

BILL ANALYSIS

Senate Research Center

S.B. 2017
By: Zaffirini
Health & Human Services
6/8/2023
Enrolled

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

The Texas Department of Licensing and Regulation regulates hearing instrument fitters and dispensers, speech-language pathologists, and audiologists. The United States Food and Drug Administration (FDA) classifies hearing instruments as medical devices. On October 17, 2022, however, the FDA created an over-the-counter category of hearing instruments and issued guidance on the regulatory requirements for those products.

Under existing state law, these over-the-counter devices would meet the definition of "hearing instruments," requiring suppliers to be licensed to sell the devices. Consequently, state law now conflicts with federal regulations. S.B. 2017 would align Texas law with federal law to eliminate confusion on who can sell a hearing instrument.

S.B. 2017 amends current law relating to the regulation of hearing aids and the practices of audiology and the fitting and dispensing of hearing instruments.

RULEMAKING AUTHORITY

Rulemaking authority is expressly granted to the Texas Commission of Licensing and Regulation in SECTION 4 (Section 401.403, Occupations Code), SECTION 7 (Section 402.152, Occupations Code), and SECTION 8 (Section 402.403, Occupations Code) of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Section 401.001(4-b), Occupations Code, to define "fitting and dispensing hearing instruments," "over-the-counter hearing aid," and "sale."

SECTION 2. Amends Section 401.058(a), Occupations Code, as follows:

(a) Provides that Chapter 401 (Speech-Language Pathologists and Audiologists) does not prohibit a person licensed under Chapter 402 (Hearing Instrument Fitters and Dispensers) from engaging in the practice of fitting and dispensing hearing instruments.

SECTION 3. Amends Subchapter B, Chapter 401, Occupations Code, by adding Section 401.061, as follows:

Sec. 401.061. OVER-THE-COUNTER HEARING AIDS. (a) Provides that this chapter, except as provided by this section, does not apply to servicing, marketing, selling, dispensing, providing customer support for, acquiring, or distributing over-the-counter hearing aids, regardless of whether the transaction occurs in person, online, or through other means.

(b) Provides that a person is not required to obtain a license under this chapter or Chapter 402 to engage in an activity described by Subsection (a).

(c) Prohibits a person from using the title "licensed dispenser" or "licensed seller" with respect to over-the-counter hearing aids or otherwise representing that the person holds a license to sell or dispense over-the-counter hearing aids unless the

person is licensed as an audiologist or audiologist intern under this chapter or as a hearing instrument fitter and dispenser under Chapter 402.

(d) Provides that the supervision, prescription, order, involvement, or intervention of a person licensed in this state is not required under this chapter for a consumer to access over-the-counter hearing aids.

(e) Authorizes a person licensed under this chapter to service, market, sell, dispense, provide customer support for, or distribute over-the-counter hearing aids. Provides that these activities do not exempt a person licensed under this chapter from any applicable provision of this chapter or Chapter 402.

SECTION 4. Amends Section 401.403(b), Occupations Code, as follows:

(b) Requires a person who holds a license as an audiologist or audiologist intern and who fits and dispenses hearing instruments to:

(1) makes no changes to this subdivision;

(2) comply with the federal Food and Drug Administration rules and guidelines for fitting and dispensing hearing instruments;

(3) when providing services in this state, use a written contract that contains the information prescribed by Texas Commission of Licensing and Regulation (TCLR) rule, rather than the name, mailing address, telephone number, and Internet website address of the Texas Department of Licensing and Regulation (TDLR); and

(4) makes no changes to this subdivision.

SECTION 5. Amends Section 402.001, Occupations Code, by amending Subdivisions (4), (5), and (7) and adding Subdivisions (4-a) and (6-a), to define "hearing aid" and "over-the-counter hearing aid" and redefine "fitting and dispensing hearing instruments," "hearing instrument," and "sale."

SECTION 6. Amends Subchapter A, Chapter 402, Occupations Code, by adding Section 402.004, as follows:

Sec. 402.004. OVER-THE-COUNTER HEARING AIDS. (a) Provides that this chapter, except as provided by this section, does not apply to servicing, marketing, selling, dispensing, providing customer support for, acquiring, or distributing over-the-counter hearing aids, regardless of whether the transaction occurs in person, online, or through other means.

(b) Provides that a person is not required to obtain a license under this chapter or Chapter 401 to engage in an activity described by Subsection (a).

(c) Prohibits a person from using the title "licensed dispenser" or "licensed seller" with respect to over-the-counter hearing aids or otherwise representing that the person holds a license to sell or dispense over-the-counter hearing aids unless the person is licensed as a hearing instrument fitter and dispenser under this chapter or as an audiologist or audiologist intern under Chapter 401.

(d) Provides that the supervision, prescription, order, involvement, or intervention of a person licensed in this state is not required under this chapter for a consumer to access over-the-counter hearing aids.

(e) Authorizes a person licensed under this chapter to service, market, sell, dispense, provide customer support for, or distribute over-the-counter hearing

aids. Provides that these activities do not exempt a person licensed under this chapter from any applicable provision of this chapter or Chapter 401.

SECTION 7. Amends Section 402.152, Occupations Code, as follows:

Sec. 402.152. COMPLAINTS. (a) Requires each license or permit holder under this chapter to at all times prominently display in the person's place of business a sign containing information about filing a complaint as prescribed by TCLR rule. Deletes existing text requiring each license or permit holder under this chapter at all times to prominently display in the person's place of business a sign containing the name, mailing address, e-mail address, and telephone number of TDLR and a statement informing consumers that a complaint against a license or permit holder is authorized to be directed to TDLR.

(b) Requires that each written contract for services in this state of a license holder contain the information prescribed by TCLR rule, rather than contain TDLR's name, mailing address, e-mail address, and telephone number.

SECTION 8. Amends Section 402.403, Occupations Code, as follows:

Sec. 402.403. WRITTEN CONTRACT. Requires the owner of a hearing instrument fitting and dispensing practice to ensure that each client receives a written contract at the time of purchase of a hearing instrument that contains the information prescribed by TCLR rule. Deletes existing text requiring the owner of a hearing instrument fitting and dispensing practice to ensure that each client receives a written contract at the time of purchase of a hearing instrument that contains:

- (1) the signature of the license holder who dispensed the hearing instrument;
- (2) the printed name of the license holder who dispensed the hearing instrument;
- (3) the address of the principal office of the license holder who dispensed the hearing instrument;
- (4) the license number of the license holder who dispensed the hearing instrument;
- (5) a description of the make and model of the hearing instrument;
- (6) the amount charged for the hearing instrument;
- (7) a statement of whether the hearing instrument is new, used, or rebuilt;
- (8) notice of the 30-day trial period under Section 402.401 (Trial Period); and
- (9) the name, mailing address, e-mail address, and telephone number of TDLR.

SECTION 9. Repealer: Section 401.058(b) (relating to providing that this chapter does not prohibit a licensed fitter and dispenser of hearing instruments from measuring human hearing by any means, including an audiometer, to make a selection, adaptation, or sale of a hearing instrument), Occupations Code.

SECTION 10. Requires TCLR, not later than December 1, 2023, to adopt rules prescribing the information required to be included:

- (1) in a contract, as required by Sections 401.403(b), 402.152(b), and 402.403, Occupations Code, as amended by this Act; and
- (2) on a sign, as required by Section 402.152(a), Occupations Code, as amended by this Act.

SECTION 11. (a) Provides that the changes in law made by this Act apply only to a contract provided to a patient on or after December 1, 2023.

(b) Provides that the changes in law made by this Act apply only to a sign displayed on or after December 1, 2023.

SECTION 12. Effective date: upon passage or September 1, 2023.