



Maryland Academy of Audiology

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February 28, 2023

The Honorable Melony G. Griffith, Chair
Senate Finance Committee
3 East, Miller Senate Office Building
Annapolis, MD 21401

RE: SB 449 Practice Audiology – Definition

Position: **SUPPORT WITH AMENDMENTS**

Alicia D.D. Spoor, Au.D. Testimony

Madam Chair Griffith, Vice Chair Klausmeier, and Committee Members,

My name is Alicia Spoor, and I am a licensed Maryland audiologist, small business owner in Howard County, and the current Legislative Chair for the Maryland Academy of Audiology (MAA). The MAA represents the more than 520 licensed audiologists in the State of Maryland.

I am here in **strong** support of Senate Bill 449 and am pleased to be working with Senators Gile, Beidle, Ellis, Hershey, Kramer, Mautz, and Ready to codify the recent Food and Drug Administration Final Rule language on Over The Counter (OTC) hearing aids by updating the Maryland Practice of Audiology Definition.

Since 2014, numerous government agencies have discussed the accessibility and affordability of hearing healthcare in the United States, including the National Academies of Science, Engineering, and Medicine¹ (NASEM), the Food and Drug Administration² (FDA) and the Federal Trade Commission³ (FTC). One of the NASEM recommendations (Recommendation 7) was to 'Implement a New Food and Drug Administration Category for Over-The-Counter Wearable Hearing Devices'. The United States Congress addressed this recommended and passed the "Over The Counter Hearing Aid Act in 2017" as part of the FDA Reauthorization Act of 2017⁴ (FDARA). In October, 2022 the FDA released the Final

¹ <https://www.nationalacademies.org/our-work/accessible-and-affordable-hearing-health-care-for-adults>

² <https://www.federalregister.gov/documents/2016/01/07/2016-00065/streamlining-regulations-for-good-manufacturing-practices-for-hearing-aids-public-workshop-request>

³ <https://www.ftc.gov/news-events/events/2017/04/now-hear-competition-innovation-consumer-protection-issues-hearing-health-care>

⁴ <https://www.congress.gov/bill/115th-congress/house-bill/2430>

Rule for OTC Hearing Aids to allow consumers aged 18 years or older to purchase non-surgical, air-conduction hearing aids for perceived mild to moderate hearing loss without the involvement of a licensed professional (e.g., audiologist, hearing aid dispenser, physician).

The FDA took additional action and created a new category of “prescription” hearing aids. A prescription hearing aid is defined as “...a hearing aid that is not an OTC hearing aid as defined in this section or a hearing aid that does not satisfy the requirements in this section.”⁵ The FDA Final Rule requires prescription hearing aids to be dispensed by licensed providers as governed by state law.

Very simply, before the FDA Final Rule became effective in October 2022, audiologists recommended, fit, sold, and dispensed what was termed “restricted” hearing aid devices. Those same identical ‘restricted’ devices are now in a new category of ‘prescription’ devices.

To make sure there is absolute, unambiguous clarifying language in the audiology practice definition, audiologists must be able to continue to prescribe and order prescription hearing aids to comport with the new Federal Rule.

Updating the audiology practice definition to mirror other Maryland clinical doctors (e.g., optometrists, chiropractors, podiatrists, dentists) and other states’ audiology practices with well-defined language to evaluate, diagnose, manage, and treat auditory and vestibular conditions in the human ear distinctly separates audiologists from physicians, who practice medicine: diagnose, heal, treat, and provide surgery.⁶

Maryland’s licensed audiologists have been prescribing hearing aids to minors for many years, in accordance with established statute (§15-838).⁷ Children are often considered one of the most vulnerable populations and significant safeguards are placed to guarantee their welfare. Audiologists are the primary providers in their hearing healthcare by virtual of audiologist’s education and training. Therefore, prescribing and ordering hearing aids to individuals over the age of 18 years do not introduce any new concerns that are not already addressed with minors.

When passed, SB 449 will update and codify the Maryland Statute with the FDA Final Rule language to ensure it does not become more difficult for your constituents to obtain hearing aids now (prescription hearing aids) than it was before October, 2022, when the hearing aids were categorized as “restricted” devices.

⁵ <https://www.govinfo.gov/content/pkg/FR-2022-08-17/pdf/2022-17230.pdf>

⁶ <https://dhs.maryland.gov/documents/Licensing-and-Monitoring/Maryland%20Law%20Articles/RCC/HEALTH%20OCCUPATIONS%20Title%2014%20Physicians.pdf>

⁷ <https://mgaleg.maryland.gov/mgawebsite/Laws/StatuteText?article=gin§ion=15-838&enactments=false>

Thank you for your time and consideration Madam Chair Griffith, Vice Chair Klausmeier, and Sponsor Senator Gile and all co-sponsors. I ask for a favorable committee report on SB 449 to help your constituents.

Alicia D.D. Spoor, Au.D.
Legislative Chair, Maryland Academy of Audiology