

## The Over-The-Counter Hearing Aid Act of 2017: Increasing the Accessibility and Affordability of Hearing Aids in the U.S.

### Key Points:

- Hearing loss is treatable, but there are significant barriers to accessing care.
- Americans with hearing loss can only obtain hearing aids from a licensed provider because of federal medical device regulations for hearing aids written >40 years ago.
- The average pair of hearing aids costs \$4700 and hearing aids remain inaccessible and unaffordable to the vast majority of Americans.
- The Over-the-Counter Hearing Aid Act was passed with bipartisan support in 2017 and requires the Food and Drug Administration to create a regulatory classification for over-the-counter hearing aids that will allow Americans to have direct access to safe and effective hearing technologies.
- The Food and Drug Administration was statutorily required to release regulations for over-the counter hearing aids in August 2020 but has delayed release because of the COVID-19 pandemic.

**Current Food and Drug Administration regulations for hearing aids were written over 40 years ago.** FDA regulations for hearing aids written in 1977 require hearing aid sales to go through a licensed provider because hearing aids then were only safe and effective if programmed by a licensed provider<sup>1</sup>. These regulations have not been updated in the intervening 40 years despite technological advances that would allow properly designed hearing aids to be safely and effectively used by adults with hearing loss without the need for a licensed provider<sup>2,3</sup>.

**Current hearing aids are expensive and inaccessible to most Americans.** Less than 20% of adults in the U.S. with hearing loss report hearing aid use. A big reason for undertreatment of this common and treatable condition is that the average cost for a pair of hearing aids is \$4,700, and hearing aids can only be obtained through a hearing care provider<sup>1</sup>. Historic FDA hearing aid regulations contributed to a market where five hearing aid manufacturers control >90% of the world hearing aid marketplace. Consumer technology (e.g., Bose, Samsung) and other companies wishing to develop hearing aids that could be safely and effectively used by consumers without the need for a hearing care provider are not permitted to market or sell these technologies to consumers under current federal hearing aid regulations.

**The bipartisan Over-The-Counter Hearing Aid Act was passed in 2017.** In response to recommendations from the White House<sup>4</sup> and the National Academy of Medicine<sup>1</sup>, the Over-the-Counter Hearing Aid Act passed with bipartisan support as a rider to the Food and Drug Administration Reauthorization Act and was signed into law in 2017. This law requires the FDA to develop a separate regulatory classification and standards for over-the-counter hearing aids that are intended for adults with perceived mild-to-moderate hearing losses. These regulations will help:

- Ensure that any hearing aid that is purchased over the counter could be safely and effectively used by a consumer without a hearing care provider.
- Spur greater market competition, affordability, and innovation in hearing technologies available to consumers.
- Eliminate the confusing market that now exists for unregulated and ineffective personal sound amplifiers that are often inappropriately marketed and sold directly to consumers as treatments for hearing loss.

**The FDA was statutorily required to release over-the-counter hearing aid regulation in August 2020.** Release of the federal regulations for over-the-counter hearing aids has been delayed because of the COVID-19 pandemic. Ensuring that the FDA meet its statutory responsibility to release these regulations is important to address the intent of Congress, the White House, and the National Academy of Medicine to create a regulatory system for hearing aids that could spur innovation and increase the accessibility and affordability of hearing aids for millions of Americans with hearing loss.

## References

1. National Academies of Sciences, Engineering, and Medicine. 2016. Hearing Health Care for Adults: Priorities for Improving Access and Affordability. Washington, DC: The National Academies Press. <https://doi.org/10.17226/23446>.
2. Reed NS, Betz J, Kendig N, Korczak M, Lin FR. Personal Sound Amplification Products vs a Conventional Hearing Aid for Speech Understanding in Noise. *JAMA*. 2017;318(1):89–90. doi:10.1001/jama.2017.6905
3. Humes LE, Rogers SE, Quigley TM, Main AK, Kinney DL, Herring C. The Effects of Service-Delivery Model and Purchase Price on Hearing-Aid Outcomes in Older Adults: A Randomized Double-Blind Placebo-Controlled Clinical Trial. *Am J Audiol*. 2017 Mar 1;26(1):53-79. doi: 10.1044/2017\_AJA-16-0111. Erratum in: *Am J Audiol*. 2019 Sep 13;28(3):730. PMID: 28252160; PMCID: PMC5597084.
4. Summary: President's Council of Advisors on Science and Technology letter report investigated age-related mild to moderate hearing loss. <https://obamawhitehouse.archives.gov/blog/2015/10/26/%E2%80%8Bpcast-recommends-changes-promote-innovation-hearing-technologies>

## About Us

At the Johns Hopkins Cochlear Center for Hearing and Public Health, we are training a generation of clinicians and researchers to study the impact that hearing loss in older adults has on public health, and to develop and implement public health strategies and solutions for hearing loss in the US and globally.

We approach our work with the foundational understanding that strategies and solutions that allow older adults with hearing loss to communicate and effectively engage with their environment are fundamental to optimizing human health and aging.

## For more information on hearing loss, hearing device legislation, and hearing care and Medicare:

### *Cochlear Center Fact sheets:*

- Hearing Loss in the US: Increasing, Undiagnosed, Undertreated
- Hearing Loss and Dementia: How Are They Related?

### *Cochlear Center Policy briefs:*

- The Over-The-Counter Hearing Aid Act of 2017: Increasing the Accessibility and Affordability of Hearing Aids in the U.S.
- Overview of Medicare Coverage for Hearing Treatment: Inadequate and Ready for Improvement
- Proposals for Medicare hearing care coverage: To be Effective, They Must Distinguish Between - and Cover - Both Hearing Care Services and Hearing Aids

Available at [www.jhucochlearcenter.org](http://www.jhucochlearcenter.org)

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