

Over-the-Counter Hearing Aids and You

BY LISE HAMLIN

For years, consumers who need them have balked at the cost of hearing aids. The very devices that, we are told, are vital to our very basic need to communicate with friends and families, help us hold down our jobs and remain vital in our communities, devices that just might stave off dementia and help prevent falls, these hearing devices cost an arm and a leg. With few private health insurance plans covering hearing aids and no coverage under traditional Medicare (although, some Medicare Advantage plans do cover the costs of hearing aids) many of us find ourselves caught between a rock and a hard place. For those of us who have a mild or moderate hearing loss, cost alone might be the reason to delay getting any hearing device at all.

The problem has not gone unnoticed. In 2016, the National Academies of Sciences, Engineering, and Medicine (NASEM) published the report, *Hearing Health Care for Adults — Priorities for Providing Access and Affordability*. In that report, they told us:

Hearing is a vital human sense that is important to communication and health and can affect quality of life. Yet for a variety of reasons, many people with hearing loss do not seek out or receive hearing health care. Estimates of hearing aid use are that 67 to 86% of people who may benefit from hearing aids do not use them, and many hearing assistive technologies as well as auditory rehabilitation services are not fully utilized. Long seen as an issue for individuals (and to some extent their families and friends), there is a growing recognition that hearing loss is a significant public health concern that can be addressed by actions at multiple levels. <https://www.nap.edu/resource/23446/Hearing-RiB.pdf>

After the NASEM report was released, Congress passed, and the president signed into law, the Over-the-Counter (OTC) Hearing Aid Act. Under this new law, OTC hearing aids are defined as devices that use the same fundamental scientific technology as traditional, prescription air conduction hearing aids (not bone conduction) hearing aids. These devices are intended only for adults and only those adults with perceived mild to moderate hearing loss.

The use of the phrase “perceived hearing loss” was intentionally included in the statute. The intent is to



allow adults to purchase these OTC hearing aids without requiring the additional step and the expense of seeking out a hearing health care professional for a hearing evaluation.

OTC hearing aids will be able to allow the user to control and customize the device to his or her own needs without the supervision, prescription or other order from a hearing health care professional, that is, a doctor, audiologist or hearing instrument specialist. That means consumers may choose to eliminate the task of searching for, finding and paying for a hearing health care professional who meets their needs.

In addition, OTC hearing aids will be available to consumers through a wider range of sources than traditional hearing aids: via in-person transactions in a professional's office if they choose, in a big box store or pharmacy, or online. That range of choices will be particularly helpful for consumers who live in rural areas or others with few hearing health care professionals nearby.

Congress gave the Food and Drug Administration (FDA) authority to provide oversight for OTC hearing aids. The FDA drafted a proposed rule that looks at the technical specifications as well as specific instructions for labeling to ensure consumers receive basic information before purchase of these devices. When introducing the proposed rule, the FDA said, "We believe the proposed actions will, in combination, promote and protect the public health by, among other things, providing reasonable assurance of safety and effectiveness of OTC and prescription hearing aids."

In October 2021, the FDA released the proposed rule. The FDA received more than 1,000 comments from a range of stakeholders including consumer organizations, hearing health care professionals' associations, members of Congress and many individuals. The FDA is reviewing those comments and will issue the final rule when they have completed that process. The rule will become effective 60 days after it is published.

I am an adult with mild to moderate hearing loss. Practically speaking, what does all this mean to me?

- Until the final rule is published, nothing changes. OTC hearing aids will not be legally available. HLAA's advice to consumers who see advertisements for devices claiming to be OTC hearing aids are to be very skeptical. At a minimum they are not correctly identifying their product: the FDA has made it very clear that this classification won't exist until after the

rules are finalized by the FDA. <https://www.fda.gov/medical-devices/consumer-products/hearing-aids>

- If you want and need hearing aids, don't wait. Go to your hearing health care professional to find the best solution for your hearing needs.

Once the FDA issues final rules, if you have a mild to moderate hearing loss, you have options available to you:

- You will still be able to turn to a hearing health care professional to guide you in the process of selecting a hearing aid. We expect that many hearing health care professionals will be ready and able to fit consumers with OTC hearing aids. If you are an adult with mild to moderate hearing loss and would prefer to work with an audiologist or hearing instrument specialist, ask the professional whether they sell and fit OTC hearing aids.
- If you feel confident doing the research needed and comfortable selecting your own OTC hearing aid, you will have the option of following that path. If you are on your own, be sure to research both the products and companies that make these devices to ensure that the product you purchase works for you. Also be sure to understand the return policy and how to return the device in case it does not work for you.

I am an adult with greater than a moderate hearing loss. Practically speaking, what does this mean to me?

- The law that provides for OTC hearing aids does not change a thing for people with greater than moderate hearing loss: you will still need to turn to a hearing health care professional licensed in your state to dispense a "prescription" hearing aid. Still, it pays to do your homework before purchasing hearing aids. Know what questions to ask your hearing health care professional, know what you want from your hearing aid and what's realistic for that hearing aid to deliver. There is a wealth of information on the internet to help you, including information on our own website: Hearing Aids (hearingloss.org)

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