



PREPROPOSAL STATEMENT OF INQUIRY

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

Do NOT use for expedited rule making

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FILED

DATE: August 14, 2023

TIME: 9:28 AM

WSR 23-17-078

Agency: Department of Health

Subject of possible rule making: Behavioral Health Agency (BHA) regulations as they relate to Opioid Treatment Programs (OTPs). The Department of Health (department) is considering amending the BHA regulations related to OTPs in chapter 246-341 WAC, including but not limited to WAC 246-341-0342, 246-341-1000, 246-341-1005, 246-341-1010, 246-341-1015, 246-341-1020 and WAC 246-341-1025 to address general cleanup, incorporate input from partners and interested parties to clarify OTP regulations, remove duplicate requirements, align with federal certification and treatment standards for OTPs in 42 Code of Federal Regulations (C.F.R.) Part 8, Subpart C, and implement Second Engrossed Second Substitute Senate Bill (2E2SSB) 5536 (chapter 1, Laws of 2023 1st Special Session) as it relates to adopting rules for fixed-site medication units to be established as part of a licensed OTP. The department is also taking this opportunity to correct two internal citations from a previous rules project in WAC 246-341-0300 and 246-341-1100.

Statutes authorizing the agency to adopt rules on this subject: RCW 71.24.037 and 2E2SSB 5536 (chapter 1, Laws of 2023 1st Special Session) codified as RCW 71.24.590.

Reasons why rules on this subject may be needed and what they might accomplish: 2E2SSB 5536 amended RCW 71.24.590 to clarify that mobile units or fixed-site medication units may be established as part of a licensed OTP to help expand access to treatment for opioid use disorder. Rules are already in place for mobile units, however, additional rulemaking is needed to develop a process and standards for licensing and approving fixed-site medication units. As part of this rulemaking project, the department will also consider:

- General cleanup to correct terminology and outdated references to federal regulations/guidance documents.
- Aligning rules with federal OTP regulations to streamline OTP licensing and certification requirements.
- Exploring input from partners and interested parties to:
 - Help clarify rules relating to the licensing and certification process, documentation requirements, and counseling expectations.
 - Reduce administrative burdens for agencies by removing duplicate requirements.

Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies: Substance Abuse and Mental Health Administration (SAMHSA), Drug Enforcement Administration (DEA), and the Washington State Health Care Authority (HCA), State Opioid Treatment Authority (SOTA). The department works closely with federal and state partners regarding OTP regulations and will continue to coordinate with them on the revision of this rule.

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

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

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

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(If necessary)

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Additional comments: Interested parties may participate in the development of draft rules prior to a formal proposal by joining the department's interested parties list (GovDelivery), attending workshops, and providing input on draft and proposed materials. To find out more information about our rulemaking and to be included on the interested parties list, please follow these steps: 1) Go to www.doh.wa.gov; 2) Click on the "Sign up for Updates from DOH" button on the bottom of the page; 3) Enter your contact information; 4) Click "Submit"; 5) Under the subscription preferences, check both the "Opioid Treatment Program (OTP)" and "Behavioral Health Care Integration" boxes under the "Health Systems Quality Assurance (HSQA) and "Facilities Licensing and Certificate of Need" headings, as well as the "Behavioral Health Care Integration" heading ; 6) Scroll to the bottom of the page and click "Submit."

Date: 8/14/2023

Name: Kristin Peterson, JD for Umair A. Shah, MD, MPH

Title: Chief of Policy for Secretary of Health

Signature:

