

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Rules

BILL: CS/SB 126

INTRODUCER: Commerce and Tourism Committee and Senator Bradley

SUBJECT: Prescription Hearing Aids

DATE: March 11, 2025

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Smith</u>	<u>Brown</u>	<u>HP</u>	<u>Favorable</u>
2.	<u>McMillan</u>	<u>McKay</u>	<u>CM</u>	<u>Fav/CS</u>
3.	<u>Smith</u>	<u>Yeatman</u>	<u>RC</u>	<u>Pre-meeting</u>

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 126 authorizes licensed hearing aid specialists or licensed audiologists to sell and distribute prescription hearing aids through the mail to consumers who are 18 years of age or older.

The bill provides an effective date of July 1, 2025.

II. Present Situation:

Hearing Aids

Federal Regulations

The Food and Drug Administration (FDA) Reauthorization Act of 2017 (FDARA), s. 709,¹ directed the FDA to establish a category of over-the-counter (OTC) hearing aids through rulemaking and set forth various requirements for OTC hearing aids, including defining general controls for reasonable assurance of safety and effectiveness, as well as Federal preemption provisions.

¹21 U.S.C. 301, Food and Drug Administration Reauthorization Act of 1917, s. 709, *Regulation of Over-The-Counter Hearing Aids*, available at <https://www.congress.gov/115/plaws/publ52/PLAW-115publ52.pdf> (last visited Feb. 28, 2025).

On August 17, 2022, the FDA finalized a rule revising 21 C.F.R. 800,² 801,³ and 874.⁴ The FDA's new rule establishes a new category for OTC hearing aids. An OTC hearing aid is an air-conduction hearing aid that does not require implantation or other surgical intervention and is intended for use by a person aged 18 or older to compensate for perceived mild to moderate hearing impairment. The device, through tools, tests, or software, allows the user to control the hearing aid and customize it to the user's hearing needs. The device may use wireless technology or may include tests for self-assessment of hearing loss.

The device is available OTC, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online, provided that the device satisfies the requirements for consumers with "perceived mild to moderate hearing impairment" who wish to buy lower cost hearing aids not bundled with professional services and not requiring professional advice, fitting, adjustment, or maintenance. The rule became effective on October 16, 2022.⁵

The FDA rule includes provisions for simplified labeling, output limits, maximum insertion depth, and conditions for sale and distribution for both OTC and prescription hearing aids. The rule prohibits states from requiring the order, involvement, or intervention of a licensed person for consumers to access OTC hearing aids; a licensed person may service, market, sell, dispense, provide customer support for, or distribute OTC hearing aids.

Florida Regulations

In Florida, there are currently 1,289 licensed hearing aid specialists, and 1,654 licensed audiologists.⁶ In 2023, Florida's practice acts for hearing aid specialists and audiologists were amended to distinguish between prescription hearing aids and OTC hearing aids to conform to the new FDA rules.⁷ Under Florida law, prescription hearing aids are dispensed by hearing aid specialists and audiologists who are subject to the Department of Health (DOH) regulation under the Board of Hearing Aid Specialist (BHAS) and Board of Speech-Language Pathology and Audiology (BSLPA).⁸ Selling or distributing prescription hearing aids through the mail to the ultimate consumer is unlawful and is punishable as a misdemeanor of the second degree.⁹

Scope of Practice

Florida law defines the scope of practice for hearing aid specialists and audiologists and specifies the procedures which each health care practitioner is authorized to perform. Both hearing aid

² 21 CFR 800.30, available at <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-800#800.30> (last visited Mar. 4, 2025).

³ 21 CFR 801.60 - 63, available at <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-801/subpart-C> (last visited Mar. 4, 2025).

⁴ 21 CFR 874.5300 available at <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-874/subpart-F/section-874.5300> (last visited Mar. 4, 2025).

⁵ 21 CFR 800.30, available at <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-800#800.30> (last visited Mar. 4, 2025).

⁶ Florida Department of Health, Division of Medical Quality Assurance, *Annual Report and Long Range Plan, 2023 - 2024*, available at <https://mqawebteam.com/annualreports/2324/> (last visited Mar. 4, 2025).

⁷ Laws of Fla. 2023-71.

⁸ See Part II, ch. 484, and Part I, ch. 468, F.S., respectively.

⁹ Sections 468.1265 and 484.054, F.S.

specialists and audiologists may provide services through telehealth within this state.¹⁰ Out-of-state hearing aid specialists and audiologists may register to provide services through telehealth to patients located in this state.¹¹

Hearing Aid Specialists

Under s. 484.041, F.S., hearing aid specialists may dispense prescription hearing aids. Dispensing prescription hearing aids includes conducting and interpreting hearing tests for purposes of selecting suitable hearing aids, making earmolds or ear impressions for the fitting of hearing aids, and providing appropriate counseling regarding a suitable hearing aid device. This also includes all acts pertaining to the selling, renting, leasing, pricing, delivery, and warranty of hearing aids.¹²

Hearing aid specialists are licensed and regulated by the BHAS.¹³ Licensure for a hearing aid specialist is in accordance with s. 484.045, F.S., and includes the following requirements:

- Graduation of an accredited high school or its equivalent;
- Meeting one of the qualifying methods:
 - Completing a Florida sponsored training program;
 - Having a valid, current license as a hearing aid specialist or its equivalent from another state and has been actively practicing¹⁴ in such capacity for at least 12 months; or
 - Is currently certified by the National Board for Certification in Hearing Instrument Sciences (NBC-HIS) and has been actively practicing for at least 12 months.
- Has successfully completed:
 - International Licensing Examination (ILE); or
 - Active certification from the National Board for Certification in Hearing Instrument Sciences (NBC-HIS).
- Completion of a two-hour course relating to Florida laws and rules taught by an instructor approved by the BHAS.

Effective July 1, 2025, an applicant for licensure must also submit to a background screening test in accordance with s. 456.0135, F.S.

Audiologists

The practice of audiology includes the application of principles, methods, and procedures for the prevention, identification, evaluation, consultation, habilitation, rehabilitation, instruction, treatment, and research, relative to hearing and the disorders of hearing, and to related language and speech disorders.¹⁵ Licensed audiologists may offer, render, plan, direct, conduct, consult, or supervise services to individuals or groups of individuals who have or are suspected of having disorders of hearing, including prevention, identification, evaluation, treatment, consultation,

¹⁰ Section 456.47, F.S.

¹¹ *Id.*

¹² Section 484.041(3)(a), F.S.

¹³ Section 484.042, F.S.

¹⁴ See Fla. Admin. Code R. 64B6-2.002 (2025), which defines “actively practicing” as dispensing hearing aids directly to clients for at least 12 months, as shown by at least two sales receipts per month for at least 12 months, each receipt bearing the applicant’s signature and address of place(s) of business.

¹⁵ Section 468.1125(6)(a), F.S.

habilitation, rehabilitation, instruction, and research.¹⁶ This includes the fitting and dispensing of hearing aids. They may also provide the following:

- Participate in hearing conservation, evaluation of noise environment, and noise control;
- Conduct and interpret tests of vestibular function and nystagmus, electrophysiologic auditory-evoked potentials, central auditory function, and calibration of measurement equipment used for such purposes;
- Habilitate and rehabilitate, including, but not limited to, hearing aid evaluation, prescription, preparation, fitting and dispensing, assistive listening device selection and orientation, auditory training, aural habilitation, aural rehabilitation, speech conservation, and speechreading;
- Fabricate earmolds;
- Evaluate tinnitus; and
- Conduct speech and language screening, limited to a pass-fail determination for identifying individuals with disorders of communication.¹⁷

Audiologists are licensed and regulated by the BSLPA.¹⁸ Licensure for audiologists includes, among other requirements, the following:

- Submission of an application and all required fees.
- A doctoral degree with a major emphasis in audiology and:
 - Applicants who have earned a doctoral degree from an approved program before January 1, 2008, must complete 60 semester hours, 24 of which must be in audiology.¹⁹
 - Applicants who earned a doctoral degree from an approved program after January 1, 2008, must complete 75 semester hours.
 - 300 clock hours of supervised experience (clinical practicum) with at least 200 hours in the area of audiology.
- Eleven months of supervised clinical experience. This requirement may be met if the applicant holds a doctoral degree, meets the requirements of s. 468.1155, F.S., and can demonstrate one year of clinical work experience within the doctoral program.
- Applicants for licensure as an audiologist with a master's degree conferred before January 1, 2008, must document that, prior to licensure, the applicant completed one year of clinical work experience.
- Passing the licensure examination no more than three years prior to the date of the application.²⁰

Effective July 1, 2025, an applicant for licensure must also submit to a background screening test in accordance with s. 456.0135, F.S.

¹⁶ Section 468.1125(6)(b), F.S.

¹⁷ *Id.*

¹⁸ Section 468.1135, F.S.

¹⁹ Section 468.1155, F.S.

²⁰ Section 468.1185, F.S. and Fla. Admin. Code R. 64B20-2.005 (2022) The BSDPA has designated the Educational Testing Services Praxis Series Examination in Speech-Language Pathology or Audiology as the licensure examination.

*Minimal Procedures and Equipment*²¹

Florida law requires hearing aid specialists, and audiologists only when indicated, to perform all of the following procedures to be used in the fitting and selling of prescription hearing aids:

- Pure tone audiometric testing by air and bone to determine the type and degree of hearing deficiency.
- Effective masking.
- Appropriate testing to determine speech reception thresholds, speech discrimination scores, the most comfortable listening levels, uncomfortable loudness levels, and the selection of the best fitting arrangement for maximum hearing aid benefit.

A wide range audiometer that meets the specifications of the American National Standards Institute for diagnostic audiometers, and a speech audiometer or a master hearing aid must be used by hearing aid specialists, and audiologists only when indicated, in the fitting and selling of prescription hearing aids.

A hearing aid specialist must make a final fitting ensuring physical and operational comfort of the prescription hearing aid. An audiologist must make such a final fitting only when indicated.

Each audiometric test must be made in a testing room that has been certified by the DOH and meets certain requirements established in statute and rule. However, this requirement may be waived by a client who has been provided written notice of the benefits and advantages of having the test conducted in a certified testing room.

III. Effect of Proposed Changes:

The bill provides that prescription hearing aids may be distributed through the mail to a patient who is 18 years of age or older before the patient's scheduled telehealth appointment with a licensed audiologist. The prescription hearing aids may not be activated unless the audiologist has prescribed them. If prescribed, the audiologist must conduct a fitting during the telehealth appointment or a subsequent appointment to ensure the physical and operational comfort of the prescription hearing aids.

The bill provides that prescription hearing aids may be distributed through the mail to a patient who is 18 years of age or older before the patient's scheduled telehealth appointment with a licensed hearing aid specialist. The prescription hearing aids must not be activated unless the hearing aid specialist has determined that the patient should be fitted for prescription hearing aids. If that determination is made, the hearing aid specialist must conduct a fitting during the telehealth appointment or a subsequent appointment to ensure the physical and operational comfort of the prescription hearing aids.

The bill establishes that any person who sells or distributes prescription hearing aids through the mail to the ultimate consumer commits a misdemeanor of the second degree.

The bill takes effect July 1, 2025.

²¹ Sections 468.1225 and 484.0501, F.S. See also Fla. Admin. Code R. 64B6-6, 64B20-8, and 64B20-9.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None Identified.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

To implement the bill, the Department of Health would need to develop a communication plan to ensure compliance and operational readiness. The department anticipates that this would include updating websites and the Artificial Intelligence chatbot, notifying stakeholder groups, and communicating the statutory changes to staff through training.²²

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

²² Department of Health, Senate Bill 126 Legislative Analysis (Feb. 11, 2025) (on file with the Senate Committee on Health Policy).

VIII. Statutes Affected:

This bill substantially amends sections 468.1265 and 484.054 of the Florida Statutes.

IX. Additional Information:**A. Committee Substitute – Statement of Substantial Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Commerce and Tourism on March 3, 2024:

The committee substitute provides that prescription hearing aids may be distributed through the mail to a patient who is 18 years of age or older before the patient's scheduled telehealth appointment with a licensed audiologist. The prescription hearing aids may not be activated unless the audiologist has prescribed them. If prescribed, the audiologist must conduct a fitting during the telehealth appointment or a subsequent appointment to ensure the physical and operational comfort of the prescription hearing aids.

The committee substitute also provides that prescription hearing aids may be distributed through the mail to a patient who is 18 years of age or older before the patient's scheduled telehealth appointment with a licensed hearing aid specialist. The prescription hearing aids must not be activated unless the hearing aid specialist has determined that the patient should be fitted for prescription hearing aids. If that determination is made, the hearing aid specialist must conduct a fitting during the telehealth appointment or a subsequent appointment to ensure the physical and operational comfort of the prescription hearing aids.

Except in the above instances, any person who sells or distributes prescription hearing aids through the mail to the ultimate consumer commits a misdemeanor of the second degree.

B. Amendments:

None.