



February 27, 2023

The Honorable Melony Griffith, Chair
The Honorable Katherine Klausmeier, Vice Chair
Senate Finance Committee
3 East
Miller Senate Office Building
Annapolis, MD 21401

RE: SB 0449 (support for amendment)

Dear Members of the Senate Finance Committee:

We write today to express appreciation for your support for licensed hearing professionals, both audiologists and hearing aid dispensers, and urge you to adopt the revisions provided in HB 0401, as amended, to SB 0449.

HB 0401, as amended, will make clear the continuing authority of both licensed audiologists and hearing aid dispensers to dispense prescription hearing aids. This change is necessary following the October 2022 effective date of the final rule establishing over-the-counter hearing aids ("OTC hearing aids"), published by the U.S. Food and Drug Administration ("FDA").¹ This rule provided that all hearing aids that are not OTC hearing aids are reclassified as "prescription hearing aids" that may "be sold only to or on the prescription or other order of a practitioner licensed by law to use or order the use of (prescribe) the devices." As part of the rule, FDA defers to States to determine appropriate licensing requirements for dispensing prescription hearing aids.

Before the effective date of the OTC hearing aid rule, FDA issued guidance to States clarifying that a prescriber need not be a physician, physician assistant, or nurse practitioner, but that the intent of FDA 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."²

HB 0401, as amended, is consistent with FDA guidance, a memo issued by the Maryland Department of health, and the actions of other States to ensure the continued authority of

¹ Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing aids, 87 Fed. Reg. 50698 (August 17, 2022)

² U.S. Food and Drug Administration, Dear State Official Letter (October 13, 2022), <https://www.fda.gov/media/163084/download>

licensed audiologists and hearing aid dispensers to provide what are now deemed “prescription hearing aids” as they have prior to the effective date of the OTC rule issued by FDA.³

We appreciate your support for licensed hearing professionals and, more importantly, support for those with hearing loss. As amended, the House bill makes clear the authority of licensed hearing professionals to provide prescription hearing aids and supports continued access for those who need them. We urge the Senate to adopt these changes to SB 0449.

Hearing health is essential, and the use of hearing aids can help avoid the negative social, emotional, and health consequences of hearing loss. Beyond the associated comorbidities of hearing loss, there are significant positive impacts on overall health and wellbeing, with 8 in 10 individuals who treat their hearing loss reporting life-changing results. Access to licensed hearing professionals is an important part of treating hearing loss, as those with hearing loss report even higher rates of satisfaction with their hearing professional.

We are pleased to support your efforts to clarify the authority of licensed audiologists and hearing aid dispensers to order the use of prescription hearing aids. We look forward to continuing to work together to support licensed hearing professionals and individuals with hearing loss.

Sincerely,

A handwritten signature in black ink that reads "Kate Carr". The signature is written in a cursive, flowing style.

Kate Carr
President
Hearing Industries Association

³ Over-the-Counter Hearing Aids FAQs, Maryland Department of Health (October 17, 2022), <https://health.maryland.gov/boardsahs/Documents/OTC%20Memo.pdf>