

Chapter 741. Speech-Language Pathologists and Audiologists.
Subchapter H. Fitting and Dispensing of Hearing Instruments
Amendment §741.102
New §741.104

Proposed Preamble

The State Board of Examiners for Speech-Language Pathology and Audiology (board), proposes an amendment to §741.102 and new §741.104, concerning the regulation and sale of hearing instruments by licensed audiologists.

BACKGROUND AND PURPOSE

The proposed rules meet the requirements and directives of Senate Bill 662, 82nd Texas Legislature, Regular Session, 2011, amending Occupations Code, §401.002, concerning the adoption of a joint rule with the State Committee of Examiners in the Fitting and Dispensing of Hearing Instruments (committee) regarding the sale of hearing instruments.

SECTION-BY-SECTION SUMMARY

The amendment to §741.102 deletes language no longer necessary for the section specific to the sale of hearing instruments in accordance with the recent new legislation.

New §741.104 creates the joint rule with the committee. The new rule establishes requirements for the sale of hearing instruments, including information required in the written contract for hearing instrument purchase, records that must be retained by a licensed audiologist, and guidelines for the 30-day trial period during which a person may cancel the purchase of a hearing instrument.

FISCAL NOTE

Joyce Parsons, Executive Director, has determined that for each year of the first five years the sections are in effect, there will be no fiscal implications to state or local governments as a result of enforcing or administering the sections as proposed.

SMALL AND MICRO-BUSINESSES ECONOMIC STATEMENT AND REGULATORY FLEXIBILITY ANALYSIS

Ms. Parsons has also determined that there will be no adverse economic impact to small businesses or micro-businesses required to comply with the sections as proposed. This was determined by interpretation of the rules that small businesses and micro-businesses will not be required to alter their business practices in order to comply with the sections. Therefore, an economic impact statement and regulatory flexibility analysis for small and micro-businesses are not required.

ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

There are no anticipated economic costs to persons who are required to comply with the sections as proposed. The amendment and new rule do not impose additional fees. There is no anticipated impact on local employment.

PUBLIC BENEFIT

Ms. Parsons has also determined that for each year of the first five years the sections are in effect, the public will benefit from adoption of the sections. The public benefit anticipated as a result of enforcing or administering the sections will be insuring the effective regulation of audiologists in Texas, which will protect and promote public health, safety, and welfare.

REGULATORY ANALYSIS

The board has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

TAKINGS IMPACT ASSESSMENT

The board has determined that the proposed rules do not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, do not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to Joyce Parsons, Executive Director, State Board of Examiners for Speech-Language Pathology and Audiology, Mail Code 1982, P.O. Box 149347, Austin, Texas 78714-9347. Comments may also be sent through email to speech@dshs.state.tx.us, identified with "Comments on Proposed Rules" in the subject line. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

STATUTORY AUTHORITY

The amendment and new rule are authorized under Texas Occupations Code, §401.202, which provides the State Board of Examiners for Speech-Language Pathology and Audiology with the authority to adopt rules necessary to administer and enforce Texas Occupations Code, Chapter 401.

The amendment and new rule affect Texas Occupations Code, Chapter 401.

Legend: (Proposed Amendments)

Single Underline = Proposed new language

[Bold print and brackets] = Current language proposed for deletion

Regular Print = Current language

(No change.) = No changes are being considered for the designated subdivision

§741.102. General Practice Requirements of Audiologists and Interns in Audiology who Fit and Dispense Hearing Instruments. In accordance with the Act, a licensed audiologist or licensed intern in audiology registered to fit and dispense hearing instruments shall:

(1) adhere to the federal Food and Drug Administration regulations in accordance with 21 Code of Federal Regulations, §801.420 and §801.421;

(2) insure that all equipment used by the licensee within his or her scope of practice shall be calibrated to insure compliance with the American National Standards Institute (ANSI), S3.6, 1989, Specification for Audiometers, or S3.6, 1996, Specification for Audiometers;[.]

(3) receive a written statement before selling a hearing instrument that is signed by a licensed physician preferably one who specializes in diseases of the ear and states that the client's hearing loss has been medically evaluated during the preceding six-month period and that the client may be a candidate for a hearing instrument. If the client is age 18 or over, the registered audiologist or intern in audiology may inform the client that the medical evaluation requirement may be waived as long as the registered audiologist or intern in audiology:

(A) informs the client that the exercise of the waiver is not in the client's best health interest;

(B) does not encourage the client to waive the medical evaluation; and

(C) gives the client an opportunity to sign this statement: "I have been advised by (the name of the individual dispensing the hearing instrument) that the Food and Drug Administration has determined that my best health interest would be served if I had a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing instrument. I do not wish medical evaluation before purchasing a hearing instrument;" and

[(4) [inform the consumer of a hearing instrument by written contract of a trial period of 30 consecutive days. The contract shall include a specific date by which the client must return the instrument to qualify for a refund. If the date falls on a holiday, weekend, or a day the business is not open, the effective date shall be the first day the business reopens.]

[(A) The written contract shall include:]

[(i) all charges and fees associated with such trial period;]

[(ii) the licensee's printed name and license number; and]

[(iii) the name, address, and telephone number of the State Board of Examiners for Speech-Language Pathology and Audiology.]

[(B) The purchaser shall receive a copy of this contract.]

[(C) Any purchaser of a hearing instrument shall be entitled to a refund of the purchase price advanced by purchaser for the hearing instrument, less the agreed-upon amount associated with the trial period, upon return of the instrument to the licensee in good working order within the trial period. Should the order be canceled by purchaser prior to the delivery of the instrument, the licensee may retain the agreed-upon charges and fees as specified in the written contract. The purchaser shall receive the refund due no later than the 30th day after the date on which the purchaser cancels the order or returns the hearing instrument to the licensee.]

(4) [(5)] verify [**Verify**] appropriate fit of the hearing instrument(s), which may include real ear measures, functional gain measures, or other professionally accepted measures.

Legend: Proposed New Rule
Regular Print = Propsoed new language

§741.104. Joint Rule Regarding the Sale of Hearing Instruments.

(a) This section constitutes the rule required by the Act to be adopted jointly with the State Committee of Examiners in the Fitting and Dispensing of Hearing Instruments. The requirements of this section shall be repealed or amended only through consultation with, and mutual action by, the State Committee of Examiners in the Fitting and Dispensing of Hearing Instruments.

(b) Guidelines for a 30 consecutive day trial period.

(1) All clients shall be informed of a 30 consecutive day trial period by written contract for services. All charges associated with such trial period shall be included in this written contract for services, which shall include the name, address, and telephone number of the State Board of Examiners for Speech-Language Pathology and Audiology.

(2) Any client purchasing one or more hearing instruments shall be entitled to a refund of the purchase price advanced by the client for the hearing instrument(s), less the agreed-upon amount associated with the trial period, upon return of the instrument(s), in good condition, to the licensed audiologist or licensed intern in audiology within the trial period ending 30 consecutive days from the date of delivery. Should the order be canceled by the client prior to the delivery of the hearing instrument(s), the licensed audiologist or licensed intern in audiology may retain the agreed-upon charges and fees as specified in the written contract for services. The client shall receive the refund due no later than the 30th day after the date on which the client cancels the order or returns the hearing instrument(s), in good condition, to the licensed audiologist or licensed intern in audiology.

(3) Should the hearing instrument(s) have to be repaired or remade during the trial period, the 30 consecutive day trial period begins anew. The trial period begins on the day the client reclaims the repaired/remade hearing instrument(s). The expiration date of the new 30 consecutive day trial period shall be made available to the client in writing, through an amendment to the original written contract. The amendment shall be signed by both the licensed audiologist or licensed intern in audiology and the client.

(4) On delivery of a new replacement hearing instrument(s) during the trial period, the serial number of the new instrument(s), the delivery date of the hearing instrument(s), and the date of the expiration of the 30 consecutive trial period must be stated in writing.

(5) If the date of the expiration of the 30 consecutive day trial period falls on a holiday, weekend, or a day the business is not open, the expiration date shall be the first day the business reopens.

(c) Upon the sale of any hearing instrument(s) or change of model or serial number of the hearing instrument(s), the owner shall ensure that each client receives a written contract that contains:

(1) the date of sale;

(2) the make, model, and serial number of the hearing instrument(s);

(3) the name, address, and telephone number of the principal place of business of the license holder who dispensed the hearing instrument;

(4) a statement that the hearing instrument is new, used, or reconditioned;

(5) the length of time and other terms of the guarantee and by whom the hearing instrument is guaranteed;

(6) a copy of the written forms (relating to waiver forms);

(7) a statement on or attached to the written contract for services, in no smaller than 10-point bold type, as follows: "The client has been advised that any examination or representation made by a licensed audiologist or licensed intern in audiology in connection with the fitting and selling of the hearing instrument(s) is not an examination, diagnosis or prescription by a person duly licensed and qualified as a physician or surgeon authorized to practice medicine in the State of Texas and, therefore, must not be regarded as medical opinion or advice;"

(8) a statement on the face of the written contract for services, in no smaller than 10-point bold type, as follows: "If you have a complaint against a licensed audiologist or intern in audiology, you may contact the State Board of Examiners for Speech-Language Pathology and Audiology, P.O. Box 149347, Austin, Texas 78714-9347, telephone 1-800-942-5540;"

(9) the printed name, license type, signature and license number of the licensed audiologist or licensed intern in audiology who dispensed the hearing instrument;

(10) the supervisor's name, license type, and license number, if applicable;

(11) a recommendation for a follow-up appointment within 30 days after the hearing instrument fitting;

(12) the expiration date of the 30 consecutive day trial period under subsection (b)(3) of this section; and

(13) the dollar amount charged for the hearing instrument and the dollar amount charged for the return or restocking fee, if applicable.

(d) Record keeping. The owner of the dispensing practice shall ensure that records are maintained on every client who receives services in connection with the fitting and dispensing of hearing instruments. Such records shall be preserved for at least five years after the date of the last visit. All of the business's records and contracts are solely the property of the person who owns the business. Client access to records is governed by the Health Insurance Portability and Accountability Act (HIPAA). The records must be available for the board's inspection and shall include, but not be limited to, the following:

(1) pertinent case history;

(2) source of referral and appropriate documents;

(3) medical evaluation or waiver of evaluation;

(4) copies of written contracts for services and receipts executed in connection with the fitting and dispensing of each hearing instrument provided;

(5) a complete record of hearing tests, and services provided; and

(6) all correspondence specifically related to services provided to the client or the hearing instrument(s) fitted and dispensed to the client.

(e) The written contract and trial period information provided to a client in accordance with this section, orally and in writing, shall be in plain language designed to be easily understood by the average consumer.