

VIA EMAIL TO: [PatientsOverPaperwork@cms.hhs.gov](mailto:PatientsOverPaperwork@cms.hhs.gov)

January 13, 2019

**RE: American Academy of Audiology Recommendations on Eliminating Medicare Regulations That Exceed State Scope of Practice Laws and Limit Health Professionals from Practicing at the Top of Their License: *The President's Executive Order (EO) #13890*:**

The American Academy of Audiology (the "Academy") is pleased to provide recommendations to the Centers for Medicare and Medicaid (CMS) as it seeks to identify and address burdensome Medicare regulations that exceed state scope of practice laws and limit health professionals from practicing and the top of their license. 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 care services through professional development, education, research, and increased public awareness of hearing and balance disorders.

Audiologists are the primary healthcare professionals who evaluate, diagnose, treat and manage hearing loss and balance disorders in patients of all ages.<sup>1</sup> 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.

**Despite Prevalence of Untreated Hearing Loss and Devastating Effects, Barriers to Care Persist in Medicare**

An estimated 48 million Americans experience age-related hearing loss, including two-thirds of adults in their seventies,<sup>2</sup> and hearing loss is now the third most commonly-reported chronic health condition in the country.<sup>3</sup> Untreated hearing loss has implications to overall health and can impose significant financial burdens to the healthcare system. Individuals with even mild

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

<sup>2</sup> <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3564588/>

<sup>3</sup> <https://www.cdc.gov/media/releases.2017/p0207-hearing-loss.html>

hearing loss are three times more likely to experience a fall, and falls are the leading cause of fatal injury for Americans over age 65.<sup>4</sup> In addition, there is emerging evidence indicating that seniors with untreated hearing loss are more likely to develop cognitive decline up to 40% faster than those without untreated hearing loss. Although hearing loss is common, barriers to accessing hearing health services still persist in spite of the potentially devastating effects of non-treatment.

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

Currently Medicare beneficiaries must first receive a physician order to see an audiologist for hearing and balance diagnostic tests. A physician order is not required by any of the fifty state or District of Columbia audiology licensure laws prior to an individual being allowed access to the care of an audiologist. The Department of Defense, the Veterans Health Administration (VA) and a majority of plans offered through the Federal Employees Health Benefit Program allow direct access to covered audiology services without a physician order.<sup>5</sup> In addition, most private insurance plans and Medicare Advantage plans allow direct access. The VA has had this policy in place since 1992. In a letter from then VA Acting Deputy Under Secretary for Health, Michael Kussman, MD to Senator 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 that requiring all veterans with hearing loss complaints to see a physician would result in unnecessary medical care, and inefficient use of VA resources. "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."<sup>6</sup>

Eliminating the physician order would improve beneficiary access to care without compromising patient safety. Opponents of direct access to audiology services for Medicare

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<sup>4</sup> <https://www.cdc.gov/mmwr/volumes/67/wr/mm6718a1.htm>

<sup>5</sup> <http://www.nationalacademies.org/hmd/Reports/2016/Hearing-Health-Care-for-Adults.aspx>

<sup>6</sup> [https://www.audiology.org/sites/default/files/advocacy\\_files/DeptofVeteranAffairs.pdf](https://www.audiology.org/sites/default/files/advocacy_files/DeptofVeteranAffairs.pdf)

beneficiaries claim that bypassing a physician evaluation and order may lead to misdiagnosis and inappropriate treatment. However, audiologists receive extensive education and training in the requisite testing necessary to identify patients that require the care of an ENT specialist. In addition, the prevalence of medical ear disorders in the Medicare beneficiary population is extremely low. An analysis published in the Journal of the American Academy of Audiology found 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.”<sup>7</sup> This same study also found strong evidence that audiologists appropriately referred patients to physicians when indicated and concluded that “direct access for patients complaining of hearing problems would not pose a risk to Medicare beneficiaries.”

#### **FDA Guidance Supports Need to Remove Medicare Physician Order Requirement**

The Food and Drug Administration weighed in on the non-essential nature of physician gatekeeper status in this area when it issued official guidance in 2016 stating that “the FDA does not intend to enforce the medical evaluation (21 CFE 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.”<sup>8</sup> This requirement was initially put into place out of concern that perhaps individuals with undetected medical conditions would bypass needed medical services. However, 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.”<sup>9</sup>

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<sup>7</sup> <https://www.ncbi.nlm.nih.gov/pubmed/20701834>

<sup>8</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/immediately-effect-guidance-document-conditions-sale-air-conduction-hearing-aids>

<sup>9</sup> <http://www.hearingreview.com/2016/06/national-academies-sciences-release-report-hearingaid-accessibility-affordability/>

### **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 to a regulatory provision requiring a physician order for a diagnostic test—was designed solely to limit payment for possible unnecessary services. Allowing Medicare beneficiaries direct access to audiologist services would reduce unnecessary physician visits and expand beneficiary access to services, perhaps staving off the harmful downstream effects of untreated hearing loss such as falls, expedited cognitive decline, and social isolation. Direct access would not expand the scope of practice of audiology nor diminish the important role played by physicians. The Academy applauds the goal of the Executive Order to recognize and allow all health care professionals to practice at the top of their license and remove outdated Medicare regulations that may impede this goal.

### **Conclusion**

The Academy appreciates this opportunity to provide these comments and suggestions as the Agency works to identify actionable items designed to modernize the Medicare program, improve patient outcomes and lower overall healthcare costs. To that end, the Academy recommends that CMS remove the outdated physician order requirement through existing regulatory authority. If there are any questions about any of the information included in this letter, please contact Susan Pilch, J.D., Senior Director of Government Relations at [spilch@audiology.org](mailto:spilch@audiology.org) or (703) 226-1036.

Sincerely,



Catherine V. Palmer, PhD  
President, American Academy of Audiology

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