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## POSITION PAPER

### Over-the-Counter Hearing Aids

**Synopsis: HLAA supports a regulated market for over-the-counter hearing aids that are intended for adults with mild-to-moderate hearing loss and which meet strict performance and labeling criteria to ensure safety and effectiveness.**

The ability to hear and communicate effectively is the foundation for nearly all of our daily life activities. For the 48 million Americans who have hearing loss, ensuring that these individuals can obtain affordable and accessible hearing care services and technology that meet their individual needs is critical.

Hearing aids currently cannot be sold over the counter (OTC) because of Food and Drug Administration regulations on hearing aids established in 1977. This position means that consumers have restricted access to such devices. However, available evidence suggests that hearing aids meeting strict performance criteria could be both safe and effective for adults with mild-to-moderate hearing loss.

In 2015 and 2016, respectively, the White House President's Council of Advisors on Science and Technology (PCAST) and the National Academies of Sciences, Engineering, and Medicine (NASEM) carefully considered the risks and benefits of OTC hearing aids. Reports from both groups concluded that the benefits to consumers and society of a regulated market for OTC hearing aids far outweighed any theoretical risks and therefore recommended that the FDA create a regulatory classification for hearing devices with strict performance and labeling criteria that could be explicitly labeled OTC. These recommendations resulted in the passage of the OTC Hearing Aid Bill in August 2017 that mandates the creation of this FDA regulatory classification by 2020.

HLAA concurs with the findings of both the PCAST and NASEM reports. We believe that consumer-friendly, readily-available, OTC hearing devices that are safe and effective will serve to destigmatize hearing loss; spark innovation in connectivity, form factor and design; increase options for consumers; and lead to greater price transparency in current models of hearing health care. Therefore, HLAA welcomes and supports the passage of the OTC Hearing Aid Bill.

Adopted February 2018, to be reconsidered February 2019.