

**Subject** Compliance with federal rules governing over-the-counter hearing aids

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## Overview

Federal rules adopted by the Food and Drug Administration in 2022 established a regulatory category of over-the-counter (OTC) hearing aid separate from prescription hearing aids. A consumer can purchase OTC hearing aids directly from a seller, without having to be examined by a health professional or obtaining a prescription for the hearing aid. To conform with these rules, this bill modifies statutes governing audiologists and hearing instrument dispensers to provide that audiologists have authority to prescribe and dispense prescription hearing aids and that hearing aid dispensers have authority to dispense prescription hearing aids. It also changes the term “hearing instrument” to “hearing aid” in chapters governing audiologists and hearing instrument dispensers, and changes the title “hearing instrument dispenser” to “prescription hearing aid dispenser.”

## Summary

Section	Description
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| 1 | <b>Hearing aid.</b><br>Amends § 148.512, subd. 10a. Amends the definition of hearing aid in the statutes governing audiologists, to specify that it is a prescribed aid.  |
| 2 | <b>Hearing aid dispensing.</b><br>Amends § 148.512, subd. 10b. Amends the definition of hearing aid dispensing in the audiologist statutes to remove from the definition, the acts of recommending a hearing aid and selling hearing aids at retail. Specifies that hearing aid dispensing does not include selling over-the-counter (OTC) hearing aids. Provides this definition applies to assisting with selecting, and dispensing, prescription hearing aids. |

<b>Section</b>	<b>Description</b>
3	<b>Over-the-counter hearing aid or OTC hearing aid.</b> Adds subd. 10c to § 148.512. Defines over-the-counter hearing aid or OTC hearing aid in the audiologist statutes.
4	<b>Prescription hearing aid.</b> Adds subd. 13a to § 148.512. Defines prescription hearing aid in the audiologist statutes.
5	<b>Hearing aid dispensers.</b> Amends § 148.513, subd. 2a. Amends the audiologist statutes to conform with changes in chapter 153A that change the title “hearing instrument dispenser” to “prescription hearing aid dispenser.”
6	<b>Dispensing audiologist examination requirements.</b> Amends § 148.515, subd. 6. Amends audiologist examination requirements to specify that the examination requirement and supervision requirement must be satisfied to dispense prescription hearing aids.
7	<b>Temporary licensure.</b> Amends § 148.5175. Provides that the practical examination required for licensure as a speech-language pathologist or audiologist is an examination for dispensing prescription hearing aids.
8	<b>Grounds for disciplinary action by commissioner.</b> Amends § 148.5195, subd. 3. In provisions establishing grounds for disciplinary action against audiologists and hearing instrument dispensers, changes the title from “hearing instrument dispenser” to “prescription hearing aid dispenser” and provides that grounds for disciplinary action apply to prescribing or dispensing prescription hearing aids. Removes references to recommending hearing aids.
9	<b>Membership.</b> Amends § 148.5196, subd. 1. In a subdivision establishing the Speech-Language Pathologist and Audiologist Advisory Council, modifies a term from “hearing instrument” to “hearing aid;” changes a title from “hearing instrument dispenser” to “prescription hearing aid dispenser;” and requires audiologist members to have experience that includes dispensing prescription hearing aids. Removes a reference to recommending hearing aids.
10	<b>Hearing aid dispensing.</b> Amends § 148.5197. Modifies provisions governing audiologist and hearing instrument dispenser contracts, use of a license number or certificate number,

<b>Section</b>	<b>Description</b>
	consumer rights information, and liability, to provide this section governs audiologist and dispenser prescribing and dispensing of prescription hearing aids.
11	<b>Restriction on sale of prescription hearing aids.</b> Amends § 148.5198. Provides the consumer protections in this section apply to audiologists' and certified dispensers' dispensing of prescription hearing aids.
12	<b>Hearing aid.</b> Amends § 153A.13, subd. 3. In the definition of "hearing instrument" in the chapter governing hearing instrument dispensers, changes the term defined, from "hearing instrument" to "hearing aid" and refers to the definition of that term in section 148.512, subd. 10a.
13	<b>Hearing aid dispensing.</b> Amends § 153A.13, subd. 4. In the definition of "hearing aid dispensing" in the chapter governing hearing instrument dispensers, changes the term defined, from "hearing instrument dispensing" to "hearing aid dispensing" and refers to the definition of that term in section 148.512, subd. 10b.
14	<b>Dispenser of prescription hearing aids.</b> Amends § 153A.13, subd. 5. In the definition of "dispenser of hearing instruments" chapter governing hearing instrument dispensers, changes the term defined to "dispenser of prescription hearing aids" and provides that these dispensers dispense prescription aids. (This is a version of the professional title used by persons who dispense hearing aids. The title "hearing instrument dispenser" is also used in this chapter and is being amended to "prescription hearing aid dispenser.")
15	<b>Advisory council.</b> Amends § 153A.13, subd. 6. Changes the name of an advisory council from "Minnesota Hearing Instrument Dispenser Advisory Council" to "Minnesota Prescription Hearing Aid Dispenser Advisory Council" to conform with other changes in this chapter.
16	<b>ANSI.</b> Amends § 153A.13, subd. 7. In the definition of "ANSI" in the chapter governing hearing instrument dispensers, strikes the existing definition of ANSI and instead refers to the definition of the American National Standard Specification for Audiometers in federal rules.

<b>Section</b>	<b>Description</b>
17	<b>Supervision.</b> Amends § 153A.13, subd. 9. In the definition of “supervision” in the chapter governing hearing instrument dispensers, changes a term and provides that trainees dispense prescription hearing aids.
18	<b>Direct supervision or directly supervised.</b> Amends § 153A.13, subd. 10. In the definition of “direct supervision” in the chapter governing hearing instrument dispensers, changes a term and provides that trainees dispense prescription hearing aids.
19	<b>Indirect supervision or indirectly supervised.</b> Amends § 153A.13, subd. 11. In the definition of “indirect supervision” in the chapter governing hearing instrument dispensers, changes a term and provides that trainees dispense prescription hearing aids.
20	<b>Over-the-counter hearing aid or OTC hearing aid.</b> Adds subd. 12 to § 153A.13. Defines over-the-counter hearing aid or OTC hearing aid for the chapter governing hearing instrument dispensers.
21	<b>Prescription hearing aid.</b> Adds subd. 13 to § 153A.13. Defines prescription hearing aid for the chapter governing hearing instrument dispensers.
22	<b>Application for certificate.</b> Amends § 153A.14, subd. 1. In a subdivision governing applications for a certificate as a hearing instrument dispenser, changes terms from “hearing instrument” to “hearing aid” and requires the applicant to provide information on training and experience in testing, fitting, and selling prescription hearing aids.
23	<b>Issuance of certificate.</b> Amends § 153A.14, subd. 2. In a subdivision governing issuance of certificates for hearing instrument dispensers, changes the title from “dispensers of hearing instruments” to “dispensers of prescription hearing aids.”
24	<b>Certification by examination.</b> Amends § 153A.14, subd. 2h. Requires the examination for certification as a hearing instrument dispenser to test applicants on prescription hearing aid selling.
25	<b>Continuing education requirements.</b> Amends § 153A.14, subd. 2i. Requires continuing education courses for hearing instrument dispensers to be directly related to prescription hearing aid dispensing.

<b>Section</b>	<b>Description</b>
26	<p><b>Required use of certification number.</b></p> <p>Amends § 153A.14, subd. 2j. Provides the requirement that a hearing instrument dispenser uses the dispenser’s certification number on certain sales items, applies to the sale of prescription hearing aids.</p>
27	<p><b>Dispensing of prescription hearing aids without certificate.</b></p> <p>Amends § 153A.14, subd. 4. Modifies criminal penalties, to make it a gross misdemeanor to dispense a prescription hearing aid without a certificate.</p>
28	<p><b>Trainees.</b></p> <p>Amends § 153A.14, subd. 4a. Changes a title, from “hearing instrument dispenser” to “prescription hearing aid dispenser” and provides the authorization for trainees to dispense hearing aids applies to the dispensing of prescription hearing aids.</p>
29	<p><b>Prescription hearing testing protocol.</b></p> <p>Amends § 153A.14, subd. 4b. Modifies the hearing testing protocol requirements to make them apply to the dispensing of prescription hearing aids. Also corrects a cross-reference to federal rules.</p>
30	<p><b>Reciprocity.</b></p> <p>Amends § 153A.14, subd. 4c. Modifies a subdivision governing reciprocity to provide it applies to persons who have dispensed prescription hearing aids in other jurisdictions.</p>
31	<p><b>Prescription hearing aids; enforcement.</b></p> <p>Amends § 153A.14, subd. 4e. Requires certain investigation costs of the Department of Health to be apportioned among professions that dispense prescription hearing aids.</p>
32	<p><b>Prescription hearing aids to comply with federal and state requirements.</b></p> <p>Amends § 153A.14, subd. 6. Provides the commissioner’s duties to ensure compliance with state and federal requirements apply to requirements governing dispensing of prescription hearing aids.</p>
33	<p><b>Consumer rights.</b></p> <p>Amends § 153A.14, subd. 9. Changes the title used, from “hearing instrument dispenser” to “prescription hearing aid dispenser.”</p>
34	<p><b>Requirement to maintain current information.</b></p> <p>Amends § 153A.14, subd. 11. Modifies information a dispenser must provide the commissioner, to require dispensers to provide information on certain judgements</p>

<b>Section</b>	<b>Description</b>
	related to dispensing prescription hearing aids and information on whether the dispenser ceases dispensing prescription hearing aids.
35	<b>Prohibited acts.</b> Amends § 153A.15, subd. 1. Changes a title, and provides the grounds for disciplinary action in this subdivision apply to dispensing prescription hearing aids.
36	<b>Enforcement actions.</b> Amends § 153A.15, subd. 2. Changes a title.
37	<b>Penalties.</b> Amends § 153A.15, subd. 4. Changes a title.
38	<b>Expenses; fees.</b> Amends § 153A.17. Changes a title. Strikes language prohibiting the legislature from transferring fees collected under this section from the state government special revenue fund to the general fund and exempting surcharges from the general requirement that expenses for administering the certification program must be paid from fees collected under this section.
39	<b>Penalty fees.</b> Amends § 153A.175. Changes a title and provides the penalty fee for dispensing without submitting a continuing education report applies to dispensing prescription hearing aids.
40	<b>Consumer information center.</b> Amends § 153A.18. Provides the Consumer Information Center must provide information about prescription hearing aids to actual and potential purchasers. Changes a title.
41	<b>Prescription Hearing Aid Dispenser Advisory Council.</b> Amends § 153A.20. Changes the name of the advisory council from “Hearing Instrument Dispenser Advisory Council” to “Prescription Hearing Aid Dispenser Advisory Council;” requires advisory council members to be persons who dispense or use prescription hearing aids; changes a title.
42	<b>Repealer.</b> Repeals § 153A.14, subd. 5, which authorizes the commissioner of health to adopt rules to implement the chapter governing hearing instrument dispensers.



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