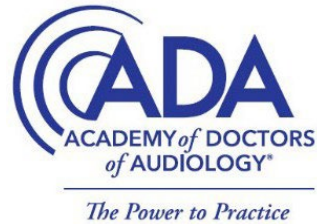


March 8, 2023

Honorable Sara Gelser Blouin
900 Court St. NE, S-405
Salem, Oregon 97301



RE: SB 558

Dear Senator Gelser Blouin and Members of the Committee,

On behalf of the Academy of Doctors of Audiology (ADA), whose members are audiologists and audiology practice owners serving patients in Oregon and across the United States, I write to applaud the introduction of SB 558 and to seek a technical amendment to its language that will align it more precisely with regulations implemented by the U.S. Food and Drug Administration (FDA) in 2022, to ensure uninterrupted access to audiology and hearing aid dispensing services for citizens of Oregon.

Please find enclosed a recommended amendment to include “order the use of” as it pertains to the definition of dealing in hearing aids. FDA regulations, implemented on October 17, 2022 establish over-the-counter (OTC) hearing aids and reclassify non-OTC Class I and Class II air conduction hearing aids (traditional hearing aids) from ‘restricted’ medical devices to ‘prescription’ medical devices, subject to dispensing requirements under 21 C.F.R. 801.109, including requirements that prescription hearing aids be dispensed upon “*the prescription or other order*” of a practitioner licensed under state law to direct the use of such devices. These provisions are intended to improve consumer access to hearing aids by allowing certain hearing aids (OTC hearing aids) to be sold without the involvement of a licensed healthcare provider *and* by removing longstanding federal preemptions dictating the ‘conditions for sale’ of traditional (non-OTC) hearing aids, transferring that authority to the states, appropriately recognizing states’ jurisdiction over practitioner licensure.

In the State of Oregon hearing aid dealers have been licensed to recommend, sell, select, fit, and dispense Class I and Class II air conduction hearing aids to consumers for the past several decades. Amending SB 558 to include “order the use of” as part of the defined activities of hearing aid dispensers will maintain Oregon’s existing policies governing hearing aid dispensing by updating existing statutes to conform with FDA’s preferred taxonomy.

ADA supports the enclosed amendment to SB 558, which will harmonize Oregon statutes with FDA’s regulations and preserve the proven, safe, effective, and accessible pathways to treatment for Oregon consumers experiencing hearing loss. Please contact me at sczuhajewski@audiologist.org if you have any questions or require additional information. Thank you for your consideration of this important request.

Sincerely,



Stephanie Czuhajewski, MPH, CAE
Executive Director

A BILL FOR AN ACT

Relating to over-the-counter hearing aids; amending ORS 694.015, 694.025 and 694.032; and declaring an emergency.

Be It Enacted by the People of the State of Oregon:

SECTION 1. ORS 694.015 is amended to read:

694.015. As used in ORS 694.015 to 694.170, unless the context requires otherwise:

(1) "Dealing in hearing aids" means the **order the use of**, sale, lease or rental or attempted sale, lease or

rental of hearing aids in conjunction with the evaluation or measurement of the powers or range of human hearing and the recommendation, selection or adaptation of hearing aids.

(2)(a) "Hearing aid" means any prosthetic instrument or device designed for or represented as aiding, improving or correcting defective human hearing and any parts, attachments or accessories of such an instrument or device. [A hearing aid is not intended to include]

(b) "Hearing aid" does not include:

(A) Any device which is surgically implanted or otherwise medically inserted by a physician

licensed by ORS chapter 677 for the purpose of treating or correcting a hearing impairment[.]; or

(B) An over-the-counter hearing aid.

(3) "Over-the-counter hearing aid" has the meaning given that term in 21 C.F.R. 800.30.

SECTION 2. ORS 694.025 is amended to read:

694.025. (1) A person may not deal in hearing aids or display a sign or in any other way advertise or represent that the person deals in hearing aids unless the person holds an active license issued by the Health Licensing Office as provided in ORS 694.015 to 694.170.

(2) Notwithstanding subsection (1) of this section, ORS 694.015 to 694.170 do not apply to:

(a) An audiologist licensed under ORS chapter 681.

(b) A physician licensed under ORS chapter 677.

(c) A person involved in the sale of an over-the-counter hearing aid

SECTION 3. ORS 694.032 is amended to read:

694.032. (1) It **is** unlawful for any person to offer for sale or sell a hearing aid in this state by direct mail.

(2) Any offer for sale or sale of a hearing aid in this state must include the availability of fitting the hearing aid in this state prior to the sale.

(3) Nothing in this section is intended to prohibit:

(a) Advertising by mail or delivery of a hearing aid by mail if the fitting and sale were completed in this state.

(b) The sale by direct mail of an over-the-counter hearing aid.

SECTION 4. This 2023 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2023 Act takes effect on its passage.