



WISCONSIN STATE REPRESENTATIVE

Shelia Stubbs

77TH ASSEMBLY DISTRICT

September 6, 2023
Assembly Bill 374
Assembly Committee on Regulatory Licensing Reform

Dear Mr. Chairman Shae Sortwell and Assembly Committee on Regulatory Licensing Reform Members,

Thank you for the opportunity to testify in support of AB 374: relating to: practice of ordering, fitting, and dealing in hearing aids and selling and fitting over-the-counter hearing aids.

I am here today to stress my strong support for AB 374 because of my confidence that passing it will help to improve affordability, accessibility, equity, inclusivity and a higher quality of life for hearing impaired Wisconsinites. AB 374 will perform the necessary task of updating our state law with regard to selling and fitting over-the-counter (OTC) hearing aids to create synergy with federal guidelines regarding this practice. This legislation can ensure that residents in our state possess the ability to be fitted and sold the medical device needed to live, work, and enjoy life comfortably.

Under current state law, Wisconsin businesses are prohibited from engaging in practice of selling, dealing and fitting OTC hearing aids. This statute directly conflicts with federal guidelines of the industry. In August of 2022, The Food and Drug Administration assigned OTC hearing aids into a new category, allowing for them to be sold to adults older than 18 with perceived mild to moderate hearing loss. This development granted the public access to acquiring the medical device online or in retail stores – bypassing traditional barriers to care that required a medical exam, prescription, or a fitting adjustment by a licensed audiologist.

This bill amends the definition of the practice of fitting and dealing in hearing aids to be the practice of ordering, fitting, and dealing in hearing aids and to include ordering the use of hearing aids intended to compensate for impaired hearing. Further, the bill provides that no license is required to sell or fit an over-the-counter hearing aid, as defined under federal law. Under federal law, air-conduction hearing aids may be sold over the counter without a prescription under certain circumstances.

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Finally, under current law, a hearing instrument specialist or an audiologist who engages in the practice of fitting and dealing in hearing aids must deliver to each person supplied with a hearing aid a receipt that contains certain information. The bill provides that a hearing instrument specialist or audiologist is not required to deliver a receipt to a person supplied with a hearing aid if the hearing aid is an over-the-counter hearing aid, as defined under federal law.

In the interest of promoting consistency in the regulatory process, our state policymakers have a responsibility to work in conjunction with the federal government on matters of public health. This clarification is needed to avoid the unintended consequences of reducing patient access to prescription hearing aids. This amendment is supported by the: Wisconsin Alliance of Hearing Professionals, The International Hearing Society (IHS), and Academy of Doctors of Audiology (ADA). The following States have updated their statute to align with the FDA's reclassification: - Kentucky (KY) – Utah (UT) – Maryland(MD) – Montana(MT) – Illinois (IL) - Oregon(OR) - Virginia(VA) - Texas(TX) - Minnesota (MN)- Rhode Island(RI)

I appreciate your time and thank you for taking the time to listen to this testimony to the importance of making over the counter hearing aids legal in Wisconsin. It is my hope that you will now have a better understanding of the transformative affect passing this bill will have for Wisconsinite families and communities. With that in mind, I implore you to vote yes for AB 374.

Thank you to the members of the committee, and to my colleagues Chairman Shae Sortwell, Senator Rachael Cabral-Guevara and Senator Tim Carpenter for their great work on this bill. I am happy to answer any questions.

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RACHAEL A. CABRAL-GUEVARA

STATE SENATOR • 19TH SENATE DISTRICT

Testimony before the Assembly Committee on Regulatory Licensing Reform

Senator Rachael Cabral-Guevara

September 6, 2023

Hello, Chairman Sortwell and members of the committee. Thank you for allowing me to provide testimony on Assembly Bill 374, an important clean-up bill on hearing aid regulations.

I'll keep this brief: evolving federal rules around the practice of ordering, selling, and fitting hearing aids have warranted a change in our state statutes. With over-the-counter hearing aids now becoming more common in the marketplace, this bill would clarify that no license is needed to sell them.

We've also introduced an amendment after consulting with the Legislative Reference Bureau to more closely mirror the federal language on "ordering" hearing aids. This bill, as amended, makes a clear distinction in statutes between over-the-counter devices and prescription hearing aids.

Additionally, we've taken into consideration the audiologists' request to ensure they are not required to issue a receipt for over-the-counter hearing aids. The original draft only exempted hearing instrument specialists from this unnecessary requirement.

I am hopeful you will be able to support this commonsense piece of legislation that clarifies existing statutes and catches us up with new federal regulations.

September 5, 2023

On behalf the Wisconsin Alliance of Hearing Professionals and the International Hearing Society (IHS), which represent hearing instrument professionals in Wisconsin and worldwide, I would like to thank Chair Sortwell, Vice-Chair Gustafson, and Committee members for this opportunity to submit comments on Assembly Bill 374 (An Act to amend 459.03 (1); and to create 459.02 (3) and 459.03 (1m) of the statutes; Relating to: selling and fitting over-the-counter hearing aids.).

Additionally, we applaud and thank Representative Stubbs for her leadership in sponsoring this important bill.

We understand that Assembly Bill 374 was introduced to ensure that Wisconsin's hearing aid laws are aligned with the United States Food and Drug Administration's (FDA) August 2022 [regulatory changes](#) that (1) created the new "Over-The-Counter (OTC) hearing aid" category and (2) reclassified any non-OTC hearing aids as "prescription" hearing aids.

However, as currently written, there remains ambiguity in the bill which could prevent Wisconsin's licensed hearing instrument specialists and licensed audiologists from "ordering the use of" non-OTC hearing aids for the growing hearing-impaired individuals of Wisconsin. As such, we have sent in a technical change that would help rectify this ambiguity.

The reason this is important is because the phrase "order the use of" can be interpreted differently from the words "making selection" or "sale" (words currently included in Chapter 459).

This is because, with the new federal OTC rule, FDA recategorized "traditional hearing aids" which have been dispensed by hearing instrument specialists and audiologists for decades, as "prescription medical devices," which must be "prescribed or ordered the use of" by a licensed hearing care professional. Since licensure is under the jurisdiction of the state, states must authorize a licensed hearing instrument specialist and a licensed audiologists to "prescribe or order the use of" these devices for their hearing-impaired patients. This is the phrase the FDA uses and that is why we recommend adding "order the use of" to Assembly Bill 374 as a technical amendment.

Additionally, the [FDA notified states in October 2022](#) 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.”

The following States have already updated their statute to align with the FDA’s OTC final rule:

- | | | | |
|---|----|---|----|
| - | KY | - | OR |
| - | UT | - | VA |
| - | MD | - | TX |
| - | MT | - | MN |
| - | IL | - | RI |

Without amending the legislation, Assembly Bill 374 could potentially require Wisconsin’s hearing-impaired patients to schedule additional medical appointments, thus incurring unexpected expenses and adding weeks or months to the process towards attaining hearing healthcare services. Office visit costs range between \$5 and \$75, depending upon one’s health plan. The average insured individual in the U.S. has a \$15 to \$25 office visit copay, in-network.

Additionally, this could potentially put numerous licensed hearing instrument specialist out of business, and it could limit hearing-impaired Wisconsinites to 50% of the points of access; at a time when Wisconsin is experiencing a health care shortage, like other states.

According to the Centers for Disease Control (CDC) [5 percent](#) (over 290,000) Wisconsin’s residents have a hearing disability. This is not just an older adult population’s health concern. Younger people are also at risk of hearing loss, with the CDC estimating that about a fifth of Americans 30 and under have had their hearing impaired.

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.

Additionally, recent research from Johns Hopkins reveals that hearing loss is also linked with walking problems, falls, and even dementia. The research found that mild hearing loss doubled dementia risk, moderate loss tripled risk, and people with a severe hearing impairment were five times more likely to develop dementia.

It is for these reasons that we respectfully recommend Assembly Bill 374 be amended to authorize licensed hearing instrument specialists and licensed audiologists to order prescription hearing aids. This is a good health care policy for Wisconsin’s hearing-impaired residents.

Thank you Chair, Vice-Chair and Committee members for this opportunity and considering an amendment to Assembly Bill 374 to authorize licensed hearing instrument specialists and licensed audiologists to order hearing aids for their patients.

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.