



ASHA
American
Speech-Language-Hearing
Association

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February 23, 2021

The Honorable Manny Diaz, Chair
The Honorable Jason Brodeur, Vice-Chair
Health Policy Committee
404 South Monroe Street
Tallahassee, FL 32399-1100

RE: SB 700

Dear Chairman Diaz and Vice-Chairman Brodeur:

On behalf of the American Speech-Language-Hearing Association, I write to express opposition to Senate Bill 700, which severely weakens Florida's requirement for a professional evaluation before dispensing a hearing aid by instituting a medical waiver for persons ages 18 and older, 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 the United States' adult population has hearing loss. 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.³ 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.⁴ Research has also found a strong correlation between hearing loss and the risk for developing dementia.⁵

Senate Bill 700 would undermine, not improve, access to safe and effective treatment for adults with suspected hearing loss. As amended, the bill weakens the professional evaluation requirement when dispensing a hearing aid by allowing persons aged 18 and older to opt-out of the evaluation via a medical waiver. Hearing aid fitting and verification for adults is a complex process representing one part of a comprehensive aural rehabilitation plan that necessitates a professional evaluation. Evaluation is also critical for adults who often experience hearing loss in conjunction with severe chronic conditions, such as heart disease and diabetes.⁶ Without appropriate assessment, adults 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 allows persons over the age of 18 to obtain a hearing aid without a waiver or evaluation under certain conditions. However, SB 700 does not include any provisions ensuring the proposed waiver adheres to FDA regulations. For instance, under 21CFR801.421 and subsequent FDA issued guidance, the following conditions apply:

- the exemption 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.⁷

Senate Bill 700 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 available 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 SB 700 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 SB 700. 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

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

⁴ 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>.

⁵ 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.

⁶ 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.

⁷ FDA, Immediately in Effect Guidance Document: Conditions for Sale for Air Conduction Hearing Aids. December 12, 2016. <https://www.fda.gov/media/101685/download>.