Maryland Academy of Audiology
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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: HB410 Practice Audiology – Definition - Position: **SUPPORT**
Melissa Segev, Au.D. Testimony

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

My name is Melissa Segev and I am a second generation licensed audiologist and small business owner of one of the largest and oldest private practices in the State of Maryland. On behalf of the Maryland Academy of Audiology, we are pleased to be working with Delegate Ariana Kelly to codify the recent Food and Drug Administration (FDA) Final Rule language on Over The Counter (OTC) Hearing Aids by updating the Maryland Practice of Audiology Definition.

Prior to the Food and Drug Administration Final Rule[1], hearing aids were categorized as "restricted" devices. When the FDA released the OTC Hearing Aid Final Rule in October, 2022, they created a new category of "prescription" hearing aids, although it was not required under the Congressional mandate. FDA defined "prescription" hearing aids as hearing aids that do not meet the definition of OTC hearing aids. Further, a prescription hearing aid is defined by technical specifications and intended use, must be dispensed by a licensed person as governed by state law, and federal preemptions are limited.

In practice, "prescription" and "restricted" hearing aids are **not** different. The labeling has changed to comply with the new category, but the requirement for a professional to dispense the device, the technical specifications, main components of the device (microphone, receiver/speaker, amplifier, and battery) and intended use are mainly unchanged. What was a "restricted" hearing aid in September, 2022 was essentially renamed a "prescription" hearing aid in October, 2022.

As an audiologist, I followed in my father's footsteps to provider quality of life to patients in the area of hearing and balance healthcare. The FDA Final Rule caused pause with the new prescription hearing aid

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

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category as it affected my patients' ability to obtain devices from my colleagues and me. HB 401 would update the semantics of the Audiology code to eliminate any ambiguity around the FDA's new hearing aid categories and ensure that my patients and your constituents can choose their path for improved hearing healthcare.

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