



February 23, 2021

### **Message from HIA Regarding Opposition to Amendment #302884 to Florida Senate Bill 700**

The Hearing Industries Association (HIA) is the national trade association representing global manufacturers advancing hearing technology innovation; these companies produce hearing aids, assistive listening devices, component parts, and power sources. HIA is committed to the safety and effectiveness of all hearing aids, as well as ensuring patient protection and satisfaction for all hearing aid wearers.

Our members have all invested in extensive research and development activities. We are proud of the tremendous resulting innovations in hearing aid technology that they have made. These advances are helping to improve the quality of and broaden the benefits that hearing aids can offer so that all those suffering from hearing loss can enjoy the improved quality of life that hearing aids may bring.

Like almost every state, Florida has a requirement for professional assistance with the testing and fitting of hearing aids to ensure patient protection (via Audiologists and Hearing Aid Specialists). The decision to purchase a hearing aid without medical assistance means the patient may therefore fail to receive timely treatment for an undiagnosed medical condition. Florida currently has protections in place that minimize the potential harm to hearing loss patients.

Amendment # 302884 to Florida Senate Bill 700 abruptly discards this important protection and removes the state's existing ban on direct-to-consumer (DTC) hearing aid sales. The amendment fails to thoughtfully differentiate between those for whom this opportunity is appropriate and those who could be harmed. Inevitably, some patients who need professional assistance will be harmed by obtaining the wrong hearing aid or by overlooked ear conditions or co-morbidities that a hearing care professional is trained to consider.

In the meantime, the U.S. Food and Drug Administration (FDA) has spent the last several years developing a regulation that will carefully define a class of over-the-counter (OTC) hearing aids that may be sold without professional assistance. This regulation will implement the federal Over the Counter (OTC) Hearing Aid Act of 2017 (P.L. 115-52) (OTC Hearing Aid Act). HIA is supportive of this act.

Under this statute, FDA is required to spell out technological and labeling requirements to ensure that OTC sale is made available only to an appropriate patient population and in a manner that provides reasonable assurance of safety and effectiveness. We recommend that Florida wait until FDA issues this regulation, which is expected in the near future (draft guidelines were expected in August of 2020; they have been delayed due to the pandemic).

By taking precipitous action now, Amendment # 302884 will cause significant confusion among Florida's large population of senior and elderly patients, as many could fall prey to direct-to-consumer offers for hearing aids that offer limited or no benefit or they may purchase a hearing aid without appropriate guidance as to the proper safe and effective use of the medical device.

Moving forward, HIA firmly favors the trend toward broader patient access to hearing aids. We view both OTC and telehealth as changes that can potentially lead to improved patient access in a safe manner. HIA believes that the testing, fitting and sale of hearing aids is best supported by a licensed hearing care professional whether in-person or in the emerging field of tele-audiology.

In light of these concerns, HIA respectfully requests the removal of Amendment #302884 in SB 700.



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