WSR 23-19-102
PROPOSED RULES
DEPARTMENT OF HEALTH
(Board of Hearing and Speech)
[Filed September 20, 2023, 11:15 a.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 23-04-023.

Title of Rule and Other Identifying Information: Over-the-counter (OTC) hearing aids; the board of hearing and speech (board) is proposing amendments to WAC 246-828-100 Hearing instruments fitting and dispensing—Minimum standards of practice, to reflect changes to relevant federal rules by the Food and Drug Administration (FDA) regarding the sale of OTC hearing aids (21 C.F.R. Parts 800, 801, 808, and 874 (2022)).

Hearing Location(s): On November 3, 2023, at 10:00 a.m., at Labor and Industries, 7273 Linderson Way S.W., Room 117, Tumwater, WA 98501; or virtual option. Join on your computer, mobile app, or room device. Link to join the meeting https://teams.microsoft.com/l/meetup-join/19%3ameeting_ODQxNWEzNzEtYzBkYi00YzlmLWI3NDEtMGYwOTE2MGIzNzI2%40thread.v2/0?context=%7b%22Tid%22%3a%2211d0e217-264e-400a-8ba0-57dcc127d72d%22%2c%22Oid%22%3a%22ae44b66e-af0e-436f-a863-213f33d92a5c%22%7d.

Date of Intended Adoption: November 3, 2023.

Submit Written Comments to: Kim-Boi Shadduck, Program Manager, Department of Health, P.O. Box 47852, Tumwater, WA 98504-7852, email https://fortress.wa.gov/doh/policyreview, fax 360-236-2901, by October 13, 2023.

Assistance for Persons with Disabilities: Contact Kim-Boi Shadduck, program manager, phone 360-236-2912, TTY 711, email kimboi.shadduck@doh.wa.gov, by October 13, 2023.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: The FDA 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 proposal would remove requirements in WAC 246-828-100 for medical clearance as a condition for sale of OTC hearing aids.

Reasons Supporting Proposal: The proposal only removes requirements no longer permitted by federal rule and would not otherwise change licensure requirements. Licensed audiologists and hearing aid specialists engaged in the sale, fitting, and dispensing of prescriptive hearing aids must still follow best practices, perform appropriate hearing test procedures, make appropriate medical referrals for conditions upon inspection or examination of the prospective user's ear canal or case history, and adhere to the respective scopes of practice, as specified under chapters 246-828 WAC and 18.35 RCW.

Statutory Authority for Adoption: RCW 18.35.161.

Statute Being Implemented: RCW 18.35.161.

Rule is necessary because of federal law, 21 C.F.R. Parts 800, 801, 808, and 874 (2022).

Name of Proponent: Board of hearing and speech, governmental.

Name of Agency Personnel Responsible for Drafting, Implementation, and Enforcement: Kim-Boi Shadduck, Program Manager, 111 Israel Road S.E., Tumwater, WA 98501, 360-236-2912.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is not required under RCW 34.05.328. The proposed rule aligns with federal requirements and is exempt under RCW 34.05.328 (5)(b)(iii).

This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:

Is exempt under RCW 19.85.061 because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Citation of the specific federal statute or regulation and description of the consequences to the state if the rule is not adopted: 21 C.F.R. Parts 800, 801, 808, and 874 (2022).

Scope of exemption for rule proposal:

Is fully exempt.

September 15, 2023
Nichole K. Furness, AuD, Chairperson
Board of Hearing and Speech

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, earaches, 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.

[Statutory Authority: 2014 c 189, RCW 18.35.161, 18.130.062, and 18.130.020. WSR 15-14-092, § 246-828-100, filed 6/29/15, effective 7/1/15. Statutory Authority: RCW 18.35.161. WSR 04-02-068, § 246-828-100, filed 1/7/04, effective 2/7/04; WSR 98-06-079, § 246-828-100, filed 3/3/98, effective 4/3/98. Statutory Authority: RCW 18.35.161 (1) and (3). WSR 95-19-017 § 246-828-100, filed 9/7/95, effective 10/8/95. Statutory Authority: RCW 18.35.161. WSR 91-11-031 (Order 165B), recodified as § 246-828-100, filed 5/8/91, effective 6/8/91; WSR 89-04-017 (Order PM 818), § 308-50-130, filed 1/23/89; WSR 84-19-018 (Order PL 478), § 308-50-130, filed 9/12/84; Order PL 159, § 308-50-130, filed 2/8/74.]