February 28, 2023

The Honorable Amanda Mays Bledsoe
702 Capital Ave
Annex Room 203
Frankfort, KY 40601

RE: SB 58

Dear Senator Mays Bledsoe,

On behalf of the Academy of Doctors of Audiology (ADA) and the Kentucky Academy of Audiology (KAA) whose members are audiologists and audiology practice owners serving patients in Kentucky and across the United States, we write to urge swift passage of SB 58, as amended, to align Kentucky statutes with regulations implemented by the U.S. Food and Drug Administration (FDA) in October 2022, thus ensuring uninterrupted access to audiology and hearing aid dispensing services for the citizens of Kentucky.

The FDA regulations created a new category of over-the-counter (OTC) hearing aids and reclassified non-OTC Class I and Class II air conduction hearing aids (traditional hearing aids) from 'restricted' medical devices to 'prescription' medical devices, subject to dispensing rules under 21 C.F.R. 801.109, including requirements that prescription hearing aids be dispensed upon *"the prescription or other order"* of a practitioner licensed under state law to direct the use of such devices. These provisions are intended to improve consumer access to hearing aids by allowing certain hearing aids (OTC hearing aids) to be sold without the involvement of a licensed healthcare provider *and* by removing longstanding federal preemptions dictating the 'conditions for sale' of traditional (non-OTC) hearing aids, transferring that authority to the states, appropriately recognizing states' jurisdiction over practitioner licensure.

In the Commonwealth of Kentucky, audiologists and hearing aid dispensers have been licensed to recommend, select, fit, and dispense Class I and Class II air conduction hearing aids to consumers for the past several decades. Additionally, Kentucky audiologists have been recognized as prescribers of hearing aids under Kentucky statute since 2002. SB 58 will maintain Kentucky's existing policies governing hearing aid dispensing by updating existing statutes to reflect the FDA's taxonomy for non-OTC Class I and Class II hearing aids under the newly defined prescription hearing aid category. In October 2022, the FDA issued specific guidance to States regarding the FDA Final Rule as follows:

"We clarify below that the final rule:

- Does not change the necessary qualifications of who may provide hearing healthcare with prescription hearing aids, including the recommendation, selection, fitting, and dispensing of these devices;
- Does not require an additional professional to take actions, for example, does not in any way require a physician's involvement prior to fitting these devices; and
- Does not require an examination of any kind to obtain a prescription hearing aid."

The FDA further stated, "FDA's intent is that the same professionals who recommended, selected, fitted, and dispensed restricted hearing aids before the effective date would continue to do so for prescription hearing aids after the effective date"… and,… "In conclusion, 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."

ADA and KAA, therefore, strongly support the enactment of SB 58, which will align Kentucky statutes with FDA's regulations and will preserve the proven, safe, effective, and accessible pathways to treatment for Kentucky consumers experiencing hearing loss. Please contact Stephanie Czuhajewski at sczuhajewski@audiologist.org or Emily Childers at echilders@kyaudio.org if you have any questions or require additional information. Thank you for your consideration of this important request.

Sincerely,

Stephanie Czuhajewski

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Emily Childers

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