



P.O. Box 30404
Portland, OR 97294
www.ohsinc.org

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On behalf of the International Hearing Society (IHS) and the Oregon Hearing Society, I would like to thank the Chair, Vice Chair, and the Committee members for the opportunity to submit comments on SB 558 (Relating to over-the-counter hearing aids; declaring an emergency.).

While we understand the intention is codify 21 CFR Parts 800, 801, 808, and 874 the U.S. Food and Drug Administration's (FDA) regulatory changes related to over-the-counter hearing aids, passage of this bill in its current form could be problematic for licensed hearing aid dealers in Oregon and the hearing-impaired public they serve. Therefore, we respectfully ask for a technical amendment that adds "order the use of" to the "Dealing in hearing aids" definition.

Specifically, SB 558 ambiguity could have the unintended consequence of preventing licensed hearing aid dealers from performing all necessary steps to provide hearing aid services to consumers. Now classified as prescription medical devices under the FDA regulatory changes adopted in October 2022, licensed hearing aid dealers, who presently dispense about half of all hearing aids to the public, must be granted the authorization to "order the use of" these devices consistent with federal requirements for prescriptive devices. Without revision, we are concerned the laws could be misinterpreted, preventing licensed hearing aid dealers from this critical function to helping someone address their hearing loss. Requiring an order, without granting licensed hearing aid dealers this authorization, could drive up consumer costs due to the need for multiple healthcare appointments, potentially put many of these providers out of business, and it could limit your hearing-impaired constituents to 50% of the points of access.

According to the Centers for Disease Control ([CDC](#)) 7 percent of Oregon's residents have a hearing disability. Hearing loss can affect a person in three main ways:

- Fewer educational and job opportunities due to impaired communication.
- Social withdrawal due to reduced access to services and difficulties communicating with others.
- Emotional problems caused by a drop in self-esteem and confidence.

The FDA notified states in October, related to its updating federal rules governing hearing aids, that its intention is for licensed hearing professionals to continue to dispense hearing aids as they have historically done, and that despite their reclassifying (non-over the counter) hearing aids as prescription devices, a licensed provider who is authorized by the state to prescribe or order hearing aids shall continue to be able to do so. **The FDA concluded the October letter by stating that "the final rule defining non-OTC hearing aids as prescription devices does not, and is not intended to, create barriers to accessing hearing aids, including prescription devices.** It does not require the involvement of different or additional health care providers or examinations upon the effective date."

It is for these reasons that we respectfully request SB 558 be amended to authorize licensed hearing aid dealers to order prescription hearing aids. This is a good health care policy for Oregon’s hearing-impaired residents.

Thank you Chair, Vice Chair and Committee members for this opportunity and considering an amendment to SB 558 to authorize licensed hearing aid dealers to order the use of prescription hearing aids.

Founded in 1951, IHS represents hearing aid dispensing professionals worldwide, including hearing aid dealers and dispensers (known federally as hearing aid specialists), dispensing audiologists, and dispensing physicians. Hearing aid dealers and dispensers dispense about half of hearing aids delivered in the public market and operate in both urban and rural areas. IHS promotes and maintains the highest possible standards for its members in the best interests of the hearing-impaired population they serve by conducting programs in competency accreditation, testing, education, and training, and encourages continued growth and education for its members through advanced certification programs.