

(f) Any licensee shipping radioactive material as defined in Rule .0104 of this Chapter intended for ultimate disposal at a land disposal facility as defined in Rule .1202 of this Chapter must document the information required on the U.S. Nuclear Regulatory Commission's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with appendix G to this 10 CFR 20.

(g) Radioactive material as defined in Rule .0104 of this Chapter may be disposed of in accordance with Rule .1628 of this Section, even though it is not defined as low-level radioactive waste. Any licensed radioactive material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under 10 CFR Part 61, must meet the requirements of this Rule.

(h) A licensee may dispose of radioactive material as defined in Rule .0104 of this Chapter, at a disposal facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.

Authority G.S. 104E-7(a)(2),(a)(3); 104E-12(a).

15A NCAC 11 .1648 REPORTS OF PLANNED SPECIAL EXPOSURES

(a) The licensee or registrant shall submit a written report to the agency within 30 days following any planned special exposure conducted in accordance with Rule .1608 of this Section, informing the agency that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by Rule .1639 of this Section.

(b) When a licensee or registrant is required by this Rule to report to the agency any exposure of an identified occupationally exposed individual or an identified member of the public to radiation or radioactive material, the licensee or registrant shall also provide the individual a report on his or her exposure data included in the report to the agency. This report must be transmitted no later than the transmittal to the agency.

Authority G.S. 104E-7(a)(2); 104E-12(a).

TITLE 21 – OCCUPATIONAL LICENSING BOARDS AND COMMISSIONS

CHAPTER 22 - HEARING AID DEALERS AND FITTERS BOARD

Notice is hereby given in accordance with G.S. 150B-21.2 that the NC State Hearing Aid Dealers and Fitters Board intends to adopt the rule cited as 21 NCAC 22A .0401; amend the rules cited as 21 NCAC 22A .0501, .0503; 22F .0107; 22I .0103; and repeal the rules cited as 21 NCAC 22A .0301, .0303, .0307-.0312.

Agency obtained G.S. 150B-19.1 certification:

- OSBM certified on:
- RRC certified on:
- Not Required

Link to agency website pursuant to G.S. 150B-19.1(c):
<http://www.nchalb.org/regulatory/rulechange.php>

Proposed Effective Date: September 1, 2013

Public Hearing:

Date: June 6, 2013

Time: 12:45 p.m.

Location: Commission Room, Office of Administrative Hearings, 1711 New Hope Church Road, Raleigh, NC 27609

Reason for Proposed Action: *The Board has done an annual review of rules, in consideration of changes in G.S. 93D. Rules are to clarify hearing testing requirements, and to provide definitions for new rules, as well as to address how applications are submitted and reviewed by the Board and to allow a registered sponsor access to apprentice exam results.*

Procedure by which a person can object to the agency on a proposed rule: *A person can object to the agency by speaking at the public hearing on June 6, 2013 or by submitting written comments to the following address no later than July 15, 2013: NC State Hearing Aid Dealers and Fitters Board, ATTN: Rulemaking, P. O. Box 97833, Raleigh, NC 27624.*

Comments may be submitted to: *Catherine Jorgensen, Rulemaking Coordinator, NC State Hearing Aid Dealers and Fitters Board, P. O. Box 97833, Raleigh, NC 27624*

Comment period ends: July 15, 2013

Procedure for Subjecting a Proposed Rule to Legislative Review: *If an objection is not resolved prior to the adoption of the rule, a person may also submit written objections to the Rules Review Commission after the adoption of the Rule. If the Rules Review Commission receives written and signed objections after the adoption of the Rule in accordance with G.S. 150B-21.3(b2) from 10 or more persons clearly requesting review by the legislature and the Rules Review Commission approves the rule, the rule will become effective as provided in G.S. 150B-21.3(b1). The Commission will receive written objections until 5:00 p.m. on the day following the day the Commission approves the rule. The Commission will receive those objections by mail, delivery service, hand delivery, or facsimile transmission. If you have any further questions concerning the submission of objections to the Commission, please call a Commission staff attorney at 919-431-3000.*

Fiscal impact (check all that apply).

- State funds affected
- Environmental permitting of DOT affected
- Analysis submitted to Board of Transportation
- Local funds affected
- Date submitted to OSBM:
- Substantial economic impact (≥\$500,000)

- Approved by OSBM
- No fiscal note required by G.S. 150B-21.4

SUBCHAPTER 22A - BOARD RULES

SECTION .0300 – DEFINITIONS

21 NCAC 22A .0301 DEFINITIONS AND INTERPRETATIONS

(a) The rules of statutory construction concerning number and gender as contained in G.S. 12-3(1) shall be applied in the construction of these Rules.

(b) The definitions cited in this Section shall serve as interpretations for terms appearing in Chapter 93D of the General Statutes of North Carolina and in these Rules. In addition, the definitions contained in the Food and Drug Administration Standards concerning Hearing Aid Devices, Title 21 of the Code of Federal Regulations Part 801, as published in the 42nd Volume of the Federal Register (February 15, 1977) page 9294 are adopted herein by reference, in accordance with G.S. 150B-14(b), with the following additions and amendments:

- (1) "Reconditioned" shall mean that the condition of the hearing aid is the same as a used hearing aid.
- (2) "Audiologist" shall mean any individual holding a valid non temporary license as an audiologist issued by the North Carolina Board of Examiners for Speech and Language Pathologists and Audiologists. Such individual is not required to serve as an apprentice, as set forth in G.S. 93D-5, before applying for issuance of a license by examination, in accordance with the consent judgment entered in 80 CVS 8161 and filed in Wake County Superior Court Division, the case entitled Audiology Council of North Carolina, Inc., v. The North Carolina Hearing Aid Dealers and Fitters Board.

Authority G.S. 93D-3(c); 150B-14.

21 NCAC 22A .0303 LICENSE

"License" shall mean the printed certificate, issued by the Board, which an individual is required to obtain before engaging in the fitting and selling of hearing aids independent of a sponsor.

Authority G.S. 93D-3(c); 93D-5.

21 NCAC 22A .0307 REGISTERED APPRENTICE

"Registered Apprentice" shall mean any individual who has duly made application to the Board and has been issued an apprentice registration certificate which entitles such individual to fit and sell hearing aids under the supervision of a licensee approved by the Board.

Authority G.S. 93D-3(c); 93D-9.

21 NCAC 22A .0308 REGISTERED APPLICANT

"Registered Applicant" shall mean any individual, including a registered apprentice, who has duly made application to the Board for issuance of a license and for which one or more of the following conditions apply:

- (1) The individual is seeking admission to the next scheduled qualifying examination given by the Board (license by examination);
- (2) The individual is seeking reciprocity pursuant to G.S. 93D-6;
- (3) The individual is seeking reinstatement of an expired license as set forth in G.S. 93D-11; or
- (4) The individual is seeking reissuance of a suspended license in accordance with the provisions of G.S. 93D-13.

Authority G.S. 93D-3(c).

21 NCAC 22A .0309 DULY MADE APPLICATION

"Duly made application" shall mean that the completed application form, including all required documents, photographs, and fees, and any supplemental information requested by the Board pursuant to 21 NCAC 22F .0004(a), is physically received in the office of the Board.

Authority G.S. 93D-3(c).

21 NCAC 22A .0310 ONE FULL YEAR OF APPRENTICESHIP

"One full year of apprenticeship" shall mean that an individual, who is not an Audiologist and does not hold a masters degree in Audiology, has held a valid apprentice registration certificate for a period of 365 calendar days, has engaged in fitting and selling hearing aids for a minimum of 30 clock hours per week for a period of 50 weeks, and has received a minimum of 750 clock hours of direct supervision from a licensee approved by the Board. The maximum time span allowed for completing the 365 calendar day requirement shall not exceed 24 consecutive months from the date of issuance of the initial apprentice registration certificate.

Authority G.S. 93D-3(c).

21 NCAC 22A .0311 DIRECT SUPERVISION

"Direct supervision" shall mean the provision of general direction and control, including immediate personal on site inspection and evaluation of work constituting the fitting and selling of hearing aids, as well as the provision of consultation and instruction.

Authority G.S. 93D-3(c).

21 NCAC 22A .0312 AUDIOMETER

"Audiometer" shall mean an electronic device, used for air conduction testing, bone conduction testing, and for obtaining speech audiometry results, which contains a masking circuit, at least one VU meter, and capability of sound field output.

Authority G.S. 93D-3(c).

SECTION .0400 - DEFINITIONS

21 NCAC 22A .0401 DEFINITIONS AND INTERPRETATIONS

(a) The rules of statutory construction concerning number and gender as contained in G.S. 12-3(1) shall be applied in the construction of these Rules.

(b) The definitions contained in the Food and Drug Administration Standards concerning Hearing Aid Devices, Title 21 of the Code of Federal Regulations Part 801.420 are adopted herein by reference, in accordance with G.S. 150B-14(b), with the following additions and amendments:

- (1) "Reconditioned" shall mean that the condition of the hearing aid is the same as a used hearing aid; and
- (2) "Audiologist" shall mean any individual holding a valid non-temporary license as an audiologist issued by the North Carolina Board of Examiners for Speech and Language Pathologists and Audiologists.

(c) The definitions cited in this Section shall serve as interpretations for terms appearing in Chapter 93D of the General Statutes of North Carolina and in these Rules.

- (1) "Advertising" means a written or oral communication that is published, disseminated, circulated, or placed before the public for the purpose of attracting public attention to a product, business, or service.
- (2) "Apprentice" means an individual who holds a valid Board-issued apprentice registration certificate to fit and sell hearing aids under the supervision of a Registered Sponsor.
- (3) "Audiometer" means an electronic device, used for air conduction testing, bone conduction testing, and for obtaining speech audiometry results, which contains a masking circuit, at least one VU meter, and capability of sound field output.
- (4) "Direct supervision" means the provision of general direction and control by a Registered Sponsor, including regular on-site inspection and evaluation of work constituting the fitting and selling of hearing aids, as well as the regular provision of consultation and instruction.
- (5) "Duly made application" means a completed application received in the office of the Board, including all required documents, photographs, fees, and supplemental information requested in the application.
- (6) "One full year of apprenticeship" means that an apprentice has satisfied each of the following requirements within 24 consecutive months from the date of issuance of the initial apprentice registration certificate:
 - (A) work under the supervision of a Registered Sponsor for a minimum of

30 clock hours per week for a period of 50 weeks;

(B) complete a minimum of 750 clock hours of fitting and selling hearing aids under the supervision of a Registered Sponsor; and

(C) hold a valid apprentice registration certificate for a period of 365 calendar days.

(7) "Personal supervision" means the provision of specific direction and control by the Registered Sponsor or a North Carolina licensed Hearing Aid Specialist approved by the Registered Sponsor, requiring immediate personal in-room supervision, including immediate personal on-site inspection and evaluation of work constituting the fitting and selling of hearing aids, as well as the provision of consultation and instruction.

(8) "Registered Applicant" means any individual, including an apprentice, approved and registered to sit for the next scheduled licensing exam.

(9) "Registered Sponsor" means a person with a permanent license as an audiologist under Article 22 of Chapter 90 of the General Statutes who is registered in accordance with G.S. 93D-3(c)(16), or a licensee of the Board who has been approved as a sponsor of an apprentice.

Authority G.S. 93D-3(c); 93D-9; 150B-14.

SECTION .0500 – SUBMISSION OF APPLICATIONS AND FEES

21 NCAC 22A .0501 FEE SCHEDULE

The Board hereby establishes the following fees:

- ~~(10)~~(1) Application for registration as an apprentice \$100.00
- ~~(11)~~(2) Renewal of apprentice registration. \$150.00
- (3) Application for registration of a Registered Sponsor not otherwise licensed by the Board. \$150.00
- ~~(7)~~(4) Application for a license by examination. \$250.00
- ~~(6)~~(5) Examination fee. \$300.00
- ~~(9)~~(6) Issuance of certificate of license after successfully passing examination. \$ 25.00
- ~~(13)~~(7) To reissue a suspended license more than 90 days after but not more than two years after license suspended. \$200.00
- ~~(12)~~(8) Annual license renewal. \$250.00
 - (a) Late fee to reinstate expired license within 60 days after license

- expiration (in addition to renewal fee). \$ 25.00
- (b) Late fee to reinstate expired license more than 60 days after license expiration (in addition to renewal fee). \$ 50.00
- ~~(3)~~(9) For approval of a continuing education program provider. \$ 40.00
- ~~(4)~~(10) Verifying and recording attendance at a continuing education program (per program, per person). \$ 15.00
- ~~(1)~~(11) For a continuing education make-up class provided by the Board, not to exceed two days (per person, per day). \$ 50.00
- ~~(5)~~(12) For a voluntary apprentice training workshop (per person, per day, not to exceed three days). \$ 50.00
- ~~(2)~~(13) For a license examination preparation course provided by the Board, not to exceed three days (per person, per day). \$ 50.00
- (14) Processing fee for a check on which payment has been refused by the payor bank because of insufficient funds or because the drawer did not have an account at that bank. \$ 25.00
- ~~(8)~~ Application for a license to fit and sell hearing aids in this state by a licensee of another state or territory. \$150.00

Authority G.S. 12-3.1; 25-3-506; 93D-3; 93D-5; 93D-6; 93D-8; 93D-9; 93D-11; 93D-13.

21 NCAC 22A .0503 SUBMISSION OF APPLICATIONS AND FEES

~~(a) An Application for Renewal or Replacement of Apprentice Certificate shall be submitted to the Board no later than ten working days after the date that any of the following conditions exist:~~

- ~~(1) a registered apprentice is separated from his sponsor for any reason and the individual wishes to obtain a new certificate to replace the invalidated certificate;~~
- ~~(2) a registered apprentice is notified by the Board that he or she failed to pass the qualifying examination and the individual wishes to renew his or her certificate; and~~
- ~~(3) the Board notifies an individual that his apprentice registration certificate has been invalidated for any reason and the individual wishes to obtain a new certificate to replace the invalidated certificate.~~

~~(b) No later than ten working days after a registered apprentice has held a valid apprentice registration certificate for 365 calendar days, the apprentice shall submit an Application for License and shall take the next scheduled licensing examination. All registered apprentices shall reapply for a license by~~

~~examination, within the time prescribed in Paragraph (c) of this Rule, each time they take and fail to pass the licensing examination.~~

~~(c) When a registered applicant makes application to take an examination, the duly made application shall be considered by the Board to be timely if it is received by the Board no later than 45 consecutive days prior to the examination date. An untimely application is grounds for denying an applicant admission to an examination.~~

~~(d) All fees shall be made payable to the N.C. Hearing Aid Dealers and Fitters Board. When a company or personal check is received in payment of any fee, the Board shall wait until final credit on the check is received before providing the license or other document requested. A processing fee of twenty dollars (\$20.00) (or any greater amount allowed by law) shall be charged for any check on which payment is refused by the payor bank because of insufficient funds or because the drawer did not have an account at that bank at the time the check was presented to the Board.~~

(a) The Board shall accept a digital image of a signed affidavit or other document required as part of an application as the original when submitted electronically in conjunction with the electronic application.

(b) If an applicant submits an incomplete application, the Board shall deny the application after 10 business days, unless the applicant provides supplemental information to make it a duly made application, as defined in 21 NCAC 22A .0401, by the 10th business day. After 10 business days, the Board will classify the application as "abandoned by the applicant" and shall not apply any fee paid or document submitted for the abandoned application to any other application. This Rule does not extend an application deadline set forth in any other rule of this Chapter.

(c) When an individual makes application to take an examination, the duly-made application shall be considered by the Board to be timely if it is received by the Board no later than 45 consecutive days prior to the examination date. An untimely application is grounds for denying an applicant admission to an examination.

(d) No later than 10 business days after an apprentice has held a valid apprentice registration certificate for 365 calendar days, the apprentice shall make application to take the next scheduled licensing examination. All apprentices shall reapply for a license by examination, within the time prescribed in Paragraph (c) of this Rule, each time they take and fail to pass the licensing examination.

(e) No later than 20 calendar days after the date printed on the Official Notice of Examination Results, a registered apprentice, who failed to pass the qualifying examination, shall make application to renew the apprentice certificate until the following examination, or the Sponsor shall submit written notice to the Board that the apprenticeship is being terminated by the current expiration date of the certificate.

(f) An applicant's failure to submit a duly made application by the application deadline is grounds for the Board to deny the application.

Authority G.S. 93D-3(c); 93D-5; 93D-9.

SUBCHAPTER 22F - GENERAL EXAMINATION AND LICENSE PROVISIONS

21 NCAC 22F .0107 COMMUNICATION OF RESULTS OF EXAMINATIONS

(a) The office of the Board shall issue written notification to each registered applicant by mailing exam results to the physical address provided by the applicant concerning the applicant's performance on the qualifying examination no later than 30 working days after the date of the examination.

(b) A copy of the applicant's exam results shall be mailed to the applicant's Registered Sponsor at the mailing address on file with the Board at the same time the results are mailed to the applicant.

Authority G.S. 93B-8; 93D-3(c).

SUBCHAPTER 22I - PROFESSIONAL AFFAIRS

21 NCAC 22I .0103 VISUAL INSPECTION AND HEARING TEST

(a) All licensees and registered apprentices shall make a visual inspection of the external auditory canal and the tympanic membrane, using a device having its own light source in order to fulfill the requirements of 21 CFR 801 (effective August 15, 1977), Subpart 801.420 concerning the warning to hearing aid dispensers.

(b) All licensees and registered apprentices shall conduct a hearing test using an audiometer, the calibration for which is on file at the Board office, or equivalent physiologic testing.

(c) A hearing test shall be conducted within 90 days prior to the dispensing of a hearing aid and a copy of the hearing test shall be maintained for a period of at least three years.

(d) The hearing test shall be conducted in an environment conducive to obtaining accurate results and shall include the following, unless physiologic testing is utilized:

~~(2)~~(1) live voice or recorded voice speech audiometry, including speech reception threshold testing and speech discrimination testing; and

~~(1)~~(2) pure tone audiometry, including air conduction testing and bone conduction testing; testing as follows:

(A) air conduction testing at least at the following frequencies: 500 Hz, 1000 Hz, 2000 Hz, 3000Hz, and 4000 Hz;

~~(B) mid-octave air conduction testing performed when there is a 20 dB or greater difference between any adjacent octaves; and~~

~~(C) bone conduction testing at least at the following frequencies: 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz;~~

~~(D) effective masking, if audiometric testing reveals a difference between the ears at any one frequency equal to or greater than 40 decibels or if there is audiometric air-bone gap of 15 dB or greater.~~

~~(3) effective masking, if audiometric testing reveals a difference between the ears at any one frequency equal to or greater than 40 decibels or if there is audiometric air-bone gap of 15 dB or greater.~~

~~(4) testing at least at the following frequencies: 500 Hz, 1000 Hz, 2000 Hz, 3000Hz, and 4000 Hz;~~

~~(5) mid-octavetesting performed when there is a 20 dB or greater difference between any adjacent octaves.~~

(e) All licensees and registered apprentices shall evaluate dispensed products to determine ~~effectiveness~~. effectiveness and shall maintain documentation of the verification for a period of at least three years. Measures of evaluation shall include at least one of the following:

- (1) sound field measurements;
- (2) real ear measurements; or
- (3) client evaluation sheets.

Authority G.S. 93D-3(c).

CHAPTER 46 - BOARD OF PHARMACY

Notice is hereby given in accordance with G.S. 150B-21.2 that the Board of Pharmacy intends to amend the rules cited as 21 NCAC 46 .3401-.3402, .3404 and repeal the rules cited as 21 NCAC 46 .3403, .3405-.3408.

Agency obtained G.S. 150B-19.1 certification:

- OSBM certified on:
- RRC certified on:
- Not Required

Link to agency website pursuant to G.S. 150B-19.1(c): www.ncbop.org/lawandrules.htm

Proposed Effective Date: November 1, 2013

Public Hearing:

Date: September 10, 2013

Time: 5:00 p.m.

Location: North Carolina Board of Pharmacy, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517

Reason for Proposed Action: Revisions simplify categorizations of automated medication systems and certain recordkeeping obligations, consolidate the rules and remove redundancies.

Procedure by which a person can object to the agency on a proposed rule: Any person may object to the proposed amendments by attending the public hearing on September 10, 2013 and/or by submitting a written objection by September 10, 2013 to Jay Campbell, Executive Director, North Carolina Board of Pharmacy, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517, fax (919)246-1056, email