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February 8, 2023

The Honorable Joseline A. Pena-Melnyk, Chair
House Health & Government Operations Committee
Taylor House Office Building, Room 241
6 Bladen Street
Annapolis, MD 21401

RE: HB 410 Practice Audiology – Definition - Position: **SUPPORT**
Alicia D.D. Spoor, Au.D. Testimony

Madam Chair Peña-Melnyk, Vice Chair Ariana Kelly, and Committee Members,

My name is Alicia Spoor and I am a licensed Maryland audiologist and 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 House Bill 401 and am pleased to be working with Delegate Ariana Kelly 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 met to discuss the accessibility and affordability of hearing healthcare in the United States, including the National Academies of Science, Engineering, and Medicine[1] (NASEM), the Food and Drug Administration[2] (FDA) and the Federal Trade Commission[3] (FTC). Many of these meetings occurred around the Washington, DC area and I was fortunate to be able to attend and even present testimony during these events, as it addresses the growing hearing loss crisis in America.

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 2017[4] (FDARA). In October, 2022 FDA released the Final Rule for OTC Hearing Aids to

[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

allow consumers aged 18 years or older to purchase air-conduction hearing aids for perceived mild to moderate hearing loss without the involvement of a licensed professional (e.g., audiologist).

The FDA took additional action and also 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 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. We must have absolute, unambiguous clarifying language inserted in our practice definition that we can prescribe these devices to comport with the new Federal Rule.

When passed, HB 401 will update and codify the Maryland Statute with the FDA Final Rule language to ensure it is not harder for patients/consumers/constituents to now obtain hearing aids (now prescription hearing aids) than it was before October, 2022, when the hearing aids were categorized "restricted" devices.

Thank you for your time consideration and to Delegate Kelly for sponsoring this legislation. I ask for a favorable committee report on HB 401.

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