ASHA
American
Speech-Language-Hearing
Association

September 16, 2022

Robert M. Califf, M.D
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

On behalf of the American Speech-Language-Hearing Association, I write to request guidance from the Food and Drug Administration (FDA) regarding the effect of its final rule for over-the-counter (OTC) hearing aids on state regulation of medical waivers and licensed practitioners related to the use of prescription hearing aids.

The American Speech-Language-Hearing Association (ASHA) is the national professional, scientific, and credentialing association for 223,000 members and affiliates who are audiologists; speech-language pathologists; speech, language, and hearing scientists; audiology and speech-language pathology support personnel; and students. ASHA represents the most audiologists of any professional association with just over 14,500 ASHA-certified audiologists. ASHA's vision is to make effective communication, a human right, accessible for all.

ASHA supports the new category for over-the-counter hearing devices, which will increase the availability and affordability of hearing aids for many Americans. While ASHA is pleased with the majority of the included provisions in the final rule issued on August 16, 2022, ASHA is concerned about the FDA's decision to 1) designate non-OTC hearing aids as "prescription devices", and 2) repeal the medical evaluation as a condition for use under § 801.421, which preempted more onerous state rules.

The following are ASHA's recommendations for guidance regarding the FDA's final rule for OTC hearing aids and its impact on state regulation of medical waivers and licensed practitioners related to the use of prescription hearing aids.

Status of Non-OTC Hearing Aids as Prescription Devices

Responding to public comments about designating non-OTC hearing aids as prescription devices, the FDA asserted that clarifying who constitutes a prescriber was unnecessary given the existing definition of a prescription device under § 801.109(a), which describes "a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such devices and (2) is to be sold only to or on the prescription or other order of such practitioner for use in the course of [their] professional practice."[1] However, this implies that a duly licensed audiologist will not be allowed to "order the use of" a prescription hearing aid if their state law does not expressly denote them as a prescriber. This confusion will severely affect access to prescription hearing devices by limiting the number of providers who can order their use, even though these providers have done so for decades.

To help remedy this issue, **ASHA strongly urges the FDA to confirm through additional guidance that reclassifying non-OTC hearing aids as "prescription devices" is not**

intended to prevent licensed practitioners—who are authorized to order the use of these devices—from continuing to do so.

Status of Medical Evaluations Under § 801.421

The FDA also clarified the impact of the final rule on the preemption of state laws requiring medical evaluations and audiological screenings before ordering the use of a prescription hearing aid. The agency noted that states can continue requiring an audiological evaluation for all patients seeking a non-OTC hearing aid, or a medical evaluation for minors seeking a hearing aid.[2] ASHA appreciates the FDA's guidance on the preemption issue because of its potential impact on minors and people with comorbidities to hearing loss. ASHA is concerned about the unintended impact of the agency's decision to completely repeal its medical evaluation condition for use under § 801.421 without addressing previously preempted laws that unnecessarily restrict access to prescription hearing aids. For example, a Rhode Island law identified in public comments will require patients first to obtain a certificate of need from a physician (without the option of a waiver) before they can obtain a hearing aid from a licensed audiologist.[3]

To help address this concern, **ASHA strongly urges the FDA to confirm through additional guidance that the OTC hearing device rule does not require states to implement medical evaluation requirements for prescription hearing aids for adults. Furthermore, ASHA urges the agency to consider establishing new conditions for the use of prescription hearing aids that only allows for a medical evaluation requirement with the option for the consumer to opt-out via a waiver.**

Thank you for considering ASHA's request for guidance and recommendations regarding the effect of its final rule for OTC hearing aids on state regulation of medical waivers and licensed practitioners related to the use of prescription hearing aids. If you or your staff have any questions, please contact Tim Boyd, director of state health care and education affairs at tboyd@asha.org.

Sincerely,

Judy Rich

Judy Rich, EdD, CCC-SLP, BCS-CL
2022 ASHA President

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[1] Federal Register. (2022). *Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids. 87 Fed. Reg. 50698*. https://www.federalregister.gov/d/2022-17230/p-226.
[2] Ibid. https://www.federalregister.gov/d/2022-17230/p-578.
[3] Ibid. https://www.federalregister.gov/d/2022-17230/p-560.