



1 *Advisory Statement:*

2 OTC Hearing Aids and
3 Professional Obligations
4 in Audiology

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7 OTC Hearing Aids and Professional Obligations in Audiology

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OTC Hearing Aids and Audiologists' Professional Obligations

Advisory Statement: Provides direction to ensure regulated members have information to comply with legislation, standards, and other minimum requirements.

Acknowledgements

The Alberta College of Speech-Language Pathologists and Audiologists (ACSLPA) would like to thank the ACSLPA over-the-counter (OTC) hearing aids ad-hoc committee members for their time and participation on this committee, and the ACSLPA members who took time to share their expertise and provide thoughtful review and revisions to this advisory statement.

Introduction

OTC hearing aids are air-conduction hearing aids that amplify sound into the ear canal and do not require surgical intervention, 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) and are considered direct-to-consumer (DTC) hearing devices.


This advisory statement addresses the minimum professional and ethical obligations of the registered audiologist, by addressing ACSLPA's Standards of Practice, Code of Ethics and other Key College Documents applicable to working in the context of OTC hearing aids with individuals over 18 years of age.

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. For more information, please refer to ACSLPA's [Over-the-Counter \(OTC\) Hearing Aids and Pediatrics Position Statement](#).

For the purpose of this document, prescription hearing aids are defined as medical-grade devices that are custom-fitted and programmed based on a comprehensive hearing assessment. They may be fitted for any degree of hearing loss and for clients of any age and are typically only available through regulated hearing care providers. Although this differs from province to province, in Alberta, a prescription is not required to obtain these devices.

Navigating this Guideline

This advisory statement provides direction to ensure registered speech-language pathologist (SLP) and audiologist have information to comply with legislation, standards and minimum requirements as they relate to OTC hearing aids. This document utilizes the following icon:

 The **Tools and Templates** icon provides the SLP or audiologist with checklists and documents to support their work with OTC hearing aids and to assist in meeting professional obligations. Click on the link to view the document.

65 Regulatory Background

66 Regulation of OTC Hearing Aids

67 The Medical Devices Directorate (MDD) of Health Canada regulates both OTC and prescription hearing
68 aids as Class II medical devices under the Canadian Medical Devices Regulation (MDR). Medical
69 devices are classified into four classes, where Class I is considered to carry the lowest potential risk,
70 and Class IV is considered to carry the greatest potential risk. Class II medical devices, including OTC
71 and prescription hearing aids, are considered to carry a moderate level of potential risk, and require a
72 medical device licence before they can be sold in Canada. Health Canada has been licensing specific
73 OTC hearing aids. You can search and verify Health Canada's license approvals of OTC hearing aids
74 using the company, licence name or device identifier etc. to determine whether the device has an
75 active licence here: <https://health-products.canada.ca/mdall-limh/prepareSearch?type=active>.

76 To receive approval, manufacturers of OTC hearing aids must attest that the product meets the current
77 standards established by the MDR. However, these standards do not outline specific details related to
78 OTC hearing aids, including acoustic or amplification requirements. The current standards pertain to
79 quality management, design and manufacturing, the integrity and compatibility of materials, device
80 performance for its intended purpose, and packaging and labeling. [Health Canada's list of recognized
81 standards for medical devices](#) is available on their website.

82 All approved Class II diagnostic and therapeutic medical devices are monitored and evaluated by the
83 MDD to ensure ongoing safety, effectiveness, and quality. The MDD monitors medical devices through
84 recalls, complaints and problem reports from consumers, health care professionals, interested parties
85 and other sources. Regulated members are encouraged to report problems or concerns with approved
86 medical devices to [Health Canada](#) online or by calling 1-800-267-9675. Examples of concerns may
87 include, but are not limited to, malfunctioning, reduced effectiveness over time, difficulty of use,
88 unclear instructions, and potential or actual harm.

89 **Alberta's Health Professions Act (HPA):**

90 Regulations and laws governing the professions of audiology and speech-language pathology and the
91 fitting and dispensing of hearing aids differ across Canadian provinces and territories.

92 In Alberta, audiologists and speech-language pathologists (SLPs) are regulated under the *Health
93 Professions Act (HPA)*. Hearing Aid Practitioners are also regulated under the *HPA* by the College of
94 Hearing Aid Practitioners of Alberta (CHAPA). There is no legislation in Alberta, including the *HPA*, that
95 governs or regulates the sale of hearing aids, whether OTC or prescription.

96 The *HPA* provides legislative guidance by defining an audiologist's area of practice (i.e., practice
97 statement), authorizing regulated health professionals in Alberta to perform restricted activities, and
98 protecting the use of professional titles. Audiologists who comply with the *HPA*, ACSLPA's Standards
99 of Practice, and Code of Ethics may provide and fit approved OTC hearing aids when appropriate for
100 their clients.

101 Providing devices, including OTC hearing aids, to treat auditory dysfunction is not a restricted activity
102 under the *HPA*. Therefore, individuals who are not regulated members of a health profession college
103 may fit or dispense OTC hearing aids in Alberta. Restricted activities such as 'inserting or removing a
104 device beyond the cartilaginous portion of the ear canal' or 'inserting into the ear canal a substance
105 that subsequently solidifies' must be performed by authorized regulated health professionals in
106 Alberta, including registered audiologists. Notably, in Alberta these restricted activities are not
107 exclusive to registered audiologists.

108 As part of its mandate, under the *HPA*, ACSLPA has a role with respect to OTC hearing aids. The
109 College is responsible for establishing, maintaining and enforcing Standards of Practice, a Code of
110 Ethics and regulatory guidance to ensure competent, safe, and ethical practice of regulated members
111 when working in the context of OTC hearing aids. ACSLPA does not regulate the availability of OTC
112 hearing aids, or the technical standards for OTC or prescription hearing aids.

113 The College supports increasing access to hearing health solutions for Albertans, while it also
114 recognizes the importance of ensuring public safety, education and product efficacy. As part of
115 ACSLPA's focus on public safety, the College has a position statement asserting that OTC hearing aids
116 are not intended for and are inappropriate for individuals under 18 years of age.

117 **Guidance**

118 In this section, the advisory statement aims to highlight the current guidance available through
119 ACSLPA's Standards of Practice, Code of Ethics and Key College Documents that should inform
120 regulated members' practice in their work with adult clients and OTC hearing aids. Please note, this
121 guidance is not exhaustive; additional College documents not explicitly highlighted in this advisory
122 statement may also be applicable to OTC hearing aids.

123 The guidance is separated into three following areas:

- 124 ▪ Client-Centered Care and Informed Choice
- 125 ▪ Audiology Practice Considerations
- 126 ▪ Risk Management

127 **Client-Centered Service and Informed Choice**



Regulated Members' Key Responsibilities

Highlighted Professional and Ethical Standards:

[Standard of Practice 1.1 Client Centered Services](#)

A regulated member of ACSLPA uses a client-centered approach in the provision of competent and safe professional services.

[Standard of Practice 1.4 Communication](#)

A regulated member of ACSLPA communicates respectfully, effectively and in a timely manner in the provision of professional services.

- Most relevant indicators: (a) (c) and (d)

[Standard of Practice 1.5 Collaboration](#)

A regulated member of ACSLPA works collaboratively to facilitate the delivery of quality client-centered services.

- Most relevant indicators: (a), (b), (d) and (e)

[Standard of Practice 2.3 Informed Consent](#)

A regulated member of ACSLPA ensures that they obtain informed consent prior to the provision of services.

- Most relevant indicators: (a), (b), (d)

[Standard of Practice 4.3 Documentation and Information Management](#)

A regulated member of ACSLPA maintains clear, confidential, accurate, legible, timely and complete records, in compliance with legislation and regulatory requirements.

- Most relevant indicators: (a), (d), (e), (q)



Code of Ethics

1.0 Respect for all Persons - Regulated members demonstrate respect for all persons, promote the well-being of others, and recognize clients' rights to autonomy in decision-making regarding their care.

Most relevant indicators:

1.1 Promote inclusive care by acknowledging individual values, cultures, languages, needs, and goals, and treat all persons with sensitivity, dignity, and respect.

1.5 Respect and support the autonomy of clients to make choices and decisions regarding their own care and/or to refuse treatment and withdraw from services at any time.

2.0 Regulated members demonstrate **professional** behaviour and integrity in the delivery of safe, ethical, quality services.

Most relevant indicator:

2.1 Promote and protect the public's trust, and the reputation of the professions, by acting with honesty, integrity, objectivity, diligence, and courtesy.

3.0 Collaboration - Regulated members foster collaborative practice with clients, service providers, and others to support integrated client-centred care.

4.0 Accountability - Regulated members take responsibility for their actions and decisions.

Most relevant indicators:

4.2 Access and use available resources conscientiously and prudently in the pursuit of quality client care.

4.3 Provide only those services that are beneficial to clients, discontinuing interventions when clients no longer benefit.

131 Collaboration

132 Regulated members are expected to involve and collaborate with clients in all decision-making related
133 to service provision (SoP 1.1, 1.4, 1.5 and CoE 3.0). This includes those clients who are using or
134 considering OTC hearing aids as an intervention. In potentially challenging situations, where a client
135 may opt for OTC hearing aids instead of the professional recommendation provided to them, regulated
136 members need to respect the client's autonomy and right to choose service options, refuse
137 recommendations or interventions, and withdraw consent at any time (SoP 2.3(d) and CoE 1.0).

138 Audiologists should also work collaboratively with other relevant health service providers, who may
139 be involved with the client to facilitate an integrated approach (SoP 1.5 and CoE 4.0). It is the regulated
140 member's responsibility to serve as an educator and advocate, when appropriate, by liaising with
141 the client, families and other professionals (SoP 1.5(d)(e), 1.3(j)). They should know and be prepared
142 to explain their scope of practice and the suitability of various hearing healthcare interventions
143 (SoP 1.5(f)).

144 **Informed Consent and Decision Making**

145 As with all aspects of service delivery, informed consent is required prior to any screening/assessment
146 or intervention. Clients need to be made aware of the potential risks, benefits and alternatives for any
147 proposed service or intervention, including interventions chosen by the client, such as OTC hearing
148 aids ([SoP 2.3\(a\)](#)). The audiologist's clinical judgement should inform their explanation of the benefits,
149 risks, and alternatives relevant for the client and support informed decision-making. The regulated
150 member should also disclose their own level of knowledge or familiarity and competence with respect
151 to OTC hearing aids. Please refer to 'Competence' section on page 8 below for more information.

152 It is a requirement to clearly and accurately document discussions, recommendations, explanations,
153 and client decisions ([SoP 4.3](#)). It may be prudent for regulated members, working with clients using
154 or considering OTC hearing aids, to establish formalized and tailored consent procedures that asks
155 the client to acknowledge and accept their understanding, recommendations and potential risks
156 or limitations that were discussed and their decision to proceed. Notably, limitations may include
157 those of the OTC hearing aid. Please refer to ACSLPA's [Clinical Documentation and Record Keeping
158 Guideline](#) (2021) for information related to documentation, record management and retention
159 requirements.

160 **Counselling, Education & Advocacy**

161 Regulated members have a professional and ethical responsibility to provide balanced, evidence-
162 informed education and counselling to clients regarding hearing healthcare options, including OTC
163 hearing aids ([SoP 1.1, 1.2 and 2.3](#)). This encompasses staying current on the benefits, risks and
164 technology related to OTC hearing aids, if relevant to an audiologist's practice. In doing so, there
165 should be consideration and use of a variety of communication strategies, styles, and language,
166 appropriate for the client. Audiologists should also incorporate principles of cultural safety and health
167 literacy in their counselling approach ([SoP 1.4\(a\)\(b\)](#)).

168 Encourage, assess and confirm the client's understanding of the suitability, risks, benefits, limitations
169 and alternatives that may be available to them in relation to OTC hearing aids, by allowing open, two-
170 way dialogue ([SoP 1.4, 2.3](#)). Audiologists are well-positioned to provide guidance on the regulatory
171 frameworks in Alberta and Canada and clinical considerations with respect to OTC hearing aids.
172 Clients and the public may benefit from their audiologist proactively raising OTC hearing aids as part
173 of hearing solution discussions. This may promote transparency and informed decision-making in
174 understanding the Canadian regulatory frameworks surrounding availability and requirements of OTC
175 hearing aids from a trusted source. Referring to reputable sources such as ACSLPA Key College
176 Documents, and SAC's Position Statement may be supportive to both the regulated member's
177 recommendations, and the client's understanding.



Regulated Members' Key Responsibilities

Highlighted Professional and Ethical Standards:

[Standard of Practice 1.2 Evidence-informed Practice](#)

A regulated member of ACSLPA actively seeks, promotes, supports and incorporates an evidence-informed approach in their practice.

[Standard of Practice 1.3 Client Assessment and Intervention](#)

A regulated member of ACSLPA selects and applies appropriate screening/assessment procedures, analyzes/interprets the information gathered to determine diagnosis and implements appropriate interventions to deliver quality services that correspond to clients' priorities and changing needs.

[Standard of Practice 3.1 Continuing Competence](#)

A regulated member of ACSLPA who is on the general register and who has been issued an active practice permit maintains their competence to practice and meets the requirements of the Continuing Competence Program.

- Most relevant indicator: (b)

[Standard of Practice 4.7 Fees and Billing](#)

A regulated member of ACSLPA, *working in a private practice environment*, ensures that fees for products/services are justifiable and that clients are informed of fee schedules prior to the delivery of services.

[Code of Ethics:](#)

2.0 Professionalism Regulated members demonstrate professional behaviour and integrity in the delivery of safe, ethical, quality service

Accountability (4.0) Regulated members take responsibility for their actions and decisions.

- Most relevant indicator:
4.5 Only seek compensation for products and services that is justifiable and fair.

[Virtual Care Guideline](#)

180 **Assessment and Intervention**

181 A regulated member's clinical judgment, and ability to analyze and interpret information to determine
182 a diagnosis or intervention, is informed by accurate and appropriate assessment results (SoP 1.3(e)).
183 There may be situations where a client presents at a clinic with OTC hearing aids, without reliable
184 or informative assessment results, but is requesting audiological support. Where appropriate, the
185 regulated member should support the client within their knowledge and competence in the area of
186 OTC hearing aids. The regulated member may recommend completing an audiological evaluation in
187 the interest of providing a quality, safe, and ethical service and to avoid misdiagnosis, or inappropriate
188 amplification and management. The regulated member needs to incorporate an evidence-informed
189 approach by ensuring an assessment of the client's priorities and needs, and any limitations or risks
190 relevant to the client (SoP 1.2, 1.3(a)(b)). This should inform appropriate screening/assessments and
191 interventions and identify any contraindications to OTC hearing aid use (SoP 1.2, 1.3(a)(b)). The
192 reasons why the audiological evaluation is necessary, and all clinical considerations, including the
193 client's priorities, associated fees, the potential outcomes of evaluation such as the OTC hearing aids
194 being unsuitable etc., need to be clearly communicated and documented prior to proceeding
195 (SoP 1.3, 2.3, 4.7).

196 **Competence**

197 Having an awareness of what is defined under an audiologist's practice statement in the *HPA*, as well
198 as the audiologist's knowledge and competence limitations, is important in maintaining and/or
199 enhancing competence in new areas of practice through learning activities (SoP 1.3(b), 3.1). Clients
200 and families may ask audiologists to work with OTC hearing aids or a manufacturer that they are
201 unfamiliar with. If an audiologist determines they lack the competencies to provide safe and
202 competent services for the client, they should disclose their concerns, and may limit their practice
203 and/or discontinue services (SoP 3.1(b)). This could be a temporary or ongoing measure, and as the
204 regulated member develops the necessary competencies these services may be introduced
205 (SoP 3.1(b)).

206 When appropriate and suitable for the client, a regulated member may discuss and offer alternative
207 products/services that they have knowledge and competence in. Facilitating and implementing
208 discharge planning and access to alternative services when there are changes to service delivery helps
209 ensure the client remains well supported (SOP 1.3(i)(j), CoE 1.0).

210 **Fees and Billing**

211 Providing professional services and clinical expertise to clients with OTC hearing aids who request
212 support may be reasonably and justifiably billed for (SoP 4.7). Fees for OTC hearing aid related
213 products/services must be fully disclosed including assessment and intervention, reports, equipment,
214 and any other associated costs and consented to by the client, prior to service delivery (SoP 4.7(b)(c)).



Regulated Members' Key Responsibilities

Highlighted Professional and Ethical Standards:

[Standard of Practice 4.1 Safety and Risk Management](#)

A regulated member of ACSLPA practices in compliance with occupational health, safety and risk management legislation and requirements in all practice settings.

- Most relevant indicators: (d), (g)

[Standard of Practice 4.2 Quality Improvement](#)

A regulated member of ACSLPA participates in continuous quality improvement activities to promote the effectiveness and safety of service delivery.

- Most relevant indicators: (a), (b)

[Standard of Practice 6.1 Restricted Activities](#)

A regulated member of ACSLPA performs only those restricted activities that they are authorized and competent to perform in compliance with legislation.

[Code of Ethics:](#)

Accountability (4.0) Regulated members take responsibility for their actions and decisions.

- Most relevant indicators:
 - 4.7** Ensure the safety of clients, other service providers, and themselves by taking appropriate actions, including documenting and reporting, to prevent and/or manage risks in relation to the provision of services.
 - 4.8** Use appropriate channels, in a timely manner, to address errors and/or issues of concern which may have an impact on the wellbeing of clients and/or other service providers.
 - 4.9** Have a duty to report other service providers who provide incompetent and/or unethical services to the appropriate authority.

[Clinical Documentation and Record Keeping Guideline](#)

[Audiological Referral to Otolaryngology Protocol](#)

216 Safety

217 Adhering to safe equipment-handling practices and infection-prevention and control standards
 218 remains applicable when working with clients and OTC hearing aids ([SoP 4.1\(e\)](#)). Equipment used
 219 when working with OTC hearing aids is also subject to maintenance and calibration requirements.
 220 This ensures compliance with manufacturer standards, client health and safety, and accuracy of
 221 assessment or intervention results. Please refer to 'equipment service records' in ACSLPA's [Clinical](#)
 222 [Documentation and Record Keeping Guideline](#) for more information relating to equipment and
 223 documentation requirements.

224 **Adverse Events and Reporting**

225 Medical conditions and contraindications to OTC hearing aid use need to be appropriately identified,
226 managed and documented, including referrals to other health care providers, as required
227 [\(SoP 1.3\(b\)\(j\)\)](#). A regulated member needs to respond to adverse events in relation to a product or
228 equipment, where they may be involved with a client using an OTC hearing aid [\(SoP 4.1\(d\)\)](#). Adverse
229 events may include over or under amplification, malfunction, technology performance issues,
230 inappropriate use, manufacture of the device etc. While an audiologist may not be directly involved
231 with the cause of an adverse event, they have an ethical responsibility to address issues of concern
232 which may have an impact on the wellbeing of clients [\(CoE 4.8\)](#). Complying with ACSLPA's Standards
233 of Practice and Code of Ethics, and provincial legislation requirements, supports transparent,
234 accountable service delivery and decision making. Problems or concerns with medical devices should
235 be reported to Health Canada and manufacturers (refer to [Regulatory Background](#) section above).

236 **Glossary**

OTC hearing aids

Air-conduction hearing aids that amplify sound into the ear canal and do not require surgical intervention or hearing healthcare professionals' involvement. They are intended for adults (18+) with perceived mild to moderate hearing loss and are considered direct-to-consumer (DTC) hearing devices.

Prescription hearing aids

Medical-grade devices that are custom-fitted and programmed based on a comprehensive hearing assessment. They may be fitted for any degree of hearing loss and for clients of any age and are typically only available through regulated hearing care providers. Although this differs from province to province, in Alberta, a prescription is not required to obtain these devices.

Competence/ competent/ competency

The combined knowledge, skills, attitudes and judgment required to provide professional services

237

238 References

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