



RULE-MAKING ORDER PERMANENT RULE ONLY

CR-103P (December 2017) (Implements RCW 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: December 18, 2023

TIME: 12:48 PM

WSR 24-01-098

Agency: Department of Health – Pharmacy Quality Assurance Commission

Effective date of rule:

Permanent Rules

31 days after filing.

Other (specify) _____ (If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

Yes No If Yes, explain:

Purpose: Increasing access to medications used for the treatment of opioid use disorder (OUD) or its symptoms using remote dispensing sites. The 2020 Washington state legislature passed Substitute Senate Bill (SSB) 6086, an act relating to increasing access to medications for people with OUD. This law allows a pharmacy to extend its pharmacy license to a remote dispensing site where technology is used to dispense medications used for the treatment of OUD or its symptoms.

SSB 6086 requires the Pharmacy Quality Assurance Commission (commission) to adopt rules that establish the minimum standards for OUD medication remote dispensing sites. The minimum standards must address who may access medications at the remote dispensing site pursuant to a valid prescription or chart order. The minimum standards must also require that the pharmacy is responsible for stocking and maintaining a perpetual inventory of the OUD medications stored in or at the remote dispensing site (referred to as the “supplying pharmacy” in the rule language).

Current rules in chapter 246-945 WAC cover requirements for drugs stored outside of a pharmacy but restrict their location to a facility that is otherwise able to store and possess drugs (i.e., a licensed pharmaceutical firm). The adopted rule, WAC 246-945-457, is necessary to establish enforceable minimum standards as directed by SSB 6086 for OUD medication remote dispensing sites. As the statute specifically requires rulemaking, no other alternatives were considered.

Citation of rules affected by this order:

New: WAC 246-945-457

Repealed: None

Amended: None

Suspended: None

Statutory authority for adoption: RCW 18.64.005 and Substitute Senate Bill 6086 (chapter 244, Laws of 2020) codified as RCW 18.64.600

Other authority:

PERMANENT RULE (Including Expedited Rule Making)

Adopted under notice filed as WSR 23-16-071 on 7/27/2023 (date).

Describe any changes other than editing from proposed to adopted version: The commission adopted the proposed rule on October 19, 2023 with the additional request to change the phrase “using this registration” to “holding this registration” for the purpose of clarity for affected entities. This is a non-significant change to the rule language.

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

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Other:

**Note: If any category is left blank, it will be calculated as zero.
No descriptive text.**

**Count by whole WAC sections only, from the WAC number through the history note.
A section may be counted in more than one category.**

The number of sections adopted in order to comply with:

Federal statute:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Federal rules or standards:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Recently enacted state statutes:	New	<u>1</u>	Amended	<u>0</u>	Repealed	<u>0</u>

The number of sections adopted at the request of a nongovernmental entity:

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted on the agency's own initiative:

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted using:

Negotiated rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Pilot rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Other alternative rule making:	New	<u>1</u>	Amended	<u>0</u>	Repealed	<u>0</u>

Date Adopted: 12/18/2023

Name: Kenneth Kenyon, PharmD, BCPS

Title: Pharmacy Quality Assurance Commission Chair

Signature:



NEW SECTION

WAC 246-945-457 Remote dispensing sites for opioid use disorder medications. A pharmacy may extend its license to register a remote dispensing site where technology is used to dispense medications used for treatment of opioid use disorder or its symptoms. A pharmacy holding this registration is the supplying pharmacy and must comply with subsections (1) through (5) of this section and all applicable regulations in Title 21 of the Code of Federal Regulations.

(1) The supplying pharmacy must separately register each remote dispensing site with the commission by completing and returning an application form supplied by the commission and pay applicable fees established by the secretary.

(2) Medications stored in registered remote dispensing sites shall remain under the control of, and be routinely monitored by, the supplying pharmacy.

(3) The supplying pharmacy shall develop and implement policies and procedures to:

(a) Prevent and detect unauthorized access to the registered remote dispensing site;

(b) Document medications used, returned, and wasted from the registered remote dispensing site;

(c) Require the supplying pharmacy to perform a perpetual inventory of medications stored at the registered remote dispensing site; and

(d) Ensure that only the supplying pharmacy is stocking medications stored at a registered remote dispensing site.

(4) Access and retrieval of medications from the registered remote dispensing site, other than by the supplying pharmacy, must be:

(a) Pursuant to a valid prescription or chart order; and

(b) Limited to health care professionals licensed under the chapters specified in RCW 18.130.040 who are acting within their scope of practice, and nursing students as provided in WAC 246-945-450.

(5) The supplying pharmacy shall ensure the registered remote dispensing site is appropriately equipped to secure and protect medications from diversion or tampering.