Lower cost hearing aids sold over-the-counter will reach more people, prevent other medical problems

The Hearing Aid Act gives the FDA three years to create a plan to regulate over-the-counter hearing aids, which might make hearing aids accessible to more people. (Kenneth K. Lam, Baltimore Sun video)

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When Marilyn Witt was fitted for her first pair of hearing aids a few weeks ago, she was stunned by the nearly $7,000 price tag.

The sticker shock was so bad the 73-year-old retiree from Elkridge contemplated just going without the devices.

“It’s outrageous,” she said. “When they told me the price I almost passed out.”

Federal legislation passed earlier this year aims to make hearing aids more affordable for people like Witt, who are elderly and have fixed incomes, by allowing some styles of the devices to be sold over-the-counter at drugstores and other retailers. The new law allows hearing aids for people with mild to moderate hearing loss to be sold at retailers and not through an audiologist — much like low-prescription “reader” eyeglasses are sold.

The legislation gives the U.S. Food and Drug Administration three years to develop standards for the over-the-counter devices before they can go on sale.

Supporters of over-the-counter hearing aids say it will increase competition and drive innovation, resulting in lower prices. But medical experts worry that people will self-diagnose hearing conditions instead of seeking the guidance of an audiologist, who is trained to evaluate hearing loss and help patients get the right hearing aid.
“It’s a double-edged sword,” said Dr. David Eisenman, an associate professor at the University of Maryland School of Medicine who specializes in otolaryngology — head and neck surgery. “I have no doubt that it will make it more accessible, but I would be very concerned it would lead to a lot of scams, and poor health outcomes and the like.”

**Medicare**, the federal health insurance program for people 65 or older and certain younger people with disabilities, does not cover the cost of hearing aids for older adults because of a 1960s era law prohibiting such coverage. At the time, there was little known about various health problems hearing loss can lead to, including dementia, depression, and a propensity to fall. Most private insurance also doesn’t pay for the devices, and in Maryland children enrolled in the state health insurance program are only covered until age 21. As result, many people who need hearing aids are going without the devices.

In the United States, 28.8 million adults could benefit from using hearing aids, according to the National Institute on Deafness and other Communication Diseases. Yet among adults age 70 and older, only about 30 percent have ever used the devices. About 16 percent of adults ages 20 to 69 who need a hearing aid have ever used one.

While costs are a significant factor, some elderly people don’t get hearing aids because they’re in denial about having hearing problems or have gotten used to living with it and don’t realize their hearing has worsened. Others think diminished hearing is part of the aging process and are not aware that it can lead to other health problems. Then there are those who just find the devices uncomfortable.

“Right now one of the barriers ... is costs because so many individuals are getting their healthcare through Medicare,” said Erin Stauder, executive director of the Hearing and Speech Agency of Baltimore, a nonprofit that provides hearings services on a sliding scale based on income.

The agency helped Witt pay for her device. Her cost was $3,500, or about half the price she was originally quoted.

“The price they gave me was a lot less, otherwise, I don’t know what I would have done,” Witt said.
Supporters of over-the-counter devices say more people should use hearing aids because untreated hearing problems can lead to more severe health issues.

Frank Lin, an associate professor of otolaryngology — head and neck surgery at Johns Hopkins University School of Medicine, has conducted research that shows mild hearing loss doubles the risk of getting dementia, while moderate loss triples the risk and severe loss increases the risk by five times.

The ear may send garbled signals to the brain making it work harder to process sound, he said. Hearing loss also may lead to faster rates of atrophy in parts of the brain.

“Now we have one model of hearing care and that is it,” Lin said. “Not everyone wants to go back and forth to an audiologist and pay a lot of money. Some people without a doubt really do need a lot of hand-holding and guidance provided by a professional. Other people do not need to see me about using a hearing aid.”

Barbara Kelley, executive director of the Hearing Loss Association of America and a proponent of over-the-counter devices, said the bill is not meant to diminish the role of audiologists.

“I think there is always going to be a need for an audiologist,” Kelley said. “There will be a need for fittings for people with more severe hearing loss.”

The new law requires the FDA to write regulations ensuring that this new category of over-the-counter hearing aids meets the same high standards for safety, consumer labeling and manufacturing protections as all medical devices. Hearing devices currently sold over the counter are not allowed to be called hearing aids and are not regulated by the FDA.

Stauder at the Hearing and Speech Agency welcomes more standards.

“We are in support of the FDA regulations to make sure the devices are safe for the consumer,” Stauder said. “As advocates for those with communications challenges of all kinds, we are encouraged by greater dialogue around hearing health and the need for high safety standards.”

Julie Norin, an audiologist with the Hearing and Speech Agency, remains concerned about people self-diagnosing. She believes even people with mild to moderate hearing loss should work with a specialist to help with fittings and avoid getting hearing aids that either under amplify or over amplify sound.
“We consider hearing loss to be a health issue and you need the guidance of a specialist or professional just as you would with any kind of a treatment of an illness,” Norin said.

Some deaf and hard-of-hearing people aren’t completely sold on over-the-counter hearing aids.

Brian McBride, a 21-year-old student who lives in Baltimore and was born with severe hearing loss in both ears, said he would rather have a specialist help him with the complicated process of finding the right hearing aids.

“There is testing and fitting services that I would rather get than going through the hassle of doing it myself,” he said.

But he acknowledged more effort is needed to reduce the costs.

“I do believe there should be some way to bring the costs down,” he said. “I am not sure how to do that outside of government programs, but something should be done.”

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