



# PREPROPOSAL STATEMENT OF INQUIRY

## CR-101 (October 2017) (Implements RCW 34.05.310)

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DATE: January 23, 2023

TIME: 5:20 PM

WSR 23-04-023

**Agency:** Department of Health – Board of Hearing and Speech

**Subject of possible rule making:** Over-the-Counter Hearing Aids. The Board of Hearing and Speech (board) is considering amending WAC 246-828-100 (Hearing instruments fitting and dispensing – Minimum standards of practice) to be consistent with the Food and Drug Administration (FDA) finalized rule regarding the sale of over-the-counter (OTC) hearing aids. The board may also consider clarifying or technical changes as needed.

**Statutes authorizing the agency to adopt rules on this subject:** RCW 18.35.161

**Reasons why rules on this subject may be needed and what they might accomplish:** The board is considering amendments to WAC 246-828-100 to align with recently adopted FDA rule (21 C.F.R. Parts 800, 801, 808, and 874 (2022)). The federal rule established a new category of “over-the-counter” hearing aid which will impact the sale, fitting, and dispensing of hearing aids by those licensed under chapter 246-828 WAC.

**Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies:** Food and Drug Administration (FDA)

**Process for developing new rule (check all that apply):**

- Negotiated rule making
- Pilot rule making
- Agency study
- Other (describe) Collaborative Rule Making

**Interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication by contacting:**

Name: Kim-Boi Shadduck, Program Manager	(If necessary)
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Other:	Web site:
	Other:

**Additional comments:** Interested parties can participate in the drafting of the proposed rules. The board will be conducting rules workshops with interested parties and subject matter experts. The board will use existing GovDelivery lists and other known contact information to inform interested parties of opportunities to provide input on proposed rule language. To find out more information about our rulemaking, visit [www.doh.wa.gov](http://www.doh.wa.gov). To subscribe to GovDelivery, please visit [www.doh.wa.gov](http://www.doh.wa.gov), and select the "Subscribe" button at the bottom of the page, select "Health Professions" and then select "Board of Hearing and Speech" and any other topics you wish to follow.

**Date:** January 23, 2023

**Name:** Jennifer Santiago

**Title:** Executive Director, Office of Health Professions

**Signature:**

A handwritten signature in black ink, appearing to read "Jennifer Santiago", written in a cursive style.