

## **BILL ANALYSIS**

S.B. 2017  
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Public Health  
Committee Report (Unamended)

### **BACKGROUND AND PURPOSE**

The Texas Department of Licensing and Regulation regulates hearing instrument fitters and dispensers, speech-language pathologists, and audiologists. The FDA classifies hearing instruments as medical devices. On October 17, 2022, 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.

### **CRIMINAL JUSTICE IMPACT**

It is the committee's opinion that this bill does not expressly create a criminal offense, increase the punishment for an existing criminal offense or category of offenses, or change the eligibility of a person for community supervision, parole, or mandatory supervision.

### **RULEMAKING AUTHORITY**

It is the committee's opinion that rulemaking authority is expressly granted to the Texas Commission of Licensing and Regulation in SECTIONS 4, 7, and 8 of this bill.

### **ANALYSIS**

S.B. 2017 amends the Occupations Code to establish that a person is not required to obtain a license under provisions relating to speech-language pathologists and audiologists and hearing instrument fitters and dispensers to engage in servicing, marketing, selling, dispensing, providing customer support for, acquiring, or distributing over-the-counter hearing aids and exempts those activities from the applicability of those provisions regardless of whether the transaction occurs in person, online, or through other means, except as provided by the bill. The bill 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 or as a hearing instrument fitter and dispenser under the applicable provisions. The bill establishes the following:

- the supervision, prescription, order, involvement, or intervention of a person licensed in Texas is not required under provisions relating to speech-language pathologists and audiologists or provisions relating to hearing instrument fitters and dispensers for a consumer to access over-the-counter hearing aids;
- a person licensed under those provisions may service, market, sell, dispense, provide customer support for, or distribute over-the-counter hearing aids; and
- such activities do not exempt a person licensed under those provisions from any applicable provision of those provisions.

S.B. 2017, with respect to provisions relating to hearing instrument fitters and dispensers, does the following:

- revises the definition of "fitting and dispensing hearing instruments" by including prescribing, ordering, or authorizing the use of hearing instruments among the activities that constitute the term;
- defines "hearing aid" as any wearable device designed for, offered for the purpose of, or represented as aiding persons with or compensating for impaired hearing and establishes that the term includes hearing instruments and over-the-counter hearing aids;
- changes the definition of "hearing instrument" from any wearable instrument or device designed for, or represented as, aiding, improving, or correcting defective human hearing, including the instrument's parts and any attachment, an earmold, or accessory to the instrument, but excluding a battery or cord, to a prescription hearing aid as that term is defined by federal regulations;
- defines "over-the-counter hearing aid" by reference to such federal regulations; and
- changes the definition of "sale" from a transfer of title or of the right to use by lease, bailment, or other contract to a lease, rental, or any other purchase or exchange of value.

S.B. 2017, with respect to provisions relating to speech-language pathologists and audiologists, defines "fitting and dispensing hearing instruments," "hearing instruments," "over-the counter hearing aid," and "sale" by reference to provisions relating to hearing instrument fitters and dispensers as amended by the bill. The bill establishes that provisions relating to speech-language pathologists and audiologists do not prohibit a person licensed under provisions relating to hearing instrument fitters and dispensers from engaging in the practice of fitting and dispensing hearing instruments.

S.B. 2017 changes the contents of a written contract that a person who holds a license as an audiologist or audiologist intern and who fits and dispenses hearing aids must use when providing services in Texas from the Texas Department of Licensing and Regulation (TDLR) name, mailing address, telephone number, and website address to information prescribed by Texas Commission of Licensing and Regulation (TCLR) rule. The bill requires such a person to comply with FDA rules for fitting and dispensing hearing instruments, in addition to complying with FDA guidelines for such as required under existing law.

S.B. 2017 changes the information contained on the sign that each hearing instrument fitter and dispenser license or permit holder must at all times prominently display in their place of business from TDLR's name, mailing address, email address, and telephone number and a statement informing consumers that a complaint against a license or permit holder may be directed to TDLR to information about filing a complaint as prescribed by TCLR rule. The bill changes the information that each written contract for services in Texas of such a license holder must contain from TDLR's name, mailing address, email address, and telephone number to information prescribed by TCLR rule. The bill changes the information contained in a written contract that the owner of a hearing instrument fitting and dispensing practice must ensure that each client receives at the time of purchase of a hearing instrument from the signature, printed name, address of the principal office, and license number of the license holder who dispensed the hearing instrument, a description of the make and model of the hearing instrument, the amount charged for the hearing instrument, a statement of whether the hearing instrument is new, used, or rebuilt, notice of the 30-day trial period during which a person may cancel the purchase of a hearing instrument, and TDLR's name, mailing address, email address, and telephone number to information prescribed by TCLR rule.

S.B. 2017 repeals Section 401.058(b), Occupations Code, which establishes that provisions relating to speech-language pathologists and audiologists do 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.

S.B. 2017 requires TCLR, not later than December 1, 2023, to adopt rules prescribing the information required to be included in an applicable contract and on an applicable sign under the bill's provisions. The bill's provisions apply only to a contract provided to a patient, and a sign displayed, on or after December 1, 2023.

**EFFECTIVE DATE**

On passage, or, if the bill does not receive the necessary vote, September 1, 2023.