WSR 26-17-010
PERMANENT RULES
DEPARTMENT OF HEALTH
(Pharmacy Quality Assurance Commission)
[Filed August 6, 2026, 8:00 a.m., effective September 6, 2026]

Effective Date of Rule: Thirty-one days after filing.

Purpose: Pharmacy registration for mobile opioid treatment program (OTP) units. The pharmacy quality assurance commission (commission) is adopting amendments for WAC 246-945-060 and 246-945-250 to exempt mobile OTP units from having to obtain separate registrations, as long as they are covered under the OTP site's controlled substance registration, and to incorporate comprehensive facility requirements for facilities that have an other controlled substance registration.

As the rules were previously written, an OTP was required to be licensed by the Washington department of health (department) as a behavioral health agency and register with the commission to obtain an "other controlled substance registration" in order to operate in Washington state and possess controlled substances. Then, if an OTP were to operate a mobile component, they were required to obtain a separate registration and licensure for each mobile component in order to possess controlled substances. In July 2021, the federal Drug Enforcement Agency lifted its moratorium on mobile units, eliminating a separate registration requirement for OTP mobile units by adding a "mobile component" to an OTP's existing registration. The department adopted permanent rules for licensed behavioral health agencies to approve these units as an extension of an existing OTP license and certification, though they must also register with the commission to possess controlled substances by obtaining the "other controlled substance registration."

The adopted rule amends WAC 246-945-060 Other controlled substance registrants—Requirements, and 246-945-250 Researcher and other controlled substance registration, to exempt mobile units from having to register separately with the commission, allowing an OTP to extend its other controlled substances registration to cover its mobile units. The adopted amendments also incorporate comprehensive facility requirements for all other controlled substance registrants, including analytical laboratories and dog handlers, focusing on enhancing drug security and product integrity. These amendments are to align with state and federal regulations and provide clarity to licensees and inspectors regarding the commission's expectations for the controlled substance registration.

Citation of Rules Affected by this Order: Amending WAC 246-945-060 and 246-945-250.

Statutory Authority for Adoption: RCW 18.64.005 and 69.50.302.

Adopted under notice filed as WSR 26-09-118 on April 21, 2026.

A final cost-benefit analysis is available by contacting Haleigh Mauldin, P.O. Box 47852, Olympia, WA 98504-7852, phone 360-236-4946, fax 360-236-2260, TTY 711, email PharmacyRules@doh.wa.gov, website https://doh.wa.gov/licenses-permits-and-certificates/facilities-z/pharmacies-and-pharmaceutical-firms/commission-information.

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 1, Repealed 0; or Recently Enacted State Statutes: New 0, Amended 0, Repealed 0.

Number of Sections Adopted at the Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's own Initiative: New 0, Amended 1, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 2, Repealed 0.

Number of Sections Adopted using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 0, Amended 2, Repealed 0.

Date Adopted: August 6, 2026.

Ann Wolken, PharmD, RPh, Chair
Pharmacy Quality Assurance Commission

RDS-6998.2

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-060 Other controlled substance registrants—Requirements. (1) All persons and firms, except persons exempt from registration, must register with the commission in order to legally possess or use controlled substances.

(2) Persons or firms which are not classified as pharmacies, wholesalers, manufacturers, or researchers will be classified as other controlled substance registrants. Examples of persons or firms in this classification include analytical laboratories, dog handlers/trainers who use dogs for drug detection purposes, school laboratories, opioid treatment programs (OTP), and other agencies which have a legitimate need to use precursor chemicals as defined in WAC 246-945-053.

(3) For the purposes of this section:

(a) "Mobile unit" means a component of an opioid treatment program that the DEA has approved to operate as a mobile narcotic treatment program pursuant to 21 C.F.R. § 1301.13.

(b) "Opioid treatment program(s)" or "OTP(s)" means a behavioral health agency that has been licensed by the department and certified as an opioid treatment program.

(4) The applicant for a controlled substance registration must complete and return an application form supplied by the commission. A list of the controlled substances to be used, the purpose for such use, and the names of the persons authorized to access the controlled substances must be listed on the application or on an addendum. An applicant for a controlled substance registration who is an OTP must also identify any mobile units operated by the agency, if any, in the application or in an addendum.

((~~(4) All controlled substances must be stored in a substantially constructed locked cabinet. The registrant shall maintain records in sufficient detail in order to account for the receipt, use, and disposition of all controlled substances. The registrant shall inventory all controlled substances in the possession of the registrant every two years on the anniversary of the issuances of the registration and shall maintain the inventory list for two years. The registrant shall return unwanted, outdated, or unusable controlled substances to the~~

~~source from which it was obtained or surrendered to the DEA.~~)) (5) An other controlled substance registrant shall:

(a) Ensure all controlled substances are stored in a substantially constructed locked cabinet to prevent unauthorized access;

(b) Maintain records in sufficient detail in order to account for the receipt, use, and disposition of all controlled substances;

(c) Inventory all controlled substances in the possession of the registrant every two years on the anniversary of the issuance of the registration and shall maintain the inventory for two years;

(d) Return unwanted, outdated, or unusable controlled substances to the source from which it was obtained, surrendered to the DEA, or as otherwise permitted by state and federal law; and

(e) Affix a label to every box, bottle, jar, tube, or other container that is dispensed and delivered to an ultimate user that meets the labeling requirements in RCW 69.41.050.

(6) Other controlled substance registrants that are OTPs, who have notified the department that they will be operating a mobile unit must:

(a) Notify the local DEA office and receive explicit written approval from the local DEA office prior to operating the mobile opioid treatment program unit;

(b) Possess valid county/city and Washington state vehicle licensing and registration prior to transporting controlled substances;

(c) Not reverse distribute, share, or transfer controlled substances from one mobile component to another mobile component while deployed away from the registered location;

(d) Establish policies and procedures to ensure, if the mobile unit becomes inoperable, that all controlled substances on the inoperable mobile unit are accounted for, removed, and secured at the registered location of the OTP;

(e) Return to the registered location at the completion of each operation and remove all controlled substances to secure within the registered location; and

(f) Notify the commission of any changes to the information provided on the application, including the addition or removal of a mobile unit.

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-250 Researcher and other controlled substance registration. (1) Applicants for initial registration and renewal for researcher or other controlled substance registrations shall submit to the commission a complete application, as described in WAC 246-945-060(4), with fees relevant to the registration type.

(a) Researcher:

(i) Noncontrolled legend drugs; or

(ii) Researchers requiring to purchase, possess, administer or dispense controlled substances shall apply for a controlled substance authority on its license with the commission and register with the DEA.

(b) Other controlled substance registrations:

(i) Opioid treatment programs;

(ii) Analytical laboratories;

(iii) Dog handler; and

(iv) Other agencies who have demonstrated a legitimate need to use precursor chemicals.

(2) ((~~The application shall:~~

~~(a) List all legend drugs and controlled substances to be used and the purpose for its use;~~

~~(b) Name the primary registrant; and~~

~~(c) List the names of the individuals authorized to access the controlled substances.~~

~~(3) Applicants~~)) An OTP who has notified the department they will be operating a mobile unit pursuant to chapter 246-341 WAC is not required to obtain a separate controlled substance registration for each mobile unit if the OTP's main fixed location has obtained an other controlled substance registration from the commission.

(3) Researcher and other controlled substance registrants shall notify the commission within 30 days of any changes to the information provided on their application.

(4) An applicant for initial registration and closure for researcher and other controlled substance registrations, including when an OTP removes a mobile unit from its registration, shall undergo an ((~~initial~~)) inspection ((~~and~~)). A registrant will be subject to periodic inspections as deemed appropriate by the commission.

(5) Researcher and other controlled substance registrants shall notify the commission and pay an inspection fee, as established in WAC 246-945-990 (5)(a), if any of the following occur:

(a) Changes to structural element(s) such as walls, floors, and load bearing elements that negatively impact security as determined by the registrant;

(b) Changes impacting square footage that negatively impact security as determined by the registrant;

(c) Changes to access to controlled substances that negatively impact security as determined by the registrant;

(d) Changes of location; or

(e) Adding a mobile unit to an OTP registration.

(6) For the purposes of this section:

(a) "Mobile unit" means a component of an opioid treatment program that the DEA has approved to operate as a mobile narcotic treatment program pursuant to 21 C.F.R. § 1301.13.

(b) "Opioid treatment program(s)" or "OTP(s)" means a behavioral health agency that has been licensed by the department and certified as an opioid treatment program.