

2017 Legislative Update

The end of 2016 saw significant changes designed to improve accessibility to hearing aids for the public. Here's a summary of this activity, and the impact it may have on your patients who need audiology services or hearing aids.



FDA Removes Requirement for Medical Evaluation/Waiver

In early December 2016, the FDA announced important steps to better support consumer access to hearing aids, issuing a guidance document explaining that it does not intend to enforce the requirement that individuals 18 and over receive a medical evaluation or sign a waiver prior to purchasing most hearing aids. This guidance was effective immediately. Medical clearance requirements for children remain in effect.¹

A medical evaluation was viewed as a barrier to availability and accessibility, and the President's Council of Advisors on Science and Technology (PCAST) and the National Academies of Sciences, Engineering and Medicine (NAS) had already concluded that regulation was providing little to no meaningful benefit to patients. This does not change the requirements for medical referral when patients are seen by audiologists who need ENT/otologic consultation.

Bottom line: A medical evaluation or waiver is no longer required to fit and dispense hearing aids for your patients over 18 with no medical contraindications. This change should streamline care for your patients.

Improving Access to Hearing Aids

In the same legislative announcement, the FDA also stated its commitment to consider creating a category of over-the-counter hearing aids that could "deliver new, innovative and lower-cost products to millions of consumers."

Shortly after, new legislation, called the Over-the-Counter Hearing Aid Act of 2016, was introduced. This act would allow hearing aids intended for use by adults with mild to moderate hearing loss to be sold over-the-counter. This new category of hearing aids also would include safety and labeling requirements.²

Bottom line: This act still must move through the legislative process before it becomes law.³

Who Could Benefit from Over-the-Counter Hearing Aids?

The goal of this new legislation is to make hearing aid technology more affordable and accessible to the more than 30 million people who have hearing loss in the United States. In fact, speculation is that availability of hearing aids over-the-counter may actually help raise awareness about audiology services and allow the public to make better informed decisions regarding their treatment options.

In addition, more and more research links hearing loss to increased risks for cognitive decline, including dementia, depression and Alzheimer's disease. Clearly, the benefits of treating hearing loss outweigh the risks, even if the patient treats him or herself.

However, there are concerns physicians should be aware of and discuss with their patients regarding any type of over-the-counter hearing aid technology, or even hearing aids purchased online:

1. Professional audiology associations recommend all individuals have a comprehensive hearing evaluation from an audiologist before purchasing any hearing aid technology, especially over-the-counter devices. This evaluation can confirm the level of hearing loss (mild, moderate, severe, profound), and may help identify any underlying medical condition contributing to the problem.
2. In this proposed legislation, over-the-counter hearing aids would only be sold for mild to moderate hearing loss. Patients with a more severe hearing loss, or who need custom hearing solutions, would still need to see a professional to be fit with appropriate hearing aid technology.

3. Audiology remains the gold standard of care for those seeking hearing help/rehabilitation for hearing loss. An audiologist can evaluate and confirm your patient's hearing loss, recommending appropriate hearing aid technology for the individual's lifestyle, budget and needs. Audiologists can utilize specialized testing to confirm the patient's hearing aids are providing the optimum benefit and if not, adjust them accordingly.

"It's difficult to forecast how this potential change in legislation could impact our patients, but we support helping more people gain access to affordable hearing aid options, potentially warding off the long-term co-morbid conditions related to untreated hearing loss."

— Tim Steele, Ph.D., FAAA, President, Associated Audiologists, Inc.



Bottom line: "Working together on behalf of our patients, we can ensure they get the most appropriate hearing aid technology for their needs and the best value for their money. It's imperative for physicians and consumers to recognize that practices like ours already offer many budget-sensitive options which include the expertise, guidance, support, verification, and validation of our audiology staff. This combination of technology and service is superior to any over-the-counter or online hearing device," Dr. Steele said.

References

- 1 <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm532005.htm>, accessed 1/2/2017.
- 2 <https://www.whitehouse.gov/blog/2016/12/07/fda-takes-action-deliver-lower-cost-innovative-hearing-aids-millions-more-americans>, accessed 1/2/2017.
- 3 <https://www.congress.gov/bill/114th-congress/senate-bill/9/text?q=%7B%22search%22%3A%5B%22S9%22%5D%7D&r=1>, accessed 1/2/2017.

To learn more about this legislation, visit www.audiology.org, or contact Dr. Steele at tim@hearingyourbest.com.

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