

OTC Hearing Aids FDA Final Rule and State Implications

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Critical Background: OTC Hearing Aids

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OTC Final Rule



- The Over-the-Counter Hearing Aid Act of 2017 directed the FDA to create a new category of OTC hearing aids for adults with mild to moderate hearing loss available for use by consumers without professional assistance.
- Final Rule implementing this law was issued on August 16, 2022 with an effective date of October 17th 2022.

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OTC Final Rule Highlights



- Two categories of hearing aids: “OTC” and “prescription”
- OTC hearing aids are defined as “devices 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.”
- No requirement to verify that purchaser is an adult (over 18)
- New federal labeling requirements for both prescription and OTC

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Highlights Continued



- Technical specs for OTC hearing aids (limits on sound output; adjustable volume control; defined device insertion depth; specific warning language inside and outside the box)
- FDA removed federal requirement for medical clearance/waiver for prescription HA
- States may not continue or enact requirements that may restrict or interfere with dispensing of OTC hearing aids—Remove Barriers!

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State Licensure and OTC



- “Audiologist”—protected term in all fifty states—still requires state licensure
- “Hearing aid dispenser”—does not imply licensure
- “Licensed dispenser”—still subject to state regulation

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State Licensure Continued....

- Person who advertises as hearing aid dispenser or seller and **only sells OTC** devices **cannot** be required to obtain state licensure or certification to engage in commercial activity involving only OTC hearing aids

OTC Rule and State Hearing Aid Laws

- FDA is clear that states “may not establish or continue in effect any requirement that would restrict or interfere with the dispensing of OTC hearing aids” –**What does this mean??**
- States currently have laws “on the books” with regard to hearing aids regarding medical clearance/waiver, warranty, receipt, etc. –**What will be allowed to remain?**

State Medical Clearance/Waiver Requirements

- Per FDA Rule; State Medical Clearance/Waiver requirements may continue to exist **FOR PRESCRIPTION HEARING AIDS ONLY**
- This would not “restrict or interfere with commercial activity involving OTC hearing aids.”

Medical Clearance/Waiver

- State laws currently make no distinction between “prescription” and “OTC”!!!
- Two states (RI, NY) w/state laws require medical evaluation without option of waiver
- These were never enforceable when there was a federal provision [more stringent than federal requirement and were preempted]
- But no longer any underlying federal requirement—now valid

Impact on General State Consumer Protection Provisions

- Many States have general consumer protection requirements – applicable to many products
- No intent for final FDA Rule to impact or preempt these general provisions–
- “FDA believes that many State or local consumer protection requirements would not be preempted under section 709(b)(4) of FDARA because they are not “specifically related to hearing products” or would not “restrict or interfere with” commercial activity involving OTC hearing aids

Preemption and State Consumer Protection -- Related to Hearing

- State or local consumer protection requirements specifically related to hearing product are **not** automatically preempted
- “Whether a State or local consumer protection requirement specifically related to hearing products would “restrict or interfere with” commercial activity involving OTC hearing aids would depend on the specific facts.”
- State legislation is preempted if compliance with the state law frustrates the purposes and objectives of federal law”.

State Consumer Protection and Hearing Products

- “However, generally, FDA believes that State or local requirements that provide for a reasonable warranty or return period for hearing aids (e.g., 60-day period) would likely promote, rather than restrict or interfere with, commercial activity involving OTC hearing aids.”
- “Additionally, State or local requirements that provide for reasonable disclosure of the terms of sale in a receipt or similar document would likely promote, rather than restrict or interfere with, commercial activity involving OTC hearing aids by providing important information in writing, such as return or warranty information, to help people with mild to moderate hearing impairment make fully informed purchasing decisions.”

State Questions about Preemption

- States or localities that have questions about preemption may contact CDRH's Ombudsman at cdrhombudsman@fda.hhs.gov or FDA's Intergovernmental Affairs Staff at IGA@fda.hhs.gov, or they may request an advisory opinion under § 10.85 with respect to whether FDA regards a particular State or local requirement as preempted.

Concerns/Clarification



- State laws now only reference “hearing aids”—No distinction between “OTC” and “prescription”— [Intersection with medical clearance/waiver requirement]
- Confusion: “prescription” hearing aid vs. “prescriptive authority”

FDA Guidance/Clarification Needed!!

- Stakeholder meeting and correspondence with FDA
- FDA clarification expected imminently

Other Potential Issues

- Audiology Codes of Conduct in State Practice Acts References to best practices re: hearing aids
- State Sales tax requirements for medical devices—Many states exempt medical devices from sales tax “if sold on a written order provided by an individual who is required to hold, and actively holds, a state license– OTC devices not required to be provided by a state licensed individual!!
- <https://salestaxhelp.com/states-tax-medical-devices>

Moving Forward....

- Adjustment Period
- New market entrants
- State laws/regs out of date / need updating
- State decisions



QUESTIONS?
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