

# F.D.A. Clears Path for Hearing Aids to Be Sold Over the Counter

The agency's action opens the door to cheaper, more accessible devices without a prescription or medical exam.

By [Christina Jewett](#)

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The Food and Drug Administration decided on Tuesday to allow hearing aids to be sold over the counter without a prescription to adults, a long-sought wish of consumers frustrated by expensive exams and devices.

The high cost of hearing aids, which are not covered by basic Medicare, has discouraged millions of Americans from buying the devices. Health experts say that untreated hearing loss can contribute to cognitive decline and depression in older people.

Under the F.D.A.'s new rule, people with mild to moderate hearing loss should be able to buy hearing aids online and in retail stores as soon as October, without being required to see a doctor for an exam to get a prescription.

The agency cited studies estimating that about 30 million Americans experience hearing loss, but only about one-fifth of them get help. The changes could upend the market, which is dominated by a relatively small number of manufacturers, and make it a broader field with less costly, and perhaps, more innovative designs. Costs for hearing aids, which tend to include visits with an audiologist, range from about \$1,400 [at Costco](#) to [roughly \\$4,700](#) or more.

"This could fundamentally change technology," said Nicholas Reed, an audiologist at the Department of Epidemiology at Johns Hopkins Bloomberg School of Public Health. "We don't know what these companies might come up with. We may literally see new ways hearing aids work, how they look."

The F.D.A.'s final rule takes effect in 60 days. Industry representatives say device makers are largely ready to launch new products, though some may need time to update labeling and packaging or to comply with technical details in the rule.

Dr. Robert Califf, the F.D.A. commissioner, said the move is meant to "unleash the power of American industry" in a way that could have global influence.

"Hearing loss has a profound impact on daily communication, social interaction and the overall health and quality of life for millions of Americans," Dr. Califf said during a news briefing. "This is a tremendous worldwide problem where I think American ingenuity can make a huge difference."

The White House hailed the move as a signature accomplishment for President Biden, who signed the Inflation Reduction Act on Tuesday. That legislation includes other health measures, [like caps on prescription drug costs for Medicare beneficiaries](#), that are likely to be popular among midterm voters.

The hearing aid change eliminates the requirement to see an audiologist for a hearing examination and fitting, a process not often covered by insurance. Federal officials estimated a \$2,800 savings on the cost of a pair of hearing aids. Brian Deese, White House director of the National Economic Council, said making the change was a “top priority” for the president.

“This is going to make a really concrete difference in the lives of millions of Americans,” Mr. Deese said.

Whether it will make a difference at the voting booth remains to be seen, said Jonathan Oberlander, a professor of health policy at the University of North Carolina. He termed the F.D.A.’s move a “consolation prize” of sorts, given the Democrats’ unsuccessful efforts to expand basic Medicare to cover vision, dental and hearing. The upside, though, is that some of the hearing aids should be on store shelves by the time voting begins.

Hearing loss is associated with [dementia](#), isolation and other health problems in older adults. Yet the barriers to getting hearing help have included costs that are not covered by Medicare. There is also stigma — such as appearing “old” — that comes with use.

April Shrum, 45, of Bremerton, Wash., has been willing to get hearing aids for years, but has been unable to get them covered by her insurance. She said she lost some hearing firing guns while training to deploy to Iraq about a decade ago. But her hearing loss never tested to a level that qualified her for coverage.

“I don’t have to have a prescription for it,” Ms. Shrum said, “which means I can buy them myself and it’s fantastic.”

Broader appreciation for the importance of keen hearing for adults is off-kilter: [A recent survey](#) found that people aged 50 to 80 were twice as likely to plan on taking their pet to the veterinarian in the coming year than to get their hearing checked.

“It breaks my heart a little bit,” said Sarah Sydlowski, associate chief improvement officer of the Cleveland Clinic’s Head and Neck Institute and lead author of the study. “I think our biggest challenge as a profession and as a health care system is to make sure that people understand that hearing is incredibly important. It deserves their attention, it deserves their action.”

The over-the-counter shift has rankled some of the nation’s audiologists, the professionals who guide people through the process of choosing the best hearing aid, adjusting the settings and achieving the right fit. The new move eliminates the longstanding requirement that consumers start the process of getting a hearing aid with them. But some in the profession see opportunity.

“The hearing health care professional is not going to go away,” said Barbara Kelley, executive director of the Hearing Loss Association of America, a consumer group. “The over-the-counter rule opens a new avenue that is huge for adults with mild to moderate hearing loss to take that step sooner than later. And that’s what we’re really excited about.”

The change has been percolating for years. In 2016, a proposal for the F.D.A. to approve over-the-counter hearing aids for adults with mild to moderate hearing was released in a [report](#) by the National Academies of Science, Engineering and Medicine. The following year, Senators Chuck Grassley, a Republican of Iowa, and Elizabeth Warren, a Democrat of Massachusetts, introduced a bill enabling the agency to make the change. Congress approved the legislation and President Trump [signed it into law](#).

Finalizing regulations has moved slowly since then, with some conflict over details, like how the federal rule would interact with state laws on hearing aid returns or warranty policies and how much the devices should amplify sound.

Mr. Biden issued an executive order last July calling for greater competition in the economy, which urged the F.D.A. to take action “to promote the wide availability of low-cost hearing aids.”

That rule [was issued](#) in the fall of 2021, followed by a period of public comment. The Hearing Industries Association, an industry group, submitted a 45-page [comment letter](#) warning the F.D.A. about companies that had come on the market in 2018, after the initial law passed, selling hearing aids that “were ineffective, of poor quality, and in some cases, dangerous.” The organization offered detailed advice on how to avoid a repeat scenario.

“We applaud the action to increase access to care for persons who have difficulty and encourage them to seek a professional,” to help navigate their options and the fitting process, said Kate Carr, president of the trade group. Other organizations raised concerns that the F.D.A. would be creating a safety issue by allowing new hearing aid makers to develop devices that allow users to hear loud sounds.

Senators Warren and Grassley released [a joint report](#) accusing the “dominant hearing aid” makers of engaging in an “astroturf lobbying” effort by flooding the F.D.A. with repetitive comments steering the agency toward a new generation of hearing aids that would be “less effective, protecting manufacturers’ existing market share and locking in their competitive advantage.”

“The logic is simple: The less effective an O.T.C. hearing aid is, the more likely consumers will be forced to abandon these options and instead opt for more expensive, prescription devices sold by the manufacturers that dominate this line of business,” the senators’ investigative report said.

The F.D.A. reviewed more than 1,000 comments submitted about the rule and made a handful of changes in the final version released on Tuesday. They include lowering the maximum sound output of the devices and revising the insertion depth limit in the ear canal. The rule also requires

that the hearing aids have a user-adjustable volume control and simplified wording on the product label.

John Prouty, 65, said on Tuesday that he would be watching the changes in the hearing aid field carefully. He said he recently underwent a test and discovered he had experienced some hearing loss.

“I don’t think it has had a huge effect on my ability to understand and stay in a conversation,” Mr. Prouty, of Santa Rosa, Calif., said. “My wife may disagree.”

He said he was not ready for hearing aids and felt even less so after finding out the devices would cost up to \$8,400 for a pair and services. Mr. Prouty welcomed the new policy, saying he hoped it would encourage the kind of consumer electronic advances that had revolutionized phones and watches.

“I’m looking forward to this,” he said.