

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).

[ARC 9424B, IAB 3/9/11, effective 4/13/11; ARC 1005C, IAB 9/4/13, effective 10/9/13; ARC 2151C, IAB 9/16/15, effective 10/21/15]

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 who is responsible for reducing the history to written form;

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 informed that it is in the individual’s best health interests 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 in accordance with these rules 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 shall be maintained in the individual’s records in accordance with the record-keeping 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 shall, prior to fitting and selling a hearing aid to any individual, suggest to that individual in writing that the individual’s best interests would be served if the individual would 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.

- f. Significant air-bone gap (greater than or equal to 15dB ANSI 500, 1000 and 2000 Hz. average).
- g. 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 shall not be 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 but not limited to 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).

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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 shall 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."

[ARC 9424B, IAB 3/9/11, effective 4/13/11; ARC 2151C, IAB 9/16/15, effective 10/21/15]

645—123.4(154A) Requirements for record keeping. 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 shall 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.

f. A written record of any adjustments or services provided on the hearing aid device, including whether such services were provided under warranty or other agreement.

g. 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 shall 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.

[ARC 9424B, IAB 3/9/11, effective 4/13/11; ARC 3559C, IAB 1/3/18, effective 2/7/18; ARC 5939C, IAB 10/6/21, effective 11/10/21]

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, shall require Iowa licensure.

123.5(3) When conducting a telehealth appointment, a licensee shall utilize technology that is secure, HIPAA-compliant, 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 shall be held to the same standard of care as a licensee who provides in-person services. A licensee shall 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 shall 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 shall 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 shall 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 shall be established by the licensee's education, training, and experience.

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

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

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