

From NJSHA's Audiology Committee:

FDA FINALIZES REGULATIONS FOR Over-the-Counter (OTC) Hearing Aids.

August 16, 2022

Today (8/16/22) the FDA finalized its regulations for over-the-counter hearing devices. The regulatory body has altered output and length of canal insertion to be more protective of the users. It continues to emphasize that these devices are for adults only, with mild to moderate hearing loss.

American Speech-Language-Hearing Association, ASHA, has formulated an initial response to the FDA announcement. It is also providing an ongoing toolkit with talking points for audiologists to share with patients, physicians, pharmacists, and the public at large. ASHA will continue to add to the toolkit as more information becomes available. We recommend bookmarking the OTC toolkit and checking back for updates. If we familiarize ourselves with the issues involved, we help our patients make appropriately informed decisions.

What can we as audiologists do with this new information and new category of self-help devices? We are not being eliminated. We are just as necessary for advising and advocating for our patients. We cannot lose sight of the importance of an audiologic assessment and the consideration of medical issues that may need to be attended. We can charge for service visits to remove cerumen from the devices or provide verification of the device's effectiveness for patients. We will be there to provide appropriate recommendations for our patients when they are ready for prescription hearing aids. We can continue to be their audiologists.

We can also speak to our local referring physicians, local pharmacists, and local TV and radio stations. If we let them know what these devices are and are not, who they are appropriate for, and when it is necessary to refer for audiologic and medical evaluation, they become our allies.

This does not eliminate audiologists or make them less important. We are more necessary than ever. Please click the link below for more information on the FDA's News Release.

[FDA Finalizes Historic Rule Enabling Access to Over-the-Counter Hearing Aids for Millions of Americans](#)

