ARC 7819C

PROFESSIONAL LICENSURE DIVISION[645]

Adopted and Filed

Rulemaking related to practice of hearing aid dispensing

The Board of Hearing Aid Specialists hereby rescinds Chapter 123, "Practice of Hearing Aid Dispensing," Iowa Administrative Code, and adopts a new chapter with the same title.

Legal Authority for Rulemaking

This rulemaking is adopted under the authority provided in Iowa Code chapters 147, 154A, and 272C.

State or Federal Law Implemented

This rulemaking implements, in whole or in part, Iowa Code chapters 17A, 147, 154A, and 272C.

Purpose and Summary

This rulemaking provides Iowans, licensees, and licensees' employers with definitions relevant to the practice of hearing aid dispensing, requirements prior to the sale of a hearing aid, requirements for sales receipts for hearing aids, and requirements for recordkeeping and telehealth appointments. This rulemaking articulates practice standards and provides a scope of practice for the profession.

Public Comment and Changes to Rulemaking

Notice of Intended Action for this rulemaking was published in the Iowa Administrative Bulletin on January 10, 2024, as **ARC 7485C**. Public hearings were held virtually and in person on January 30 and 31, 2024, at 10:50 a.m. at 6200 Park Avenue, Des Moines, Iowa. No one attended the public hearings. A public comment was received through email, requesting that telehealth appointments be allowed to occur through audio-only modalities. No changes from the Notice have been made.

Adoption of Rulemaking

This rulemaking was adopted by the Board on February 28, 2024.

Fiscal Impact

This rulemaking has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rulemaking, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rulemaking would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 481—Chapter 6.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rulemaking by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rulemaking at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rulemaking will become effective on May 22, 2024.

The following rulemaking action is adopted:

ITEM 1. Rescind 645—Chapter 123 and adopt the following **new** chapter in lieu thereof:

CHAPTER 123
PRACTICE OF HEARING AID DISPENSING

645—123.1(154A) Definitions. For the purposes of these rules, the following definitions apply:

"Health history" means a series of questions pertaining to all of the following: client hearing needs and expectations, communication issues, otological conditions, medications, and previous amplification.

"Hearing aid fitting" means any of the following: the measurement of human hearing by any means for the purpose of selections, adaptations, and sales of hearing aids, and the instruction and counseling pertaining thereto, and demonstration of techniques in the use of hearing aids, and the making of earmold impressions as part of the fitting of hearing aids.

"Sales receipt" means a written record that is provided to a person who purchases a hearing aid. The sales receipt must be in compliance with these rules and be signed by the purchaser and the licensed hearing aid specialist. The requirements for the sales receipt may be found in rule 645—123.3(154A).

645—123.2(154A) Requirements prior to sale of a hearing aid.

123.2(1) Except as otherwise stated in these rules, no hearing aid shall be sold to an individual 18 years of age or older unless the individual:

a. Provides a health history to a licensed hearing aid specialist;

b. Presents a physician statement verifying that a medical evaluation, preferably by a physician specializing in diseases of the ear, has been done within the previous six months and stating the individual's hearing loss, and that the individual may benefit from a hearing aid. In lieu of this requirement, the individual may verify in writing that the individual has been advised to obtain a medical evaluation by a licensed physician specializing in diseases of the ear, or if no such licensed physician is available in the community, then a duly licensed physician, and that the individual chooses to waive said evaluation; and

c. Is given a hearing examination that utilizes appropriate established procedures and instrumentation for the measurement of hearing and the fitting of hearing aids and that includes but is not limited to an assessment of the following: air conduction, bone conduction, masking capability, speech reception thresholds, speech discrimination, uncomfortable loudness levels (UCL), and most comfortable levels (MCL).

123.2(2) Any medical evaluation completed by a licensed physician requires all of the following prior to the sale of a hearing aid to an individual: receipt of the physician statement and clearance for amplification; and completion by the licensed hearing aid specialist of a current written health history and hearing examination that includes all of the procedures required in these rules, unless the physician order specifies otherwise. In the event an audiogram is provided by the physician, this testing requirement is waived. All records provided to the licensed hearing aid specialist will be maintained in the individual's records in accordance with the recordkeeping requirements in these rules.

123.2(3) Whenever any of the following conditions are found to exist either from observations by the licensed hearing aid specialist or person holding a temporary permit or on the basis of information furnished by a prospective hearing aid user, the hearing aid specialist or person holding a temporary permit will, prior to fitting and selling a hearing aid to any individual, suggest to that individual in writing that the individual should consult a licensed physician specializing in diseases of the ear, or if no such licensed physician is available in the community, then a duly licensed physician:

a. Visible congenital or traumatic deformity of the ear.

b. History of, or active drainage from the ear within the previous 90 days.

c. History of sudden or rapidly progressive hearing loss within the previous 90 days.

d. Acute or chronic dizziness.

e. Unilateral hearing loss of sudden or recent onset within the previous 90 days. Significant air-bone gap (greater than or equal to 15dB ANSI 500, 1000 and 2000 Hz. average).

f. Obstruction of the ear canal by structures of undetermined origin, such as foreign bodies, impacted cerumen, redness, swelling, or tenderness from localized infections of the otherwise normal ear canal.

123.2(4) Testing is not required in cases in which replacement hearing aids of the same make or model are sold within one year of the original sale, unless a medical evaluation occurs during this period, which requires compliance with the requirements stated in 123.2(2).

123.2(5) Except as otherwise provided in these rules, for individuals younger than 18 years of age, all of the requirements stated in these rules are applicable. In addition, the following are required:

a. Written authorization of a parent or legal guardian consenting to the services covered in these rules, and

b. An original signature on all documents required by law or these rules to be signed, including all sales transactions and receipts, required notifications, and warranty agreements.

123.2(6) For individuals 12 years of age or younger, all of the requirements stated in these rules are applicable. In addition, the parent or legal guardian must first present a written, signed recommendation for a hearing aid from a licensed physician specializing in otolaryngology. The recommendation must have been made within the preceding six months. In the event of a lost or damaged hearing aid, a replacement of an identical hearing aid may be provided within one year, unless a medical evaluation occurs during this period, which requires compliance with the requirements stated in 123.2(2).

645—123.3(154A) Requirements for sales receipt. Upon sale of a hearing aid device, the licensee shall provide to the person a sales receipt, which will include the following:

1. Licensee's signature.
2. Licensee's business address.
3. Licensee's license number.
4. Client signature and address.
5. Make, model, and serial number of the hearing aid furnished.
6. Statement to the effect that the aid or aids delivered to the purchaser are used or reconditioned, if that is the fact.
7. Full terms of sale, including:

- The date of sale;
- Specific warranty terms, including whether any extended warranty is available through the manufacturer;
- Specific return policy; and
- Whether any trial period is available.

8. The following statement in type no smaller than the largest used in the body copy portion of the receipt: "The purchaser has been advised that any examination or representation made by a licensed hearing aid specialist in connection with the fitting or selection and selling of this hearing aid is not an examination, diagnosis, or prescription by a person licensed to practice medicine in this state and therefore, must not be regarded as medical opinion or advice."

645—123.4(154A) Requirements for recordkeeping. A licensee shall keep and maintain records in the licensee's office or place of business at all times, and each such record shall be kept and maintained for a seven-year period.

123.4(1) The records for each person will include:

a. A complete record of each test performed and the results of the test.

b. A copy of any written recommendations.

c. A copy of medical clearances or waivers.

d. A copy of the written sales receipt.

e. A copy of terms of sale, including any warranty. A record of any adjustments or services provided on the hearing aid device, including whether such services were provided under warranty or other agreement.

f. A notation that the client consented, either verbally or in writing, to a service or services provided through a telehealth appointment, if applicable.

123.4(2) No less than 30 days prior to closure of a licensee's business, the licensee will provide written notification to clients of the location at which records will be maintained for a period of no less than 30 days following closure and the procedure to obtain those records. The licensee may arrange the transfer of records to another licensee for the purpose of maintenance of the records, provided that all contractual agreements have been satisfied.

645—123.5(154A) Telehealth appointments. A licensee may conduct a telehealth appointment so long as the services are provided in accordance with this rule.

123.5(1) A "telehealth appointment" is one wherein the licensee provides testing or adjustment services to a client using technology where the hearing aid specialist and the client are not at the same physical location during the appointment.

123.5(2) Conducting a telehealth appointment with a client who is physically located in Iowa during the appointment, regardless of the location of the hearing aid specialist, requires Iowa licensure.

123.5(3) When conducting a telehealth appointment, a licensee will utilize technology that is secure, HIPAA-compliant (Health Insurance Portability and Accountability Act of 1996, PL 104–191, August 21, 1996, 110 Stat 1936), and that includes, at a minimum, audio and video equipment that allows for two-way, real-time interactive communication between the licensee and the client. The licensee may use non-real-time technologies to prepare for an appointment or to communicate with clients between appointments.

123.5(4) A licensee who conducts a telehealth appointment will be held to the same standard of care as a licensee who provides in-person services. A licensee will not utilize a telehealth appointment if the standard of care for the particular service cannot be met using telehealth technology.

123.5(5) Prior to the first telehealth appointment with a client, the licensee will obtain informed consent from the client that is specific to the service or services that will be provided in the telehealth appointment. The informed consent will specifically inform the client of, at a minimum, the following:

a. The risks and limitations of the use of technology to the specific service;

b. The potential for unauthorized access to protected health information; and

c. The potential for disruption of technology during a telehealth appointment.

123.5(6) A licensee will only conduct a telehealth appointment if the licensee is competent to provide the particular service using telehealth technology. A licensee's competence to provide a particular service using telehealth technology will be established by the licensee's education, training, and experience.

123.5(7) A licensee who conducts a telehealth appointment will note in the client's record that the service or services were provided through a telehealth appointment.

These rules are intended to implement Iowa Code chapter 154A.

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 4/17/24.