

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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