PREPROPOSAL STATEMENT OF INQUIRY

CR-101 (October 2017)
(Implements RCW 34.05.310)
Do **NOT** use for expedited rule making

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DATE: June 10, 2026
TIME: 10:13 AM

WSR 26-13-036

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, to address general cleanup, incorporate input from partners and interested parties, revise requirements for fixed-site medication units (FMUs), and establish standards for emerging dispensing technology.

Statutes authorizing the agency to adopt rules on this subject: RCW 71.24.037 and 71.24.590

Reasons why rules on this subject may be needed and what they might accomplish: Adopting additional FMU licensing and certification standards in rule will help protect patient safety when accessing treatment for opioid use disorder (OUD) in these settings. After more than a year of implementing the FMU rules, the department has determined that additional standards and requirements may be needed. There is currently no cap on the distance or number of medication units that can be attached to an existing OTP. However, the Medical Director and Program Sponsor from the main location are responsible for all associated medication units. With no limit on distance or number of allowed units, there is concern about how many sites they can reasonably oversee. Additional parameters will be considered to help ensure these facilities are sited appropriately and that they have adequate staffing and Medical Director oversight.

In addition to the department's assessment, the Washington state Health Care Authority (HCA) State Opioid Treatment Authority (SOTA), has requested the department to consider rule revisions regarding OTPs in multiple areas, including FMUs as described above, as well as potentially developing standards related to emerging technology for use in an OTP setting. There are currently no state rules related to this topic.

The department will also consider technical amendments to address a general cleanup of OTP rules.

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), the federal 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:

		(If necessary)
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Other:	Other:

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, 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: June 10, 2026 **Name:** Kristin Peterson, JD for Dennis E. Worsham **Title:** Chief of Policy for Secretary of Health	**Signature:**