



# Position Statement

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

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ADAPTED WITH PERMISSION FROM THE ALBERTA COLLEGE OF SPEECH-LANGUAGE PATHOLOGISTS AND AUDIOLOGISTS (ACSLPA).

***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

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RCASLPNB maintains that **over-the-counter (OTC) hearing aids** are neither intended for nor appropriate for individuals under 18 years of age. The Regulatory College acknowledges the potential risk of harm associated with pediatric use of OTC hearing aids.

## Regulatory Background

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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 RCASLPNB 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

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

Registrants 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.

Children under 18 years benefit from having prescription amplification fit and monitored by a regulated audiologist. When providing amplification services to this population, registrants should follow RCASLPNB standards of practice and recognized pediatric amplification protocols to ensure care is safe, developmentally appropriate, and evidence informed.

## Definition

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### 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

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