**WAC 246-945-005 Commission inspections and investigations.** (1) Records subject to commission inspection. A pharmaceutical firm shall make available for inspection upon request by the commission or designee records created, maintained, or retained in compliance with statutes or rules enforced by the commission. It is unlawful to refuse to permit or to obstruct a commission inspection.

(2) Initial inspections. Prior to starting a business, as applicable, and upon presentation of appropriate identification, a pharmaceutical firm shall permit the commission, or its designee, to enter and inspect the premises and to audit the records of each entity for compliance with laws enforced by or under the commission's jurisdiction.

(3) Periodic commission inspection. A pharmaceutical firm is subject to periodic inspections to determine compliance with the laws regulating the practice of pharmacy.

(a) Statement of deficiency.

(i) At the end of the inspection, the commission, or its designee, will conduct an exit meeting with the responsible pharmacy manager, or designee, or equivalent manager, addressing unresolved deficiencies identified during the inspection.

(ii) The commission, or its designee, shall provide a written statement of deficiency to the pharmaceutical firm within ten business days of the exit meeting.

(iii) The statement of deficiency may include unresolved deficiencies identified at the end of a periodic commission inspection, describing the unresolved deficiencies in detail with a reference to all applicable laws.

(b) Plan of correction. A pharmaceutical firm shall submit a plan of correction to the commission, or its designee, addressing each identified unresolved deficiency within ten business days of receipt of a statement of deficiency.

(i) The commission, or its designee, shall notify the pharmacy within ten business days, whether or not a submitted plan of correction adequately addresses the unresolved deficiencies identified in the statement of deficiency.

(ii) Implementation of the corrective action is required within the time frames set in the approved plan of correction, and are subject to verification by the commission, or its designee, which may require the pharmacy to submit a progress report(s) attesting to the correction of deficiencies, or a follow-up inspection.

(c) Pharmaceutical firms with deficiencies that represent an imminent or immediate risk or threat to public health, safety, or welfare may be subject to summary suspension of the pharmacy license, at the discretion of the commission.

(4) Self-inspections. The responsible pharmacy manager, or equivalent manager, is required to conduct an annual self-inspection of the pharmaceutical firm on the self-inspection worksheet(s) provided by the commission. The self-inspection must be completed within the month of March each year.

(a) The responsible pharmacy manager, or equivalent manager, shall sign and date the completed self-inspection worksheet(s), and maintain completed worksheets for two years from the date of completion.

(b) When a change in responsible pharmacy manager, or equivalent manager occurs, the new responsible pharmacy manager, or equivalent manager, shall conduct a self-inspection as required under this section. The new responsible pharmacy manager, or equivalent manager,

shall sign and date the self-inspection worksheet(s) within thirty days of becoming responsible pharmacy manager, or equivalent manager, and maintain completed worksheets for two years from the date of completion.

(5) Inspection informal dispute process.

(a) A pharmaceutical firm may dispute within ten business days:

(i) Any or all deficiencies included on a statement of deficiency issued by the commission;

(ii) The rejection of the first submitted plan of correction;

(iii) The pharmaceutical firm may request a one-time extension.

(b) A pharmaceutical firm shall submit a dispute under this subsection to the commission in writing. The dispute must be in detail and include any supporting documentation for commission consideration.

(c) The commission may review and consider a second rejection of a plan of correction.

(d) The commission shall consider any dispute and notify the pharmaceutical firm of its determination.

(6) Investigations. A pharmaceutical firm shall cooperate with commission investigations conducted to confirm compliance with laws enforced by the commission, to gather information pertinent to a complaint received by the commission, or to enforce disciplinary actions.

[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, § 246-945-005, filed 6/1/20, effective 7/1/20.]