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September 23, 2020

The Honorable Seema Verma
Administrator
U.S. Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

RE: Medicare Program; CY 2021 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy [CMS-1734-P]

Dear Administrator Verma,

The American Academy of Neurology (AAN) is the world's largest neurology specialty society representing more than 36,000 neurologists and clinical neuroscience professionals. The AAN is dedicated to promoting the highest quality patient-centered neurologic care. A neurologist is a physician with specialized training in diagnosing, treating, and managing disorders of the brain and nervous system. These disorders affect one in six people and include conditions such as multiple sclerosis (MS), Alzheimer's disease, Parkinson's disease, headache, stroke, migraine, epilepsy, traumatic brain injury, ALS, and spinal muscular atrophy.

Payment for Office/Outpatient Evaluation and Management (E/M) Visits

The AAN applauds CMS for moving forward with the finalized coding and reimbursement structure for evaluation and management (E/M) services. The AAN remains highly supportive of the new coding and reimbursement policies and supports CMS's decision to implement them on January 1, 2021. The AAN was deeply involved in the AMA CPT/RUC process to develop the new structure and concurs with CMS that it will produce a simplified and more intuitive system of E/M coding that is more consistent with the current practice of medicine. The AAN urges CMS to implement

the new structure as finalized and without any additional delay. In support of this goal, the AAN offers the following comments.

Comment Solicitation on the Definition of HCPCS code GPC1X

CMS finalized a descriptor for the GPC1X add-on code stating: "Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition."[1] The AAN supports payment for the finalized GPC1X add-on code, as it accounts for the complexity of non-procedural specialized medical care. We applaud CMS's intent to recognize and reward physicians who provide E/M services to complex patients, regardless of specialty, with the finalization of the GPC1X add-on code. The AAN concurs with CMS's rationale that there are different per-visit resource costs associated with non-procedural specialized medical care and the AAN is grateful this code is not restricted by specialty or to primary care practitioners. As such, the AAN supports the finalized code to account for "additional resource costs inherent in furnishing some kinds of office/outpatient E/M visits."[2] The AAN agrees with CMS that there are additional resource costs associated with visits related to a patient's single serious, or complex chronic condition that are not included in the value of the standalone E/M code. 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.

Noting the concerns that CMS has identified related to a possible lack of clarity in the code descriptor, the AAN does not recommend making any changes to the code descriptor, but instead recommends that the agency should give clear guidance to the physician community about the correct use for the GPC1X add-on code. The AAN suggests that CMS publish a list of examples that meet the definition of a "single, serious or complex, chronic problem," and a list of examples that do not meet the definition. The medical community is familiar with using clinical analogy for coding, as similar clinical guidelines were embedded in the 1995 and 1997 coding guidelines.

Prolonged Office/Outpatient E/M Visits (CPT code 99XXX)

The AAN supports payment for the new prolonged visit add-on code, referred to in the Proposed Rule as 99XXX, henceforth referred to by its updated CPT code 99417, that can be paid for each additional 15-minute increment of service. The AAN believes this code should be available to clinicians who care for the most complex patients. Multiple units of 99417 is allowed per the code descriptor and the AAN supports this feature of the code. CMS proposes to modify the conditions under which the 99417 code can be used so that it can be reported when the maximum time for the level 5 office/outpatient E/M visit is exceeded by at least 15 minutes on the date of service. This is a modification of policy finalized in the previous year's Final Rule. Under the previous policy, the agency would allow reporting of CPT code 99417 after the minimum time for the level 5 visit is exceeded by at least 15 minutes. CMS states that this modification is necessary to avoid double counting of time.

[1] 84 Fed. Reg. at 62855.
[2] 84 Fed. Reg. at 62854.

The AAN understands CMS's concerns surrounding double counting of time and appreciates the clarification of the requirements.

Revaluing Services that are Analogous to Office/Outpatient E/M Visits

The agency notes that that there are certain services, other than the global surgical codes, for which the values are closely tied to the values of the office/outpatient E/M visit codes. Many of these services were valued via a building block methodology and have office/outpatient E/M visits explicitly built into their definition or valuation. The AAN notes that the revaluation of these services is distinct from any potential revaluation of the global surgery packages. This is because the AAN is not aware of ongoing questions related to the accuracy of the number or intensity of the E/M services that are used in building the analogous services contained in this section. As such, it is appropriate to ensure that relativity is maintained by revaluing these codes. This is not the case for the revaluation of the global surgery codes as a revaluation of the current packages is likely to exacerbate existing relativity issues and magnify the inappropriate values for those codes. The AAN offers the below comments on two of the analogous services that CMS is proposing to revalue.

The agency proposes to revalue the transitional care management codes 99495-99496 because both codes were valued to include one established patient E/M visit: a level 4 visit for 99495 and a level 5 visit for 99496. As such, CMS is proposing to increase the work RVUs associated with these transitional care management codes commensurate with the new valuations for the level 4 and level 5 office/outpatient E/M visits for established patients. The AAN supports this change and believes it more accurately reflects the work involved in this service.

The agency proposes to revalue CPT code 99483, assessment and care planning for patients with cognitive impairment. CMS notes that this code was initially valued so that the "valuation of this service reflected the complexity involved in assessment and care planning for patients with cognitive impairment by including resource costs that are greater than the highest valued office/outpatient E/M visit." The agency notes that due to the increase in value for E/M services that "the current work RVU for CPT code 99483 would have a lower work RVU than a new patient level 5 office/outpatient E/M visit, which would create a rank order anomaly between the two codes." So as to avoid 99483 having a lower work RVU than the highest valued office/outpatient E/M visit, the agency proposed to increase this code's work RVUs from 3.44 to 3.80. The AAN supports this change and believes it will maintain the appropriate rank order of complexity between these codes and the highest-level office/outpatient E/M visits.

Valuation of Global Surgery Packages

The AAN supports the agency's decision to exclude office visits bundled into the global surgery package from the increase applied to outpatient E/M services. The AAN believes it would be inappropriate for CMS to revalue global surgery packages while they are currently examining data related to global surgery valuations. The AAN appreciates that CMS appears to share this concern, noting in the 2020 Final Rule: "it is unclear whether it would be appropriate to use a building-block approach to increase the valuation for global surgical

packages in a way that could disrupt potentially more accurate estimates of total work for procedures with global periods from magnitude estimation." Furthermore, the AAN agrees with CMS's previously stated reasoning that a premature revaluation could "result in inappropriate shifts in relativity under the PFS, and the associated budget neutrality adjustment could result in potentially inappropriate adjustments to payment rates for services without global periods, such as separately-billed E/M visits."

The AAN concurs with CMS that "there are now important, unresolved questions regarding how post-operative visits included in global surgery codes should be valued relative to stand-alone E/M visit analogues." The AAN appreciates that CMS noted the key distinction that while post-operative visits may be similar to stand-alone E/M services, they are not the same. The medical-decision-making for the typical post-procedure outpatient visit is less complex than the typical stand-alone E/M. The post-procedure visit usually is concerned with a well-defined problem; and, by definition, the provider has taken a medical history and examined the patient a short time before the visit in the global period. Practice expense may differ for post-procedure visits, some of which require supplies such as suture removal kits and dressings. The resources required for postprocedural visits in the global period differ from resources needed for the typical office visit and we agree with CMS that these visits should be valued independently of typical office E/M visits. This approach is supported by MedPAC, which recommended "a budget-neutral payment adjustment for ambulatory E&M services – excluding the ambulatory E&M services currently considered when valuing global packages."[3]

The AAN appreciates that CMS is carefully considering the findings from RAND related to the disparity between expected and observed post-operative visits. We note that RAND, the Office of the Inspector General, and other reports support the conclusion that CMS is now paying for many postprocedural visits that do not actually occur.[4,5] The AAN concurs with CMS that "if the number of E/M services for global codes is not appropriate, adopting the AMA RUC-recommended values for E/M services in global surgery codes would exacerbate rather than ameliorate any potential relativity issues." Any investigation of the global billing periods will have limitations, but the AAN is not aware of any independent data that support the number of postprocedural visits indicated in RUC surveys and in current CMS global periods. The AAN is in agreement with CMS's assessment in the 2020 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." Given the current evidence, increasing the values of the global surgery codes is in direct opposition to the mandate that services must be resourced-based.

It is of the utmost importance that the valuation of the global packages accurately reflects the work being done and that the values are supported by data. The AAN recommends that CMS

[3] Rebalancing Medicare's Physician Fee Schedule toward Ambulatory Evaluation and Management Services. June 2018. www.medpac.gov/docs/default-source/reports/jun18_ch3_medpacreport_sec.pdf?sfvrsn=0. p. 79.
[4] Kranz, Ashley M., Teague Ruder, Ateev Mehrotra, and Andrew W. Mulcahy, Claims-Based Reporting of Post-Operative Visits for Procedures with 10- or 90-Day Global Periods: Final Report. Santa Monica, CA: RAND Corporation, 2019. https://www.rand.org/pubs/research_reports/RR2846.html.
[5] Department of Health and Human Services, Office of the Inspector General. Cardiovascular Global Surgery Fees Often Did Not Reflect the Number of Evaluation and Management Services Provided, 1 May 2012. oig.hhs.gov/oas/reports/region5/50900054.pdf.

continue to work to collect and analyze all relevant data, and to develop a resourced-based payment model.

Conversion Factor and Budget Neutrality

CMS applied a budget neutrality adjustment to the fee schedule to offset the increase in total spending that would have resulted from the changes in the RVUs for E/M and other services, as generally required by Medicare statute. The AAN understands that the agency cannot waive the budget neutrality requirement without modification of existing legislation. The AAN strongly supports the new E/M coding and reimbursement structure but notes that the subsequent reduction of the conversion factor may detrimentally impact some clinicians. The AAN is supportive of requests to Congress to waive budget neutrality for the 2021 Medicare Fee Schedule RVU increases, provided that this would not result in a delay or in any way undermine CMS's decision to fully implement the new E/M coding and payment structure on January 1, 2021.

Telehealth and Other Services Involving Communications Technology

The AAN applauds CMS for taking swift action in response to the COVID-19 public health emergency (PHE) to promote access to telehealth services. The AAN concurs that it was necessary to remove numerous restrictions surrounding telehealth services during the PHE. The AAN believes that telehealth services are critical in maintaining continuity of care, while preventing the healthcare system from being burdened by otherwise avoidable emergency care and face-to-face services throughout the PHE. Improved access to telehealth services also benefits populations rendered vulnerable because they find it difficult to travel for medical care and allows at-risk patients to stay home and maintain social distancing. The benefits of telehealth services for at-risk patients will continue following the PHE.

Telehealth and communication technology-enabled services (CTBS), such as telephone encounters, have become a lifeline connecting neurology patients with neurology providers. The choice to use telehealth technology is determined by the needs of the patient, the ability to access and use the technology, and the clinical problem to be addressed. Patients and caregivers alike have benefitted from expanded access to telehealth services both before and during the PHE. Patients report that access to care has improved, and that in many instances, telehealth services are more convenient and comfortable, and provide additional privacy. Most importantly, as COVID-19 case numbers increase in many states, provision of telehealth services removes the fear of contagion, and eliminates the risk of exposure. Our providers report that it is often easier to relate to patients one-on-one via telehealth, than via in-person encounters conducted in full PPE, through face masks, face shields, and gloves. Benefits accrue to outpatient and inpatient populations and apply to new and established patients requiring physician services and other services such as physical therapy and speech and language therapy.

Even before the beginning of the PHE, an October 2019 survey by J. D. Power revealed that, for early adopters, customer satisfaction with the experience ranked among the highest of any

consumer category studied[6] and there is also ample evidence of the benefits of telehealth and related services in the peer-reviewed literature. For people with chronic diseases, those who live in remote locations, and those with mobility problems and other disabilities, telehealth and related services is more than a choice, it is a necessity.[7] Medical economic studies have shown that it reduces healthcare costs,[8] saving money for patients, physicians and insurance companies, helps avoid unnecessary non-urgent visits to emergency rooms and related transportation expenses, and minimizes lost time from work.[9,10] For caregivers and parents, who often need to accompany patients to physician offices, telehealth likewise reduces the burden of care and loss of wages. Use of telehealth can also improve patient compliance, by enabling family members to attend appointments, thus ensuring that necessary communication can take place. The workforce is also enhanced by the use of telehealth. During the PHE, providers who were quarantined but not symptomatic, were still able to provide care via telehealth and related technologies. Providers who were at high risk for adverse consequences stemming from COVID-19 infection were also able to provide care, such as those who were elderly or who had chronic medical conditions.

The healthcare system is experiencing revolutionary changes as providers have quickly developed new telehealth capabilities and have gained experience delivering care via new modalities. These changes present a unique opportunity to leverage new capabilities, promote access to care, advance chronic care management, and reduce disparities. Without government action, the temporary policy changes made in response to the coronavirus pandemic are set to be phased out when the PHE ends. Absent necessary actions from CMS, patients will lose access to critical services, the time and capital that went into rapidly building telehealth infrastructure will have been wasted, and the healthcare system will not experience the myriad benefits of the telehealth revolution.

The AAN appreciates CMS exercising its regulatory flexibility to ensure continued access to telehealth services. The AAN notes that site restrictions remain one of the most persistent long-term barriers to the expansion of telehealth. The AAN understands that the agency may be limited by Section 1834(m) but urges CMS to exercise its maximal degree of regulatory flexibility to promote access to telehealth services in all parts of the country.

Additionally, the AAN urges CMS to consider how it can promote access to telehealth services, including via collaboration with the Federal Communications Commission and other relevant agencies to ensure that more Medicare beneficiaries have access to high-quality broadband internet access. It will be important to ensure that much-needed regulatory

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[6] J. D. Power U.S. Telehealth Satisfaction Study. October 2019. https://www.jdpower.com/business/healthcare/us-telehealth-satisfaction-study.

[7] Hirko, Kelly A, et al. "Telehealth in Response to the Covid-19 Pandemic: Implications for Rural Health Disparities." Journal of the American Medical Informatics Association, 2020, doi:10.1093/jamia/ocaa156.

[8] Demaerschalk BM, Switzer JA, Xie J, Fan L, Villa KF, Wu EQ. Cost utility of hub-and-spoke telestroke networks from societal perspective. Am J Manag Care. 2013 Dec;19(12):976-85.

[9] Reider-Demer M, Raja P, Martin N, Schwinger M, Babayan D. Prospective and retrospective study of videoconference telemedicine follow-up after elective neurosurgery: results of a pilot program. Neurosurg Rev. 2018 Apr;41(2):497-501. doi: 10.1007/s10143-017-0878-0. Epub 2017 Jul 22.

[10] Ross L, Bena J, Bermel R, McCarter L, Ahmed Z, Goforth H, Cherian N, Kriegler J, Estemalik E, Stanton M, Rasmussen P, Fernandez HH, Najm I, McGinley M. Implementation and Patient Experience of Outpatient Teleneurology. Telemed J E Health. 2020 Jun 23. doi: 10.1089/tmj.2020.0032. Online ahead of print.

changes do not exacerbate existing access and outcomes disparities. As CMS continues to modernize the telehealth regulations, the AAN urges CMS to collect relevant data on how changes in telehealth regulations impact various communities and how existing disparities are being addressed or exacerbated in the new environment. Additionally, the agency can consider how demonstration projects may address these disparities. The AAN notes that there are a number of recently announced studies through the Patient Centered Outcomes Research Institute that seek to better understand how Covid-19 related policy and telehealth in particular have impacted healthcare disparities.[11]

Experiential Feedback

The AAN notes that CMS is collecting information from the public regarding which, where and how various telehealth services have been in use during the COVID-19 response. We understand that CMS seeks to better understand how the use of telehealth services may have contributed to the quality of care provided to patients so that CMS is better informed as it moves forward with modifying regulations and payment policies surrounding telehealth. In support of that goal, the AAN offers the below comments describing the experiences of neurologists throughout the PHE.

Telehealth was rapidly adopted by AAN members in response to the PHE. There is consensus among our members that telemedicine has been extremely valuable during the PHE. In many cases, delivering care via telemedicine has been a faster and easier modality to deliver care than via a comparable in-person visit. The expanded availability of telehealth services and additional administrative flexibilities have allowed AAN members to continue to provide care to patients who otherwise would have missed critical appointments with serious potential consequences.

In certain cases, the expansion of telehealth services for the Medicare population has been particularly beneficial to the cognitively impaired and mobility impaired patient population. AAN members report that being able to complete appointments at home has increased patient satisfaction. Often, patients with dementia are reluctant to come to the office for evaluation, partially due to the lack of recognition that a problem exists. The ability to complete telehealth visits eliminates the barrier of coming into a doctor's office to be seen. The ability to conference in additional family members without their needing to take extended time away from work to attend appointments has improved care coordination for this vulnerable population.

Additionally, AAN members believe that expanded access to telehealth has made it so they can deliver timely specialized consultations while limiting exposure to COVID-19 infection. AAN members note that utilization of telehealth visits has been a useful strategy during the PHE to keep large volumes of patients away from the office, while increasing the number of employees that could work from home to improve social distancing. An additional benefit is that this creates added flexibility to hours of operation, and generally creates additional staffing model flexibility, allowing for extended hours of operation.

[11] "PCORI Approves $23 Million for Seven COVID-19 Research Studies." 18 Aug. 2020, www.pcori.org/news-release/pcori-approves-23-million-seven-covid-19-research-studies.

In some cases, AAN members report that telehealth visits can be faster than comparable in person visits, as some patients receiving care via telehealth are more goal directed, lateness and the no-show rate can be diminished, and family members participating in the visit can provide a more directed history. The AAN notes that a decrease in the no-show rate can reduce utilization of more expensive care in the future stemming from preventable admissions. Our members report that telehealth is not always faster, and in some cases, visits are longer than comparable in-person visits. Visits may be longer if there are technological challenges, family is present and provides further context leading to longer discussions, or care is being delivered to certain patients who have complex disorders.

The AAN urges the administration to carefully analyze data that specialty societies and other healthcare stakeholders have and will collect regarding service utilization, program integrity, and quality of care to better understand the implications of removing restrictions on telehealth services after the termination of the PHE. Additionally, the AAN asks the agency to consider beneficiary preferences related to telehealth services and how medically appropriate care delivered via telehealth can improve beneficiary experience and access to care.

Adding Services to the Medicare Telehealth Services List

The agency raises concerns associated with the expanded availability of telehealth services including: whether there are increased patient safety concerns if certain services are furnished via telehealth, whether there are concerns about quality of care associated with the provision of certain services via telehealth, and whether all elements of certain services could fully and effectively be performed by a remotely located clinician using two-way, audio/video telecommunications technology. Access and patient satisfaction are well-covered in the literature.[12,13] The AAN has examined the use of telemedicine for neurologic disorders. Our findings show that telemedicine is noninferior to traditional, in-person evaluations in terms of patient and caregiver satisfaction. Additionally, telemedicine has benefits in expediting care, reducing cost, increasing access to care, and improving health outcomes and diagnostic accuracy.[14] The AAN notes that studies are underway to expand the evidence base comparing remote neurologic examination techniques with in-person examinations and to assess diagnostic accuracy, cost-effectiveness, and outcomes of virtual neurologic care. The agency should be aware that three recent papers describe methods to

[12] Hanson RE, Truesdell M, Stebbins GT, Weathers AL, Goetz CG. Telemedicine vs Office Visits in a Movement Disorders Clinic: Comparative Satisfaction of Physicians and Patients. Mov Disord Clin Pract. 2018 Dec 13;6(1):65-69. doi: 10.1002/mdc3.12703. eCollection 2019 Jan. PMID: 30746418.
[13] Hatcher-Martin JM, Adams JL, Anderson ER, Bove R, Burrus TM, Chehrenama M, Dolan O'Brien M, Eliashiv DS, Erten-Lyons D, Giesser BS, Moo LR, Narayanaswami P, Rossi MA, Soni M, Tariq N, Tsao JW, Vargas BB, Vota SA, Wessels SR, Planalp H, Govindarajan R. Telemedicine in neurology: Telemedicine Work Group of the American Academy of Neurology update. Neurology. 2020 Jan 7;94(1):30-38.
[14] Id.

perform the elements of a neurological examination remotely, except for fundoscopy, even when the patient does not have an assistant on-site.[15,16,17]

The AAN supports the addition of the new codes that CMS is proposing to add to the Medicare Telehealth Services list. In particular, the AAN supports the addition of the new add-on codes for E/M services to the telehealth list and believes it is important to maintain consistency with the new coding and payment structure for E/M services. In addition to those that CMS is proposing to add, the AAN believes that it is appropriate to add additional codes to the telehealth list. Since G-codes already in existence cover most inpatient, critical care and emergency department services via telehealth, the AAN believes that it may be appropriate to avoid redundancy. Although this approach may lessen administrative complexity, the agency should also consider whether it would benefit beneficiary access to care to cover the relevant CPT codes for inpatient, critical care, and emergency department services as well. The AAN urges CMS to reconsider its proposal to not add the inpatient discharge day management codes, new and subsequent observation and observation discharge day management codes to the telehealth list. The AAN notes that these services are not covered by existing G codes. The AAN believes that it would be appropriate for these codes to be folded into existing G codes or be assigned new G codes so that patients do not lose access to these services via telehealth.

Continuing, the AAN supports permanently adding the psychological and neuropsychological testing codes to the Medicare Telehealth list. These codes lend themselves especially well to telehealth visits. Using technology to do some of the tests (trail making, MMSE, MOCA, depression screening, etc.) can be done and should be developed and encouraged.[18] Additionally, patients with dementia, or other cognitive or psychological impairment folks may require the assistance of additional parties during a visit. Providing these services remotely can allow for conferencing in other people, including family, significant others, and other providers, which can provide substantial benefits. For live visits these other people may not be able to get off work or travel to the appointments. Virtual visits allow for everyone to be in different locations while still being able to participate in the visit. Additionally, psychiatric patients often have social anxiety issues, leading to limitations on leaving safe places like their home, facility, or family, so remote visits are important ways to ensure these patients maintain access to care. However, it is also important to note that the lack of access to technology could be a barrier to receiving care for some in the community. Appropriateness of care should be determined by the provider without financial disincentives between in-person and telehealth care.

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[15] Boes CJ, Leep Hunderfund AN, Martinez-Thompson JM, Kumar NJ, Savica R, Cutsforth-Gregory JK, Jones LK. A primer on the in-home teleneurologic examination. A COVID-19 pandemic imperative. Neurol Clin Pract. First published May 21, 2020, DOI: https://doi.org/10.1212/CPJ.0000000000000876.

[16] Grossman SN, Han SC, Balcer LJ, Kurzweil A, Weinberg H, Galetta SL, Busis NA. Rapid implementation of virtual neurology in response to the COVID-19 pandemic. Neurology. 2020 Jun 16;94(24):1077-1087. doi: 10.1212/WNL.0000000000009677. Epub 2020 May 1.

[17] Tarolli CG, Biernot JM, Creigh PD, Moukheiber E, Salas RE, Dorsey ER, Cohen AB. Practicing in a pandemic. A clinician's guide to remote neurological care. Neurol Clin Pract. First published May 21, 2020, DOI: https://doi.org/10.1212/CPJ.0000000000000882.

[18] Grossman SN, Han SC, Balcer LJ, Kurzweil A, Weinberg H, Galetta SL, Busis NA. Rapid implementation of virtual neurology in response to the COVID-19 pandemic. Neurology. 2020 Jun 16;94(24):1077-1087. doi: 10.1212/WNL.0000000000009677. Epub 2020 May 1.

The AAN believes that it would be appropriate for CMS to defer to the physician's judgment as to whether in-person visits are needed or whether comparable quality of care can be delivered via telehealth methods. The AAN believes that, given ongoing patient access issues, neurologic care given remotely, is clearly superior to receiving no neurologic care if there are no on-site neurologists. Additionally, it would not be necessary to transfer all patients with serious neurologic conditions to tertiary care hospitals if teleneurology can be implemented.

Furnishing Telehealth Visits in Inpatient and Nursing Facility Settings, and Critical Care Consultations

CMS seeks comment on whether it is appropriate to maintain COVID-19 PHE flexibilities that allow physicians and NPPs to perform required visits for nursing home residents via telehealth using two-way, audio/visual communications technology. The AAN supports making this change permanent. The AAN believes that telehealth coverage for patients in nursing facilities would expand access for these patients to specialty care. AAN members report instances in which seeing a patient residing in a nursing facility in-person poses significant challenges and can impose significant burdens on patients due to difficulties associated with traveling. Expanding coverage to nursing homes would allow specialists to see patients in a variety of situations without travel-associated difficulties, thus allowing for increased efficiency and expansion of patient access.

CMS is also proposing to revise the frequency limitation for nursing home residents from one visit every 30 days to one visit every 3 days. The AAN notes that CMS is not proposing to revise its policies surrounding in-patient visits. The AAN concurs that the once every 30-day frequency limitation for subsequent nursing facility visits furnished via Medicare telehealth limits access to care for Medicare beneficiaries in the nursing facility setting. While CMS's proposed modification is a step in the right direction, the AAN instead supports the permanent removal of frequency limitations for subsequent inpatient and nursing facility visits. Instead of arbitrary frequency limits, the AAN recommends that CMS should permanently modify their policies so that frequency is determined based on medical necessity and with clear definitions of what is appropriate and reasonable. 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.

Proposed Technical Amendment to Remove References to Specific Technology

The AAN appreciates CMS's technical clarification to remove the specific reference to telephones from the regulation at § 410.78(a)(3) that "prohibits the use of telephones, facsimile machines, and electronic mail systems for purposes of furnishing Medicare telehealth services." The AAN concurs with CMS that the reference to "telephones" in the regulation as an impermissible technology could cause confusion in instances where an otherwise eligible device, such as a smart phone, may also be used as a telephone.

Comment Solicitation on Continuation of Payment for Audio-only Visits

The AAN believes that the agency should permanently cover the telephone services E/M codes 99441-99443. The use of audio only telehealth has been a tremendous benefit for many older patients and others that struggled with audio/video technology for a variety of reasons. There is a substantial proportion of the neurology patient base who do not have access to or cannot operate computers or mobile devices that have video and audio capability. Furthermore, there are a number of patients who cannot afford broadband wireless access or robust enough cellular data plans that would allow audio/video encounters to take place. Lack of internet connectivity is correlated with several social determinants of health including race, income, and geography.[19] As such, the AAN believes that access to audio-only visits may preferentially benefit those that are detrimentally impacted by health disparities. Bandwidth can also be a problem inside healthcare facilities and within the homes of the providers. Although this bandwidth issue will likely improve over time, on occasion, signal quality can be an issue on the "doctor's end," resulting in a necessary conversion to a telephone encounter.

The AAN is aware of CMS's position that outside of the circumstances of the PHE, the agency "is not able to waive the requirement that telehealth services be furnished using an interactive telecommunications system that includes two-way, audio/video communication technology." Acknowledging this prohibition, absent a statutory change, the AAN urges the agency to examine whether coverage of these codes can be permanently maintained under the agency's authority to cover communication-technology based services, while excluding these services from the Medicare telehealth list. The AAN concurs with CMS that coverage of audio-only services is necessary as beneficiaries continue to try to avoid sources of potential infection, such as a doctor's office. Additionally, almost all patients have a telephone and these services are valuable for patients who lack internet access or who are otherwise uncomfortable with using an audio-video telehealth platform.

Acknowledging the agency's inability to waive the requirement that telehealth services be furnished using an interactive telecommunications system that includes two-way, audio/video communication technology, the agency is soliciting feedback on whether CMS should develop coding and payment for a service similar to the virtual check-in code (G2012) but for a longer unit of time and with an accordingly higher value. The AAN is concerned that this process may result in a gap in coverage for audio-only services and that patients may lose access to services that they utilized during the PHE, while CMS develops the new coding and payment policies. If CMS determines that it cannot move forward with permanent coverage of the existing telephone service E/M codes 99441-99443, absent a statutory change, then the AAN believes that separate payment for telephone-only services should remain in place temporarily while CMS develops separate coding and payment for the longer virtual check-in service. The AAN notes that if CMS were to develop separate coding for a longer virtual check-in code, that the phone service should not be bundled into a previous in-person E/M visit.

[19] Demographics of Internet and Home Broadband Usage in the United States. Pew Research Center, 5 June 2020, www.pewresearch.org/internet/fact-sheet/internet-broadband/.

The AAN notes that utilizing a phone encounter rather than an audio/video or in person visit still requires the physician's skill and time to understand the problem. The AAN believes that payment adequacy is key and that audio only services must be valued more similarly to an E/M visit than to the current valuation for audio-only visits or for the current virtual check-in (G2012). Unless the phone codes are appropriately revalued, they are unlikely to be utilized to a significant degree, which will result in demographic disparities in access to care. The AAN believes that coverage should extend to both new and established patients and reimbursement should be close to the mid-level (2-4) established patient E/M reimbursement rates as is currently the case for the telephone CPT codes during the PHE. The wRVUs are similar since time is the driving factor in both and work intensity is comparable.

The AAN recommends that telehealth and phone services should be better defined after the PHE has passed. Some telehealth visits may be performed from the physician's smartphone to the patient's, but others require the presence of a video technologist and nurse. It will also be important to incorporate the need for translator services. Another cost variable may arise when physicians who perform office visits in a facility, instead schedule some providers to perform telehealth visits to be done from an outside setting. While CMS now values direct and indirect expenses differently for different specialties, based on data from the (outdated) 2007-2008 Physician Practice Information Survey, it is not clear that telehealth expenses differ among medical specialties. For these reasons, the AAN recommends that CMS encourage the AMA CPT/RUC committees to better identify and value the emerging types of telehealth and phone services and the costs at different sites of service.

Communication Technology Based Services

The AAN urges CMS to reconsider the requirement that "in instances when the brief communication technology-based service originates from a related E/M service (including one furnished as a telehealth service) provided within the previous 7 days by the same physician or other qualified health care professional, this service would be considered bundled into that previous E/M service and would not be separately billable." Communication technology-based services allow patients more frequent access to care when needed, eliminates much of the travel cost, and improves access for rural and urban patients alike. Therefore, the AAN recommends permanent easing of restrictions for all communication technology-based services. The AAN believes that communication technology-based services are separate and distinct services from E/M services and should be treated as such. Bundling these services into previous E/M services reduces patient access to these services and leads to delays in care. The AAN believes that the provision of more timely care will sufficiently reduce costs to offset an increase in utilization associated with eliminating the 7-day requirement.

The AAN believes that CMS should delete the requirement that the virtual check-in code G2012 not be billed if related to an E/M service performed within the previous week, or an E/M service or procedure performed within 24 hours of the soonest available appointment after the encounter. The AAN proposes that this change would be consistent with the new E/M coding structure, which is based on the total time personally spent by the reporting practitioner on the day of the visit. If G2012 were performed on another day, the provider's time would not overlap with the work of the E/M visit, and the provider would not be

double-paid. The AAN also believes that phone services should be able to be initiated by the provider and that the current prohibition reduces patient access to care. CMS also should allow G2012 to be performed for new patients as well as established patients. This service in some cases may eliminate the need for a specialty care face-to-face-visit during the PHE, and we expect it to be similarly effective under newer advanced care models after the PHE. The AAN believes that CMS should also allow the virtual check-in code G2012 to be performed at any time.

Additionally, CMS should reform requirements for online digital E/M services (CPT codes 99421, 99422, 99423). CMS now requires that the encounter be initiated by the patient, and that the service may not be billed within seven days of an E/M service. We note, however, that patients may need these services even if the patient did not initiate the communication, for example, to revise care based on the results of testing and imaging after an E/M service. This is especially important for patients with dementia or who are facing other social determinants of health disparities. As we noted above for code G2012, the practitioner time for these codes, performed on a different day, would not overlap with the work of the E/M visit.

Direct Supervision by Interactive Telecommunications Technology

For the duration of the PHE, CMS adopted a policy revising the definition of direct supervision to include virtual presence of the supervising physician or practitioner using interactive audio/ video real-time communications technology. CMS is proposing to extend this policy until the latter of the end of the calendar year in which the PHE ends or December 31, 2021. The AAN appreciates that the agency is seeking feedback on "circumstances where the flexibility to use interactive audio/video real-time communications technology to provide virtual direct supervision could still be needed and appropriate." The AAN supports permanently modifying direct supervision requirements so that direct supervision can be performed via real-time interactive audio-video technology in certain cases. Telemedicine based supervision, when appropriately utilized, can be an excellent way to maximize supervised team-based care across a more distributed geography. It also allows a quarantined team member or a team member that is located at a distant site for any other reason (e.g. vacation, at another site within the health care organization, traveling on business) to participate in the delivery of care.

The AAN believes that, in cases in which supervision is provided via interactive telecommunications technology, supervision should be robustly documented to ensure that patients are safely receiving clinically appropriate care from members of the care team. The AAN does not support remote supervision of in-person diagnostic or therapeutic procedures since the physician would not be physically available to help the individual being supervised if the need arises. Similarly, the AAN has concerns regarding quality of care related to situations in which a remote physician is not on-site for an evaluation and management service that requires finesse in performing the physical examination in person. The AAN does support remote supervision of data interpretation such as imaging studies or certain physiologic studies where the patient is not physically present. In summary, the AAN supports in-person direct supervision of those who need supervision while providing in-

person services, and telehealth supervision of those who need supervision for telehealth encounters.

Care Management Services and Remote Physiologic Monitoring Services

Digitally Stored Data Services/Remote Physiologic Monitoring/Treatment Management Services (RPM)

The AAN believes that remote monitoring in combination with video visits are critical elements to be incorporated along with coordination of care to improve patient outcomes. The AAN supports CMS's proposal to allow consent to be obtained at the time that RPM services are furnished as this will reduce administrative burdens and promote beneficiary access to these services. The AAN also supports the agency's proposal to allow auxiliary personnel to furnish services described by CPT codes 99453 and 99454 under the general supervision of the billing physician or practitioner. CMS is also proposing that upon the termination of the PHE, RPM services must be furnished only to an established patient. The AAN believes this is appropriate and concurs with CMS's rationale that during the new patient E/M service, the physician or practitioner would have collected relevant information that is needed to understand the current medical status and needs of the patient prior to ordering RPM services or developing a treatment plan.

Transitional Care Management

The AAN supported CMS's decision in the 2020 Physician Fee Schedule to revise the billing requirements for transitional care management (TCM) services by allowing TCM codes to be billed concurrently with additional codes. The AAN believes that TCM services are in the interests of the patient, but are underutilized, in part, due to insufficient reimbursement and substantial administrative burden. The AAN believes that allowing additional codes to be concurrently billed with TCM can effectively promote the use of TCM services. This will be beneficial for the complex patients that need services related to the additional codes that can be billed concurrently.

The AAN believes that these changes benefit neurologists and neurology patients in relation to the transitional care services that neurologists provide, including medication acquisition and follow-up for adherence. CMS is proposing to continue its policy of allowing additional codes to be billed concurrently with transitional care management services. Specifically, the agency proposes to allow the new chronic care management code, HCPCS code G2058, to be billed concurrently with TCM when reasonable and necessary. The AAN believes this change is appropriate and we have previously supported policies to allow chronic care management codes to be billed concurrently with TCM. The AAN appreciates the additional proposed flexibility to bill this add-on code concurrently with TCM, in addition to the chronic care management codes that were approved in the 2020 Final Rule.

Scope of Practice and Related Issues

Supervision of Residents in Teaching Settings through Audio/Video Real-Time Communications Technology

During the PHE, CMS modified the requirement for the presence of a teaching physician during the key portion of the service furnished with the involvement of a resident so that the requirement can be met using audio/video real-time communications technology. Under this policy, the teaching physician must be present, either in person or virtually through audio/video real-time communications technology, during the key portion of the service. CMS is considering whether to extend this policy beyond the PHE and whether to make it permanent. The AAN supports making this policy permanent but urges the agency to clarify how the "key portion of the service" will be determined under the new E/M structure that is set to be implemented in 2021. Under the new structure, the level of E/M service can be determined either by time or by medical decision making. If the level is determined by medical decision making, the AAN believes that the supervising physician should be required to be present for the key elements of the history, the physical examination and the review of elements that determine the level of medical decision making. When the level of E/M service is determined by time, the AAN is concerned that supervision may be insufficient if the key portion of the service is determined solely on the basis of time. It is possible, if time is counted in isolation to determine whether the key portion of the service requirement is met, that the supervising physician may not actually be present during the key portion of the encounter that led to the diagnosis and treatment plan. It is necessary for policies related to both time and medical decision making to be clarified to ensure that sufficient supervision is provided to residents.

During the PHE, CMS modified the primary care exception to allow teaching physicians to direct care furnished by a resident, and to review the services furnished by the resident during or immediately after the visit, remotely using audio/video real-time communications technology. The AAN has concerns that there may be negative patient safety impacts associated with allowing virtual supervision of in-person physical examinations that are conducted while providing E/M services. The AAN recommends that CMS should allow for in-person supervision of residents doing in-person services and telehealth supervision of residents doing telehealth visits.

Additionally, during the PHE, CMS allowed payment to be made for the interpretation of diagnostic radiology and other diagnostic tests if the interpretation is performed by a resident when the teaching physician is present through audio/video real-time communications technology. The AAN supports making this policy permanent as the data is in an electronic form and this form of remote supervision is unlikely to negatively impact patient safety. The AAN agrees that it is appropriate to require that a physician other than the resident must still review the resident's interpretation of the results.

Virtual Teaching Physician Presence during Medicare Telehealth Services

CMS adopted a policy on an interim basis to allow for payment for teaching physician services when a resident furnishes Medicare telehealth services to beneficiaries while a teaching physician is present using audio/video real-time communications technology. CMS is considering whether this policy should be extended on a temporary basis or be made permanent. The AAN strongly supports this policy and urges the agency to permanently extend it beyond the PHE. The AAN believes that virtual teaching physician presence during

Medicare telehealth services is reasonable, necessary, and appropriate. CMS raises concerns related to patient safety in cases in which the technological connection between the supervising physician and the trainee breaks down, making supervision impossible. The AAN notes that this situation is likely to be infrequent and could be addressed by a requirement that visits must be paused until the connection between the resident and teaching physician can be reestablished. If the connection cannot be re-established, the AAN recommends that the encounter should then be rescheduled until a time during which supervision can be sufficiently conducted.

Primary Care Exception Policies

Under the "primary care exception" CMS makes payment for certain services of lower and mid-level complexity furnished by a resident without the physical presence of a teaching physician. During the PHE, CMS has permitted all levels of office/outpatient E/M visits to be furnished by a resident and billed by a teaching physician under the primary care exception. CMS also allowed PFS payment to the teaching physician for services furnished by residents via telehealth under the primary care exception if the services were also on the list of Medicare telehealth services. CMS is considering whether to extend these changes beyond the PHE and whether to make them permanent. The AAN does not support making these flexibilities permanent and urges the agency to terminate these flexibilities upon the conclusion of the PHE. The AAN concurs with CMS's concern that extending the primary care exception to include all levels of outpatient E/M services would fundamentally undercut the rationale for the existence of the exception, as the exception was crafted to cover services of lower and mid-level complexity. The AAN is concerned that allowing higher level E/M services to be furnished by residents without supervision could pose significant risks to patient safety and poses a high risk for abuse. Additionally, the AAN recommends applying the same primary care exception to lower level telehealth services, on par with coverage for in-person visits.

Supervision of Diagnostic Tests by Certain NPPs

In response to the PHE, CMS implemented a policy to allow certain NPPs to supervise the performance of diagnostic tests. CMS is proposing to make these changes permanent, as allowed by state scope of practice laws. CMS is also proposing that supervision of diagnostic psychological and neuropsychological testing services can be done by NPs, CNS's, PAs or CNMs to the extent that they are authorized to perform the tests under applicable State law and scope of practice. The AAN opposes these proposals and urges CMS to sunset these waivers when the PHE concludes. CMS should maintain its existing policy that all diagnostic tests paid under the PFS must be furnished under an appropriate level of supervision by a physician. At a minimum, CMS should postpone any efforts change these requirements until after the conclusion of the PHE. Furthermore, if CMS moves forward with this proposal to expand supervision of diagnostic tests, the AAN notes that reimbursement for these tests depends on interpretation of the test and believes that it would be inappropriate for a non-physician to interpret the results of these tests.

While we are greatly appreciative of CMS's rapid and substantial removal of regulatory barriers to allow providers to continue providing care during the PHE, we also strive to

continue to work with CMS to support patient access to physician-led care teams during and after the PHE. Throughout the coronavirus pandemic, physicians, nurses, and the entire health care community have been working side-by-side caring for patients and saving lives. Now more than ever, we need health care professionals working together as part of physician-led health care teams. The AAN vigorously opposes efforts that undermine the physician-patient relationship and physician-led health care teams during and after the pandemic. Nurse practitioners and physician assistants are integral members of the care team, but the skills and acumen obtained by physicians throughout their extensive education and training make them uniquely qualified to oversee and supervise patient care. Physician-led team-based care has a proven track record of success in improving the quality of patient care, reducing costs, and allowing all health care professionals to spend more time with their patients.

Comprehensive Screenings for Seniors: Section 2002 of the Substance Use-Disorder Prevention that Promote Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act)

CMS is proposing to codify the provisions in the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act that require the Medicare Initial Preventive Physical Examination (IPPE) and the Annual Wellness Visit (AWV) to include screening for potential substance use disorders (SUDs) and a review of any current opioid prescriptions.

The AAN agrees these provisions are complementary to the existing components of these services and help underscore the importance of prevention and appropriate pain management to stymie the opioid epidemic. While in 2018 Medicare emphasized a review of opioid prescriptions is appropriate when collecting a patient's medical and social history within the IPPE and AWV, adding explicit requirements regarding opioid use and SUD screening is an important distinction.

Notification of Infusion Therapy Options Available Prior to Furnishing Home Infusion Therapy Services

Section 5012 of the 21st Century Cures Act added section 1834(u) to the Social Security Act, which establishes the payment and related requirements for home infusion therapy benefit. CMS notes that Section 1834(u)(6) of the Social Security Act requires that, prior to the furnishing of a home infusion therapy to an individual, the physician who establishes the plan of care shall provide notification of the options available for the furnishing of infusion therapy.

We appreciate that CMS is not proposing to create a mandatory form or specific manner or frequency of notification options available for infusion therapy under Part B prior to establishing a home infusion therapy plan of care. We agree with the agency that current practice provides appropriate notification. CMS notes if current practice is later found to be insufficient in providing appropriate notification to patients, it may consider additional requirements regarding this notification in future rulemaking. The AAN stresses this could

lead to more burdensome documentation requirements on physicians. We will provide comments in the future if CMS revises this policy.

Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D drug under a Prescription Drug Plan or an MA-PD plan

Due to the PHE, CMS is delaying implementation of the statutory requirements related to the electronic prescribing for controlled substances for a covered Part D drug by 1 year, from January 1, 2021 to January 1, 2022. Specifically, CMS is modifying the requirement so that all prescribers conduct electronic prescribing of Schedule II, III, IV, and V controlled substances using the NCPDP SCRIPT 2017071 standard by January 1, 2022. The AAN concurs with CMS that the ongoing PHE may present additional challenges for some prescribers. The AAN supports the delay and lauds CMS for addressing the administrative burdens associated with complying with this program by allowing for additional time to address ongoing workforce challenges and to implement necessary EHR system upgrades.

Updates to Certified Electronic Health Record Technology due to the 21st Century Cures Act Final Rule

The AAN appreciates CMS's efforts to harmonize its own policies with those finalized by the Office of the National Coordinator for Health IT (ONC) in the 21st Century Cures Act Final Rule. Separate deadlines and requirements would create significant burdens and confusion among providers while they work to comply with the requirements finalized by ONC. As such, the AAN supports CMS's proposal that the technology used by healthcare providers to satisfy the definitions of CEHRT must be certified in accordance with the updated 2015 Edition of health IT certification criteria as finalized in ONC's 21st Century Cures Act Final Rule.

Additionally, the AAN notes that ONC is taking a phased in approach to implementing the requirements of the Final Rule. ONC has finalized that health IT may be certified to the current 2015 Edition certification criteria or the 2015 Edition Cures Update for a period of 24 months, as described in the timelines finalized in the 21st Century Cures Act Final Rule. The AAN supports CMS's proposal for healthcare providers to be required to use technology that is considered certified under the ONC Health IT Certification Program according to the timelines finalized in the Cures Act Final Rule. Additionally, due to the PHE, ONC announced additional enforcement discretion related to the use of certified Health IT. The AAN supports CMS's proposal to reduce administrative burdens by allowing providers to use technology certified to either version during the period of enforcement discretion.

Appropriate Use Criteria

The AAN applauds CMS for its recent decision to extend the educational and operations testing period for the Appropriate Use Criteria (AUC) program through the end of 2021. The AAN appreciates that CMS has recognized the impact that the ongoing PHE has had on providers ability to meaningfully participate in the current educational and operations testing period. Delaying this program is necessary because during the PHE providers must ensure that resources are devoted to patient care, rather than compliance with burdensome

regulatory programs. Additionally, due to the PHE, providers are unlikely to have gained the experience they will need to fully participate in the AUC program after the education and testing period has elapsed. The AAN also believes that further implementation of this program is likely to have significant detrimental impacts on timely patient access to care, which is already hindered by the ongoing PHE. As such, the AAN urges CMS to consider additional delays in implementation of the AUC program if the PHE were to continue during 2021. CMS should also consider whether the standalone AUC program is necessary or if programmatic requirements have become redundant due to provider participation in the Quality Payment Program.

Quality Payment Program (QPP)

The AAN appreciates CMS's ongoing consideration of the extraordinary stresses that the PHE are placing on the healthcare system in developing updates to the Quality Payment Program (QPP). The AAN believes that it is of the utmost importance that during the PHE, providers are focusing on their patients, rather than administrative reporting and programmatic compliance. The AAN urges CMS to reduce burdens associated with the QPP as much as possible throughout the PHE.

It is important to note that prior to the emergence of the PHE, the QPP has been particularly challenging for small and solo practitioners. This is acknowledged by the United States Government Accountability Office[20] and supported by the variation in performance scores between small and large practices.[21] Challenges related to selecting a functional EHR system are particularly problematic for small and solo practitioners as they have fewer resources and less capacity to share costs across providers.[22] Small and solo practices also face unique challenges when managing cost measures because they see fewer patients and are far more exposed to the risk of performing poorly on cost measures due to a small number of extremely high cost patients. Additionally, financial and staff resource constraints can be especially problematic for small and solo practices when complying with the QPP due to the resources required to select, track, and report on measures.

The AAN notes that small and solo practices, especially those in rural or remote locations, are particularly sensitive to the impacts of the PHE as they face substantial challenges due to reduced workforce capacity and revenues. In our comments in response to the 2020 Proposed Rule, we highlighted a number of concerns that the AAN has in relation to the fairness of the current scoring methodology for small and solo practices, that were present prior to the PHE. The AAN believes that the impact of potential structural biases against small and solo practices that are inherent to the QPP are likely to be magnified due to the PHE. The AAN urges CMS to carefully consider policies that can aid small and solo practices in being successful in the QPP, both during and after the PHE. CMS should also consider whether modifications to the extreme and uncontrollable circumstances policy are necessary regardless of practice size, if the impacts of the PHE extend into 2021.

[20] 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.
[21] Centers for Medicare & Medicaid Services, 2020, 2018 Quality Payment Program (QPP) Experience Report, https://www.cms.gov/blog/2018-quality-payment-program-qpp-performance-results.
[22] Government Accountability Office, *supra* note 20.

Scoring Threshold

While the AAN appreciates CMS's efforts to reduce burdens by proposing to lower the performance year 2021 performance threshold from 60 points to 50 points, the AAN notes that this still represents an increase in the performance threshold from the 45 point threshold that was in place for the 2020 performance year. The AAN urges CMS to maintain the 45-point threshold for the 2021 performance year. Providers should not be subjected to additional burdens or increased thresholds while they are still addressing the effects of the PHE. The AAN notes that an increased scoring threshold is particularly problematic for small and solo practices as they have fewer resources available to devote to quality reporting and are likely to be disproportionately impacted by the compounding economic impacts of the PHE along with a negative payment adjustment.

Complex Patient Bonus

The AAN supports the continuation of the complex patient bonus. The AAN concurs with CMS's rationale that there is a need for a bonus to protect access to complex care by ensuring that clinicians who care for complex patients are not at a potential disadvantage in terms of MIPS performance. The AAN concurs with CMS's assessment that more data is needed based on future years of MIPS performance to more fully understand how patient complexity impacts MIPS performance. The AAN agrees that it is appropriate to reevaluate the existing complex patient bonus methodology in the context of the PHE, as patients with comorbidities and social risk factors are likely to be disproportionately impacted by the PHE.

Additionally, the AAN concurs with CMS that there are direct effects of COVID-19 for those patients who have the disease and indirect effects of COVID-19 for other patients, including increased complexity and barriers such as postponing care, accessing care via different modalities, and disruptions to lab results and medications, which are not accounted for in the existing methodology. The AAN supports CMS's proposal to double the complex patient bonus to a maximum of ten points to be added to a clinician's final MIPS score. The AAN shares CMS's concerns about potentially misidentifying poor performers due to the impacts of the PHE. Those that care for the most complex patients and face magnified challenges due to the PHE, should not unfairly receive negative payment adjustments due to performance that can be attributed to patient complexity.

Final Score Hierarchy Used in Payment Adjustment Calculation

CMS notes that there are cases in which a TIN/NPI could have multiple scores associated with it from a single performance period, if the MIPS eligible clinician submitted multiple data sets. In cases in which there are multiple scores, CMS proposes to use the virtual group final score to determine the MIPS payment adjustment if a TIN/NPI has a virtual group final score. If a TIN/NPI does not have a virtual group final score associated with it, the agency proposes to use the highest available final score associated with the TIN/NPI to determine the MIPS payment adjustment. The AAN notes that CMS is statutorily required to prioritize virtual group scores over other scores. The AAN supports CMS's proposal to use its regulatory flexibility to ensure that payment adjustments are determined based on the clinician's highest possible score.

MIPS Value Pathways (MVPs)

The AAN appreciates CMS's continued efforts to reduce the confusing and burdensome requirements currently required of eligible clinicians participating in MIPS through the establishment of MVPs. However, we remain concerned that the new framework will present many of the same issues that MIPS currently suffers from, while also creating additional challenges within many specialty or condition specific pathways that will be difficult to manage and compare for both CMS and stakeholders developing MVPs. While we appreciate the additional information included in this Proposed Rule, including more information on the MVP development process and submission criteria, there are still several critical gaps including little to no information on MVP assignment, scoring, payment adjustments, benchmarking, and risk-adjustment by specialty. We implore CMS to address these gaps and implement MVPs carefully, with a ramp up period, to ensure a reliable MVP framework from its inception.

Additionally, the AAN believes that the agency should specify what constitutes minimum requirements for approval and CMS endorsement of MVP models developed by specialty societies. Absent a clear outline of these minimum criteria, the AAN believes that specialty societies may be hesitant to expend substantial resources to develop models that may never be adopted. Having this kind of commitment from CMS would encourage specialty societies to collaborate in support of model development.

MVP Timeline

AAN concurs with CMS's proposed delay of MVP implementation to at least 2022 and supports delay until CMS addresses all elements of MVP development and implementation including assignment, scoring, and payment adjustment. Our members are committed to providing the best care for their patients while simultaneously dealing with the current public health emergency and its many practice and personal implications. Implementation of the MVP framework before the pandemic is contained would take away from patient care and place additional burdens onto clinicians already strained from the effects of the pandemic and pre-existing administrative burdens related to MIPS and other programs.

CMS should continue traditional MIPS as an option for the foreseeable future. We agree with CMS that the transition to MVPs should be gradual and that MIPS should remain an option for eligible clinicians. Currently, eligible clinicians are in their fourth reporting year of MIPS and many continue to struggle to understand program requirements, meet performance thresholds, select measures that are applicable and meaningful to their practice, and maintain EHR and other requirements. Chief among those struggling with these issues are small and solo practitioners, a subset of clinicians with significantly fewer resources than others participating in MIPS to meet current requirements and to prepare for new changes and shifts within the program. The AAN urges CMS to continue the traditional MIPS reporting option beyond performance year five to ensure eligible clinicians can participate meaningfully in the Quality Payment Program. However, while it is important that providers demonstrate clinical quality, the AAN requests that CMS also consider the value of the current MIPS program given the vast majority of providers across the nation demonstrate high quality yearly based on current metrics. Given the data, the AAN urges the agency to consider the administrative

burdens and costs associated with compliance, in relation to the value generated by the current program. The AAN encourages CMS to begin the process of evaluating and publishing the impact of this program on quality and cost outcomes.

MVP Participation

CMS should provide more detailed information on how MVPs would be assigned and on the process for eligible clinicians to select whether to report to a given MVP or continue reporting in traditional MIPS. We encourage CMS to explore a hybrid approach between CMS-assigned and self-assigned MVPs as an appropriate method to ensure clinicians are presented with the most applicable and appropriate MVPs for reporting. We strongly urge CMS to consider how best to address specialties with a variety of condition-specific specialists, like neurology. Given that an increasing number of neurologists focus on a specific condition within neurology, CMS could determine the selection of MVPs that apply to an eligible clinician based on specialty designation and from there, the eligible clinician could choose the most applicable, condition-specific MVP within neurology. CMS must work with specialty societies individually to understand the unique characteristics of a given specialty and its conditions and take them into consideration when developing and approving MVPs. The AAN urges CMS to substantively engage with specialty societies as soon as possible to ensure that CMS understands the needs of specialists and the specific challenges related to meaningfully measuring, assessing, and incentivizing quality across specialties.

We also suggest that CMS should consider implementing an incentive for MVP participation in its first few years. This would not only incentivize MIPS eligible clinicians but also would motivate stakeholders, including specialty societies, to develop MVPs on behalf of their members. While we understand the intent of MVPs, we know from past experience, that it takes years for clinicians to become familiar and comfortable with the requirements of new quality reporting programs and that they are increasingly frustrated by the many changing requirements over the years. In addition to incentives during the early implementation phase of MVPs, CMS should consider longer-term incentives for small and solo practices to participate in MVPs.

MVP Principles and Criteria

The AAN appreciates CMS's work to clarify many of the MVP proposals finalized last year, including the five guiding principles of MVPs and to provide more information on the criteria used for the evaluation of MVP proposals. The AAN notes that while the MVP development criteria and questions associated with each sheds light on what CMS expects from stakeholders submitting MVP proposals, CMS must also provide more detail and clear, standard definitions and expectations for each of the development criteria. For example, one criterion is "comprehensibility," however one stakeholder may define a comprehensive MVP differently than another. Absent these clarifications, we are concerned that it will be unfeasible to meet each of the criterion and urge CMS to allow some flexibilities in MVP development as not all criteria may apply to each specialty and condition-specific MVP. CMS should clarify how criteria are weighted or which are most meaningful from CMS's perspective. For example, there may be situations where an MVP should be developed to focus on large academic institutions for a condition such as stroke, and as a result there

would be of little consideration given to small rural practices. It is difficult for the AAN to see how each of the criterion could be objectively applied. The shift to MVPs will be difficult for many MIPS participants for a variety of reasons already, so we strongly urge CMS to be clear and realistic in defining and clarifying each of the criterion and their components.

MVP Development Process

The AAN appreciates CMS's commitment to developing MVPs collaboratively with stakeholders, specifically clinicians and specialty societies who have distinct expertise regarding the nuances of their respective specialty and subspecialties. We agree with CMS's proposal to establish a streamlined approach for MVP submission using a standardized template to ensure that MVPs are evaluated consistently, with the understanding that some flexibility may be warranted depending on the unique nuances of a specialty or condition. The AAN also appreciates CMS's proposal to establish a feedback loop with stakeholders following evaluation to discuss feedback and next steps for MVP submissions. The AAN notes that because the MVP program is in the early stages, it is important to recognize the need for continued conversation and opportunities for improvement. The AAN also urges the agency to substantively engage with specialty societies in the exploratory phases of MVP development to ensure that proposals are developed in alignment with CMS's expectations and that time and resources are not unnecessarily wasted.

The AAN opposes the establishment of an NQF-convened panel to evaluate MVPs. Current NQF processes are inefficient and lack objectivity, despite continued work to rectify these issues. The AAN supports the overall intent of MVPs and sees the merit and potential in implementing this new framework at a later date, but cautions CMS against using current, inefficient and subjective processes to evaluate MVPs. We do, however, support the inclusion of specialty experts who are board certified in the relevant specialty or sub-specialty in the review process of candidate MVPs. CMS should include a specialty representative that can objectively provide a perspective related to the nuances of a given specialty, subspecialty, or condition related to the MVP under review. Furthermore, the AAN recommends that CMS work with specialty societies to ensure that designated specialty experts are appropriately identified and included in the process.

Incorporating QCDR measures into MVPs

The AAN opposes CMS's proposal to require QCDR measures be used the year prior to being included in an MVP. This prevents inclusion of new, novel measures that may be more appropriate and meaningful to both physicians and patients and undermines one of the main benefits of QCDR measures, which is capturing the quality of clinical actions more nimbly than other types of measures. CMS should allow for QCDR measures to be included in MVPs as long as they meet all of CMS's other QCDR measure requirements.

Patient Voice

The AAN strongly supports patient-centered care and appreciates CMS's commitment to ensuring patients are involved in the development of models and programs that affect their

care. However, we are concerned about how CMS will measure patient engagement during the MVP development process. While specialty societies may have relationships with patient groups, it can be difficult to identify a patient with sufficient in-depth experience, knowledge, and understanding of regulatory programs such as the QPP. The AAN encourages CMS to further clarify the level of involvement expected of stakeholders to engage with patients and believes the agency should provide resources to connect patients interested in this work with stakeholders developing MVPs. CMS should again consider the burden to stakeholders, and especially clinicians, of adding ever-increasing requirements during the MVP development stages in light of the many other competing priorities.

Qualified Clinical Data Registry (QCDR) Feedback

Regarding measure ownership versus measure licensing, CMS requires that a QCDR take over ownership of a non-QCDR's measure instead of allowing a measure license between the QCDR and non-QCDR. The license could stipulate needing agreement of edits/updates to the QCDR measure as requested by CMS. The AAN has encouraged CMS to consider changes to the QCDR licensing requirements to facilitate greater measure harmonization. Due to CMS requirements for verification that legal permissions have been granted from one QCDR to another, often requiring prolonged contract negotiations, QCDRs independently develop similar measures with slightly different specifications. The current requirements potentially supersede measure developers' intellectual property ownership of a measure to another QCDR. The AAN believes CMS should reconsider these restrictions to allow for increased collaborative measure implementation across specialty registries and greater benchmarking opportunities across QCDRs.

Regarding measure testing changes, the AAN supports a phased in approach to measure testing and appreciates CMS's acknowledgement of the burden that testing places on QCDRs. The AAN believes there should be flexibility in testing standards. Standards should allow for evolving healthcare guidelines and that they should not stifle meaningful data collection. CMS should consider allowing for a proportion of total QCDR measures tested sufficient as a demonstration of a QCDRs commitment to collection of high-quality data.

CMS should maintain the approval of QCDR measures for two years and not remove CMS endorsement unless approved by the measure steward. To ensure stability in the program and allows QCDRs and measure developers adequate time to prepare for measures to be retired or replaced, CMS should not remove a measure before its second year solely due to it being topped out or duplicative of a more robust measure.

Quality Component of QPP

The AAN offers the following comments on the Quality component changes to the QPP. First, we support the retirement of the CMS web interface. Second, we support the use of CY2018 data for benchmarks. By using CY2018 data, eligible providers will know what their performance aims are for the year. If CY2021 data was used, reliability and validity concerns may be identified as a result of substantive changes to measures, due to inclusion of telehealth codes, and these should be considered prior to functioning as a benchmark.

Regarding topped-out measures, the AAN continues to believe the methodology used by CMS to assess topped-out measures should be improved. CMS should allow for greater cross-QCDR collaboration to establish benchmarks and an assessment of any disparities in care prior to removing a measure because it is topped-out. On high priority measures and bonus points, we support the decision to retain high priority measures and bonus points. Additionally, regarding the complex patient bonus, we support the increase in potential bonus points and scoring option. The AAN agrees that the current pandemic has resulted in greater complexity of care for all patients, even those not actively being treated with the COVID-19 diagnostic codes.

The AAN also supports the specialty measure changes to the neurology and geriatric measurement sets, specifically the addition of sleep apnea measures and the removal of the retired opioid measures. The AAN requested the removal of Medicare Part B Claims Measure Specifications for Measure #268 Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy and #419 Overuse of Imaging for the Evaluation of Primary Headache through the measure review process. The AAN notes that these changes are not reflected in the Proposed Rule and the measure specifications should be removed, as the AAN is no longer maintaining these specifications.

Improvement Activities Component of QPP

The AAN supports the suggested changes for the MIPS Improvement Activities component, including changes to the annual call for activities. Specifically, the AAN supports an exception to the nomination period timeframe during the public health emergency, a new criterion for nominating new improvement activities, a process for HHS-nominated improvement activities, and modifications to two existing improvement activities.

Cost Component of QPP

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

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

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

The AAN further supports the addition of telehealth services to previously established cost measures. Given the considerable increase in telehealth services due to the public health emergency, we recognize the relevance of expanding the services included in cost measures to include telehealth services.

Alternative Payment Models (APMs)

The AAN continues to support the move towards value-based payment and Advanced Alternative Payment Models (Advanced APMs), however we remain concerned about the lack of approved models that address the patients and services for which neurologists are responsible. While we generally support the MVP framework, it is still unclear how clinicians are expected to transition from an MVP into an Advanced APM. We caution CMS from implementing the MVP framework with the intended goal to transition clinicians into Advanced APMs without clearly directing clinicians on how to make this transition.

CMS should continue its work to streamline efforts for meaningful participation in APMs and provide clear guidance to stakeholders. The AAN supports the proposal to terminate the APM scoring standard and low-volume threshold determination and appreciates CMS's efforts to reduce complex and infeasible policies for APM entities. With the elimination of

the APM scoring standard and the introduction of the APP track, it is imperative that CMS eliminate confusing requirements, streamline efforts, and equip APM entities and their clinicians with clear information and guidance. CMS should also provide detailed participation and performance data for specialists within APMs. Although we believe publishing data for both MIPS and APMs is imperative, to date, CMS has not shared sufficient data on APMs, especially as they relate to specialists. We hope that CMS will provide clinicians and other stakeholders like the AAN with data on Advanced APMs, MIPS APMs and Other Payer Advanced APMs including detailed participation and performance results, including by specialty. Again, we believe that providing stakeholders with a rich dataset that can offer an overview of the landscape of participation in value-based care models will help with understanding the breadth and opportunity that adaption of these models provides. 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.

The AAN also strongly supports the proposal to allow MIPS-APM entities to submit an application to reweight any or all MIPS components due to extreme and uncontrollable circumstances during performance year 2020. The extension of the extreme and uncontrollable circumstances policy to MIPS-APMs during the ongoing public health emergency is consistent with what is offered to MIPS participants. Additionally, we support the four scoring scenarios proposed for ACOs and believe they seem feasible and appropriate.

APM Performance Pathway (APP)

While the AAN understands and generally supports the implementation of the APM Performance Pathway (APP), we believe that the proposal to implement the APP by January 1, 2021 will prevent meaningful engagement from ACOs. Pending the release of the Final Rule, ACOs would have two months at most, and potentially as little as one month, to transition their data collection practices to focus on the proposed measure set, while simultaneously marshalling resources for driving improvement for these measures. Given this fast timeline, and the current public health emergency, it is unrealistic that many ACOs will adopt the APP in year one.

The AAN believes that the APP proposal will be attractive to many clinicians participating in a MIPS-APM, however we are concerned that this new pathway is not practical or meaningful for specialists or their patients because the quality measures are not relevant beyond internal medicine. CMS notes that if a clinician on a MIPS-APM entity's Participation List or Affiliated Practitioner List, elects to be scored through the APP and did not meet the case minimums or the patient population for a given measure was unavailable, that the measure would be removed for that clinician. Given that the measures in the proposed set are not generally applicable to specialists, including neurologists, it is possible that several measures would be removed when a neurologist was scored under the new pathway which could seriously impact or skew a clinician's performance score under the Quality component. The AAN requests more information on scoring and reweighting quality measures under the APP, as it is unclear how specialists could meaningfully use this proposed pathway. Determining a meaningful cross-cutting set of measures that would be

applicable to specialists may be more appropriate and may incentivize additional provider participation.

The AAN additionally supports the waiving of the Cost performance category for APP participants. Attributing cost to an individual clinician is difficult as random variation and small patient populations can lead to inaccurate performance scores. Clinicians participating in an APM entity should continue to have cost assessed at the entity level. CMS should consider extending this wavier to individuals in traditional MIPS as well, as we believe the process of cost attribution at the individual MIPS-level is not reliable or accurate.

Conclusion

We greatly appreciate this opportunity to express the views of the AAN in response to the Proposed Rule. The AAN strongly urges CMS to consider our comments so that the Final Rule further reduces regulatory burdens on neurologists and promotes the highest quality patient-centered neurologic care. Please contact Daniel Spirn, Senior Regulatory Counsel for the AAN at dspirn@aan.com or Matt Kerschner, Government Relations Manager, at mkerschner@aan.com with any questions or requests for additional information.

Sincerely,

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