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Submitted electronically via: https://www.regulations.gov

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1734-P
P.O. Box 8016
Baltimore, MD 21244-8013

Re: Medicare Program; CY 2021 Revisions to 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; Updates to the Quality Payment Program; Medicare Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Requirement for 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; Proposal to Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy Proposed Rule

#### Dear Administrator Verma:

The American Academy of Audiology (the Academy) appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule (CMS-1734-P), published on August 17, 2020 in the *Federal Register*, regarding proposed policy revisions to the CY 2021 Medicare Physician Fee Schedule (PFS). The Academy is the world's largest professional organization of, by and for audiologists. Representing the interests of approximately 14,000 audiologists nationwide, the Academy is dedicated to providing quality hearing and balance care services through professional development, education, research, and increased public awareness of hearing and balance disorders.

Several provisions in the proposed CY2021 Medicare PFS rule would adversely impact practicing audiologists and the Medicare beneficiaries they treat. In this letter, we offer comments on the following provisions:

- 2021 Proposed Conversion Factor
- Technical Expert Panel Related to Practice Expense
- Telehealth and Other Services Involving Communications Technology
- Requests to Add Services to the Medicare Telehealth Services List for CY 2021
- Proposed Temporary Addition of a Category 3 Basis for Adding to or Deleting Services from the Medicare Telehealth Services List
  - Comment Solicitation on Requirements of Scope of Service / In-State Licensure

- Comment Solicitation on the Definition of HCPCS code GPC1X
- Quality Payment Program
- Valuation of Specific Codes
  - Vestibular Evoked Myogenic Potential Testing (CPT codes 92517, 92518 and 92519)
  - Auditory Evoked Potentials (CPT codes 92650, 92651, 92652 and 92653)

### **2021 Proposed Conversion Factor**

The Academy strongly urges CMS to waive budget neutrality rules for the purpose of applying the proposed conversion factor for calendar year CY 2021. The proposed CY 2021 Medicare PFS conversion factor is \$32.26, which represents an almost 11 percent reduction from the CY 2020 conversion factor of \$36.09. The drastic 11 percent reduction in the Medicare conversion factor is necessitated by proposed additional spending of \$10.2 billion, due, in part, to changes to evaluation and management (E/M) services and related codes. Implementation of proposed payment increases for E/M services results in significant payment decreases for many specialties, including audiology. The proposed -7 percent cut in reimbursement for audiology will be detrimental to practices that are already struggling to absorb costs of altered patient care protocols and required purchases of personal protective equipment.

We note the proposed CY 2021 conversion factor will be the lowest annual conversion factor since 1994. We are disturbed that societies can be expected to absorb a conversion factor that is consistent with a valuation that is 16-17 years old. Cuts of this magnitude are exactly what the enabling legislation sought to avoid and therefore justifiably supports implementing the budget neutrality emergency. Additionally, the physician fee schedule updates for years 2020 through 2025 will be 0 percent. Clearly, this is an unsustainable policy change for all Medicare Part B providers. We request that CMS utilize its authority and flexibilities under the public health emergency (PHE) declaration to waive the requirement to adjust Medicare payments for budget neutrality. CMS must explore all regulatory avenues to waive budget-neutrality rules.

In recent history, either Congress or CMS has acted to mitigate negative impacts by phasing in reimbursement cuts over time. If CMS chooses not to use its authority to waive budget neutrality during this PHE, we urge the Agency to consider a phase-in of the cuts. For example, in the 2010 physician fee schedule final rule, CMS began using a new survey of practice expenses that resulted in significant redistributions in payment. CMS used its regulatory authority to adopt these changes over a transition period (74 FR 61751). We ask CMS to utilize a similar approach for specialties that are slated to receive cuts due to the E/M restructuring. We believe that, if budget neutrality cannot be waived, the cuts should be phased in over multiple years.

### **Technical Expert Panel Related to Practice Expense**

We appreciate CMS' willingness to hold a Town Hall meeting to provide an open forum for discussion of CMS' ongoing interest in potentially updating the practice expense (PE) methodology and the underlying inputs. We also applaud CMS for seeking to make refinements based on current actual costs to improve payment accuracy. We urge CMS to consider practice type (e.g., small and medium size practices) as a factor in determining practice expense pricing, taking into consideration that not all entities benefit from the price discounts that large institutions are able to negotiate. We support CMS' decision not to make any proposals at this time but to continue to seek feedback from all interested stakeholders.

Further, the Academy remains concerned that since the elimination of the non-physician work pool in 2007, the transition of audiology services to professional component has continued to have a negative impact on practice expense components. We continue to advocate for a fair reimbursement formula that recognizes that audiologists are licensed healthcare professionals and not technicians. Previous discussions with CMS focused on the need to minimize the impact of losing the non-physician work pool and the conversion of our codes to the standard practice expense formula. As CMS seeks to improve the underlying inputs for practice expense, we urge CMS to reevaluate the formula for non-physicians and the conversion of services to the standard practice expense formula. Permitting clinical staff for audiologists is one of several concepts we wish to explore. We look forward to participating in the future Town Hall meeting, and we urge CMS to add non-physician services to the discussion.

# <u>Telehealth and Other Services Involving Communications Technology</u>

We commend CMS on addressing telehealth and communications technology. At the present time, many seniors are effectively cut off from the world as senior living facilities across the country continue to enforce lockdowns due to COVID-19. This situation can lead to increased feelings of isolation and depression and untreated hearing loss is linked to these conditions as well. This is a frightening time for many seniors and communicating adequately is essential for them to interact with caregivers and to stay connected with family members. Individuals with even mild hearing loss are three times more likely to experience a fall, and falls are the leading cause of fatal injury for Americans over the age of 65<sup>1</sup>. Research shows that seniors with untreated hearing loss are more likely to develop cognitive decline up to 40% faster than those without hearing loss<sup>2</sup>.

Under the best of circumstances, Medicare beneficiaries face significant financial and logistical barriers in accessing the services of an audiologist. Seniors must first obtain a physician order before the diagnostic services of an audiologist will be reimbursed by the Medicare program. In addition, even though audiologists are able to provide both diagnostic and treatment services under the licensing laws of all fifty states, Medicare will only reimburse for the diagnostic services that audiologists provide.

Finally, audiologists do not have practitioner status under Medicare statute. Audiologist's current classification has outlived the evolution of the profession – our current classification has not changed since the inception of the Medicare program. Most other similarly situated allied health professionals have seen their status evolve and are deemed "practitioners" in Medicare, including those professionals included in the recent telehealth expansion.

Audiologists stand ready to provide critical services to seniors at this time to ensure they remain connected to their surroundings and are able to understand their caregivers and medical professionals. We urge CMS to move CPT codes 92601-92604 from Category 3 to Category 1 to allow these essential services to be provided to beneficiaries via telehealth.

<u>Proposed Temporary Addition of a Category 3 Basis for Adding to or Deleting Services from the Medicare Telehealth Services List</u>

<sup>&</sup>lt;sup>1</sup> Centers for Disease Control and Prevention. (May 2018) *Deaths from Falls Among Persons Aged* ≥65 *Years* — *United States, 2007–2016.* https://www.cdc.gov/mmwr/volumes/67/wr/mm6718a1.htm;

<sup>&</sup>lt;sup>2</sup> Lin, Frank and Yaffe, Kristine. Journal of the American Medical Association: *Hearing Loss and Cognitive Decline in Older Adults*. (February 2013) https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1558452

We thank CMS for adding a broad range of services to the Medicare telehealth services list in response to the PHE for the COVID-19 pandemic, including cochlear implant programming services 92601-92604. We agree with CMS that it would be disruptive to both clinical practice and beneficiary access to abruptly eliminate Medicare payment for telehealth services as soon as the PHE ends without first providing an opportunity to use information developed during the PHE to support requests for permanent changes to the Medicare telehealth services list.

When assessing the addition of a service to the Medicare telehealth services list on a Category 3 basis, CMS proposes to consider the following factors:

- Whether, outside of the circumstances of the PHE, there are increased concerns for patient safety if the service is furnished as a telehealth service.
- Whether, outside of the circumstances of the PHE, there are concerns about whether the provision of the service via telehealth is likely to jeopardize quality of care.
- Whether all elements of the service could fully and effectively be performed by a remotely located clinician using two-way, audio/video telecommunications technology.

The ability to perform these crucial programming services has been a vital lifeline allowing Medicare beneficiaries access to needed services while allowing them to stay safe at home during the PHE. We urge CMS to maintain cochlear implant programming services on the Telehealth list so that services can be provided to Medicare beneficiaries on a permanent basis.

# <u>Comment Solicitation on Requirements of Scope of Service / In-State Licensure</u>

In the 2021 Medicare PFS proposed rule, CMS is soliciting public comments regarding qualified healthcare professionals practicing to the full scope of their state licensure. We acknowledge and thank CMS for addressing this flexibility as it has the potential to impact the ability of patients to receive coverage for services that are within the scope of an audiologist, rather than facing the added logistical and financial burden of seeing a physician or NPP for a referral. Audiologists, by state law, can and do practice in independent settings using their training and skills to address problems related to hearing, tinnitus and balance. They are also trained to recognize and refer to other professionals for medical intervention that is beyond their scope of practice. **The Academy urges CMS to adopt the same criteria**.

A patient encounter can result in the audiologist's use of professional skills, time and practice expense for which other provider types are reimbursed under Medicare while audiologists are not. The following scenario demonstrates how this may be achieved for the best possible patient care:

Typical Patient - a 66-year-old male patient referred to audiologist by his PCP for an evaluation due to recent onset of tinnitus, unknown etiology.

**Practice setting:** Independent Audiology practice. **Payer:** Traditional Medicare B with supplement. **Physician's Order:** "Tinnitus, evaluate and treat"

The audiologist reviews the written referral, patient demographics and the medical case history information that was provided by the referring PCP. The audiologist reviews the medical/case history form and medication forms completed by the patient.

The audiologist reviews with the patient the reason for the visit, asking clarifying questions regarding the medical history forms. Based on the review of this information, the audiologist then proceeds to <u>ask more focused questions</u> regarding hearing history and tinnitus, such as the following:

- What previous audiology tests were done (and when?)
- description of tinnitus in terms of pitch/frequency, intensity, laterality etc
- events leading up to onset of the tinnitus, including any changes in medications
- Hx of cervical, dental or jaw problems and/or treatment
- Hx of noise exposure

The audiologist performs a physical examination of the ears (external and otoscopic). Ear canals are clear, TM's clearly visualized, normal light reflex.

Based on the medically relevant history and exam, the audiologist decides to administer the following diagnostic tests:

- 92557 (Comprehensive audiometry threshold evaluation and speech recognition) to determine the nature and degree of hearing loss.
- Tinnitus Handicap Inventory (THI) no code for this to quantify the subjective tinnitus.

The audiologist interprets the tests.

Test results reveal a mild high frequency, symmetrical, bilateral, sensorineural hearing loss. THI - Score = 58 indicates Grade 4 tinnitus, severe handicap. The patient indicates on the questionnaire that he suffers from disturbed sleep patterns and interference with daily activities.

Based on the above findings, the audiologist decides to additionally administer the following diagnostic tests

- 92588 (comprehensive diagnostic evaluation (quantitative analysis of outer hair cell function by cochlear mapping, minimum of 12 frequencies).
- 92625. (Assessment of tinnitus (includes pitch, loudness, matching, and masking).

Based on the Medicare Quality Measures Denominator Triggers – the audiologist administers the following additional screening tools and provides additional patient management. 92557

- 130 Documentation of Current Medications in the Medical Record
- 226 Tobacco Use: Screening and Cessation Intervention\*
- 181 Elder Maltreatment Screen and Follow-up Plan\*

#### 92625

134 Screening for Depression and Follow-Up Plan\*

\*Note, audiologists are not currently reimbursed by Medicare for the work required for the activities outlined in these quality measures.

Following the completion of all of the diagnostic tests and screening tools, the audiologist reviews the test results and discusses applicable treatment options and/or referral options with patient. The patient asks multiple questions regarding experimental tinnitus therapies they have researched online including repetitive transcranial magnetic stimulation and deep brain

stimulation, use of antioxidants and herbal supplements. (The discussion of results reviewing options and questions a minimum of 35 minutes).

The report prepared for the referring physician includes, results, interpretation and recommendations. The audiologist has utilized his/her professional skills within the scope of practice for services providing additional services beyond the provision of diagnostic tests.

While Medicare is currently only allowed by statute to reimburse the audiologist for the diagnostic tests 92557, 92558 and 92625, the audiologist has also provided evaluation, decision making, counseling and management that other providers are reimbursed for from Medicare via E&M codes.

### Comment Solicitation on the Definition of HCPCS code GPC1X

In the CY 2020 PFS final rule, CMS finalized the HCPCS add-on code GPC1X which describes the "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 condition."

In the 2021 Medicare PFS proposed rule, CMS is soliciting public comments regarding what aspects of the definition of HCPCS add-on code GPC1X are unclear, how they might address those concerns, and how they might refine their utilization assumptions for the code. The Academy encourages CMS to delay implementation of this code until the CPT Editorial Panel can provide further guidance. If CMS chooses to move forward with implementation, the Academy urges CMS to provide more transparency about its assumptions regarding frequency of submission and financial impact on specialties. We urge the Agency to publish clear reporting instructions and documentation guidelines to prevent misuse.

# **Quality Payment Program (QPP)**

The Academy appreciates CMS' proposal to maintain, without change, the nine extant quality measures available to audiologists under the Merit-based Incentive Payment System (MIPS). Given a year of substantive practice protocol changes and challenges in the provision of patient care due to the pandemic, we also appreciate CMS' willingness to postpone implementation of the MIPS Value Pathways initiative until at least 2022.

# **Valuation of Specific Codes**

<u>Vestibular Evoked Myogenic Potential (VEMP) Testing (CPT codes 92517, 92518 and 92519)</u>

The Academy thanks CMS for proposing to accept the RUC recommended work RVUs and direct PE inputs for CPT codes 92517, 92518 and 92519. Additionally, we request that CMS create a professional and technical component (PC/TC) split for the new VEMP CPT Codes 92517, 92518 and 92519 to permit audiologists who may find it necessary to report the PC separately from a facility to have the flexibility to do so. There are audiologists that are not hospital employees that have relationships/contracts (similar to physicians and other clinicians) that are performing the professional component of these procedures. It is important to have the ability to accurately code and capture these services as delivered to patients. There is precedent in audiology services such as CPT codes 92548 and 92549 (computerized dynamic posturography), which have both PC/TC split. The Academy urges CMS

to finalize the proposed valuations for codes 92157, 92518 and 92519 and to publish a PC/TC split for these services in the final rule.

Electrocochleography (92584) and Auditory Evoked Potentials (CPT codes 92650, 92651, 92652 and 92653)

The Academy appreciates CMS' proposal to accept the recommended work RVUs and direct PE inputs for CPT codes 92584 and 92650-92653. However, CMS did not publish proposed practice expense and malpractice RVUs for 92650 (auditory evoked potentials; screening), although the RUC recommendations included direct PE inputs and a crosswalk for professional liability insurance (PLI). The Academy understands that CMS did not propose valuation for CPT code 92650 because it is not a covered Medicare service. However, we urge CMS to display the total RVUs for 92650 to include the work, PE, and malpractice RVUs based on the RUC's recommendations. There is precedent from other hearing screenings, such as CPT code 92558 (evoked otoacoustic emissions, screening), which is marked as a non-payable code but for which CMS displays work, PE, and malpractice RVUs. It is critical for CMS to display the total RVUs to allow state Medicaid agencies, newborn hearing programs, and commercial insurers to appropriately value 92650.

Additionally, we request that CMS create a professional and technical component split for CPT codes 92651, 92652 and 92653 to permit audiologists who may find it necessary to report the PC separately from a facility to have the flexibility to do so, as their derivative codes, 92585 and 92586 both had TC/PC splits. There are audiologists who perform professional services for these procedures in a facility setting and the ability to accurately report the services performed is required.

The Academy urges CMS to finalize the proposed valuations for codes 92650, 92651, 92652 and 92653 in the final rule. Additionally, we request that CMS publish the RVUs for CPT code 92650 and create PC/TC split for codes 92651, 92652 and 92653.

# **Conclusion**

To recap, the American Academy of Audiology is urging CMS to take the following actions in the final rule:

- Use its authority and flexibilities under the COVID-19 PHE declaration to waive the requirement to adjust Medicare physician payments for budget neutrality.
- Add CPT codes 92601 92604 (cochlear implant programming) to the Medicare Telehealth Services Category 1 List for CY 2021, with the consideration of additional services.
- Confirm the proposal to permit providers to practice to the full scope of their in-state licensure
- Provide transparency on how the calculations for utilization of GPC1X were established
- Finalize proposed values for CPT codes 92517, 92518 and 92519 (VEMP testing) and publish PC/TC split for codes 92517, 92518 and 92519.
- Finalize proposed values for CPT codes 92650, 92651, 92652, and 92653 (Auditory Evoked Potentials) and establish a PC/TC split for CPT codes 92651, 92652 and 92653.
- Publish the RVUs associated with CPT code 92650.

On behalf of the Academy, we appreciate the opportunity to provide feedback to CMS on these important issues. If you have any questions regarding the information included in this letter, please contact Susan Pilch, Senior Director, Government Relations at spilch@audiology.org.

Sincerely,

Angela Shoup, PhD

President, American Academy of Audiology