

**WAC 246-945-410 Facility standards.** A facility must meet the following minimum requirements:

(1) The facility shall be constructed and equipped with adequate security to protect equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use.

(2) The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity.

(3) The facility shall be staffed sufficiently to allow appropriate supervision, operate safely and, if applicable, remain open during posted hours of operation.

(4) The facility shall be adequately stocked to maintain at all times a representative assortment of drugs in order to meet the pharmaceutical needs of its patients in compliance with WAC 246-945-415.

(5) The facility shall designate a responsible pharmacy manager:

(a) By the date of opening; and

(b) Within thirty calendar days of a vacancy.

(6) The facility shall create and implement policies and procedures related to:

(a) Purchasing, ordering, storing, compounding, delivering, dispensing, and administering legend drugs, including controlled substances.

(b) Accuracy of inventory records, patient medical records as related to the administration of controlled substances and legend drugs, and any other records required to be kept by state and federal laws.

(c) Adequate security of legend drugs, including controlled substances.

(d) Controlling access to legend drugs, including controlled substances.

(7) Prescription drugs must only be dispensed pursuant to a valid prescription as required by WAC 246-945-011.

(8) A drug utilization review of each prescription before dispensing and delivery shall occur except in emergent medical situations, or if:

(a) The drug is a subsequent dose from a previously reviewed prescription;

(b) The prescriber is in the immediate vicinity and controls the drug dispensing process;

(c) The medication delivery system is being used to provide access to medications on override and only a quantity sufficient to meet the immediate need of the patient is removed; or

(d) Twenty-four hour pharmacy services are not available, and a pharmacist will review all prescriptions added to a patient's profile within six hours of the facility opening.

(9) Each drug dispensed and delivered to a patient must bear a complete and accurate label as required by WAC 246-945-015 through 246-945-018. The information contained on the label shall be supplemented by oral or written information as required by WAC 246-945-325.

(10) Access to the drug storage area located within the facility should be limited to pharmacists unless one of the following applies:

(a) A pharmacy intern, or pharmacy ancillary personnel enter under the immediate supervision of a pharmacist; or

(b) A pharmacist authorizes temporary access to an individual performing a legitimate nonpharmacy function under the immediate supervision of the pharmacist; or

(c) The facility has a policy and procedure restricting access to a health care professional licensed under the chapters specified in RCW 18.130.040, and the actions of the health care professional are within their scope of practice.

(11) In accordance with RCW 18.64A.060 prior to utilizing pharmacy ancillary personnel a facility shall submit to the commission a utilization plan for pharmacy technicians and pharmacy assistants:

(a) Utilization plan for pharmacy technicians. The application for approval must describe the manner in which the pharmacy technicians will be utilized and supervised, including job descriptions, task analysis or similar type documents that define the duties performed and the conditions under which they are performed, number of positions in each category, as well as other information as may be required by the commission. The commission will be notified of all changes to the utilization plan. A copy of the utilization plan must be maintained in the pharmacy. The utilization plan must comply with WAC 246-945-315 and 246-945-320.

(b) Utilization plan for pharmacy assistants. The application for approval shall list the job title or function of the pharmacy assistant and comply with WAC 246-945-315(3).

(12) A facility's paper prescriptions must be maintained in accordance with WAC 246-945-020 and as follows:

(a) Paper prescriptions for Schedule II drugs must be maintained as a separate file from other prescriptions.

(b) Paper prescriptions for Schedule III, IV, and V drugs must be maintained as a separate file, or maintained in a separate file with prescriptions for noncontrolled legend drugs as allowed under federal law.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-410, filed 6/1/20, effective 7/1/20.]