



ASHA
American
Speech-Language-Hearing
Association

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March 5, 2021

The Honorable William Robinson, Chair
The Honorable Juan Fernandez-Barquin, Vice-Chair
Professions and Public Health Subcommittee
404 South Monroe Street
Tallahassee, FL 32399-1100

RE: HB 957

Dear Chairman Robinson and Vice-Chairman Fernandez-Barquin:

On behalf of the American Speech-Language-Hearing Association, I write to express opposition to House Bill 957, which severely weakens Florida's requirement for a professional evaluation before dispensing a hearing aid by instituting a medical waiver for all patients and removes the state ban on dispensing hearing aids through the mail.

The American Speech-Language-Hearing Association (ASHA) is the national professional, scientific, and credentialing association for 218,000 members and affiliates who are audiologists; speech-language pathologists; speech, language, and hearing scientists; audiology and speech-language pathology support personnel; and students. Over 11,000 ASHA members reside in Florida.¹

Communication skills are central to a successful and productive life for all Americans. Communication disorders impact education, employment, and the well-being of 1 in 6 Americans and their families.²

ASHA shares the committee's goal of improving access to safe and effective treatment for adults with suspected hearing loss. It is estimated that 15% of school-age children and adults have some degree of hearing loss in one or both ears.³ Furthermore, the incidence of hearing loss increases with age, with 5.5% of adults ages 18–39, 19% of adults ages 40–69, and 43% of adults over age 70 with self-reported difficulty hearing without a hearing aid.⁴ Without intervention, hearing loss leads to many social and economic factors, including depression, reduced alertness and increased risk to personal safety, impaired memory and ability to learn new tasks, reduced job performance and earning potential, and diminished psychological and overall health.⁵ Research has also found a strong correlation between hearing loss and the risk for developing dementia.⁶

House Bill 957 would undermine access to safe and effective treatment for adults and children with suspected hearing loss. As amended, the bill weakens the professional evaluation requirement when dispensing a hearing aid by allowing any person to opt-out of the evaluation via a medical waiver. Hearing aid fitting and verification is a complex process representing one part of a comprehensive aural rehabilitation plan that necessitates a professional evaluation. Evaluation is also critical for persons who often experience hearing loss in conjunction with severe chronic conditions, such as heart disease and diabetes.⁷ Without appropriate

assessment, people seeking treatment for suspected hearing loss may not be appropriately referred for treating an underlying health condition causing their hearing impairment.

ASHA acknowledges that, in altering Florida's hearing aid dispensing requirements, this legislation may be seeking to align state policy with U.S. Food and Drug Administration (FDA) guidance, which limits federal enforcement of medical evaluation requirements for persons over the age of 18 under certain conditions. However, the changes proposed in HB 957 are inconsistent with federal rules on this matter. The FDA guidance does not preclude states from requiring a professional evaluation. In fact, the agency still recommends that patients seeking a hearing aid obtain a medical examination or audiological evaluation.⁸ In addition, HB 957 does not include any provisions for ensuring the proposed waiver adheres to FDA regulations. For instance, under 21CFR801.421 and subsequent FDA issued guidance, the following conditions apply:

- exemption to the medical evaluation requirement only applies to the subset of hearing aids that are regulated as class I air-conduction hearing aids under 21 CFR 874.3300(b)(1) and class II wireless air-conduction hearing aids;
- the required notice for prospective hearing aid users under 21 CFR801.420(c)(3) still applies; and
- upon request by a person who is considering purchasing a hearing aid, a dispenser must provide a copy of the User Instructional Brochure for the hearing aid, which details that it is recommended that a person with a hearing loss have a medical evaluation before purchasing a hearing aid.⁹

House Bill 957 also removes the state ban on dispensing hearing aids through the mail. The FDA is in the process of establishing new regulations to allow hearing aids to be available to consumers over-the-counter (OTC). When OTC hearing aids become available, it will eliminate Florida's need to revise its ban since eligible consumers will be able to purchase these devices (including online) without a hearing care professional's involvement. In addition, the forthcoming FDA regulations are limited to consumers with mild to moderate hearing loss to ensure proper safety and effectiveness. The broad rescission of the state ban in HB 957 would apply no such protections to populations in need of appropriate evaluation before obtaining a hearing aid.

ASHA, its state affiliate, the Florida Association of Speech-Language Pathologists and Audiologists (FLASHA), and other expert organizations are dedicated to increasing access and treatment for all individuals with hearing loss and would be happy to work with the committee to revise the bill language to help Floridians with hearing loss receive the appropriate hearing aid technology that they need and deserve to achieve success.

Thank you for your consideration of ASHA's position on HB 957. If you or your staff have any questions, please contact Tim Boyd, ASHA's director of state health care and education affairs, at tboyd@asha.org.

Sincerely,



A. Lynn Williams, PhD, CCC-SLP
2021 ASHA President

March 5, 2021

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cc: Honorable James Mooney
Honorable Chris Sprowls

¹ American Speech-Language-Hearing Association. (2020). *Florida* [Quick Facts]. <https://www.asha.org/siteassets/uploadedfiles/Florida-State-Flyer.pdf>.

² Ruben, R. J. (2000). Redefining the Survival of the Fittest: Communication Disorders in the 21st Century. *The Laryngoscope*, 110, 241-245.

³ Niskar, A.S., Kieszak, S.M., Holmes, A., Esteban, E, Rubin, C., & Brody, D.J. (1998). *Prevalence of Hearing Loss Among Children 6 to 19 Years of Age: The Third National Health and Nutrition Examination Survey*. *JAMA*, 279(14), 1071–1075. doi:10.1001/jama.279.14.1071.

⁴ Centers for Disease Control and Prevention. (2015). *NCHS Data Brief*. <http://www.cdc.gov/nchs/data/databriefs/db214.htm>.

⁵ Emmett, S. D., & Francis, H. W. (2015). The socioeconomic impact of hearing loss in U.S. adults. *Otology & neurotology: official publication of the American Otological Society, American Neurotology Society [and] European Academy of Otology and Neurotology*, 36(3), 545–550. <https://doi.org/10.1097/MAO>.

⁶ Lin, F. R., Metter, J., O'Brien, R. J., Resnick, S. M., Zonderman, A. B., & Ferrucci, L. (2011). Hearing loss and incident dementia. *Archives of Neurology*, 68, 214–220.

⁷ Marlow NM, Malaty J, Jo A, Tanner RJ, Beau de Rochars VM, Carek PJ, Mainous AG 3rd. Hearing Impairment and Undiagnosed Disease: The Potential Role of Clinical Recommendations. *J Speech Lang Hear Res*. 2017 Jan 1;60(1):231-237.

⁸ Food and Drug Administration. (2018). *How to Get Hearing Aids*. <https://www.fda.gov/medical-devices/hearing-aids/how-get-hearing-aids>.

⁹ Food and Drug Administration. (2016). *Immediately in Effect Guidance Document: Conditions for Sale for Air Conduction Hearing Aids*. <https://www.fda.gov/media/101685/download>.