



RULE-MAKING ORDER EMERGENCY RULE ONLY

CR-103E (August 2017) (Implements RCW 34.05.350 and 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: August 10, 2017

TIME: 4:12 PM

WSR 17-17-048

Agency: Department of Health – Pharmacy Quality Assurance Commission

Effective date of rule:

Emergency Rules

- Immediately upon filing.
- Later (specify)

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

- Yes
 - No
- If Yes, explain:

Purpose: Chapter 246-873A WAC Hospital Pharmacy Associated Clinics. The Pharmacy Quality Assurance Commission (commission) is establishing standards supporting the regulatory, inspection, and investigation of pharmacy services provided in individual practitioner offices and multi-practitioner clinics owned and operated by a hospital based on a level of risk and the type of pharmacy services provided at a particular location. This filing replaces emergency rules filed as WSR 17-09-025 on April 12, 2017.

Citation of rules affected by this order:

New: WAC 246-873A-010, WAC 246-873A-020, WAC 246-873A-030, WAC 246-873A-040, WAC 246-873A-050, WAC 246-873A-060, WAC 246-873A-070, WAC 246-873A-080, WAC 246-873A-090, WAC 246-873A-095

Repealed: None

Amended: None

Suspended: None

Statutory authority for adoption: RCW 18.64.005

Other authority: Substitute Senate Bill 6558 (Chapter 118, Laws of 2016)

EMERGENCY RULE

Under RCW 34.05.350 the agency for good cause finds:

- That immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.
- That state or federal law or federal rule or a federal deadline for state receipt of federal funds requires immediate adoption of a rule.

Reasons for this finding: Substitute Senate bill 6558 amended RCW 18.64.043 directing the commission to adopt emergency rules to implement the bill and to keep the emergency rules in effect until permanent rules are adopted. The standards in this emergency rule have not changed from the previous emergency rule. The commission has filed a preproposal statement of inquiry, WSR 16-16-025, and has initiated stakeholder work on developing proposed rules.

**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>10</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>10</u>	Amended	<u>0</u>	Repealed	<u>0</u>

Date adopted: August 10, 2017

Name: Tim Lynch, PharmD, MS

Title: Chair, Pharmacy Quality Assurance Commission

Signature:



**Chapter 246-873A WAC
HOSPITAL PHARMACY ASSOCIATED CLINICS**

NEW SECTION

WAC 246-873A-010 Definitions. The definitions in this section apply throughout this chapter, unless the context clearly indicates otherwise:

(1) "Clinic" means a facility that is established primarily to furnish outpatient health care services by an individual or group of practitioners.

(2) "Commission" means the Washington state pharmacy quality assurance commission.

(3) "Compounding" means the preparation or combining of any two or more active ingredients or components into a drug product as the result of a practitioner's prescription drug order or initiative based on the practitioner, patient, and pharmacist relationship in the course of professional practice or for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing. Compounding also includes the preparation of drugs in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns. Compounding does not include mixing, reconstituting or other such acts that are performed in accordance with the directions contained in approved labeling provided by the product's manufacturer.

(4) "Hospital pharmacy associated clinic" or "HPAC" means an individual practitioner's office or multipractitioner clinic owned, operated, or under common control of a parent hospital or health system, where the physical address of the office or clinic is identified on a hospital pharmacy license.

(5) "Parent hospital pharmacy" means a hospital pharmacy licensed under chapter 70.41 RCW, adding hospital pharmacy associated clinics to their hospital pharmacy license in accordance with chapter 18.64 RCW and this chapter.

(6) "Practice of pharmacy" shall have the same meaning as RCW 18.64.011.

(7) "Practitioner" has the same meaning as RCW 18.64.011, and those individuals authorized to possess drugs.

(8) "Prescription" has the same meaning as RCW 18.64.011.

(9) "Responsible manager" has the same meaning as WAC 246-869-070.

(10) "Transfer" means to move drugs from the parent hospital pharmacy to the hospital pharmacy associated clinic.

NEW SECTION

WAC 246-873A-020 Hospital pharmacy associated clinic—Licensing.

(1) New hospital pharmacy license. A parent hospital pharmacy applying

for a new hospital pharmacy license or submitting a change in hospital ownership must:

(a) Submit a full application to the department and identify any HPACs to be included under the hospital pharmacy license, along with the applicable fees established under WAC 246-907-030 and 246-907-040; and

(b) Pass an inspection by a commission pharmacist investigator in accordance with this chapter.

(2) Current hospital pharmacy license holders. The parent hospital pharmacy must notify the commission in writing of any change of HPAC ownership, location of HPACs, and addition or removal of HPACs from the parent hospital pharmacy license.

(a) Adding HPACs. A parent hospital pharmacy may add HPACs on a hospital pharmacy license at any time and must file a hospital pharmacy license addendum with the commission along with applicable fees set forth in WAC 246-907-0302. Added HPACs are subject to inspection in accordance with this chapter.

(b) Removing HPACs. A parent hospital pharmacy removing HPACs from the parent hospital pharmacy license must comply with WAC 246-873A-095.

(3) HPAC locations are identified as follows:

(a) Category 1 HPAC: Receives drugs transferred from the parent hospital pharmacy to the HPAC, and does not perform sterile or non-sterile compounding of drugs. This does not infer that pharmaceutical services are provided at this location.

(b) Category 2 HPAC: Receives drugs transferred from the parent hospital pharmacy to the HPAC, and performs sterile or nonsterile compounding of drugs.

(4) A HPAC licensed under the parent hospital pharmacy license must obtain a Drug Enforcement Administration (DEA) registration for purposes of possessing controlled substances.

NEW SECTION

WAC 246-873A-030 Responsible manager. The responsible manager shall comply with the requirements of WAC 246-873-080 (3), (4), (7) and (8).

NEW SECTION

WAC 246-873A-040 Physical requirements of a HPAC. Physical requirements must be consistent with the applicable subsections of WAC 246-873-070 according to the HPAC category type.

NEW SECTION

WAC 246-873A-050 HPAC drug transfer and control. The following apply to both Category 1 and Category 2 HPACs:

(1) General drug transfer. A licensed hospital pharmacy is permitted without a wholesaler license to engage in intracompany sales, being defined as any transaction or transfer between any division, subsidiary, parent company, affiliated company, or related company under common ownership and control of the corporate entity;

(2) Patient specific drugs. A licensed hospital pharmacy dispensing appropriately labeled, patient specific drugs to a HPAC licensed under the parent hospital pharmacy may do so only pursuant to a valid patient order or prescription and the order or prescription information is authenticated in the medical record of the patient to whom the legend drug or controlled substance will be provided according to the policy and procedures of the parent hospital pharmacy.

(3) Storage. The parent hospital pharmacy's policy and procedures must specify HPAC drug storage parameters consistent with WAC 246-869-150.

(4) Drug samples. Nothing in this chapter prohibits a practitioner from dispensing drug samples in accordance with state and federal laws and regulations.

(5) Controlled substance accountability. The responsible manager of the parent hospital pharmacy must include accountability standards of controlled substances consistent with WAC 246-873-080(7) in the HPAC policies and procedures.

(6) Drug recall. A recall procedure must be in place to assure that potential harm to patients within a HPAC is prevented and that all drugs included on the recall are returned to the parent hospital pharmacy for proper disposition.

NEW SECTION

WAC 246-873A-060 Labeling. (1) Labels on medications dispensed to HPAC patients, including drug samples, must meet the requirements of RCW 69.41.050. This does not apply to HPAC administered medications.

(2) Parenteral and irrigation solutions in Category 2 HPACs. When drugs are added to intravenous solutions, a suitable label shall be affixed to the container and at a minimum should include the following:

- (a) The name of the patient;
- (b) Name and amount of drug(s) added;
- (c) Beyond use date; and
- (d) Initials of the personnel who prepared and checked the solution.

NEW SECTION

WAC 246-873A-070 Records. All transaction and inventory records must be maintained in compliance with applicable sections in chapter 246-875 WAC according to the HPAC category type.

NEW SECTION

WAC 246-873A-080 Administration of drugs. (1) Drugs administered in a HPAC shall only be administered by Washington state credentialed personnel, acting within their scope of practice, in accordance with state and federal laws and regulations governing such acts.

(2) Drugs must be administered only upon the valid order of a practitioner, as defined in RCW 69.50.101, who is licensed to prescribe legend drugs or controlled substances and who has been granted clinical privileges to write such orders.

(3) All medications administered to HPAC patients must be recorded in the patient's medical record.

NEW SECTION

WAC 246-873A-090 Inspections of HPAC. The commission shall conduct inspections of HPACs in conjunction with associated hospital pharmacy inspections under WAC 246-869-190 and consistent with WAC 246-869-110. All deficiencies shall be noted on the hospital pharmacy inspection form.

(1) A representative sample of Category 1 HPACs not performing compounding are subject to inspection as determined by the commission investigator. Category 1 HPACs will be inspected to the standards established in this chapter.

(2) All Category 2 HPACs performing on-site sterile or nonsterile compounding will be inspected. Category 2 HPACs will be inspected to standards established in this chapter, RCW 18.64.270, and chapter 246-878 WAC.

NEW SECTION

WAC 246-873A-095 Removal of HPAC from a hospital pharmacy license. (1) The parent hospital pharmacy shall notify the commission of the removal of a HPAC from the hospital pharmacy license no later than fifteen days prior to the anticipated date of removal or closing of the HPAC. This notice must be submitted in writing and shall contain all of the following information:

(a) The date the HPAC will no longer be listed under the parent hospital pharmacy;

(b) The names and addresses of the person(s) who will have custody of the prescription files, the repackaging records, and the controlled substances inventory records of the HPAC being removed from the parent hospital pharmacy license or closed; and

(c) The names and addresses of any persons who will acquire any of the legend drugs, including controlled substances, from the HPAC.

(2) A written statement containing the following information must be filed with the commission no later than fifteen days after the planned removal of the HPAC:

(a) Confirmation that all legend drugs have been transferred to an authorized person(s) or destroyed. If the legend drugs were trans-

ferred, the names and addresses of the person(s), or alternate HPAC location(s) to whom they were transferred;

(b) If controlled substances were transferred, a list of the name(s) and address (or addresses) of the DEA registrant(s) to whom the substances were transferred, the substances transferred, the amount of each substance transferred, and the date on which the transfer took place;

(c) Confirmation that the DEA registration and all unused DEA 222 forms (order forms) were returned to the DEA;

(d) Confirmation that all labels and blank prescriptions in the possession of the HPAC were destroyed or otherwise accounted for; and

(e) Confirmation that all signs and symbols indicating the ownership or affiliation to the parent hospital pharmacy have been removed.