DAWN D. GILE
Legislative District 33
Anne Arundel County

Finance Committee

Miller Senate Office Building
11 Bladen Street, Suite 3 East
Annapolis, Maryland 21401
410-841-3568 · 301-858-3568
800-492-7122 *Ext.* 3568
Dawn.Gile@senate.state.md.us

THE SENATE OF MARYLAND
ANNAPOLIS, MARYLAND 21401

Testimony in Support of SB449
Health Occupations - Practice Audiology – Definition

Madame Chair, Vice Chair Klausmeier, and Fellow Members of the Senate Finance Committee:

Through the Food and Drug Administration Reauthorization Act of 2017 (FDARA), Congress directed the Food and Drug Administration (FDA) to establish a category of over-the-counter (OTC) hearing aids through regulatory rulemaking. FDA's final rule establishing this new category of hearing aids became effective on October 22, 2022.[1] In conjunction with the new OTC hearing aids, the FDA created a new category of "prescription" hearing aids that did not exist previously.

Prior to October 2022, hearing aids were "restricted" devices, meaning they could only be sold on oral or written authorization by a licensed practitioner or under conditions specified by regulation. The final rule does not change the hearing aids being used; it only changes the conditions for sale.

The intent of the law and the corresponding rule is to provide more accessibility and affordability to hearing aids. Under the new FDA regulation, a consumer may obtain a hearing aid through a "prescription" or "order" from an audiologist or hearing instrument specialist. However, the FDA left it up to the states to update their laws to ensure that these practitioners have the authority to do so.

SB 449 updates the practice of audiology definition to mirror the FDA's final rule language, including ordering and prescribing prescription hearing aids. While the FDA uses the term "prescription" hearing aids, the agency is referring to the exact same hearing aids that audiologists and dispensers have been selling to consumers for decades.

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

Since the finalized rule was published, third party commercial insurance payers (e.g., BlueCross/BlueShield, United Healthcare) have started referencing prescription hearing aids in their 2023 benefits. SB 449 will now ensure patients can use their insurance hearing aid benefits when purchasing prescription hearing aids.

To respond to stakeholder feedback and concerns raised in the Health and Government Operations Committee hearing on the House cross-file of this bill (HB401), I have submitted an amendment that would:

- Add language to include hearing aid dispensers' ability to continue working with (now) prescription hearing aids.
    - This alleviates the concerns from the International Hearing Society (IHS), Hearing Industry Association (HIA), and Amplifon/Miracle Ear.
- Remove all references of osseo-integrated hearing aid, bone anchored hearing device, and cochlear implants.
    - This alleviates the concerns from the American Speech-Language-Hearing Association (ASHA) and ensures there is no scope of practice misunderstandings.
- Remove the clarifying language "ORDER, EVALUATE, DIAGNOSE, MANAGE, OR TREAT ANY AUDITORY OR VESTIBULAR CONDITION IN THE HUMAN EAR" from page 2, lines 15-16 that would have mirrored the practice of audiology definition with other clinical doctoring professions in Maryland and other audiology practice definitions in other states.
    - This alleviates the concerns from the ear, nose, and throat (ENT) surgeons and MedChi.

The FDA terminology must be codified to remove any ambiguity or misinformation to allow constituents to obtain prescription hearing aids from their provider, which this bill does.

For these reasons, I respectfully request a favorable report on Senate Bill 449.