



Alberta College of
Speech-Language Pathologists
and Audiologists

Position Statement:

Over-the-Counter (OTC) Hearing Aids and Pediatrics

October 2025

Position Statement: Sets out the official position or stand of “the College” on an issue or matter that is significant to the professions, and to outside agencies or groups.

Position

It is ACSLPA's position that **over-the-counter (OTC) hearing aids** are not intended for and are inappropriate for use by individuals under 18 years of age. ACSLPA recognizes the risk of harm from pediatric use of OTC hearing aids.

Regulatory Background

In Canada, both OTC and prescription hearing aids are regulated federally by Health Canada. The approval process for these devices requires manufacturers to apply for a medical device license for their product, attesting that it meets the safety, effectiveness, and quality standards established by the Medical Devices Regulations. The current standards pertain to quality management, design and manufacturing, the integrity and compatibility of materials, device performance for its intended purpose, packaging, and labeling. Notably, labeling may not include the risks specific to pediatric use.

While ACSLPA recognizes the benefits of OTC hearing aids in terms of accessibility and affordability, vulnerable populations, including individuals under 18 years of age, may be at higher risk of harm from over- or under-amplification. Inappropriate amplification could lead to further hearing damage and possible long-term negative developmental and academic outcomes. Similarly, the American Food and Drug Administration's (FDA) regulation on OTC hearing aids, established in 2022, asserts that OTC hearing aids are not intended to be used by individuals under the age of 18 years.

Guidance:

Regulated members are encouraged to report harm or potential harm caused by OTC hearing aids with pediatric clients to Health Canada via their website.

Regulated members have an ethical responsibility to either provide education and counselling about the risks of OTC hearing aids for pediatric clients, or to refer to a colleague who has the required competence to do so.

When providing amplification services to individuals under the age of 18 years, regulated audiologists should follow [ACSLPA's Pediatric Amplification Protocol](#), which supports the delivery of safe, developmentally appropriate, evidence-informed services, tailored to the unique needs of each individual. As noted in the Protocol, children from birth to 18 years benefit from having a regulated audiologist fit and monitor prescription amplification.

Definition

Over-the-counter (OTC) hearing aids

are air-conduction hearing aids that amplify sound into the ear canal and do not require surgical intervention, a prescription, or hearing healthcare professionals' involvement. OTC hearing aids are intended for use by individuals 18 years of age and older, to help with perceived mild to moderate hearing loss. (FDA, 2022).

References

- Alberta College of Speech-Language Pathologists and Audiologists. (2022). *Code of ethics*. https://www.acslpa.ca/wp-content/uploads/8/06/2022-06-04-Code-of-Ethics_Final.pdf
- Alberta College of Speech-Language Pathologists and Audiologists. (2022). *Standards of practice*. <https://www.acslpa.ca/members/standards-of-practice/>
- Alberta College of Speech-Language Pathologists and Audiologists. (2025). *Pediatric amplification protocol*. https://www.acslpa.ca/wp-content/uploads/2023/03/2025-02-12_Pediatric-Amplification-Protocol_Final.pdf
- Department of Justice Canada. (2025). *Medical devices regulations SOR/98-282*. <https://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/fulltext.html>
- Federal Register: The Daily Journal of the United States Government. (2022). *Medical devices; ear, nose, and throat devices; establishing over-the-counter hearing aids*. <https://www.federalregister.gov/documents/2022/08/17/2022-17230/medical-devices-ear-nose-and-throat-devices-establishing-over-the-counter-hearing-aids>
- McCreery, R., Walker, E., Spratford, M., Kirby, B., Oleson, J., & Brennan, M. (2016). Stability of audiometric thresholds for children with hearing aids applying the American academy of audiology pediatric amplification guideline: implications for safety. *Journal of the American Academy of Audiology*, 27(3), 252–263. <https://doi.org/10.3766/jaaa.15049>
- Speech-Language and Audiology Canada. (2025). *SAC position paper on over-the-counter hearing aids in Canada*. <https://www.sac-oac.ca/wp-content/uploads/2025/07/2025-PP-AUD-OTC-Hearing-Aids-in-Canada-FINAL-EN.pdf>
- U.S. Food and Drug Administration. (2022). *OTC hearing aids: what you should know*. <https://www.fda.gov/medical-devices/hearing-aids/otc-hearing-aids-what-you-should-know>