AMERICAN ACADEMY OF AUDIOLOGY

ISSUE BRIEF

Over-the-Counter Hearing Aid Act of 2017 (S. 670, H.R. 1652)

Senators Elizabeth Warren (D-MA) and Charles Grassley (R-IA), along with Senators Maggie Hassan (D-NH) and Johnny Isakson (R-GA), introduced the Over-the-Counter Hearing Aid Act of 2017 (S. 670). A companion bill (H.R. 1652) was introduced in the House by Representatives Marsha Blackburn (R-TN) and Joe Kennedy (D-MA). The Academy has been actively engaged on this legislation since the start of the 115th Congress and was able to see several key changes made to the original version of the bill that was introduced at the end of the 114th Congress. The Academy's conversations have been based on its two statements addressing "OTC Devices" and "Accessibility and Affordability for Hearing Care". Academy leaders have visited Capitol Hill to discuss this important legislation and will continue to work with key stakeholders to ensure that consumers are protected and the interests of audiologists are understood.

If signed into law, this legislation will:

- Prompt the Department of Health and Human Services (HHS) to create a new category of hearing aids that can be sold over-the-counter and are intended for use by adults over the age of 18 to compensate for perceived mild to moderate hearing impairment.
- Direct the Secretary of HHS to include labeling requirements, requirements to establish or adopt output limits, and descriptions of how the devices can be sold.
- Preempt state law to ensure that licensing bodies cannot restrict the sale of OTC devices. There will be no other changes to how state licensing boards operate.

As mentioned, there were a number of changes made to the legislation that was originally introduced in the 114th Congress. The legislation introduced in the 115th Congress now includes specific language clarifying the following:

- "Adults" refers to individuals over the age of 18
- FDA regulations related to OTC hearing aids must establish or adopt output limits appropriate for OTC hearing aids
- FDA regulations related to OTC hearing aids must include requirements for appropriate labeling, including:
    - How consumers may report adverse events
    - Any conditions for which use is not advised
    - Any appropriate advisements to consult promptly with a licensed physician

The Academy stands committed to making an impact on this legislation as the process evolves and will continue to advocate for the profession and the patients we serve. The Academy encourages its members to contact their own members of Congress to discuss the complex nature of hearing loss and the role of the audiologist in supporting positive patient outcomes with regard to hearing aid devices. The Academy will keep members apprised of any updates related to this legislation.