

Frequently Asked Questions on Over-the-Counter (OTC Hearing Aids)

What is an Over-The-Counter (OTC) hearing aid?

Federal law defines an over-the-counter (OTC) hearing aid as

- (1) uses the same fundamental scientific technology as air conduction hearing aids or wireless air conduction hearing aids;
- (2) is intended to be used by adults age 18 and older to compensate for perceived mild to moderate hearing impairment;
- (3) through tools, tests, or software, allows the user to control the over-the-counter hearing aid and customize it to the user's hearing needs;
- (4) may use wireless technology or include tests for self-assessment of hearing loss; and
- (5) is available over-the-counter, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to the consumer through in-person transactions, by mail, or online.

Pub. Law. 115-52, § 709; 21 U.S.C. § 360j(q)(1)(A). However, the term “over-the-counter hearing aid” does not include personal sound amplification products intended to amplify the sound of nonhearing impaired customers in situations including hunting and bird-watching. 21 U.S.C. § 360j(q)(1)(B).

What is a prescription hearing aid?

A prescription hearing aid is any hearing aid that does not meet the definition of an OTC hearing aid. *See* 21 C.F.R. § 800.30(b).

Is a prescription by a physician necessary for selling and dispensing prescription hearing aids?

No. Although federal regulations classify prescription hearing aids as “prescription” devices, the FDA clarified that “the same professionals who recommended, selected, fitted, and dispensed restricted hearing aids before [the OTC Rule] would continue to do so for prescription hearing aids after the effective date.” U.S. Food & Drug Admin., Opinion Letter (Oct. 13, 2022). Thus, a licensed hearing aid specialist may continue to sell and dispense prescription hearing aids to individuals 18 years of age or older without the involvement of a physician, provided the individual waives the physician evaluation, if applicable. *See* 645 Iowa Admin. Code r. 123.2(1)“b”.

However, federal regulations do require that prescription hearing aids be sold “on the prescription or other order” of a provider. *See* 21 C.F.R. § 801.10(a)(2) (emphasis added). The FDA has clarified that “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.” U.S. Food & Drug Admin., Opinion Letter (Oct. 13, 2022).

Is a “hearing aid use authorization,” “hearing aid certificate of need,” or other “order” by a licensed practitioner necessary for selling and dispensing prescription hearing aids?

Yes. Federal regulations now require that prescription hearing aids be sold only upon an “order” from a practitioner. *See* 21 C.F.R. § 801.109. The FDA has clarified that a “hearing aid use authorization” or “hearing aid certificate of need” issued by a licensed audiologist or licensed hearing aid specialist satisfies the “order” requirement. A licensed audiologist may, after performing a hearing examination, issue a “hearing aid use authorization” or “hearing aid certificate of need” to a person who would benefit from a prescription hearing aid.

Can licensed audiologists issue “hearing aid use authorizations” or “hearing aid certificates of need”?

Yes. Licensed audiologists currently perform hearing exams to determine whether a person may benefit from a hearing aid. Accordingly, the Board believes licensed audiologists have existing authority under Iowa law to issue a “hearing aid use authorization” or “hearing aid certificate of need” to a person who, after examination, is determined to benefit from a prescription hearing aid. Other practitioners, such as licensed physicians or licensed hearing aid specialists, may also have the authority to issue such authorizations.

Is a license required to sell or dispense OTC hearing aids in Iowa?

No. A person does not need any professional license to sell, dispense, service, market, use, distribute, or provide customer support for OTC hearing aids. *See* 21 C.F.R. § 800.30(h)(1).

Is a license required to service an OTC hearing aid?

No. A person does not need any professional license to sell, dispense, service, market, use, distribute, or provide customer support for OTC hearing aids. *See* 21 C.F.R. § 800.30(h)(1).

Is a license required to provide fitting services for OTC hearing aids?

Yes, a hearing aid specialist license is required. The FDA’s regulations do not preempt state law requiring licensure for fitting services. In Iowa, any person who provides hearing aid fitting services – either for prescription or OTC hearing aids – must have a hearing aid specialist license. Iowa Code § 154A.1. While many OTC hearing aids are self-fitting, OTC hearing aids are not required to be self-fitting. Thus, if a person needs fitting assistance with OTC hearing aids, such fitting services must be performed by a licensed hearing aid specialist. Iowa Code §§ 154A.1(6); 147.2(1). Iowa law defines “hearing aid fitting” as “the measurement of human hearing by any means for the purpose of selections, adaptations, and sales of hearing aids, the instruction and counseling pertaining to the selections, adaptations, and sales of hearing aids, demonstration of

techniques in the use of hearing aids, and the making of earmold impressions as part of the fitting of hearing aids.” Iowa Code § 154A.1(5).

I’m a licensed audiologist, do I need a hearing aid specialist license to sell or dispense OTC hearing aids?

No. A licensed audiologist does not need a hearing aid specialist license to sell or dispense OTC hearing aids. A licensed audiologist may choose to sell and dispense OTC hearing aids as part of their practice. Please note that when you hold yourself out as a licensed audiologist to the public, all laws and rules governing your audiologist license apply. The Board of Speech Pathology & Audiology retains jurisdiction to investigate and discipline licensees based on actions taken while holding themselves out as licensed audiologists, even if the actions exclusively arise out of OTC hearing aid commercial activity. *See* 21 C.F.R. § 800.30(h)(2)(iii).

I’m a licensed hearing aid specialist, can I sell and dispense OTC hearing aids?

Yes. Licensed hearing aid specialists may sell and dispense both OTC and prescription hearing aids. Although a license is not required to sell and dispense OTC hearing aids, a licensed hearing aid specialist may choose to sell and dispense both OTC and prescription hearing aids in their practice. Please note that when you hold yourself out as a licensed hearing aid specialist to the public, all statutes and rules governing licensed hearing aid specialists apply. The Board of Hearing Aid Specialists retains jurisdiction to investigate and discipline licensees based on actions taken while holding themselves out as licensed hearing aid specialists, even if the actions exclusively arise out of OTC hearing aid commercial activity. *See* 21 C.F.R. § 800.30(h)(2)(iii).

Even though a hearing aid specialist license is not required to sell and dispense OTC hearing aids, can an OTC hearing aid seller choose to become licensed?

Yes. A person who sells, dispenses, services, markets, distributes, and/or provides customer support for OTC hearing aids may voluntarily choose to obtain a hearing aid specialist license. The requirements for licensure can be found at 645 Iowa Admin. Code chapter 121. Please note the Board of Hearing Aid Specialists retains jurisdiction to investigate and discipline licensees based on actions taken while individuals are holding themselves out as licensed hearing aid specialists, even if the actions exclusively arise out of OTC hearing aid commercial activity. *See* 21 C.F.R. § 800.30(h)(2)(iii).

Is a medical examination required before purchasing OTC hearing aids?

No. An OTC hearing aid may be purchased without any involvement of a licensed person and does not require a preliminary medical examination. Please note that OTC hearing aids are for adults aged 18 and older, and children must continue to use prescription hearing aids. Children who experience hearing loss and who would like hearing aids should contact a licensed physician, preferably an ENT, for a hearing-loss examination.

What changes did the FDA's Final Rule make?

The FDA's Final Rule made several changes, including (1) established a regulatory category for OTC hearing aids; (2) repealed the conditions for sale of hearing aids under 21 C.F.R. § 801.421; (3) defined non-OTC hearing aids as prescription devices under 21 C.F.R. § 801.109; and (4) updated labeling requirements for prescription hearing aids under 21 C.F.R. § 801.422. Practitioners should consult with their facility and facility's counsel to ensure compliance with all new and amended regulations.