**OPERATIONAL STANDARDS**

**PART 1 – PHARMACIES, HEALTH CARE ENTITIES, AND HOSPITAL PHARMACY ASSOCIATED CLINICS**

**WAC 246-960-005 Definitions**

The definitions in RCW 18.64.011 and WAC 246-945-010 apply throughout this chapter unless the context clearly requires otherwise.

**WAC 246-960-006 Responsibility for Compliance**

The responsible pharmacy manager, all pharmacy credentialed personnel, and the pharmacy each have corresponding and individual responsibility for compliance with applicable state and federal laws and these rules.

**WAC 246-960-010 – Applicability.**

1. The rules in this section apply to pharmacies as defined in RCW 18.64.011(26), health care entities as defined in RCW 18.64.011(15), and hospital pharmacy associated clinics as defined in WAC 246-945-010.
2. Unless the context clearly requires otherwise, the term facility as used in this section includes pharmacies as defined in RCW 18.64.011(26), health care entities as defined in RCW 18.64.011(15), and hospital pharmacy associated clinics as defined in WAC 246-945-010.

**WAC 246-960-020 – Minimum Standards**

1. The facility must 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 must be properly equipped to ensure the safe, clean, and sanitary condition necessary and appropriate for proper operation, the safe preparation of prescriptions, and to safeguard product integrity.
3. The facility must be staffed sufficiently to allow appropriate supervision, to otherwise operate safely and, if applicable, to remain open during posted hours of operation.
4. The facility shall designate a responsible pharmacy manager
	1. There must be designated responsible pharmacy manager by the date of opening.
	2. Must not allow a vacancy of a designated responsible pharmacy manager to continue for more than thirty 30 calendar days and must be reported in compliance with WAC 246-960-170.
	3. A person may neither be designated nor function as a responsible pharmacy manager for more than three pharmacies concurrently. This limitation does not apply to health care entities licensed under RCW 18.64.450.
5. Prescription drugs must only be dispensed pursuant to a valid prescription as set forth in WAC 246-945-200.
6. Drug utilization review of each prescription drug order shall occur except in emergent medical situations, or if:
	1. The drug is a subsequent dose from a previously reviewed drug order;
	2. The prescriber is in the immediate vicinity and controls the drug dispensing process;
	3. The 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;
	4. When twenty-four hour pharmacy services are not available, a pharmacist shall review all medication orders added to a patient's profile within six hours of opening.
7. Each drug dispensed and delivered to a patient must bear a complete and accurate label as set forth in WAC 246-945-070 through WAC 246-945-090 and the information contained on the label shall be supplemented by oral or written information as required by WAC 246-955-045.
8. Access to the drug storage area located within the facility should be limited to pharmacists unless one of the following applies:
	1. A pharmacy intern, pharmacy technician and pharmacy assistant enter the facility’s drug storage area under the immediate supervision of a pharmacist, or
	2. A pharmacist authorizes temporary access to the drug storage area to an individual performing a legitimate non-pharmacy function under the immediate supervision of pharmacist, or
	3. The facility has a policy and procedure restricting access to the facility’s drug storage area to title 18 credentialed individuals, issued by the Department, within their scope.
9. A facility’s paper prescriptions must be maintained in accordance with WAC 246-945-120(4) and as follows:
	1. Paper prescriptions for Schedule II drugs must be maintained as a separate file from other prescription drugs orders.
	2. Paper prescriptions for Schedule III, IV, and V drugs must be maintained as a separate file, or maintained in a separate file with prescription drug orders for non-controlled prescription drugs as allowed under federal law.

**WAC 246-960-025 Minimum Standards for Dispensing and Delivering of Prescription Drugs**

1. A pharmacy may deliver filled prescriptions as long as appropriate measures are taken to ensure product integrity and receipt by the patient or patient’s agent.
2. Filled prescriptions may be picked up or returned for delivery by authorized personnel when the pharmacy is closed for business if the prescriptions are placed in a secured delivery area outside of the restricted drug storage area. Provided the area is a part of a licensed pharmacy, and equipped with adequate security, including an alarm or comparable monitoring system, to prevent unauthorized entry, theft or diversion under the policies and procedures developed by the responsible pharmacy manager.
3. HCEs must dispense in accordance with RCW 18.64.450.

**WAC 246-960-030 – Electronic Systems for Patient Medication Records, Prescriptions, Chart Orders, and Controlled Substance Records**

1. A pharmacy must use an electronic recordkeeping system to establish and store patient medication records and prescription drug order, refill, transfer information, and other information necessary to provide safe and appropriate patient care.
2. The electronic recordkeeping system must be capable of real-time, online retrieval of information, and have functionality that allows refill data to be readily retrievable and produced upon request.
3. The electronic recordkeeping system must have audit trail functionality that documents for each prescription drug order the identity of each individual involved at each step of its processing, fulfillment, and dispensing or, alternatively, the identity of the pharmacist responsible for the accuracy of these processes.
	1. Systems must prevent auto-population of user identification information.
	2. Pharmacies that utilize offsite pharmacy services for product fulfillment or prescription processing must track the identity of each individual involved in each step of the offsite pharmacy services.
4. The electronic recordkeeping system must include security features to protect the confidentiality and integrity of patient records including:
5. Safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription drug order information and patient medication records; and
6. Functionality that documents any alteration of prescription drug order information after a prescription drug order is dispensed, including the identification of the individual responsible for the alteration.
7. The pharmacy must have policies and procedures in place for system downtime.
8. The pharmacy shall maintain records in accordance with WAC 246-945-120.
9. Electronic prescriptions for prescription drugs must be maintained in a system that meets the requirements of 21 C.F.R. § 1311.
10. HCE's or HPAC’s that maintain an electronic record system must be done in accordance with (2)-(7)

**WAC 246-960-040 – Facility Inventory Requirements**

1. A facility shall conduct its own separate inventory of prescription drugs when it closes.
2. A facility shall conduct its own separate inventory of controlled substances in the following situations:
	1. The incoming responsible pharmacy manager, or designee, must conduct a complete controlled substance inventory, within thirty (30) days of becoming the responsible pharmacy manager.
	2. On the effective date of an addition of a substance to a schedule of controlled substances, each facility that possesses the substance shall take an inventory of the substance on hand, and thereafter, include the substance in each inventory.

(3) A pharmacy that stores, dispenses and/or delivers controlled substances without a pharmacist onsite shall maintain a perpetual inventory.

(4) A pharmacy that stores, dispense and/or delivers prescription drugs without pharmacy staff physically on site shall maintain a perpetual inventory.

**WAC 246-960-050 –Shared Pharmacy Services**

Pharmacy services may be provided offsite at one (1) or more locations. When the services being performed are related to prescription fulfillment or processing, the pharmacy or pharmacist must comply with the following:

1. The originating pharmacy must have written policies and procedures outlining the offsite pharmacy services to be provided by the central pharmacy, or the offsite pharmacist or pharmacy technician, and the responsibilities and accountabilities of each party.
2. The parties must share a secure real-time database or utilize other secure technology, including a private, encrypted connection that allows access by the central pharmacy or offsite pharmacist or pharmacy technician to the information necessary to perform offsite pharmacy services.
3. A single prescription drug order may be shared by an originating pharmacy and a central fill pharmacy or offsite pharmacist or pharmacy technician. The fulfillment, processing and delivery of a prescription drug order by one pharmacy for another pursuant to this section will not be construed as the fulfillment of a transferred prescription or as a wholesale distribution.

**WAC 246-960-080 – Pharmacies Storing, Dispensing and Delivering Drugs to Patients Without a Pharmacist Physically On-site**

1. The pharmacy must maintain visual surveillance with an adequate number of views of the full pharmacy and retain a high quality recording for a minimum of thirty (30) calendar days.
2. Access to pharmacy by individuals must be limited, authorized and regularly monitored.
3. A visual and audio communication system used to counsel and interact with each patient or patient’s caregiver, must be clear, secure, and HIPAA compliant.
4. The responsible pharmacy manager, or designee, must complete and retain, in accordance WAC 246-945-030 (General Provisions), a monthly in-person inspection of the pharmacy.
5. A pharmacist must be capable of being on site at the pharmacy within three (3) hours if an emergency arises.
6. The pharmacy must be closed to the public if any component of the surveillance or visual and audio communication system is malfunctioning, and remain closed until system corrections or repairs are completed or a pharmacist is on site to oversee pharmacy operations.

**WAC 246-960-090 Provision of emergency department discharge medications when pharmacy services are unavailable.**

The responsible pharmacy manager of a hospital or free standing emergency department may, in collaboration with the appropriate medical staff committee of the hospital, develop policies and procedures in compliance with RCW [70.41.480](http://app.leg.wa.gov/RCW/default.aspx?cite=70.41.480) which must be implemented to provide discharge medications to patients released from hospital emergency departments during hours when community or outpatient hospital pharmacy services are not available. The delivery of a single dose for immediate administration to the patient is not subject to this regulation. Such policies shall allow the practitioner or registered nurse to distribute medications, pursuant to the policies and procedures, as specified in RCW [70.41.480](http://app.leg.wa.gov/RCW/default.aspx?cite=70.41.480) and the following:

(1) An order of a practitioner authorized to prescribe a drug is presented. Oral or electronically transmitted orders must be verified by the practitioner in writing within seventy-two hours.

 (2) The medications distributed as discharge medications must be stored in compliance with the laws concerning security and access. They must be stored in or near the emergency department in such a manner as to preclude the necessity for entry into the pharmacy when pharmacy services are not available.

**WAC 246-960-100 Administration of Patient Owned Medications.**

Facilities shall develop written policies and procedures for the administration of patient owned medications.

(1) Patient owned medications shall be administered only when there is a written order by a practitioner. Prior to use, such medications shall be identified and examined by the pharmacist to ensure acceptable quality for use in the facility.

(2) Patient owned medications which are not used during the patient's admittance to the facility shall be packaged and sealed, stored in the facilities locked drug storage area until discharge or given to the patient's family.

(3) Return of patient owned medications may be prohibited due to possible jeopardy of the patient's health and documented in the patients’ health record.

(4) Written procedures shall be developed for the disposal of unreturned patient owned medications.

**WAC 246-960-110 Investigational drugs.**

(1) Distribution. Storage, distribution, and control of approved investigational drugs used in an institutional setting shall be the responsibility of the responsible pharmacy manager or their designee. The pharmacy shall be responsible for maintaining and providing information on approved investigational drugs.

(2) General. Investigational drugs shall be properly labeled and stored for use only under the explicit direction of the authorized principal investigator, or coinvestigator(s), or per study protocol requirements. Use of such drugs shall be approved by an appropriate medical staff committee, or institution review board, or equivalent committee.

**WAC 246-960–120 Accessing Technology Used to Dispense – Nursing Students**

1. Nursing students may be given access privileges to technology used to dispense medications for patient administration.
2. Nursing students must be enrolled in a Washington state nursing care quality assurance commission approved nursing program.
3. A facility that provides a clinical opportunity to nursing students must meet the following to grant access to technology used to dispense medications for patient administration:
4. The health care facility, in collaboration with the nursing program, shall provide nursing students with orientation and practice experiences that include the demonstration of competency of skills prior to using the dispensing technology;
5. Nursing programs, and participating facilities shall provide adequate training for students accessing dispensing technology; and
6. The nursing programs and participating facilities shall have policies and procedures for nursing students to provide medication administration safely.
7. The nursing program and participating facilities shall develop and have a way of reporting and resolving any nursing student medication errors, adverse events, and alleged diversion.

**WAC 246-960-130 – Drugs Stored Outside of the Pharmacy**

1. In order for drugs to be stored in a designated area outside the pharmacy including, but not limited to, floor stock, in an emergency cabinet, in an emergency kit, or as emergency outpatient drug delivery from an emergency department at a registered institutional facility, the following conditions must be met:
	1. Drugs stored in such a manner shall remain under the control of, and be routinely monitored by, the supervising pharmacy.
	2. The supervising pharmacy shall develop and implement policies and procedures; to prevent and detect unauthorized access, document drugs used, returned and wasted, and regular inventory procedures.
	3. Access should be limited to title 18 credentialed individuals, issued by the Department, within their scope, except nursing students as provided in WAC 246-960-120.
	4. The area is appropriately equipped to ensure security and protection from diversion or tampering.
2. For nursing homes and hospice programs an emergency kit or supplemental dose kit must comply with RCW 18.64.560.

**WAC 246-960-160 – Staffing and Supervision of Pharmacy Staff**

1. The ratio of pharmacy technicians to pharmacist(s) on duty is to be determined by the responsible pharmacy manager.
2. The responsible pharmacy manager will ensure that the number of pharmacy technicians on duty can be satisfactorily supervised by the pharmacist(s) on duty.

**WAC 246-960-170 – Reporting Requirements**

1. The outgoing and incoming responsible pharmacy manager must report to the Commission a change in a responsible manager designation within ten (10) business days of the change.
2. Permanent closing. All facilities must report the following, unless otherwise specified.
	1. No later than thirty (30) calendar days prior to closing:
		1. The date the facility will close;
		2. The names and addresses of the persons who shall have custody of the prescription files, bulk compounding records, repackaging records, invoices and controlled substances inventory records of the pharmacy to be closed; and
		3. The names and addresses of any person(s) who will acquire any legend drugs from the facility to be closed, if known at the time the notification is filed.
		4. In addition to the above requirements pharmacies will provide notification to customers noting the last day the pharmacy will be open, name and address of the pharmacy to which prescription records will be transferred and instructions on how patients can arrange for transfer of their prescription records to a pharmacy of their choice and the last day a transfer may be initiated. Notification should include:
			1. Distribution by direct mail; or
			2. Public notice in a newspaper of general circulation in the area served by the pharmacy; and
			3. Posting a closing notice sign in a conspicuous place in the public area of the pharmacy
	2. No later than fifteen (15) days after closing:
		1. Return the facility license ; and
		2. Confirm that all legend drugs were transferred or destroyed. If the legend drugs were transferred, provide the names and addresses of the person(s) to whom they were transferred;
		3. Confirm if controlled substances were transferred, including the date of transfer, names, addresses and a detailed inventory of the drugs transferred;
		4. Confirm return of DEA registration and all unused DEA 222 forms to the DEA
		5. Confirm all pharmacy labels and blank prescriptions were destroyed; and
		6. Confirm all signs and symbols indicating the presence of the pharmacy have been removed
		7. The commission may conduct an inspection to verify.
3. Disasters, accidents and emergencies which may affect the strength, purity or labeling of drugs, medications, devices or other materials used in the diagnosis or the treatment of injury, illness and disease shall be immediately reported to the commission.
4. Any facility credentialed by the commission must report to the commission any disciplinary action, including denial, revocation, suspension, or restriction to practice by another state, federal, or foreign authority.

**WAC 246-960-190 Destruction or Return of Drugs or Devices – Restrictions.**

1. Otherwise a dispensed drug or prescription device must only be accepted for return and reuse as follows:
	1. Non-controlled drugs that have been maintained in the custody and control of the institutional facility, dispensing pharmacy, or their related clinical facilities may be returned and reused if product integrity can be assured.
	2. Those that qualify for return under the provisions of the chapter 69.70 RCW - Access to Prescription Drugs related to the donation of prescription drugs.
2. Otherwise a dispensed drug or prescription device may be accepted for return and destruction as follows:

(a) Those that were dispensed in a manner inconsistent with the prescriber’s instructions may be returned for quarantine and destruction purposes only.

(b) As part of the Washington state safe medication return program and consistent with chapter 69.48 RCW and chapter 246-480 WAC.

(c) As part of the facilities waste and destruction policies and procedures.

**246-960-205 Nuclear pharmacies.**

1. A permit to operate a nuclear pharmacy providing radiopharmaceutical services shall only be issued to a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals shall be under the supervision of a nuclear pharmacist. The nuclear pharmacist shall be responsible for all operations of the licensed area. In emergency situations, in the nuclear pharmacist's absence, he or she may designate one or more qualified, registered or certified health care personnel to have access to the licensed area. These individuals may obtain radiopharmaceuticals for the immediate emergency and must document such withdrawals in the control system.
2. Nuclear pharmacies shall have adequate space, commensurate with the scope of services to be provided. The nuclear pharmacy area shall be separate from the pharmacy areas for nonradiopharmaceuticals and shall be secured from access by unauthorized personnel. A nuclear pharmacy handling radiopharmaceuticals exclusively may be exempted from the general space requirements for pharmacies by obtaining a waiver from the commission. Detailed floor plans shall be submitted to the commission and the state radiation control agency before approval of the license.
3. Nuclear pharmacies shall prepare, compound, and dispense radiopharmaceuticals in accordance with accepted professional standards set forth in the United States Pharmacopeia 800 and 825.
4. The commission recognizes that the preparation of nuclear pharmaceuticals involves the compounding skills of the nuclear pharmacist to assure that the final drug product meets accepted professional standards set forth in the United States Pharmacopeia 800 and 825.
5. Nuclear pharmacies shall maintain records of acquisition and disposition of all radiopharmaceuticals in accordance with applicable regulations of the commission, the state radiation control agency and other state and federal agencies.
6. For nuclear pharmacies handling radiopharmaceuticals exclusively, the commission may waive regulations pertaining to the pharmacy permits for nonradiopharmaceuticals for requirements that do not pertain to the practice of nuclear pharmacy.
7. Radiopharmaceuticals are to be dispensed only upon a prescription from a practitioner authorized to possess, use and administer radiopharmaceuticals. A nuclear pharmacy may also furnish radiopharmaceuticals for office use to these practitioners. In absence of a prescription for an individual identified patient, the statement “Office Use Only” should be applied.
8. A nuclear pharmacist may transfer to authorized persons radioactive materials not intended for drug use, in accordance with regulations of the state radiation control agency.
9. In addition to any labeling requirements of the commission for nonradiopharmaceuticals, the immediate outer container of the radiopharmaceutical to be dispensed shall also be labeled with:
	1. Standard radiation symbol;
	2. the words "caution-radioactive material";
	3. radionuclide and chemical form (generic name)
	4. activity dispensed with units (millicuries or microcuries) at calibration date and time;
	5. if a liquid, the volume in milliliters;
	6. calibration date and time for the dose;
	7. BUD and special storage and handling instructions for non-immediate use; and
	8. specific concentration of radioactivity;
	9. For all therapeutic and blood-products, the patient name/identifier, number of dosage units dispensed.
10. The immediate container shall be labeled with:
	1. The standard radiation symbol;
	2. the words "caution-radioactive material";
	3. the name of the nuclear pharmacy;
	4. the prescription number;
	5. radionuclide and chemical form (generic name)”;
	6. the date; and
	7. activity dispensed with units (millicuries or microcuries) at calibration date and time;
	8. For all therapeutic and blood-products, the patient name/identifier.
11. The amount of radioactivity shall be determined by radiometric methods for each individual preparation immediately prior to dispensing.
12. Nuclear pharmacies may redistribute NDA approved radiopharmaceuticals if the pharmacy does not process the radiopharmaceuticals in any manner or violate the product packaging.
13. The nuclear pharmacy shall have the current revisions of state laws and regulations of the commission and state radiation control agency.

(14) The nuclear pharmacy shall maintain a library commensurate with the level of radiopharmaceutical service to be provided. A detailed library listing shall be submitted to the commission and state radiation control agency before approval of the license.

**246-960-206 Nuclear Pharmacies: Minimum equipment requirements.**

(1) Nuclear pharmacies shall have adequate equipment commensurate with the scope of radiopharmaceutical services to be provided. A detailed list of equipment and description of use must be submitted to the commission and radiation control agency before approval of the license.

(2) The commission may, for good cause shown, waive regulations pertaining to the equipment and supplies required for nuclear pharmacies handling radiopharmaceuticals exclusively.

**WAC 246-960-210 Continuous Quality Assurance Program**

(1) Each facility shall create or participate in a quality assurance program to detect, identify, and prevent medication errors. The quality assurance program shall include necessary documentation, internal reporting, and assessment of prescription errors to determine the cause and an appropriate response.

(2) The primary purpose of the quality assurance program shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a prescription error to assess the cause and any contributing factors such as system or process failures.

(3) Each facility shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent prescription errors, as well as communicate those findings to all pharmacy personnel.

**Registrations**

**WAC 246-960-220 Animal Control Agencies – Designated Person and Authorized Personnel**

1. The designated responsible person shall be responsible:
	1. To ensure only authorized trained personnel administer approved legend drugs, and approved controlled substances;
	2. For ordering and safe storage of all approved drugs;
	3. To ensure all records are available for inspection by the commission or its designee.
2. Approved training shall include didactic and practical training under the direction of a licensed veterinarian or completed through a program recognized by the national veterinarian association. The authorized trained personnel shall be able to demonstrate adequate knowledge of the potential hazards and proper techniques used in administering approved legend and controlled substances.
3. A registered animal control agency, humane society, or department of fish and wildlife chemical capture program shall notify the commission within 10 (ten) business days of a change in the designated responsible person.
4. The department of fish and wildlife’s designated responsible person may authorize the following trained individual to possess and administer approved legend drugs and controlled substances. Department of fish and wildlife:
	1. Officers;
	2. Biologists; and
	3. Veterinarians

**WAC 246-960-230 Animal Control Agencies – Approved legend drugs and approved controlled substances**

1. The following legend drugs are designated as approved legend drugs for use by animal control agencies registered by the Pharmacy Quality Assurance Commission for pre-euthanasia sedation:
2. Acetylpromazine;
3. Dexmedetomidine;
4. Medetomidine;
5. Xylazine.
6. Animal Control Agencies and humane societies can only purchase, possess, or administer sodium pentobarbital and approved legend drugs as provided in subsection 1 of this section. Staff may administer legend drugs and controlled substances which have been prescribed by a licensed veterinarian for a specific animal, which have been dispensed by a pharmacy or a veterinarian and are properly labeled in accordance with either RCW [18.64.246](http://app.leg.wa.gov/RCW/default.aspx?cite=18.64.246) or [69.41.050](http://app.leg.wa.gov/RCW/default.aspx?cite=69.41.050) and WAC 246-945-210 (General Provisions). This excludes the department of fish and wildlife chemical capture program.
7. Sodium pentobarbital shall be labeled “For veterinary use only.”
8. In addition to the legend drugs provided in (1) the following legend drugs are designated as approved legend drugs for use by officers and biologists of the department of fish and wildlife’s chemical capture programs only:
	1. Atipamezole;
	2. Azaperone;
	3. Detomidine;
	4. Isoflurane;
	5. Naltrexone;
	6. Tolazoline; and
	7. Yohimbine;
9. Additional controlled substances are approved for use by officers and biologists of the Washington state department of fish and wildlife for chemical capture programs only:
10. Butorphanol;
11. Diazepam;
12. Diprenorphine;
13. Carfentanil;
14. Fentanyl;
15. Ketamine;
16. Midazolam;
17. Tiletamine and
18. Zolazepam.

**WAC 246-960-240 Animal Control Agencies – Recordkeeping and reports**

1. An animal control agency registered to use sodium pentobarbital shall use a logbook with consecutively numbered pages to record the receipt, use, and disposition of approved legend drugs and sodium pentobarbital. Only one drug may be recorded on any single page. Or any record required to be kept under this section may be electronically stored and maintained if they remain legible and are in a readily retrievable format, provided federal law does not require them to be kept in a hard copy format.
2. The logbook or electronic record must have sufficient detail to allow an audit of the drug usage to be performed and must include:
	1. Date and time of administration;
	2. Route of administration;
	3. Identification number or other identifier assigned to the animal;
	4. Estimated weight of the animal;
	5. Estimated age and breed of the animal;
	6. Name of drug used;
	7. Dose of drug administered;
	8. Amount of drug wasted; and
	9. Initials of the primary person administering the drug.
3. The logbook may omit subsections (2)(b), (d), and (e) of this section if the information is recorded in other records cross-referenced by the animal identification number or other assigned identifier.
4. Personnel of the registered entity shall document any errors or discrepancies in the drug inventory in the logbook or electronic record and report to the designated responsible person for investigation.
5. The registered entity shall report any unresolved discrepancies in writing to the commission and to the federal Drug Enforcement Administration if the loss includes a controlled substance.
6. The designated responsible person shall perform a physical inventory or count of approved legend drugs and sodium pentobarbital every six months. The physical inventory must be reconciled with the logbook.
7. The designated responsible person or designee shall destroy legend drugs that are unfit for administration. A second member of the staff shall witness the destruction or waste of drugs. The destruction of drugs will be documented in the logbook with the date of the event and signatures of the individuals involved.
8. A registered entity shall return all unwanted or unused sodium pentobarbital to the manufacturer or destroy them in accordance with the rules and requirements of the commission, the FDA, and the department of ecology.
9. A registered entity must maintain a readily retrievable list of all authorized personnel who have demonstrated the qualifications to possess and administer approved legend drugs, and sodium pentobarbital.
10. All records of the registered entity must be available for inspection by the commission or any officer who is authorized to enforce this chapter.
11. The registered entity must maintain the logbook and other related records in accordance with WAC 246-960-050 (Operational Standards).

**WAC 246-960-250 Drug Storage and Field Use**

1. An animal control agency must store all approved legend drugs, and approved controlled substance(s) in a substantially constructed securely locked cabinet or drawer. Only those persons authorized to possess, and administer drugs shall have keys to the storage area.
2. The registered entity may designate only the following agents or personnel to possess and administer approved legend drugs and sodium pentobarbital for locations other than the registered location:
	1. Humane officer;
	2. Animal control enforcement officer;
	3. Animal control authority;
	4. Peace officer authorized by the chief of police, sheriff, or county commissioner; or
	5. Department of fish and wild life officer, biologists, and veterinarians.
3. Designated agents of the registered entity may possess a supply of approved legend drugs and approved controlled substances for emergency field use. Such emergency supply must be stored in a locked metal box securely attached to the vehicle. The designated agent is responsible for:
	1. The drug inventory present at the beginning of a shift and is present or accounted for at the end of each shift.
	2. Recording all receipts and use of approved legend drugs and controlled substances from the emergency supply.

**Distributors**

**WAC 246-960-260 Drug manufacturers**

These rules are applicable to drug manufacturers located within the state of Washington. Non-resident manufacturers engaged in wholesale drug distribution within or into Washington must comply with Washington statutes and rules, as applicable.

1. A manufacturer must ensure compliance with the federal “Current Good Manufacturing Practice” requirements.
2. A manufacturer must adopt policies and procedures for maintaining records pertaining to the production, process control, labeling, packaging, quality control, distribution, complaints, and any information from WAC 246-960-050 (Operational Standards).

**WAC 246-960-270 Wholesaler Standards**

These wholesaler rules establish the minimum standards for the storage and handling of drugs by wholesalers and their officers, designated representative, agents, and employees and for the establishment and maintenance of records required for persons engaged in wholesale drug distribution.

**WAC 246-960-280 Wholesaler: Facility Requirements**

1. Facilities where drugs are stored, warehoused, handled, held, offered, marketed, or displayed for wholesale distribution must:
	1. Be of suitable size, construction, and location to accommodate cleaning, maintenance, and proper operations;
	2. Have adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security;
	3. Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated or that are in immediate or sealed secondary containers that have been opened;
	4. Be maintained in a clean and orderly condition;
	5. Be free from infestation by insects, rodents, birds, or vermin of any kind; and
	6. Not be part of a home or residential dwelling.
2. Facilities used for wholesale drug distribution must be secure from unauthorized entry, as follows:
	1. Access from outside the premises must be kept to a minimum and well controlled;
	2. The outside perimeter of the premises must be well lit;
	3. Entry into areas where drugs are held must be limited to authorized personnel;
	4. Facilities must be equipped with an alarm system to detect entry after hours; and
	5. Facilities must be equipped with security systems sufficient to protect against theft, diversion, or record tampering.
3. Drugs must be stored at temperatures and under conditions required by the labeling of the drugs, if any, or by current requirements of the USP-NF, to preserve product identity, strength, quality, and purity. Temperature and humidity recording equipment, devices, or logs must document proper storage of drugs.
4. Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be physically separated from other drugs in a designated quarantine area until destroyed or returned to the original manufacturer or third party returns processor.
	1. Used drugs and those whose immediate or sealed outer or sealed secondary containers have been opened are adulterated and must be quarantined.
	2. Drugs must be quarantined under any condition that causes doubt as to a drug’s safety, identity, strength, quality, or purity unless under examination, testing, or other investigation the drug is proven to meet required standards.

**WAC 246-960-290 Wholesaler – Drug Shipment Inspection Requirements**

1. Each shipping container must be visually examined on receipt for identity and to avoid acceptance of drugs that are contaminated or otherwise unfit for distribution.
2. Outgoing shipments must be inspected to verify the accuracy and product integrity of the shipment contents.

**WAC 246-960-300 Wholesaler – Recordkeeping Requirements**

1. Wholesalers and other entities engaged in wholesale drug distribution must establish and maintain inventories and records of transactions pertaining to the receipt and distribution or other disposition of drugs.
	1. The records must include at least:
		1. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;
		2. The identity and quantity of the drugs received and distributed or disposed of; and
		3. The dates of receipt and distribution or other disposition of the drugs.
2. Records must be maintained in an readily retrievable manner

**WAC 246-960-310 Wholesaler –Personnel**

1. A wholesaler must establish and maintain a list of officers, directors, managers, a designated representative, and other persons responsible for wholesale drug distribution, storage, and handling and must include a description of each individual’s duties and a summary of their qualifications.
2. A wholesaler must employ personnel in sufficient numbers and with adequate education, training, and experience to safely and lawfully engage in wholesale drug distribution activities.

**WAC 246-960-320 Wholesaler –Policies and Procedures**

Wholesalers must adopt policies and procedures for the receipt, security, storage, inventory, and distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting errors and inaccuracies in inventories

**WAC 246-960-330 Drug Distribution – Authorized Distributor**

The following may distribute legend drugs within or into Washington State, in compliance with these rules, pursuant to the following restrictions:

1. A licensed wholesale distributor and a licensed manufacturer in compliance with the state and federal laws and rules;
2. An FDA registered outsourcing facility in compliance with Section 503b of the Food, Drug and Cosmetic Act and licensed under RCW 18.64.045 for in-state facility or RCW 18.64.046 for out-of-state facilities;
3. A pharmacy or prescriber is not required to obtain a license as a wholesale distributor if engaged in the following activities:
	1. Intracompany sales;
	2. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;
	3. The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
	4. The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control; for purposes of this section, common control means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise;
	5. The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; for purposes of this section, emergency medical reasons includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;
	6. The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;
	7. The distribution of drug samples by manufacturers' representatives or distributors' representatives; or
	8. The sale, purchase, or trade of blood and blood components intended for transfusion.
	9. Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with 203.23 of 21 CFR 205.3; or
	10. The sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use.

**WAC 246-960-340 Drug Distributor - Distribution**

Unless exempted in state or federal law:

1. An authorized distributor can distribute drug products:
	1. to a person or pharmaceutical facility that is credentialed to manufacture, wholesale, distribute, dispense, conduct research, or independently administer such drugs;
	2. to a person or facility properly credentialed to possess controlled substances by the DEA and the Commission
2. Authorized distributors must maintain and include with each distribution all federally required transaction documentation, including transaction information, transaction history, and transaction statements; and
3. Authorized distributors must deliver drug products to the registered address of the authorized receiving person only. Delivery to a hospital pharmacy receiving area satisfies this requirement, provided that authorized receiving personnel sign for receipt at the time of delivery.
4. Controlled Substance Distribution Invoice. Distributions must be pursuant to an invoice and not a prescription drug order. For controlled substances, each dispenser must retain a signed receipt of the distribution that includes at least:
	1. The date of the transaction;
	2. The name, address, and DEA registration number of the distributor;
	3. The name, address, and DEA registration number of the receiving authorized prescriber or entity;
	4. The drug name, strength, and quantity for each product distributed; and
	5. The signature of the person receiving the drugs.

**WAC 246-960-350 Drug Distributor – Prohibited Acts**

The following acts are prohibited:

1. Distribution of any drug product that is adulterated, misbranded, counterfeit, expired, damaged, recalled, stolen, or obtained by fraud or deceit.
2. Failing to obtain a license or registration when one is required to distribute within or into Washington State.
3. To sell or distribute any prescription drugs or devices except to an individual, corporation, or entity who is authorized by law or regulation to possess such drugs or devices.
4. To sell any prescription drugs or devices to an ultimate consumer. Except for the distribution of bulk drugs directly to livestock farmers, pursuant to an order written by a veterinarian, if the pharmaceuticals are to be administered to an animal raised for the purpose of producing an agricultural product that will be sold.