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June 1, 2020

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency [CMS-1744-IFC]

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, stroke, migraine, epilepsy, traumatic brain injury, ALS, and spinal muscular atrophy.

The AAN applauds the Centers for Medicare and Medicaid Services (CMS) for its swift action to address administrative burdens that have created barriers to delivering care during the COVID-19 Public Health Emergency (PHE). The AAN appreciates the opportunity to comment on policies that were finalized in response to COVID-19 and offer recommendations on policy changes both during and after the PHE.

Access to Telehealth Services

The AAN applauds the Secretary of Health and Human Services (HHS) and the Administrator of CMS for taking swift action to promote access to telehealth services. The AAN concurs that it is necessary to remove numerous restrictions surrounding telehealth services during the PHE. Additionally, the AAN believes that telehealth services are critical in maintaining continuity of care and preventing the healthcare system from being burdened by otherwise avoidable emergency care and face-to-face services throughout the COVID-19 outbreak. The AAN notes that increased utilization of telehealth services will help ensure that PPE is not unnecessarily used but is instead conserved for those who really need it to deliver face-to-face care. 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.

Based on historical and rapidly accumulating scientific evidence, the AAN believes that telehealth will continue to play an essential role in the health care delivery system once the PHE has passed. 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. The AAN believes it would be unwise, especially given the magnitude of the human and financial resources that are being invested in improving the country's telehealth infrastructure, to develop capabilities that would only be temporarily utilized during the PHE. The AAN recommends that the administration should consider making permanent many of the changes to telehealth services that have been implemented for the duration of the PHE across federally funded healthcare programs. These include:

- Payment parity for evaluation and management (E/M) services for established patients delivered via real-time interactive audio-video technology with in-person E/M services.[1]
- Elimination of the originating site requirement for telehealth services.[2]
- Removal of frequency limitations for subsequent inpatient and nursing facility visits, to instead determine frequency based on medical necessity and with clear definitions of what is appropriate and reasonable.[3]
- Modification of direct supervision requirements so that direct supervision can be performed via real-time interactive audio-video technology.[4]
- Addition of telehealth services that were added on a category 2 basis for the duration of the PHE.[5]
- Coverage of the remote physiologic monitoring codes.[6]
- Coverage of the telephone services E/M codes 99441-99443.[7]
- Coverage of new patient visits via audio-video telehealth technology.[8] These visits are necessary to preserve patient access to care and for the long-term viability of practices. The AAN recommends that new patient visits delivered via telehealth should be considered distinct services from in-person new patient office visits, with separate reimbursement rates.

Telehealth allows 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 also recommends permanent easing of restrictions for all communication technology-based

[1] 85 Fed. Reg. at 19233.
[2] Id.
[3] 85 Fed. Reg. at 19241.
[4] 85 Fed. Reg. at 19246.
[5] 85 Fed. Reg. at 19234-19241.
[6] 85 Fed. Reg. at 19264.
[7] 85 Fed. Reg. at 19265.
[8] Medicare Telemedicine Health Care Provider Fact Sheet. Centers for Medicare & Medicaid Services, 17 Mar. 2020, www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet.

services. The AAN believes that CMS should allow the virtual check-in code G2012 to be performed at any time. CMS should delete the requirement that it 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 practitioner time would not overlap with the work of the E/M visit, and the physician would not be double-paid. 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.

CMS should also 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. 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.

The AAN supports CMS' decision to pay non-facility rates for telehealth services furnished by distant site practitioners.[9] The AAN concurs with CMS' rationale that this approach is necessary during the PHE to ensure that physicians do not have an economic incentive to provide care in the office, rather than via telehealth during the PHE. The AAN further agrees that this decision is appropriate because the technology cost of providing services via telehealth is being borne by the physician's practice, rather than by the originating site for visits that are being delivered to patients in their homes. While the AAN believes that this is a welcome change that will encourage use of telehealth services and allow clinicians to determine whether visits should be conducted in-person or via telehealth based on clinical appropriateness, the AAN is concerned that this approach in the long-term may result in unforeseen consequences that may hurt the economic viability of some practices. If this policy is made permanent, the AAN urges CMS to monitor relevant data for significant shifts in how care is being delivered that may be driven by economic incentives, rather than by evidence regarding the proper roles of telehealth encounters versus in-person visits.

Although the AAN is supportive of HHS' larger efforts to reduce administrative burdens during the PHE to maintain patient access to care, the AAN notes that some changes that are necessary during the PHE should not be extended past the PHE. Specifically, the AAN has concerns surrounding the waiver of penalties associated with using non-HIPAA compliant telehealth platforms.[10] While ensuring continuity of care and lowering barriers to entry during the PHE is paramount, patient privacy and data security also must be protected. After

[9] 85 Fed. Reg. at 19233.

[10] Office for Civil Rights. Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency. US Department of Health and Human Services, 30 Mar. 2020, www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html.

the PHE, the Office for Civil Rights should resume enforcement to ensure that only HIPAA compliant telehealth platforms are used.

Additionally, waiving enforcement of provisions of waste, fraud, and abuse laws related to patient cost-sharing is another necessary step to decrease barriers to accessing needed care during the PHE, but may result in adverse consequences if extended beyond the PHE. The AAN notes that the policies put in place by the administration place the financial cost of waiving cost-sharing solely on providers. During the PHE, the AAN urges the administration to provide patients with financial relief and certainty surrounding cost-sharing by covering out-of-pocket cost-sharing for medically necessary services delivered via telehealth.

While the AAN is appreciative of CMS' recent decision to pay for telephone E/M services at parity with the rates paid for analogous services, 99212-99214, the AAN is concerned that long-term payment parity of these services would not accurately capture the relative work inputs inherent to the various types of services.[11] The AAN concurs with CMS' rationale that in the short term, telephone services are acting as a substitute for E/M services that would have otherwise occurred either in-person or via an audio-video telehealth platform, but this is likely not to be the case in the long term. The AAN recommends that telehealth and phone services should be better defined after the PHE has passed. Some televideo visits may be performed from the physician's smartphone to the patient's, but others require the presence of a video technologist and nurse. Another cost variable may arise when physicians who perform office visits in a facility, instead schedule some providers to perform televideo 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.

The AAN also 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.

E/M Services

The AAN notes that CMS is implementing temporary guidelines related to determining the appropriate coding levels for E/M services delivered via telehealth.[12] The AAN is aware of confusion related to these temporary guidelines and requests guidance on appropriate coding for these services during the PHE. Additional guidance will aid practices in ensuring that they are in compliance with CMS policies during the PHE and would promote Medicare program integrity.

[11] 85 Fed. Reg. at 27590.
[12] 85 Fed. Reg. at 19269.

Additionally, the AAN remains highly supportive of the coding and reimbursement structure that was finalized in the 2020 Physician Fee Schedule final rule.[13] The AAN supports CMS' decision to fully implement the new policies on January 1, 2021. The AAN urges CMS to fully implement the new structure as finalized in 2021, without any additional delay and without modification. If CMS were to consider delaying implementation or making any changes to the finalized E/M structure or values, the AAN urges CMS to consult with relevant specialty groups, including the AAN, to better understand any potential negative consequences, prior to releasing a proposal.

Supervision of Home Infusions

The AAN notes that during the PHE, Medicare beneficiaries in need of care unrelated to COVID-19 are faced with the difficult choice of forgoing needed services and medications by staying home or potentially risking exposure by seeking care in a hospital setting or physician's office. The AAN concurs with CMS that it is necessary for continuity of care to allow patients to receive needed infusions safely in their homes, when medically appropriate, during the PHE. The AAN agrees that furnishing these services in the home during the PHE may be appropriate when a supervising physician can ensure that the standard of care is met and that the medication can be safely infused in the patient's home via remote supervision. Additionally, the AAN believes that restrictions on the number of patients an individual physician may supervise remotely are needed and appropriate so that each individual patient can receive sufficient supervision. The AAN also believes that patients need to be fully informed with relevant cost-sharing information associated with receiving infusions at home.

Although loosening the restrictions on infusions in the home may be necessary in the short-term, the AAN notes that it is important that patients maintain access to in-office infusion services in cases in which that is the patient's preference and that the decision as to the appropriateness of administering at home is made by the patient's physician. The AAN is concerned that the relaxation of requirements related to supervision of infusions may lead to adverse consequences, as those with intentions not in the best interest of the patient may exert pressure that leads to inappropriate administration of infusions in the home. The AAN is concerned that payers may mandate that infusions that necessitate physician supervision be administered in the home and that the supervising physician be readily available throughout the infusion. Such mandates would be extremely burdensome on providers. Additionally, it is important to note that there are neurology infusions, including some disease modifying therapies for multiple sclerosis, that should never be administered in the home. The medical appropriateness of such treatments should be determined by neurologists in accordance with relevant clinical practice guidelines.

The AAN urges CMS to carefully balance patient access to necessary in-person care with expanded access to home infusion services. To promote continuity of care and patient safety, policies set forth by the administration must ensure beneficiary access to Part B drugs, provide appropriate payment for these drugs, and sufficiently reimburse for services rendered when provided in the home setting.

[13] 84 Fed. Reg. at 62844-62859.

Relief from Prior Authorization

The AAN appreciates CMS' recent decision to issue guidance that encourages Medicare Advantage (MA) plans to consider waiving or relaxing "prior authorization requirements at any time in order to facilitate access to services with less burden on beneficiaries, plans, and providers."[14] The AAN lauds CMS for recognizing the degree to which prior authorization serves as an impediment to patient access to care during the PHE. Although the change in CMS' guidance is a welcome step, the AAN urges CMS to require, rather than merely encouraging, MA plans to suspend PA requirements for the duration of the PHE. Prior authorization is particularly burdensome during the PHE for a number of reasons. Many practices are operating with significantly reduced staff capacity and most practices are urgently developing telehealth services, learning new E/M coding criteria, and adapting to frequent changes in guidance from the Centers for Disease Control and Prevention and local health authorities. Most have taken staff and funding from other practice activities to adapt to these emergency changes. Many CMS contractor resources have been reassigned away from routine prior authorization duty. Complying with PA requirements imposed by MA and other health plans consumes considerable resources and complicates scheduling for non-coronavirus related cases that are, by definition, urgent, as non-urgent care has been delayed due to the PHE. Prior authorization requirements that require an office visit for medication refills also may pose a potential danger to patients and to health care staff and this danger must be balanced against the immediate threat posed by sudden medication withdrawal. Additionally, the AAN notes that the medical necessity for imaging, medication, and other services may be different for patients evaluated by telehealth, compared to those evaluated by face-to-face office visit.

During the PHE, the AAN believes that prior authorizations should be reduced as much as possible, and at a minimum, there should be no prior authorization for COVID-19 testing and related therapies and treatments under any insurance arrangement. Additionally, the AAN calls on CMS to delay implementation of prior authorization requirements for certain procedures, including botulinum toxin injections, in the hospital outpatient setting for the duration of the PHE. The AAN believes that Medicare program integrity can be adequately protected during the PHE by appropriate post-service audits and by screening for potentially inappropriate changes in practice patterns among providers and health care systems. In addition to much needed temporary suspension of prior authorization in federally funded healthcare programs, the AAN encourages the administration to press other commercial insurers to temporarily waive prior authorization requirements that stand in the way of patients accessing needed care and medications. These would include barriers to prescribing and refilling medications without an in-person visit.

Additional Relief from Administrative Burdens

The administration should also modify Quality Payment Program requirements for 2020, as the nation's physicians should focus on their patients, rather than administrative reporting and programmatic compliance. Providers do not have the bandwidth to make the changes

[14] "Memo to All Medicare Advantage Organizations, Part D Sponsors, and Medicare-Medicaid Plans." Information Related to Coronavirus Disease 2019 - COVID-19, Centers for Medicare & Medicaid Services, 21 Apr. 2020, www.cms.gov/files/document/updated-guidance-ma-and-part-d-plan-sponsors-42120.pdf.

necessary to participate in alternative payment models and deadlines for other CMS quality programs should be delayed. The AAN appreciates CMS' recent decision to reduce burdens on providers by extending the MIPS data submission deadline, identifying the PHE as a triggering event for the extreme and uncontrollable circumstances policy, and reopening the extreme and uncontrollable circumstances application.[15] The AAN believes that providers should not be required to submit an extreme and uncontrollable circumstances application to receive relief during the PHE, as all providers across the country are currently experiencing extreme and uncontrollable circumstances. As such, the AAN believes that providers should be automatically exempted from MIPS penalties for the 2019 and 2020 performance periods, unless the provider chooses to opt-in to participating in MIPS. This policy should apply to all individual clinicians, those participating in MIPS in groups, and those participating in virtual groups. The AAN also urges CMS to account for any long-term effects that the PHE may have on measure benchmarks and to delay any increase in performance thresholds by at least a year, due to providers inability to substantively participate in MIPS during the PHE.

CMS should also work to reduce regulatory burdens and associated costs on health care practices to help physicians focus on providing necessary, high-quality care to their patients. Specifically, the AAN asks that regulatory burdens be reduced as much as possible by suspending or delaying further implementation of the Medicare Appropriate Use Criteria (AUC) Program for advanced diagnostic imaging. During the current emergency, many providers will not have the capacity to meaningfully participate in the current AUC education and testing year because providers must ensure that resources are devoted to patient care, rather than compliance with burdensome regulatory programs. The AAN also believes that this program is likely to have significant detrimental impacts on timely patient access to care, which is already hindered by the ongoing PHE. 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.

Changes to the Medicare Shared Savings Program

Neurologists are eager to participate in value-based care but have no substantive APM options. At present, the Medicare Shared Savings Program is one of few ways for neurologists to participate in an alternative payment model to any degree. The AAN supports CMS' efforts to promote the sustainability of Accountable Care Organizations (ACOs) during the public health emergency, by providing ACOs with relief from cost sharing associated with the high cost of care during the PHE. Specifically, the AAN supports CMS reducing an ACO's shared losses based on the percentage of the total months in the performance year affected by an extreme and uncontrollable circumstance.[16] While this is necessary, the AAN notes that more must be done to ensure the viability of ACOs.

The AAN notes that many ACOs were recently required to take on downside risk at an accelerated pace under the redesigned "Pathways to Success." Many of these ACOs have not had sufficient time to optimize their processes internally to ensure efficiency and to protect

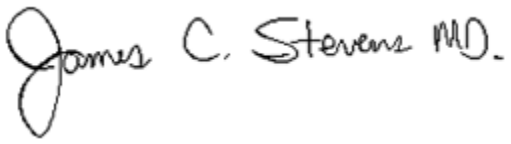
[15] "Quality Payment Program – COVID-19 Response." Quality Payment Program, Centers for Medicare & Medicaid Services, 29 Apr. 2020, qpp-cm-prod-content.s3.amazonaws.com/uploads/966/QPP%20COVID-19%20Response%20Fact%20Sheet.pdf.
[16] 85 Fed. Reg. at 19267-19268.

against losses, without accounting for the extreme volatility that is attributable to the ongoing PHE. The PHE represents a severe shock to the healthcare system whose effects will likely be felt for years to come. Although the AAN supports CMS' decision to implement extreme and uncontrollable circumstances policies to address shared losses incurred during the current performance year, the AAN notes that these policies do not adjust benchmarks or performance year expenditures, which will impact the viability of ACOs for many years. It is critical to ensure that ACOs are not measured against compromised benchmarks based on data collected during the PHE and that attribution is not skewed by temporary shifts in patient behavior as healthy patients delay care during the PHE.

Conclusion

The AAN appreciates CMS' efforts to reduce regulatory burdens and promote access to care throughout the COVID-19 pandemic. The AAN is encouraged by CMS' emphasis on utilizing telehealth services to ensure patient access to necessary care. The AAN urges CMS to implement our recommendations to ensure that Medicare beneficiaries maintain access to needed neurologic care and to ensure the permanent modernization of practices and policy innovations developed during the PHE. Please contact Matt Kerschner, the AAN's Government Relations Manager at mkerschner@aan.com or Daniel Spirn, the AAN's Senior Regulatory Counsel at dspirn@aan.com, with any questions or requests for additional information.

Sincerely,



James C. Stevens, MD, FAAN
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