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August 22, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-1770-P; Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts – Section K

Comments submitted electronically via www.regulations.gov

Dear Administrator Brooks-LaSure:

The American Academy of Audiology (the Academy) wishes to comment on ***CMS 1770-P; Medicare Program; CY 2023 Payment Policies under the Physician Fee Schedule (PFS) and Other Changes to Part B Payment Policies***. The Academy is the largest organization of, by, and for audiologists. We are dedicated to the provision of quality hearing and balance care services through professional development, education, research, and increased public awareness of hearing and balance disorders. The Academy proudly holds a seat on the Health Care Professionals Advisory Committee (HCPAC) for both American Medical Association (AMA) Current Procedural Terminology (CPT) and Relative Value Update (RUC) Committees. We have dedicated the last 15 years to making important contributions to the audiology profession through these established entities and processes.

The Academy commends CMS for acknowledging the importance of Medicare beneficiaries having timely access to direct access to diagnostic hearing and balance testing through a proposal in the PFS (Section K). We recognize the significant effort by CMS to develop such a proposal. However, the current proposal is unworkable and presented in a construct that will add to provider burden and present challenges that will impede beneficiary access to care. The Academy is very receptive to working with CMS to identify a direct access strategy that will be advantageous to beneficiaries, streamline the process for providers, and reduce unnecessary administrative burden for the agency. **Our comments herein delineate our concerns with the proposal and offer an alternative strategy built around the foundations of the existing CPT code construct that could provide needed data to shape a highly valuable, long-term Medicare program benefit.**

DIRECT ACCESS TO DIAGNOSTIC TESTING

Currently, Medicare beneficiaries under CFR 410.32 must first obtain a physician order to see an audiologist for coverage for diagnostic hearing and balance tests. In contrast, a physician order is not required under any state or District of Columbia audiology licensure law prior to an individual being allowed access to the care of an audiologist. The Department of Defense, the Veterans Health Administration (VHA) and most plans offered through the Federal Employees Health Benefit Program allow direct access to covered diagnostic testing without a physician referral.[1] We support Medicare beneficiaries having control of their health care decisions, including access to safe and affordable hearing care. Improving accessibility, encouraging appropriate assessment and management of hearing loss, and recognizing the impact of affordability are common goals. Audiologists are qualified to identify, diagnose, manage, and treat disorders of hearing and balance. The Academy's objective is to remove any unnecessary barriers to the delivery of quality hearing and balance healthcare so that the public can easily receive access and appropriate diagnostic and treatment services.

Direct access would not expand the scope of practice of audiology or diminish the important role played by physicians and other primary care providers. Audiologists are already responsible for determining medical necessity. Allowing Medicare beneficiaries to have coverage when seeking direct access to audiology services would reduce unnecessary physician visits and improve beneficiary access. This translates to timely beneficiary care, saves unnecessary costs of physician visits requiring an order, and staves off the harmful downstream effects of untreated hearing loss such as falls, social isolation, and accelerated cognitive decline.

The proposed rule text and initial follow-up discussions with CMS to date reflect an effort toward broader direct access to diagnostic testing. Workable regulations are needed to ensure the successful implementation of this concept. Further, revisions are necessary to ensure adequate and fair reimbursement for the services provided by audiologists, as well as the ability of CMS to track these services. A single HCPCS code, GAUDX, blending 36 separate and distinct services under one payment construct will not allow tracking nor monitoring of services performed by the audiologist without a physician order.

The Academy supports direct access to diagnostic testing; however, the proposal as written must be revised to be a workable and effective Medicare program benefit. We look forward to continuing dialogue with the Agency to ensure appropriate implementation and achievement of CMS' stated goals.

SAFETY CONCERNS

The Academy takes great exception to the presumptive safety concerns referenced in the direct access proposal. The statements in the proposal have no supporting documentation, and we challenge the CMS to provide evidence for the safety claims. We are unaware of studies that document evidence or widespread concerns about the safety of direct access to audiology diagnostic testing.

[1] http://www.nationalacademies.org/hmd/Reports/2016/Hearing-Health-Care-for-Adults.aspx

We concur with the CMS Claims Processing Manual Section 30.3 (B)(1)(a) which discusses the professional skills of an audiologist.

> "*...The skills required when professionals furnish audiology services for payment under the MPFS are masters or doctoral level skills that involve clinical judgment or assessment and specialized knowledge and ability including, but not limited to, knowledge of anatomy and physiology, neurology, psychology, physics, psychometrics, and interpersonal communication. The interactions of these knowledge bases are required to attain the clinical expertise for audiology tests. Also required are skills to administer valid and reliable tests safely, especially when they involve stimulating the auditory nerve and testing complex brain functions. Diagnostic audiology services also require skills and judgment to administer and modify tests, to make informed interpretations about the causes and implications of the test results in the context of the history and presenting complaints, and to provide both objective results and professional knowledge to the patient and to the ordering physician."*

Audiologists possess the requisite knowledge and training to recognize conditions needing medical treatment and have an ethical obligation to refer patients that require medical services. In 2010, a Mayo Clinic study presented a retrospective review of 1500 Medicare-aged electronic medical charts to examine the safety of audiologists as the entry point to hearing health care. The study showed no difference in treatment plans recommended by audiologists compared with otolaryngologists in more than 95% of the cases. Furthermore, no case was associated with significant mortality or morbidity. In 78% of the cases, only direct access to diagnostic testing was warranted, which is consistent with studies that indicate approximately 90% of hearing loss in the Medicare population is sensorineural hearing loss related to age-related factors and noise, and the prevalence of ear-related life-threatening medical pathologies is low.[2,3] The authors concluded, "that audiology direct access would not pose a safety risk to Medicare beneficiaries complaining of hearing impairment (Zapala et al, p.366)."

In 2016, the National Academies of Sciences, Engineering, and Medicine (NASEM) concluded: "…after weighing the rareness of the medical conditions, the incidence of hearing loss in adults, the widespread need for hearing health care, and wide use of the medical waiver, there was no evidence that the required medical evaluation or waiver of that evaluation provides any clinically meaningful benefit." The report highlighted barriers for Medicare beneficiaries accessing timely hearing services, noting the obstacles associated with securing a physician referral.[4] The report findings led to a recommendation for the FDA to remove the medical waiver for adults which was included in the regulation for over-the-counter (OTC) hearing aids. Neither the FDA nor the NASEM report cited any safety concerns in allowing direct access to audiologists.

Since 1992, the Veterans Health Administration (VHA) has allowed veterans to have direct access to audiologists without first obtaining a medical evaluation. Although the VHA program does cover hearing aids and related services, which are statutorily prohibited under the Medicare program, veterans also receive direct access to audiologists for a range of diagnostic services also available to Medicare

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[2] Hoffman, H.J. et al. (2017). Declining prevalence of hearing loss in US adults aged 20 to 69 years. *AMA Otolaryngol Head Neck Surg*. 2017 March 01; 143(3): 274–285;

[3] Zapala, DA, et al. (2010). Safety of direct access for Medicare patients complaining of impaired hearing. *J Am Acad Audiol* 21:365–379.

[4] Blazer, D., Domnitz, S., Liverman (editors) (2016). *Hearing Healthcare for Adults. National Academies of Sciences, Engineering, and Medicine.* National Academies Press, Washington, DC.

beneficiaries. Many commercial payers independently enroll audiologists in their networks. Their PPO and POS plans allow for direct access to qualified audiologists for diagnostic audiology services without a physician order. We are not familiar with any insurance data to substantiate the CMS' concerns of patient safety.

The Academy requests that CMS remove any suggestions of safety concerns without detailing evidentiary support.

DEFINING ACUTE AND NON-ACUTE HEARING LOSS

It is common for patients, new or existing, to use an audiologist as the entry point for hearing related issues. Restricting beneficiary direct access to the services of an audiologist based on the definition of acute vs non-acute creates a barrier for seeking timely audiology services. If a Medicare beneficiary presents with an acute onset hearing loss, such as a sudden sensorineural hearing loss described in your draft rule example, the diagnostic tests performed by the audiologist are needed before the physician or NPP can make decisions for treatment. In a case like this, where the patient would see the audiologist first, there would be an immediate coordination of care with the patient's physician/NPP, and the critical diagnostic test results would be provided allowing the physician/NPP to appropriately treat the patient emergently.

The Academy recommends removal of the acute criterion as determining and coordinating care for patients with hearing related issues is within current scope of practice for audiologists. We welcome additional discussions with the Agency and other stakeholders to discuss further.

ADMINISTRATIVE CHALLENGES WITH IMPLEMENTATION

If CMS proposes a time-limited benefit of coverage for direct access diagnostic services performed by an audiologist, a real-time verification of whether or not the beneficiary has already exhausted their benefit will need to be operationalized. Audiologists will need this information to correctly administer an ABN to the beneficiary if it is necessary.

The Academy would recommend that CMS make the time-limited eligibility information accessible via currently established online tools (such as MAC portals, Clearinghouses etc) that providers already use to obtain other Medicare eligibility information.

DISRUPTION OF FEE SCHEDULE RELATIVITY WITH GAUDX CODE

CMS proposes 36 audiology CPT codes be encompassed into a new HCPCS code, GAUDX, for audiology service(s) furnished personally by an audiologist without a physician/NPP order for non-acute hearing assessment unrelated to disequilibrium, or hearing aids or examinations for the purpose of prescribing, fitting, or changing hearing aids once in a period of 12 months. CMS proposes a work RVU of 0.8 and practice expense inputs using the combined values of CPT codes 92557 Comprehensive audiometry threshold evaluation and speech recognition (92553 and 92556 combined) (work RVU = 0.60, 20 minutes intra-service time, and 28 minutes total time) and 92567 Tympanometry (impedance testing) (work RVU = 0.20, 4 minutes intra-service time, and 6 minutes total time). CMS further describes that both CPT codes make up 72% of all billings for audiologists (92557 is billed with 92567 over 60% of the time; 92567 is billed with 92557 over 83% of the time in the same clinical encounter).

The Academy is greatly concerned with the unprecedented proposal to value such disparate services outside of the AMA RUC process. The CMS proposed blended work RVU of 0.8 does not accurately reflect the relative clinical work established by RUC procedures and accepted by CMS. Additionally, the method used to calculate the proposed work RVU does not preserve relativity and ignores the clinical input and expertise of the audiologists that furnish the service.

Further, GAUDX coding method or blended payment method violates Section 1848(a)&(b) of the Social Security Act which requires each service to be priced. (Citation below)

(a) Payment Based on Fee Schedule. —
(1) In general. —Effective for all physicians' services (as defined in subsection (j)(3)) furnished under this part during a year (beginning with 1992) for which payment is otherwise made on the basis of a reasonable charge or on the basis of a fee schedule under section 1834(b), payment under this part shall instead be based on the lesser of—
(A) the actual charge for the service, or
(B) subject to the succeeding provisions of this subsection, the amount determined under the fee schedule established under subsection (b) for services furnished during that year (in this subsection referred to as the "fee schedule amount").

(b) Establishment of Fee Schedules. —
(1) In general, Before November 1 of the preceding year, for each year beginning with 1998, subject to subsection (p), the Secretary shall establish, by regulation, fee schedules that establish payment amounts for all physicians' services furnished in all fee schedule areas (as defined in subsection (j)(2)) for the year. Except as provided in paragraph (2), each such payment amount for a service shall be equal to the product of—
(A) the relative value for the service (as determined in subsection (c)(2)),
(B) the conversion factor (established under subsection (d)) for the year, and
(C) the geographic adjustment factor (established under subsection (e)(2)) for the service for the fee schedule area.

Therefore, the Academy strongly disagrees with the implementation of HCPCS code, GAUDX, as it does not represent a service in which relative resource-based costs have been assessed through the conventional RUC process. The CMS proposed work value of .08 appears random and not consistent with assessment of work that results from the RUC procedure. Further, a single, umbrella HCPCS code does not permit accurate tracking of services provided to Medicare beneficiaries.

ALTERNATIVE TO GAUDX: CPT CODE + NEW MODIFIER

The selection of multiple CPT codes with widely varying work and practice expense inputs and applying a blended value does not accurately consider the relative clinical work and practice expense inputs. Additionally, a single code is contrary to CMS's stated goal of better understanding the situations and services for which beneficiaries would seek audiologic assessments without the physician order. The Academy views this as a missed opportunity to achieve what we believe is the common goal of direct access to diagnostic testing services. We welcome the opportunity to participate collaboratively with CMS to ensure the appropriate audiology codes are included in a robust direct access program.

As an alternative to implementing the single GAUDX HCPCS code, the Academy suggests that services selected for inclusion in the direct access program be reported with the existing CPT codes, reimbursed at the current fee schedule payment rate, and appended with a newly created modifier. The modifier would clearly identify services that are performed by audiologists via direct access to Medicare beneficiaries, serving the purpose of tracking,via CMS claims, the use and frequency of direct access to an audiologist. Data collected with this change would allow the Agency to accurately assess the benefit of direct access to its beneficiaries.

The Academy proposes that CMS use existing CPT codes at the current fee schedule payment rate with a new modifier to identify the distinct services that are being provided by the audiologist via direct access. The data gathered at the individual code level would inform the Agency when deciding how best to provide more timely and robust beneficiary access to critical hearing and balance services provided by audiologists so this may effectively become a standard for CMS.

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Thank you for your consideration of these comments and recommendations. As stated earlier, the Academy stands ready to work with CMS to revise and implement a direct strategy that can truly be a benefit for Medicare participants. If you have questions or require additional information, please contact Susan Pilch, JD, Senior Director of Government Relations, at spilch@audiology.org.

Sincerely,

Sarah Sydlowski, AuD, PhD, MBA
President, American Academy of Audiology