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OTC Sales Of Hearing Aids For Mild To Moderate Loss Allowed Under US FDA Final Rule

by [Brian Bossetta](#)

After requirement from Congress and push from President Biden, FDA establishes regulatory category for hearing aids to allow US consumers with mild to moderate hearing loss to purchase the devices without a prescription or prior exam.

After years in the making, the US Food and Drug Administration has established an OTC category for hearing aids to allow consumers to purchase the devices at stores or online.

OTC access, which will help the nearly 30m US consumers the National Institutes of Health say could benefit from a hearing aid, will take effect as early as mid-October.

The category allows adults to purchase the devices without a prescription or consultation with an audiologist.

The FDA says its final rule, [Establishing Over-the-Counter Hearing Aids](#), will improve access to “safe, effective, and affordable” hearing aids for millions of Americans.

The new rule goes into effect 60 days from publication in the Federal Register scheduled for 17 August.

Although the category is limited to basic hearing aids designed for mild to moderate hearing loss and not more complex devices for severe hearing impairment, it will be broad enough to help to most Americans with trouble hearing.

Roughly 94% of US consumers with trouble hearing have a mild to moderate case, said Christian Gormsen, the CEO of hearing aid manufacturer Eargo, in July. For those people, OTC availability

is “a relatively simple fix,” he said. (Also see "[Eargo CEO ‘Enthusiastic’ About Pending OTC Hearing Aid Sales](#)" - Medtech Insight, 15 Jul, 2022.)

“When too few companies dominate, American consumers pay higher costs.” – President Biden

After reviewing nearly 1,000 comments on a draft before issuing the final rule, the FDA made a few changes to the category from its proposed rule issued in October 2021, such as lowering the maximum sound output, revising the insertion depth limit, and requiring that the OTC devices have a user-friendly volume control feature and product labeling.

Proponents of the category have argued that OTC availability not only will make the hearing aids less of hassle, but less expensive. And for many, that’s key.

A pair of hearing aids with a professional exam and fitting can run as much as \$4,000 to \$6,000 – and since they are not covered under Medicare, many who need them most either cannot afford them or choose to go without.

President Biden called for establishment of the OTC category in a July 2021 executive order. In a statement, he said the FDA’s final rule will deliver nearly \$3,000 in savings on a pair of hearing aids, while boosting competition in the marketplace.

Four of the largest hearing aid manufacturers control 84% of the market, according to the White House. “When too few companies dominate, American consumers pay higher costs,” Biden said.

David Akbari, senior medical science, regulatory and clinical affairs liaison at Intricon Corp., said the FDA opened the door for “quality and affordable” hearing aids.

“These actions reflect the FDA's commitment to safely lowering barriers to entry, providing Americans with greater access at lower prices and will facilitate innovation in hearing aid technology,” Akbari said.

Long Time Coming

Biden’s executive order jump started the plan to create an OTC hearing aids category, which began in 2016 when the classification was proposed in a report from the National Academies.

In 2017, Congress passed bipartisan legislation requiring the FDA to establish the category, giving the agency until 2020 to issue the guidelines for the OTC sales category. But the agency failed to meet that timeline and the initiative stalled.

Hearing Industries Association strongly supports the final rule but recommends consumers with hearing loss consult a professional to “determine the cause and severity of the hearing loss.”

The FDA says only one-fifth of US consumers with hearing loss get help, leaving many with a condition that, though treatable, can greatly cut down on quality of life.

Hearing loss has long been linked to depression and cognitive decline.

"Hearing loss is a critical public health issue that affects the ability of millions of Americans to effectively communicate in their daily social interactions," said FDA Commissioner Robert Califf.

Industry Reaction Mixed

While lawmakers and patient advocacy groups have largely embraced the OTC proposal, industry reactions have been a mixed bag, with some expressing concern about those with hearing loss purchasing hearing aids without the benefit of seeing an audiologist beforehand.

Some were even hostile to the move and have tried to stop it, according to Sens. Elizabeth Warren, D-MA, and Chuck Grassley, R-IA. In July, the senators accused the “dominant” hearing aid manufacturers of submitting fraudulent comments to the FDA to undercut the OTC proposal.

Those comments – nearly half the FDA received on its proposed rule – were written under the guise of ordinary citizens, the senators charged, but in fact were submitted by industry, such as Starkey, the largest player in the hearing aid space.

Although Starkey didn't address the senators' allegations that it submitted fake comments, CEO Brandon Sawalich said he agreed the OTC category would further increase access to hearing health. But he added, “We must also follow the science to ensure patient safety and satisfaction.” (Also see “[US Lawmakers: Hearing Aid Manufacturers Tried To Undermine OTC Proposal](#)” - Medtech Insight, 5 Jul, 2022.)

The Hearing Industries Association (HIA), which represents hearing aid manufacturers,

suppliers, distributors, and hearing health professionals, said it strongly supports the final rule, though it recommends those with hearing loss still consult a professional to “determine the cause and severity of the hearing loss.”

HIA president Kate Carr said hearing loss is unique to each person and most with hearing impairment do not know whether theirs is mild or moderate or perhaps severe, which is often caused by a separate medical issue. However, Carr added, the final rule represents a “significant step forward for the millions of Americans who suffer hearing loss yet are untreated.”

Blake Cadwell, founder and CEO of online hearing aid sales and testing firm Soundly Inc., said the final rule will change the hearing health landscape while significantly increasing access to better hearing health. He, too, said audiologists will remain critical for those looking improve their hearing.

“Now the real work will be education consumers on their options in a more complex market,” said Cadwell, who launched Soundly after the FDA published its proposed rule in October 2021. (Also see "[US Proposed OTC Hearing Aid Rule Inspired Soundly Founder To ‘Make This Process Easier’](#)" - HBW Insight, 15 Aug, 2022.)

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