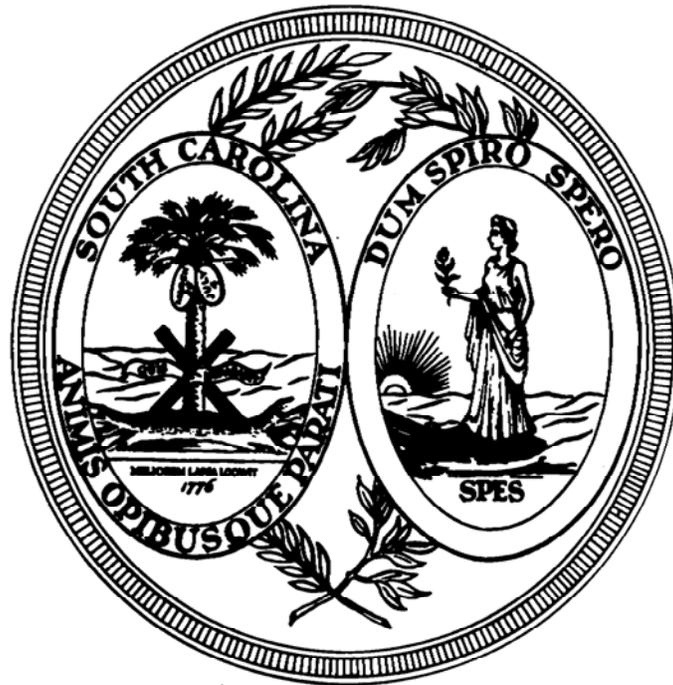




Regulation Number 61-3 The Practice of Selling and Fitting Hearing Aids



Promulgated by the Board of Health and Environmental Control

Administered by the Division of Health Licensing

Including Changes

Published in the *State Register*, Volume 12, Issue 1, January 22, 1988

This is a courtesy copy of Regulation R61-3

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DIVISION OF HEALTH LICENSING REGULATIONS

Provider-Wide Exceptions

In the interest of establishing reasonable standards that can be met by providers and yet do not compromise the health and well-being of the patients, residents, and participants cared for in South Carolina licensed facilities, it has been determined that alternative standards will be considered as acceptable. A Provider-Wide Exception (PWE) is the tool that is used to achieve a working relationship between the facility and their regulators.

Provider-Wide Exceptions for the facilities and activities that are licensed by the Division of Health Licensing can be downloaded from our Internet Website:

<http://www.scdhec.gov/health/licen/pwe.htm>

This website may also contain Position Statements that give guidance or interpretations of the regulation.

Provider-Wide Exceptions and Position Statements may also be obtained by contacting our office at (803) 545-4370. There is a ten-dollar (\$10.00) processing and handling fee assessed when copies are obtained through our office. Copies obtained over the Internet through our Website are free of charge. Payment must be by credit card, personal check or money order (no cash can be accepted).

Note: Some Provider-Wide Exceptions pre-date the publishing dates of specific Regulations established by the *State Register* and may no longer be in effect. In these instances, if there is a conflict between a PWE that pre-dates the publishing date of the regulation, the standard in the regulation shall supercede the PWE.

TABLE OF CONTENTS - Regulation 61-3

DEFINITIONS AND INTERPRETATIONS	1
I. Definitions	1
II. Interpretations	2
PART I.....	2
CHAPTER 1 - MANAGEMENT	2
Section 101. Application.....	2
Section 102. License.....	4
Section 103. Temporary Permit.....	4
Section 104. Display of License/Temporary Permit.....	4
Section 105. Fees	5
Section 106. Conduct/Ethics	5
Section 107. Corporation or Like Organizations.....	7
PART II.....	7
CHAPTER 2 - PROCEDURES.....	7
Section 201. Procedures/Equipment.....	7
Section 202. Examination	9
Section 203. Inspections	10
Section 204. General	11
Section 205. Continuing Education Programs - Approval	11

61-3. THE PRACTICE OF SELLING AND FITTING HEARING AIDS

DEFINITIONS AND INTERPRETATIONS

I. Definitions:

For the purpose of these rules and regulations, the following definitions shall apply:

A. The Act: The "Fitting and Selling of Hearing Aids Act" enacted June 25, 1971. [1976 Code §§ 40-25-10 et seq.]

B. The Department: The South Carolina Department of Health and Environmental Control.

C. The Commission: The State Commission for Hearing Aid Dealers and Fitters.

D. License: A license issued by the Department under this Act to a hearing aid dealer and fitter.

E. Temporary Permit: A permit issued by the Department under this Act while the applicant is in training to become a licensed hearing aid dealer and fitter.

F. Hearing Aid: Any acceptable wearable instrument or device designated for or offered for the purpose of aiding or compensating for impaired human hearing and any parts, attachments or accessories, including earmold, but excluding batteries and cords.

G. Practice of Fitting and Dealing in Hearing Aids: The measurement of human hearing by means of an audiometer or by any other established means for the purpose of making selections, adaptations or sale of hearing aids. The term also includes the making of impressions for earmolds. Counseling and instruction relative to the above.

H. Sale of Hearing Aids: Any transfer of title or of the right to use by lease, bailment, or any other contract, excluding wholesale transactions with distributors or representatives.

I. Otolaryngologist: A licensed physician specializing in diseases of the ear, nose and throat.

J. Audiologist: An individual completing satisfactory graduate work and holding a Certificate of Clinical Competence and who is actually engaged in audiological practice.

K. Licensee: The individual authorized to engage in the practice of fitting and selling hearing aids and on whom rests the responsibility for complying with the provisions of the Act and these rules and regulations promulgated thereunder.

L. Application: Application means a form which shall contain all of the prescribed information established by the Department as set forth in the Act.

M. Examination: Examination means the testing of knowledge and proficiency of an applicant required for fitting and selling hearing aids.

N. Registrant: Registrant shall be synonymous with licensee, holder of a certificate of registration, trainee and temporary permit holder.

II. Interpretations:

A. License: A license is issued by the Department pursuant to the provisions of the Act and these rules and regulations promulgated thereunder. This license shall be posted in a conspicuous place in his office or place of business at all times in full view at the address specified on the license. A license is not assignable or transferable and is subject to revocation or suspension for a fixed period by the Department for cause as defined within Section 13(2) of the Act [§ 40-25-160(2)].

B. Term of License:

1. Each person licensed to fit and sell hearing aids shall annually, on or before January 30, pay to the Department a fee of \$50.00 for issuance or renewal of license.

2. A 30-day grace period shall be allowed after January 30, during which time licenses may be renewed on payment of a fee of \$60.00 to the Department. After expiration of the grace period, the Department may renew such license upon payment of a fee of \$75.00 to the Department. No person who applies for renewal, whose license has expired, shall be required to submit to any examination as a condition to renewal provided such renewal application is made within a period of two years from the date of such expiration.

3. A license shall be effective for a 12-month period, beginning January 31 and ending January 30 of the succeeding year.

C. Temporary Permit: A temporary permit shall be issued to an applicant who fulfills the requirements of the Act but does not meet the experience qualifications and shall entitle applicant to engage in the fitting and selling of hearing aids for a period of one year under the supervision of a licensed hearing aid dealer and fitter.

PART I

CHAPTER 1 - Management

Section 101. Application:

A. No person shall fit, or offer for sale, hearing aids in this State unless such person has complied with the requirements hereof as to registration and licensing.

B. An individual, in making his first registration hereunder, shall write or cause to be written upon the application blank, so furnished by the Department, his full name, business address, residence address and such other facts for identification of the applicant as may be deemed necessary, and shall duly execute and verify the same before a notary public and shall file the same with the Department.

C. The Department on or before December 1 of each year, after the first registration, shall mail to each licensee or registrant a blank form of application for registration addressed to the last known business address of such person.

D. The Department shall, in accordance with the Act, issue to any individual who has submitted his application for registration complete with the information as may be deemed applicable by the Department, a license or temporary permit under the seal of the Department for the ensuing year.

1. Any licensee or temporary permit holder must maintain a progressing level of professional competence by participation during each calendar year in educational programs designed to keep such licensee informed of changes, current practices, and developments pertaining to the fitting of hearing aids and rehabilitation as appropriate to hearing aid use.

2. The licensee shall annually submit to the Commission proof of having participated in a minimum of eight hours of continuing education during the calendar year. A licensee who is granted a license during a calendar year shall not be required to complete such requirements during that year and such requirement shall begin the second full licensing year. The requirement may be fulfilled by attending and participating in training activities approved by the Commission.

3. Failure to complete the minimum educational requirements shall result in a license suspension until the requirements are met. The Commission, upon sufficient cause shown by the licensee, may allow the licensee to make up the necessary hours during the next calendar year. The make-up allowance shall not waive the full annual requirements for continued education.

E. Application for Examination Fee: An application for examination shall be accompanied by a check or money order made payable to the South Carolina Department of Health and Environmental Control in the amount of \$50.00. It shall be understood by the applicant that the examination fee shall in no instance be refunded, applied as payment for temporary permit, or transferred to the license fee.

F. Failure to complete all forms and provide all information required by law may be just

cause for the application to be rejected by the Department.

G. Any person furnishing false information or omitting pertinent information in such application shall be denied the right to the examination, or if the applicant has already been licensed before the falseness of such information has been made known to the Department, such license shall be subject to suspension or revocation.

Section 102. License:

A license under this Act shall confer upon the holder the right to select, fit and sell hearing aids.

A. Licenses or temporary permits shall not by any manner or means be duplicated by the licensee or other persons.

B. Any change in status of licensee or temporary permit, such as address or name, shall make the license null and void and shall be returned to the Department for proper disposition.

C. Persons who hold a license or temporary permit shall notify the Department in writing of his regular address, business address, office address or the place where he engages or intends to engage in the fitting or the sale of hearing aids. Notification of any change of status must be made to the Department within 15 days subsequent to such change.

Section 103. Temporary Permit:

An applicant who fulfills the requirements of the Act, and who has not previously applied to take the examination delineated in Section 202 of these rules and regulations, may apply to the Department for a temporary permit.

A. Prior experience or a waiting period shall not be required provided he shall be reasonably supervised and trained for a period of one year by a currently licensed hearing aid dealer.

B. Annual reports of progress must be maintained on each person with a temporary permit by a licensed dealer verifying adequate personal contact supervision, and training and all such reports shall be kept on file at the Department. The phased training reports shall be submitted quarterly to complete the annual reports of progress.

C. If any person who holds a temporary permit has not successfully passed the licensing examination within one year from the date of issuance, the temporary permit may, at the discretion of the Department, be renewed or he shall be required to reapply at a date specified by the Department.

Section 104. Display of License/Temporary Permit:

The license or temporary permit shall be prominently displayed in his office or place of business in full view of any customer or client. The wallet-sized identification shall be in the possession of licensed hearing aid dealers and temporary permit holders at all times and shall be displayed upon request by a any customer, client, or agent of the Department, or peace officer. Where there is more than one office or place of business, duplicate licenses shall be issued by the Department.

Section 105. Fees:

A. All fees shall be made payable to the South Carolina Department of Health and Environmental Control and are not transferable.

B. Licensing fee or renewal fee established in the Act is \$50.00 and duplicate licenses will be issued where more than one office or place of business is in operation.

C. Temporary permit fee has been established at \$25.00.

D. Examination fee is set in the amount of \$50.00 and is not refundable.

Section 106. Conduct/Ethics:

1. It shall be the responsibility of the licensee or the temporary permit holder, under the Act, to be familiar with and to avoid commission of any acts regarded as unethical conduct including, but not limited to, the following:

a. The obtaining of any fee or making any sale by fraud or misrepresentation;

b. Employing directly or indirectly any suspended or unregistered person to perform any work covered by the Act;

c. Engaging in falsification of name or using an alias with fraudulent intent for the purposes of fitting and selling hearing aids;

d. Gross incompetence or negligence shall be considered in dispensing or selling a hearing aid to a customer, client or person without that person having been given the opportunity of tests utilizing appropriate established procedures and instrumentation to determine the extent or type of hearing impairment except in cases of selling replacement hearing aids, in which case retesting hearing within 18 months of original purchase except in extenuating circumstances as determined by the Department;

e. Using or causing or promoting the use of any advertising matter, promotional literature, testimonial, guarantee, warranty, label, brand, insignia, or any other representation, however disseminated or published, which is misleading, deceiving, or

untruthful;

f. Advertising or offering for sale a particular model, type or kind of hearing aid when the offer is not a bonafide effort to sell the product so offered as advertised and at the advertised price. In determining whether there has been a violation of this rule, consideration will be given to actions or practices indicating that the offer was not made in good faith for the purpose of selling the advertised product, but was made for the purpose of contacting prospective purchasers and selling them a product offered.

g. Violation of any of the provisions of the Act.

2. Actions or procedures which shall be considered for the purpose of determining misrepresentation shall be the following:

a. The creation, by virtue of the initial offer or advertisement, of a false impression of the product offered in any material respect;

b. A refusal to show, demonstrate or sell the product offered in accordance with the terms of offer;

c. To vilify by actions or words, the product offered, credit terms, availability of service, repairs or parts in connection with the offer or advertisement;

d. To delay, in the event of sale, the delivery of such product or the service of such product offered within a reasonable time thereafter;

e. Representing, advertising or implying that the hearing aid or repair is guaranteed without complete disclosure of the nature and extent of the guarantee and any conditions or limitations thereof;

3. Representing that the professional services or advice of a physician will be used or made available in the selling or fitting, adjustment, maintenance or repair of hearing aids when that is not true, or using the words "doctor", "clinic", "audiologist", or any similar words, abbreviations, or symbols which tend to connote the audiological or medical profession when such is not the case;

4. Permitting another the use of license or temporary permit;

5. The indulgence in excessive consumption of beverages or drugs for purposes of intoxication shall constitute habitual intemperance;

6. Offering for sale, rent, or lease, by advertisement, a manufacturer's product or using a manufacturer's name or trademark which implies a relationship with the manufacturer(s) that does not exist;

7. Directly or indirectly giving or offering to give, permitting or causing the exchange of anything of value, whether it be money or otherwise, to any person who advises another as an inducement to influence him or others to purchase or contract for purchase products sold or offered for sale by a hearing aid dealer or fitter;

8. Making any statement or implying that the use of any hearing aid will restore or preserve hearing, prevent or regress hearing impairment;

9. To conduct business during any affliction thereby causing to be spread any contagious or infectious disease which may constitute a hazard to the well-being of any client;

10. Committing or contributing to any of the above actions or deeds shall be construed a violation of the Act.

Section 107. Corporation or Like Organizations:

Nothing in this law shall prohibit a corporation, partnership, trust, association or other like organizations from engaging in the business of fitting and selling, or offering for sale, hearing aids at retail without a license, if it employs licensed persons in the direct sale and fitting of such products. Such corporations, partnerships, trusts, associations, or other like organizations shall also file annually with the Department and Commission a list of all licensed hearing aid dealers, fitters, and holders of temporary permits directly or indirectly employed by it. Corporate officers or agents of such organizations shall file with the Department by affixing their signature(s) to the application and thereby submit themselves to the rules and regulations and the provisions of this Act which the Department may deem applicable.

PART II

CHAPTER 2 - Procedures

Section 201. Procedures/Equipment:

1. The following procedure shall be used in the fitting and selling of hearing aids where applicable:

a. Pure tone audiometric testing by air and bone conduction to determine the level of hearing impairment;

b. Speech reception threshold, speech discrimination, sound pressure measurement of the speech frequency range for the purpose of determining the best ear(s) for maximal hearing aid benefit and comfort. Selection of the best instrument to compensate for degree of loss.

c. Only when the above procedures are clearly impractical, then the selection of the best instrument to compensate the loss may be made by trial of several instruments.

2. The following minimal equipment shall be used in the fitting and selling of hearing aids:

a. Pure tone audiometer which shall meet with the latest specification standards as determined by the Department;

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

c. Ear light or an otoscope, for revealing any obstruction of the auditory canal, shall be free of cerumen and maintained in an aseptic manner at all times;

d. Audiometers shall be checked for proper calibration as often as deemed necessary but not less than once each year. Evidence of calibration shall be furnished with the license renewal application and a copy maintained on file in the office.

(1) Calibration shall be conducted by person, or an institution of higher learning equipped with proper instruments for calibrating as determined by the Department.

e. Maintain or have access to facilities for making ear molds.

f. A hearing aid office of place of business must have available or access to a selection of hearing aids and supplies and offer services complete enough to accommodate within reasonable limits the various needs of the clientele.

g. The testing room shall be sufficient in dimensions to accommodate all equipment necessary for the proper testing and evaluation of the client.

h. Every person who fits and sells hearing aids shall transmit to each person supplied with a hearing aid a receipt which shall contain the licensee's signature, show his business address and the license or temporary permit number together with the make, model and serial number of the hearing aid furnished and full terms of the sale clearly stated thereon. In the event of a used or rebuilt, reconditioned hearing aid, it shall be so specified on said receipt and shall indicate the length of time of the guarantee and by whom guaranteed.

(1) The licensee shall advise the purchaser prior to any sale, testing or evaluation by the hearing aid dealer that any examination or representation is not to be construed as a diagnosis, a medical opinion or that such examination imparts to the purchaser a prescription by a person licensed to practice medicine in this State.

(2) Any person engaging in the fitting and sale of hearing aids will, when dealing with a child 12 years of age or under, ascertain whether the child has been examined by an otolaryngologist for his recommendation within 90 days prior to the fitting. If such is not the case, a recommendation to do so must be made and this fact noted on the receipt.

Section 202. Examination:

1. An applicant for license, or holder of a temporary permit who meets all the requirements of the Act, shall appear at a time, place, and before such persons as prescribed by the Department to be examined by written and practical testing. The examination shall be such that it will establish knowledge and proficiency in each of the following categories:

- a. Basic physics of sound;
- b. Anatomy and physiology of the ear;
- c. Basic structure and functions of hearing aids;
- d. Pure tone audiometry, air and bone conduction;
- e. Live voice or recorded speech, speech audiometry including speech reception threshold testing and speech discrimination testing.
- f. Masking (when indicated);
- g. Recording and evaluation of audiograms;
- h. Speech audiometry;
- i. Taking earmold impressions.

2. Examination and Fee:

- a. A fee of \$50.00 has been established for the examination and is not transferable or refundable.
- b. Receipt shall be transmitted to applicant.
- c. Application for examination shall be kept on file by the Department.
- d. Applicant shall be notified within a reasonable time of the results of the prescribed tests.

e. Examinations for applicants shall be given not less than once each year.

3. The examination shall not constitute criteria or standards nor be conducted in a manner requiring college training in order to pass, or imply that the applicant possess a degree of competence normally expected of physicians or audiologists.

Section 203. Inspections:

Inspection(s) shall be conducted periodically by the Department; such inspection(s) shall include but not be limited to the following:

1. Calibration check of audiometric equipment; evidence of calibration check

shall be furnished upon request or shall be affixed to audiometer and shall have date and name of person(s) calibrating such equipment.

a. Calibration shall be conducted on each audiometer as often as deemed necessary but not less than once each year.

b. Calibration shall be accomplished by the manufacturer or properly trained person or an institution of higher learning equipped with proper instruments for calibrating audiometer as determined by the Department.

c. Calibration of audiometers and earphones shall be in accordance with the American National Standards and Specification of Audiometers, recent edition.

2. Records or receipts applicable to the sale of hearing aid:

a. Such records or receipts shall contain the signature or initials of licensee, the business address, make, model and serial number of the hearing aid offered.

b. Full disclosure of the terms of the sale.

c. The warranty or guarantee and by whom.

d. Any person engaging in the fitting and sale of hearing aids will, when dealing with a child 12 years of age or under, ascertain whether the child has been examined by an otolaryngologist for his recommendations within 90 days prior to the fitting. If such not be the case, a recommendation to do so must be made and this fact noted on the receipt.

e. These records and receipts shall be retained, by the licensee or dealer, for a period of time not less than 10 years in keeping with good practice.

f. Suggest all employees be required to check in to the owner of the business all pertinent records on termination of association with said owner of business.

3. The facility and individuals who work with, or handle, the equipment shall be clean at all times and all necessary precautions shall be taken to prevent the spread of any communicable disease.

4. Audiograms shall be recorded when applicable, and shall transmit the following information:

- a. Date of evaluation;
- b. Name of customer or client;
- c. Address of customer or client;
- d. Sex;
- e. Age;
- f. Signature of individual conducting test;

g. Audiogram shall be filed by the dealer, licensee or permit holder at his place of business for a period of 10 years or until such time as good practice may dictate.

5. An otoscope or ear light shall be operational and maintained in a clean manner and free of any debris or cerumen at all times.

Section 204. General:

Conditions arising which have not been covered in these regulations shall be handled in accordance with the best practices as interpreted by the Department.

Section 205. Continuing Education Programs - Approval:

Any person or organization desiring to conduct continuing education training programs must submit such programs to the Commission for approval.

A. Courses which have been approved by the National Institute of Hearing Instruments Studies (NIHIS) of the National Hearing Aid Society will be approved by the Commission under the following conditions:

1. The organization offering the program furnishes to the Department, not later than 30 days prior to its presentation, an outline which identifies the course content and NIHIS approved hours;

2. The course is publicized and available to all South Carolina licensed hearing aid dealers; and

3. The organization offering the courses furnishes the Department the names of such dealers who attended the program and the courses and hours creditable to each one.

B. Courses which do not meet the requirements outlined in "A" above, may be approved by the Commission under the following conditions:

1. The organization offering the program furnishes to the Department, not later than 60 days prior to its presentation, an outline which includes:

- a. Date and location;
- b. A description of each course;
- c. Hours of each course; and
- d. Biographical data of the instructors.

2. The course is publicized and available to all South Carolina licensed hearing aid dealers; and

3. The organization offering the courses furnishes the Department the names of such dealers who attended the program and the courses and hours creditable to each one.

C. The Department will secure Commission approval as appropriate and notify the training organization of the hours approved.

INDEX

A

Advertising	6
Alias	5
American National Standards and Specification of Audiometers	11
Annual Reports	4
Application.....	3
Audiogram.....	12
Audiologist.....	1, 7
Audiometer.....	1, 8, 10, 11

C

Calibration	8, 10
Child	9, 11
Commission	1, 3, 7, 12, 13
Conduct.....	5
Contagious or Infectious Disease.....	7
Continuing Education	3, 12
Corporation or Like Organizations.....	7

D

Definitions	1
Delay Delivery	6
Display of License	5
Duplicate Licenses	5

E

Ear Light.....	8, 12
Ear Molds	8, 10
Earphones.....	11
Equipment.....	8
Ethics	5
Examination	9
Examination Fee	3, 5, 10

F

Falsification of Name.....	5
Fees	2, 4, 5, 10

G

Gross Incompetence	6
Guarantee	6, 9, 11

I

Inspections 10
 Interpretations 2
 Intoxication 7

L

License 1, 2, 4, 5
 Licensee 1, 2, 3, 4, 5, 9, 11, 12
 Licensing Fee 2, 5

M

Management 3
 Masking 10

N

Negligence 6

O

Otolaryngologist 1, 9, 11
 Otoscope 8, 12

P

Phased Training Reports 4
 Procedures 8
 Pure Tone Audiometer 8
 Pure Tone Audiometric Testing 8

R

Receipt 9
 Record Retention 11
 Refusal To Show, Demonstrate or Sell The Product 6
 Relationships That Do Not Exist 7

S

Sale By Fraud 5
 Sales Receipt 9, 11
 Selection of Hearing Aids 8
 Serial Number 11
 Sound Pressure Measurement 8
 Speech Discrimination 8, 9
 Speech Reception Threshold 8

T

Temporary Permit2, 3, 4, 5, 7, 9
Temporary Permit Fee5
Terms of the Sale9, 11
Testing Room9

W

Warranty6, 11