

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

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**WAC 246-873A-010      Definitions**

The following definitions apply throughout this chapter, unless the context clearly indicates otherwise:

- (1) “Commission” means the Washington state pharmacy quality assurance commission.
  - (2) “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.
  - (3) “Hospital pharmacy associated clinic” or “HPAC” means an individual practitioner’s office or multipractitioner clinic identified on a hospital pharmacy license and owned, operated, or under common control of the parent hospital.
  - (4) “Parent hospital pharmacy” means a hospital pharmacy licensed under chapter 70.41 RCW adding hospital associated clinics to their hospital pharmacy license in accordance with RCW 18.64.043.
  - (5) “Practice of pharmacy” shall have the same meaning as RCW 18.64.011.
  - (6) “Prescription” means an order for drugs or devices issued by a practitioner duly authorized by law or rule in the state of Washington to prescribe drugs or devices in the course of his or her professional practice for a legitimate medical purpose.
  - (7) “Transfer” means to move drugs from the parent hospital pharmacy to the hospital pharmacy associated clinic.
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**WAC 246-873A-020            Hospital Pharmacy Associated Clinic – Licensing**

- (1) For a HPAC to be deemed licensed under the parent hospital pharmacy license, the facility must:
    - (a) Submit an application along with the applicable fees set forth in WAC 246-907-030 and WAC 246-907-040; and
    - (b) Pass an inspection by a commission pharmacist investigator.
  - (2) The parent hospital pharmacy must notify the commission in writing of any change of ownership, location of clinic, and addition or removal of a clinic(s) from the parent hospital pharmacy license.
    - (a) A parent hospital pharmacy adding clinic locations on the pharmacy license must file an amended hospital pharmacy application with the commission along with applicable fees set forth in WAC 246-907-030.
    - (b) A parent hospital pharmacy removing clinic locations from the parent hospital pharmacy license must comply with WAC 246-873A-095.
  - (3) Clinic locations are identified as follows:
    - (a) **Category 1 HPAC:** receives drugs transferred from the parent hospital pharmacy to the clinic, and does not perform sterile or non-sterile compounding of drugs.
    - (b) **Category 2 HPAC:** receives drugs transferred from the parent hospital pharmacy to the clinic, and performs sterile or non-sterile compounding of drugs.
  - (4) A HPAC deemed licensed under the parent hospital pharmacy license does not replace the need for a Drug Enforcement Administration (DEA) registration for purposes of possessing or transferring controlled substances.
  - (5) Any clinic not included as part of a parent hospital pharmacy license must be licensed as a separate entity by the pharmacy quality assurance commission, if drugs are being transferred from the hospital pharmacy to the clinic, or sterile or non-sterile compounding is occurring by a practitioner consistent with their scope of practice.
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**WAC 246-873A-030            Director of Pharmacy**

- (1) The director of pharmacy for the parent hospital pharmacy or their appointed designee, who is a pharmacist licensed in the state of Washington, shall be responsible for:
    - (a) Creating and implementing applicable policy and procedures relating to:
      - (i) Purchasing, ordering, storing, transferring, or administering of controlled substances or legend drugs.
      - (ii) 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 regulations.
      - (iii) Adequate security of legend drugs and controlled substances, including but not limited to controlling access to all drugs.
    - (b) A monthly inspection of the HPAC where medications are administered or stored. Monthly inspection reports must be maintained for two years at the parent hospital pharmacy.
    - (c) In addition for a Category 2 HPAC, the director of pharmacy shall:
      - (i) Establish, annually review, and update comprehensive written policies and procedures governing the responsibilities and functions related to sterile and non-sterile compounding.
      - (ii) Establishing specifications for procurement, transfer and the Maintenance of a system of accountability for drugs, IV solutions, chemicals and biologicals related to the practice of pharmacy.
      - (iii) Ensure that all sterile and nonsterile compounded products are prepared in accordance with RCW 18.64.270(2).
  - (2) It is the joint responsibility of the director of pharmacy and the clinic manager to ensure that the drug handling, security, preparation and storage are carried out in conformance with the established policies and procedures.
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**WAC 246-873A-040      Physical requirements of a HPAC**

- (1) Physical requirements for a Category 1 HPAC shall include:
    - (a) Appropriate transportation and communications systems for the transfer and control of drugs within the HPAC.
    - (b) Sufficient space and equipment for secure, environmentally controlled storage of drugs and other pharmaceutical supplies that ensures that all drugs will be stored under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security.
    - (c) All flammable material must be stored and handled in accordance with applicable local and state fire regulations, and there must be written policy and procedures for the destruction of these flammable materials.
  - (2) Physical requirements for a Category 2 HPAC shall include:
    - (a) Requirements set forth under subsection (1) above;
    - (b) In order to meet the medical services need for drugs within the Category 2 HPAC, the on-site sterile compounding clinic pharmacy shall include:
      - (i) Space for the management and clinical functions of the pharmaceutical service;
      - (ii) Space and equipment for the preparation of parenteral admixtures and other sterile or non-sterile compounding and packaging; and
      - (iii) Other equipment necessary.
    - (c) Any area within the Category 2 HPAC, designated as the on-site sterile compounding pharmacy, shall maintain adequate security in order to deter diversion of drugs by personnel or the public and prevent access by unauthorized personnel. Compounding services by licensed pharmacy personnel, including infusion and parenteral products, shall occur only when a licensed pharmacist is present and in accordance with RCW 18.64.270(2). The director of pharmacy of the parent hospital pharmacy shall, if necessary, maintain a list, by title and position those individuals who shall have authorized access to the on-site sterile compounding pharmacy.
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**WAC 246-873A-050            HPAC drug transfer and control**

The following apply to both Category 1 and Category 2 HPACs:

- (1) 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, unless the transfer occurs between a wholesale distributor and a health care entity or practitioner.
- (2) A licensed hospital pharmacy transferring 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 shall 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.** Policies and procedures shall establish accountability standards of controlled substances, and such other drugs as appropriate, in compliance with state and federal laws and regulations, that include, but are not limited to:
  - (a) Complete, accurate, and current records must be kept of receipt of all controlled substances and in addition, the HPAC shall maintain a perpetual inventory of Schedule II controlled substances.
  - (b) The parent hospital pharmacy shall maintain records of Schedule II drugs transferred from the parent hospital pharmacy to the HPAC, records shall include:
    - (i) Date
    - (ii) Name of drug(s)
    - (iii) Amount of drug(s) issued
    - (iv) Name and/or initials of the pharmacist who issued the drug

- (v) Name of the DEA registrant receiving the drug(s).
- (c) Procedures for the proper destruction of controlled substances for the HPAC that conform to state and federal laws and regulations. A copy of procedures must be forwarded to the DEA and the commission. At a minimum, procedures shall include the following:
  - (i) All destructions shall render the drugs unrecoverable.
  - (ii) Destruction must be accomplished by the pharmacist and one other licensed health professional.
  - (iii) The parent hospital pharmacy and the HPAC must maintain records of all destructions. Quarterly summary reports must be mailed to the DEA with copies to the commission.
  - (iv) The parent hospital pharmacy and the HPACX must maintain a copy of the destruction record for two years.
- (d) All controlled substance records must be kept for two years.
- (e) A HPAC wishing to use record systems other than that used by the parent hospital pharmacy must submit an application to and receive approval from the commission prior to implementation.
- (f) Significant losses or disappearance of controlled substances and the facts surrounding the discrepancy must be reported to the commission, the DEA, the chief executive officer of the hospital and other appropriate authorities as required by state and federal law.
- (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.

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**WAC 246-873A-051      Category 2 HPAC pharmaceutical services**

- (1) Category 2 HPAC pharmaceutical services shall include:
  - (a) Preparation, storage, and control of all drugs throughout the HPAC.
  - (b) Monitoring of drug therapy.
  - (c) Provisions for drug information to patients, physicians, and other.

- (d) Surveillance and reporting of adverse drug reactions and drug product defect(s).
  - (e) Obtaining and recording comprehensive drug histories.
  - (f) Preparation of all sterile products (e.g. IV admixtures, piggybacks, irrigation solutions, parenteral solutions).
  - (g) Administration of drugs.
  - (h) Prescribing.
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**WAC 246-873A-060      Labeling**

- (1) Labels on medications used for clinic patients, including drug samples dispensed to patients, shall meet the requirements of RCW 18.64.246.
  - (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 in accordance with WAC 246-873-080(5)(c). At a minimum the label shall indicate:
    - (a) The name of the patient
    - (b) Name and amount of drug(s) added;
    - (c) Appropriate dating; and
    - (d) Initials of the personnel who prepared and checked the solution.
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**WAC 246-873A-070      Records**

All transaction and inventory records shall be maintained in accordance with WAC 246-873-080 and chapter 246-875 WAC.

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**WAC 246-873A-080      Administration of drugs**

- (1) Drugs must be administered only upon the 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. Verbal orders for drugs shall only be issued in emergency or unusual circumstances and can only be accepted by a licensed nurse, pharmacist, or physician, and must be immediately recorded and signed by the person receiving the order. Such orders must be authenticated by the prescribing practitioner within 48 hours.

- (2) All medications administered to clinic patients must be recorded in the patient's medical record.
  - (3) Drugs administered in a HPAC shall only be administered by licensed personnel in accordance with state and federal laws and regulations governing such acts and in accordance with medical staff approved by hospital policy.
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**WAC 246-873A-090            Inspections of HPAC**

- (1) The commission shall conduct inspections of HPACs in conjunction with associated hospital pharmacy inspections. All deficiencies shall be noted on the hospital pharmacy inspection form along with associated point deductions or plan of correction. The director of pharmacy shall correct all deficiencies associated with the HPAC.
  - (a) A representative sample of Category 1 HPACs not performing compounding or providing infusion services are subject to inspection as determined by the commission investigator. Category 1 HPACs will be inspected to the standards set forth in this chapter.
  - (b) All Category 2 HPACs performing on-site sterile or non-sterile compounding and Category 1 HPACs providing infusion services are subject to inspection. Category 2 HPACs will be inspected to standards set forth in this chapter, RCW 18.64.270, and chapter 246-878 WAC.
- (2) The refusal to permit an authorized commission representative to examine the premises, inventory, or records relating to drugs of the HPAC, during normal business hours constitutes grounds for disciplinary action on the parent hospital's pharmacy license and that of the Director of Pharmacy

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**WAC 246-873A-095            Removal of clinic 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 (15) days prior to the anticipated date of removal or closing of the clinic site. This notice must be submitted in writing and shall contain all of the following information:

- (a) The date the clinic 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 (15) days after the planned removal of the clinic site:
- (a) Confirmation that all legend drugs have been transferred to an authorized person(s) or destroyed. If the legend drugs were transferred, 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.