October X, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1734-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: CMS–1734-P: 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

Dear Administrator Verma:

On behalf of the American Clinical Neurophysiology Society (ACNS), thank you for the opportunity to provide comments on the Medicare Physician Fee Schedule (MPFS) proposed rule for Calendar Year 2021. Founded in 1946, ACNS is the professional home of more than 1,300 physicians, researchers and allied health professionals devoted to the establishment and maintenance of standards of professional excellence in clinical neurophysiology in the practice of neurology, neurosurgery and psychiatry. ACNS members utilize neurophysiology techniques in the diagnosis and management of patients with disorders of the nervous system and in research examining the function of the nervous system in health and disease.

Our members are grateful for the flexibilities implemented by the Centers for Medicare & Medicaid Services (CMS) in response to the pandemic, which have allowed them to continue to deliver high quality care to patients while minimizing their risk of exposure to COVID-19. ACNS is pleased the agency is proposing additional policies to expand some flexibilities and make other permanent. Specifically, ACNS will be submitting comments on the following issues:

- Evaluation and management (E/M) services;
- Telehealth policies;
- Scope of practice;
- The valuation of certain services; and
- The National Coverage Determinations (NCDs).
Evaluation and Management Services

ACNS continues to support the code definitions and values as finalized in the CY 2020 PFS final rule. We appreciate the improvements to the outpatient E/M code family, and specifically the increase in values for both level 4 and 5 visits, which are frequently billed by neurologists when evaluating patients with intractable epilepsy, multiple sclerosis, muscular dystrophy, brain tumors, dementia, and other chronic disabling conditions, and urge the agency to implement this policy as planned on January 1, 2021.

ACNS recognizes that CMS is statutorily mandated to implement changes to the MPFS in a budget neutral manner. With outpatient E/M services accounting for 20 percent of MPFS services, the resulting 10.6 percent decrease in the conversion factor could limit patient access to specialized medical services, like those provided by ACNS members. Besides billing a significant number of higher-level E/M services, our members regularly bill for specialized medical services, like long-term EEG and sleep studies to evaluate our patients and will see significant cuts. The long-term EEG services were just redefined and revalued for 2020 and saw a reduction in value of approximately 30 percent. It will be difficult for ACNS members who remain committed to providing the highest quality care to a particularly vulnerable patient population to withstand another 10 percent to these services.

Medicare payments have failed to keep pace with inflation since the inception of the MPFS in 1992. The 2021 conversion factor of $32.2605 will be below that of the 1994 conversion factor of $32.9050, which is worth approximately $58.02 today. Therefore, we urge CMS to work with the Secretary to use the authority provided under the public health emergency to mitigate the redistributive effects of the E/M policy. As physicians struggle to address the impact of COVID-19 on their practices and patients, they cannot withstand the additional financial pressures this proposal creates.

Complexity Add-On Code

ACNS continues to support the complexity add-on code, GPC1X, which can be added to any outpatient office visit, and believes it will be useful for neurologists. We agree with CMS that the revised outpatient E/M family still does not capture all of the work required to treat patients with a single, serious chronic condition, like intractable epilepsy. Patients receiving a new diagnosis or patients with epilepsy, or those that need medication change or a surgical intervention, need to be counseled on their underlying diseases, complex medical treatments and adverse effects. Patients may also have breakthrough seizures even with optimal treatment, and the ultimate goal is to keep the patient out of emergency departments between visits. In addition, discussions are often needed with caregivers on the care plan. All of this work previously had been uncompensated.

This code would be particularly useful for our patients with ongoing care of a chronic neurologic disorder that affects a person’s physical and motor skills. One example is a patient with a seizure disorder, which may limit driving or hobbies and may cause increased emergency department visits or hospitalizations. Treatment includes the use of medications with common untoward side effects or life-threatening rarer effects, and may require periodic blood tests. This condition has a death rate that is two to three times greater than the age adjusted normal population. Regarding the documentation of this service, we would expect the physician to document the patient an ongoing seizure disorder, and not restate medically obvious in the note, e.g. increased death rate, limits on driving, and other well-known complexities for patients with epilepsy. It is overly burdensome to both providers and patients to have to repeat the medical consequences of a patient who has continued seizures.

ANCS urges the agency to retain the add-on code, which will capture some of this previously uncompensated work, and we would like to continue to be a resource as you further define the code moving forward.
**Telehealth Proposals**  

**Permanent and Temporary Telehealth Lists**

ACNS applauds the agency for increasing the number of services available to be provided via telehealth during the public health emergency. We also support the agency’s proposal to permanently add eight services to the telehealth services list, including GPC1X and 99XXX, and the proposal to create a new category of services to be added to the telehealth services list for the duration of the public health emergency. Encouraging both patients and providers to utilize telehealth services will not only help protect the health and safety of patients, but will allow providers to appropriately bill for these services without risking their own health. Patients with epilepsy often are not able to drive and have to rely on caregivers to provide transportation to each appointment, which may be far from the patient’s home. Improved access and reimbursement for telehealth would also help protect these patients from the burden of having to come to in-person visits. Furthermore, the creation of a temporary Medicare telehealth list will allow Medicare to collect the data needed to appropriately whether these services should eventually be added to the permanent telehealth list.

ACNS requests that CMS add CPT code 95970 to the list of codes so that providers are able to perform and bill services remotely during the public health emergency using this expanded authority. Many of the patients our members treat have chronic conditions that require regular care by a neurophysiologist even during this public health emergency. CPT Code 95970 is an analysis code that is frequently used by our providers to treat patients with epilepsy. The code descriptor for 95970 is:

Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming

Typically, a patient with intractable epilepsy has a Responsive Neuro-Stimulation device surgically implanted and it is then queried for its battery status and settings to be reviewed during face-to-face visits. As patients remain at home during the public health emergency, this service is still medically necessary to manage their epilepsy and can be provided via telehealth in order to protect the patient and the provider from potential COVID infection. The RNS devices are often queried every month and based on the results, the physician will decide if the patient needs to come in for a visit. Furthermore, these devices only save up to four 90-second session at a time, so it is important that they be reviewed regularly. Implanted devices are checked using a wand, the patient can hold over the device, while a provider can read the digital output, allowing all of this to occur virtually. However, CPT code 95970 is not currently on the CMS telehealth list.

**Audio-Only Visits**

ACNS appreciates the flexibility that the agency has provided for expanded use of telehealth through both audio/video and audio-only visits. Both audio/video and audio-only visits have been particularly useful for our epilepsy patients, who often have transportation challenges that make it difficult for them to attend in-person visits on a regular basis. Through video, providers are able to complete patient history and check-in on other patient needs, as long as a physical exam is not required for the visit. Audio-only calls have been particularly helpful for our Medicare patients with epilepsy, as it can be difficult for patients with neurologic impairments to skillfully utilize digital devices. Reducing these technological barriers has greatly improved access to care during the pandemic and we support the agency’s proposal to continue coverage and reimbursement for these vital telehealth services once the public health emergency ends.

ACNS recognizes that the current telehealth regulations require telehealth services have a simultaneous audio/visual connection, but we respectfully request that CMS revise these regulations to provide for audio-only services to continue once the public health emergency ends. Should this not be possible, we urge the agency to continue to allow audio-only visits to be provided through the end of the calendar year in which the public health emergency concludes. Not only do a number of our patients have difficulty using the digital devices required to establish a simultaneous audio/visual connection, others may not have access to the high-speed internet required to complete these visits. Continuing to require a simultaneous audio/visual connection may exacerbate existing health disparities as those patients with limited or no access to video visits are typically some of the most vulnerable.
Scope of Practice
ACNS supports the agency’s proposal to continue to provide flexibility for teaching physicians to be present virtually through audio/video real-time communication technology. Our members have used video-supervision for inpatient and outpatient care, which has allowed for a more complete yet safe interaction between the patient, family, and supervising physician. We support making this flexibility permanent after the public health emergency ends.

Valuation of Specific Codes - AEP, Long-term EEG, chronic care management services

Auditory Evoked Potentials
ACNS supports the agency’s proposal of the RUC-recommended work RVUs for the Auditory Evoked Potentials code family (CPT codes 92584, 92X51, 92X52, 95X53, 92X54). We also support adopting the RUC-recommended direct PE inputs for the code family without refinement.

Long-term EEG Services
ACNS supports the agency’s proposal to continue to carrier price the long-term EEG TC codes (CPT codes 95700, 95705-95716) in CY 2021.

Chronic Care Management Services
ACNS supports the agency’s proposed code valuations for the Chronic Care Management Services (CPT code 994XX and HCPCS code G2058). CMS proposed the RUC-recommended work RVU of 0.54 and the RUC-recommended direct PE input for 994XX, which we support finalizing.

Proposal to Remove Certain National Coverage Determinations (NCD)
ACNS supports the agency’s proposal to remove NCDs that have been on the books for more than ten-years, since these are often no longer clinically relevant. After ten years, CMS should seek input from stakeholders on whether the NCD should be removed, renewed, or revised with updated research.

An example of an NCD that should be removed is the 1984 NCD on Ambulatory EEG Monitoring (NCD 160.22). ACNS, along with the American Academy of Neurology (AAN) and the National Association of Epilepsy Centers (NAEC) have requested that CMS remove NCD 160.22 and allow coverage to be determined by local Medicare contractors. We reiterate this request in these comments, with the following rationale.

In the case of NCD 160.22, it is appropriate to remove the NCD based on the criteria that allowing local contractor discretion would better serve the needs of the Medicare program and its beneficiaries. While the original policy was intended to apply to ambulatory EEGs, in recent years auditors have applied the NCD to EEGs performed in inpatient hospital settings, such as Epilepsy Monitoring Units (EMUs) and Intensive Care Units (ICUs).

Auditors have also required a routine EEG be performed before a long-term EEG will be covered, using this NCD as the rationale even though it does not specifically address this issue. Some auditors require routine EEG to be provided within the past 3-12 months before covering long-term EEGs. This results in CMS paying for unnecessary tests that are not clinically indicated or medically necessary, but merely required by the auditor. It also places an additional burden on providers and patients by delaying access to appropriate care.

As an example, a patient gets a routine EEG that does not capture any seizure activity. To treat his or her epilepsy, the patient tries and fails two drugs before becoming a surgical candidate. The patient must be admitted to the inpatient EMU for long-term EEG monitoring to be evaluated for surgery, but it is over a year since the initial routine EEG. The auditors would deny payment for the long-term EEG services provided in the inpatient EMU since the prior EEG was done more than 3-12 months (depending on the auditor) before the EMU visit.

The practice of medicine has evolved significantly in this field since the agency promulgated NCD 160.22 in 1984. The coding and payment structure for ambulatory EEGs has also changed significantly. In order to align the current standard of care and the revised coding and reimbursement structure, we respectfully request that the agency remove NCD
160.22 and allow coverage decisions to be determined by local Medicare administrators through the local coverage process.

Thank you again for the opportunity to provide comments on CMS' CY 2021 Physician Fee Schedule proposed rule. ACNS looks forward to continuing to work with CMS on these important issues. Please address any questions on the issues contained in this letter to Erika Miller at 202-484-1100 or emiller@dc-crd.com.

Sincerely,

Gloria M. Galloway, MD, MBA, FACNS
ACNS President