Congress of the United States

Washington, DC 20510

April 23, 2019

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Verma,

We write today to urge you to allow streamlined access to audiology services for Medicare Part B beneficiaries.

Access to hearing health services is an integral part of overall health care. An estimated 48 million Americans experience age-related hearing loss, including two-thirds of adults in their seventies.[1] According to the Centers for Disease Control and Prevention, hearing loss is now the third most commonly-reported chronic health condition in the country.[2] Though hearing loss is common, access to hearing health services is not. A minority of Americans in their seventies have had a recent hearing test and only about 14 percent of people with hearing loss use assistive hearing technologies.[3] A recent report by the National Academies of Science, Engineering, and Medicine concluded that hearing health care is "often expensive and underutilized by many of the people who need it."[4]

The Social Security Act defines "audiology services" as "such hearing and balance assessment services furnished by a qualified audiologist as the audiologist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law), as would otherwise be covered if furnished by a physician."[5] These services, which include comprehensive hearing tests and evaluation of hearing, tinnitus, or balance disorders, are covered by Medicare because they are considered diagnostic tests under section 1861(s) of the Social Security Act.[6]

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[1] Frank R. Lin, John K. Niparko, and Luigi Ferrucci. 2011. "Hearing Loss Prevalence in the United States," *Archives of Internal Medicine* 171: 1851-1853 (online at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3564588/).

[2] Centers for Disease Control and Prevention, "New Vital Signs Study Finds Noise-Related Hearing Loss Not Limited to Work Exposure" Press Release (February 7, 2017) (online at: https://www.cdc.gov/media/releases/2017/p0207-hearing-loss.html).

[3] National Academies of Sciences, Engineering, and Medicine. *Hearing Health Care for Adults: Priorities for Improving Access and Affordability,* 2016, Washington, DC: The National Academies Press, http://www.nationalacademies.org/hmd/Reports/2016/Hearing-Health-Care-for-Adults.aspx, p. 79, 183.

[4] National Academies of Science, Engineering and Medicine, *Hearing Health Care for Adults: Priorities for Improving Access and Affordability,* 2016, Washington, DC: The National Academies Press, http://www.nationalacademies.org/hmd/Reports/2016/Hearing-Health-Care-for-Adults.aspx, p.75.

[5] Section 1861(ll)(3) of the Social Security Act

[6] Section 1861(s)(3) of the Social Security Act authorizes Medicare coverage of diagnostic tests. For treatment of audiology services as diagnostic tests, see Chapter 15 – Covered Medical and Other Health Services, Medicare Benefit Policy Manual, February 2, 2018, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf. Some types of audiology services are not covered by Medicare. Specifically, "hearing aids or examinations therefor" are excluded from Medicare coverage by Section 1862(a)(7) of the Social Security Act.

Unfortunately, although Medicare covers a range of hearing health services, outdated regulations prevent many Medicare beneficiaries from actually accessing these services. Medicare is an outlier among most federal and private insurance providers in requiring a physician order for coverage of audiology services provided by a qualified audiologist. The Department of Defense, the Veterans Health Administration, and a majority of plans offered through the Federal Employees Health Benefit system allow direct access to covered audiology services without a physician referral.[7] Many private insurance plans and Medicare Advantage plans similarly allow direct access.

In 2006, Congress asked the Centers for Medicare and Medicaid Services (CMS) to provide a "determination as to the legal authority to permit direct access to licensed audiologists under similar terms and conditions used by the Department of Veterans Affairs and the Office of Personnel Management."[8] CMS's conclusion that it did not have clear legal authority to allow direct access was based on Medicare regulations adopted in 1996, which require all diagnostic tests to be ordered by a treating physician in order to be eligible for reimbursement.[9] Yet these regulations also specify that nonphysician practitioners may be treated as physicians for the purposes of ordering diagnostic tests if they are acting within the scope of their authority within State law.[10] Although audiologists are not specifically listed nonphysician practitioners in the part of Medicare regulations dealing with the ordering of diagnostic tests, they are listed as nonphysician practitioners in other parts of the Medicare rules.[11]

Furthermore, it is clear that CMS's refusal to allow Medicare beneficiaries direct access to audiologists is a policy choice, not a requirement under the Medicare statute. No statutory language prohibits Medicare from allowing direct access to audiologists. The 1996 regulations that put in place the requirement for a physician order for diagnostic tests refer only to the statutory prohibition in the Social Security Act against Medicare paying for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."[12] However, this language is simply a broad prohibition against paying for unnecessary services and in no way explicitly mandates a physician referral requirement for audiology services.[13]

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[7] National Academies of Sciences, Engineering, and Medicine. *Hearing Health Care for Adults: Priorities for Improving Access and Affordability,* 2016, Washington, DC: The National Academies Press, http://www.nationalacademies.org/hmd/Reports/2016/Hearing-Health-Care-for-Adults.aspx, p. 128.

[8] H. Rept. 109-337, Making Appropriations for the Departments of Labor, Health and Human Services, and Education, and Related Agencies for the Fiscal Year Ending September 30, 2006, and for Other Purposes, https://www.congress.gov/congressional-report/109th-congress/house-report/337/1.

[9] 42 CFR 410.32; Centers for Medicare and Medicaid Services, "Report to Congress: Direct Access to Licensed Audiologist Under the Fee for Service Medicare Program," 2007, https://www.audiology.org/sites/default/files/advocacy_files/CMSDirectAccessReporttoCongress2.pdf.

[10] 42 CFR 410.32

[11] For instance, the part of the Medicare regulations laying out screening levels for Medicare providers at 42 CFR 424.518 defines nonphysician practitioners as a group "including nurse practitioners, CRNAs, occupational therapists, speech/language pathologists, and audiologists."

[12] Section 1862(a)(1)(A) of the Social Security Act

[13] Memorandum from Sheree Kanner, Hogan Lovells, to Academy of Doctors of Audiology, "Medicare Coverage of Diagnostic Audiology Services," October 14, 2016.

Medicare's requirement for a physician order for audiology services creates an unnecessary barrier that prevents patients from accessing important hearing health services. Research suggests that the convenience of accessing hearing health care, appointment wait times, and the distance to services are key factors that can affect patient utilization of hearing health care and the choice of a hearing intervention.[14] Allowing Medicare beneficiaries direct access to audiologists in their communities could reduce the number of appointments and referrals needed before a patient receives needed health care, speed access to care, and could also offer beneficiaries more choices of local hearing health providers.

Eliminating the requirement for a physician order for audiology services would improve access to hearing health care without compromising the health and safety of Medicare beneficiaries. Opponents of audiology direct access for Medicare beneficiaries argue that "bypassing a physician evaluation and referral can lead to misdiagnosis and inappropriate treatment."[15] However, the prevalence of ear disorders in the Medicare beneficiary population is low; a 2010 analysis published in the *Journal of the American Academy of Audiology* concluded that "under the most conservative assumptions, greater than 89% of Medicare beneficiaries complaining of hearing loss would not be expected to have active otologic disease or medically treatable conditions affecting hearing."[16]

Moreover, evidence indicates that audiologists appropriately evaluate and treat older adults, including making appropriate decisions about whether to refer a patient to a medical doctor when necessary. The same 2010 study, which reviewed records of Medicare-eligible patients complaining of a hearing impairment to compare assessment and treatment plans developed by audiologists and otolaryngologists, found that audiology treatment plans "were not substantially different from otolaryngologist plans for the same condition," that "there was no definitive evidence that audiologists were likely to miss significant symptoms of otologic disease," and that "there was strong evidence that audiologists referred to otolaryngology when appropriate." The study authors concluded that "direct access for patients complaining of hearing problems would not pose a risk to Medicare beneficiaries."[17]

The Food and Drug Administration (FDA) reached similar conclusions in December 2016 when it eliminated the requirement – originally enacted out of concern that individuals with undetected medical conditions would bypass needed health care – that individuals receive a medical evaluation or sign a waiver before purchasing hearing aids. In taking this step, the FDA cited a report by the National Academies of Sciences, Engineering, and Medicine that concluded that after "weighing the rareness of the medical conditions, the incidence of hearing loss in adults, the widespread need for hearing health care, and the wide use of the medical waiver,"

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[14] Margaret Barnett et al., "Factors Involved in Access and Utilization of Adult Hearing Healthcare: A Systematic Review," *Laryngoscope*, May 2017, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5322257/. Ariane Laplante-Leveseque et al., "Factors Influencing Rehabilitation Decisions of Adults with Acquired Hearing Impairment," International Journal of Audiology, 2010, https://www.ncbi.nlm.nih.gov/pubmed/20528667.

[15] Letter from James C. Denny III, Executive Vice President and CEO, American Academy of Otolaryngology-Head and Neck Surgery and Theodore P. Mason, President, Massachusetts Association of Otolaryngology to Senator Elizabeth Warren, March 28, 2018.

[16] David A. Zapala et al., "Safety of Audiology Direct Access for Medicare Patients Complaining of Impaired Hearing," *Journal of the American Academy of Audiology*, 2010, https://www.ncbi.nlm.nih.gov/pubmed/20701834.

[17] David A. Zapala et al., "Safety of Audiology Direct Access for Medicare Patients Complaining of Impaired Hearing," *Journal of the American Academy of Audiology*, 2010, https://www.ncbi.nlm.nih.gov/pubmed/20701834.

there was "no evidence that the required medical evaluation or waiver of that evaluation provides any clinically meaningful benefit."[18]

Finally, there is little indication that increased access to hearing health services already covered by Medicare would substantially increase Medicare costs. Since 2008, CMS has assigned audiologists responsibility for determining the medical necessity of diagnostic testing for Medicare beneficiaries, meaning audiologists are already charged with preventing improper utilization of covered Medicare services.[19] Analyses have also repeatedly estimated Medicare cost savings from the implementation of direct access to audiology services.[20] The most recent analysis estimated that Medicare could save more than $173 million over a decade by eliminating unnecessary and duplicative services if Medicare beneficiaries had direct access to audiologists.[21] The authors suggested that direct access could save as much as $240 million over ten years if access to audiologists prevented medical costs in beneficiaries who currently go untreated for hearing loss, dizziness, and vestibular conditions – even accounting for a potential 30% increase in utilization of audiology services covered by Medicare.

CMS has the authority to allow Medicare beneficiaries streamlined access to audiology services by updating the Medicare policy manual or pursuing regulatory changes. Evidence indicates that this change would improve access to critical hearing health care services, would not pose increased risk to Medicare beneficiaries, and could result in cost savings to the Medicare program.

We urge CMS to take action to improve hearing health for seniors and people with disabilities covered by the Medicare program. Please contact Julia Frederick in the office of Senator Elizabeth Warren, Agnes Rigg in the office of Senator Paul, or Walker Truluck in the office of Congressman Tom Rice with any questions related to this letter.

Sincerely,

Elizabeth Warren
United States Senator

Rand Paul
United States Senator

Tom Rice
Member of Congress

[18] Food and Drug Administration, "Immediately in Effect Guidance Document: Conditions for Sale for Air-Conduction Hearing Aids Guidance for Industry and Food and Drug Administration Staff, December 12, 2016, http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM531995.pdf; National Academies of Sciences, Engineering, and Medicine. *Hearing Health Care for Adults: Priorities for Improving Access and Affordability,* 2016, Washington, DC: The National Academies Press, http://www.nationalacademies.org/hmd/Reports/2016/Hearing-Health-Care-for-Adults.aspx, p. 103.

[19] Centers for Medicare and Medicaid Services, "Pub 100-02 Medicare Benefit Policy," February 29, 2008, https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R84BP.pdf.

[20] Gene Bratt et al., "The Audiologist as an Entry Point to Healthcare: Models and Perspectives," *Seminars in Hearing*, 1996. Barry A. Freeman and Brandon S. Lichtman, "Audiology Direct Access: A Cost Savings Analysis," *Audiology Today*, 2005, https://www.audiology.org/sites/default/files/advocacy_files/freeman_lichtman.pdf.

[21] Dobson DaVanzo and Associates, "Determining Potential Medicare Savings by Streamlining Beneficiary Access to Audiology Services," 2012, https://www.audiology.org/sites/default/files/documents/DobsonDAFinalReport.pdf.

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