

Amendment - 1st Reading-white - Requested by: Terry Vermeire - (S) Business, Labor, and Economic Affairs

- 2023

68th Legislature 2023

Drafter: Erin Sullivan, 406-444-3594

SB0456.001.001

1 SENATE BILL NO. 456
2 INTRODUCED BY T. VERMEIRE
3
4 A BILL FOR AN ACT ENTITLED: "AN ACT GENERALLY REVISING LAWS RELATED TO HEARING AID
5 DISPENSERS; REORGANIZING AND CLARIFYING GENERALLY APPLICABLE ADMINISTRATIVE
6 PROVISIONS; REMOVING REDUNDANT PROVISIONS; TRANSFERRING OVERSIGHT AUTHORITY FROM
7 THE BOARD OF HEARING AID DISPENSERS TO A DEPARTMENT OF LABOR AND INDUSTRY
8 PROGRAM; ELIMINATING REQUIRED LICENSURE OF A PERSON TO SELL OVER-THE-COUNTER
9 HEARING AIDS, MEDICAL EVALUATION REQUIREMENTS, AND RIGHT TO CANCEL CONTRACT;
10 EXTENDING RULEMAKING; AMENDING SECTIONS 37-1-401, 37-15-102, 37-15-103, 37-16-102, 37-16-103,
11 37-16-202, 37-16-301, 37-16-303, 37-16-402, 37-16-408, AND 37-16-411, MCA; AND REPEALING SECTIONS
12 2-15-1740, 37-16-201, 37-16-203, 37-16-304, 37-16-405, 37-16-406, AND 37-16-413, MCA."
13

14 WHEREAS, the United States Food and Drug Administration amended regulations effective October
15 17, 2022 (87 F.R. 50698, August 17, 2022), that preempt the Montana Code Annotated regulating the sale of
16 over-the-counter hearing aids.
17

18 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:
19

20 **Section 1.** Section 37-1-401, MCA, is amended to read:

21 **"37-1-401. Uniform regulation for licensing programs without boards -- definitions.** As used in
22 this part, the following definitions apply:

- 23 (1) "Complaint" means a written allegation filed with the department that, if true, warrants an
24 injunction, disciplinary action against a licensee, or denial of an application submitted by a license applicant.
25 (2) "Department" means the department of labor and industry provided for in 2-15-1701.
26 (3) "Investigation" means the inquiry, analysis, audit, or other pursuit of information by the
27 department, with respect to a complaint or other information before the department, that is carried out for the

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1 purpose of determining:

2 (a) whether a person has violated a provision of law justifying discipline against the person;

3 (b) the status of compliance with a stipulation or order of the department;

4 (c) whether a license should be granted, denied, or conditionally issued; or

5 (d) whether the department should seek an injunction.

6 (4) "License" means permission in the form of a license, permit, endorsement, certificate,

7 recognition, or registration granted by the state of Montana to engage in a business activity or practice at a

8 specific level in a profession or occupation governed by:

9 (a) Title 37, chapter 16, 35, 72, or 73; or

10 (b) Title 50, chapter 39, 74, or 76.

11 (5) "Profession" or "occupation" means a profession or occupation regulated by the department

12 under the provisions of:

13 (a) Title 37, chapter 16, 35, 49, 72, or 73; or

14 (b) Title 50, chapter 39, 74, or 76."

15

16 **Section 2.** Section 37-15-102, MCA, is amended to read:

17 **"37-15-102. Definitions.** As used in this chapter, the following definitions apply:

18 (1) "Audiologist" means a person who practices audiology and who meets the qualifications set
19 forth in this chapter. A person represents to the public that the person is an audiologist by incorporating in any
20 title or description of services or functions that the person directly or indirectly performs the words "audiologist",
21 "audiology", "audiometrist", "audiometry", "audiological", "audiometrics", "hearing clinician", "hearing clinic",
22 "hearing therapist", "hearing therapy", "hearing center", "hearing aid audiologist", or any similar title or
23 description of services.

24 (2) "Audiology assistant" means any person meeting the minimum requirements established by the
25 board of speech-language pathologists and audiologists who works directly under the supervision of a licensed
26 audiologist.

27 (3) "Board" means the board of speech-language pathologists and audiologists provided for in 2-

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1 15-1739.

2 (4) "Department" means the department of labor and industry provided for in Title 2, chapter 15,
3 part 17.

4 (5) "Facilitator" means a trained individual who is physically present with the patient and facilitates
5 telehealth at the direction of an audiologist or speech-language pathologist. A facilitator may be but is not
6 limited to an audiology assistant or a speech-language pathology assistant.

7 (6) "Over-the-counter hearing aid" has the definition specified in 21 CFR 800.30 in effect on
8 January 1, 2023.

9 (6)(7) "Patient" means a consumer of services from an audiologist, a speech-language pathologist, a
10 speech-language pathology assistant, or an audiology assistant, including a consumer of those services
11 provided through telehealth.

12 (7)(8) "Practice of audiology" means nonmedical diagnosis, assessment, and treatment services
13 relating to auditory and vestibular disorders as provided by board rule and includes the ordering, selling,
14 dispensing, and fitting of over-the-counter hearing aids and prescription hearing aids.

15 (8)(9) "Practice of speech-language pathology" means nonmedical diagnosis, assessment, and
16 treatment services relating to speech-language pathology as provided by board rule.

17 (10) "Prescription hearing aid" has the definition specified in 21 CFR 801.422 in effect on January 1,
18 2023. The term does not include an over-the-counter hearing aid.

19 (9)(11) "Speech-language pathologist" means a person who practices speech-language pathology and
20 who meets the qualifications set forth in this chapter. A person represents to the public that the person is a
21 speech-language pathologist by incorporating in any title or description of services or functions that the person
22 directly or indirectly performs the words "speech pathologist", "speech pathology", "speech correctionist",
23 "speech corrections", "speech therapist", "speech therapy", "speech clinician", "speech clinic", "language
24 pathologist", "language pathology", "voice therapist", "voice therapy", "voice pathologist", "voice pathology",
25 "logopedist", "logopedics", "communicologist", "communicology", "aphasiologist", "aphasiology", "phoniatriest",
26 "language therapist", "language clinician", or any similar title or description of services or functions.

27 (10)(12) "Speech-language pathology assistant" means a person meeting the minimum requirements

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1 established by the board who works directly under the supervision of a licensed speech-language pathologist.

2 ~~(11)~~(13) "Telehealth" has the meaning provided in 37-2-305."

3

4 **Section 3.** Section 37-15-103, MCA, is amended to read:

5 **"37-15-103. Exemptions -- rulemaking.** (1) This chapter does not prevent a person licensed in this
6 state under any other law from engaging in the profession or business for which that person is licensed.

7 (2) This chapter does not restrict or prevent activities of a speech-language pathology or audiology
8 nature or the use of the official title of the position for which the activities were performed on the part of a
9 speech-language pathologist or audiologist employed by federal agencies.

10 (3) Those persons performing activities described in subsection (2) who are not licensed under this
11 chapter may perform those activities only within the confines of or under the jurisdiction of the organization in
12 which they are employed and may not offer speech-language pathology or audiology services to the public for
13 compensation over and above the salary they receive for performance of their official duties with organizations
14 by which they are employed. However, without obtaining a license under this chapter, these persons may
15 consult or disseminate their research findings and scientific information to other accredited academic
16 institutions or governmental agencies. They also may offer lectures to the public for a fee without being licensed
17 under this chapter.

18 (4) This chapter does not restrict the activities and services of a student in speech-language
19 pathology or audiology from pursuing a course of study in speech-language pathology or audiology at an
20 accredited or approved college or university or an approved clinical training facility. However, these activities
21 and services must constitute a part of a supervised course of study, and a fee may not accrue directly or
22 indirectly to the student. These students must be designated by the title "speech-language pathology or
23 audiology intern", "speech-language pathology or audiology trainee", or a title clearly indicating the training
24 status appropriate to the level of training.

25 (5) This chapter does not restrict a person from another state from offering speech-language
26 pathology or audiology services in this state if the services are performed for not more than 5 days in any
27 calendar year and if the services are performed in cooperation with a speech-language pathologist or

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1 audiologist licensed under this chapter. However, by securing a temporary license from the board subject to
2 limitations that the board may impose, a person not a resident of this state who is not licensed under this
3 chapter but who is licensed under the law of another state that has established licensure requirements at least
4 equivalent to those established by this chapter may offer speech-language pathology or audiology services in
5 this state for not more than 30 days in any calendar year if the services are performed in cooperation with a
6 speech-language pathologist or audiologist licensed under this chapter.

7 (6) This chapter does not restrict a person holding a class A certificate issued by the conference of
8 executives of American schools of the deaf from performing the functions for which the person qualifies.

9 (7) This chapter does not restrict a person who is licensed in this state as a hearing aid dispenser
10 from performing the functions for which the person qualifies and that are described in Title 37, chapter 16.

11 (8) (a) An audiologist who orders, sells, dispenses, or fits prescription hearing aids is exempt from
12 the licensing requirements or other provisions of Title 37, chapter 16, ~~except for the provisions of 37-16-304.~~

13 (b) The board may adopt rules pertaining to the selling, dispensing, and fitting of prescription
14 hearing aids and prescription hearing aid parts, attachments, and accessories."

15

16 **Section 4.** Section 37-16-102, MCA, is amended to read:

17 **"37-16-102. Definitions.** Unless the context requires otherwise, in this chapter, the following
18 definitions apply:

19 (1) ~~"Board" means the board of hearing aid dispensers provided for in 2-15-1740.~~

20 (2)(1) "Department" means the department of labor and industry provided for in Title 2, chapter 15,
21 part 17.

22 (3) ~~"Hearing aid" means an instrument or device designed for or represented as aiding or improving
23 defective human hearing and parts, attachments, or accessories of the instrument or device.~~

24 (4) ~~"License" means a regular or trainee license.~~

25 (2) "Licensed hearing aid dispenser" is an individual who orders, fits, sells, and dispenses
26 prescription hearing aids.

27 (3) "Over-the-counter hearing aid" has the definition specified in 21 CFR 800.30 in effect on

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1 January 1, 2023.

2 ~~(5)(4)~~ "Permanent place of business" means the primary site in this state at which a person licensed
3 under this chapter conducts testing and fitting of prescription hearing aids and related devices ~~and that is open~~
4 ~~to the public at least 5 days a week.~~

5 ~~(6)~~ "Place of practice" means ~~either a permanent place of business or a location on record with the~~
6 ~~department at which a person licensed under this chapter makes occasional visits. A place of practice must be~~
7 ~~affiliated with a permanent place of business.~~

8 ~~(7)(5)~~ "Practice of ordering, selling, dispensing, and fitting prescription hearing aids" means the
9 evaluation or measurement of the powers or range of human hearing by means of an audiometer and a visual
10 examination of the ear and canal or by any other means devised and the consequent ordering, selection,
11 adaption, sale, dispensing, or fitting of prescription hearing aids intended to compensate for hearing loss,
12 including eyeglass prescription hearing aids and their fittings, and the making of an impression of the ear and
13 the subsequent selection of a proper ear mold, but does not include batteries, cords, or accessories.

14 ~~(6)~~ "Prescription hearing aid" has the definition specified in 21 CFR 801.422 in effect on January 1,
15 2023. The term does not include an over-the-counter hearing aid."

16

17 **Section 5.** Section 37-16-103, MCA, is amended to read:

18 **"37-16-103. Exemptions.** This chapter does not apply to a person who is:

19 (1) a physician licensed to practice by the state board of medical examiners;
20 (2) engaged in the practice of fitting prescription hearing aids if the person's practice is part of the
21 academic curriculum of an accredited institution of higher education or part of a program conducted by a public
22 agency; or

23 (3) licensed as an audiologist under the provisions of Title 37, chapter 15, ~~except that the~~
24 ~~provisions of 37-16-304 apply to licensed audiologists."~~

25

26 **Section 6.** Section 37-16-202, MCA, is amended to read:

27 **"37-16-202. Powers and duties -- licensed hearing aid dispenser program.** (1) The powers and