265 CMR 6.00: STANDARDS OF PRACTICE

Section

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6.01: Minimal Procedures and Equipment

(1) The following minimum procedures shall be used in the fitting and selling of hearing instruments:

(a) pure tone audiometric testing by air and bone conduction pathways through a calibrated system in the appropriate environment to determine the type and degree of hearing deficiency;

(b) effective masking when indicated;

(c) appropriate testing using a calibrated system or other acceptable verification technique in the appropriate environment to determine client's hearing ability, as measured by the percentage words the client is able to repeat correctly, the client's ability to discriminate speech, the client's most comfortable and uncomfortable loudness levels in decibels, and the best fitting arrangement for maximum hearing aid benefit;

(d) otoscopic inspection of the outer ear;

(e) a pertinent case history; and

(f) a final fitting ensuring physical and operational comfort of the hearing aid.

(2) Mandatory Disclosure. Any person with a 15 dB or greater difference between air conduction and bone conduction hearing, at three frequencies of 500 hz, 1000hz, and 2000hz in either ear, must be advised of the possibility of medical correction.

(3) At a minimum, the following required equipment shall be used:

(a) a wide-range audiometer which meets the specifications of the American National Standards Institute for diagnostic audiometers;

(b) a speech audiometer or a master hearing aid in order to determine the most comfortable listening level and speech discrimination.

6.02: Certification of Test Equipment

(1) Each audiometric test conducted by a registrant or apprentice in the fitting or selling of hearing aids must be conducted on equipment that has been calibrated on at least an annual basis.

(2) It is the responsibility of a registrant to maintain records proving that all test equipment is properly calibrated on at least an annual basis.

(3) Upon request, a registrant shall furnish to Division or Board copies of documentation certifying proper calibration of test equipment used.

6.03: Medical Evaluation Requirements/Clients Younger than 18 Years Old

(1) Medical Evaluation Requirements.

(a) General. Except as provided in 265 CMR 6.03(1)(b), a hearing aid dispenser shall not sell a hearing aid unless the prospective user has presented to the hearing aid dispenser a written statement signed by a licensed physician that states that the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid. The medical evaluation must have taken place within the preceding six months.

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(b) Waiver to the Medical Evaluation Requirements. If the prospective hearing aid user is 18 years of age or older, the hearing aid dispenser may afford the prospective user an opportunity to waive the medical evaluation requirement of 265 CMR 6.03(1) provided that the hearing aid dispenser:

1. Informs the prospective user that the exercise of the waiver is not in the user's best health interest;
2. Does not in any way actively encourage the prospective user to waive such a medical evaluation; and
3. Affords the prospective user the opportunity to sign the following statement: "I have been advised by -------- -------- (Hearing aid dispenser's name) that the Food and Drug Administration has determined that my best health interest would be served if I had a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. I do not wish a medical evaluation before purchasing a hearing aid."

(2) Clients Younger than 18 Years Old. A registrant or apprentice shall not sell a hearing instrument to a person younger than 18 years old unless the client, a parent, or guardian has presented to the registrant or apprentice a written statement signed by a licensed physician that states that the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing instrument. The physician's evaluation must have taken place within the preceding six months.

(3) If, upon inspection of the ear canal during a hearing aid fitting and upon questioning of the client, there is recent history of infection, any observable anomaly, deformity of ear, unilateral loss of hearing within 90 days, bilateral loss of hearing within 90 days, evidence of cerumen or other occlusion, pain in the ear, discharge, ear bone gap at 15 Db at 500 hz, 1000 hz, and 2000 hz or dizziness, the client shall be instructed to see a physician (preferably a physician who specializes in diseases of the ear). A hearing aid shall not be fitted until medical clearance is obtained for the condition noted or a waiver of informed consent for the specific condition noted or complained of is signed by the client. If, upon the client's return, the condition noted is no longer observable and the client signs a medical waiver, a hearing aid may be fitted.

6.04: Cancellation of Sale

(1) 30-day Trial Period.

(a) In addition to any other rights and remedies a purchaser of a hearing instrument in Massachusetts is afforded, such purchaser shall have a 30-day trial period after date of receipt of the hearing instrument during which time such purchaser shall be entitled to a limited money back guarantee.

(b) During the 30-day period after receiving the hearing instrument, the purchaser shall be able to cancel the purchase by returning the hearing instrument or sending to the seller by certified mail a written notice of cancellation. If written notice is sent, the purchaser must return the hearing instrument to the seller within ten days of the written notice being sent in order for the money back guarantee to apply.

(c) If the hearing instrument must be repaired, remade, or adjusted during the 30-day trial period, the running of the 30-day trial period is suspended one day for each 24-hour period that the hearing aid is not in the purchaser's possession. For purposes of the computation of the trial period, a repaired, remade or adjusted hearing aid must be reclaimed by the purchaser within three working days after notification of availability. The running of the 30-

day trial period resumes on the day the purchaser reclaims the repaired, remade or adjusted hearing aid or on the fourth day after availability.

(2) If a purchaser cancels or rescinds a sale within the terms of 265 CMR 6.04, the seller shall be entitled to retain the charges for ear molds; service provided to fit the hearing aid; and any repair, remake or adjustment performed that is not contained within any other warranty of sale or service, not to exceed 20% of the purchase charge. Any charges retained shall be explained in writing to the purchaser.

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(3) Regarding refunds, if a purchased hearing instrument has been damaged, the seller may deduct from any refund due the purchaser the reasonable costs incurred in repairing the hearing instrument to make it suitable for resale. If the hearing instrument has been damaged beyond repair, the purchaser is liable for the full purchase price.

6.05: Bill of Sale Requirements

(1) A registrant shall provide to each person to whom he or she sells or leases a hearing instrument a bill of sale that shall at a minimum contain the following information:

(a) the registrant's hearing instrument specialist license number;
(b) the name of the registrant or the registrant's current business name as listed with the Secretary of the Commonwealth;
(c) the current business telephone number and address of the registrant;
(d) the brand, model, manufacturer or manufacturer's identification code, and serial number of the hearing instrument furnished at point of delivery;
(e) an itemization of the total purchase price including, but not limited to the cost of the hearing instrument, ear mold, batteries and other accessories, and any services provided,
(f) a statement notifying the purchaser of the limited money back guarantees as set forth in 265 CMR 6.04 and a clear and precise statement of any guarantee or trial period;
(g) the name, address and signature of the purchaser;
(h) the date of consummation of the sale;
(i) a statement whether the hearing aid is new, used or reconditioned; and
(j) the waiver required by the provisions of M.G.L. c. 93, § 74.

(2) The registrant/seller shall provide the purchaser of a hearing instrument with any applicable manufacturer's instructional brochure that contains operating instructions, purchase privileges including manufacturer's warranty at the point of delivery.

(3) Statement if Hearing Aid Is Used or Rebuilt. If a hearing aid has been used or rebuilt, this fact shall be declared on the container in which the hearing aid is packaged and on a tag that is physically attached to such hearing aid. Such fact may also be stated in the *User Instructional Brochure*.

6.06: Delivery of Hearing Instruments by Mail

No hearing instrument shall be delivered to a consumer in Massachusetts through the mail unless all provisions of 265 CMR 6.03 are met.

6.07: Updated Licensure Information/Notification of Employment

Personal Information. It is the responsibility of every individual registrant to notify the Board of any errors or changes in personal information displayed on his or her certificate of licensure or maintained on record by the Board including, but not limited to, name and address. Any change of information must be sent to the Board in writing within 30 days of such change.

6.08: Facility and Record Inspection Requirements

(1) Display of License. Each licensed hearing instrument specialist shall conspicuously display a current and accurate certificate of Board license in his or her place of business. Original and

duplicate certificates shall be issued by the Board for a reasonable fee to a registrant operating or working in more than one location. Upon request, the registrant shall present his or her license to a customer when dispensing hearing instruments outside of his or her place of business.

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(2) Record Keeping Requirement.

(a) Each registrant shall keep records of all services rendered and of all equipment testing and maintenance for a minimum of four years. These records shall contain the names and addresses of all persons to whom services were rendered; the date the hearing instrument warranty expires; a description of the services and the dates the services were provided; and copies of any contracts, bills of sale and receipts.

(b) All records as required by 265 CMR 6.08(2) shall be owned by the establishment or facility and shall remain with the establishment or facility in the event the registrant changes employment. If a contract between the establishment or facility and a registrant provides that the records are to remain with the registrant, copies of such records shall be provided to the establishment or facility.

(3) Right of Inspection. Any duly authorized agent or employee of the Division of Registration shall have the right to make such inspections and investigations as are necessary in order to determine the state of compliance with the provisions of M.G.L. c. 13, §§ 93 through 95, M.G.L. c. 112, §§ 196 through 200 and 265 CMR 2.00 through 8.00. Such duly authorized agent or employee of the Division may enter the premises of a licensee during business hours and inspect the records of same upon a reasonable belief that a violation of applicable laws or regulations is being or has been committed or the registrant has failed or is failing to comply with provisions of the applicable laws, regulations and rules governing hearing instrument specialists.

6.09: Label and Labeling Requirements/Requirements Regarding the *User Instructional Brochure*

(1) Label Requirements for Hearing Aids. Hearing aids shall be clearly and permanently marked with:

(a) The name of the manufacturer or distributor, the model name or number, the serial number, and the year of manufacture.

(b) A "+" symbol to indicate the positive connection for battery insertion, unless it is physically impossible to insert the battery in the reversed position.

Labeling information required by 265 CMR 6.09 shall be included in a *User Instructional Brochure* that shall be developed by the manufacturer or distributor, shall accompany the hearing aid, and shall be provided to the prospective user by the dispenser of the hearing aid in accordance with 265 CMR 6.09(2) and (3).

(2) Availability of *User Instructional Brochure*. Upon request by an individual who is considering purchase of a hearing aid, a dispenser shall, with respect to any hearing aid that he dispenses, provide a copy of the *User Instructional Brochure* for the hearing aid or the name and address of the manufacturer or distributor from whom a *User Instructional Brochure* for the hearing aid may be obtained. In addition to assuring that a *User Instructional Brochure* accompanies each hearing aid, a manufacturer or distributor shall with respect to any hearing aid that he manufactures or distributes: Provide sufficient copies of the *User Instructional Brochure* to sellers for distribution to users and prospective users; and provide a copy of the *User Instructional Brochure* to any hearing aid professional, user, or prospective user who requests a copy in writing.

(3) Opportunity to Review *User Instructional Brochure*. Before signing any statement and before the sale of a hearing aid to a prospective user, the hearing aid dispenser shall:

(a) Provide the prospective user a copy of the *User Instructional Brochure* for a hearing aid that has been, or may be selected for the prospective user;

(b) Review the content of the *User Instructional Brochure* with the prospective user orally, or in the predominate method of communication used during the sale;
(c) Afford the prospective user an opportunity to read the *User Instructional Brochure*.

(4) Warning Statement. The *User Instructional Brochure* shall contain the following warning statement: Warning to Hearing Aid Dispensers. A hearing aid dispenser should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid if the hearing aid dispenser determines through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions:

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(a) Visible congenital or traumatic deformity of the ear;
(b) History of 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) Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz;
(g) Visible evidence of significant cerumen accumulation or a foreign body in the ear canal;
(h) Pain or discomfort in the ear. Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels because there may be risk of impairing the remaining hearing of the hearing aid user. (265 CMR 6.09(4)(h) is required only for those hearing aids with a maximum sound pressure capability greater than 132 decibels (dB).)

(5) Notice for Prospective Hearing Aid Users. The *User Instructional Brochure* shall contain the following notice: Important Notice for Prospective Hearing Aid Users. Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased. Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid. The physician will refer you to a hearing aid dispenser for a hearing aid evaluation. The hearing aid dispenser will conduct a hearing aid evaluation to assess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the dispenser to select and fit a hearing aid to your individual needs. If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial-rental or purchase-option program. Many hearing aid dispensers now offer programs that permit you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid. Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged. Children with Hearing Loss. In addition to seeing a physician for a medical evaluation, a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation since hearing loss may cause problems in language development and the educational and social growth of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss.

(6) Technical Data. Technical data useful in selecting, fitting, and checking the performance of a hearing aid shall be provided in the *User Instructional Brochure* or in separate labeling that accompanies the device. The determination of technical data values for the hearing aid labeling shall be conducted in accordance with the test procedures of the American National Standard *Specification of Hearing Aid Characteristics*, ANSI S3.22-2003 (Revision of ANSI S3.22-1996) (Includes April 2007 Erratum), as incorporated by reference into 21 CFR 801.420(c)(4). Copies are available from the Standards Secretariat of the Acoustical Society of America, 120 Wall St., New York, NY 10005-3993 or go to

http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. As a minimum, the *User Instructional Brochure* or such other labeling shall include the appropriate values or information for the following technical data elements as these elements are defined or used in such standard:

(a) Saturation output curve (SSPL 90 curve);
(b) Frequency response curve;
(c) Average saturation output (HF-Average SSPL 90);
(d) Average full-on gain (HF-Average full-on gain);
(e) Reference test gain;
(f) Frequency range;

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(g) Total harmonic distortion;
(h) Equivalent input noise;
(i) Battery current drain;
(j) Induction coil sensitivity (telephone coil aids only);
(k) Input-output curve (ACG aids only);
(l) Attack and release times (ACG aids only).

(7) Statements in *User Instructional Brochure* Other than Those Required. A *User Instructional Brochure* may contain statements or illustrations in addition to those required by 265 CMR 6.09(4) through (6) if the additional statements:

(a) Are not false or misleading in any particular, *e.g.*, diminishing the impact of the required statements; and

(b) Are not prohibited by 21 CFR 1.0 or by the regulations of the Federal Trade Commission.

REGULATORY AUTHORITY

265 CMR 6.00: M.G.L. c. 93, §§ 72 through 75; c. 112, § 199.