

SENT ELECTRONICALLY

June 2, 2020

The Honorable Seema Verma
Administrator, Centers for Medicare and Medicaid
Department of Health and Human Services
200 Independence Avenue
Washington, DC 20201

RE: National Audiology Community Recommendation on Eliminating Medicare Barrier That Exceeds State Scope of Practice Laws, Impedes Access to Care and Adds Unnecessary Cost to the Program

Dear Administrator Verma:

On behalf of three national organizations representing the profession of audiology; the Academy of Doctors of Audiology, the American Academy of Audiology and the American Speech-Language-Hearing Association, we are pleased to provide a recommendation to the Centers for Medicare & Medicaid Services (CMS) as it seeks to identify and address burdensome Medicare regulations in response to the May 19 Executive Order on Regulatory Relief to Support Economic Recovery. Our organizations request that CMS remove the requirement under Medicare that beneficiaries obtain a physician order prior to an appointment with an audiologist because it exceeds state scope of practice laws, impedes beneficiary access to care and adds unnecessary cost to the healthcare system.

Audiologists are the primary healthcare professionals who evaluate, diagnose, treat and manage hearing loss and balance disorders in patients of all ages.¹ Audiologists dispense and fit hearing aids and other forms of hearing technology, such as cochlear implants, osseointegrated implants and hearing assistance technologies, and are often heavily involved in the design and implementation of hearing conservation and newborn hearing screening programs.

Medicare's Physician Order Requirement for Beneficiary Access to Audiology Services is an Unnecessary Outlier and Impediment to Care

Currently, Medicare beneficiaries under 42 CFR 410.32 must first obtain a physician order to see an audiologist for coverage for diagnostic hearing and balance tests. 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 a majority of plans offered through the Federal Employees Health Benefit Program allow direct access to covered audiology services without a physician referral.² In addition, most private insurance plans and Medicare Advantage plans allow direct access. The VHA implemented its audiology direct access policy in 1992. In a letter from then VHA Acting Deputy Under Secretary for Health, Michael Kussman, MD to Senator Charles Grassley in 2004, he states that the VA direct access policy "provides high-quality, efficient and cost-effective hearing care." Dr. Kussman goes on to state

¹ <https://www.audiology.org/sites/default/files/publications/resources/WhatIsAnAuD.pdf>

² <http://www.nationalacademies.org/hmd/Reports/2016/Hearing-Health-Care-for-Adults.aspx>

that requiring all veterans with hearing loss complaints to see ENT physicians would result in unnecessary medical care, inefficient use of VA resources, and longer wait times for veterans who need the specialized care of ENT physicians. “The [direct access] policy is cost-effective because an unnecessary clinic visit is avoided.” In addition, Dr. Kussman states that “the VA has not experienced patient complaints or problems as a result of the direct access policy.”³

FDA Guidance Supports Removal of Medicare Physician Order Requirement

The Food and Drug Administration (FDA) issued official guidance in 2016 stating that “the FDA does not intend to enforce the medical evaluation (21 CFR 801.421(a)) or recordkeeping (21 CFR 801.421(d)) requirements prior to the dispensing of certain hearing aid devices to individuals 18 years of age and older.”⁴ In issuing its guidance statement on the issue, the FDA cited a report by the National Academies of Sciences, Engineering, and Medicine that concluded that after “weighing the rareness of medical conditions, the incidence of hearing loss in adults, the widespread need for hearing health care, and the wide use of the medical waiver,” there was “no evidence that the required medical evaluation or waiver of that evaluation provides any meaningful benefit.”⁵

CMS Has the Authority to Allow Medicare Beneficiaries Direct Access to Audiology Services

There is no statutory language that prohibits Medicare from allowing direct beneficiary access to audiologist services. The retention of this requirement—generally cited as a policy provision requiring a physician order for a diagnostic test—was designed solely to limit payment for possible unnecessary services. As audiologists are already responsible for determining medical necessity, allowing Medicare beneficiaries to apply coverage when seeking direct access to audiologist services would reduce unnecessary physician visits and improve beneficiary access to services, perhaps staving off the harmful downstream effects of untreated hearing loss such as falls and expedited cognitive decline. Direct access would not expand the scope of practice of audiology nor diminish the important role played by physicians and other primary care providers.

Audiologists could also be added to the list of certain non-physician providers currently able to administer diagnostic tests without a physician order under 42 CFR 410.32(a)(2)(2016). HHS could also effect this change by amending the requisite Medicare manuals clarifying that audiologists are included in the list of non-physician providers under 42 CFR 410.32(a)(2)(2016).

President’s Executive Orders Support the Removal of the Physician Order Requirement

On October 3, 2019, the Administration issued an Executive Order on *Eliminating Medicare Regulations that Exceed State Scope of Practice Laws and Limit Health Professionals from Practicing at the Top of Their License* (EO #13890). On May 19, 2020, the Administration issued an Executive Order on *Regulatory Relief to Support Economic Recovery* that directs regulatory agencies to identify those regulatory waivers that should remain permanent as well as other regulations that could be eliminated that would support economic recovery and increase patient access. The physician order requirement

³ https://www.audiology.org/sites/default/files/advocacy_files/DeptofVeteranAffairs.pdf

⁴ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/immediately-effect-guidance-document-conditions-sale-air-conduction-hearing-aids>

⁵ <http://www.hearingreview.com/2016/06/national-academies-sciences-release-report-hearingaid-accessibility-affordability/>

exceeds state audiology scope of practice requirements in all fifty states. In addition, removing the physician order requirement would eliminate unnecessary physician visits and would provide tangible savings to the Medicare program. Eliminating unnecessary expenditures for the program will enable CMS and HHS to deploy these funds to areas of greater need. Finally, requiring a physician order for services provided by clinicians with the training and expertise of providers such as audiologists stems from outdated models and unnecessarily serves as a barrier to beneficiary care.

Conclusion

The audiology community appreciates this opportunity to provide these comments and suggestions as CMS works to identify actionable items designed to modernize the Medicare program, improve patient outcomes and lower overall healthcare costs. The undersigned organizations met with Brendan Fulmer, Advisor to Secretary Azar for Value-based Transformation and Innovation in November 2019 to discuss this issue in the wake of the October 2019 Executive Order. We would appreciate the opportunity to continue the dialogue and discuss this issue in greater detail at your earliest convenience.

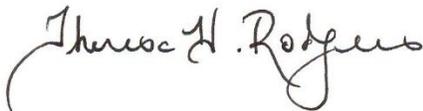
Sincerely,



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