



THE COMMONWEALTH OF MASSACHUSETTS
William Francis Galvin
Secretary of the Commonwealth

Regulation Filing *To be completed by filing agency*

CHAPTER NUMBER: 265 CMR 3.00

CHAPTER TITLE: Procedure for Registration

AGENCY: Board of Registration of Hearing Instrument Specialists

SUMMARY OF REGULATION: *State the general requirements and purposes of this regulation.*
This regulation establishes licensing application procedures and states minimum qualifications for licensure as a Hearing Instrument Specialist. It also includes process for renewing a license and reinstating a lapsed, suspended or revoked license.

REGULATORY AUTHORITY: M.G.L. c. 13, s. 94 and c. 112, ss. 197, 197A and 198

AGENCY CONTACT: Lynn Read, Board Counsel PHONE: 617-727-4423

ADDRESS: Div. of Prof. Licensure, 1000 Washington Street, Suite 710, Boston, MA 02118

Compliance with M.G.L. c. 30A

EMERGENCY ADOPTION - *if this regulation is adopted as an emergency, state the nature of the emergency.*

PRIOR NOTIFICATION AND/OR APPROVAL - *If prior notification to and/or approval of the Governor, Legislature or others was required, list each notification, and/or approval and date, including notice to the Local Government Advisory Commission.*

EO 562 approval received - 04/06/16

DHCD & MA Municipal Assoc. notified by letter - 04/20/16

Notice of Public Hearing published in Boston Globe & Springfield Republican - 05/06/16

PUBLIC REVIEW - *M.G.L. c. 30A sections 2 and/or 3 requires notice of the hearing or comment period, including a small business impact statement, be filed with the Secretary of the Commonwealth, published in appropriate newspapers, and sent to persons to whom specific notice must be given at least 21 days prior to such hearing or comment period.*

Date of public hearing or comment period: Hearing 05/27/16; comment ended 06/08/16

FISCAL EFFECT - Estimate the fiscal effect of the public and private sectors.

For the first and second year: None

For the first five years: None

No fiscal effect: No fiscal effect

SMALL BUSINESS IMPACT - M.G.L. c. 30A section 5 requires each agency to file an amended small business impact statement with the Secretary of the Commonwealth prior to the adoption of a proposed regulation. If the purpose of this regulation is to set rates for the state, this section does not apply.

Date amended small business impact statement was filed: 07/20/16

CODE OF MASSACHUSETTS REGULATIONS INDEX - List key subjects that are relevant to this regulation:
Hearing Instrument Specialists, Hearing Instruments, Hearing Aids, Licensure, Registration, Renewal, Reinstatement

PROMULGATION - State the action taken by this regulation and its effect on existing provisions of the Code of Massachusetts Regulations (CMR) or repeal, replace or amend. List by CMR number:

Amends 265 CMR 3.00

ATTESTATION - The regulation described herein and attached hereto is a true copy of the regulation adopted by this agency. ATTEST:

SIGNATURE: [Signature] DATE: 7/28/16

Publication - To be completed by the Regulations Division

MASSACHUSETTS REGISTER NUMBER: 1319 DATE: 8/12/16

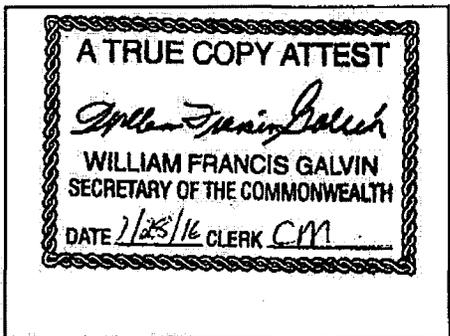
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CODE OF MASSACHUSETTS REGULATIONS

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265 CMR: BOARD OF REGISTRATION OF HEARING INSTRUMENT SPECIALISTS

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265 CMR: BOARD OF REGISTRATION OF HEARING INSTRUMENT SPECIALISTS

265 CMR 3.00: PROCEDURE FOR REGISTRATION

Section

- 3.01: Application and Licensing
- 3.02: Procedures for Renewal of a License and Renewal of a Lapsed/Expired License
- 3.03: Procedures for Reinstatement of a License Which Has Been Revoked, Suspended, Surrendered or Placed on Probation
- 3.04: Board Notification of Change in Name or Address
- 3.05: License Fee
- 3.06: Late Filing Fee
- 3.07: Application Fee
- 3.08: Reimbursement of Fees

3.01: Application and Licensing

(1) Application.

- (a) Application for licensure must be made on forms furnished by the Board.
- (b) No application shall be acted upon by the Board unless said application is made on forms furnished by the Board, and unless said application is completely and properly filled out, signed under the penalties of perjury, and accompanied by such information as the Board requires.

(2) Licensure. In order to be licensed as a hearing instrument specialist applicants must meet the following requirements for licensure set by M.G.L. c. 112, § 197:

- (a) be 18 years of age or older;
 - (b) have a high school diploma or its equivalent;
 - (c) be of good moral character;
 - (d) have successfully completed a board approved apprenticeship of a minimum of 12 months, including completion of the apprentice training program and supervised work experience, and meet one of the following criteria:
 - 1. hold current certification as a hearing instrument specialist from a board approved, nationally recognized body certifying hearing instrument specialists; or
 - 2. pass a written or electronic examination approved by the board and designed to test competencies and knowledge needed in hearing aid fitting and dispensing; and
 - (e) pay the appropriate fee set by the secretary of administration and finance.
- These requirements are subject to the exceptions provided in 265 CMR 3.01(3).

(3) Licensure by Reciprocity. An individual who holds a license as a hearing instrument specialist or the equivalent thereof as determined by the board from a state which is deemed by the board to have substantially equivalent or higher licensure requirements than those of the commonwealth may be licensed as a hearing instrument specialist without satisfying the requirements of M.G.L. c. 112, § 197(f)(4) or the requirements 265 CMR 3.01(2)(d). The word "state" as used in 265 CMR 3.01(3), shall include a state or territory of the United States, the District of Columbia, the Commonwealth of Puerto Rico or a foreign country, state or province.

3.02: Procedures for Renewal of a License and Renewal of a Lapsed/Expired License

(1) Requirements for Renewal of a License.

- (a) A registrant must renew his or her license every two years. Each license originally issued to an individual shall be valid until April 1st on the odd year next occurring. Upon renewal, the license will be valid until April 1st on the odd year next occurring.
- (b) A registrant must submit to the Board a completed renewal application and the required fees prior to the expiration date of the license; and
- (c) A registrant must fulfill and document the continuing education requirements and standards of practice and conduct as required in 265 CMR 3.00.

3.02: continued

(2) Procedures for Renewal of a Lapsed/Expired License.

(a) If a registrant fails to meet the requirements for renewal of his or her license as set forth in 265 CMR 3.02(1), the license of such person is considered expired and not in good standing. A registrant with an expired license is not authorized to dispense hearing instruments or use the title "hearing instrument specialist" during the period in which the license is expired.

(b) If a registrant requests that his or her expired license be reinstated within four years from the time a registrant's license expires, that individual must pay the renewal fee for the current licensure period, pay one late fee, and document completion of all continuing education contact hours required by the Board since the date the license was last issued/renewed.

(c) If an individual fails to renew his or her license within four years, the registrant must submit a completed renewal form, pay the current renewal fee, pay a late fee, and document completion of the continuing education contact hours required by the Board for the current renewal period. The Board may require the registrant to: appear before the Board, take an examination, complete additional continuing education or to practice under supervision prior to or as a term or condition of issuing said late renewal license.

3.03: Procedures for Reinstatement of a License Which Has Been Revoked, Suspended, Surrendered or Placed on Probation

Procedures for the reinstatement of a license after discipline shall be determined by guidelines established by the Board or, in specific matters, by consent agreement, decision and order of the Board.

3.04: Board Notification of Change in Name or Address

(1) Official Mailing Address. The mailing address supplied to the Board by the Registrant will suffice as the legal address for the receiving of official process or notification from the Board. Failure to supply the Board with an official address for the receiving of legal process or other Board notifications may result in default judgment in any adjudicatory proceeding before the Board.

(2) Change of Address. The registrant shall notify the Board of any change in his or her name, or address. Such notification shall be in writing and shall be submitted within 30 days of the change in name or address. Such written notification may be submitted by electronic mail to the Board's contact address on the Board's website, or by other electronic means approved by the Board.

3.05: License Fee

Biennial license fees are set by the Secretary of Administration and Finance of the Commonwealth of Massachusetts. Fees for those applying between renewal dates shall not be prorated.

3.06: Late Filing Fee

Renewal forms and fees received after the due date will be subject to a late filing fee set by the Secretary of Administration and Finance.

3.07: Application Fee

A separate application fee will be charged for each new application.

3.08: Reimbursement of Fees

Application and license fees are not refundable.

REGULATORY AUTHORITY

265 CMR 3.00: M.G.L. c. 13, § 94; c. 112, §§ 197, 197A and 198.

NON-TEXT PAGE



THE COMMONWEALTH OF MASSACHUSETTS

William Francis Galvin
Secretary of the Commonwealth**Regulation Filing** *To be completed by filing agency*CHAPTER NUMBER: 265 CMR 4.00CHAPTER TITLE: Apprentice Training and Registration RequirementsAGENCY: Board of Registration of Hearing Instrument SpecialistsSUMMARY OF REGULATION: *State the general requirements and purposes of this regulation.***This regulation establishes licensing application procedures and minimum qualifications for licensure as Apprentice Hearing Instrument Specialists.**REGULATORY AUTHORITY: M.G.L. c. 112, s. 198AGENCY CONTACT: Lynn Read, Board Counsel PHONE: (617) 727-4423ADDRESS: Div. of Prof. Licensure, 1000 Washington Street, Suite 710, Boston, MA 02118**Compliance with M.G.L. c. 30A**EMERGENCY ADOPTION - *if this regulation is adopted as an emergency, state the nature of the emergency.*PRIOR NOTIFICATION AND/OR APPROVAL - *If prior notification to and/or approval of the Governor, Legislature or others was required, list each notification, and/or approval and date, including notice to the Local Government Advisory Commission.*

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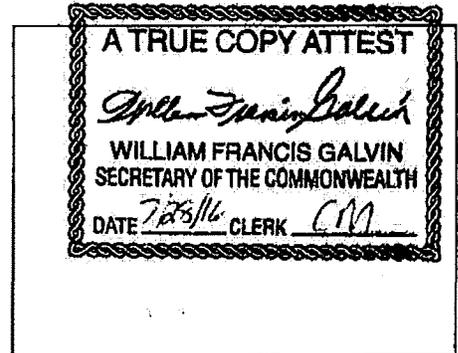
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CODE OF MASSACHUSETTS REGULATIONS

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265 CMR: BOARD OF REGISTRATION OF HEARING INSTRUMENT SPECIALISTS

265 CMR 4.00: APPRENTICE TRAINING AND REGISTRATION REQUIREMENTS

Section

- 4.01: Application for Apprentice's Certificate
- 4.02: Terms of Apprenticeship Program, Disputed Terminations
- 4.03: Formal Training Program and Educational Equivalents
- 4.04: Duties/Work Requirements of Apprentice
- 4.05: Duties and Responsibilities of Apprenticeship Supervisor
- 4.06: Home Visits

4.01: Application for Apprentice's Certificate

- (1) Any person 18 years of age or older who holds a high school diploma from an accredited high school or has equivalent proof of high school education may apply in writing for certification as an apprentice. The application shall be made on a form or electronic application prescribed by the Board.
- (2) As a condition for applying for an apprentice's certificate, the applicant shall agree in writing to participate in and perform the training, functions and responsibilities prescribed for apprentices in 265 CMR 4.00 and agree to uphold standards of ethics and professional conduct.
- (3) The applicant's apprenticeship supervisor shall certify the application as prescribed on the application form. The certification shall include a verification of the statements of the apprentice and a statement that the supervisor agrees to participate in the apprenticeship program described in 265 CMR 4.00 including the provision of applicable instruction of the formal training requirements of 265 CMR 4.03 and to perform the functions and duties prescribed in 265 CMR 4.06.
- (4) The applicant's apprenticeship supervisor shall certify in writing that he/she is registered in good standing in the Commonwealth as a hearing instrument specialist or licensed as an audiologist. He or she shall provide the appropriate license number and date of expiration to the Board.
- (5) The applicant shall accompany his or her application with the filing fee set by the Secretary of Administration and Finance. The fee shall be paid by personal check or money order.
- (6) The Board shall notify an applicant promptly in writing whether or not his/her apprentice application has been approved. The initial written notification may be in electronic form. If the Board approves the application, the Board shall issue to the applicant an apprentice's certificate, and such certificate shall include the name of the applicant's apprenticeship supervisor and the date on which the period of training and experience referred to in M.G.L. c. 112, § 198 shall begin.

4.02: Term of Apprenticeship Program, Disputed Terminations

- (1) Term. The term of the apprenticeship program shall be a minimum of one year of full time or the equivalent part-time employment under the rules of supervision as specified in M.G.L. c. 112, § 198 and 265 CMR 4.00 and shall include instruction through a training program as set out in 265 CMR 4.03. Apprentices who work in excess of the normal work day or week shall nevertheless be required to complete the minimum one year term in order to qualify for a certificate of completion of the apprenticeship program. If the minimum one year full-time or equivalent part time employment hours are not completed, the apprentice registration shall expire 18 months after it is granted. An apprentice registration may be reissued once for a period of 18 months at the discretion of the Board for good cause shown. Such one-time reissuance shall be available if either the minimum one year full time or equivalent part time employment has not been completed or has been completed but the examination has not been passed.
- (2) The supervisor shall be responsible for providing supervision until either:
 - (a) the apprentice obtains a certificate of registration as a hearing instrument specialist from the Board; or

4.02: continued

- (b) the supervisor or apprentice gives written notification to the Board that he or she is terminating supervision and training.
- (3) An apprentice may cancel his or her apprenticeship program at any time during the program, upon written notice to the Board and the employer/supervisor of the termination and its effective date.
- (4) Disputed Terminations.
 - (a) An employer/supervisor may terminate the apprenticeship program of an apprentice whom he or she reasonably determines does not demonstrate aptitude or interest in the practice of a hearing instrument specialist. The supervisor must first notify the Board and the apprentice in writing of his or her intent to terminate the apprentice's participation no less than two weeks before the termination becomes effective. Upon written request to the Board by the apprentice affected, the Board or its designee may hold a conference with the apprentice and the supervisor within one month after the supervisor's notice of the intent to terminate has been received by the Board, unless the supervisor and the apprentice agree to a later date. The date on which the conference is scheduled to be held shall not affect or alter the intended date of termination unless the apprentice and supervisor otherwise agree.
 - (b) The purpose of the conference described in 265 CMR 4.02(4) is to review and consider on an informal basis the intended termination, in an effort to resolve the disputes or differences, if any, between the supervisor and the apprentice. The conference does not constitute an adjudicatory proceeding as defined in M.G.L. c. 30A. The Board (or its designee) may recommend to the supervisor/employer that he/she continue to employ the apprentice. Neither the Board nor its designee may require that an employer continue to employ an apprentice.

4.03: Formal Training Program and Educational Equivalents

- (1) Home Study Course.
 - (a) During the period of apprenticeship, the apprentice shall complete the course entitled, *Distance Learning for Professionals in Hearing Health Sciences*, also referred to as the International Hearing Society Home Study Course, and shall submit proof of passing the home study course prior to taking the licensure exam.
 - (b) If the apprentice passes the home study course final examination but fails the Massachusetts licensure exam, he or she will not have to repeat the home study course prior to the next available Massachusetts licensure examination.
 - (c) The Board may accept home study courses other than the International Hearing Society Course. If the apprentice enrolls in a home study course other than the International Hearing Association Course, he or she must submit in writing to the Board a request to take such home study course. The request must contain a description of the course including a syllabus and grading criteria. If approved, the apprentice will be required to submit proof of passing the home study course prior to taking the licensure exam.
- (2) Substitute for Home Study Course.
 - (a) An apprentice who has a certificate, an associates degree or a higher degree in audiology or hearing instrument technology from an accredited college or university and has received passing grades in every audiology or hearing instrument class may substitute such certificate or degree for the home study requirement. The apprentice must submit an official transcript to the Board prior to taking the licensure exam.
 - (b) The Board may accept a college certificate or degree in a discipline other than audiology or hearing instrument technology as a substitute for the home study program if the Board determines such degree is significantly related to the field of hearing instrument technology. The apprentice must submit to the Board a written request to substitute a certificate or degree in a discipline other than audiology or hearing instrument technology. Such request must include a copy of the official transcript.
- (3) Practicum.
 - (a) During the apprenticeship period, the apprentice shall be required to have at least 150 hours of directly supervised practicum that shall include the following:

4.03: continued

1. 25 hours of pure tone air conduction, bone conduction, and speech audiometry, recorded and/or live voice;
2. 25 hours of hearing instrument evaluations post fitting;
3. 20 hours of instrument fittings with actual clients;
4. ten hours of earmold orientation types, uses, and terminology;
5. 15 hours of earmold impressions and otoscopic examinations of the ear;
6. 15 hours of troubleshooting of defective hearing instruments;
7. 20 hours of case history with actual clients;
8. Ten hours of Massachusetts general laws and regulations governing the licensing of persons fitting and dispensing hearing instruments and federal Food and Drug Administration and Federal Trade Commission regulations relating to the fitting and dispensing of hearing instruments; and
9. Ten hours of supplemental work in one or more of the above areas.

(b) The specific required hours of practical instruction as set out in 265 CMR 5.03(3) are to be provided by the apprentice's supervisor or a designee of the supervisor. If any training is provided by a designee of the supervisor, such designee must be licensed in the Commonwealth as a hearing instrument specialist or audiologist and the Board, as needed may request a copy of such license.

(c) The time spent by apprentices in related instruction during the regular workday is to be classified as hours of work, and apprentices are to receive their normal hourly compensation for this time. Such hours will be counted as part of the term of the apprenticeship. Time spent by apprentices in related instruction at local educational institutions outside the regular work hours is not to be classified as hours of work, and the employer is not required to pay the apprentice their normal hourly compensation for this time.

(d) Prior to applying for licensure, an apprentice must submit in writing to the Board certification from his or her supervisor that all of the specific required hours of practical training have been successfully completed.

4.04: Duties/Work Requirements of Apprentice

(1) In entering into apprenticeship program prescribed by 265 CMR 4.00, an apprentice shall assume all of the responsibilities described in 265 CMR 4.00 and shall follow all of the state and federal laws, rules and regulations governing or related to the dispensing of hearing instruments.

(2) An apprentice shall perform diligently and faithfully the work of dispensing hearing instruments and such duties as are assigned by his or her employer or supervisor.

(3) An apprentice shall perform the functions of a hearing instrument specialist in accordance with Board rules only under the supervision of a licensed hearing instrument specialist or licensed audiologist. Such supervision shall be direct, on site and full time, or the equivalent part time, for a minimum of 30 days after the initial hiring of the apprentice.

(4) It is the responsibility of an apprentice to fulfill the formal training and practicum requirements as set forth in 265 CMR 4.03 and obtain and submit to the Board all required documentation concerning these requirements.

(5) An apprentice shall treat all customers and coworkers in a professional and courteous manner and shall respect the property of customers, the employer and colleagues and shall abide by the employer's work rules.

4.05: Duties and Responsibilities of Apprenticeship Supervisor

(1) Every apprentice shall have one designated supervisor who shall carry out all the duties, functions and responsibilities of a supervisor as set forth in 265 CMR 4.00. Such supervisor shall sign the application form of the apprentice as set out in 265 CMR 4.01(3) certifying his or her agreement to be designated as the apprenticeship supervisor. Such supervisor may or may not be the employer of the apprentice. If the supervisor is not the employer of the apprentice, he or she must be an employee of the apprentice's employer.

4.05: continued

- (2) In entering into the apprenticeship program described by 265 CMR 4.00, a supervisor shall assume all of the responsibilities described in 265 CMR 4.00 and shall follow all of the state and federal laws, rules and regulations governing or related to the practice of dispensing hearing instruments and shall treat all customers, coworkers and apprentices in a professional and courteous manner.
- (3) A supervisor may supervise only one designated apprentice at any given time.
- (4) Direct Supervision. For a minimum of 30 days full-time or the equivalent part-time after the initial hiring of the apprentice, the supervisor is responsible for direct, on site supervision of the apprentice. Such direct supervision shall include:
- (a) the presence of the supervisor in the office to which the apprentice is assigned all of the time which the apprentice works;
 - (b) the physical presence of the supervisor in the same work area with the apprentice a minimum of 50% of the time in which the apprentice is providing services;
 - (c) supervisor approval of the selection of a hearing aid by an apprentice;
 - (d) actual oversight by the supervisor of all testing and taking of ear mold impressions performed by the apprentice;
 - (e) written approval by the supervisor of the results of all hearing tests performed by the apprentice; and
 - (f) countersignature by the supervisor of all sales documents prepared by the apprentice.
- (5) Supervision Subsequent to Direct Supervision Period. After the minimum 30 day full-time or equivalent part-time direct supervision period, for the remainder of the apprenticeship, the supervisor shall:
- (a) review and approve in writing all hearing aid fittings by the apprentice, including the physical inspection of ear mold impressions, ear mold plans, and hearing aid recommendations and fittings;
 - (b) give final approval to work performed by the apprentice; and
 - (c) attempt to contact the consumer who purchased the hearing aid by phone or through a follow up appointment within one week of purchase to ensure satisfaction with the fitting.
- (6) Written Report.
- (a) A supervisor shall personally approve the progress of the apprentice he or she is supervising and shall make a detailed written evaluation of the apprentice periodically, but not less frequently than once every three months.
 - (b) The report shall describe in detail the specific types and hours of work experience and training and related technical instruction which the apprentice has received during the three-month reporting period.
 - (c) A supervisor shall sign the report under the penalties of perjury.
 - (d) A supervisor shall give a copy of each written evaluation and each written report concerning an apprentice to the apprentice.
- (7) A supervisor shall notify the Board of the completion of all apprenticeship programs.

4.06: Home Visits

- (1) During the first 60 days of an apprenticeship, no apprentice shall conduct or participate in a home visit to a customer for the purpose of testing or fitting without being accompanied by his or her supervisor or a licensed hearing instrument specialist or audiologist licensed in Massachusetts and designated by the supervisor. Such licensee designated by a supervisor shall act as the apprentice's supervisor for purposes of the home visit and is responsible for following all state and federal laws and rules and regulations governing or related to the practice of dispensing hearing instruments. A supervisor is responsible for the conduct of the apprentice on all unsupervised visits during the entire length of the apprenticeship.

4.06: continued

(2) While on a home visit, the apprentice and supervisor shall abide by all state and federal laws and rules and regulations governing or related to the practice of dispensing hearing instruments including 265 CMR 7.04: *Conduct for Home Visits* specifically governing professional conduct for home visits.

REGULATORY AUTHORITY

265 CMR 4.00: M.G.L. c. 112, § 198.

NON-TEXT PAGE



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William Francis Galvin
Secretary of the Commonwealth

Regulation Filing *To be completed by filing agency*

CHAPTER NUMBER: 265 CMR 5.00

CHAPTER TITLE: Continuing Education

AGENCY: Board of Registration of Hearing Instrument Specialists

SUMMARY OF REGULATION: *State the general requirements and purposes of this regulation.*
This regulation sets out requirements that Hearing Instrument Specialists obtain continuing education during every license renewal cycle and states the nature of the programs accepted and the process for verifying or obtaining exemptions from the requirements.

REGULATORY AUTHORITY: M.G.L. c. 112, s. 197, 199

AGENCY CONTACT: Lynn Read, Board Counsel PHONE: (617) 727-4423

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For the first five years: None

No fiscal effect: No Fiscal Effect

SMALL BUSINESS IMPACT - M.G.L. c. 30A section 5 requires each agency to file an amended small business impact statement with the Secretary of the Commonwealth prior to the adoption of a proposed regulation. If the purpose of this regulation is to set rates for the state, this section does not apply.

Date amended small business impact statement was filed: 07/20/16

CODE OF MASSACHUSETTS REGULATIONS INDEX - List key subjects that are relevant to this regulation:
Hearing Instrument Specialists, Hearing Instruments, Hearing Aids, Continuing Education, Renewal, Exemptions

PROMULGATION - State the action taken by this regulation and its effect on existing provisions of the Code of Massachusetts Regulations (CMR) or repeal, replace or amend. List by CMR number:

Amends 265 CMR 5.00

ATTESTATION - The regulation described herein and attached hereto is a true copy of the regulation adopted by this agency. ATTEST:

SIGNATURE: [Signature] DATE: 7/29/16

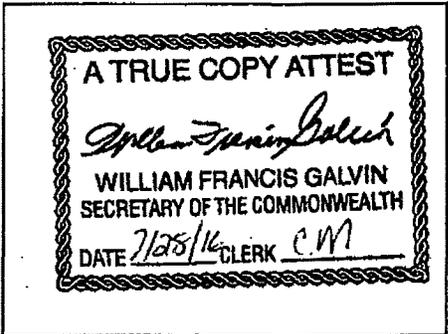
Publication - To be completed by the Regulations Division

MASSACHUSETTS REGISTER NUMBER: 1319 DATE: 8/12/16

EFFECTIVE DATE: 8/12/16

CODE OF MASSACHUSETTS REGULATIONS

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17 - 20.	17 - 20



265 CMR 5.00: CONTINUING EDUCATION

Section

- 5.01: Continuing Education Requirements
- 5.02: Verification/Approval of Registrant's Continuing Education Activities
- 5.03: Verification/Approval of Provider Continuing Education Programs and Activities
- 5.04: Waivers of Continuing Education Requirements
- 5.05: Appeals on Continuing Education Matters

5.01: Continuing Education Requirements

(1) Licensed hearing instrument specialists are required, as a condition of license renewal, to complete a minimum of 20 contact hours of continuing education activities per continuing education period. (For lapsed, expired, suspended, revoked or surrendered licenses, *see* 265 CMR 3.02: *Procedures for Renewal of a License and Renewal of a Lapsed/Expired License* and 3.03: *Procedures for Reinstatement of a License which has been Revoked, Suspended, Surrendered or Placed on Probation*). A minimum of ten of the total required 20 hours must be obtained through Board-recognized continuing education programs. The remaining ten hours may be obtained through Board approved continuing education activities as set forth in 265 CMR 5.01(2)

(2) Board-approved Continuing Education Activities.

(a) Published books, chapters of published books and/or articles in refereed journals related to the science or practice of the dispensing of hearing instruments or the science of hearing aids, authored by the licensee, may be submitted for not more than ten of the total 20 contact hours of continuing education activities required per continuing education period. A maximum of three hours may be credited per book chapter or article.

(b) Instructors of courses, workshops, or seminars may be credited one contact hour for each continuing education hour of the activity taught by the instructor, up to a maximum of ten of the required 20 hours of continuing education activity required per continuing education period.

(c) Any one academic course related to the contemporary practice of dispensing hearing instruments or the science of hearing aids may be submitted for not more than ten of the 20 required hours of continuing education activity required per continuing education period.

(d) Independent studies related to the science or practice of the dispensing of hearing instruments or the science of hearing aids approved by the Massachusetts Commission for the Deaf and Hard of Hearing, the Massachusetts Hearing Society or the Massachusetts Speech, Language and Hearing Association may be submitted for not more than ten of the 20 required hours of continuing education activity required per continuing education period.

(3) Only those continuing education activities which are completed during the required continuing education period (24 months prior to each renewal date) will be acceptable as qualifying continuing education activities for that period.

(4) All continuing education activities other than Board approved continuing education programs set forth in 265 CMR 5.02 are subject to approval by the Board.

5.02: Verification/Approval of Registrant's Continuing Education Activities

(1) At the time of license renewal, each registrant is required to submit to the Board a signed statement on a form provided by the Board attesting under the pains and penalty of perjury to satisfaction of the continuing education requirements.

(2) For each continuing education contact hour earned by participation in a continuing education program, a registrant must be able to provide documentation of the following:

- (a) the title of the program or course;
- (b) the number of hours spent in the program or course;
- (c) the name of the Board-recognized entity or the academic institution that sponsored the program or course; and
- (d) the date(s) and location that the program or course was given.

5.02: continued

(3) For each continuing education activity hour earned from publication of books, chapters of books and/or articles in refereed journals, a registrant must be able to provide documentation of the following information:

- (a) the title of the book, chapter or article and, in the case of a chapter or article, the title of the book or name of the journal in which it appears;
- (b) the date of publication; and
- (c) the names of any co-authors.

The Board may require the licensee to provide a copy of the book, chapter or article submitted in fulfillment of continuing education activity requirements.

(4) For each continuing education activity hour earned by the teaching of courses, workshops or seminars or participation in an independent study, the registrant must be able to document the following information:

- (a) the title of the course or independent study;
- (b) date(s) the course or independent study was presented or participated in;
- (c) institution or sponsoring agency; and
- (d) the number of hours the registrant spent teaching or participating in the independent study.

(5) The Board may review and/or randomly audit the documentation of any registrant's continuing education requirements and may request the documentation described in 265 CMR 5.02(1) through (4) for two prior licensure renewal/continuing education periods. The Board shall determine whether the activity/program documentation submitted meets all criteria for continuing education as specified in 265 CMR 5.00.

(6) Continuing education activities which do not meet the requirements of 265 CMR 5.00 may be rejected in part or in whole by the Board.

(7) Any incomplete or inaccurate documentation of continuing education may be rejected in part or in whole by the Board.

(8) The Board may determine requirements to be fulfilled in order to allow a registrant who has not met the continuing education requirement to renew his or her license.

(9) Failure to complete or provide required documentation of completion of continuing education requirements may result in non-renewal of a license or disciplinary action.

5.03: Verification/Approval of Provider Continuing Education Programs and Activities

(1) For a program to be eligible for approval for continuing education hours, the course content shall directly relate to the practice of fitting and dispensing hearing aids and the educational objectives shall exceed a basic level of knowledge as it relates to fitting and dispensing hearing aids. The course work shall include the following subjects:

- (a) procedures in the selection and fitting of hearing aids;
- (b) pre and post fitting management of clients;
- (c) instrument circuitry and acoustic performance data;
- (d) ear mold design and modification contributing to improved client performance;
- (e) audiometric equipment or testing techniques which demonstrate an improved ability to identify and evaluate hearing loss;
- (f) auditory rehabilitation;
- (g) ethics;
- (h) federal and state statutes, regulations and rules;
- (i) assistive listening devices; and
- (j) business-related courses (maximum four credits in this subject per continuing education period).

(2) Course work meeting the requirements of 265 CMR 5.03(1) and endorsed or sponsored by the following organizations shall be deemed approved for continuing education hours:

- (a) International Hearing Society;
- (b) National Institute of Hearing Instrument Studies;

5.03: continued

- (c) American Academy of Audiology;
- (d) Academy of Dispensing Audiologists;
- (e) American Academy of Otolaryngology - Head and Neck Surgery;
- (f) Massachusetts Hearing Society;
- (g) Massachusetts Speech and Hearing Association; or
- (h) American Speech-Language-Hearing Association.

(3) The Board may approve other continuing education course work that complies with 265 CMR 5.03(1) if the organization providing the course work submits to the Board the following information 90 days prior to commencement of the course:

- (a) name, date, and location of continuing education course work;
- (b) detailed description of the course content;
- (c) description of the educational objectives;
- (d) description of each instructor's education, training, and experience background; and
- (e) continuing education hours offered for completing the course.

The provider shall report any change in the course content or instructor to the Board prior to commencement of the course.

(4) The Board shall revoke the approval of any continuing education course work for failure of the provider to comply with the provisions of 265 CMR 5.00.

5.04: Waivers of Continuing Education Requirements

(1) The Board may waive the continuing education requirement for any registrant who, for reasons of health, disability, out of state military service, or undue hardship, cannot meet the requirements.

(2) An application for a waiver shall be submitted to the Board in writing, and may be submitted electronically.

(3) Waivers of continuing education requirements shall be effective for no more than one license renewal period.

(4) After expiration of a waiver, a registrant may apply for up to two more consecutive waivers.

(5) If a temporary waiver is granted, the registrant shall comply with all continuing education requirements for all subsequent renewal periods, after such time that the waiver expires unless a subsequent waiver is granted.

5.05: Appeals on Continuing Education Matters

Any individual who wishes to appeal the decision of the Board regarding continuing education matters must submit a letter of appeal to the Board within 21 days of the receipt of the Board's decision. The applicant must supply the Board with any requested additional data and may be asked to appear before the Board. The Board reserves the right, upon request of registrant, to allow the applicant to practice dispensing hearing instruments during the Board's appeals process.

REGULATORY AUTHORITY

265 CMR 5.00: M.G.L. c. 112, §§ 197 and 199.

NON-TEXT PAGE



THE COMMONWEALTH OF MASSACHUSETTS
William Francis Galvin
Secretary of the Commonwealth

Regulation Filing *To be completed by filing agency*

CHAPTER NUMBER: 265 CMR 6.00

CHAPTER TITLE: Standards of Practice

AGENCY: Board of Registration of Hearing Instrument Specialists

SUMMARY OF REGULATION: *State the general requirements and purposes of this regulation.*
This regulation establishes minimum procedures used in fitting and selling of hearing instruments and standards for equipment used in hearing tests, medical clearances, bill of sale, delivery of hearing instruments by mail, and facility and record inspection requirements.

REGULATORY AUTHORITY: M.G.L. c. 93, ss. 72 through 75, and c. 112, s. 199

AGENCY CONTACT: Lynn Read, Board Counsel PHONE: (617) 727-4423

ADDRESS: Div. of Prof. Licensure, 1000 Washington Street, Suite 710, Boston, MA 02118

Compliance with M.G.L. c. 30A

EMERGENCY ADOPTION - *if this regulation is adopted as an emergency, state the nature of the emergency.*

PRIOR NOTIFICATION AND/OR APPROVAL - *if prior notification to and/or approval of the Governor, Legislature or others was required, list each notification, and/or approval and date, including notice to the Local Government Advisory Commission.*

EO 562 approval received - 04/06/16

DHCD and MA Municipal Assoc. notified by letter - 04/20/16

Notice of Public Hearing published in Boston Globe & Springfield Republican - 05/06/16

PUBLIC REVIEW - *M.G.L. c. 30A sections 2 and/or 3 requires notice of the hearing or comment period, including a small business impact statement, be filed with the Secretary of the Commonwealth, published in appropriate newspapers, and sent to persons to whom specific notice must be given at least 21 days prior to such hearing or comment period.*

Date of public hearing or comment period: Hearing on 05/27/16; comment ended on 06/08/16

FISCAL EFFECT - Estimate the fiscal effect of the public and private sectors.

For the first and second year: None
For the first five years: None
No fiscal effect: No Fiscal Effect

SMALL BUSINESS IMPACT - M.G.L. c. 30A section 5 requires each agency to file an amended small business impact statement with the Secretary of the Commonwealth prior to the adoption of a proposed regulation. If the purpose of this regulation is to set rates for the state, this section does not apply.

Date amended small business impact statement was filed: 07/20/16

CODE OF MASSACHUSETTS REGULATIONS INDEX - List key subjects that are relevant to this regulation:
Hearing Instrument Specialists, Hearing Instruments, Hearing Aids, Standards of Practice, Equipment, Medical Evaluation, Bill of Sale, Inspection, Label, Labeling

PROMULGATION - State the action taken by this regulation and its effect on existing provisions of the Code of Massachusetts Regulations (CMR) or repeal, replace or amend. List by CMR number:

Amends 265 CMR 6.00

ATTESTATION - The regulation described herein and attached hereto is a true copy of the regulation adopted by this agency. ATTEST:

SIGNATURE: [Signature] DATE: 7/28/16

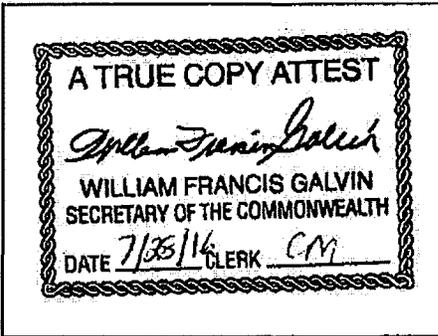
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MASSACHUSETTS REGISTER NUMBER: 1319 DATE: 8/12/16

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CODE OF MASSACHUSETTS REGULATIONS

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265 CMR 6.00: STANDARDS OF PRACTICE

Section

- 6.01: Minimal Procedures and Equipment
- 6.02: Certification of Test Equipment
- 6.03: Medical Evaluation Requirements/Clients Younger than 18 Years Old
- 6.04: Cancellation of Sale
- 6.05: Bill of Sale Requirements
- 6.06: Delivery of Hearing Instruments by Mail
- 6.07: Updated Licensure Information/Notification of Employment
- 6.08: Facility and Record Inspection Requirements
- 6.09: Label and Labeling Requirements/Requirements Regarding the *User Instructional Brochure*

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.

6.03: continued

(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.

6.04: continued

(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.

6.08: continued

(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:

6.09: continued

- (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;

265 CMR: BOARD OF REGISTRATION OF HEARING INSTRUMENT SPECIALISTS

6.09: continued

- (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.



THE COMMONWEALTH OF MASSACHUSETTS

William Francis Galvin
Secretary of the Commonwealth

Regulation Filing *To be completed by filing agency*

CHAPTER NUMBER: 265 CMR 7.00

CHAPTER TITLE: Professional Competence and Conduct

AGENCY: Board of Registration of Hearing Instrument Specialists

SUMMARY OF REGULATION: *State the general requirements and purposes of this regulation.*
This regulation establishes grounds for discipline, prohibits deceptive advertising, and establishes standards of ethical and professional conduct for Hearing Instrument Specialists

REGULATORY AUTHORITY: M.G.L. c. 112, ss. 198 through 200

AGENCY CONTACT: Lynn Read, Board Counsel PHONE: (617) 727-4423

ADDRESS: Div. of Prof. Licensure, 1000 Washington Street, Suite 710, Boston, MA 02118

Compliance with M.G.L. c. 30A

EMERGENCY ADOPTION - *If this regulation is adopted as an emergency, state the nature of the emergency.*

PRIOR NOTIFICATION AND/OR APPROVAL - *If prior notification to and/or approval of the Governor, Legislature or others was required, list each notification, and/or approval and date, including notice to the Local Government Advisory Commission.*

EO 562 approval received - 04/06/16

DHCD and MA Municipal Assoc. notified by letter - 04/20/16

Notice of Public Hearing published in Boston Globe & Springfield Republican - 05/06/16

PUBLIC REVIEW - *M.G.L. c. 30A sections 2 and/or 3 requires notice of the hearing or comment period, including a small business impact statement, be filed with the Secretary of the Commonwealth, published in appropriate newspapers, and sent to persons to whom specific notice must be given at least 21 days prior to such hearing or comment period.*

Date of public hearing or comment period: Hearing on 05/27/16; comment ended on 06/08/16

FISCAL EFFECT - Estimate the fiscal effect of the public and private sectors.

For the first and second year: None

For the first five years: None

No fiscal effect: No Fiscal Effect

SMALL BUSINESS IMPACT - M.G.L. c. 30A section 5 requires each agency to file an amended small business impact statement with the Secretary of the Commonwealth prior to the adoption of a proposed regulation. If the purpose of this regulation is to set rates for the state, this section does not apply.

Date amended small business impact statement was filed: 07/20/16

CODE OF MASSACHUSETTS REGULATIONS INDEX - List key subjects that are relevant to this regulation:
Hearing Instrument Specialists, Hearing Instruments, Hearing Aids, Discipline, Advertising, Ethical Standards, Professional Conduct

PROMULGATION - State the action taken by this regulation and its effect on existing provisions of the Code of Massachusetts Regulations (CMR) or repeal, replace or amend. List by CMR number:

Amends 265 CMR 7.00

ATTESTATION - The regulation described herein and attached hereto is a true copy of the regulation adopted by this agency. ATTEST:

SIGNATURE: [Signature] DATE: 7/28/16

Publication - To be completed by the Regulations Division

MASSACHUSETTS REGISTER NUMBER: 1319 DATE: 8/12/16

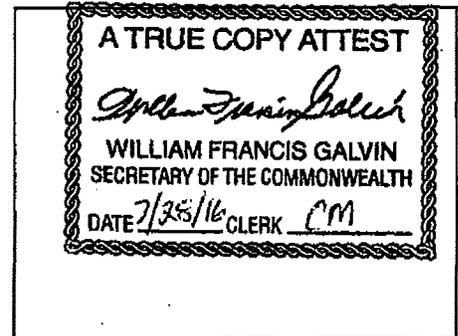
EFFECTIVE DATE: 8/12/16

CODE OF MASSACHUSETTS REGULATIONS

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25 - 28

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265 CMR 7.00: PROFESSIONAL COMPETENCE AND CONDUCT

Section

- 7.01: Grounds for Imposition of Disciplinary Sanctions
- 7.02: Prohibition Against Deceptive Advertising and Fee Setting Practices
- 7.03: Ethical Standards and Professional Conduct
- 7.04: Conduct of Home Visits

7.01: Grounds for Imposition of Disciplinary Sanctions

- (1) Any one or combination of specified conduct set forth in M.G.L. c. 112, § 199 is considered unprofessional and improper conduct subject to Board hearing and discipline as set forth in M.G.L. c. 112, § 200.
- (2) Any violation of or failure to comply with any of the laws of the Commonwealth relating to the practice of dispensing hearing instruments or a violation of or failure to comply with a rule or regulation adopted thereunder is considered unprofessional and improper conduct subject to Board hearing and discipline as set forth in M.G.L. c. 112, § 200.
- (3) If a current licensee is convicted of or admits to sufficient facts or pleads nolo contendere to a crime in any jurisdiction, whether felony or misdemeanor, in the Commonwealth or outside of the Commonwealth, regardless of adjudication or sentence, which directly relates to dispensing hearing instruments or the ability to safely and effectively practice dispensing hearing instruments, including, but not limited to violations of any federal laws or regulations regarding hearing instruments, the conduct of that licensee is considered unprofessional and improper conduct subject to Board hearing and discipline as set forth in M.G.L. c. 112, § 200.
- (4) The definition of "gross incompetence" contained in M.G.L. c. 112, § 199(5) shall include, but not be limited to, failure of the registrant to advise a prospective hearing instrument user prior to fitting and dispensing a hearing instrument that the user should first consult a licensed physician specializing in diseases of the ear whenever any serious conditions are found or should have been found to exist, either as a result of observations of the registrant or from information furnished by such prospective hearing instrument user, including, but not limited to, the following conditions:
 - (a) visible congenital or traumatic deformity of the ear, including perforation of the eardrum;
 - (b) a history of, or active drainage from the ear within the previous 90 days;
 - (c) a history of sudden or rapidly progressive hearing loss within the previous 90 days;
 - (d) acute or chronic dizziness;
 - (e) any unilateral hearing loss;
 - (f) significant air-bone gap when generally acceptable standards have been established as defined by the Food and Drug Administration (FDA);
 - (g) visible evidence of significant cerumen accumulation or a foreign body in the ear canal; or
 - (h) pain or discomfort in the ear.

7.02: Prohibition Against Deceptive Advertising and Fee Setting Practices

- (1) Deceptive Advertising. The following advertising practices are considered fraudulent, false, deceptive or misleading and are prohibited:
 - (a) advertising which contains a misrepresentation of facts or false statements regarding the registrant's professional achievements, degrees, trained skills, and qualifications in the hearing instrument profession;
 - (b) advertising the content or the context of which makes only a partial disclosure of relevant facts, such as advertising which advertises a discounted price without identifying the specific product or service to which the discounted price applies and without specifying the usual price for the product or services identified;
 - (c) advertising or permitting to be advertised the price of a specifically-identified hearing instrument if more than one hearing instrument appears in the same advertisement without an accompanying price;

7.02: continued

- (d) advertising which contains a representation that a product innovation is new, when in fact the product was first introduced by that manufacturer to the general public in the Commonwealth more than 12 months ago;
 - (e) advertising which contains a representation that a continuing education or training program is approved by the Board, if the content of the program departs from the content approved by the Board or is not in fact approved;
 - (f) advertising which contains any representation, statement or claim which the Board determines is misleading or deceptive to the public.
- (2) All advertisements must include the name and license number of a licensee responsible for the content. Individuals licensed by the Board shall refer to themselves on all advertisements as licensed hearing instrument specialists.
- (3) Fee Setting. Fees which are significantly greater than the usual and customary fees accepted by hearing instrument industry standards as evidenced by third party insurance payment rates, comparable market values and other industry standard indicators shall be considered unprofessional and improper and are prohibited.

7.03: Ethical Standards and Professional Conduct

- (1) Requirement to Respond to Board.
- (a) A registrant shall respond to a written communication from the Board or its designee and shall make available to the Board any relevant and authorized records with respect to an inquiry or complaint about the registrant's professional conduct.
 - (b) A registrant shall cooperate with any reasonable request from a Division agent or employee acting on behalf of the Board while investigating a complaint or allegation regarding the registrant's professional conduct as a hearing instrument specialist.
- (2) Welfare of Persons Served.
- (a) Registrants shall not provide any services beyond the scope of their practice or for which they are not appropriately licensed.
 - (b) Registrants shall not misrepresent qualifications, affiliations, educational background or experience in the profession to the public, colleagues or other individuals or institutions.
 - (c) Registrants shall fully inform persons served of the nature, possible effects, and limitations of services rendered or to be rendered.
 - (d) Registrants' fees must be commensurate with services rendered. Under no circumstances shall a registrant charge for services not rendered.
 - (e) Registrants shall provide clients with reasonable access to their records at the request of the client. Unless required by law, the registrant shall not reveal to any unauthorized person any confidential information obtained from the individual that the registrant serves professionally without the client's permission.
 - (f) Registrants shall take all reasonable precautions to avoid injuring persons in the delivery of professional services.
 - (g) Services rendered should be evaluated to determine effectiveness. If not effective, and benefit cannot reasonably be expected to accrue, professional services should not be initiated or continued.
 - (h) Registrants shall establish professional relationships with clients and colleagues and follow acceptable patterns of professional conduct with such persons regardless of race, religion, gender or age.
 - (i) Activities engaged in for experimental teaching purposes should be explained in full to the person being served. Consent must be obtained for such activities.
 - (j) Registrants shall not guarantee the result of any service rendered or hearing instrument provided or state that a hearing instrument can fully restore hearing.
- (3) Professional Objectivity/Conflict of Interest.
- (a) Registrants shall maintain objectivity in all matters concerning the welfare of persons served professionally.

7.03: continued

(b) Hearing instrument products are to be dispensed to persons served as part of a program of comprehensive habilitative/rehabilitative care. Fees established for professional services must be determined independent of whether a product is dispensed. No professional shall require, directly or indirectly, that any person served should or should not obtain a service or product from a particular source. Upon request, at time of sale, price information about professional services rendered and products dispensed must be disclosed by providing to clients a complete schedule of fees and services including what services and replacement parts are included in the price and the length of time that such services and replacement parts will be available for the price paid. Products dispensed shall be evaluated to determine effectiveness.

(c) Registrants must guard against conflicts of professional interest. They shall not engage in commercial activities that conflict with responsibility to clients or to colleagues. Registrants shall not accept fees, gifts, or other forms of gratuities for recommending a particular product or use of a particular referral source.

7.04: Conduct of Home Visits

(1) Limited Authorization. A registrant is authorized to provide hearing instrument dispensing services to a client in such client's residence only if the following limited circumstances are present:

- (a) the client requests such home visit for services;
- (b) the registrant fully discloses to the customer that any services provided at a residence may be without the benefit of certain test equipment available at the registrant's place of business;
- (c) the home visit is prearranged and scheduled for an agreed upon date and time.

(2) Fees Applying to Home Visits.

- (a) A reasonable surcharge may be added to a client's bill for a home visit by a registrant.
- (b) Other than the surcharge, all fees for services rendered and products supplied shall be the same for a home visit as those assessed at the registrant's place of business.
- (c) The surcharge for home visits must be the same or comparable for all clients and shall be disclosed to the client at the time the home visit is requested and clearly noted on the customer's bill.

(3) While in a client's house, a registrant shall act in a professional and courteous manner and only enter rooms that he or she is invited into by the client, and if asked to leave the residence by the client, the registrant shall leave immediately.

REGULATORY AUTHORITY

265 CMR 7.00: M.G.L. c. 112, §§ 198 through 200.

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THE COMMONWEALTH OF MASSACHUSETTS
William Francis Galvin
Secretary of the Commonwealth

Regulation Filing *To be completed by filing agency*

CHAPTER NUMBER: 265 CMR 9.00

CHAPTER TITLE: Procedures for Hearings and Appeals

AGENCY: Board of Registration of Hearing Instrument Specialists

SUMMARY OF REGULATION: *State the general requirements and purposes of this regulation.*
The agency is rescinding this regulation, which states procedures for adjudicatory hearings and appeals. The regulation is being rescinded because it duplicates hearing standards and procedures set forth in M. G.L. c. 30A, c. 112 ss. 61-65 and 801 CMR.

REGULATORY AUTHORITY: M.G.L. c. 112, ss. 198 through 200

AGENCY CONTACT: Lynn Read, Board Counsel PHONE: (617) 727-4423

ADDRESS: Div. of Prof. Licensure, 1000 Washington Street, Suite 710, Boston, MA 02118

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Repeals 265 CMR 9.00

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SIGNATURE: [Signature] DATE: 7/28/16

Publication - To be completed by the Regulations Division

MASSACHUSETTS REGISTER NUMBER: 1319 DATE: 8/12/16

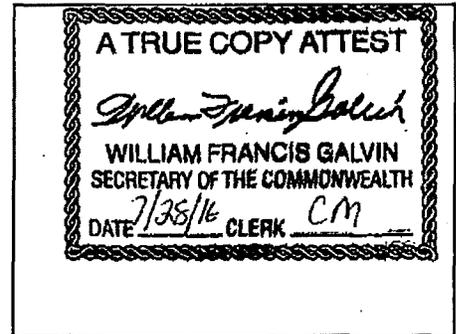
EFFECTIVE DATE: 8/12/16

CODE OF MASSACHUSETTS REGULATIONS

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265 CMR: BOARD OF REGISTRATION OF HEARING INSTRUMENT SPECIALISTS

(265 CMR 9.00: RESERVED)

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