

AAO-HNS Summary of OTC Hearing Aids Proposed Rule

On October 19, the Food and Drug Administration (FDA) released the [Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids](#) proposed regulations. The rule, which implements a key provision of the FDA Reauthorization Act of 2017, creates a regulatory pathway for a new category of air conduction hearing aids for adults age 18 and older with perceived mild to moderate hearing loss. If finalized, the proposal would allow air conduction hearing aids to be sold directly to consumers without a medical exam, prescription, or fitting by an audiologist.

The proposed rule was published in the Federal Register on October 20, 2021 and has a 90-day public comment period. The AAO-HNS will submit comprehensive comments to the agency on elements of the regulations affecting the specialty by the January 18 deadline. The FDA outlines that if finalized, the regulations will take effect 60 days after the publication of the final rule in the Federal Register.

Regarding enactment timeline, the compliance date for hearing aids not legally offered for sale prior to the effective date must be achieved on or after the effective date of the final rule. The compliance date for hearing aids that are legally offered for sale prior to the effective date must be achieved 180 days after the effective date of the final rule (240 days after the publication of the final rule). After that date, if a person continues to market such a device but does not comply with the new requirements than the FDA could take enforcement action.

The primary purpose of the proposed regulation is to address an estimated 80% of people with hearing loss who do not seek treatment for a myriad of reasons including cost, and perceived stigma. The following summary provides a high-level overview of the major elements of the FDA proposed rule.

Background

The proposed rule establishes a regulatory category for OTC hearing aids and makes related amendments to update the framework for hearing aids. Following enactment of the final rule, devices will be available to those 18 years of age or older “without the supervision, prescription, or intervention of a licensed person to consumers through in-person transactions, by mail, or online.” The term “licensed person” has a broad definition and includes physicians, audiologists, and hearing aid dispensers. Hearing aids for children under age 18 and adults with higher levels of hearing loss will still require a diagnosis and prescription from a physician.

The FDA does not propose to create or classify a new device type or exempt additional devices from the premarket notification requirements. It does however clarify that self-fitting hearing aids are eligible for regulation as OTC hearing aids. The FDA proposes to separate the classification regulations for bone-conduction and air-conduction hearing aids.

Definition

The FDA defines an OTC hearing aid as “an air-conduction hearing aid that does not require implantation or other surgical intervention and is intended for a use by a person age 18 or older to compensate for perceived mild to moderate hearing impairment. The device, through tools, tests, or software, allows the user to control the hearing aid and customize it to the user’s hearing needs. The device may use wireless technology or may include tests for self-assessment of hearing loss. The device is available over-the-counter, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online, provided that the devices satisfy the requirements in this section.”

Classification

Hearing aids are defined as class I and class II wearable sound-amplifying devices intended to compensate for impaired hearing. The FDA proposes to realign hearing aids classification regulations by sound conduction mode so that legacy air-conduction hearing aids, wireless air-conduction hearing aids, and self-fitting air-conduction hearing aids would be under one classification regulation and bone-conduction hearing aids would fall under a separate classification regulation.

Package Labeling

Under the proposed rule, the outside of an OTC hearing aid package must include information for proper consumer safety and device efficacy, including proposed statements outlining the following:

- A conspicuous warning that the device is not for users younger than 18 years old;
- The symptoms of perceived mild-to-moderate hearing loss;
- Considerations for seeking a consultation with a hearing healthcare professional; and
- Red flag conditions: Warnings to consumers regarding signs and symptoms that should prompt a consultation with a licensed physician.

The FDA is also proposing that manufacturers clearly disclose their return policy. The regulation does not propose requiring a return, only that conditions for return, if returns are allowed, be disclosed.

There will also be certain labeling requirements for inside the OTC hearing aids package. These will include the red flag conditions and warnings about age. They will also include:

- Illustrations and information about the controls, use adjustments, and battery compartment;
- Descriptions of accessories that accompany the hearing aids;
- Directions for use;
- Technical specifications;
- Descriptions of commonly occurring, avoidable events that could adversely affect or damage the hearing aid;
- Identification of known physiological side effects;
- Information on repair services; and
- A summary of all clinical and non-clinical trials conducted by or for the manufacturer to support the performance of the hearing aid (if trials were performed).

Finally, the FDA is also proposing to require labeling on the hearing aid itself. This labeling will include a serial number for the device and symbols for battery insertion. If the device has been used or rebuilt, a tag indicating this would have to be attached to the device.

Proposed Output Limits

The rule proposes a maximum OSPL90 output level of 115 dB sound pressure level (SPL). However, a limit of 120 dB SPL for an OTC hearing aid would be permissible if it implements input-controlled compression and a user-adjustable device volume control. The FDA is also proposing electroacoustic performance requirements including:

- Distortion control limits;
- Self generated noise limits;
- Latency limits;
- Frequency response bandwidth; and
- Frequency response smoothness limits.

Design Requirements

The FDA proposes OTC hearing aids meet certain design requirements to ensure both proper physical fit and prevention of user injury via a maximum device insertion depth. The Agency proposes a practical way to describe the depth limit is to base it on the area of the ear canal corresponding to where cartilage meets bone.

Furthermore, the FDA proposes that device eartips be made from atraumatic materials and contain features that enable users to achieve a safe, customized, acoustically favorable, and comfortable physical fit in the ear canal. For example, the manufacturer may wish to provide interchangeable eartips of varying sizes. Manufacturers may elect to include tools, tests, or software allowing the lay user to control the device and customize it to the user's hearing needs.

The Agency welcomes comments, particularly with support from peer-reviewed sources, about other design requirements to limit insertion depth and prevent against injury.

Condition for Sale

The proposed condition for sale is consistent with the Food, Drug, & Cosmetic (FD&C) Act. In this regulation, the FDA proposes to prohibit OTC hearing aid sales to people under age 18. The FDA is seeking comments on how to enforce this ban but is not considering obtaining proof of age as a requirement as that may make obtaining hearing aids more difficult.

Preemption Provisions

Device requirements established by a state that relate to the safety or efficacy of the device are preempted. The FDA has granted exemptions to this policy in the past that allowed states' requirements to apply instead of, or in addition to, FDA's requirements for the following:

- Specifying the physician expertise needed to examine prospective purchasers who are younger than 18 years of age
- Advising purchasers when to seek medical attention based on "red flag" conditions
- Providing purchasers with certain information and disclosures on receipts and other documentation
- Providing written notice of a money-back guarantee where a State court held the State requirement was preempted.

The proposed rule would preempt any state or local requirement specifically related to hearing products that would restrict or interfere with commercial activity involving OTC hearing aids, that is different from the OTC Hearing Aid Controls. The FDA is also interpreting the FDARA to include hearing products generally in the pre-emption and not just hearing aids. However, FDARA does not necessarily preempt state requirements regulating professional services such as speech pathology, audiology, or fitting.

Conditions for Sale

The conditions for sale of hearing aids require a statement of medical evaluation, unless waived by a user aged 18 or older, the availability of a user instructional brochure, and records of the statements of medical evaluation or waiver.

The FDA clarifies that non-OTC hearing aids would be prescription devices and be subject to state and local requirements for obtaining written or oral authorization of a practitioner licensed by state law to administer the use of the devices.

Under the proposed rule, hearing aids that do not meet the definition of, or requirements for, OTC would all be prescription devices and no longer be restricted. Specifically, hearing aids will be either prescription or OTC.

Requirements for professional establishments

Under the proposed rule, the FDA interprets the FDARA as preempting certain kinds of professional or establishment requirements. For example, many states have established definitions for hearing aid fitters, dispensers, or other sellers and servicers. Identification as a hearing aid ‘dispenser’ would not imply licensure. However, identification as an audiologist or hearing aid fitter may imply licensure and be subject to State requirements that apply to audiologists or hearing aid fitters.

An entity that advertises itself as a hearing aid dispenser cannot be required to obtain specialized licenses to engage in selling OTC hearing aids. However, an entity which only sells OTC hearing aids but advertises as a licensed dispenser even though licensing is not required to sell OTC hearing aids would be subject to state or local requirements that apply to licensed dispensers.

FDA proposes to repeal the conditions for sale of hearing aids and replace the current labeling requirements for hearing aids with prescription labeling requirements.

Revised labeling for Prescription Hearing Aids

The FDA proposes the following labeling requirements as necessary to provide reasonable assurance of safety and effectiveness of prescription hearing aids. This includes requiring information for dispensers to ensure necessary warnings are conveyed in an adequate manner for every device. It is also proposed to require the disclosure of certain technical specifications, which is necessary to provide fitters and dispensers information for safe use of the device.

If enacted, the rule would require dispensers to ensure necessary warnings in language that is understandable are conveyed including:

- Possibilities for underlying pathological conditions
- Prohibition of use in people younger than 18 without a medical evaluation
- Injury potential from high output
- Prohibition use in certain pathological “red flag” conditions