THE ASHA LEADER blog

Now That President Trump Signed It Into Law, 5 Steps to OTC Hearing Aid Implementation

August 18, 2017 By Michelle Mannebach

President Trump just signed into law legislation requiring the Food and Drug Administration (FDA) to develop regulations related to over-the-counter (OTC) hearing aids. This new category would apply to adults with perceived mild to moderate hearing loss.

The FDA will have three years to develop the regulations, as directed by the legislation (H.R. 2430), passed by the House of Representatives in July and the Senate in August. So what's next for OTC hearing aids under this legislation? Here's a step-by-step look.

1. Once a bill is signed into law, it typically falls under the responsibility of one federal agency to determine how to carry out the law. For this particular law, the FDA will develop the regulations.

2. Once the law is in effect, the FDA has three years to develop rules on how OTC hearing aids will be regulated.

3. Regulations are developed through a two-step rule-making process. First, the FDA will publish a proposed rule in the Federal Register, and will ask for public comments on the proposal.

ASHA will provide public comments focused on:

- Setting output limits on the devices.
- Labeling that indicates the devices are intended for consumers 18 years of age or older.
- Warning signs for conditions for which consumers should seek medical advice.
- Ensuring that only those with mild to moderate hearing loss purchase the devices.

After comments are considered, the FDA will publish the final rule in the Federal Register and include a date for when the rule goes into effect.

4. Hearing aid manufacturers will need to produce OTC hearing aids that meet the requirements established by the FDA; identify retail outlets to sell their products; develop marketing plans to reach consumers; and adhere to the FDA regulations.

5. The U.S. Department of Health and Human Services is required to collect data on user safety and satisfaction with the devices and report back to Congress on any

adverse effects two years after the regulations are in place. Therefore, it will take about **five years** to be able to measure the effectiveness of OTC hearing aids.

ASHA's position is to encourage anyone with greater than a mild degree of hearing loss to seek treatment by a certified, licensed audiologist. We will continue advocacy for this position throughout the rule-making process with the FDA.

For additional information, please contact Ingrida Lusis, ASHA's director of federal and political advocacy, at ilusis@asha.org. Sign up for updates on OTC hearing aids and other policy and advocacy developments crucial to the professions at www.asha.org/Publications/ASHA-Headlines.