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— a market of tens of millions of people, many of whom have until now avoided getting help because devices were so expensive.v

Oct. 19, 2022



By Phil Galewitz, Kaiser Health News (TNS).

Starting this week, consumers are able to buy hearing aids directly off store shelves and at dramatically lower prices as a 2017 federal law finally takes effect.

Where for decades it cost thousands of dollars to get a device that could be purchased only with a prescription from an audiologist or other hearing professional, now a

new category of over-the-counter aids are selling for hundreds of dollars. Walmart

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new market to shake out as manufacturers and retailers get accustomed to selling aids and consumers become familiar with the options.

Hearing care experts say they are pleased to see the lower prices. Lin said he believes prices will fall further as more competitors enter the market in the next two years.

Prices and features will vary for the new OTC hearing aids — much as they do for prescription aids. A pair of prescription devices typically sells for \$2,000 to \$8,000. Some of the technology found in the pricier prescription aids will be available in the cheaper OTC aids.

The OTC aids cost less partly because they do not bundle the services of an audiologist for a hearing evaluation, fitting, and fine-tuning the device. Instead, the new devices are intended to be set up by the consumers themselves, although manufacturers will offer technical assistance through apps and by phone.

Some new companies have entered the market, [including Sony](#). It will sell its lowest-cost, self-fitting OTC hearing aid for \$999 at Best Buy and other retailers.

Walmart said it will offer an assortment of OTC hearing aids, including some at \$199 to \$299 per pair from the South Africa-based company hearX, which also makes Lexie devices. Initially, the devices will be available at Walmart stores in Colorado, Michigan, Missouri, Ohio, Pennsylvania, Tennessee, and Texas. But the company expects to make them available nationwide soon.

[Walgreens will offer the Lexie Lumen](#) OTC hearing aid for \$799 a pair. The offerings at Walgreens, CVS, Best Buy, and Walmart will also include a Lexie hearing aid developed in [partnership with Bose](#).

Costco, one of the largest sellers of hearing aids dispensed through a hearing professional, would not reveal whether it will offer any over the counter.

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for-service Medicare and most health insurers cover routine hearing tests. But Medicare and most private insurers don't cover the cost of hearing aids, although many private Medicare Advantage plans do.

Consumers can also take hearing tests online or through an app on their phone or computer, Lin said.

Another factor that could fuel demand for the new devices is that the stigma of wearing a hearing aid is diminishing because people commonly use ear devices to listen to music.

More than **37 million American adults** have trouble hearing, and only **1 in 4 adults** who could benefit from a hearing aid have used one, federal health officials estimate.

The hearing aid industry has remained largely insulated from price competition because of consolidation among manufacturers, widespread state licensing laws that mandate sales through audiologists or other hearing professionals, and the acquisition of hearing professionals' practices by device-makers.

Spurred by decades of complaints about the high cost of hearing aids, Congress in 2017 ordered the Food and Drug Administration to set rules that would enable over-the-counter sales, with hopes it would boost competition and lower prices. But the covid pandemic slowed the FDA effort, and last year President Joe Biden ordered the FDA to produce those rules. The final regulations **were announced two months ago**. Under the federal rules, the new category of hearing aids bypasses state dispensing laws.

Audiologists, who could lose business, caution that the new category won't help people with severe hearing loss. And over-amplifying sound can damage hearing, said **Sarah Sydlowski**, past president of the American Academy of Audiology.

However, [Nicholas Reed](#), an audiologist and assistant professor at the Bloomberg

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Reed recommends looking for OTC hearing aids with generous return policies, exceeding a month. Consumers may want to try a device for a few weeks to see how it works. If one brand doesn't work, they should try another.

Switching may be necessary, since it's unclear whether consumers will get in-store help in selecting an aid without an audiologist. Some stores plan to provide assistance. Walmart said it would include information on its website to help people find devices that are right for them.

Reed also said consumers should look for devices labeled as "self-fitting" because it shows the companies have proved to the FDA that people can set up these devices themselves about as well as if they had professional help.

"If you are tech savvy, then I say jump right in," Reed said, though noting "there is nothing wrong with talking to a trained audiologist."

Nancy M. Williams, president of Auditory Insight, a hearing health care management consulting firm, said she reviewed eight major OTC hearing aid products, from \$499 to \$1,299. Some look like earbuds or are nearly invisible, while some look like traditional hearing aids that wrap around the ear. The OTC aids she reviewed largely have limited or no Bluetooth connectivity, a feature that allows users to customize the devices, and only about half have rechargeable batteries. But all eight allow the user to personalize the devices based on the results of their hearing test.

She recommends that people try at least three OTC aids to see which works best for them.

The American Academy of Audiology, a professional organization for audiologists, posted [information online for consumers](#) about OTC hearing aids, and the Hearing Loss Association of America, a consumer advocacy group, also has [online advice](#).

Barbara Kelley, executive director of the Hearing Loss Association of America, said

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an endowed nonprofit organization providing information on health issues to the nation.)

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