.
[2] Zha, Alicia M, et al. "Inpatient Teleneurology Follow-up Has Comparable Outcomes to in-Person Neurology Follow-Up." Neurology. Clinical Practice, U.S. National Library of Medicine, Dec. 2022, www.ncbi.nlm.nih.gov/pmc/articles/PMC9757113/.
[3] Demaerschalk, Bart M, et al. "Assessment of Clinician Diagnostic Concordance with Video Telemedicine in the Integrated Multispecialty Practice at Mayo Clinic during the Beginning of Covid-19 Pandemic from March to June 2020." JAMA Network Open, U.S. National Library of Medicine, 1 Sept. 2022, www.ncbi.nlm.nih.gov/pmc/articles/PMC9440401/.
[4] Thawani, Sujata P et al. "Neurologists' Evaluations of Experience and Effectiveness of Teleneurology Encounters." Telemedicine journal and e-health: the official journal of the American Telemedicine Association vol. 29,3 (2023): 442-453. doi:10.1089/tmj.2021.0551
[5] Skinner, Holly J et al. "Comparison of care accessibility, costs, and quality with face-to-face and telehealth epilepsy clinic visits." Epilepsy & behavior: E&B vol. 127 (2022): 108510. doi:10.1016/j.yebeh.2021.108510
[6] "Alzheimer's Disease Facts and Figures." Alzheimer's Disease and Dementia, Alzheimer's Association, 2022, https://www.alz.org/alzheimers-dementia/facts-figures.

results in otherwise avoidable hospitalizations and adverse events. Patient caregivers may also experience physical limitations or live distantly, further interfering with an individual's ability to travel for an office visit. Furthermore, telehealth is poised to address workforce shortages facing many medical specialties, including neurology. It is estimated that by 2025, the demand for neurologists will exceed the number of practitioners in the United States by 19%.[7] The flexibilities granted under PHE waivers allow neurology providers to drastically reduce wait times across all geographies, including densely populated urban as well as rural settings, while maintaining high-quality neurologic care.

Now that the PHE has ended, AAN members report that many patients have expressed the desire to maintain access to affordable and high-quality telehealth services. Nevertheless, a subset of neurologists identified the elimination of PHE waivers, coverage, and payment policies as the primary barriers to offering telehealth services.[8] The AAN predicts that telehealth will continue to play an essential role in the care of patients with neurologic conditions. To the extent that it is legally feasible, the AAN strongly urges CMS to implement administrative policies that promote permanent stability and patient access to virtual services.

Requests to Add Services to the Medicare Telehealth Services List for CY 2024

Hospital Care, Emergency Department and Hospital

CMS is proposing that Current Procedural Terminology (CPT) codes 99221-99223, 99234-99239, and 99281-99283 that describe hospital and emergency department services remain on the Medicare Telehealth Services list on a temporary basis through CY 2024, as the agency believes they may continue to be furnished safely via real-time audiovisual communication technology. In January 2023, the AAN submitted a request to CMS for the addition of CPT codes 99221-99223 and 99234-99236 to the Medicare Telehealth Services List permanently on a Category 1 basis.[9] The AAN appreciates CMS' decision to maintain these codes for CY 2024, as AAN members report frequent use of inpatient real-time audiovisual telehealth without any adverse patient outcomes.

In the 2021 MPFS, CMS declined to include CPT codes 99221-99223 on the Medicare Telehealth list because the agency had concerns that the codes "describe an evaluation for potentially high acuity patients that is comprehensive and includes in-person physical examination […] the need for an in-person interaction would rise above any specific diagnosis, and serves as the foundation upon with any and all clinical decisions are based for these services."[10]

Given specific reference to the code descriptors, the AAN believes the above rationale was reasonable during the CY 2021 rulemaking process. With the revised code set finalized in the

[7] Dall, Timothy M et al. "Supply and demand analysis of the current and future US neurology workforce." Neurology vol. 81,5 (2013): 470-8. doi:10.1212/WNL.0b013e318294b1cf
[8] American Medical Association. (2021). Telehealth Survey Report – Neurology.
[9] American Academy of Neurology Request for Addition to the Medicare Telehealth List, 25 January 2023, https://www.aan.com/siteassets/home-page/policy-and-guidelines/advocacy/comment-letters/aan-request-for-additions-to-the-medicare-telehealth-list.pdf
[10] 85 Fed. Reg. at 84517

2023 MPFS for inpatient care, the AAN notes the exclusion of specific requirements for what is done at the bedside or on the unit. The revised set of codes instead refer to a medically appropriate history and/or examination, the relevant level of medical decision-making for the specific code level, as well as total time thresholds on the date of the encounter for purposes of code selection. The AAN appreciates CMS' concerns about patient safety and quality of care but believes that the code's service elements, including medically appropriate history and/or examination and the relevant level of medical decision-making, map to the equivalent in-person service that is payable under the MPFS. Moreover, recent data indicates that inpatient neurology telestroke care results in comparable outcomes to in-person inpatient neurologic care.[11]

Deep Brain Stimulation

In the same January 2023 letter to CMS, the AAN highlighted developing evidence for safe and effective remote electronic analysis of implanted neurotransmitter pulse generator/transmitter devices. These services, described by CPT codes 95970, 95983, and 95984, were performed remotely by AAN members throughout the PHE to expand access and timely delivery of care to patients with limited mobility. Recent evidence indicates that there may be clinical benefit when these services are provided to patient populations without access to appropriate in-person care through fewer future hospitalizations and/or physician visits.[12][13] Further, the ongoing Remote Optimization, Adjustment and Measurement for Deep Brain Stimulation (ROAM-DBS) study aims to compare the efficacy and safety of in-person versus remote programming of a patient's DBS device.[14] Recently presented data demonstrated that Parkinson's patients who underwent remote DBS programming, as compared to patients who had in-person programming, improved faster with respect to the Patient's Global Impression of Change. The virtual group also had more programming visits than the in-person group over the course of 3 months because it was easier to arrange this virtually rather than in-clinic.[15] The AAN notes that this study is ongoing.

Given continued research into remote DBS services, the AAN appreciates CMS' proposal to temporarily add CPT codes 95970, 95983, and 95984 to the Medicare Telehealth Services List for CY 2024. The AAN urges CMS to remain informed of developing evidence and to consider assigning these codes as permanent telehealth services.

<u>Proposed Clarifications and Revisions to the Process for Considering Changes to the Medicare Telehealth Services List</u>

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[11] Wilcock, Andrew D et al. "Reperfusion Treatment and Stroke Outcomes in Hospitals with Telestroke Capacity." JAMA neurology vol. 78,5 (2021): 527-535. doi:10.1001/jamaneurol.2021.0023

[12] Esper, Christine D, et al. "Necessity and Feasibility of Remote Tele-Programming of Deep Brain Stimulation Systems in Parkinson's Disease." Parkinsonism & Related Disorders, Elsevier, 24 Jan. 2022, https://www.sciencedirect.com/science/article/pii/S1353802022000256.

[13] Pintér, Dávid, et al. "Potential Clinical and Economic Benefits of Remote Deep Brain Stimulation Programming." Nature News, Nature Publishing Group, 19 Oct. 2022, https://www.nature.com/articles/s41598-022-22206-z.

[14] Details on ROAM-DBS can be found here: https://clinicaltrials.gov/ct2/show/NCT05269862

[15] Gharabaghi A. et al. "Teleprogramming Reduces the Time Needed to Optimize DBS therapy: Results from the ROAM-DBS Study, 2023 International Congress of Parkinson's Disease and Movement Disorders, 30 Aug. 2023, Copenhagen, Denmark.

CMS noted potential confusion among stakeholders about the agency's regulatory authority to add services to the Medicare Telehealth Services List. In an effort to clarify the decision-making process by which stakeholders request updates, CMS is proposing to describe accepted additions as either "permanent" or "provisional." Additionally, the agency proposes to modify the current Category 1, 2, and 3 methodology and implement a series of five steps to aid in classifying updates to the Medicare Telehealth Services List.

The AAN appreciates CMS' desire to clarify the process by which stakeholders can request additions to the Medicare Telehealth Services List. One component of the proposed stepwise process that remains unclear is the evidentiary standard by which CMS will deem a service as a "permanent" or "provisional" addition to the Medicare Telehealth Services List. In previous rulemaking, CMS included examples of clinical benefits that are required for adding a code on a Category 2 basis, but the AAN requests more transparency and specificity surrounding the agency's expectations for demonstrating that "a service is a substitute for an equivalent in-person service."[16] Similarly, the AAN requests further clarification regarding the evidentiary standard required for a code to move from the "provisional" to the "permanent" classification. Lastly, the AAN urges CMS to reconsider its proposal that the agency will not assign the provisional status when it is improbable that the code would ever achieve permanent status. Given the evolving landscape of virtual care, the AAN believes that this is overly restrictive and may ultimately impact the future of virtual care options available to Medicare beneficiaries.

Telephone Evaluation and Management Services

In alignment with the provisions in the CAA, 2023, CMS is proposing to maintain coverage and payment of telephone CPT codes 99441-99443 and CPT codes 98966-98968 that describe telephone evaluation and management (E/M) services and assessment and management services provided by non-physician health care professionals.

The AAN is pleased that audio-only services will remain on the list of telehealth services for 2024. A substantial portion of the neurology patient community does not have reliable or affordable access to broadband services and/or devices that are capable of real-time audiovisual communication. Recent data indicates that use of telehealth modality is correlated with patient demographics, including income and rurality.[17] For many neurology patients and their families, especially the elderly, those with adverse social risk factors, or patients with Alzheimer's disease and related disorders, audio-only services have been a successful model of health care delivery.

CMS has acknowledged the utility of audio-only visits for mental health services that "primarily involve verbal conversation where visualization between the patient and furnishing physician or practitioner may be less critical to the provision of the service."[18] The AAN believes that certain neurology visits, such as medication refills or check-ins for patient with chronic neurologic illness, may also primarily involve verbal interaction between the

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[16] 88 Fed. Reg. at 52297
[17] Uscher-Pines, Lori et al. "Changes in In-Person, Audio-Only, and Video Visits in California's Federally Qualified Health Centers, 2019-2022." JAMA vol. 329,14 (2023): 1219-1221. doi:10.1001/jama.2023.1307
[18] 86 Fed. Reg. at 39148

patient and provider and that visualization may not always be necessary or critical to the provision of the E/M service. 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 when audiovisual telehealth is not a feasible option.

Given the potential for audio-only telehealth to serve patients who may not otherwise have timely access to services that they utilized during the PHE, the AAN supports the permanent coverage and reimbursement of audio-only telehealth. The AAN is aware of the CPT Editorial Panel's removal of CPT codes 99441-99443 effective January 2025 and the creation of new codes for reporting telemedicine E/M office visits. The AAN urges CMS to consider ways in which, absent statutory changes, the agency can maintain permanent coverage of audio-only services through its authority to cover other communication-technology based services while also implementing streamlined billing methodologies with the new office visit codes.

Place of Service for Medicare Telehealth Services

CMS is proposing that practitioners append either place of service (POS) "02" (Telehealth provided in a location other than in a patient's home) or POS "10" (Telehealth provided in a patient's home) to all telehealth claims. CMS is also proposing to tie reimbursement to these POS codes, whereby claims billed with POS 02 be paid at the facility PFS rate and claims billed with POS 10 be billed at the non-facility PFS rate. The AAN appreciates CMS' understanding that many practitioners that provide hybrid virtual and in-person care must functionally maintain their practice expenses associated with their physical office, and thus would be more appropriately reimbursed by the non-facility payment.

While the AAN understands CMS' rationale that claims billed with POS 02 (Telehealth provided in a location other than in a patient's home) will be furnished in originating sites that were typical prior to the PHE, the AAN believes this rationale is inconsistent with the proposed reimbursement strategy that aims to fairly reimburse practitioners in an office-based setting. In the proposed rule, CMS states that the "facility rate more accurately reflects the PE of these [facility-based] telehealth services; this applies to non-home originating sites such as physicians' offices and hospitals."[19] Under this logic, physicians providing telehealth to patients located in another practitioner's office would not be reimbursed at the non-facility rate.

In a report conducted by the American Medical Association, 18% of neurologists reported that their patient was located in another clinic during their telehealth visit.[20] This hub and spoke model is particularly beneficial for patients that need specialty care in rural or other underserved locations. This model can also be employed in urban settings where a neurology subspecialist provides multidisciplinary care for patients in the office of another care provider. Even within a medical center there may be many buildings distant and functionally inaccessible because of patient mobility. Not all office settings, which under this proposal would be reflected by POS 02 (Telehealth provided in a location other than in a patient's home), are in a hospital or outpatient facility. The AAN believes that CMS should consider

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[19] 88 Fed. Reg. at 52300

[20] "Telehealth Survey Report - Neurology." 2021. American Medical Association.

revising the proposed POS codes so that the determination of the facility or non-facility rate should be based on whether the services are provided in a facility-based setting rather than a "location other than a patient's home."

Lastly, the AAN supports fair reimbursement for practitioners providing telehealth, which includes allowing for payment of an originating site facility fee. Nevertheless, the AAN believes that many patients do not understand differential cost-sharing obligations for services provided in a facility versus non-facility setting. CMS should consider ways in which the agency can inform Medicare beneficiaries of potential cost-sharing responsibilities to avoid inadvertently discouraging patients from accessing medically appropriate health care services.

Frequency Limitations on Medicare Telehealth Subsequent Care Services in Inpatient and Nursing Facility Settings, and Critical Care Consultations

CMS has previously placed restrictions on how frequently a Medicare service may be furnished via telehealth due to concerns about patient acuity in certain settings. These frequency restrictions were removed during the PHE but were reinstated on May 12, 2023. CMS is proposing to remove telehealth frequency limitations for the duration of CY 2024 for subsequent inpatient visits (CPT codes 99231-99233), nursing facility visits (CPT codes 99307-99310), and critical care consultations (codes G0508-G0509).

The critical care consultations as well as the subsequent inpatient visits constitute a considerable portion of inpatient neurology practice. The AAN believes that these frequency limitations are arbitrary and do not correspond with the standard of care for inpatient neurology. In fact, there are many situations in which a neurologist can perform routine virtual evaluations in a critical care setting for patients who do not reach the level of needing in-person exams. Further, the AAN is concerned that reinstating frequency limitations would create a differential access to neurologic care for patients who live in an area without a robust neurology workforce. The AAN recommends that CMS permanently modify its policies so that frequency of telehealth and in-person care is determined based on the medical needs of the patient.

The AAN understands that CMS may have program integrity concerns associated with removing frequency limitations and urges the agency to closely monitor utilization patterns to determine whether the elimination of these limitations leads to an increase in inappropriate utilization.

Direct Supervision via Use of Two-Way Audiovisual Communications Technology

Virtual Supervision of Auxiliary Personnel

Throughout the PHE, CMS changed its requirements for direct supervision as it pertains to the in-person supervision of diagnostic tests, physicians' services, and some hospital outpatient services to allow the supervising professional to be immediately available through a virtual presence using two-way audiovisual communications technology. The temporary exception to allow "immediate availability" for direct supervision through a virtual presence

is due to expire after CY 2023, but CMS is proposing to extend this flexibility for CY 2024 to avoid abrupt disruptions in practice patterns.

The AAN appreciates this proposed extension and supports permanently modifying direct supervision requirements to permit supervision via real-time audiovisual communications technology. Virtual supervision has allowed AAN members to expedite access to care across a more distributed geography without any evidence of adverse patient outcomes.

The AAN believes that CMS' proposal to permanently establish this virtual presence flexibility for services that are nearly always performed in their entirety by auxiliary personnel is overly restrictive. Such services would include any service wholly furnished incident to a physician's professional service, as well as the Level I office or other outpatient E/M visit for established patients and the Level I Emergency Department visit. As the agency mentions, Level I visits are almost entirely performed by auxiliary personnel, which the AAN believes often negates the need for supervision by a physician. Requiring a supervising practitioner to be immediately available in-person operates in contrast to the principles of a successful telehealth model, such as increasing workforce capacity and reducing patient travel.

The AAN appreciates CMS' attention to patient safety and health outcomes. The AAN maintains its position that virtual supervision of incident-to services is appropriate and safe in the majority of E/M visits. The AAN believes virtual supervision would not be appropriate for procedures, nor in instances in which a nuanced physical examination would be crucial for medical decision-making. The AAN requests that CMS defer to the physician's judgment as to whether in-person supervision is necessary. When 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.

Supervision of Residents in Teaching Settings

Upon expiration of the PHE, CMS reverted to payment policies whereby teaching physicians present for the key or critical portion of a service furnished involving residents through real-time audiovisual communications technology for both in-person and telehealth visits may be reimbursed only when the resident and patient are located outside of a metropolitan statistical area, as defined by the Office of Management and Budget.

CMS has previously stated various concerns about whether a virtual presence would allow the teaching physician to recognize specialized needs or testing. Nevertheless, CMS is again concerned that a transition back to the pre-PHE policy may impact access to care and could require an abrupt change of practice patterns that have been established during the PHE. The agency is proposing to permit teaching physicians to have a virtual presence in all residency teaching settings through December 31, 2024, but only for services furnished via telehealth. The AAN strongly supports permanent adoption of virtual supervision in all residency settings for telehealth services, including when a service is furnished as a three-way telehealth visit with the teaching physician, resident, and patient in separate locations. The AAN disagrees with any policy that limits virtual supervision opportunities to residents in

rural locations, as geographic location does not have a bearing on the ability for a resident or supervising physician to recognize specialized needs or testing. Given permanent expansion of telehealth in many settings, it is imperative that all neurology residents, regardless of geography, gain experience with this modality of care. The clinical judgment of the supervising physician will help determine whether a more nuanced or specialized in-person examination would be necessary.

The AAN would also like to make CMS aware of the cases in which the virtual presence of a supervising physician is particularly useful for ensuring access to care in settings where the patient and resident are co-located in-person and the supervising physician is remote. The AAN believes that in situations where there is adequate audiovisual technology to allow a teaching physician to be present for a key or critical component of a visit, it would be more appropriate for a subspecialized expert, such as a stroke physician, to supervise a resident than an in-person physician with little specialized experience. PHE-related flexibilities allowed this to become acceptable and safe in neurologic practice, and the AAN believes it would be beneficial for CMS to allow remote supervision of residents when clinically appropriate.

Clarifications for Remote Monitoring Services

The AAN appreciates the clarifications from CMS regarding the appropriate use of remote physiologic monitoring (RPM) and remote therapeutic monitoring (RTM) codes. Considering the current formats of asynchronous care, the AAN supports policies that require an established patient-provider relationship for reimbursement. For CPT code 99457 (*Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes*) the AAN requests that CMS consider redefining "interactive communication" to include asynchronous and/or telephone communication. In many clinically appropriate cases, a practitioner can perform these services through other modalities of communication.

The AAN also requests that CMS consider combining CPT codes 99454 and 99457 (and their analogous RTM codes) so that the unit of time measurement is based on minutes rather than days. AAN members report confusion with the requirement to track different units of measurement (minutes and days) during the provision of these services. Additionally, the 16-day minimum data collection requirement is arbitrary and could encourage problematic clinical care, as the amount of time spent over a day to meet the service requirement is undefined. The AAN believes that using total minutes as the "unit" of measurement, similar to principal care management or chronic care management services, could incentivize practitioners to implement RPM or RTM services more easily.

Lastly, in the CY 2023 MPFS, CMS solicited feedback about the creation of a generic device code for RTM. The AAN was disappointed that this proposal was not finalized nor reintroduced in the current proposed rule. The AAN believes it is necessary to expand RTM to include products used for neurological and other organ systems. The Food and Drug Administration (FDA) has 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, ultimately limiting access to asynchronous services for Medicare beneficiaries. Additionally, the AAN requests clarification regarding how best to communicate data to CMS related to products that could qualify for a future generic code.

II. E. Valuation of Specific Codes

Payment for Caregiver Training Services

Code	Descriptor
96202	Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); initial 60 minutes
96203	Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); each additional 15 minutes (List separately in addition to code for primary service
9X015	Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (eg, activities of daily living [ADLs], instrumental ADLs [IADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face; initial 30 minutes
9X016	Each additional 15 minutes (List separately in addition to code for primary service) (Use 9X016 in conjunction with 9X015)
9X017	Group caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (eg, activities of daily living [ADLs], instrumental ADLs [IADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face with multiple sets of caregivers

CMS is proposing to establish an active payment status for CPT codes 96202 and 96203 (*caregiver behavior management/modification training services*) and CPT codes 9X015, 9X016, and 9X017 (*caregiver training services under a therapy plan of care established by a physical therapist, occupational therapist, or speech language pathologist*). The AAN is supportive of establishing separate coding and payment for caregiver training services. While the AAN is supportive, we do note that small and solo practices are unlikely to have the resources to hire necessary staff and implement the procedures to operationalize these codes. As such, the detrimental impacts of budget neutrality adjustments may disproportionately fall on small and solo practices. Additionally, the AAN notes that the proposed code descriptors are inconsistent with recent changes implemented for E/M services, which account for the total time relating to the care delivered on a particular day, rather than merely the face-to-face time. CMS should consider the appropriateness of utilizing the total time of the associated service to be consistent with other outpatient E/M services.

In proposing this code, CMS is defining a caregiver as "an individual who is assisting or acting as a proxy for a patient with an illness or condition of short or long-term duration (not necessarily chronic or disabling); involved on an episodic, daily, or occasional basis in managing a patient's complex health care and assistive technology activities at home; and

helping to navigate the patient's transitions between care settings."[21] Included in CMS' definition are guardians who are the caregiver for minor children or other individuals who are not legally independent. The AAN supports CMS' proposed definition and believes it is reasonable.

CMS notes that a caregiver is a layperson assisting the patient in carrying out a treatment plan that is established for the patient by the treating physician or practitioner and assists the patient with aspects of their care, including interventions or other activities directly related to a treatment plan established for the patient to address a diagnosed illness or injury. CMS proposes that payment be made for CTS services when the treating practitioner identifies a need to involve and train one or more caregivers to assist the patient in carrying out a patient-centered treatment plan. The AAN concurs with CMS that "[c]aregiver understanding and competence in assisting and implementing these interventions and activities from the treating practitioner is critical for patients with functional limitations resulting from various conditions."[22]

CMS also provides several examples of appropriate uses of caregiver training services (CTS). The AAN appreciates CMS providing these illustrative examples and in addition to the examples provided, wants to highlight the applicability of CTS services to epilepsy and for neuromuscular disorders, including the need for education on first aid, safety, lifestyle modification, triggers, and comorbidities.

CMS is proposing to require that the full 60 minutes of time be performed to report CPT code 96202. The add-on code, CPT code 96203, may be reported once 75 minutes of total time is performed. The AAN notes that the utility of CPT code 96202 may be limited by the required time threshold of 60 minutes if CMS finalizes its proposal to only count face-to-face time. In educational settings caregivers are already aware of several key elements, including the diagnosis, allowing for the presentation of relevant information to be more directed and specific. The AAN recommends that this code may be more useful if the time threshold were reduced to 30 minutes, with requisite reduction in the wRVU, so that shorter sessions can be utilized as appropriate.

CMS is seeking comment on how the clinician and caregiver interactions would typically occur, including when the practitioner is working with multiple caregivers and how often these services would be billed considering the established treatment plan involving caregivers for the typical patient. Currently, many hospitals are incentivized to discharge patients quickly, meaning that increasingly complex health issues are managed at home by caregivers, who typically do not have experience delivering healthcare. Providing targeted education regarding managing new diagnoses is highly valuable and can likely be delivered in 1-2 sessions.

Although caregivers may be able to acquire necessary skills in a single visit, the proposed once per beneficiary limitation would not be appropriate as it would be unreasonable to expect every caregiver to learn needed skills and information in a single visit. Documentation that certain caregivers could not successfully demonstrate or teach-back the targeted skills

[21] 88 Fed. Reg. at 52323
[22] Id.

would be one way to justify a repeat encounter. Additionally, certain neurodegenerative diseases, such as Alzheimer's and Parkinson's progress over time and could require iterative training. A training session for caregivers will be quite different depending on the stage of degeneration. Early training may include helping family members understand what their loved one is going through, as well as how to handle conversations when the patient forgets what was just said, prepare for and manage new onset depression due to the diagnosis (or because of the diagnosis), assess safety of driving, and oversight of finances. A later stage may include assisting the caregiver to oversee decisions in assisted living, nursing homes, and with a 24-hour aide, managing swallowing dysfunction, fall risks, and urinary urgency or incontinence. Lastly, a third conversation could be end of life training. It would be unreasonable to expect every caregiver to fully absorb and retain the full breadth of information relating to each stage of disease progression over the course of several years. Allowing for iterative training sessions would promote retention of timely information and improve the utility of caregiver training services.

CMS is seeking comments on the appropriateness of delivering caregiver training in a group setting. The AAN believes that a group setting, allowing for multiple caregivers to receive the same information simultaneously is helpful. Currently this type of information is frequently conveyed informally in support group settings. Additionally, the AAN believes that the proposed requirements surrounding patient consent are reasonable.

Although the AAN is supportive of this proposal, we note that the level of education needed for this service is likely something that a nurse educator could provide incident to the services provided by the treating practitioner. The AAN believes uptake of this code may be limited by the required time to meet the threshold for this service.

Services Addressing Health-Related Social Needs (Community Health Integration services, Social Determinants of Health Risk Assessment, and Principal Illness Navigation Services)

Community Health Integration (CHI) Services

Code	Descriptor
GXXX1	Community health integration services performed by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address social determinants of health (SDOH) need(s) that are significantly limiting ability to diagnose or treat problem(s) addressed in an initiating E/M visit: • Person-centered assessment, performed to better understand the individualized context of the intersection between the SDOH need(s) and the problem(s) addressed in the initiating E/M visit. o Conducting a person-centered assessment to understand patient's life story, strengths, needs, goals, preferences and desired outcomes, including understanding cultural and linguistic factors. o Facilitating patient-driven goal-setting and establishing an action plan. o Providing tailored support to the patient as needed to accomplish the practitioner's treatment plan. • Practitioner, Home-, and Community-Based Care Coordination o Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; and from home- and community-based service providers, social service providers, and caregiver (if applicable).

	o Communication with practitioners, home- and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors. o Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities. o Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) to address the SDOH need(s). • Health education- Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, and preferences, in the context of the SDOH need(s), and educating the patient on how to best participate in medical decision-making. • Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services addressing the SDOH need(s), in ways that are more likely to promote personalized and effective diagnosis or treatment. • Health care access / health system navigation o Helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care and helping secure appointments with them. • Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals. • Facilitating and providing social and emotional support to help the patient cope with the problem(s) addressed in the initiating visit, the SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals. • Leveraging lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.
GXXX2	Community health integration services, each additional 30 minutes per calendar month (List separately in addition to GXXX1

CMS is proposing to establish separate coding and payment for community health integration (CHI) services. CMS is proposing to create two new G codes describing CHI services performed by certified or trained auxiliary personnel, which may include a community health worker (CHW), incident to the professional services and under the general supervision of the billing practitioner. CMS is proposing that CHI services could be furnished monthly, as medically necessary, following an initiating E/M visit (CHI initiating visit) in which the practitioner identifies the presence of SDOH need(s) that significantly limit the practitioner's ability to diagnose or treat the problem(s) addressed in the visit. The AAN supports establishing separate coding and payment for these services and supports the proposed values and code descriptors. The AAN believes establishing these codes will promote health equity and improve the healthcare system's ability to address SDOH related needs. While the AAN is supportive, we do note that small and solo practices are unlikely to have the resources to hire necessary staff and implement the procedures to provide CHI services. As such, the detrimental impacts of budget neutrality adjustments may disproportionately fall on small and solo practices who will not be able to provide these services.

CMS states that "certain types of E/M visits, such as inpatient/observation visits, ED visits, and SNF visits would not typically serve as CHI initiating visits because the practitioners furnishing the E/M services in those settings would not typically be the ones to provide

continuing care to the patient."[23] While the AAN concurs that typically a CHI initiating visit would occur in the outpatient setting, the AAN notes that providers frequently engage in a mix of inpatient and outpatient work. It is possible that a relationship that begins in a hospital could continue in a community-based outpatient setting. In some cases, requiring a separate outpatient visit prior to initiating CHI services could be duplicative and unnecessary, while delaying access to care. As an example, a person who is hospitalized for a stroke or Guillain-Barre syndrome may see a neurologist who identified SDOH needs while seeing the patient in an inpatient setting, and subsequently directs his/her staff to address the SDOH needs before seeing the patient for an in-office follow-up. In this scenario, it is unclear to the AAN why billing for CHI services would be contingent on the outpatient visit, rather than the inpatient visit in which the SDOH related needs were identified.

Social Determinants of Health (SDOH) –Proposal to establish a stand-alone G code

Code	Descriptor
GXXX5	Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5-15 minutes, not more often than every 6 months.

CMS is proposing a new stand-alone G code, GXXX5 for administration of an evidence based SDOH assessment. The AAN believes that standardization is key in promoting data capture to address SDOH needs. The AAN believes developing separate coding and payment for a standardized assessment is a positive step to promote health equity. The AAN concurs with CMS that the resources associated with the taking of a social history in support of patient-centered care "are not appropriately reflected in current coding and payment policies."[24]

CMS is proposing that the SDOH risk assessment must be furnished by the practitioner on the same date they furnish an E/M visit, as the SDOH assessment would be reasonable and necessary when used to inform the patient's diagnosis, and treatment plan established during the visit. The SDOH needs identified through the risk assessment must be documented in the medical record and may be documented using a set of ICD-10-CM codes known as "Z codes." The AAN believes that allowing a trained staff member to perform the assessment incident to but before the visit promotes access to this service while ensuring that providers can spend their time focusing on patient care, rather than data collection. Additionally, the AAN supports CMS' proposal to add this code to the Medicare Telehealth list on a permanent basis.

Principal Illness Navigation (PIN) Services

Code	Descriptor
GXXX3	Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator or certified peer specialist; 60 minutes per calendar month, in the following activities: • Person-centered assessment, performed to better understand the individual context of the serious, high-risk condition.

[23] 88 Fed. Reg. at 52327
[24] 88 Fed. Reg. at 52331

	o Conducting a person-centered assessment to understand the patient's life story, strengths, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors. o Facilitating patient-driven goal setting and establishing an action plan. o Providing tailored support as needed to accomplish the practitioner's treatment plan. • Identifying or referring patient (and caregiver or family, if applicable) to appropriate supportive services. • Practitioner, Home, and Community-Based Care Coordination o Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; home- and community-based service providers; and caregiver (if applicable). o Communication with practitioners, home-, and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors. o Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities. o Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) as needed to address SDOH need(s). • Health education- Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, preferences, and SDOH need(s), and educating the patient (and caregiver if applicable) on how to best participate in medical decision-making. • Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services (as needed), in ways that are more likely to promote personalized and effective treatment of their condition. • Health care access / health system navigation. o Helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care, and helping secure appointments with them. o Providing the patient with information/resources to consider participation in clinical trials or clinical research as applicable. • Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals. • Facilitating and providing social and emotional support to help the patient cope with the condition, SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals. • Leverage knowledge of the serious, high-risk condition and/or lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.
GXXX4	Principal Illness Navigation services, additional 30 minutes per calendar month (List separately in addition to GXXX3).

CMS is proposing to "better recognize through coding and payment policies when certified or trained auxiliary personnel under the direction of a billing practitioner, which may include a patient navigator or certified peer specialist, are involved in the patient's health care navigation as part of the treatment plan for a serious, high-risk disease."[25] The AAN supports establishing separate payment and coding for principal illness navigation and appreciates CMS' acknowledgement of the need for these services among neurology patients. Currently

[25] 88 Fed. Reg. at 52326

neurology nurse navigators frequently provide these services, but the work is unpaid, making it difficult to justify the time spent assisting with care navigation to their employer. Professional navigation services are highly necessary for patients who can become overwhelmed while navigating the healthcare system to coordinate care for their complex or high-risk condition. Implementation of PIN services may pose challenges for small and solo practices, who may not be able to hire the staff needed to implement these services. The AAN remains concerned about the detrimental impacts of budget neutrality on these providers.

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

Office/Outpatient (O/O) E/M Visit Complexity Add-on Implementation

The AAN is strongly supportive of the establishment of HCPCS code G2211 *(Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established))*.[26] While the AAN was highly supportive of the American Medical Association's Relative Value Scale Update Committee recommendations for the revised office/outpatient E/M CPT visit code set, the AAN concurs with CMS that "those values did not fully account for the resource costs associated with primary care and other longitudinal care of complex patients."[27] The AAN agrees with CMS that implementation of G2211 is necessary to accurately account for the cost associated with the longitudinal care of complex patients. The AAN believes the resources needed for these visits are greater due to increases in the probability of morbidity and mortality and a vital need for collaboration between providers. The AAN believes that implementation of this code is likely to benefit neurologic care when it serves as a medical home and as principal care. The AAN also recognizes that this code will prove invaluable to the treatment of MS, brain tumors, neuromuscular disorders, dementia, stroke, epilepsy, Parkinson's disease, and in rural settings.

The AAN was pleased to see in previous rulemaking that CMS recognized that neurologic patients generally present with complex diseases and that it is necessary to account for the additional complexity inherent to providing E/M services to these patients.[28] We applaud CMS' intent to recognize and reward physicians who care for complex patients, regardless of specialty. The AAN concurs with CMS' rationale that there are different pre-visit resource costs associated with non-procedural specialized medical care and is grateful that this code is not restricted by specialty or to primary care practitioners. Additionally, the AAN appreciates CMS' decision to ensure that the code is available to both new and established patients.

The AAN has previously expressed concern regarding the need for further guidance on the use of this code once it is implemented and appreciates CMS offering additional clarification surrounding inappropriate use of this code "such as when the care furnished during the O/O

[26] 88 Fed. Reg. at 52353
[27] 88 Fed. Reg. at 52352
[28] Id.

E/M visit is provided by a professional whose relationship with the patient is of a discrete, routine, or time-limited nature" or "where comorbidities are either not present or not addressed, and/or when the billing practitioner has not taken responsibility for ongoing medical care for that particular patient with consistency and continuity over time, or does not plan to take responsibility for subsequent, ongoing medical care for that particular patient with consistency and continuity over time."[29] Additionally, the AAN appreciates that CMS has heeded the AAN's advice and listed several examples that do not meet CMS' definition of a "single serious condition or a complex condition."

CMS is seeking stakeholder comments in response to the agency's utilization assumptions for G2211. CMS estimates that G2211 will be billed with 38 percent of all O/O E/M visits initially, with utilization increasing to 54 percent of all O/O E/M visits when the code is fully adopted. The AAN notes that while the code may be widely applicable, historical precedent indicates that utilization could be far lower initially. In developing the appropriate estimate, CMS could examine the past utilization history for Transitional Care Management (TCM) codes (99495 & 99496). This code set serves as a helpful barometer for measuring the provision of "ongoing care" and adoption of relevant coding changes in the real world. As an illustrative example, CMS previously estimated that there would be approximately 5.6 million claims for TCM. In practice, the actual utilization for TCM came in just under 300,000 in the first year. Utilization for TCM was still less than one million after 3 years of implementation. While the AAN recognizes numerous substantive differences between the TCM codes and G2211, based on historical precedent the AAN believes that adoption of G2211 will be slow at first and follow a similar trend. This is partially attributable to the need for medical societies to educate their members about the appropriate use of this code. Practices will also need time to make updates and integrate new coding policies. The AAN firmly believes CMS should be cognizant of the historical uptake of similar codes when determining appropriate utilization estimates and that CMS should consider the need to further revise its utilization estimates, so as to not overestimate the redistributive impacts of implementing G2211 on the Medicare conversion factor.

Informing these utilization assumptions is that the agency is proposing that "the O/O E/M visit complexity add-on code, HCPCS code G2211, would not be payable when the O/O E/M visit is reported with payment modifier-25."[30] In justifying this decision, CMS states that "[w]e continue to believe that separately identifiable O/O E/M visits occurring on the same day as minor procedures (such as zero-day global procedures) have resources that are sufficiently distinct from the costs associated with furnishing stand-alone O/O E/M visits to warrant different payment."[31] The AAN believes that this is an appropriate decision, recognizing the substantial impact that inclusion of G2211 will have on the conversion factor. The AAN believes that while O/O E/M office visits occurring on the same day as a minor procedure may for the most part have resources appropriately captured by the procedure code, the AAN believes that a blanket exclusion may not be appropriate and that there may be a need for limited exceptions.

Request for Comment About Evaluating E/M Services More Regularly and Comprehensively

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[29] 88 Fed. Reg. at 52353
[30] 88 Fed. Reg. at 52350
[31] 88 Fed. Reg. at 52353

The AAN appreciates that CMS is examining strategies to evaluate E/M services more regularly and comprehensively. The AAN concurs with commenters that the agency should prioritize addressing "growing distortions in resource allocations under the PFS for certain types of services, including evaluation and management visits and other non-procedural/non-surgical services."[32] Additionally, the AAN appreciates CMS' commitment to ensuring that "data collection from, and documentation requirements for, physician practices are as least burdensome as possible while also maintaining strong program integrity requirements."[33]

The AAN is concerned with the structural impacts of passive devaluation on all services in the MPFS, particularly on the 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."[34] 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 2024 MPFS, all services that aren't directly updated in the MPFS are subject to a 2.17% reduction in payment.[35] E/M services are uniquely vulnerable to the impacts of passive devaluation due to structural constraints inherent to the process by which the relative values of code sets are updated and implemented in CMS rulemaking. The AAN urges CMS to work with Congress to ensure that cognitive work maintains its appropriate value.

Recognizing CMS' interest in reform, the AAN's answers to selected CMS' questions are as follows:

a. Do the existing E/M HCPCS codes accurately define the full range of E/M services with appropriate gradations for intensity of services?

The AAN was highly supportive of the implementation of new coding and reimbursement policies for E/M services. The AAN was involved in the AMA CPT/RUC process to develop the new structure and believes that it produces a simplified and more intuitive system of E/M coding that is more consistent with the current practice of medicine. Although the AAN is highly supportive, the AAN notes that the acuity between higher level E/M codes is often quite steep and inconsistent with the differential between lower-level codes. The AAN strongly believes that there is a need to account for this higher acuity and for the cost associated with the longitudinal care of complex patients. The AAN believes that rapid implementation of G2211 is a necessary step in accounting for this higher acuity and complexity.

The AAN is highly supportive of the use of telehealth to deliver E/M services as well as the implementation of the non-face-to-face codes. The AAN notes that while the care

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32 88 Fed. Reg. at 52354
33 Id.
34 "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.
35 Table 102, 88 Fed. Reg. at 52679

management codes are well-defined and appropriate, persistent implementation challenges have limited their utilization.

The AAN appreciates that CMS is taking steps in this proposed rule to provide separate coding and payment for services provided by auxiliary personnel incident to E/M services, including care navigation and education. Reimbursing for the work of physician extenders allows neurology practices to utilize all members of an insufficient workforce to perform at the top of their license to better maintain population health.

b. Are the methods used by the RUC and CMS appropriate to accurately value E/M and other HCPCS codes?

The current survey methodology has several limitations that impact both E/M and non-E/M services. These include low response rates, an inability to determine if the responses received are accurate reflections of real-world clinical practice, and substantial variations in modern day clinical practice for the same HCPCS code across specialty. More direct methodologies may be more costly and burdensome to implement but would also more accurately reflect the actual time and effort involved inherent to a particular HCPCS code. The AAN believes that time and motion studies could be used to more accurately determine the resources needed in a resource-based relative value scale reimbursement program.

d. Are the methods used by the RUC and CMS appropriate to accurately value the non- E/M codes?

Please see the AAN's response for question b.

e. What are the consequences if services described by HCPCS codes are not accurately defined?

Inappropriate utilization, particularly if no health benefit is obtained for the patient or population, can lead to excessive costs to the healthcare system and sub-optimal care. An illustrative example from neurology is the historical use of the video-monitoring code for less acute patients receiving ambulatory EEG in their home when the intended use of this code was for the inpatient setting with clinician monitoring and the ability to intervene and respond to abrupt changes in medical status. The misuse of this code led to increased inappropriate utilization and a subsequent substantial reduction in reimbursement for neurologists. This has had long-term negative impacts on neurology departments and on access to neurologic care.

f. What are the consequences if services described by HCPCS codes are not accurately valued?

When HCPCS codes are not accurately valued, the healthcare system can become distorted as financial incentives at least partially drive behavior, rather than the goal of delivering medically appropriate care and promoting population health. The AAN notes anecdotal reports of coaching on how to respond to procedure surveys, potentially leading to increased reimbursement for those procedures. This has substantial downstream impacts, both on the

healthcare workforce and on healthcare system decision making. Medical students disproportionately seek out higher-paid specialties, making it so the workforce for relatively underpaid specialties can be detrimentally impacted. Additionally, given budget neutrality requirements, when certain HCPCS codes are overvalued, other specialties face reimbursement cuts, straining practices and leading to misallocation of resources across the healthcare system. This problem is compounded as a need for increased productivity to off-set financial losses can drive burnout, making relatively less lucrative specialties even less attractive to medical students, further harming the workforce.

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 2025, the AAN is extremely 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."[36]

The AAN believes this new definition is not aligned with changes already implemented for outpatient and more recently 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 the establishment of a different paradigm for determining which practitioner may bill for split (or shared) E/M visits is unnecessarily burdensome and confusing for practitioners. The AAN also believes CMS' policy is not aligned with the actual workflow that has safely developed over time within neurologic care teams.

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."[37] 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 that determines the plan of care.[38] The

[36] 86 Fed. Reg. at 65153
[37] Id.
[38] See AAN comments found at: https://www.aan.com/siteassets/home-page/policy-andguidelines/advocacy/final-aan-split-shared-letter.pdf

AAN urges CMS to consider the AAN's recommendations and to prioritize the minimization of documentation burden.

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 if CMS were to accept an attestation-based solution. 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. We strongly urge CMS not to disrupt team-based care in facility settings and to revise the split (or shared) visit policy to allow the physician or NPP who is doing the cognitive work that drives the patient's care to bill for the service. The AAN believes that it is 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.

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 2024 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 for E/M services implemented in 2023. The AAN is grateful to CMS for continuing to delay implementation of the previously finalized policy, as we believe it will be a significant impediment for neurology practices and thereby lead to delays or limitations to access to care for their patients. However, the AAN is concerned about the confusion and disruption caused by the lack of clarity regarding permanent policy continuing to loom over providers. The AAN encourages 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.

To that end, the AAN appreciates CMS' acknowledgment of the ongoing process being undertaken by the AMA CPT Editorial Panel to revise guidance relating to key elements of split (or shared) visits that would provide CMS clear direction on how the physician community believes this policy should be adjusted. The AAN anticipates that a methodology for determining the substantive portion of MDM will be included in this forthcoming guidance. The AAN is highly supportive of efforts to define the substantive portion of MDM in the context of a split or shared visit and urges the agency to ensure that updated CPT guidance is appropriately 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.

Strategies for Improving Global Surgical Package Valuation

The AAN was pleased that CMS solicited comments regarding the development of strategies for improving global surgical package valuation in the 2023 Medicare Physician Fee Schedule proposed rule. The AAN has long believed, in alignment with the findings of the RAND studies[39], 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" [40] 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 ensure that the valuation of the global packages accurately reflects the work being done and that the values are supported by data. The AAN notes that in response to comments received from stakeholders that CMS noted that "the spectrum of comments demonstrates that there is not, at this time, clear public consensus on this issue or the preferred strategy for valuing globals."[41] Recognizing the urgent need for a solution, the AAN is disappointed that CMS has not included further information regarding the agency's preferred approach to improving global surgical package valuation and urges the agency to consider the most appropriate approach in forthcoming rulemaking, as soon as practicable.

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. The AAN concurs with CMS that "[a]ccurately valuing the work and other inputs of the globals is critically important to ensure not only that the practitioners providing those services are paid accurately for the work performed, but that there is no inequitable impact on practitioners paid outside of 10-and 90-day global packages."[42] 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.

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 qualified healthcare professional. It is possible that the observed discrepancy is due to improvements in comprehensive discharge planning.

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[39] "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-.

[40] 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

[41] 87 Fed. Reg. at 69437

[42] Id.

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) 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."[43] 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.

In determining the most appropriate path forward, the AAN believes 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' stated concern with the potential disruption that would be caused by drastically changing or eliminating all the 10 and 90-day global packages abruptly. Furthermore, the AAN concurs with CMS that "[t]he diversity of procedures paid under global packages may mean that blanket approaches to valuation or revaluation may not achieve the desired degree of accuracy."[44] That is why the AAN is recommending that CMS take a transitional approach, instead of addressing all potentially misvalued packages simultaneously. The AAN believes the most prudent approach would be to 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[45] 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 inequitable impact that existing inappropriate values of the global packages have had on practitioners that are paid outside of the 10-and 90-day global packages. This approach will hold harmless physicians performing the allocated post-operative visits while allowing CMS to evaluate the true

[43] 84 Fed. Reg. at 62858.
[44] 87 Fed. Reg. at 69437
[45] Mulcahy, Andrew W et al. "Using Claims-Based Estimates of Post-Operative Visits to Revalue Procedures with 10- and 90-Day Global Periods: Updated Results Using Calendar Year 2019 Data." Rand health quarterly vol. 9,3 10. 30 Jun. 2022

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 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.

III. A. Drugs and Biological Products Paid Under Medicare Part B

Provisions from the Inflation Reduction Act Relating to Drugs and Biologicals Payable Under Medicare Part B

The AAN recognizes the requisite updates to regulatory language in order to include provisions from the Inflation Reduction Act in the 2024 MPFS and supports CMS' proposed implementation of relevant provisions. The AAN does want to reiterate our support for the substance of many of these provisions, specifically, those aimed at addressing ever-rising patient costs for their prescription drugs. The majority of treatments for neurologic disorders rely on pharmacotherapies, making access to affordable prescription drugs crucial for patient health. High drug costs and associated cost-sharing for patients are directly linked with a higher likelihood of patients abandoning or rationing their treatments, which may result in permanent disability.[46] When individuals are forced to ration therapeutics for chronic diseases, as is the case with many neurologic conditions, both patients and the healthcare system stand to lose as morbidity and mortality accrue, and can result in an overall increase in health care expenditures at the patient level.[47] The AAN is highly supportive of CMS expeditiously implementing provisions that affect payment limits or beneficiary out-of-pocket costs.

Request for Information (RFI): Drugs and Biologicals which are Not Usually Self-Administered by the Patient, and Complex Drug Administration Coding

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[46] Bauchner, Howard. "Rationing of Health Care in the United States: An Inevitable Consequence of Increasing Health Care Costs." JAMA vol. 321,8 (2019): 751-752. doi:10.1001/jama.2019.1081
[47] Centers for Disease Control and Prevention. Cost-Related Nonadherence and Mortality in Patients with Chronic Disease: A Multiyear Investigation, National Health Interview Survey, 2000-2014. December 3, 2020. Accessed March 23, 2023. https://www.cdc.gov/pcd/issues/2020/20_0244.htm

The AAN is grateful that CMS is seeking to better understand the provider and patient communities' concerns pertaining to the self-administered drug list processes and CMS' interest in helping to clarify points of confusion or inconsistency faced by providers. The AAN's paramount concern regarding the manner and venue in which a drug is administered is the safety of patients. A variety of factors are considered between the physician-led care team, caregivers, and patients when determining what the patient should be prescribed and whether that drug should be administered on-site by the care-team or by the patient or caregiver. A continued concern of the AAN is the effective allowance for the Medicare Administrative Contractors (MACs) to insert themselves into patient-provider decision-making by publishing "self-administered drug" (SAD) exclusion lists that impact patient access and associated out-of-pocket costs for these drugs, and which could alter a plan of care to the detriment of the patient.

The AAN notes that many drugs prescribed to treat neurologic disease are sometimes self-administered, while at other times are administered by the physician-led care team. The appropriateness of who administers a particular drug is dependent on that patient's specific risk profile, comfort level with self-administration, and history of adverse reactions or other factors for that particular drug. This variation is medically appropriate in many cases and is likely to grow over the coming years as forthcoming drugs receive FDA approval that fit these characteristics, including potential subcutaneous formulations of the newly approved monoclonal antibody therapies directed against amyloid for the treatment of Alzheimer's Disease. The AAN notes that a patient may begin their treatment on a particular therapy by having it administered in the office or at an infusion center and then begin self-administering at home or work as they, and their physician, learn more about their experience with the drug. It would be a mistake for CMS to disrupt this pattern of care by continuing to allow the MACs to potentially arbitrarily determine whether a drug may or must be self-administered.

That is why the AAN is requesting that CMS act to increase flexibility for patients and providers alike to determine the best treatment plan by covering these drugs under Part B whenever possible and then only resorting to Part D when there is clear and unambiguous evidence that the drug can be safely administered at home by the patient or the patient's caregiver. A MAC placing a drug on the SAD list should not preclude a patient and physician from making the joint determination that physician-led care team administration is the best course of treatment for an individual patient. The appropriateness of that determination should be based on clinical factors and patient comfort, rather than a restriction on reimbursement to the provider.

The AAN is also grateful for CMS' request for information on complex drug administration coding. Each year more therapies are approved for the treatment of neurologic disease, and frequently these treatments are infused drugs that present novel challenges for neurology providers on how to best incorporate them into their practice patterns. These challenges are compounded by the increasingly inadequate reimbursement for the infusion and monitoring necessary to ensure optimal patient safety and effectiveness. For many of these drugs, as many as three hours of post-infusion monitoring is recommended.[48] AAN members report that the reimbursement levels associated with Therapeutic, Prophylactic, and Diagnostic

[48]Cummings, Jason et al. "Lecanemab: Appropriate Use Recommendations." The journal of prevention of Alzheimer's disease vol. 10,3 (2023): 362-377. doi:10.14283/jpad.2023.30

Injections and Infusion services billed using CPT code series 96360-96379 have proven to be wholly inadequate, resulting in large hospitals having to subsidize these services and for smaller practices to reconsider whether they are able to provide these treatments to their patients. At a time when access to critically needed neurologic specialists is already dismally insufficient, inadequately reimbursing this needed care only serves to exacerbate access issues. This inevitably leads to more concentration of specialist care in large centers that can better offset the loss associated with these infusions, furthering health disparities across geography and socioeconomic status. The AAN recommends that CMS broaden the applicability of Chemotherapy and Other Highly Complex Biological Agent Administration ("Chemotherapy Administration") services that are billed using CPT code series 96401-96549 or increase reimbursement for the series 96360-96379 codes in order to rectify this discrepancy as soon as possible.

Additionally, the AAN is concerned with the MACs' inappropriate use of Local Coverage Articles (LCAs) to issue policy changes impacting access to infusible therapeutics. Instead of abiding by requirements stemming from the 21st Century Cures Act, some MACs have used LCAs to unilaterally issue policy changes that restrict coverage or access, which harms Medicare beneficiaries and undermines the transparent Local Coverage Determination process intended by Congress and CMS. Specifically, the AAN is deeply concerned with recent actions by the MACs that have recategorized infusion of complex biologics as "simple, therapeutic" infusions or injections by issuing LCAs that characterize changes as either re-education relating to coding corrections or mere billing instructions. In reality these are substantive changes that are likely to have a significant impact on patient access to treatment. While the AAN appreciates that CMS has taken steps to intervene to prevent inappropriate down coding of certain claims, the AAN believes it is critical that CMS promulgate additional guidance to the MACs to ensure that the complexity of infusing neurologic therapies is appropriately accounted for and to ensure that forthcoming products receive adequate reimbursement that reflects their real-world complexity of administration.

Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs to Provide Refunds With Respect to Discarded Amounts

The Academy appreciates CMS' continued effort to establish this refund program in order to reign in drug costs and mitigate waste across the health care system. Many of the proposals are technical in nature relating to the specific volume levels and even physical characteristics of the drugs eligible for refund, and the AAN applauds the diligence shown therein.

However, this does also raise a degree of caution for our members as this system may end up being overly contrived and complicated, thereby limiting its effectiveness. The Academy does wish to acknowledge CMS' recognition of the burdens of complexity through the proposal that self-administered drugs only be billed with the JZ modifier to clear up confusion and reduce administrative burden on beneficiaries and providers. The Academy also appreciates CMS' efforts towards predictability and efficiency in aligning reporting timelines for this program with the Part B and Part D inflation rebate reports.

While the AAN does not have any specific recommendations regarding the technical and process proposals in this year's proposed rule, we would encourage CMS to retain its focus

on simplicity and minimizing burden to ensure this program's success. The AAN notes that specialty societies must expend significant resources to provide our membership with much-needed clarity surrounding programmatic changes impacting reimbursement. Given ongoing strains on the workforce, it is critical that CMS work to ensure that compliance is not overly burdensome.

III. G. Medicare Shared Savings Program

Mitigating the Impact of Negative Adjustments to Encourage Caring for Complex Beneficiaries

The AAN agrees with the stated aim of promoting access to care for more dual-eligible and complex beneficiaries. The AAN also supports the work that CMS has done to mitigate the impact of negative adjustments on Accountable Care Organizations (ACOs) that care for clinically complex patients, as neurologists often treat medically complex patients. The AAN appreciates CMS' recognition that physicians and medical organizations should not be punished for caring for complex patients and that structural barriers for complex beneficiaries should be mitigated. The AAN appreciates CMS' work to develop adjustments to ensure that ACOs are not penalized for their high cost of care because of the complexities of the patient population being treated by a particular ACO.

Although the AAN supports the mitigation efforts proposed, we urge CMS to make the data used to make the calculations of adjustments transparent to the ACO. The AAN believes that doing so would aid providers in planning how to care for these patients. The ACO should have a reliable way to appeal CMS' determination within a reasonable amount of time, and certainly enough time to have the appeal investigated and resolved prior to those determinations impacting payment and participation in subsequent performance years. In addition to addressing potential disincentives to enrolling dual-eligible and complex beneficiaries, the AAN strongly encourages CMS to explore additional opportunities to provide ACOs with positive incentives.

MIPS Value Pathway (MVP) Reporting for Specialists in Shared Savings Program ACOs (RFI)

A goal of MVP reporting for specialists within ACOs is for "patients to make informed decisions about the care they receive."[49] CMS does not provide further information around how this will be achieved with the data that is being collected. The AAN requests further clarification from CMS regarding how quality performance information will be shared with ACOs, MVP participants, and beneficiaries attributed to ACOs. It is critical for patients to be informed and able to make clinical decisions that are sound, however, the AAN is concerned that the information provided to beneficiaries may be unclear or lacking in relevance.

The AAN acknowledges that neurologic providers have three MVPs to report and are thankful that there are specialty specific options available. The current iteration of MVPs still lacks comprehensive means to address value-based care widely. While the AAN appreciates the development of the current comprehensive MVPs, the AAN encourages further development of measures and care delivery models that are targeted and condition specific.

[49] 88 Fed. Reg. at 52437

CMS is considering bonus points for ACOs with specialists reporting on MVPs that would be applied after Merit-based Incentive Payment System (MIPS) scoring is complete. The AAN is concerned that these bonuses will diminish over time and could potentially turn into penalties for medical organizations that participate. The AAN will continue to work with Congress and relevant stakeholders to develop meaningful incentives over the long term to strengthen APM participation. CMS should encourage the reporting of MVPs for ACO specialists and non-specialists to be an identical process to streamline the process across different medical organizations.

Potential Future Developments to Shared Savings Program Policies (RFI)

Incorporating a Higher Risk Track than the ENHANCED TRACK

The AAN believes shared savings programs provide incentives too little and too late to be effective for many participants. Moreover, shared savings programs do not provide timely enough feedback to ACO's to have a meaningful impact on quality of care delivered. The AAN believes that the complexity, conditions, and caveats of the shared savings calculations result in demotivation and adds to the need for further administrative support and subsequent cost to determine legitimacy.

In response to the specific questions posed by CMS, the AAN believes that the compensation mechanism has to fundamentally change in ways that the AAN and other specialty societies have proposed to the Center for Medicare and Medicaid Innovation (CMMI) in the past but have not been implemented.[50] It remains critical that ACOs are not prematurely asked to take on risk and that transition to higher risk levels is both gradual and voluntary.

Approaches to Promote ACO and Community-Based Organizations (CBO) Collaboration

The AAN supports the promotion of collaboration between ACOs and CBOs. The AAN suggests making these activities high-priority MIPS improvement activities to encourage such collaboration.

III. J. Appropriate Use Criteria for Advanced Diagnostic Imaging

The AAN applauds CMS' proposal to indefinitely suspend the Appropriate Use Criteria (AUC) program. The AAN believes that abandoning this program is necessary as further implementation could have significant detrimental impacts on timely patient access to care. The AAN has repeatedly recommended CMS to take this step and is aware of many other stakeholders who hold the same view.[51] The AAN is grateful to CMS for recognizing the potential risks of this program as well as its limited benefits, given the redundancy that the AUC program would have shared with aspects of the Quality Payment Program. The AAN

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[50] American Academy of Neurology Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations-Pathways to Success, 18 September 2018, https://downloads.regulations.gov/CMS-2018-0101-0081/attachment_1.pdf

[51] American Academy of Neurology Joins Comments on the Implementation of CMS' Appropriate Use Criteria Program, 18 May 2022, https://www.aan.com/siteassets/home-page/policy-and-guidelines/advocacy/final-sign-on-letter-to-cms-re-auc-report.pdf

urges CMS, in considering its mandate under the Protecting Access to Medicare Act, to take steps to limit prior authorization burden for any impacted clinicians.

III. K. Medicare and Medicaid Provider and Supplier Enrollment

The AAN recognizes CMS' need to ensure program integrity and is certainly supportive of appropriate steps to prevent fraud in the Medicare program. However, the AAN has concerns with the proposals relating to the revocation of Medicare eligibility and the potential for unintended consequences stemming from an overly broad policy.

For example, under this proposal, it appears that Medicare may be able to retroactively deny a claim submitted by a physician otherwise in good standing should they, or potentially another employee, be convicted of nearly any misdemeanor. The AAN appreciates that CMS uses language throughout the proposed rule that suggests CMS would aim to "deem" a misdemeanor "detrimental to the best interest of the Medicare program" when it rises to a certain level of severity or, as exemplified in the proposed rule, directly relates to the function of Medicare such as the controlled substances example. However, from the perspective of an employer, absent further clarification, any misdemeanor, such as operating a motor vehicle without proper insurance/documentation, could potentially be deemed as a liability to the best interest of the Medicare program, subjecting the practice to substantial risk. The AAN questions how a practice, especially a large hospital center, could possibly effectively monitor and prevent any such person from participating in a Medicare beneficiary visit.

The Academy appreciates the challenges associated with ensuring equitable and efficient program integrity standards across jurisdictions with different legal codes, but we urge that far more clarity be provided as to exactly what misdemeanors could jeopardize a physician's eligibility and how physicians and their employers can ensure they are able to remain in compliance with all eligibility requirements. The AAN believes this is in line with the agency's intent, based on the proposed creation of the "Stay of Enrollment" designation which seems to be designed with the goal of ensuring that revocation of eligibility is not the only, rather blunt, instrument at CMS' disposal when attempting to intercede with a perceived or potential bad actor. The AAN strongly urges CMS to develop and publish additional illustrative examples of conduct that CMS would deem as detrimental to the best interest of the Medicare program. Further, the AAN encourages CMS to create and publish clear guidelines for how the agency will evaluate this behavior in addition to furnishing illustrative examples. Those guidelines should be open for comment from stakeholders prior to enactment. This will be critical for employers making hiring decisions and for managing current employees.

Provider Home Address Disclosure

The AAN is deeply concerned with the implications of the expiration of policy stemming from the Public Health Emergency that allowed providers flexibility in certain reporting requirements as a condition of Medicare enrollment. Specifically, during the PHE, physicians could perform telehealth visits from their homes without having to report their home addresses. It is our understanding that, effective January 1, 2024, this will no longer be

permissible. This would result in the home addresses of thousands of physicians becoming publicly available should they wish to continue the now well-established practice of performing telehealth visits from their homes, to ensure broader access to high-quality care for their patients. The AAN believes this will significantly disincentivize provision of telehealth services and drastically alter current practice patterns to the detriment of patients and providers alike. The AAN does not see any value in making the home address of physicians so readily accessible to the public.

The AAN notes that there is substantial risk associated with requiring providers to disclose their home address. We strongly urge CMS to consider the implications that this policy may have on provider safety, especially in the current climate of increasing threats and violence being directed towards healthcare workers.[52] Further, the AAN is deeply concerned with the potential detrimental impact that disincentivizing telehealth may have on the neurology workforce and on provider burnout. The AAN urges CMS to continue to allow physicians to report their office address for the purpose of Medicare enrollment, regardless of the originating site of service for telehealth visits as has been the case, without issue, throughout the PHE.

III. M. 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)

CMS is proposing to allow prescribers the ability to request a waiver from the Electronic Prescribing for Controlled Substances (EPCS) program regardless of whether the agency triggers the recognized emergency exception. Additionally, CMS will also identify which events trigger the recognized emergency exception and would inform prescribers of which emergencies or disasters automatically qualify for the exception without requesting a waiver, as determined by CMS, using normal communication channels such as listservs and the CMS EPCS Program website. CMS is also proposing that prescribers impacted by the CMS EPCS Program recognized emergency exception will be excepted for the entire measurement year, and not just for the duration of the emergency. The AAN supports this proposal but requests further clarification regarding how CMS will determine the length of a requested emergency, especially if it occurs close to the end of the year, given that a granted exception would apply for the full measurement year. It will be critical for providers to understand this information when CMS grants an exception in response to an application to avoid inadvertent non-compliance.

CMS is proposing to continue the practice of issuing a prescriber notice of non-compliance as the non-compliance action under the EPCS program. In justifying this continuation, CMS states that the agency believes the risk of fraud, waste, or abuse can be mitigated without the need for further penalties for non-compliance. The agency notes that they may use this information in processes for assessing potential fraud, waste, and abuse, which, in some instances, could result in a referral to law enforcement or revocation of billing privileges, in the event that evidence of fraud, waste, or abuse is present. We acknowledge CMS' authority

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[52] Boyle, Patrick. Threats against Health Care Workers Are Rising. Here's How Hospitals Are Protecting Their Staffs, Association of American Medical Colleges, 18 Aug. 2022, www.aamc.org/news/threats-against-health-care-workers-are-rising-heres-how-hospitals-are-protecting-their-staffs.

to recommend significant non-compliance issues to law enforcement and emphasize that we strongly support the CMS position that risk of fraud, waste, or abuse can be mitigated without need for further penalties for non-compliance. We would further recommend that a series of escalating notices be considered by the agency and that a process should be made available to ensure that prescribers are given reasonable, peer-reviewed opportunities and appropriate time to address issues noted in non-compliance notices.

III. R. Updates to the Definitions of Certified Electronic Health Record Technology

CMS is proposing revisions to the CEHRT definitions in the Medicare Promoting Interoperability Program and the Quality Payment Program to support the proposed transition from the historical state of year themed "editions" to the "edition-less state" proposed in the Office of the National Coordinator for Health Information Technology's (ONC) Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) proposed rule, if the ONC HTI-1 rule is finalized. The AAN supports this proposal and believes that alignment across agency policies is critical to minimizing the administrative burden on providers.

IV. Updates to the Quality Payment Program

<u>*Transforming the Quality Payment Program*</u>

Advancing CMS National Quality Strategy Goals

The AAN appreciates ongoing efforts to promote the transition towards a healthcare delivery system based on value-based care. However, the AAN believes that the Quality Payment Program (QPP) continues to fall short in providing a meaningful pathway to participation for neurologists in alternative payment models and is a major cause of regulatory burden for providers. Efforts to measure and report on quality compound on existing administrative burdens, including prior authorization requirements, and continue to interfere with patient care. The AAN strongly believes that CMS should focus on reducing the time that providers spend on administrative tasks so that patient care can be prioritized.

The AAN understands CMS' interest in aligning quality measures and programs across the agency. However, we remain concerned that new goals, such as The Universal Foundation,[53] will present the same issues that current programs, like MIPS and Advanced Alternative Payment Models (APMs), and past programs, such as the Physician Quality Reporting System, experienced. Although the vision of The Universal Foundation goal is admirable, the AAN is concerned that the introduction of another quality program component is reminiscent of retired programs that did not move the needle of value-based care. The AAN notes that the Universal Foundation measures may not be universally relevant to all providers. We encourage CMS to continue developing MVPs relevant to neurologic care so clinicians will have relevant measures to report on. Further, recognizing the burden associated with neurologic disease, the AAN encourages CMS to incorporate strategies aimed at promoting brain health and prevention of neurologic disease.

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[53] Aligning Quality Measures Across CMS - The Universal Foundation, Centers for Medicare and Medicaid Services, 1 May 2023, www.cms.gov/aligning-quality-measures-across-cms-universal-foundation.

The ongoing introduction of new quality components and programs to rectify programs that have not been successful in capturing value of care is a persistent strain on providers. The ongoing implementation of value-based payment reforms has increased the regulatory burden on practices year over year, while the return on investment to become educated and perform highly in Medicare quality programs is extremely limited. According to the 2022 Medical Group Management Association (MGMA) Regulatory Buden Report, 65% of medical practices report that QPP reporting is very or extremely burdensome on their organizations while 90% of respondents reported that positive payment adjustments do not cover the cost of time and resources spent on reporting under the MIPS program.[54] This is highly concerning and fundamental shifts are needed to incentivize participation by covering the cost of time and resources spent on data collection and reporting.

Promoting Continuous Improvement in MIPS

CMS is seeking comments on how the agency can modify policies under the QPP to foster clinicians' continuous performance improvement and positively impact care outcomes for Medicare beneficiaries. The agency is considering implementing new policies including requiring more rigorous performance standards, emphasizing year-to-year improvement in the performance categories, or requiring that MIPS eligible clinicians report on different measures or activities once they have demonstrated consistently high performance on certain measures and activities. The AAN's responses to select questions from CMS are as follows:

- What potential policies in the MIPS program would provide opportunities for clinicians to continuously improve care?

The AAN appreciates CMS' continued efforts to make quality measurement through the MIPS program more meaningful to clinicians. The AAN is also appreciative of the efforts undertaken by CMS throughout the PHE to mitigate the reporting burden associated with complying with the MIPS program. Despite these efforts, physicians continue to report substantial challenges associated with complying with MIPS. A recent survey from the Medical Group Management Association indicated that 76% of respondents believed that the move towards value-based payment in Medicare has increased burden for their practice.[55] These challenges are acutely felt by small and solo practices. This is acknowledged by the United States Government Accountability Office[56] and supported by the persistent variation in performance scores between small and large practices.[57]

The AAN is opposed to any changes in the MIPS program that force clinicians to pick new measures every few years. The cost of implementing and reporting on measures is prohibitive for clinicians, no matter the practice setting. The MIPS program should maintain

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[54] 2022 Medical Group Management Association Regulatory Buden Report, 11 October 2022, https://www.mgma.com/federal-policy-resources/mgma-annual-regulatory-burden-report-2022
[55] 2022 Medical Group Management Association Regulatory Buden Report, 11 October 2022, https://www.mgma.com/federal-policy-resources/mgma-annual-regulatory-burden-report-2022
[56] Small and Rural Practices' Experiences in Previous Programs and Expected Performance in the Merit-Based Incentive Payment System, May 2018. www.gao.gov/assets/700/692179.pdf.
[57] Centers for Medicare and Medicaid Services, 2021 Quality Payment Program Experience Report, 2021, https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2433/2021%20QPP%20Experience%20Report.pdf

a period of stability before seeking out new ways to challenge participants. The AAN believes that this RFI seems premature given the transition that is underway to yet another updated version of MIPS that will require clinicians to report on new measures through the Foundational Measures and MVP system. In addition to these changes, clinicians will need to learn a new way of practicing and documenting their care due to the transition to digital quality measures. The AAN advises that the agency avoid implementing additional substantive policy changes until the program has remained stable for several years.

Continuing, the AAN believes that the focus of this RFI is misguided. Instead of implementing new and burdensome policies to modify existing programs, CMS ought to be focused on ensuring that quality reporting does not create undue burdens for practices and detrimentally impact access to care. The AAN is deeply concerned that additional MIPS requirements will further strain neurology practices without yielding the desired result of driving quality improvement for the majority of practices. Fundamentally underpinning this RFI is an underappreciation from CMS of the work required of high-performing practices to remain high performers on quality metrics year over year. It requires substantial effort on the part of providers and institutions to maintain systems that are aimed at ensuring high performance on key quality measures. Additionally, CMS should acknowledge that quality improvement is not linear. The greatest quality improvements are often front-loaded as practices identify and address the highest priority items and subsequent improvements can be marginal. Asking providers to continually show improvement, when it may not be possible to do so to a significant degree, may introduce perverse incentives. Instead of penalizing clinicians for consistent high performance, CMS could consider implementing bonuses for clinicians demonstrating significant improvement on particular measures, and/or for those who sustain high levels of performance. This may incentivize practices to try reporting on new measures, rather than those for which they have been consistent high performers. It may also be reasonable to allow providers to identify areas that need to be addressed, without penalty, with the goal of improving in subsequent years.

- Should we consider, for example, increasing the reporting requirements or requiring that specific measures are reported once MVPs are mandatory?

The AAN strongly opposes policy changes that would create additional burdens for providers. The AAN does not believe that additional and potentially duplicative reporting requirements are likely to meaningfully impact quality of care. The AAN notes that 64% of surveyed providers report that the move towards value-based payment in Medicare has not improved the quality of care for their patients.[58] Increased administrative burdens also increase costs and decrease the amount of time that providers can spend on patient care, leading to increased burnout and strains on the existing workforce. The AAN believes that CMS should focus primarily on ensuring that MIPS reporting drives meaningful quality improvement and cost containment, without imposing substantial burdens on clinicians. To date, the value that MIPS has yielded for neurology in terms of cost containment and quality improvement is not clear.

[58] 2022 Medical Group Management Association Regulatory Buden Report, 11 October 2022, https://www.mgma.com/federal-policy-resources/mgma-annual-regulatory-burden-report-2022

The AAN does not support CMS requiring that specific measures be reported once MVPs are mandatory. To date, the AAN has collaborated with CMS to develop three MVPs: Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes, Optimal Care for Patients with Episodic Neurological Conditions, Supportive Care for Neurodegenerative Conditions. In developing these MVPs, the measures listed were conceived of as a menu of options to be available for clinicians to report according to the relevance to their specific practice. CMS should not arbitrarily restrict reporting options and should instead defer to clinicians to determine the most appropriate measures for their practices. There will be many instances where very few measures in a particular MVP directly apply to a clinician's work, even if the condition falls within its specialty. As an illustrative example, the 'Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes' MVP is centered around a neurological condition, however, there are few outpatient stroke measures included, thus disqualifying many neurologists from participating meaningfully in the MVP because most of the measures are for the inpatient setting. CMS should be aware of and prepare for cases such as this. It would be inappropriate and disconnected from the quality of care provided for CMS to restrict neurologists, who primarily practice in the outpatient setting, to solely reporting on inpatient measures.

- Should we consider creating additional incentives to join APMs in order to foster continuous improvement, and if so, what should these incentives be?

The AAN continues to support the move towards value-based payment and APMs. The AAN strongly supports the establishment of additional incentives for clinicians to join APMs. 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 opportunities to participate.

The AAN is deeply concerned that CMS is contemplating introducing additional requirements into the MIPS program without providing substantive options that are relevant to neurology. The AAN strongly urges CMS to work to develop APM participation opportunities that are relevant to neurologists and neurology patients. We note that there is great diversity within neurology across specialties and sub-specialties, as well as across settings. As such, we anticipate that a diverse set of models will be needed to appropriately capture the value of neurologic care. Furthermore, the AAN urges CMS to work with Congress and relevant stakeholders, including the AAN, so that clinicians who have not had the opportunity to benefit from incentive payments are given the opportunity to benefit from incentive payments while transitioning to APMs. Clinicians would also benefit from additional education on available APMs and how to determine whether participating in a particular model is appropriate.

- We acknowledge the potential increase in burden associated with increasing measure reporting or performance standards. How should we balance consideration of reporting burden with creating continuous opportunities for performance improvement?

As noted above, the AAN strongly opposes policy changes that would create additional burdens for providers. The AAN does not believe that additional and potentially duplicative reporting requirements are likely to meaningfully impact quality of care.

The United States is facing a shortage of between 54,100 and 139,000 physicians by 2034 which will likely be exacerbated by rising rates of physician burnout and early retirement due to the COVID-19 pandemic.[59] In addition, the population of Americans over 65 years old is expected to double to 95 million by 2060,[60] and a dramatic rise in neurodegenerative disease is expected with incidence of stroke rising 20% by 2030,[61] prevalence for Parkinson disease doubling by 2040,[62] and incidence of Alzheimer's disease and related disorders doubling by 2050.[63] For neurologic patients, prompt access to care is essential to minimize risks of dangerous complications and side effects. There is great concern among AAN members that increased administrative requirements and compliance burdens under the QPP contribute to burnout, further exacerbating the inadequate supply of clinicians in the workforce. An estimated 60% of neurologists experience at least one symptom of burnout. CMS should be prioritizing policies that lessen administrative burden, rather than seeking out new opportunities to make compliance with the QPP more difficult.

- While we are aware of potential benefits of establishing more rigorous policies, requirements, and performance standards, such as developing an approach for some clinicians to demonstrate improvement, we are also mindful that this will result in an increasing challenge for some clinicians to meet the performance threshold. Are there ways to mitigate any unintended consequences of implementing such policies, requirements, and performance standards?

As noted above, recent MIPS performance data indicates that there is a large disparity in performance scores between large and small practices, with MIPS-eligible clinicians achieving an overall median performance score of 97.22, whereas clinicians in small practices achieved a median performance score of 66.36.[64] The AAN recognizes that the observed performance scores for both large and small practices are likely inflated due to measures taken by CMS to mitigate reporting burden in response to the PHE. The AAN is highly skeptical that this large disparity in performance is an accurate reflection of a real difference in the quality and value of care delivered by large practices as compared to small practices. Instead, the AAN believes that this difference is more likely explained by the

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[59] American Academy of Medical Colleges, The Complexities of Physician Supply and Demand: Projections From
2019 to 2034, June 2021, https://www.aamc.org/media/54681/download?attachment
[60] Mather, Mark, et al. Fact Sheet: Aging in the United States, Population Reference Bureau, 15 July 2019, www.prb.org/resources/fact-sheet-aging-in-the-united-states/.
[61] Ovbiagele, Bruce et al. "Forecasting the future of stroke in the United States: a policy statement from the American Heart Association and American Stroke Association." Stroke vol. 44,8 (2013): 2361-75. doi:10.1161/STR.0b013e31829734f2
[62] Kowal, Stacey L et al. "The current and projected economic burden of Parkinson's disease in the United States." Movement disorders: official journal of the Movement Disorder Society vol. 28,3 (2013): 311-8. doi:10.1002/mds.25292
[63] Alzheimer's Association. 2015 Alzheimer's disease facts and figures. Alzheimers Dementia. 2015;11(3):332-384. doi:10.1016/j.jalz.2015.02.003
[64]Centers for Medicare and Medicaid Services, 2021 Quality Payment Program Experience Report, 2021, https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2433/2021%20QPP%20Experience%20Report.pdf

variation in resources, time, and expertise that large practices can devote to MIPS compliance and performance, as compared to small practices. In the absence of substantial evidence indicating that small practices deliver lower value care when compared to large practices, the AAN believes that this disparity in performance is inappropriate and likely reflective of systematic bias within the MIPS program. The AAN is deeply concerned that implementing more rigorous requirements and performance standards will disproportionately impact small practices. Potential mitigation strategies for this unintended consequence include:

- Delaying any increase in the performance threshold until the differential in performance between small and large practices is sufficiently addressed.
- Implementing a program of additional bonus points to eliminate the substantial gap in average performance between small and large practices.
- Establishing differential performance thresholds for small and large practices based on the average performance of practices of varying sizes.
- Providing additional resources and funding to help small practices succeed in MIPS.
- Ensuring that measure changes in future updates to the QPP are not uniquely burdensome for small practices.
- Exempting small practices from MIPS penalties until the differential in performance between small and large practices is sufficiently addressed.
- Crafting new payment models that cover the costs of current and additional quality programs.
- Increasing transparency and shortening time for performance measurement reporting using payment models that allow accurate, auditable measurement of quality metrics.
- Increasing the use of certified registries, such as the AAN's Axon Registry®.
- Implementing a least burdensome documentation approach that would enable smaller practices with comparatively less administrative support to participate in more equitable ways.

Major MIPS Provisions

MIPS data has a two-year lag time in distributing the data collected through the program to providers, which makes it difficult to use this data to drive improvement. To promote a more nimble and adaptable care delivery system, clinicians must be provided with timely data and support in both understanding their scores and how to improve them. The AAN believes that offering stakeholders this data can help participants understand the breadth and opportunity available by adopting new models under these programs, including MVPs. The AAN feels that the program, as it is currently structured, yields limited benefits for providers to participate due to the complexities of participation and the program's focus on reporting requirements rather than on furthering high-quality patient care.

MVP Development, Maintenance, and Scoring

The AAN recognizes CMS' effort to continue to develop relevant MVPs focused on a multitude of specialties and subspecialties. The AAN would like to reiterate its appreciation that CMS prioritized neurological MVPs by finalizing three relevant MVPs for 2023. The development of specialty-relevant MVPs and subsequent measures is critical to the viability

of this program going forward. 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 APMs. The AAN is concerned that, absent clearly applicable APM models and opportunities for participation, MVPs do not provide clinicians with the experience needed to participate in APMs. MVPs as they are currently constructed fail to align with APM participation opportunities. When compared to the ACO program, wherein lower-level tracks do not qualify as Advanced APMs, but rather serve as an on-ramp to higher levels of risk which do qualify as Advanced APMs, MVPs appear to be lacking as there is no clear target or endpoint. CMS should reconsider offering compensation models that pay for progress toward clinical milestones adjusted for severity and assuring quality, rather than individual services. This experience would provide a path for providers to learn how to manage risk. An illustrative example of this is the headache APM that the AAN submitted to CMMI in 2018.[65]

The AAN continues to support the comment period when soliciting feedback from stakeholders during the development and maintenance process of MVPs, including posting model drafts online. The AAN continues to urge CMS to extend the public comment period to 60-days rather than the current 30-day period to maximize stakeholder input. The AAN asks for clarification in how topics for MVPs are selected for development and what specialty societies can do to aid in the development of such models and selection of focus areas for the agency.

Although the AAN supports MVPs conceptually, the AAN believes it is critical that CMS demonstrate that MVP reporting has proven effective in improving long-standing issues with the MIPS program, including increasing the relevance of reported measures to the participating clinician's practice and hastening participation in APMs. CMS should also demonstrate that there is buy-in from the provider community prior to making MVPs mandatory. The AAN notes that early feedback from our membership on MVPs indicates a slow transition to using MVP reporting for a variety of reasons. These include the fact that the measures included in neurology-relevant MVPs do not address cost for most outpatient providers and are not meaningful to all neurology providers. The AAN also notes that the transition to MVPs requires additional information technology (IT) support that can be cost prohibitive in many instances, even for large institutions.

MVP Maintenance on Previously Finalized MVPs

The AAN voted to remove three measures due to lack of participation and use of keywords to satisfy measure components. One of these measures, Axon 55, is included in the Episodic Neurological Conditions MVP. The removal of the quality measures from Axon Registry® will be effective on January 1st, 2024.

Axon ID	CMS ID	Official Measure Title	Eligible for MIPS submission in Axon
Axon 48	AAN26	Activity Counseling for Back Pain	Yes

[65] "The Patient-Centered Headache Care Payment (PCHCP)." PTAC Proposals & Materials, Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, 12 Oct. 2017, /aspe.hhs.gov/sites/default/files/private/pdf/255906/ProposalAAN.pdf.

Axon 55	AAN29	Comprehensive Epilepsy Care Center Referral or Discussion for Patients with Epilepsy	No
Axon 67	AAN30	Migraine preventive therapy management	Yes

CMS is proposing to add MIPS quality measure, Q487: Screening for Social Drivers of Health, to all three of the neurology-relevant MIPS value pathways. The AAN notes several problems associated with mandating inclusion of this measure in this MVP. First, this measure is a process measure without any follow-up or outcome measure. We note that CMS has declined these types of measures for neurology-specific items in the past and believe it is inappropriate to make an exception for a non-neurology-specific measure to be included in these MVPs which are targeted for neurology providers. Second, the AAN is concerned with the burden that this measure may place on institutional quality improvement efforts and on Qualified Clinical Data Registries (QCDRs) themselves.

Q487 is more appropriate for a patient's primary care provider or medical home team as they coordinate care, rather than their neurologist, who may not be providing the patient with principal or chronic care management services. Practically speaking, the AAN believes that this measure will likely be taken on by neurologists closing the primary care gap when there is awareness of measure status, such as within the same organization or same EHR, but could result in duplicative services when such awareness is low. Given the limited time to deliver care, duplication on this item could be at the expense of other neurological services. This is compounded by the complexity of this measure, requiring screening across five discrete concepts. In the AAN's experience, measures with complex specifications, especially those using natural language, are not pursued, or are not accurately measured.

The AAN is also concerned that this measure could be demotivational to the neurology community who are earnestly wanting measures to represent the value of neurologic care more clearly but are left lacking. The AAN firmly believes that collecting SDOH data is critically important, and that SDOH data clearly impacts neurologic care, but it may be reasonable to delay specialty adoption of this measure until its value has been demonstrated for primary care. Further, given that neurologists often provide time-sensitive care, for example stroke care, it may not be appropriate to prioritize collecting this data in all scenarios.

While Q487 may have an exception for instances in which the patient declines to share information in response to the screening, the AAN is concerned that implementing this measure may be a substantial burden for QCDRs, as QCDRs are required to support submission of all measures within the MVP when supporting MVP reporting. The AAN is concerned that QCDRs will implement this measure, while reaping limited value from reporting, as this data has already been captured by the patient's primary care provider or the patient declines to provide data during their visit with a neurology provider.

Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP:

The AAN supports the addition of the quality measure and four improvement activities to this MVP. We appreciate CMS' initiative to ensure these MVPs remain clinically relevant with robust options to report.

Optimal Care for Patients with Episodic Neurological Conditions MVP:

CMS will be required to remove *AAN29 - Epilepsy Care Center Referral or Discussion for Patients with Epilepsy* measure from the Optimal Care for Patients with Episodic Neurological Conditions MVP. The AAN agrees with CMS' proposed change to remove *AAN30 - Migraine Preventative Therapy Management* measure to align with the AAN's decision to retire this measure.

Complex Patient Bonus for Subgroups

The AAN strongly supports the continuation of the complex patient bonus to appropriately account for the unique challenges faced by providers that treat the most complex patients in scoring highly within the MIPS program. To ensure appropriate access to this bonus and recognizing limitations in the available information accessible through claims data, CMS is proposing to provide that for subgroups, "beginning with the CY 2023 performance period/2025 MIPS payment year, the affiliated group's complex patient bonus will be added to the final score."[66] The AAN concurs with CMS that it is in the public interest to do this, so that clinicians reporting at the subgroup level can receive appropriate patient complexity credit under the MIPS program.

MIPS Performance Category Measures and Activities

Quality Performance Category

The AAN agrees with the changes, removals, and additions to the neurology specialty set. These include the removal of the "Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management" and "Tobacco Use and Help with Quitting Among Adolescents" measures, as well as the proposed addition of the "Connection to Community Service Provider" and "Gains in Patient Activation Measure (PAM®) Scores at 12 Months" measures.

The AAN continues to have concerns about increasing the data completeness threshold year over year. The data completeness threshold is proposed to increase to 80 percent in 2027. The AAN believes that this will be a burden on practices and providers who have taken the hardship exception for the past years. The AAN urges CMS to consider maintaining the 70 percent threshold until there is evidence that practices and providers are able to submit their MIPS data without the hardship exception.

The AAN is also concerned about the aggressive timeline to transition to digital quality measures by 2025. The workload burden and cost associated with this transition will overwhelm specialty societies and will limit the measures available to be reported. Most organizations do not have the expertise in-house to translate their measures and will need to seek consultants which are cost prohibitive.

Cost Performance Category

[66] 88 Fed. Reg. at 52554

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 unlikely that many clinicians will begin to voluntarily adopt MVPs. According to the MGMA report, 86% of respondents felt that CMS' feedback was not actionable in the cost performance category in improving clinical outcomes or reducing health costs.[67] CMS must dedicate funds to the rapid development of meaningful cost measures to ensure the success of MVPs prior to sunsetting traditional 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.

Improvement Activities Performance Category

CMS is proposing to add five new, modify one existing, and remove three existing improvement activities from the MIPS inventory. The AAN agrees with the changes, removals, and additions to the improvement activities available for MIPS reporting.

Promoting Interoperability Performance Category

CMS had previously finalized exclusions to the "Query of Prescription Drug Monitoring Program" measure to exclude any MIPS eligible clinician who writes fewer than one hundred permissible prescriptions during the performance period. CMS notes that an issue with this exclusion has come to the agency's attention as it does not address situations where the MIPS eligible clinician does not electronically prescribe Schedule II opioids or Schedule III and IV drugs, in accordance with applicable law during the performance period, but does write more than 100 permissible prescriptions during the performance period. CMS is therefore proposing to modify the existing exclusion criterion to state that any MIPS eligible clinician who does not electronically prescribe any Schedule II opioids or Schedule III or IV drugs during the performance period can claim the exclusion. The AAN believes this proposal is consistent with the intent of this measure and provides necessary clarity surrounding reporting requirements.

Under the existing SAFER Guides measure, MIPS eligible clinicians are currently required to attest to whether they have conducted an annual self-assessment using the High Priority Practices SAFER Guide at any point during the calendar year in which the performance period occurs, with one ''yes/no'' attestation statement. An attestation of "yes" or "no" is currently acceptable, and a MIPS eligible clinician can attest "no" without penalty. CMS is proposing to amend the SAFER Guides measure to require MIPS eligible clinicians to conduct this self-assessment annually, and attest a "yes" response, accounting for completion of the self-assessment for the High Priority Practices SAFER Guide. Under this proposal a "yes" response on the attestation will constitute completion of this measure, and a "no" response will result in a score of zero for the whole Promoting Interoperability performance category, indicating that the MIPS eligible clinician failed the requirements of the Promoting Interoperability performance category and is not a meaningful user of CEHRT. The AAN supports this proposal and believes it promotes safe patient care.

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[67] 2022 Medical Group Management Association Regulatory Buden Report, 11 October 2022, https://www.mgma.com/federal-policy-resources/mgma-annual-regulatory-burden-report-2022

<u>MIPS Final Scoring Methodology</u>

Cost Improvement Scoring

The AAN does not believe that MIPS cost measures accurately measure costs that are under the control of neurology providers. MIPS puts too much emphasis on an individual clinician's role in the healthcare system with respect to cost and holds clinicians responsible for expenditures that they may not have control over. The AAN's proposed headache APM model helps clarify accountability for costs relevant to the neurologists and can be looked to as an example for how to properly attribute costs associated with neurologic care.[68]

CMS' cost improvement methodology is complicated and difficult for busy clinicians to understand how improvement on cost measures drives overall MIPS performance. The AAN believes that CMS should prioritize clinician education so that providers can understand how improvement on the cost category impacts overall MIPS performance. We recognize that CMS is obligated to account for cost improvement when calculating final MIPS scores. We note that CMS' proposed modifications to the cost improvement methodology are expected to have a negligible impact on overall MIPS performance as the maximum impact would represent a 0.3-point difference in overall score. We believe this negligible impact is appropriate given our overarching concerns related to the measures included in the MIPS cost category.

<u>MIPS Payment Adjustments</u>

Recognizing the flexibility of the term, "prior period" CMS reviewed the data from prior MIPS performance periods and believes it would be appropriate to specify a "prior period" as three performance periods for the purpose of determining the MIPS performance threshold. CMS believes that using three performance periods as the prior period would prevent the performance threshold from being dependent on a single potentially anomalous performance period, or on two performance periods, whose mean or median final score may be an outlier compared to other performance periods. CMS requested comments on the proposal to use three performance periods as the "prior period" used to establish annual MIPS performance thresholds.

The AAN concurs with CMS that using three performance periods would promote predictability and programmatic stability but has concerns with CMS' proposal to increase the performance threshold to eighty-two points, from the current performance threshold of seventy-five points. Noting issues with using data from 2020-2022, associated with score inflation stemming from flexibilities that were in place during the PHE that have since been terminated, CMS is proposing to use the 2017-2019 performance periods to determine the 2024 performance threshold. Although the AAN agrees with CMS' decision to not utilize data impacted by the PHE to set the 2024 performance threshold, the AAN notes that 2019 performance data is substantially distorted by CMS' decision to apply the extreme and uncontrollable circumstances exception to all participants who had not reported data prior by

[68] "The Patient-Centered Headache Care Payment (PCHCP)." PTAC Proposals & Materials, Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, 12 Oct. 2017, /aspe.hhs.gov/sites/default/files/private/pdf/255906/ProposalAAN.pdf.

April 30, 2020.[69] Without a firm understanding of the impacts of this policy on the eventual observed mean performance, there is no way of knowing whether the performance threshold that CMS selected based in part on 2019 data is appropriate.

Furthermore, the MIPS program has substantially transformed since the 2017-2018 performance periods, as MIPS-eligible clinicians have become more familiar with the program and reporting requirements have increased. It is unreasonable to use 2017 as a baseline for determining payment for performance in 2024, given the magnitude of programmatic change within the MIPS program during that timeframe.

The AAN recommends that CMS implement its proposed policy to use three prior performance periods to determine the performance threshold, while also pausing any increases in the performance threshold above the current 75-point threshold until CMS has access to three consecutive years of performance data, unaffected by the COVID-19 PHE. Doing so will allow for a reasonable comparison of performance to a previous period for which programmatic requirements are similar and observed performance is unaffected by PHE-related reporting and scoring flexibilities.

Third Party Intermediaries

In updating the QCDR self-nomination process, CMS is proposing the elimination of the IT vendor category of third-party intermediaries to ensure consistent standards, with the goal of improving data integrity for the QPP. The AAN believes that this proposal is appropriate as Health IT vendors currently operate under different requirements for data validation than other registries and the AAN believes that requiring consistency is appropriate.

In updating policies surrounding third-party intermediary support of MVPs, CMS is proposing an exception so that QCDR measures are only required to be reported by the QCDR measure owner. In instances where a QCDR does not own the QCDR measures in a particular MVP, the QCDR may only support the QCDR measures if they have the appropriate permissions. The AAN supports this proposal.

CMS is considering policies relating to limitations on the number of QCDR measures submitted for self-nomination. Under current policy, a QCDR measure may be rejected if the QCDR submits more than thirty quality measures not included on the annual list of MIPS quality measures for CMS consideration. CMS is considering a lower limit given that clinicians in traditional MIPS are only required to report on six quality measures and clinicians reporting via MVPs may report even fewer. The AAN supports maintaining the thirty-measure limit for QCDRs. A lower number would make it difficult to support the many subspecialties that report through the AAN's Axon Registry®. CMS should recognize that there are diverse specialties, like neurology, for whom some QCDRs serve more diverse clinical populations and could conceivably wish to submit as many as thirty measures as part of self-nomination.

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[69] Centers for Medicare and Medicaid Services, CMS Announces Relief for Clinicians, Providers, Hospitals and Facilities Participating in Quality Reporting Programs in Response to COVID-19, 22 March 2020, https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting

Public Reporting on Compare Tool

Telehealth Indicator

The Affordable Care Act provides for the development of a Physician Compare Internet Website ("Physician Compare") with certain patient-relevant information on physicians and other eligible professionals enrolled in Medicare. CMS has previously finalized the addition of an indicator to the profile pages of clinicians who furnish telehealth services using established processes and coding policies to identify such clinicians. CMS had previously proposed to use certain relevant POS codes and modifiers to identify the correct clinicians. CMS is proposing to update the existing policy for identifying clinicians furnishing telehealth services, such that the agency can remain current with coding changes, without proposing and finalizing such coding changes via rulemaking. Specifically, instead of only using POS code 02, 10, or modifier 95 to identify telehealth services furnished by a provider, CMS would use the most recent codes at the time the data are refreshed that identify a clinician as furnishing services via telehealth. The AAN supports this proposed change and believes it is important that Physician Compare profiles accurately provide detail to Medicare beneficiaries regarding whether a particular clinician is actively providing care via telehealth.

Publicly Reporting Utilization Data on Profile Pages

The Medicare Access and CHIP Reauthorization Act (MACRA) requires the Secretary of Health and Human Services to make publicly available on an annual basis, in an easily understandable format, information on the items and services furnished by providers to Medicare beneficiaries. CMS finalized a policy to report the most recent available utilization data in downloadable format beginning in late 2017. In the 2023 Medicare Physician Fee Schedule final rule, CMS established a policy for publicly reporting procedure information on clinician profile pages to provide patients more information in their clinician searches in an understandable format. CMS also established that priority procedures selected for utilization data public reporting will meet one or more of the following criteria:

- Have evidence of a positive relationship between volume and quality in the published peer reviewed clinical research;
- Are affiliated with existing MIPS measures indicating importance to CMS;
- Represent care that a patient might shop for a clinician to provide; and/or
- Are an HHS priority.

Citing gaps in the available information using Restructured Berenson-Eggers Type of Service (BETOS) and procedure code sources used in MIPS, CMS proposes to define meaningful procedure categories using subject matter expert, including clinician, input to create new, clinically meaningful, and well-understood procedure categories as needed. The AAN supports this proposal and notes that specialty societies including the AAN could provide helpful feedback to aid CMS in making accurate determinations.

CMS is also proposing to publicly report aggregated counts of procedures performed by providers based on MA encounter data in addition to the Medicare FFS utilization data that is currently reported. CMS believes using and analyzing MA encounter data as part of the

aggregated information disclosed through the Care Compare website will more completely fulfill the public reporting obligation that is required under existing statute. CMS also notes that the inclusion of data about utilization in the MA program would reduce the low volume procedure counts subject to exclusion, in which precise counts less than ten procedures or patients cannot be publicly reported, allowing for more accurate reporting of the types of services that clinicians provide. The AAN agrees that from a patient standpoint, reporting procedural data is useful. Given the growth in the Medicare Advantage program, the AAN believes it is important to include MA data so that beneficiaries receive accurate information regarding what procedures are conducted by a specific provider. The AAN notes that Medicare FFS and MA are significantly different in structure, benefits, and underlying patient population, making it so that it may be appropriate that results are published separately, rather than being aggregated together. If CMS does move forward with aggregating this data, it may be helpful to display the percentage of claims used in the reported data that come from MA as compared to FFS.

CMS has historically published a PDC file that is a subset of the most commonly performed procedures in the public use file. With the upcoming release of the initial procedural utilization data, CMS will publish a second utilization file in the PDC that will reflect the procedure category information on clinician profile pages. CMS believes it would be of greater use for the PDC to only have one utilization downloadable file that reflects the same subset of data, in the same format, as what will be publicly reported on clinician profile pages. CMS states that doing so aligns the criteria for selecting utilization data in the PDC to reflect the same criteria for selection on clinician profile pages and will assist researchers in analyses of utilization data on clinician profile pages. CMS also believes the researcher and clinician communities, who are the primary users of the PDC, would appreciate having the single downloadable dataset that reflects the same procedure utilization data that would appear on clinician profile pages. The AAN strongly supports making the data on clinician profile pages available for researchers and believes it is important that researchers have access to the most granular data possible, without creating harm for patients or providers.

Request for Information: Publicly Reporting Cost Measures

CMS has previously finalized policy requiring the public reporting of performance category scores, and measure-level scores, including cost measure data, in an easily understandable format on Physician Compare profile pages. To date, CMS has not publicly reported any cost measure information from the cost performance category since the inception of MIPS, due in part to the lack of meaningful data in the first few years of MIPS and the reweighting of the cost category during the PHE. Given the termination of the PHE, CMS intends "to propose in future rulemaking to publicly report MIPS cost measures beginning with data from the CY 2024 performance period/2026 MIPS payment year in CY 2026 on Compare tool clinician and group profile pages and in the PDC in 2026."[70]

While the AAN recognizes CMS' authority to report this information and is supportive of transparency and the disclosure of information useful to patient decision-making, the AAN is concerned that reporting of MIPS cost measure information could be confusing for patients reviewing the profiles of neurology providers. We believe that the risk adjustment and

[70] 88 Fed. Reg. at 52616

attribution methods used by CMS have not been adequately developed for MIPS cost measures. More education is needed for clinicians that treat complex patient populations, including how this complexity is considered when calculating cost performance. In addition to more education, more transparency within this component is imperative. We request clear, accessible guidance for clinicians who want to understand their cost performance and how it may be impacted by a small population of complex patients.

Given these issues, it will be critical that patients are made aware that clinicians' performance on cost measures may be attributed to costs that are outside of the direct control of the provider, including acute hospital care costs, such as patient transportation, hospital overhead charges, some concurrent care during the acute episode, and skilled nursing facility charges. It should also be made clear that patient complexity may be impacting performance on these measures. It will also be critical that patients understand that clinician performance on cost measures are not accurate reflections of potential out-of-pocket costs associated with receiving care from a particular provider.

Major APM Provisions

The AAN continues to support the move towards value-based payment and APMs to improve quality of care and patient outcomes. While the AAN is supportive of ongoing efforts, we feel that there has been a lack of prioritization to develop or implement value-based care models for specialists, including neurologists. Year over year, neurologists have limited to no opportunity to transition to APMs due to the lack of measures and models that meaningfully capture quality and costs associated with delivering neurologic care.

While the AAN appreciates CMS' work to create additional incentives to join APMs to foster continuous improvement, we strongly support the need to address the lack of approved models for medical specialties. Currently, 78% of medical practices do not have an Advanced APM option that is clinically relevant to their practice, however, 61% of respondents are interested.[71]

The AAN is thankful that there are three MVPs that are clinically relevant to neurologists, but the AAN remains concerned about MVPs being developed to steer providers into APMs. As currently implemented, this pathway is ineffective for neurologists when there are so few meaningful opportunities to participate in APMs and available opportunities are disconnected from MVPs. The AAN strongly urges that the agency prioritize the development of APM participation opportunities that are relevant to neurologists, other specialists, and their patients. It is critical that neurology providers have the opportunity to benefit from incentive payments while transitioning to Advanced APMs.

The AAN supports detailed participation and performance data for specialists in APMs to help strengthen involvement. The need for timely data is critical in promoting the transition to value-based care and for organizations implementing policies and procedures that can substantively impact quality of patient care and associated costs.

[71] 2022 Medical Group Management Association Regulatory Buden Report, 11 October 2022, https://www.mgma.com/federal-policy-resources/mgma-annual-regulatory-burden-report-2022

APM Performance Pathway

The AAN appreciates the recent efforts of CMS to develop the *Guiding an Improved Dementia Experience (GUIDE) Model.* While we are appreciative that it has the potential to qualify as a MIPS APM in the future, CMMI should be developing models with the goal of an on-ramp to being an Advanced APM. CMS should consider whether the model as currently constructed could qualify as an Advanced APM. If not, the AAN urges CMS to prioritize developing additional track(s) to ensure participants can get Qualifying APM Participant (QP) status as they progress within the model. Constructing a model that does not evolve beyond MIPS should not be the goal.

The AAN learned the details of the GUIDE model with the public upon its release on July 31, 2023. The focus of the model, supporting people living with dementia and their unpaid caregivers, is directly focused on a patient population that neurologists care for. The AAN advises that CMS partner with medical societies, including the AAN, in the development and maintenance of such models. The AAN is eager to lend our expertise and recommendations to ensure that CMMI models, such as GUIDE are meaningful for neurology providers and impactful for neurology patients.

Overview of QP Determinations and the APM Incentive

Absent Congressional action, the 3.5 percent lump sum APM Incentive Payment is scheduled to expire at the end of the 2023 performance year (2025 payment year). Beginning in the 2024 performance year (2026 payment year), under current law QPs will instead receive a positive 0.75 percent conversion factor update, while non-QPs will receive a 0.25 percent CF update. The AAN is deeply concerned regarding the scheduled expiration of these incentive payments, noting that many neurology providers have not had the opportunity to benefit from these payments during the transition to value-based care. The AAN strongly urges CMS to work with Congress and relevant stakeholders to maintain bonus payments at appropriate levels. Furthermore, CMS and Congress should work together to develop meaningful incentives over the long term, to strengthen APM participation.

The AAN also 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 up-to-date 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 or practice.

The AAN is aware of anecdotal reports that certain APM entities have excluded certain specialists from participating directly in a particular APM because of the existence of perverse incentives relating to beneficiary attribution. Specifically, the AAN is concerned that certain APM entities may be excluding certain specialists, including neurologists who furnish relatively fewer services that lead to attribution in order to meet the threshold. CMS

is proposing to modify the agency's methodology for determining QP status with the aim of mitigating the existing incentives for APMs to exclude certain specialists. The AAN supports efforts that promote accurate attribution and increased inclusion of neurology providers in APMs.

Conclusion

Thank you for the opportunity to comment on the 2024 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 and Policy at mkerschner@aan.com with any questions or requests for additional information.

Sincerely,

Carlayne E. Jackson, MD, FAAN
President, American Academy of Neurology