



March 7, 2025

The Health and Government Operations Committee
Maryland General Assembly
241 Taylor House Office Building
Annapolis, MD 21401

RE: Support amendment to HB1355

Dear Health and Government Operations Committee:

I am the Chief Audiology Officer for Miracle-Ear, Inc., a leading hearing aid provider with 23 offices in Maryland. Miracle-Ear believes that patient safety, satisfaction, and access are paramount in helping individuals address their hearing needs.

I write in support of HB1355, authorizing hearing aid dispensers to order the use of prescription hearing aids under Maryland’s mandatory hearing aid insurance coverage law.¹ At the same time, **we strongly encourage the following underlined amendment to be made:**

(2) ORDERED, FITTED, AND DISPENSED BY A LICENSED HEARING AID DISPENSER, without requiring a prescription or authorization from another healthcare provider except as required by the insurance or health plan.

We ask for the underlined amendment to avoid any confusion that hearing aid dispensers have the same authority as audiologists for purposes of this mandatory coverage law—i.e., to “order the use of” (synonymous with “prescribe” under the U.S. Food and Drug Administration’s prescription device regulation)—ensuring insurance plans fully understand the operative effect of this legislation.

As you know, in August 2022, FDA promulgated regulatory changes to increase access to hearing aids, including establishing OTC hearing aids as a new category of medical devices.² In the same regulation, FDA reclassified all non-OTC hearing aids (i.e., traditional hearing aids that have been dispensed by state-licensed audiologists and hearing aid dispensers for the last 50 years) from “restricted medical devices” to “prescription medical devices” governed by 21 C.F.R. 801.109. Pursuant to 21 C.F.R. §801.109, non-OTC hearing aids may only be dispensed upon “the prescription or other order” of a practitioner licensed by law to direct the use of such device.

FDA issued supplemental guidance to states in a “[Dear State Official](#)” letter, making it clear that “FDA’s intent is that the same professionals who recommended, selected, fitted, and dispensed restricted hearing aids before the effective date would continue to do so for prescription hearing aids after the effective date.” Additionally, states can authorize many kinds of practitioners “to order the use of (or prescribe) a prescription device.” In other words, states can use either term “prescribe” or “order” to

¹ Md. Code, Ins. § 15-838.1

² U.S Food and Drug Administration, Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids, (August 17, 2022), *available at* <https://www.federalregister.gov/documents/2022/08/17/2022-17230/medical-devices-ear-nose-and-throat-devices-establishing-over-the-counter-hearing-aids>

authorize providers to dispense prescription hearing aids. The terms “prescribe” and “order” have the same effect as far as FDA is concerned. This is critically important to point out because there appears to be confusion within the Fiscal and Policy Note prepared by the Department of Legislative Services, which comments that hearing aid dispensers “are not authorized to prescribe a hearing aid.”³ This is not accurate.

In fact, in 2023, Maryland changed its statute to ensure that audiologists and hearing aid dispensers both have the authority to “order” (again, the same as “prescribe” for purposes of FDA’s prescription device regulation) the use of prescription hearing aids so consumers could continue having the access they have always had for prescription hearing aids and would not suddenly be required to obtain a separate prescription from a physician. Audiologists also included the term “prescribe” in their definitions. However, as mentioned above, the terms are interchangeable.

Then, in 2024, Maryland signed into law a bill mandating health plans to provide “coverage for all medically appropriate and necessary hearing aids for an adult who is covered under a policy or contract if the hearing aids are prescribed, fitted, and dispensed by a licensed audiologist.” But, only audiologists were specifically listed as able to order and dispense for purposes of this coverage law— hearing aid dispensers were left out. The legislation at hand now seeks to correct the omission of hearing aid dispensers. As such, we encourage this bill to be amended as recommended above, which is supported by the Maryland Academy of Audiology.

This amendment would ensure that consumers who have coverage for hearing aids will be able to use their hearing aid benefits through either an audiologist or a hearing aid dispenser. It will also ensure that health plans understand that both audiologists and hearing aid dispensers have the same authority to order the use of prescription hearing aids for purposes of the coverage mandate, ensuring there is no confusion. As such, we urge you to adopt this amendment.

Please know I am available at (763) 710-1830 to answer any questions you or your policy staff may have regarding the concerns expressed herein.

Respectively,

Thomas J. Tedeschi

Dr. Thomas J. Tedeschi, AuD., FNAP
Chief Audiology Officer
Miracle-Ear, Inc.

³ https://mgaleg.maryland.gov/2025RS/fnotes/bil_0001/sb0641.pdf