



PROPOSED RULE MAKING

CR-102 (July 2022)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

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STATE OF WASHINGTON
FILED

DATE: September 20, 2023

TIME: 11:15 AM

WSR 23-19-102

Agency: Department of Health - Board of Hearing and Speech

Original Notice

Supplemental Notice to WSR

Continuance of WSR

Preproposal Statement of Inquiry was filed as WSR 23-04-023 ; or

Expedited Rule Making--Proposed notice was filed as WSR _____; or

Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or

Proposal is exempt under RCW _____.

Title of rule and other identifying information: (describe subject) Over-the-counter 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 over-the-counter (OTC) hearing aids (21 C.F.R. Parts 800, 801, 808, and 874 (2022)).

Hearing location(s):

Date: November 3, 2023	Time: 10:00 am	Location: (be specific) Physical Location: Labor and Industries 7273 Linderson Way SW Room 117 Tumwater, WA 98501 Virtual Option: Join on your computer, mobile app or room device. Link to join the meeting https://teams.microsoft.com/l/meeting/join/19%3ameeting_ODQxNWEzNzEtYzBkYi00YzlmLWI3NDEtMGYwOTE2MGlzNzI2%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	Comment: The Board of Hearing and Speech will hold a hybrid hearing with both the option to attend in-person or virtually.
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Date of intended adoption: November 3, 2023 (Note: This is **NOT** the effective date)

Submit written comments to:

Name: Kim-Boi Shadduck, Program Manager

Address: Department of Health
PO Box 47852

Assistance for persons with disabilities:

Contact Kim-Boi Shadduck, Program Manager

Phone: (360) 236-2912

<p>Tumwater, WA 98504-7852 Email: https://fortress.wa.gov/doh/policyreview Fax: (360) 236-2901 Other: By (date) October 13, 2023</p>	<p>Fax: TTY: 711 Email: kimboi.shadduck@doh.wa.gov Other: By (date) October 13, 2023</p>
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Purpose of the proposal and its anticipated effects, including any changes in existing rules: The Food and Drug Administration adopted a federal rule regarding the sale of over-the-counter (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 chapter 246-828 WAC and chapter 18.35 RCW.

Statutory authority for adoption: RCW 18.35.161

Statute being implemented: RCW 18.35.161

Is rule necessary because of a:

Federal Law?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Federal Court Decision?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
State Court Decision?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

If yes, CITATION: 21 C.F.R. Parts 800, 801, 808, and 874 (2022)

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None

Type of proponent: Private Public Governmental

Name of proponent: (person or organization) Board of Hearing and Speech

Name of agency personnel responsible for:

Name	Office Location	Phone
Drafting: Kim-Boi Shadduck, Program Manager	111 Israel Rd SE Tumwater, WA 98501	(360) 236-2912
Implementation: Kim-Boi Shadduck, Program Manager	111 Israel Rd SE Tumwater, WA 98501	(360) 236-2912
Enforcement: Kim-Boi Shadduck, Program Manager	111 Israel Rd SE Tumwater, WA 98501	(360) 236-2912

Is a school district fiscal impact statement required under [RCW 28A.305.135](#)? Yes No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:

- Name:
- Address:
- Phone:
- Fax:
- TTY:
- Email:
- Other:

Is a cost-benefit analysis required under [RCW 34.05.328](#)?

Yes: A preliminary cost-benefit analysis may be obtained by contacting:

- Name:
- Address:
- Phone:
- Fax:
- TTY:

Email:

Other:

No: Please explain: The proposed rule aligns with federal requirements and is exempt under RCW 34.05.328(5)(b)(iii).

Regulatory Fairness Act and Small Business Economic Impact Statement

Note: The [Governor's Office for Regulatory Innovation and Assistance \(ORIA\)](#) provides support in completing this part.

(1) Identification of exemptions:

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see [chapter 19.85 RCW](#)). For additional information on exemptions, consult the [exemption guide published by ORIA](#). Please check the box for any applicable exemption(s):

This rule proposal, or portions of 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. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.

Citation and description: 21 C.F.R. Parts 800, 801, 808, and 874 (2022)

This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by [RCW 34.05.313](#) before filing the notice of this proposed rule.

This rule proposal, or portions of the proposal, is exempt under the provisions of [RCW 15.65.570\(2\)](#) because it was adopted by a referendum.

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025\(3\)](#). Check all that apply:

- | | |
|---|---|
| <input type="checkbox"/> RCW 34.05.310 (4)(b)
(Internal government operations) | <input type="checkbox"/> RCW 34.05.310 (4)(e)
(Dictated by statute) |
| <input type="checkbox"/> RCW 34.05.310 (4)(c)
(Incorporation by reference) | <input type="checkbox"/> RCW 34.05.310 (4)(f)
(Set or adjust fees) |
| <input type="checkbox"/> RCW 34.05.310 (4)(d)
(Correct or clarify language) | <input type="checkbox"/> RCW 34.05.310 (4)(g)
(i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit) |

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025\(4\)](#) (does not affect small businesses).

This rule proposal, or portions of the proposal, is exempt under RCW _____.

Explanation of how the above exemption(s) applies to the proposed rule:

(2) Scope of exemptions: Check one.

The rule proposal is fully exempt (*skip section 3*). Exemptions identified above apply to all portions of the rule proposal.

The rule proposal is partially exempt (*complete section 3*). The exemptions identified above apply to portions of the rule proposal, but less than the entire rule proposal. Provide details here (consider using [this template from ORIA](#)):

The rule proposal is not exempt (*complete section 3*). No exemptions were identified above.

(3) Small business economic impact statement: Complete this section if any portion is not exempt.

If any portion of the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

- No Briefly summarize the agency's minor cost analysis and how the agency determined the proposed rule did not impose more-than-minor costs.
- Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses and a small business economic impact statement is required. Insert the required small business economic impact statement here:

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name:

Address:

Phone:

Fax:

TTY:

Email:

Other:

Date: 09/15/23

Name: Nichole Kingham Furness, AuD.

Title: Board of Hearing and Speech, Chairperson

Signature:

A handwritten signature in cursive script that reads "Nichole K. Furness". The signature is written in black ink on a white background.