



October 13, 2022

Dear State Official:

It has come to our attention that there may be some confusion with FDA's final rule establishing a regulatory category for over-the-counter (OTC) hearing aids and amending certain FDA regulations. We published the final rule on August 17, 2022, and it goes into effect on October 17, 2022 (see 87 FR 50698). The final rule primarily establishes a category of OTC hearing aids that consumers aged 18 years and older with perceived mild to moderate hearing impairment can purchase without the involvement of a hearing healthcare professional. The final rule also makes several changes to Federal regulations that apply to hearing aids, including: repealing the conditions for sale for hearing aids under 21 CFR § 801.421; defining non-OTC hearing aids as prescription devices, subject to 21 CFR § 801.109, rather than restricted devices (see 87 FR at 50755, removing § 801.421); and providing updated labeling requirements for such prescription hearing aids (see *id.*, adding new 21 CFR § 801.422).

We have received questions about some implications of these actions, including who may prescribe hearing aids and whether medical evaluations are necessary to obtain non-OTC hearing aids, which will be defined as prescription hearing aids under the rule. 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.

A State can authorize many kinds of practitioners to order the use of (or prescribe) a prescription device. Federal regulations in § 801.109 do not require that a prescriber be a physician (a person licensed to practice allopathic or osteopathic medicine), physician assistant, or nurse practitioner. Instead, the relevant requirements for prescription devices apply in the case of practitioners licensed by the law of the State to use or order the use of the device (see § 801.109). 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. Further, the final rule does not require the involvement of an additional licensed practitioner such as a physician. A licensed audiologist, for example, would not need to consult a physician under FDA's final rule.

Similarly, Federal regulations in § 801.109 do not require that a prescriber provide or require a medical or other examination prior to using or ordering the use of a prescription device. As has been observed elsewhere, medically treatable causes of hearing loss are relatively rare, and while certain circumstances may warrant the involvement of a physician in some individual cases—for example, those included as “red flag conditions” in required labeling for prescription hearing aids—the final rule does not state or imply that a medical evaluation is generally necessary or generally more advisable for people 18 and older under Federal regulations to obtain a prescription hearing aid.¹

Regarding terminology and the use of the word “prescription,” we note that FDA regulations for prescription devices refer to a “prescription *or other order*” (emphasis added) and a practitioner who is licensed “to use or order the use” of the device (see § 801.109). Therefore, the document or action to obtain a prescription hearing aid need not be called a “prescription” under State law. Thus, for example, if a hearing aid purchaser obtained a document called a “hearing aid use authorization” or a “hearing aid certificate of need” from an audiologist or hearing instrument specialist who had authority in that State to provide such a document, this would likely satisfy the practitioner-order requirements under § 801.109.

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.

States or localities that have questions may contact FDA’s Intergovernmental Affairs Staff at IGA@fda.hhs.gov.

Sincerely,

Jeffrey E. Shuren -S
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Jeffrey Shuren, M.D., J.D.
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¹ See reference 7 for the final rule, from the National Academies of Sciences, Engineering, and Medicine, “Hearing Healthcare for Adults: Priorities for Improving Access and Affordability,” Board on Health Sciences Policy, Committee on Accessible and Affordable Hearing Health Care for Adults; Blazer, D.G., S. Domnitz, and C.T. Liverman, Eds., 2016. DOI: 10.17226/23446. Available at: <https://www.nap.edu/catalog/23446/hearing-health-care-for-adults-priorities-for-improving-access-and>. Unlike conditions such as otitis media (an infection of the middle ear) or ear canal blockages, “most sensorineural hearing loss...cannot be repaired using current medical or surgical interventions,” (p. 22).