



Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Secretary

**BOARD OF EXAMINERS FOR AUDIOLOGISTS, HEARING AID DISPENSERS,
SPEECH-LANGUAGE PATHOLOGISTS & MUSIC THERAPISTS**

Over-the-Counter Hearing Aids

Effective October 17, 2022 the Food and Drug Administration will begin classifying hearing aids as either “Over the Counter Hearing Aids” (“OTC Hearing Aids”) or “Prescription Hearing Aids.”

OTC Hearing Aids are devices that meet specific criteria located in 21 CFR §800.30 and are intended to assist with perceived mild to moderate hearing impairment.

Prescription Hearing Aids are any device that is not an OTC Hearing Aid. Prescription Hearing Aids are classified as “prescription devices” pursuant to 21 CFR §801.109(a)(2).

Pursuant to 21 CFR §800.30(h) State and local governments are now prohibited from enacting any legislation or regulations that would interfere with the sale or distribution of OTC Hearing Aids including enacting any licensing requirements on individuals who wish to sell or distribute OTC Hearing Aids.

For the full text of the new Federal Rule on OTC Hearing Aids [click here](#).

Please be advised that neither the Board nor Board Staff are authorized to provide legal advice. However, a list of frequently asked questions is posted below.

This flier is intended for informational purposes only.

Frequently Asked Questions:

<u>Hearing Aid Type</u>	<u>Over the Counter (“OTC”)</u>	<u>Prescription (“Prescription”)</u>
<p>What are the differences? (For the full description of the different functions of OTC and prescription hearing aids please consult 21 CFR §800.30)</p>	<p>“OTC” Hearing Aids are intended to assist with perceived mild to moderate hearing impairment.</p>	<p>Prescription Hearing Aids are “prescription devices” that fall outside the definition of “OTC Hearing Aids”.</p>

<p>How will I know if I'm purchasing an OTC Hearing Aid or Prescription Hearing Aid? (For the full description of the different packaging requirements for OTC and prescription hearing aids please consult 21 CFR §800.30)</p>	<p>OTC hearing aids are required to carry outside package labeling containing warnings informing consumers that the hearing aid is for adults with signs of mild to moderate hearing loss.</p> <p>OTC hearing aids are required to have warnings inside the package informing consumers that OTC hearing aids are only intended for use by individuals over 18 years of age.</p> <p><i>*This is not a complete list of packaging requirements for OTC hearing aids. The above is intended for informational purposes only to illustrate some of the ways consumers will know that they are in possession of an OTC hearing aid.</i></p>	<p>Prescription hearing aids are required to carry outside package warnings against use in individuals under 18 years of age without prior medical evaluation.</p> <p>Prescription hearing aids are required to have warnings inside the package informing consumers that individuals under the age of 18 should have a recent medical evaluation.</p> <p><i>*This is not a complete list of packaging requirements for prescription hearing aids. The above is intended for informational purposes only to illustrate some of the ways consumers will know that they are in possession of an OTC hearing aid.</i></p>
<p>How can I get each type of hearing aid?</p>	<p>Beginning October 17, 2022 the Federal government has prohibited States from enacting any restrictions on who may sell or distribute OTC hearing aids.</p> <p>This includes prohibiting States from requiring individuals who wish to distribute OTC hearing aids to submit to any licensing standards.</p> <p>An OTC hearing aid may be available to purchase without any prescription or other order.</p>	<p>Prescription hearing aids are considered “prescription devices” and may only be sold on the prescription or other order of a licensed individual. <i>21 CFR §801.109(a)(2)</i></p> <p>States are responsible for establishing licensing qualifications for individuals who wish to treat members of the public for hearing loss.</p> <p>A licensed professional is able to order a prescription hearing aid based on your individual hearing impairment needs.</p>
<p>Can my audiologist provide me with each type of hearing aid? (For the full text of a licensed audiologist’s scope of practice please consult Code)</p>	<p>At present there are no restrictions on who may or may not distribute OTC hearing aids and effective October 17, 2022, States are prohibited from enacting restrictions on</p>	<p>Prescription hearing aids are considered “prescription devices” and are only sold on the prescription or other order of a licensed individual. <i>21 CFR §801.109(a)(2)</i></p> <p>States are responsible for establishing licensing</p>

<p>of Maryland Annotated Health Occupations §2-101)</p>	<p>individuals who wish to sell OTC hearing aids.</p> <p>The FDA’s stated aim with the October 17, 2022 rule was to increase access to OTC hearing aids to treat perceived mild to moderate hearing impairment.</p>	<p>qualifications for individuals who wish to treat members of the public for hearing loss.</p> <p>Audiologists in Maryland are individuals licensed by the Board to apply the principles, methods and procedures of evaluation, testing, counseling and consultation related to hearing disorders.</p> <p>Audiologists in Maryland are also licensed to fit and sell hearing aids.</p>
<p>Can a hearing aid dispenser provide me with each type of hearing aid? (For the full text of a licensed hearing aid dispenser’s scope of practice please consult Code of Maryland Annotated Health Occupations §2-101)</p>	<p>At present there are no restrictions on who may or may not distribute OTC hearing aids and effective October 17, 2022, States are prohibited from enacting restrictions on individuals who wish to sell OTC hearing aids.</p> <p>The FDA’s stated aim with the October 17, 2022 rule was to increase access to OTC hearing aids to treat perceived mild to moderate hearing impairment.</p>	<p>Prescription hearing aids are considered “prescription devices” and are only sold on the prescription or other order of a licensed individual. <i>21 CFR §801.109(a)(2)</i></p> <p>States are responsible for establishing licensing qualifications for individuals who wish to treat members of the public for hearing loss.</p> <p>Hearing aid dispensers in Maryland are individuals licensed by the Board who perform, conduct and interpret hearing assessment procedures to determine the type and extent of hearing loss for the purpose of selecting a suitable hearing instrument, including hearing aids.</p> <p>Hearing aid dispensers in Maryland are also licensed to sell hearing aids.</p>
<p>I’m not certain which type of hearing aid I require. Can the Board assist me?</p>	<p>The Board cannot assist individual consumers with respect to their own healthcare decisions.</p> <p>OTC Hearing Aids may be purchased without any consultation from either a licensed audiologist or hearing aid dispenser.</p> <p>OTC Hearing Aids are only intended to treat perceived mild to moderate hearing impairment.</p>	<p>The Board cannot assist individual consumers with respect to their own healthcare decisions.</p> <p>OTC Hearing Aids may be purchased without any consultation from either a licensed audiologist or hearing aid dispenser.</p> <p>OTC Hearing Aids are only intended to treat perceived mild to moderate hearing impairment.</p> <p>Members of the public who believe they require assistance from a licensed</p>

	<p>Members of the public who believe they require assistance from a licensed professional may seek care from an audiologist or hearing aid dispenser of their choice. Members of the public may work with a licensed audiologist or hearing aid dispenser to develop a treatment plan tailored to their needs that may or may not include the use of hearing aids to assist with hearing impairment.</p>	<p>professional may seek care from an audiologist or hearing aid dispenser of their choice. Members of the public may work with a licensed audiologist or hearing aid dispenser to develop a treatment plan tailored to their needs that may or may not include the use of hearing aids to assist with hearing impairment.</p>
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