



Order on Over-the-Counter Hearing Aids Released

On July 9th, 2021, President Biden passed an executive order allowing over-the-counter hearing aids (OTC) to be sold as newly regulated devices for adults with perceived **mild to moderate hearing loss**. A person with **moderate to profound hearing loss still needs to seek the services of a hearing health care provider** and the proper technology to improve the patient's listening needs.

Basically, President Biden has allowed for the invention of the “reader glasses” version of hearing aids for people who have a mild hearing loss.

NOTE: OTC have long been on the market for many years, through big box stores and even online. Traditionally called PSAPs (personal sound amplification system), this order mandates FDA regulation.

FDA regulation is mandated and critical because these are medical devices that need to be safe and effective for the user to wear. Safety concerns include dangerous volume levels that could harm your hearing, or electronic malfunctions while wearing the device. The device needs to work, but most importantly it needs to be safe to use. All traditional hearing aids are already regulated by the FDA.

Regulations should be clarified in the next 120 days. Now Hear This® (NHT) is excited to hear about this new order as people who need **entry level aids** will be able to get the help that they need in an affordable and convenient manner. NHT is looking forward to being a leader in providing OTC hearing aids to our community. This not only provides entry level aids for people with mild hearing loss in an affordable and convenient manner, but it also means that the consumer has the added benefit of being supervised by a Doctor of Audiology.

Elaboration from the American Academy of Audiology

According to the U.S. Dept. of Health & Human Services' NIH/NIDCD, approx. 28.8 million U.S. adults could benefit from hearing aids. The Academy is hopeful that many of these consumers suffering from hearing loss will seek the assistance of an audiologist and when deemed to be appropriate, will either try over-the-counter hearing aids and/or consider devices that are recommended, prescribed, and verified by an audiologist. It is important to understand that hearing loss is more complex than a lack of volume; thus, management of hearing loss is best after a comprehensive hearing assessment conducted by an audiologist. Audiologists are highly educated to determine the cause of hearing loss, refer for medical intervention when necessary, and implement an effective management plan, which often is more than simply increasing the volume through a device.

Common Questions about Over-the-Counter Hearing Aids

Are OTC hearing aids available for sale yet?

They are not available for purchase yet. Anything you find at a store is currently not a hearing aid, but a stock amplifier device that is not a regulated FDA medical device.

What's all this talk about hearing aid pricing?

The media is marketing this bill as a way to prevent healthcare providers from “price gouging”. Audiologists, as a profession, cannot price gouge as we cannot bill insurance for our professional fees, counseling, or cerumen removal services. The only billable service for audiologists is the hearing test itself, and Medicare will only pay about \$37 for this hour-long service. Audiologists make up this cost by providing valuable patient care and service in the hearing aid fitting process and in follow up care. Unfortunately, pharmacies and big box stores are not able to provide the same level of care. It's important that people with hearing loss choose their Audiologist carefully so that the person programming their aids

is using best practices and the best technology on the market today. People with hearing loss need to know exactly what they need so they can receive proper treatment and care.

This executive order was marketed in a way to make hearing aids appear more affordable. However, most people who do their research learn that hearing aid pricing today is very affordable and that most reputable clinics have a hearing aid plan that will work with almost any budget.

While the type of hearing aid chosen by the patient and their Audiologist is critical in getting them to *hear their best*, the programming by the Audiologist is equally as important and should not in any way be circumvented. The Audiologist **must** be skilled at programming aids and **must** be using verification software that includes Real Ear Measurements. Each hearing aid recommendation should be based on the individual patient's lifestyle and listening needs and not the cost of the aids.

Is there any risk when purchasing these OTC products?

Yes! Hearing loss is not always easily treatable. Bypassing the professional recommendations of an Audiologist could result in an important missed diagnosis or treatment that can be very serious such as an acoustic tumor, earwax, eardrum issues, and more. NHT will be a lead seller of an array of OTC aids manufactured by reputable manufacturers that we know are safe and regulated for people to use and wear *on a daily basis*. Our patients will be able to safely wear OTC hearing aids while at the same time get the professional hearing care and treatment they deserve and need.

Is this a solution for people who cannot afford hearing aids?

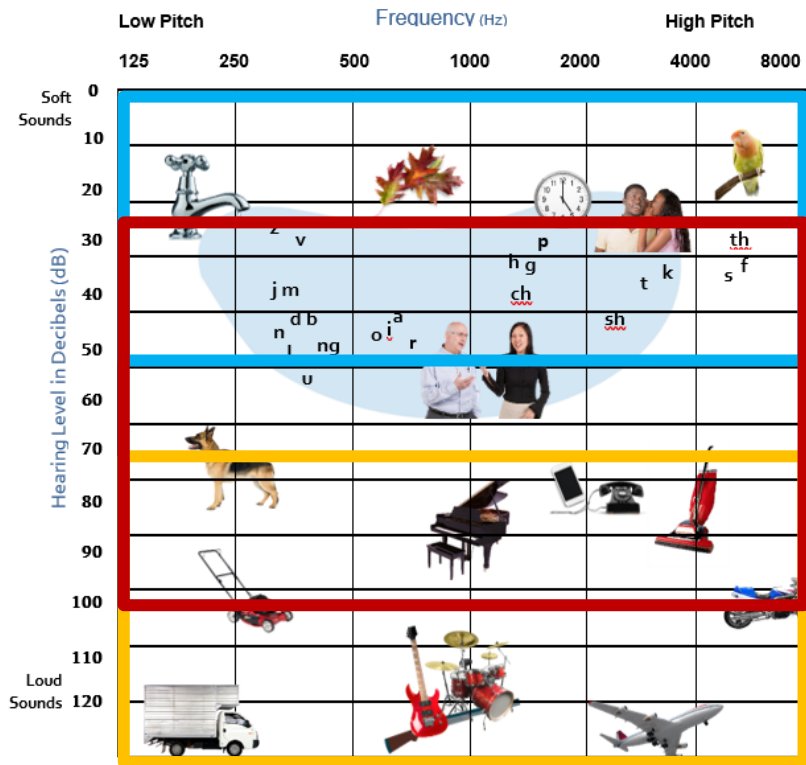
No. OTC aids are only a solution for people who have mild hearing loss. People who have a significant amount of hearing loss and cannot afford hearing aids have a variety of options available to them to get the hearing devices they need according to their hearing loss levels. NHT has the means and connections to recommend patients with little or no financial means to reputable resources so they able to obtain the hearing devices they need.

See Below for a Visual of the Range of Hearing Devices

PSAPS /
OTCs

Hearing
Aids

Cochlear
Implants



More
Affordable

Less Hearing
Loss

Greater
Investment

More Hearing
Loss

Now Hear This® is dedicated to providing honest and valuable hearing loss and hearing aid research to our community. For questions, call us or email us at your convenience at **919.256-2898** or **info@NowHearThisClinic.com**. You can also visit our website at www.NowHearThisClinic.com. We are conveniently located at: 4701 Creedmoor Road, Suite 111 in Raleigh, NC