

December 9, 2019

The Honorable Vincent C. Gray
Council of the District of Columbia
1350 Pennsylvania Avenue
Washington, D.C. 20004

Re: American Academy of Audiology concerns regarding the proposed Hearing Aid Sales Amendment Act of 2019

Dear Councilmember Gray:

I am writing on behalf of the American Academy of Audiology to express our concerns and to share some relevant information with respect to B23-0565—the Hearing Aid Sales Amendment Act of 2019. The American Academy of Audiology (the “Academy”) is the world's largest professional organization of, by and for audiologists. Representing the interests of approximately 14,000 audiologists nationwide, the Academy is dedicated to providing quality hearing care services through professional development, education, research, and increased public awareness of hearing and balance disorders.

Under current District of Columbia regulations, all prospective hearing aid users must receive medical clearance prior to receiving a hearing aid. This bill would replace the single medical clearance requirement with two separate requirements—one for children and one for adults. Children under 18 must receive medical clearance within the preceding three months and adults over the age of 18 must receive medical clearance within the preceding 6 months.

However, maintaining and reinforcing the medical clearance requirement for adults stands in direct contradiction with current FDA efforts to promote the availability and accessibility of hearing aids. The Food and Drug Administration (FDA) announced in a 2016 guidance document that **“the FDA does not intend to enforce the medical evaluation (21 CFR 801.421(a)) or recordkeeping (21 CFR 801.421(d)) requirements prior to the dispensing of certain hearing aid devices to individuals 18 years of age and older.”**¹In addition, the FDA Reauthorization Act of 2017 directed the FDA to establish an OTC category of hearing aids for adults with mild to moderate hearing loss—and the Agency is currently working on implementing regulations. It is also worth mentioning that the American Academy of

¹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/immediately-effect-guidance-document-conditions-sale-air-conduction-hearing-aids>

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Otolaryngology-Head and Neck Surgery (AAO-HNS) supported the creation of the OTC hearing aid category.

In light of the growing federal emphasis on removing existing barriers and increasing accessibility to hearing aids—particularly for adults, the Academy would recommend the Councilmember to consider removing the medical clearance requirement for those over the age of 18 in this legislation. If you have any questions about any of the information included in this letter, please contact me at spilch@audiology.org or at (703) 226-1036.

Sincerely,

Susan Pilch, J.D.

Senior Director, Government Relations

American Academy of Audiology