

Registration of Hearing Aid Dispensers

(March 2026)

New York State
DEPARTMENT OF STATE
Division of Licensing Services
<https://dos.ny.gov>

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Registration of Hearing Aid Dispensers

Article 37-A, General Business Law

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Registration of Hearing Aid Dispensers

§788. Legislative intent

The legislature recognizes and acknowledges the value of hearing aids to many individuals with hearing loss and recognizes the valuable service provided by hearing aid dispensers and dispensing audiologists to such individuals by providing access to appropriate amplification devices and other valuable services related to their use. Due to the large number of individuals with hearing loss who do not use hearing aids, the legislature furthermore recognizes the positive benefits of the increased use of hearing aids. It is the intent of the legislature and this article to protect the hearing-impaired public by ensuring competent, honest and accountable dispensers of hearing aids who will protect the health, safety and welfare of the people of this state.

The legislature finds and declares that existing laws regulating the dispensing of hearing aids have been ineffective in providing adequate protection. To ensure against consumer abuses and thereby protect the public, the legislature determines that more rigorous education, training and business practice standards should be applied to those persons registered to dispense hearing aids pursuant to this article. It is the intention of the legislature to apply standards to more fully protect the general public, and to ensure continued consumer access to safe, reliable and appropriate hearing aid dispensing services.

§789. Definitions

As used in this article:

1. "Account" shall mean the hearing aid dispensing account.
2. "Audiologist" means an individual who is licensed under article 159 of the Education Law to evaluate hearing, and hearing and communication disorders and to engage in those practices defined in §8203 of the Education Law.
3. "Board" shall mean the hearing aid dispensing advisory board.
4. "Business" means any individual, partnership, trust, association, organization or corporation.
5. "Department" means the Department of State.
6. "Dispensing of hearing aids," means the act of fitting, selecting, selling, renting, adapting or servicing of hearing aids or any other instrument to compensate for impaired hearing; provided that such term shall include testing of hearing, solely for the purpose of fitting, selecting, selling, distribution, renting, adapting or servicing hearing aids or any instrument to compensate for impaired hearing, the making of impressions, castings and shells and appropriate counseling and instructions pertaining to the selection, adaptation and sale or rental of hearing aids and further provided that such term shall include any tasks, procedures, acts, or practices that are necessary (a) for the non-diagnostic testing of hearing solely for the purpose of fitting a hearing aid; (b) for training in the use of amplification including hearing aids; (c) for the making of ear molds for hearing aids; (d) for the fitting, dispensing, and sale of hearing aids; or (e) for otoscopic observation of solely the ear canal for the purposes of fitting, dispensing or sale of hearing aids; provided, however, that nothing contained in this subdivision shall be deemed to permit the performance of or reference to an otoscopic evaluation for medical diagnosis; and (f) for those other procedures necessary to determine proper amplification needs and the specific hearing aid which will be of maximum benefit to aid or to compensate for the impaired ear. Testing for the purpose of fitting a hearing aid shall include only such tests meeting standards acceptable to the secretary as needed to verify the optimum fitting characteristics and cir-

cuitry of any hearing aids or amplification devices needed and shall not be for the purposes of, make any reference to, or include any medical diagnosis whatsoever. No hearing aid dispenser shall verbally or in writing make a statement or reference to a prospective hearing aid user regarding any medical condition or diagnosis except such communications required pursuant to §798(8)(c) of this article. Nothing in this subdivision shall restrict or limit any person licensed under article 159 of the Education Law from performing any activity authorized thereunder; provided, however, that every such person shall be registered as a hearing aid dispenser pursuant to the requirements of this article in order to dispense hearing aids.

7. "Hearing aid" means any wearable instrument or device designed for or offered for the purpose of aiding or compensating for impaired human hearing and any parts, attachments or accessories but excluding batteries and cords or accessories thereto.

8. "Hearing aid dispenser" means any person 21 years of age or older or an audiologist licensed under article 159 of the Education Law who is engaged in the dispensing of hearing aids who is registered and dispensing hearing aids in accordance with this article.

9. "Otolaryngologist" means a physician licensed under article 131 of the Education Law, who practices that branch of medicine which treats diseases of the ear, nose and throat.

10. "Secretary" means the Secretary of State.

11. "Sell" or "sale" means any transfer of title or of the right of use by sale, conditional sales contract, lease bailments, including rentals of hearing aids hire-purchase, or any other means; excluding wholesale transactions of dealers and distributors.

12. "Trainee" means a person 21 years of age or older, who upon receiving a temporary certificate of registration, is studying hearing aid dispensing full-time for the purpose of qualifying to sit for the registration examination.

§790. Certificate of registration required; qualifications and application

1. Any person desiring to be engaged in the dispensing of hearing aids in this state shall be registered biennially pursuant to this article. Such person shall file with the secretary an application to be registered as a hearing aid dispenser. The secretary shall examine each application and issue a certificate of registration if either of the following criteria are satisfied:

- (a) (i) the applicant is 21 years of age or older;
- (ii) is of good moral character;
- (iii) has received a high school diploma or its equivalent;
- (iv) has two years college accredited coursework or its equivalent;
- (v) has fully completed the required training program;
- (vi) has achieved a passing score on the required examination;
- (vii) has not had a registration, license or other authorization to dispense hearing aids suspended or revoked;
- (viii) has paid the appropriate fees according to the provisions of §797 of this article; and
- (ix) on or after January 1, 2003, the applicant shall demonstrate the successful completion of post-secondary coursework approved by the secretary in conjunction with the advisory board; or
- (b) (i) the applicant has submitted proof of licensure under article 159 of the Education Law as a licensed audiologist;

(ii) has paid the appropriate fees according to the provisions of §797 of this article;

(iii) has achieved a passing score on the practical test of proficiency required pursuant to §796(6) of this article or who submits evidence satisfactory to the secretary of experience in dispensing hearing aids; and

(iv) has not had a registration, license or other authorization to dispense hearing aids suspended or revoked according to the provisions of §799 of this article.

2. An application for a certificate of registration as a hearing aid dispenser shall be filed with the secretary in such form and detail as the secretary shall prescribe, duly signed and verified, setting forth:

- (a) the name and address of the applicant;
- (b) the name and business address or addresses at which the individual will be employed;
- (c) the information contained in subdivision one of this section; and
- (d) any further information deemed necessary and prescribed by rule or regulation by the secretary.

3. (a) Any person who has been continuously registered as a hearing aid dealer pursuant to the former article 37-A of this chapter for the three years immediately preceding January 1, 2000 or who submits evidence satisfactory to the secretary of experience in the business of dispensing hearing aids in this state for the three years immediately preceding January 1, 2000, upon payment of applicable fees, shall be registered as a hearing aid dispenser and shall be exempt from requirements set forth in subparagraphs (iv), (v), (vi) and (ix) of paragraph (a) of subdivision one of this section.

(b) Any person who has been continuously registered as a hearing aid dealer pursuant to the former article 37-A of this chapter for less than three years but more than one year immediately preceding January 1, 2000, or who submits evidence satisfactory to the secretary of less than three years but more than one year's continuous experience in the business of dispensing hearing aids in this state immediately preceding January 1, 2000, may pay the applicable fees and register as a hearing aid dispenser. Such registrant shall be exempt from the requirements set forth in subparagraphs (iv), (v) and (ix) of paragraph (a) of subdivision one of this section. Such registrant shall achieve a passing score on the required registration examination by December 31, 2000; provided further that, upon failing to achieve a passing score such person shall continue under the supervision of a registered hearing aid dispenser until such time as a passing score is achieved, provided that such passing score is achieved on an examination administered within 12 months of the first examination.

(c) Any individual who has been continuously registered as a hearing aid dealer pursuant to the former article 37-a of this chapter for less than 12 months immediately preceding January 1, 2000 or any individual with less than 12 months experience in the business of dispensing hearing aids in this state immediately preceding January 1, 2000 shall be required to comply with all the requirements set forth in subdivision one of this section.

(d) Any person licensed pursuant to article 159 of the Education Law, who submits evidence satisfactory to the secretary of experience of dispensing hearing aids in this state for the period immediately preceding January 1, 2000, upon payment of applicable fees shall be registered as a hearing aid dispenser and shall be exempt from requirements set forth in subparagraph (iii) of paragraph (b) of subdivision one of this section.

4. Upon application to the secretary, a temporary certificate of registration authorized under §795 of this article shall be issued to: (i) individuals who prove to the satisfaction of the secretary that he or she will be supervised and trained by one or more registered hearing aid dispensers for a period of 12 months or (ii) individuals who are candidates for licensure under article 159 of the Education Law, have satisfied the educational requirement in subdivision two of §8206 of the Education Law, and are actively engaged in completing the experience requirement in subdivision three of §8206 of the Education Law. A temporary certificate of registration may be renewed only once.

- (a) A person holding a temporary certificate of registration shall not be the sole proprietor of, manage, or independently operate a business which engages in the business of dispensing hearing aids unless such business employs a registered hearing aid dispenser.
- (b) A person holding a temporary certificate of registration shall not advertise or otherwise represent that he or she holds a certificate of registration as a hearing aid dispenser.
- (c) A person holding a temporary certificate of registration who is a candidate for licensure under article 159 of the Education Law shall be exempt from the requirement to complete the course of instruction prescribed by §796 of this article.

5. (a) Any individual, corporation, partnership, trust, association or other organization maintaining an established New York state business address desiring to engage in the business of dispensing hearing aids at retail, shall register with the department and submit the following information:

(i) name and address or addresses of each permanent business location;

(ii) names and addresses of the principal owner or manager of the business and if such owner is a corporation the names and titles of the corporate officers; if a partnership, the name and title of the general partners, if a limited liability company the name of the members or managers, if a limited liability partnership, the names of the partners, if a trust, the name of the trustee, if an association, the principal officers; and

(iii) the appropriate fees.

(b) No such individual, corporation, partnership, trust, association or other organization maintaining an established New York state business address shall engage in the business of dispensing hearing aids unless such organization:

(i) has obtained a valid business certificate of registration from the secretary;

(ii) employs at least one registered hearing aid dispenser at each business location who regularly dispenses hearing aids at that location;

(iii) files annually with the secretary a list of registered hearing aid dispensers currently employed; and

(iv) files a statement with the secretary that such organization is in compliance with the provisions of this article and rules and regulations promulgated pursuant thereto and the regulations of the Federal Food and Drug Administration and the Federal Trade Commission.

6. The secretary may grant a certificate of registration upon submission of an application and appropriate fees where such application contains satisfactory proof that the applicant holds a valid hearing aid dispenser's license or registration in another state, where the secretary has determined such state has requirements equivalent to or higher than those in effect pursuant to this article.

7. Notwithstanding the provisions of any law to the contrary, on or after January 1, 2000, no person shall engage in the dispensing of hearing aids in this state unless such person is registered as a hearing aid dispenser in accordance with the provisions of this article.

8. Notwithstanding the requirements of this section, the secretary shall take steps necessary to provide for the immediate and orderly registration of applicants qualified pursuant to this article. Persons seeking to qualify for registration pursuant to paragraphs (b) and (c) of subdivision three of this section shall be immediately entitled to a temporary certificate of registration. Within 120 days of the effective date of this subdivision, the secretary shall approve an examination for completed registration pursuant to §796 of this article.

9. Anyone registered as a hearing aid dealer on the effective date of this article or who possesses the requisite experience for registration pursuant to paragraphs (a) and (b) of subdivision three of this section shall register on or before January 1, 2000 and may continue to dispense hearing aids as if registered if an application for registration is submitted to the department within 30 days of the effective date of this article.

§791. Hearing aid dispensing advisory board

1. There is created within the department a hearing aid dispensing advisory board which shall consist of 13 members to be appointed by the secretary: four of whom shall be non-audiologist hearing aid dispensers who shall have been engaged in the business of dispensing hearing aids primarily in this state for at least five years immediately preceding their appointment, two to be appointed upon the recommendation of the governor, one to be appointed upon the recommendation of the temporary president of the senate and one to be appointed upon the recommendation of the speaker of the assembly; four members shall be audiologists who are engaged in the dispensing of hearing aids for at least five years immediately preceding their appointment, two to be appointed upon the recommendation of the governor, one to be appointed upon the recommendation of the temporary president of the senate and one to be appointed upon the recommendation of the speaker of the assembly; two shall be otolaryngologists; and the remaining three members, none of whom shall derive nor have derived in the past economic benefit from the business of dispensing hearing aids, shall be from the resident lay public of this state who are knowledgeable about issues related to hearing loss. At least one lay member shall be an individual representing adults over the age of 50. At least one of the lay members shall be a hearing aid user. Of the otolaryngologists and lay members, one shall be appointed by the secretary on the recommendation of the minority leader of the senate and one shall be appointed by the secretary on the recommendation of the minority leader of the assembly and three shall be appointed by the secretary on the recommendation of the governor. Each member of the board shall be appointed for a term of two years. Any member may be appointed for additional terms. In the event that any member shall die or resign during his or her term, a successor shall be appointed in the same manner and with the same qualifications as set forth in this section. A member may be reappointed for successive terms but no member shall serve more than a total of 10 years. The secretary or the designee of the secretary shall serve in an ex officio non-voting position. The secretary shall serve as chairperson. The Commissioner of Education, the Commissioner of Health, the chair and Executive Director of the Consumer Protection Board and the Attorney General or their designees shall serve as non-voting ex officio members.

2. The board shall advise and make recommendations regarding, and the secretary, upon consideration of such advice, shall promulgate rules and regulations, governing the implementation of the provisions of this article and the development of such rules and regulations as are required. In addition to other advice, the board shall advise the secretary with respect to the promulgation of rules and regulations governing:

- (a) the rights of consumers of hearing aids including but not limited to (i) procedures whereby a consumer may file a complaint against those in violation of this article; and (ii) requirements for hearing aid dispensers to provide consumers with printed educational information on the general use of hearing aids and assistive listening devices and on the advantages and disadvantages of binaural hearing aid use and (iii) the training of individuals in the use and maintenance of such instruments;
- (b) continuing education including but not limited to (i) the content of such course of study, (ii) the procedures for approval of such course of study and (iii) those individuals and organizations who may permissibly offer such continuing education course or courses provided for in §794 of this article;
- (c) the content, delivery and evaluation of any examination required as a condition of registration;
- (d) the standards for advertisements, including but not limited to, proscriptions against misleading advertising relating to the scope of hearing aid dispensing practices, credentials of individual hearing aid dispensers, and the function, use and reliability of a particular hearing instrument;
- (e) requirements for the secretary to regularly examine compliance with this article;
- (f) requirements pertaining to the non-diagnostic testing of hearing and sale of hearing aids at office, residential and other out of office settings and the development of environmental standards for testing at office, residential and other out of office settings; requirements pertaining to telemarketing; and
- (g) procedures that the secretary could use to increase public awareness of how to properly purchase, fit, adjust and use a hearing aid, as well as the rights of hearing aid purchasers under State law. In addition to such duties and other duties which may be assigned by the secretary, the board shall consult with the secretary, the Commissioner of Education and such other persons as may be appropriate to determine the proper level and degree of education for a hearing aid dispenser, the type of degree and the proper educational institution to offer such education and all other related issues.

3. Meetings of the board shall be set at such times as determined by the secretary but in no event fewer than four times annually.

4. The members of the board shall serve without compensation, however, they shall receive reimbursement for their actual and necessary expenses incurred in the performance of their duties.

5. The secretary shall keep a record of all proceedings of the board and such record shall be open to public examination.

§792. Hearing aid dispensers account

There is hereby established in the custody of the State Comptroller and the secretary a hearing aid dispensers account into which all fees collected pursuant to this article shall be deposited. The money in such account shall be utilized solely for the purpose of administering and enforcing the provisions of this article.

§793. Registry

The secretary shall establish a state registry which shall list and identify on a county-by-county basis all registered hearing aid dispensers, trainees, audiologists engaged in the business of dispensing hearing aids and businesses registered pursuant to subdivision five of §790 of this article. The registry shall contain all information relevant to the status of their registration including their standing, location of practice and telephone number.

§794. Continuing education requirements

1. Prior to the expiration of a certificate of registration and as a condition of renewal, each hearing aid dispenser registered pursuant to subdivision one of §790 of this article shall submit documentation showing successful completion of 20 continuing education credits through a course or courses approved by the secretary in consultation with the advisory board, or, in relation to audiologists licensed pursuant to article 159 of the Education Law, the Office of the Professions in the Education Department. Such formal courses of learning shall include, but not be limited to, collegiate level of credit in non-credit courses, professional development programs and technical sessions offered by national, state and local professional associations and other organizations acceptable to the secretary and any other organized educational and technical programs acceptable to the secretary. The secretary may, in his or her discretion, and as needed to contribute to the health and welfare of the public, require the completion of continuing education courses in specific subjects to fulfill this mandatory continuing education requirement. Courses shall be taken from a sponsor approved by the secretary pursuant to regulations promulgated pursuant to this section.

2. A hearing aid dispenser registered under paragraph (b) of subdivision one of §790 of this article may satisfy the requirements of subdivision one of this section by demonstrating to the secretary compliance with such continuing competency requirements as are prescribed by article 159 of the Education Law, provided, however, that, such persons shall submit documentation showing the successful completion of four continuing education credits relating to the dispensing of hearing aids.

3. (a) Within one year of the effective date of this article, the secretary shall promulgate rules and regulations establishing the method, content and supervision requirements for the continuing education course or courses provided for in this section. Properly prepared written materials of the subject matter of each course shall be distributed and each course shall be taught by an instructor who meets requirements established by the secretary upon the recommendation of the board. Any person or organization offering a course shall apply to the secretary for authorization to offer such course or courses pursuant to said rules and regulations.
- (b) Credits shall be awarded based on one hour of credit for each 60 minutes of participation. The secretary may prescribe the form or forms on which participation and credits are documented. At the conclusion of each approved course, a certificate of completion shall be transmitted to the secretary.

§795. Renewal of certificate of registration or temporary certificate of registration

1. The secretary shall provide a method for the biennial review of a certificate of registration and temporary certificate of registration.

2. The department shall reissue a certificate of registration upon receipt of a renewal application, the renewal fee, and a written statement affirming compliance with all other requirements set forth in this article including evidence of compliance with §794 of this article. A registrant shall retain, if applicable, a certificate from a manufacturer or independent testing agent certifying that the testing room utilized by such registrant meets the requirements of §798 of this article and, if applicable, a certificate from a manufacturer or independent testing agent stating that all audiometric testing equipment used by the registrant has been calibrated on an annual basis according to rules and regulations promulgated by the secretary, consistent with ANSI requirements or in accordance with standards promulgated under article 159 of the Education Law.

3. Any certificate of registration which is not renewed at the end of the biennial period of registration as prescribed by the secretary shall automat-

ically revert to an inactive status. If the certificate of registration has not been renewed within 30 days subsequent to the biennial expiration date, the secretary shall send notice by mail to the last known address of the registrant. Such notice shall advise the registrant of the inactive status and the procedures required to reactivate a valid certificate of registration. Such notice shall detail the criteria and fees to be satisfied for reactivation. If such registration is not reactivated, on the 90th day after the end of the biennial registration period, such registration shall lapse.

4. The department shall reissue a temporary certificate of registration valid for a period of one year upon the receipt of a renewal application, the renewal fee and a written statement verifying continued supervision by a registered hearing aid dispenser.

§796. Training program; requirements; examination and re-examination

1. The secretary, in consultation with the board, shall establish a full-time, 12 month training program for those persons wishing to apply for registration as a hearing aid dispenser, except those hearing aid dispensers otherwise licensed pursuant to article 159 of the Education Law. For the purposes of this section, "full-time" shall mean seven hours per day for five days a week. Such program shall be conducted by a registered hearing aid dispenser or taught by appropriate faculty with credentials to verify substantial educational knowledge in the topics outlined below. Any trainee entering such a program shall operate under the direct supervision of a registered hearing aid dispenser for the first three months of such program. In addition, during such period, the trainee shall satisfactorily complete a course of instruction, which includes, but is not limited to, the following topics:

- (a) acoustics: general principles.
- (b) acoustics: hearing and speech.
- (c) the human ear.
- (d) disorders of hearing.
- (e) puretone audiometry.
- (f) speech audiometry.
- (g) hearing analysis.
- (h) hearing aids and instruments.

2. (a) During the first three months of such program, no trainee shall perform any activity directly related to the dispensing of a particular hearing aid or hearing aids unless such activity is conducted under the direct supervision of a registered hearing aid dispenser. For purposes of this section, "direct supervision" shall mean activity under the immediate observation and control of a registered hearing aid dispenser and shall require the registered hearing aid dispenser to be physically present during all dispensing activities of the trainee.

(b) For the next three months, no trainee shall perform any activity directly related to the dispensing of a particular hearing aid or hearing aids unless such activity is conducted with the immediate consent, review and approval of a registered hearing aid dispenser. For such purposes, the registered hearing aid dispenser shall be located on the premises and immediately available to the trainee but shall not be required to be physically present at all times.

3. For the entire 12 month training period, the registered hearing aid dispenser shall be held fully responsible for all actions of the trainee. Any aspect of the dispensing of hearing aids performed by a trainee shall be reviewed and approved by the registered hearing aid dispenser prior to the final disposition of any contractual agreement. The signatures of both the

trainee and the registered hearing aid dispenser shall be required on all contracts in which a trainee has participated.

4. Upon application, payment of the required registration fee to the secretary, and satisfaction of all applicable registration requirements, the applicant shall receive a temporary certificate of registration and shall enter a training program. The 12 month program shall commence from the date of issuance of the temporary certificate of registration. No individual may begin a training program or otherwise engage in the dispensing of hearing aids without a valid temporary certificate of registration.

5. (a) A trainee may take the required course of instruction under the supervision of a registered hearing aid dispenser provided that such course of instruction has been approved by the secretary.
 - (b) A trainee may take the required course of instruction from any other provider offering a course of instruction approved by the secretary.
 - (c) At the conclusion of each component, the performance of the trainee shall be evaluated by the registered hearing aid dispenser or offeror of such approved course. Upon satisfactory completion of all components of the course of instruction, the trainee and the registered hearing aid dispenser or offeror shall transmit to the secretary proof of the satisfactory completion of each component which shall have been signed and affirmed as true under the penalties of perjury.
6. Upon satisfactory completion of the course of instruction required by this section and successful completion of at least six months of the training program, the trainee may take the written examination and practical test of proficiency offered by the secretary.
7. (a) Each applicant shall be required to pass a written examination covering the following areas, including but not limited to areas of required instruction in the training program, as they pertain to the dispensing of hearing aids:
 - (i) basic physics of sound;
 - (ii) the anatomy and physiology of the ear; and the pathology of the ear as it relates to hearing aid fitting;
 - (iii) the function of hearing aids;
 - (iv) hearing aid evaluation; and
 - (v) knowledge and understanding of this article and the regulations adopted pursuant to it.
 - (b) in addition, the trainee shall also pass a practical test of proficiency in techniques that pertain to the fitting of hearing aids.
8. (a) If a trainee fails to pass the written examination or practical test of proficiency, he or she may request, and be given the opportunity to review the score of the exam according to the rules and regulations of the secretary.
- (b) During the period of registration and the renewal thereof, a trainee may sit for the written exam and the practical test of proficiency exam or any combination thereof up to three times. The exam shall include both the written and practical components. A trainee who has passed any component of the examination within the prior six months need not re-take that component for final passage. A trainee who takes the exam three times but does not pass the entire exam or remaining individual component of the exam shall be terminated and shall be required to commence the training program including direct supervision and courses of study as if he or she is a new applicant. No trainee who fails such examination three times during such period shall be eligible for permanent registration until he or she has repeated the traineeship and passed the examination as required.

9. The examination shall be given at convenient times and places during the calendar year but in no event fewer than four times per year. The secretary shall prescribe the content and format of such examination.

§797. Fees

The secretary shall receive the following fees to be deposited into a special revenue fund - other entitled the "hearing aid dispensers account" for the implementation, operation and enforcement of this article:

1. a nonrefundable fee of \$50 dollars from each person who takes the required examination or any component thereof pursuant to this article;
2. for an individual certificate of registration, \$150 dollars and for the renewal of such registration, \$100;
3. for a business certificate of registration and renewal thereof:
 - (a) for a business certificate of registration for each permanent business location with 10 or less employees, \$150 and for the renewal of such registration, \$100;
 - (b) for a business certificate of registration for each permanent business location with more than 10 employees, \$200 and for the renewal of such registration, \$150;
4. for a temporary certificate of registration, \$30 and for the renewal of such registration, \$30;
5. for filing a change of business address or change of name of the registrant whether individual or business, \$10;
6. for a duplicate certificate of registration, \$10;
7. except fees associated with a temporary certificate of registration the fees set forth shall be those for registrations issued for a period of two years; and
8. employees of a not-for-profit corporation doing business in this state who are required to register pursuant to this article who are not otherwise engaged in the dispensing of hearing aids for profit shall be exempt from payment of the registration fee required by this section.

§798. Business practice; requirements

1. Every registrant who engages in the dispensing of hearing aids shall have and maintain a principal office or place of business. Each registrant shall report to the secretary the address of each such office or place of business at which he or she engages in such dispensing. Changes in address shall be reported within 30 days.
2. Except as limited by the provisions of this article, each registrant shall conspicuously post a valid individual certificate of registration in open view within his or her office or place of business at all times.
3. A hearing aid dispenser who is the owner, manager, or franchisee at a location where hearing aids are dispensed, shall be responsible for the dispensing of any hearing aid at that location.
4. The secretary shall in consultation with the hearing aid advisory board prescribe the minimum criteria, procedures and equipment which shall be used in the dispensing of hearing aids, including but not limited to:
 - (a) a relevant personal history questionnaire;
 - (b) a disclosure statement;
 - (c) requirements for a testing room, if applicable;
 - (d) requirements for the annual calibration and maintenance of audiometric equipment;
 - (e) requirements for out of office dispensing of hearing aids; and
 - (f) if applicable, requirements otherwise provided under article 159 of the Education Law.

5. (a) Unless otherwise authorized by Federal law, rule or regulation, no hearing aid shall be sold by a hearing aid dispenser under this article, to any person, unless that person provides the dispenser with a written statement from an otolaryngologist, or if none is available by another licensed physician stating that the prospective user's hearing loss has been medically evaluated and that the prospective user is a candidate for a hearing aid.
- (b) A replacement of an identical hearing aid within one year shall be an exception to such requirement.
- (c) This subdivision shall not apply to any individual over the age of 16 who has within the preceding three years been examined by an otolaryngologist, or if none was available by another licensed physician who issued a medical evaluation of their hearing loss for such individual.
6. If it is required by Federal law or regulation, a hearing aid dispenser shall afford to an individual, who is 18 years of age or older, the opportunity to waive the medical evaluation requirement of this section, provided however, the hearing aid dispenser shall:
- (a) take no action to encourage, in any way, the prospective user to waive such a medical or audiological evaluation;
- (b) prior to the performance of any activity required pursuant to subdivision eight of this section and prior to the performance of any hearing test the hearing aid dispenser shall inform the prospective user that, "Federal law requires a medical evaluation of their hearing loss. Medical evaluation shall be conducted by an otolaryngologist, or if none is available, by another licensed physician. You have the right to waive this requirement. You must sign a statement of waiver of your rights if you elect to do so";
- (c) provide the prospective user with a copy of the manufacture's user instructional brochure for a hearing aid that has been or may be selected for the prospective user;
- (d) review the contents of such brochure with the prospective user orally;
- (e) conspicuously post a sign in at least 40 point bold-faced type which states: "Federal law requires a medical evaluation of your hearing loss by an otolaryngologist, or if none is available, by another licensed physician. You have the right to waive this requirement. If you waive this requirement, you must sign a statement of waiver of your rights". Such sign shall also indicate the toll-free number required under §803 of this article that individuals wishing to register a complaint can call; and
- (f) should the prospective user elect to waive his or her rights, the prospective user shall sign the following advisory 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 specializing in diseases of the ear) before purchasing a hearing aid. I do not wish a medical evaluation before purchasing a hearing aid. I have also been advised that although the examination conducted by (hearing aid dispenser's name) reveals no indicators mandating referral to a licensed physician, preferably one specializing in diseases of the ear, for medical evaluation as required by law, it is in my best health interest to be examined by a physician specializing in diseases of the ear for any medical condition or disease at least once every three years". If the prospective user is or the parent or guardian of any person under the age of 18 years is a member of any church or religious denomination whose tenets and practices include reliance upon spiritual means through prayer alone and objects to medical treatment and so states in

writing to the hearing aid dispenser or hearing aid trainee, such individual shall undergo a hearing examination as provided by this section, but no proof, ruling out any medically treatable problem causing hearing loss, shall be required.

7. No hearing aid dispenser shall verbally or in writing make a statement or reference to a prospective hearing aid user regarding any medical condition or medical diagnosis.

8. It is unlawful for a registered hearing aid dispenser to dispense a hearing aid unless he or she has first:

- (a) conducted a direct observation of the purchaser's ear canals;
- (b) inquired and made general observations for any of the following conditions:
- (i) visible congenital or traumatic deformity of the ear;
- (ii) history of, or active drainage from the ear within the previous 90 days;
- (iii) history of sudden or rapidly progressive hearing loss within the previous 90 days;
- (iv) acute or chronic dizziness;
- (v) unilateral hearing loss of sudden or recent onset within the previous 90 days;
- (vi) audiometric air-bone gap equal to or greater than 15 decibels at 500, 1,000, and 2,000 hertz (hz);
- (vii) visible evidence of bleeding, significant cerumen accumulation, or a foreign body in the ear canal; and
- (viii) pain or discomfort in the ear.
- (c) Whenever any of the conditions listed in paragraph (b) of this subdivision is found to exist, no hearing aid dispenser shall dispense a hearing aid to such prospective user. The hearing aid dispenser shall advise the prospective user of the observed condition and shall advise him or her to promptly consult a licensed physician, preferably a specialist in diseases of the ear. The prospective user shall be advised that he or she may consult with another licensed physician, if no otolaryngologist is available. A hearing aid dispenser may dispense a hearing aid to such prospective user after such user has obtained a medical clearance. No prospective user may waive medical evaluation under this subdivision if any of the conditions listed in paragraph (b) of this subdivision is found to exist except that a prospective user or the parent or guardian thereof may request a waiver on the basis that medical treatment violates his or her religious tenets or beliefs. A hearing aid dispenser shall read to and then present a waiver to such prospective user or parent or guardian thereof which shall provide: "at my request, (name of hearing aid dispenser) has informed me that I may waive medical evaluation of my hearing due to my personal religious beliefs, signed (name of prospective user or parent or guardian)." No hearing aid dispenser shall seek to induce a prospective user or parent or guardian of a prospective user to execute a waiver in order to effect the sale of a hearing aid.

9. It is unlawful for a registered hearing aid dispenser to dispense a hearing aid unless he or she has first:

- (a) complied with all provisions of state laws and regulations relating to the dispensing of hearing aids; and
- (b) has informed the purchaser of the address and office hours at which the registrant shall be available for fitting or post-fitting adjustments and servicing of the hearing aid or aids sold.

10. (a) A hearing aid dispenser, not otherwise licensed pursuant to article 159 of the Education Law, shall provide any prospective hearing aid users with a copy of their audiogram which shall in-

clude puretone (air and bone conduction) and speech audiometry test results, upon completion of such audiometric tests. Such audiogram shall clearly and conspicuously contain the following statement: "This information is intended for the sole purpose of fitting or selecting a hearing aid and is not a medical examination or audiological evaluation".

- (b) Hearing aid dispensers licensed under article 159 of the Education Law shall comply with the provisions of such article in the conduct of audiological evaluations and shall further provide a copy of the results of any audiological evaluation to any prospective hearing aid users with the following statement: "This is an audiological evaluation and is not a medical examination."

11. Registrant shall, upon the consummation of a sale of a hearing aid, deliver to the purchaser a written receipt or purchase agreement, signed by the purchaser, the registrant and if applicable, the trainee, containing all of the following:

- (a) the date of consummation of the sale;
- (b) specifications as to the make, serial number, and model number of the hearing aid or aids sold;
- (c) the address of the principal place of business of the registrant, and the office hours available for fitting or post-fitting adjustments and servicing of the hearing aid or aids sold;
- (d) a statement to the effect that the hearing aid or aids delivered to the purchaser are used or reconditioned, as the case may be;
- (e) the number of the registrant's certificate and the name and registration number of any other hearing aid dispenser or trainee who provided any recommendation or consultation regarding the purchase of the hearing aid;
- (f) the terms of any written warranty, as required by this article;
- (g) such receipt shall bear, or have attached to it in no smaller than 14 point type, the following: "The purchaser has been verbally advised at the outset of his or her relationship with the registered hearing aid dispenser that any examination or representation made by a hearing aid dispenser in connection with the business of dispensing this hearing aid, or hearing aids, is not an examination, diagnosis, or prescription by a person licensed to practice medicine in this state, and therefore, must not be regarded as medical opinion.";
- (h) such written receipt or purchase agreement shall also outline the purchaser's right to return as required by subdivision 12 of this section. (i) The receipt shall include, in immediate proximity to the space reserved for the signature of the buyer, the following statement in all capital letters of no less than 12 point bold-faced type: "IN ADDITION TO OTHER RIGHTS, THE BUYER HAS THE RIGHT TO CANCEL THIS PURCHASE FOR ANY REASON AT ANY TIME PRIOR TO TWELVE MIDNIGHT OF THE 45TH CALENDAR DAY () AFTER RECEIPT OF THE HEARING AID AND RETURN THE HEARING AID IN THE SAME CONDITION, ORDINARY WEAR AND TEAR EXCLUDED. BY LAW, THE SELLER IS ALLOWED TO RETAIN AN AMOUNT UP TO TEN PERCENT OF THE TOTAL PURCHASE PRICE OF THE CANCELLED HEARING AID, INCLUDING BATTERIES AND CORDS OR ACCESSORIES THERETO, INCLUSIVE OF ALL FEES RELATED TO THE HEARING AID."; (ii) if the dispenser is a not-for-profit hospital or facility licensed or certified pursuant to article 28 of the Public Health Law, the receipt shall include, in immediate proximity to the space reserved for the signature of the buyer, the following statement in all capital letters of no less than 12 point bold-faced type: "IN ADDITION TO OTHER

RIGHTS, THE BUYER HAS THE RIGHT TO CANCEL THIS PURCHASE FOR ANY REASON AT ANY TIME PRIOR TO TWELVE MIDNIGHT OF THE 45TH CALENDAR DAY () AFTER RECEIPT OF THE HEARING AID AND RETURN THE HEARING AID IN THE SAME CONDITION, ORDINARY WEAR AND TEAR EXCLUDED. BY LAW, THE DISPENSER IS ALLOWED TO RETAIN AN AMOUNT UP TO FIVE PERCENT OF THE TOTAL PURCHASE PRICE OF THE CANCELLED HEARING AID, INCLUDING BATTERIES AND CORDS OR ACCESSORIES THERETO, INCLUSIVE OF ALL FEES RELATED TO THE DISPENSING OF THE HEARING AID, PLUS A SERVICE FEE OF NOT MORE THAN TWO HUNDRED DOLLARS, UNLESS A SECOND HEARING AID WAS FITTED AND DISPENSED AT THE SAME TIME AS THE FIRST, THEN SUCH FEE SHALL NOT EXCEED THREE HUNDRED DOLLARS FOR BOTH HEARING AIDS."

12. No hearing aid shall be sold to any person unless accompanied by a 45 calendar day money-back written guarantee.

- (a) If an individual returns a hearing aid in the same condition, ordinary wear and tear excluded, within the guarantee period, the customer shall be entitled to the return of the cost of the hearing aid and accessories as itemized on the receipt provided pursuant to subdivision 11 of this section; provided however that any hearing aid that has been used for a 45 calendar day period as described in this subdivision, when refinished and totally reconditioned by the manufacturer or by the manufacturer's agent and such manufacturer or manufacturer's agent certifies that such hearing aid meets all the acoustical standards of a new hearing aid and is in all other respects the equivalent of a new hearing aid and with all warranties and guarantees that accompany a new hearing aid, shall be considered a new hearing aid and so designated; and further provided, however, that a hearing aid dispenser shall retain as a cancellation fee for return of the hearing aid, including batteries and cords or accessories thereto, a charge not in excess of 10 per centum of the total purchase price of the cancelled hearing aid, including batteries and cords or accessories thereto, inclusive of all fees related to dispensing of hearing aids, as defined in subdivision six of §789 of this article. Provided, however, if the hearing aid dispenser is a not-for-profit hospital or facility licensed or certified pursuant to article 28 of the Public Health Law, such dispenser is allowed to retain an amount up to five per centum of the total purchase price of the cancelled hearing aid, including batteries and cords or accessories thereto, inclusive of all fees related to the dispensing of the hearing aid, plus a service fee of not more than \$200, unless a second hearing aid was fitted and dispensed at the same time as the first, then such fee shall not exceed \$300 for both hearing aids. Such money-back guarantee as provided in this subdivision shall not be in lieu of or in anyway affect the right of the purchaser to recover the full amount paid and for any damages sustained for a breach of guarantee of fitness for use.
- (c) The 45 calendar day return period shall be tolled for any period during which a hearing aid dispenser takes possession or control of a hearing aid after its original delivery.

13. (a) Within one year from the date of purchase, in addition to any other rights and remedies the purchaser of a hearing aid may have, the purchaser shall have the right to rescind the transaction if: (i) the purchaser consults a licensed otolaryngologist, or if no such licensed otolaryngologist is available then another licensed physician, qualified to diagnose diseases of the ear, subsequent

to purchasing a hearing aid, (ii) and the physician certifies in writing that, in his or her professional judgement, at the time the dispensing occurred the purchaser had either a hearing impairment for which a hearing aid provides no benefit or had a medical condition which contraindicates the use of a hearing aid, and (iii) as the result of either condition, the purchaser experienced no improvement in the quality of hearing.

- (b) If the conditions of paragraph (a) of this subdivision are met, the seller shall refund to the purchaser, within 10 days of the receipt of notice to rescind, a full and complete refund of all moneys received, in compliance with paragraph (a) of this subdivision. The purchaser shall incur no additional liability for rescinding the transaction.
- (c) Any dispute over a purchaser's right to rescind the transaction as provided in this subdivision that is not resolved administratively by the department shall be determined by a court of competent jurisdiction.

14. A registrant shall, upon the consummation of a sale of a hearing aid, keep and maintain records in his or her office or place of business at all times and each such record shall be kept and maintained for a six year period. These records shall include:

- (a) results of the hearing test, fitting, selection, sales, rental and adaptation or service practices as required under this article;
- (b) a copy of the written receipt required by subdivision 11 of this section;
- (c) a copy of the signed written waiver, if any; and
- (d) any other material which the secretary may feel is necessary.

15. A registrant shall comply with applicable statutes, rules and regulations regarding advertising of his or her services. In addition:

- (a) no hearing aid dispenser shall, through advertisement, indicate or imply that any type of medical examination or audiological evaluation will be provided or that the dispenser has been recommended by anyone other than an individual licensed to perform such examination or evaluation; provided, however, that nothing in this paragraph shall restrict or limit any person licensed under article 159 of the education law from performing any activity thereunder or from stating in an advertisement that an audiological evaluation will be provided where an audiological evaluation is to be provided;
- (b) no hearing aid device, part or accessory thereof shall be advertised as a new invention or involving a new mechanical or scientific principle unless such claim is true; and
- (c) except for those hearing aid dispensers licensed as audiologists under article 159 of the Education Law, no hearing aid dispenser shall, through advertisement, indicate or imply that he or she may perform a hearing test, examination, evaluation or consultation unless he or she includes the statement, "unless administered by an audiologist or physician, this test is for the purpose of amplification only. It is not a medical test."

16. No registered hearing aid dispenser, trainee or an employee of the registered hearing aid dispenser or trainee, shall canvass from house to house for the purpose of selling or renting a hearing aid. No registered hearing aid dispenser or trainee shall personally visit the home of a prospective customer for the purpose of selling or renting a hearing aid without the prior request of the prospective customer.

17. No registered hearing aid dispenser, manufacturer, organization or distributor shall sell or rent a hearing aid to a resident of this state through direct mail order sales.

18. No registered hearing aid dispenser or trainee shall conduct or consummate the sale of a hearing aid over the telephone unless the prospective user has been tested by that dispenser within the previous 30 days or a hearing aid user has initiated a request for a replacement of a specific hearing aid.

19. If a registered hearing aid dispenser utilizes telemarketing techniques or telephone contact, he or she shall comply with all applicable provisions of Federal and State law. Any initial telephone contact undertaken by a registered hearing aid dispenser or trainee shall include the following information:

- (a) a hearing aid will not restore normal hearing;
- (b) any hearing test or examination is not a medical test or examination and is solely for the purposes of fitting a hearing aid;
- (c) if there are indications of potential medical conditions, as defined by law, the prospective user will be referred to an otolaryngologist or if none is available to a physician; and
- (d) the costs of testing or office visits; and, the range of costs of hearing aids available from the registered hearing aid dispenser.

20. A registered hearing aid dispenser shall distribute printed educational information approved by the secretary to prospective hearing aid purchasers about the general use of hearing aids and assistive listening devices and on the advantages and disadvantages of binaural hearing aids, as well as rights and remedies available to the consumer pursuant to this article.

§799. Administration; suspension and revocation of registrations; fines; reprimands

- 1. (a) The secretary shall refer each complaint which alleges conduct constituting a violation of article 159 of the Education Law committed by an individual licensed pursuant to article 159 of the Education Law to the office of professional discipline within the education department. Such complaints shall be processed pursuant to article 130 of the Education Law.
- (b) Any order to suspend, revoke or refuse to issue a certificate of registration for hearing aid dispensing of a licensed audiologist shall be issued by the Commissioner of Education. Where such complaints allege violation of the provisions of this article relating to the dispensing of hearing aids by a registrant who is also subject to the provisions of article 159 of the Education Law, the secretary shall have the powers as provided in this section. Such powers relate exclusively to the registration as a hearing aid dispenser.

2. Except as provided in subdivision one of this section, the secretary may suspend or revoke any registration issued pursuant to this article, and/or impose a fine of up to \$1,000 per violation payable to the secretary. Such penalties may be imposed for the following reasons:

- (a) engaging in the business of dispensing hearing aids unless the person is a registered hearing aid dispenser or a holder of a temporary certificate of registration.
- (b) incompetency which includes, but is not limited to, the improper or unnecessary dispensing of a hearing aid.
- (c) negligence and/or repeated negligent acts.
- (d) conviction of any crime substantially related to the qualifications, functions and duties of a hearing aid dispenser.
- (e) obtaining a certificate of registration by fraud or deceit; or presenting as his or her own the certificate of registration of another.

- (f) use of the term “doctor” or “physician” or “clinic” or “hearing specialist” or “audiologist,” or any derivation thereof, unless authorized by law; or any terms which suggest or imply medical board certification, medical training, competency or expertise. Any reference to certification or other professional training shall specify the grantor of such credential.
- (g) fraud or misrepresentation in the dispensing of a hearing aid or aids.
- (h) the employment, to perform any act covered by the provisions of this article, of any person whose certificate of registration has been suspended, revoked, or who does not possess a valid certificate of registration or temporary certificate of registration issued under this article.
- (i) the use or causing the use, of any advertising or promotional literature in such manner as to have the capacity or tendency to mislead or deceive purchasers or prospective purchasers including any reference to “hearing consultation”, unless permitted pursuant to article 159 of the Education Law for those hearing aid dispensers licensed under such article, or medical consultation, diagnosis or treatment.
- (j) the registrant’s permitting another to use his or her certificate of registration for any purpose.
- (k) failure to display the certificate of registration as provided in this article.
- (l) violation of any provision of this article, other applicable Federal or State law, rule or regulation, or of any existing applicable sanitary code.
- (m) failure or refusal to perform repairs or service on any hearing aid sold by such trainee and/or registrant.
- (n) no hearing aid dispenser, registrant or hearing aid trainee shall state or imply that the use of any hearing aid will restore hearing to normal, or preserve hearing, or prevent or retard the progression of a hearing impairment or any false or misleading or medically or audilogically un-supportable claims regarding the efficacy or benefits of hearing aids.
- (o) fraud or bribery in securing a certificate of registration or permission to take an examination therefor.
- (p) violation of a lawful order of the department previously entered in a disciplinary hearing or failure to comply with investigations or a lawfully issued subpoena of the department.
- (q) making any predictions or prognostications as to the future course of a hearing impairment, either in general terms or with reference to an individual person, except where such predictions and prognostications are made by a hearing aid dispenser licensed pursuant to the provisions of article 159 of the Education Law and consistent with such law.
- (r) exerting influence on a client in such a manner as to exploit the client for financial gain for the registrant or for a third party.
- (s) sale of a hearing aid by telephone or telemarketing. Such prohibition shall not limit the scheduling of appointments, offering of services or the sale of a hearing aid to a person whom has been tested by that dispenser or dispensing audiologist within the previous 30 days or is a hearing aid user who has initiated or specifically requested the telephone sale or offer of sale.
- (t) inducing a prospective user or the parent or guardian of a prospective user to execute a religious waiver through the use of a false or misleading statement to effect the sale of a hearing aid.
- (u) performing an otoscopic observation or testing of hearing for medical diagnostic purposes.

3. Whenever a certificate of registration is revoked, such certificate of registration shall not be reinstated or reissued until after the expiration of a period of five years from the date of such revocation.

4. The secretary may issue an order directing the cessation of any activity for which registration is required by this article upon a finding that a person, including a partnership, limited liability company, corporation, trust or other business organization has engaged in or acted as a hearing aid dispenser or a hearing aid dispensing business within this state without a valid registration. The department shall, before making such determination and order, afford such person including a partnership, limited liability company, corporation, trust, association or business organization, an opportunity to be heard in person or by counsel in reference to an adjudicatory proceeding held pursuant to this article.

5. [Repealed]

6. Upon the suspension or revocation of a certificate of registration by the secretary and the issuance of a notice thereof, the registrant shall within five business days deliver to the secretary the certificate of registration. If surrendered by mail, the certificate of registration shall be sent by registered or certified mail, postmarked no later than three business days following notice of suspension or revocation. Failure to return a certificate of registration which has been revoked or suspended pursuant to this section within the prescribed time shall constitute a violation punishable by the payment of a fine of up to \$500.

7. In the event that the registrant shall contest the charge of the violation, a hearing on the charge shall be conducted in accordance with the provisions of subdivisions one and two of §800 of this article.

§800. Denial of registration; complaints; notice of hearing

1. Denial of registration. The secretary shall, before making a final determination to deny an application for a registration, notify the applicant in writing of the reasons for such denial and shall afford the applicant an opportunity to be heard in person or by counsel prior to the denial of the application. Such notification shall be served personally or by mail or in any manner authorized by the Civil Practice Law and Rules for service of a summons. If a hearing is requested, such hearing shall be held at such time and place as the secretary shall prescribe. If the applicant fails to make a written request for a hearing within 30 days after receipt of such notification, then the notification shall become the final determination of the secretary. If, after hearing, the registration is denied, written notice of such denial shall be served upon the registrant personally or by certified mail or in any manner authorized by the Civil Practice Law and Rules.

2. Revocation, suspension, reprimands, fines. The secretary shall, before revoking or suspending any registration or imposing any fine or reprimand on the holder of such registration, or before issuing any order directing the cessation of unregistered activity shall send notification of such action to the holder. Such notice shall be provided at least 10 days prior to the date set for the hearing, notify the registrant or the person deemed to have engaged in such unregistered activities, of any charges made and shall afford the person an opportunity to be heard in person or by counsel in reference thereto. Such written notice may be served upon the registrant in person or by mailing the notice by certified mail to the registrant to the last known business address of such person, or by any method authorized by the Civil Practice Law and Rules for the service of a summons. The hearing shall be at such time and place as the secretary shall prescribe. After the applicant is notified of such denial, in the event a certificate of registration or temporary certificate of registration or an application is denied, no such registration shall be issued to such former registrant or applicant for at least six months, nor thereafter, except at the discretion of the secretary. The applicant or registrant may be heard in person or by

counsel. Such hearing shall be at such time and place as the secretary shall prescribe.

3. In any hearing held pursuant to the provisions of this article, the secretary acting by such officer or person in the department as he or she may designate, shall have the power to subpoena and bring before the officer or person so designated any person in this state, or document, record or relevant evidence, and administer an oath to and take the testimony of any such person or cause his or her deposition to be taken. A subpoena issued under this section shall be regulated by the Civil Practice Law and Rules.

§801. Judicial review

The action of the secretary pursuant to a hearing in refusing to grant or to renew a certificate of registration or a temporary certificate of registration, in revoking or suspending such registration or imposing a civil penalty, shall be subject to review by the supreme court in the manner provided in article 78 of the Civil Practice Law and Rules.

§802. Special provisions; not-for-profit sales

1. No otolaryngologist or other licensed physician who has conducted a medical evaluation of hearing loss shall engage in the business of dispensing hearing aids for a profit. No otolaryngologist or other licensed physician who has dispensed a hearing aid shall refuse or fail to perform repairs or service on any hearing aid that they have dispensed.

2. Every licensed physician who engages in the dispensing of hearing aids in compliance with the provisions of this section shall be required to comply with §§791, 798 and 803 of this article, in addition to compliance with this section.

§803. Powers of the secretary

1. The secretary shall promulgate such rules and regulations as are deemed necessary to effectuate the purposes of this article, and shall provide written notification of the provisions of this article and a copy of the registration application within 90 days of the effective date of this article to all dealers as were registered under former article 37-a of this chapter prior to such effective date and to audiologists licensed pursuant to article 159 of the Education Law. Such notification shall inform all such dealers, their dispensing employees and audiologists of the obligation to register pursuant to subdivision nine of §790 of this article.

2. The secretary shall review implementation of the provisions of this article in consultation with the board and shall vigorously and proactively ensure the enforcement of its provisions through site visits, regular examination of compliance with this article, public outreach and education, promulgation of regulations, delivery of technical assistance, and such other forms as would increase awareness of and adherence to the protections and process prescribed in this article. The secretary shall examine compliance with this article for each business registered pursuant to subdivision one of §790 of this article at least once every four years.

3. In addition to the powers and duties specified elsewhere in this article, the secretary, upon the complaint of any individual or upon the secretary's initiative, shall have the power to make and to conduct such investigations as are deemed necessary to effectuate the purposes of this article. The secretary shall have the power to require the attendance of witnesses and issue subpoenas in accordance with the provisions of this section, in the conduct of such investigations.

4. In conjunction with the board, the secretary shall:

- (a) develop procedures for promptly investigating all complaints regarding violations of this article;

- (b) develop procedures for assisting consumers in resolving a dispute with those persons registered pursuant to this article and mediating on behalf of consumers when needed;
- (c) establish a toll-free number at which consumers, including persons who are hard of hearing or deaf, can register a complaint; and
- (d) develop other procedures as necessary to increase public awareness of how to properly purchase, fit, adjust and use a hearing aid, as well as the rights of hearing aid consumers pursuant to this article, which shall include the distribution of written information concerning this subject matter and the toll-free number to those subject to this article, the media, and the general public.

5. The secretary, in conjunction with the board shall cause to be prepared and distributed printed educational information to registered hearing aid dispensers and others about the general use of hearing aids and assistive listening devices and on the advantages and disadvantages of hearing aids as well as rights and remedies available to the consumer pursuant to this article.

6. The secretary shall regularly communicate with the commissioner of education regarding the discipline and/or prosecution of violations of this article by audiologists licensed pursuant to article 159 of the Education Law.

7. On or before January 31st of each year, the secretary shall develop and distribute a report to the governor, the speaker of the assembly, the temporary president of the senate, the minority leader of the assembly, the minority leader of the senate, the chair of the assembly ways and means committee, and the chair of the Senate Finance Committee, and make it available for public examination. Such report shall entail specific efforts made by the secretary, the board and hearing aid dispensers to comply with the provisions of this article, a compilation of actions taken in response to recommendations submitted to the secretary from the board, a summary of the results of compliance efforts and anticipated efforts to improve public education, compliance and enforcement during the subsequent year, as well as recommendations, if any, to amend this article.

§804. Penalties

Any person found to have engaged in the dispensing of hearing aids or in the business of dispensing hearing aids without being registered pursuant to this article shall be guilty of a class A misdemeanor.

§805. Separability

If any section or provision of this article shall be adjudged by any court of competent jurisdiction to be invalid or inapplicable to any person or situation, such judgment shall not affect, impair or invalidate any other section or provision of this article or the applicability of such section or provision to other persons or other situations.

EDUCATION LAW

§8208. Special provisions

* * *

- 4. (a) The commissioner, pursuant to the recommendation of the board shall promulgate regulations defining appropriate standards of conduct for the dispensing of hearing aids by licensed audiologists. Such regulations shall also define continuing education requirements which such dispensing audiologist shall meet as a condition of maintaining registration pursuant to this article.

- (b) Audiologists engaged in the practice of dispensing hearing aids shall comply with the applicable provisions of article 37-a of the General Business Law.

RULES AND REGULATIONS

TITLE 19 NYCRR

HEARING AID DISPENSERS

PART 192

§192.1 Definitions

(a) The General Business Law (“GBL”) Article 37-A contains many specific requirements on the provision of hearing aids. Where appropriate, a regulation may contain a specific reference to a statutory provision. The regulation and the statute should be read together.

(b) The term “registrant” or “business registrant” means any individual, corporation, partnership, trust, association or other organization maintaining an established New York state business address who engages in the business of dispensing hearing aids at retail.

(c) The term “binaural hearing aids” means “hearing aids” as defined in GBL §789(7) involving both ears.

(d) The term “otolaryngologist” shall include a physician who uses the designation otorhinolaryngologist or otologist to describe his medical specialty and is similarly entitled to practice such specialty.

(e) The term “consumer” includes a purchaser, customer or user of a hearing aid, or the parent or guardian of a purchaser, customer or user.

(f) A professional corporation formed thereby shall be deemed equivalent to any otolaryngologist or audiologist referred to in this Part.

§192.2 Application form for a business registrant

(a) Contents of application. In addition to the information listed in GBL §790, the application shall set forth:

(1) the name and business address of each stockholder owning more than 10 percent of the issued and outstanding stock of a corporation.

(2) the name of the dispenser who is the manager or supervisor at each permanent business location.

(3) the principal office of the business entity, whether or not the dispensing of hearing aids is conducted at such principal office.

(4) whether the applicant, any partner or officer thereof has had a license or registration denied, suspended or revoked in any jurisdiction. If so, the details thereof shall be supplied.

(5) whether any administrative charges or complaints have been brought against the applicant, any partner or officer thereof in any jurisdiction. If so, details thereof shall be supplied.

(6) whether the applicant, any partner or officer thereof has been convicted of a crime or offense other than a minor traffic violation in any jurisdiction. If so, a certified copy of the conviction shall be attached to the application.

(7) whether the applicant, any partner or officer thereof has ever been engaged in the business of fitting, renting or selling hearing aids in any jurisdiction. If so, the name under which and the address at which such business was conducted shall be supplied.

(b) Assumed name. If the application is submitted by an individual or unincorporated association using an assumed name or by a partnership, the application shall include a certified copy of the certificate of doing business under the assumed or partnership name filed with the county clerk. If

the application is submitted by a corporation, limited partnership or limited liability company using an assumed name, the application shall include a copy of the certificate of assumed name filed with the department.

(c) Signing of application. The application shall be signed and affirmed by the applicant under penalty of perjury. An application made on behalf of a partnership or corporation shall be executed by the managing general partner or corporate officer who shall have been named in the application as the principal partner or officer.

(d) Restriction as to name. A name may not contain any word or words which may imply that the applicant provides any medical treatment or audiometric examinations.

(e) A not-for-profit corporation, agency, association or entity which dispenses hearing aids shall register and comply with the provisions of this Part, where applicable.

§192.3 Certificate of registration

(a) Posting of certificates. The business certificate of registration and the individual certificate of each dispenser employed at a permanent business location shall be conspicuously posted in open view at such location.

(b) Changes in information. If there is a change in any information set forth in the application after the issuance of a certificate of registration, a statement of amendment on a form prescribed by the department and executed in the manner required for an application shall be filed by the registrant within 10 days of such change. However, a change of address shall be reported within 30 days.

(c) Transfer of ownership. No individual, partnership or corporation or other entity or group of persons shall operate under an existing certificate of registration, if there has been a transfer of ownership of the business. For the purpose of this subdivision, a transfer of ownership shall mean a transfer by an individual owner of any portion of his interest, or a transfer of 50 percent or more of the partnership interest or of the issued and outstanding stock of a corporation or other entity.

§192.4 Education

(a) Approved entities.

(1) Hearing aid dispensers. The course of instruction may be conducted by a registered hearing aid dispenser who has a minimum of three years full-time experience in the dispensing of hearing aids.

(2) Educational providers. The course of instruction may be given by: any college or university accredited by the Commissioner of Education of the State of New York; public and private vocational schools; audiology, hearing and/or hearing aid professional societies and organizations; medical facilities; and hearing instrument manufacturers.

(b) Application for approval of a course of study.

(1) An application for approval to conduct a course of study by an educational provider shall be made 60 days before the proposed course is to begin.

(2) The application shall include the following:

(A) name and business address of the proposed school;

(B) if applicant is a partnership, the names and addresses of all the partners of the entity;

(C) if applicant is a corporation, the names and addresses of persons who own five percent or more of the stock of the entity;

(D) the name, home and business address and telephone number of the education coordinator who will be responsible for administering the regulations contained in this part;

(E) locations where classes will be conducted;

(F) description of materials that will be distributed; and

(G) the books that will be used for the course.

(c) Subjects for Study for Hearing Aid Dispensers.

(1) The following are the subjects required to be included in the course of instruction for licensure as a hearing aid dispenser, and the required number of hours to be devoted to each such subject. All approved courses must use this course syllabus in conducting their program.

Subject	Theory	Practical
(A) Acoustics: General Principles	5 hours	10 hours
(B) Acoustics: Hearing and Speech	5 hours	10 hours
(C) The Human Ear	5 hours	10 hours
(D) Disorders of Hearing	5 hours	10 hours
(E) Puretone Audiometry	20 hours	40 hours
(F) Speech Audiometry	15 hours	30 hours
(G) Hearing Analysis	45 hours	90 hours
(H) Hearing Aids and Instruments	45 hours	90 hours
(I) Infection Control	5 hours	10 hours
(J) New York State and Federal Law, Regulations and Professional Conduct	5 hours	10 hours
Total Theory and Practical Hours	155 hours	310 hours
Total Hours		465 hours

(2) Educational providers may be approved to teach the theory portion of the above syllabus. The student attending the program must be informed by the provider prior to registering for the course that the remaining practical hours must be completed with a registered hearing aid dispenser.

(d) Attendance. To satisfactorily complete any course offered for study, a person must complete at least 124 theory hours and 310 practical hours of the course of instruction.

(e) Certificate of successful completion.

(1) Upon satisfactory completion of the course of instruction, the approved entity must submit to the student a certificate of completion which shall be signed and affirmed as true under the penalties of perjury. The certificate shall include the following: name of the registered hearing aid dispenser and/or educational provider; Hearing Aid Dispenser Course; 155 theory hours and 310 practical hours; if completed with a registered hearing aid dispenser the dispenser's registration number; if completed with an approved educational provider the assigned course code number; a statement that the trainee/student, who shall be named, has satisfactorily completed a course of study in the provisions of General Business Law, Article 37-A, and that such course was completed on a stated date. The certificate must be signed by the registered dispenser or course coordinator and dated.

(f) Faculty. Each instructor who is a registered hearing aid dispenser with three years of full time experience in the dispensing of hearing aids and each instructor of an approved educational provider who has three years of experience in the field directly related to hearing aid dispensing must submit a one-time application to the Division of Licensing Services, Bureau of Educational Standards, on an application form as promulgated by the Division, along with a resume.

(g) Retention of records. All persons and organizations conducting approved courses of study shall retain papers for persons completing the course of instruction for a period of five years after completion thereof, and such papers shall at all times during such period be available for inspection by duly authorized representatives of the Department.

(h) Facilities. Each course shall be presented in such premises and facilities as necessary to properly present the course.

(i) Auditing. A duly authorized designee of the department may audit any course offered and inspect the records of attendance of the course at any time during its presentation or for a period of five years after completion thereof.

(j) Suspension and denials of course approval. The department may deny, suspend or revoke the approval of a hearing aid dispenser course or a hearing aid dispenser instructor, or location, if it is determined that it is not in compliance with the law and rules, or if the offering does not adequately reflect and present current hearing aid dispenser knowledge. If disciplinary action is taken, a written order of suspension, revocation or denial of approval will be issued. A person who objects to such denial, suspension or revocation shall have the opportunity to appeal to the Secretary of State or designee.

(k) Training program credit for completion of course work. If an individual successfully completes the theory portion of the course of instruction with an educational provider approved by the department, the trainee may be granted up to three months of credit toward the required 12 month training program. The individual must then complete the remaining practical hours with a registered hearing aid dispenser who has a minimum of three years of full-time experience in the dispensing of hearing aids.

(l) Credit for comparable education in the hearing aid dispensing field. The department may credit equivalent education upon evidence of the issuance of a completion certificate and transcript satisfactory to the department of a course of study at any accredited college or university, which includes course work substantially similar to that set forth in Section 192.4(c) of this Part. Attendance at such hearing aid dispenser course of study may not be less than 155 hours. Upon issuance of equivalency credit, the applicant must complete the remaining 310 practical hours with a registered hearing aid dispenser who has a minimum of three years of full-time experience in the dispensing of hearing aids.

(m) Registration period. Each registration or renewal period for hearing aid dispenser courses for approved educational providers shall be for 12 months or a part thereof; said period shall commence on January 1 or a date thereafter and continue until December 31st of each year.

§192.5 Training program

(a) A trainee who receives up to three months' credit for completing the theory portion of a course of instruction pursuant to section 192.4(k) of this Part may not perform any activity directly related to the dispensing of a particular hearing aid or hearing aids unless such activity is conducted under the direct supervision of a registered dispenser for a period of three months. For the next three months, such trainee may not perform any activity directly related to the dispensing of a particular hearing aid or hearing aids unless such activity is conducted with the immediate consent, review and approval of a registered dispenser.

(b) For the purpose of applying to take the written examination, up to three months' course credit may be counted toward satisfying the six months' training program. However, no trainee may apply to take the written examination or practical test until the conclusion of the three month period of direct supervision.

§192.6 Examinations

(a) The fee for the initial taking of the written exam and/or practical test, administered at the same time, is \$50. There is an additional fee of \$50 for the re-taking of either the written exam or the practical test, or the taking of the exam and practical at different times.

(b) An applicant may review the score of a failed examination by making such request in writing to the department. Such review will be made available within a reasonable time at an office of the department. The applicant may not copy the exam or the scoring thereof.

§192.7 Continuing Education

(a) General requirements. No offering of a course of study shall be acceptable for credit unless such course of study shall have been approved by the department.

(b) Proof of compliance. A registrant shall maintain and, upon request, provide to the department proof of satisfactory completion of the continuing education requirements for the registrant's current and immediately preceding term of registration.

(c) Approved entity. Dispenser continuing education courses and offerings may be presented by: any college or university accredited by the Commissioner of Education of the State of New York; public and private vocational schools; audiology, hearing and/or hearing aid professional societies and organizations; medical facilities; or hearing instrument manufacturers.

(d) Application for approval of a continuing education course of study.

(1) An application for approval to conduct a course of study by an educational provider shall be submitted 60 days before the proposed course is to begin.

(2) The application shall include the following:

(A) name and business address of the proposed school;

(B) if applicant is a partnership, the names and addresses of all the partners of the entity;

(C) if applicant is a corporation, the names and addresses of persons who own five percent or more of the stock of the entity;

(D) the name, home and business address and telephone number of the education coordinator who will be responsible for administering the regulations contained in this Part;

(E) locations where classes will be conducted;

(F) title of each course or program to be conducted;

(G) a detailed outline of the subject matter, together with time sequence of each segment; and

(H) a description of materials that will be distributed.

(e) Basic course or program requirements. Approval for continuing education courses may be granted for courses which cover hearing aid dispenser-related topics. No credit will be granted for sales or sales-related courses or components thereof.

(f) Length of programs. A program must contain a minimum of one contact hour and may contain a maximum of 20 contact hours of instruction.

(g) Program approval. A sponsor of a course which is conducted on one day may file an application for approval within 30 days of the completion of the course. The sponsor must advise registrants that approval has not been granted.

(h) Facilities. Each course shall be conducted in such premises and facilities as necessary to properly present the course.

(i) Change of approved course of study. There shall be no change or alteration in any approved course of study of any subject without prior written notice to and approval by the department.

(j) Attendance. In order to obtain a certificate of completion for continuing education, a dispenser must complete at least 90 percent of the outlined course of instruction. A student may complete hours that are missed at the discretion of the approved entity.

(k) Certificate of completion. An educational provider shall issue a certificate of successful completion of a course approved by the Department of State to a person who has attended the required aggregate number of hours of such a course.

(l) Availability. An approved course shall be open to any registrant.

(m) Retention of records. An approved entity shall retain the records of all students for a period of five years after the completion of a course, and such papers shall be available for inspection by duly authorized representatives of the department at all times during such period.

(n) Auditing. A duly authorized representative of the department may audit any course, verify attendance and inspect the records of attendance of a course, at any time during its presentation or for a period of five years after completion thereof, without prior notice to the sponsor.

(o) Suspensions and denials of course approval.

(1) Within 60 days after the receipt of the application for approval of an offering, the department shall inform the sponsor as to whether the course has been approved, denied, or whether additional information is needed to determine the acceptability of the offering.

(2) The department may deny, suspend or revoke the approval of a dispenser course, instructor or location, if it is determined not to be in compliance with law and regulations, or if the offering does not adequately reflect and present current hearing aid dispenser knowledge. If disciplinary action is taken, a written order of suspension, revocation or denial of approval shall be issued. Anyone who objects to such denial, suspension or revocation shall have the opportunity to appeal to the Secretary of State or designee within 30 days.

(p) Faculty approval and qualifications.

(1) Each instructor who is a registered hearing aid dispenser with three years of full time experience in the dispensing of hearing aids and each instructor of an approved educational provider who has three years of experience in the field directly related to hearing aid dispensing must submit a one-time application to the Division of Licensing Services, Bureau of Educational Standards, on an application form as promulgated by the Division, along with a resume.

(2) An instructor in technical subjects, closely related to hearing aid dispensing, but not classified as specific subject matter pertaining to hearing aid dispensing theory, who does not satisfy the three year experience qualification under section 192.7(p)(1) must submit a technical instructor application certifying to the claimed expertise along with a resume.

(q) Policy on course cancellation and tuition refund. An educational provider must submit to the department its written policy relating to course cancellation and tuition refunds. Such policy must be provided in writing to prospective students prior to the acceptance of any fees.

(r) Registration period. Each registration or renewal period for approved courses shall be for 12 months or a part thereof. The period shall commence on each January 1st or a date thereafter and continue until December 31st of each year.

(s) Equivalency credit.

(1) A registrant who completes a course of study offered outside of the State of New York, which course has not been approved by the department, may file a request to the department for review and evaluation of such course. An application for such consideration may be submitted along with official documentation of satisfactory completion, and the official description of the course.

(2) An instructor of an approved qualifying or continuing education course may be awarded one hour of continuing education credit for each direct hour of instruction during the registration cycle. Credit shall not be awarded for teaching the same course more than once in a registration cycle. Instructors must submit evidence of such experience with an equivalency application.

(3) An application for and evidence of equivalency credit must be submitted to the department for consideration at least 30 days prior to the expiration of the registration.

(t) Individual credit for continuing education. Any course approved under this section cannot be taken more than once during the same registration cycle.

(u) Continuing education extension. A registrant who is unable to complete continuing education requirements due to an extreme ongoing illness or other catastrophe may request an extension from the department. Medical documentation or other evidence of the claimed problem must be submitted along with the request for the extension.

(v) Infection Control and New York State and Federal Law, Regulation and Professional Conduct for Hearing Aid Dispensers. As a condition of renewing a hearing aid dispenser registration, each hearing aid dispenser shall successfully complete a total of 20 continuing education credits per registration period as set forth in section 794 of the General Business Law. At least one of the required credit hours shall be devoted to the subject of infection control as prescribed by the Secretary of State, at least one of the required credit hours shall be devoted to the subject of telecoil (t-coil) and other assistive listening devices, and at least one of the required credit hours shall be devoted to the subject of New York State and Federal law, regulations and professional conduct as prescribed by the Secretary of State.

(w) Infection Control and New York State and Federal Law, Regulation and Professional Conduct for Audiologists. As a condition of renewing a hearing aid dispenser registration, each audiologist who is registered as a hearing aid dispenser under General Business Law section 790, subdivision one, paragraph (b) shall successfully complete four continuing education credits relating to the dispensing of hearing aids as set forth in section 794 of the General Business Law. At least one of the required credit hours shall be devoted to the subject of infection control, at least one of the required credit hours shall be devoted to the subject of telecoil (t-coil) and other assistive listening devices, and at least one of the required credit hours shall be devoted to the subject of New York State and Federal law, regulations and professional conduct.

§192.8 Employment of dispensers

Prior to the dispensing of a hearing aid, a dispenser must present a certificate of registration, either permanent or temporary, to a prospective employer (business registrant).

§192.9 [Reserved]

§192.10 Decontamination and infection control

(a) Definitions. As used in this section:

(1) OSHA means the Occupational Safety and Health Administration and the statutes, rules and regulations relevant thereto.

(2) EPA means the Environmental Protection Agency.

(3) Cleaning is the removal of gross contamination from an object or surface by the physical removal of all visible dust, soil, and any other foreign material.

(4) Disinfection is the process that kills or destroys a specific number of disease producing organisms, the number of which is determined by the level of disinfectant used.

(5) Sterilization is the process that kills all disease producing organisms (including bacteria, viruses, fungi and spores).

(b) The dispenser shall follow the OSHA Standard for Bloodborne Pathogens (29 CFR §1910.1030) and the OSHA Standard for Hazardous Material Communication (29 CFR §1910.1200), where appropriate, incorporated by reference herein. In addition, the dispenser shall comply with the procedures, where not in conflict with OSHA regulations, set forth in this section. Such federal regulations are authored by the United States

Department of Labor, Occupational Safety and Health Administration, revised as of July 1, 1999, and published by the United States Government Printing Office via GPO Access, Washington, DC. A copy is available for public inspection and copying at the Office of Administrative Rules, NYS Department of State, 3rd Floor, 41 State Street, Albany, New York 12231.

(c) General procedures for cleaning, disinfection and sterilization. The dispenser shall use scientifically accepted infection prevention techniques appropriate for the cleaning and disinfection or sterilization of instruments, devices, materials and work surfaces, utilization of protective garb, and the storage of contamination-prone equipment. Such techniques shall include but not be limited to the following:

(1) Prior to disinfection or sterilization, all items and surfaces must first be cleaned of gross contamination. This should be accomplished by cleaning with warm water and soap or detergent, rinsing thoroughly, drying with clean or disposable toweling, or allowing to thoroughly air dry. Disinfection and sterilization must be accomplished in accordance with the manufacturer's recommendations for the item or surface.

(2) All disinfectant processes prescribed herein must be accomplished by the use of an EPA-approved hospital grade disinfectant.

(3) Sterilization may be accomplished by using an autoclave or by soaking for a minimum of 10 hours in an approved 2 percent glutaraldehyde solution or in any other EPA-approved chemical sterilant solution in accordance with the manufacturer's directions. Porous items should not be soaked in glutaraldehyde solution.

(4) Items for autoclaving must be packaged prior to sterilization. Gloves must be worn when handling chemical sterilant solution and precautions must be taken to insure that the solution does not come into contact with any skin surface.

(5) Following disinfection or sterilization, items must be rinsed, dried and stored in a clean drawer, cabinet or covered container.

(6) All solutions and equipment used for disinfection and sterilization must be stored, maintained and monitored according to the manufacturer's directions so as to protect from contamination and to assure the continued integrity of the intended process. Such solution and equipment must be maintained in the original packaging with active ingredients and scope of use clearly described on the original label.

(7) Each registered business location must have on file all Material Safety Data Sheets (MSDS) for inspection. MSDS must be stored in a metal file accessible to all employees.

(8) All "clean" and "dirty" equipment or items must be transported to and from remote locations in covered containers. Clean items and supplies must be kept in containers separate from those that have been used and all items and supplies must be marked according to their status.

(d) Specific procedures and schedules for cleaning, disinfection and sterilization of surfaces and implements.

(1) Hearing aids and earmolds must be cleaned and disinfected prior to any handling by office staff. Hearing aids must be disinfected using an approved wipe or spray; earmolds must be disinfected using approved wipe, spray or submersion system. In all cases, disinfection must be accomplished according to the manufacturer's directions. In addition, clients must be instructed in the appropriate manner of cleaning and disinfecting appliances for their own use.

(2) In general, headphone ear cushions, bone conduction oscillators, and headbands must be cleaned and disinfected using an approved disinfectant wipe or spray at least once per week. Following use on a client with evidence of a sore on the ear, scalp or face, with any ear drainage, or with questionable hygiene, disinfection must be performed prior to re-use.

(3) Otoloscope specula, real ear probe tubes, otolight tips, or any other item that comes in contact with the ear must be cleaned and disinfected using an approved wipe or submersion system prior to each client use. The use of disposable specula, probe tubes and tips after each client use is encouraged and will eliminate the need for disinfection.

(4) Hearing aid cleaning tools and listening stethoscope couplers must be cleaned and disinfected using an approved wipe or submersion system before re-use.

(5) Reception countertops and tabletops used in testing rooms must be cleaned and disinfected using an approved wipe or spray at least once per day.

(6) Arm rests used by clients in testing rooms must be cleaned and disinfected using an approved wipe or spray at least once per week.

(e) Procedures with respect to blood, body fluids and client contact.

(1) All blood, mucous or other body fluid encountered in the workplace must be treated as if infectious. Direct contact with blood should be avoided and disposable gloves used whenever such contact can be reasonably anticipated. Cerumen is a potentially infectious material only when it is contaminated with blood or mucous (drainage). Since cerumen is dark and viscous it is often difficult to determine if it is contaminated and the content of cerumen cannot be determined through visual inspection. Consequently, cerumen should be treated as an infectious substance. In addition to any other statutory or regulatory procedures with respect to blood, body fluids and client contact, the following precautionary measures must be taken:

(2) A hearing aid or earmold must not be handled upon removal from the ear with bare hands until it has been cleaned.

(3) Either gloves must be worn while disinfecting a hearing aid appliance or earmold, or a disinfectant towelette or spray must be used to hold, clean and disinfect the appliance.

(4) Any disposable materials coming into contact with blood or other contaminated or potentially contaminated body fluids must be disposed of in a plastic bag which will be sealed in a manner that protects the dispenser, dispenser's staff, client and others, such as sanitation workers, who may come into contact with the material.

(5) Any disposable sharp object that comes into contact with blood or other body fluids shall be disposed of in a sealable rigid puncture proof container which is strong enough to protect from accidental cuts or puncture wounds that could happen during the disposal process.

(f) Hygienic practices.

(1) Hands must be washed before and after direct contact with each client.

(2) Bar soap for more than one person is prohibited. Liquid or powder soap dispensers or antimicrobial waterless hand cleaners may be used.

(3) Disposable paper towels or hot air dryers shall be available for hand drying when antimicrobial waterless hand cleaners are not used.

(4) Direct client care and handling of client care equipment is forbidden if the dispenser has exudative lesions or weeping dermatitis and the condition has not been medically evaluated and determined to be safe or capable of being safely protected against in providing direct client care or in handling client care equipment.

§192.11 Environmental standards for testing

(a) Office. Audiometric testing shall take place in a test environment meeting the criteria for background noise in accordance with prevailing hearing related industry standards.

(b) Residential. When a customer is home-bound and not able physically or psychologically to receive services in an office setting or it is geographically inconvenient to do so, the dispenser must arrive at the customer's residence with the proper calibrated equipment and a sound level meter to measure ambient noise in the room and be able to perform the test where the ambient sound is not so loud as to interfere with the testing. If the prevailing hearing related industry standards can not be met, such fact must be noted on the audiogram.

(c) Other non-office setting. In such settings as a nursing home, the dispenser must have the proper equipment and the ambient sound in the site of testing must be such that it does not interfere with the testing. If the prevailing hearing related industry standards can not be met, such fact must be noted on the audiogram.

§192.12 Non-diagnostic testing procedures

(a) Prior to audiometric testing, the hearing aid dispenser shall:

(1) conduct a direct otoscopic observation of the client's ear canals;

(2) inquire and/or make general observations regarding any of the following conditions:

(A) visible congenital or traumatic deformity of the ear;

(B) history of or presence 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) visible evidence of bleeding, significant cerumen accumulation, or presence of a foreign body in the ear canal;

(G) pain or discomfort in the ear; and

(3) inquire as to any additional medical conditions, physical considerations or surgical history with reference to the client's hearing and potential hearing aid use.

(b) Appropriate testing procedures shall include:

(1) determination of pure-tone thresholds for each ear, in accordance with prevailing hearing related industry standards, including:

(A) pure tone air conduction thresholds for each ear;

(B) masked pure-tone air conduction thresholds if there is a difference of 40dB or more between the air conduction thresholds of the two ears or the air conduction threshold of the poorer ear and the bone conduction threshold of the better ear;

(C) pure-tone bone conduction thresholds for each ear; and

(D) masked pure-tone bone conduction thresholds if there is a difference of 15dB or greater between the bone conduction threshold of the better ear and the air conduction threshold of the poorer ear;

(2) determination of speech audiometry for each ear including:

(A) the Speech Recognition Threshold (SRT) for each ear (or, if undeterminable, the Speech Awareness Threshold) utilizing appropriate spondaic word lists or other acceptable methods;

(B) the Most Comfortable Loudness (MCL) for speech for each ear;

(C) the Threshold of Discomfort (TD) or Uncomfortable Level (UCL) for speech for each ear; and

(D) Speech Recognition scores for each ear and/or binaurally (as appropriate) utilizing appropriate phonetically balanced word lists or other acceptable methods.

(c) Where it is not appropriate or possible to conduct any or all tests listed in subdivision (b), a dispenser may conduct such tests as appropriate
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ate. The dispenser must record in the patient's file those tests which are not conducted and the reasons therefor, in accordance with the clinical judgment of the dispenser.

§192.13 45-day guarantee

(a) A registrant may make a guarantee which grants rights to the consumer in addition to those contained in GBL §798(12).

(b) In a rental of a hearing aid or sale thereof under an installment contract or other non-sale transaction covered under GBL §789(11), the cancellation fee shall be measured by the charge the registrant would make for a similar hearing aid and accessories sold outright to a customer. The cancellation fee shall be payable out of such sum the customer may have paid on account of the rental or purchase price and any security the customer may have deposited with the registrant. If the amount paid or deposited is insufficient to pay for the cancellation fee the registrant may be entitled to, the customer shall be required to pay the difference due in order to effect cancellation of the agreement. If such payments exceed the amount so due, the registrant shall return the difference to the customer forthwith.

(c) A contract of sale or rental may be utilized as the receipt and contain any guarantee.

(d) The registrant shall deliver to the purchaser a written statement setting forth the amount returned to the purchaser.

(e) A registrant may refuse to accept the return of a hearing aid within the 45-day guarantee period if the wear and tear on the hearing aid exceeds that which is reasonable. A registrant may not refuse to accept the return of a hearing aid for such reason unless the registrant provides a written statement to the customer which shall specifically describe the condition of the hearing aid upon which the registrant bases such refusal. A copy of such statement shall be placed in the customer's file. Within the 45-day guarantee period a registrant may not demand or receive from a customer the payment of any special or additional fee or charge for accepting the return of a hearing aid on the ground that the registrant has the right to refuse to accept the return by reason of unreasonable wear and tear on the instrument.

§192.14 Repair and service

(a) A registrant shall accept for repair and other necessary service any hearing aid or accessory thereof, sold or rented by the registrant to the customer, for a period of five years from the date of sale or rental. The repair or service may be made by the registrant or referred by the registrant to the manufacturer or supplier of the hearing aid or accessories or to any other person.

(b) The charge for any necessary repair or service shall be reasonable and no more than that which is provided in any outstanding sale or rental agreement. The registrant shall deliver an itemized receipt showing the repair and service provided and the charge therefor. If the charge for the repair or service shall exceed \$50, no work may be performed unless the customer shall have been first advised of the work to be performed, the charge therefor, and shall have approved same.

(c) If the registrant or the manufacturer or other person making the repair shall charge a non-refundable fee for an estimate of the cost of such repair, the customer shall be advised thereof in writing prior to the acceptance of the instrument. The registrant is entitled to retain such fee if the customer determines not to proceed with the repair after receiving the estimate.

(d) In addition to the provision for payment for the specific repair of a damaged or otherwise defective instrument, the registrant may offer to repair such instrument on a flat-rate basis, with at least a 30-day written guarantee that the instrument shall operate properly, except for subsequent

damage caused by the customer. If the customer accepts repair on a flat-rate basis, the itemized statement as to the repairs made need not set forth the specific charges therefor.

(e) When a hearing aid is brought in for repair or service, the registrant may supply a suitable loan of an instrument to the consumer for the period the instrument is being repaired or serviced. If such a loaner is available and there is a charge therefor, the customer shall not be required to accept any such loaner as a condition to the repair or service.

§192.15 Records to be maintained

(a) A registrant shall maintain a file for each customer which shall contain the information listed in GBL §798(14) and:

(1) A copy of the written guarantee;

(2) A copy of the invoice or other record of purchase by the registrant of the hearing aid and custom ear mold, if any;

(3) Copy of any correspondence from and to the customer; and

(4) A copy of the statement given to the customer upon the exercise of the right of cancellation under a 45 day guarantee.

(b) A registrant shall maintain a file which shall contain a copy of all advertisements placed in any media or sent to a customer or prospective customer.

(c) A registrant shall maintain a file containing the invoices on the purchases of batteries, and the records of rebates, discounts and allowances on the purchases of batteries and custom ear molds. The invoice shall specify the particular ear mold to which the rebate, discount or other allowance applies.

(d) A registrant shall maintain a file containing customer requests for home visits for the purpose of soliciting the sale or rental of hearing aids, showing the name of the customer, date and manner of the request and date of the home visit.

(e) All records required to be maintained at each business location shall, upon request, be open to inspection by duly authorized employees of the department during regular business hours.

§192.16 Advertisements

(a) A registrant shall comply with GBL §798(15).

(b) A registrant shall maintain an advertising file at its principal office.

(c) The advertising file shall contain the materials supporting a claim that a hearing aid, device, part or accessory is a new invention or involves a new mechanical or scientific principle. The filing of any such materials shall not relieve the registrant of any liability under the provisions of any law and this Part, if it is determined such advertising claim is not true. In order to comply with these filing requirements, the registrant may place in the advertising file a written statement signed by the manufacturer of the instrument, part or accessory, setting forth the nature of the claim, the basic principle underlying the claim, and that further detailed material supporting such claim is on file at the manufacturer's listed office and available to the department upon request.

(d) A registrant shall place in its advertising file the original of a testimonial used in advertising hearing aids or accessories. The testimonial must be in writing duly signed and acknowledged by the person and indicate the residence address of the person making same.

(e) A registrant may not advertise the availability of the services of an otolaryngologist or authorized physician or the approval or recommendation of the registrant's services by any otolaryngologist, audiologist or authorized physician. A registrant may not advertise the availability of the services of an audiologist unless such advertisement shall indicate: that the audiologist provides services at the business location of, and as part of the

overall service provided by, the registrant; and whether there shall be an extra charge therefor.

(f) A registrant may not publish, promulgate or disseminate, in any communications form, any false or misleading advertising relating to the scope of hearing aid dispensing practices, the credentials of an individual dispenser, or the function, use or reliability of a particular hearing instrument.

§192.17 Canvassing

A registrant shall comply with GBL §798(16). A bona fide visit by a registrant in the ordinary course of business for the purpose of determining whether a hearing aid sold or rented is properly functioning shall not require the prior request or assent of the customer.

§192.18 Consumers

(a) Complaints. A consumer may register a complaint with any office of the department in person, in writing or by telephone.

(b) Printed educational information. Printed educational materials should include:

(1) Procedures by which a consumer may file a complaint.

(2) General information about the general use of hearing aids and the advantages and disadvantages of monaural and binaural hearing aid use, including: information of the value of hearing aid use for a prospective purchaser; consumer protection piece - what to be aware of in sales pitches and “hard sell” techniques, such as “giveaways” and sales pitches that minimize the need for medical and audiological exams; basic “how to” use a hearing aid for a new consumer; and information about the advantages of purchasing and using the telecoil switch (t-switch).

(3) General information on assistive listening devices (ALDs), including a basic overview of the types of ALDs currently available and how ALDs may be used with hearing aids.

(4) A statement regarding the availability of support groups for people who are deaf and hard of hearing.

(c) Training of consumers.

(1) The dispenser shall instruct new users of hearing aids on basic information about how to use the aid. This training should include, at a minimum, the following:

basic care and use of the hearing aid;

communication strategies to adjust to a new hearing aid;

information on support groups;

storage of the hearing aid when not being used;

protection of the hearing aid from perspiration and moisture;

installation of a battery;

frequency of necessity to purchase batteries;

use of the telecoil-switch;

telephone usage;

reasonable longevity of the hearing aid;

information about purchasing insurance to cover loss or damage;

review of 45 day return policy; and

review of complaint policy.

(2) Such training may be offered in a group setting provided provisions are made to allow all participants to hear the presentation (e.g., provide ALDs compatible with their hearing aids) and/or to provide written materials, and shall be offered to all new purchasers of hearing

aids and those who need to review the hearing aid orientation materials.