

WSR 24-01-087

PERMANENT RULES

DEPARTMENT OF HEALTH

(Board of Hearing and Speech)

[Filed December 18, 2023, 7:43 a.m., effective January 18, 2024]

Effective Date of Rule: Thirty-one days after filing.

Purpose: Over-the-counter (OTC) hearing aids. The board of hearing and speech (board) is adopting rules to reflect federal changes for OTC hearing aids. The Food and Drug Administration adopted a federal rule regarding the sale of OTC hearing aids (21 C.F.R. Parts 800, 801, 808, and 874 (2022)). Effective since October 2022, OTC hearing aids may be sold to adults over 18 years of age without a medical examination or fitting from a licensed audiologist or hearing aid specialist. To align with the changes in federal regulation, the board's adopted amendment removes requirements in WAC 246-828-100 for medical clearance as a condition for sale of OTC hearing aids. The adopted changes to WAC 246-828-100 only remove requirements no longer permitted by federal rule and do not otherwise change licensure requirements.

Citation of Rules Affected by this Order: Amending WAC 246-828-100.

Statutory Authority for Adoption: RCW 18.35.161.

Other Authority: Food and Drug Administration (21 C.F.R. Parts 800, 801, 808, and 874 (2022)).

Adopted under notice filed as WSR 23-19-102 on September 20, 2023.

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 1, Repealed 0; or Recently Enacted State Statutes: New 0, Amended 0, Repealed 0.

Number of Sections Adopted at the Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's own Initiative: New 0, Amended 0, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 0, Repealed 0.

Number of Sections Adopted using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 0, Amended 1, Repealed 0.

Date Adopted: November 3, 2023.

Nichole K. Furness, AuD
Board of Hearing and Speech Chairperson

OTS-4624.2

AMENDATORY SECTION (Amending WSR 15-14-092, filed 6/29/15, effective 7/1/15)

WAC 246-828-100 Prescription hearing instrument fitting and dispensing—Minimum standards of practice. Federal Food and Drug Administration rules preempt Washington state laws and rules for over-the-counter hearing aids; over-the-counter hearing aids are not regulated

under chapter 18.35 RCW or 246-828 WAC. Minimum procedures in the fitting and dispensing of prescription hearing instruments include:

(1) Obtaining case history including:

(a) Documentation of referrals.

(b) Historical evaluation including inquiry regarding hearing loss, onset of loss, and any associated symptoms including significant noise in the ears, vertigo, acute or chronic dizziness, nausea, ear-aches, or other such discomfort which may indicate the presence of medical illness. Specific inquiry should be made to determine if hearing loss has been sudden or rapidly progressive in the past (~~ninety~~) 90 days, if there has been any active drainage or infection in ears during the past (~~ninety~~) 90 days, and if there are any specific physical problems that may relate to the use of a hearing instrument.

(2) Examining the ears to reasonably determine if any of the following conditions exist:

(a) Impacted ear wax.

(b) Foreign body within the ear canal.

(c) Discharge in the ear canal.

(d) Presence of inflammation or irritation of the ear canal.

(e) Perforation of the ear drum.

(f) Any other abnormality.

(3) Hearing testing to include the following:

(a) Hearing loss, or residual hearing, must be established for each ear using pure tone threshold audiometry by air and bone conduction with effective masking as required.

(b) Appropriate live voice or recorded speech audiometry by ear phones to determine the following: Speech reception threshold, most comfortable level, uncomfortable level, and word recognition score.

(c) Hearing testing must be conducted in compliance with WAC 246-828-080 and 246-828-090.

(d) When pure tone audiometry indicates an air-bone gap of 15 decibels (dB) or more at 500, 1000, and 2000 hertz (Hz); the presence of unilateral hearing loss; or any inconsistent audiometric findings, the patient or client must be advised of the potential help available through medical treatment. If the patient or client declines medical treatment, has been appropriately treated previously, or has been advised against medical treatment, the licensee must make an appropriate notation in the patient's or client's record.

(e) In the event a patient or client is referred to a licensee by an audiologist, otologist, otolaryngologist, or by a hearing aid specialist licensed under chapter 18.35 RCW, and the audiometric results obtained within the previous six months are provided to the licensee as a part of this referral, the applicable provisions of WAC 246-828-100 are not required. However, a confirmatory audiometric examination is recommended.

(4) Medical evaluation requirements: (~~((a) Except as provided in (b) of this subsection,))~~ A hearing aid specialist or audiologist may not sell a hearing instrument to a patient or client under the age of 18 years old unless the prospective patient or client has presented a written statement signed by a licensed physician that states that the patient's or client's hearing loss has been medically evaluated and the patient or client may be considered a candidate for a hearing instrument. The medical evaluation must have taken place within the preceding six months.

~~((b) If the prospective patient or client is eighteen years of age or older, the hearing aid specialist or audiologist may afford the prospective patient or client an opportunity to waive the medical~~

~~evaluation requirements of (a) of this subsection if the hearing aid specialist or audiologist:~~

~~(i) Informs the prospective patient or client that the exercise of the waiver is not in the patient or client's best health interest;~~

~~(ii) Does not in any way actively encourage the prospective patient or client to waive the medical evaluation;~~

~~(iii) Offers the prospective patient or client the opportunity to sign the following statement:~~

~~I have been advised by (hearing aid specialist or audiologist name) the Food and Drug Administration has determined that my best health interest would be served if I had a medical evaluation before purchasing a hearing instrument; and~~

~~(iv) Provides the prospective patient or client with a copy of the signed waiver statement.)~~

(5) Selection and fitting of the hearing instrument includes providing the patient or client:

(a) Information regarding the selection of the most appropriate method and model for amplification for the needs of the patient or client.

(b) The cost of the recommended instruments and services.

(c) A custom made ear mold, when applicable.

(d) Final fitting of the hearing instrument to ensure physical and operational comfort.

(e) Adequate instructions and appropriate post-fitting adjustments to ensure the most successful use of the hearing instrument.

(6) Keeping records for every patient or client in connection with the dispensing of a hearing instrument. Cumulative records must be retained for all hearing instruments dispensed for at least three years from the date the last hearing instrument was dispensed to the patient or client. The records must be available for the department inspection and must include:

(a) Patient's or client's case history.

(b) Source of referral and documents.

~~(c) ((Medical clearance for the hearing instrument patient or client or the waiver set forth in subsection (4)(b)(iii) of this section which has been signed after being fully informed that it is in the best health interest to seek medical evaluation.~~

~~(d))~~ Copies of any contracts and receipts executed in connection with the fitting and dispensing of each hearing instrument provided.

~~((e))~~ (d) A complete record of tests, test results, and services provided.

~~((f))~~ (e) All correspondence specifically related to the service given or the hearing instrument(s) dispensed to the patient or client.