Operational Standards

Pharmacies, Healthcare entities, and Hospital Associated Clinics

WAC 246-XXX-X30 Health Care Entities

A Health care entity is an organization that provides health care services credentialed under RCW 18.64.450.

WAC 246-XXX-X25 Hospital Pharmacy Associated Clinics

Staffing/Supervision

WAC 246-xxx-xxx Tech Ratio

~~(a)~~ (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-XXX-XX4 Pharmacies That Dispense Drugs to Patients Without An Onsite Pharmacist.

(1) ~~In addition to all other preceding rules of this chapter, a~~A pharmacy that dispenses drugs to patients in Washington that does not have a pharmacist onsite to perform or supervise pharmacy operations must comply with the following requirements:

(a) The pharmacy must maintain video surveillance with an adequate number of views of the full facility and retain a high quality recording for a minimum of ninety (90) days.

(b) Proper identification controls of individuals accessing the restricted drug storage area must be utilized and access must be limited, authorized, and regularly monitored.

(2) ~~The ratio of pharmacists to support personnel may not exceed one (1) pharmacist for every six (6) pharmacy technicians and pharmacy interns in total across all practice sites.~~

(3) The video and audio communication system used to counsel and interact with each patient or patient's caregiver, must be clear, secure, and HIPAA-compliant.

(4) A perpetual inventory must be kept for all Schedule II controlled substances.

(5) If a ~~perpetual~~ continual inventory is not kept for Schedule III through V controlled substances, the pharmacist must inventory and audit Schedule III through V substances at least three (3) times ~~quarterly~~every 3 months.

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Commented [BD(1]: General concepts. Need clarification on counseling and supervision of technicians. – Flagged to return to this at a later time.

Commented [GCO(2]: Moved new language into its own section

(6) A pharmacist must complete and retain, in accordance with [cross reference Recordkeeping WAC] a monthly in-person self- inspection of the off-site pharmacy using a form designated by the Commission.

(7) A pharmacist must be capable of being on site at the pharmacy within twelve (12) hours if an emergency arises.

(8) The pharmacy must ~~be, or remain, closed~~be closed to the public if any component of the surveillance or video and audio communication system is malfunctioning, and remain closed until system corrections or repairs are completed.

(9) A self-service automated drug dispensing device (ADDD) that is operating as a pharmacy is exempt from the video surveillance requirement and the self-inspection requirement of this rule. In addition, if counseling is provided by an onsite prescriber or pharmacist, a self-service ADDD is exempt from the video and audio communication system requirements of this rule.

~~(9)~~ **WAC 246-873-050 Absence of a Pharmacist within a Hospital Pharmacy**

(1) General. Pharmaceutical services shall be available on a 24-hour basis. If round-the-clock services of a pharmacist are not feasible, arrangements shall be made in advance by the director of pharmacy to provide reasonable assurance of pharmaceutical services.

(2) Access to the pharmacy. Whenever a drug is required to treat an immediate need and not available from floor stock when the pharmacy is closed, the drug may be obtained from the pharmacy by a designated registered nurse, who shall be accountable for his/her actions. One registered nurse shall be designated in each hospital shift for removing drugs from the pharmacy.

(a) The director of pharmacy shall establish written policy and recording procedures to assist the registered nurse who may be designated to remove drugs from the pharmacy, when a pharmacist is not present, in accordance with Washington State Pharmacy Practice Act, RCW 18.64.255(2), which states that the director of pharmacy and the hospital be involved in designating the nurse.

(b) The stock container of the drug or similar unit dose package of the drug removed shall be left with a copy of the order of the authorized practitioner to be checked by a pharmacist, when the pharmacy reopens, or as soon as is practicable.

(c) Only a sufficient quantity of drugs shall be removed in order to sustain the patient until the pharmacy opens.

(d) All drugs removed shall be completely labeled in accordance with written policy and procedures, taking into account state and federal rules and regulations and current standards.

~~(10)~~

Commented [GCO(3]: Is there a length of time it needs to be retained for?

Commented [WTM(4]: Didn't we already say this earlier in the same paragraph

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Commented [GCO(5]: Taken from Hospital Pharmacy Standards

Commented [WTM(6]: Do we really need this? Do any of our other new provisions speak to this topic where we could drop some of the concepts? E.g. having access for a nurse.

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WAC 246-XXX-XX5 Drugs Stored Outside of a Pharmacy for Retrieval by a Licensed Health Professional.

Drugs may be stored in a~~n alternative~~ 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, ~~provided~~ the following conditions ~~are~~ 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~~regarding authorized access to drugs stored in the alternative designated area~~, to prevent and detect unauthorized access, documentation of drugs used, drug returned~~s~~ and wasted~~age~~, and regular inventory procedures.

(3) The area is appropriately equipped to ensure security and protection from diversion or tampering.

(4) Nursing students accessing automated drug dispensing devices (ADDD). If a facility provides a clinical opportunity for nursing students enrolled in a Washington state nursing commission approved nursing program, a nursing student may access the ADDD only ~~under~~ if the following conditions are met:

(a) Nursing programs shall provide students with orientation and practice experiences that include a demonstration of competency of skills prior to using an ADDD;

(b) Nursing programs, health care facilities, and pharmacies shall provide adequate training for students accessing ADDD; and

(c) The nursing commission approved nursing programs, health care facilities, and pharmacies shall have policies and procedures for nursing students to provide medication administration safely, including:

(i) Access and administration of medications by nursing students based on student competencies;

(ii) Orientation of students and faculty to policies and procedures related to medication administration and distribution systems; and

(iii) Reporting of student medication errors, near misses and alleged diversion

WAC 246-XXX-X13 Reporting Requirements

(1) ~~Both an~~The ~~-~~ outgoing and incoming responsible pharmacy manager must report to the Commission a change in a responsible manager designation within ten (10) days of the change.

Commented [BD(7]: Related to ADDD rules and HPAC (what about EMS?) Institutional, inpatient treatment facilities, nursing homes, etc.

Flagged to cover gaps if needed.

Commented [WTM(8]: Not sure this is the most appropriate place for this language. This isn't just in EDs but in all licensed locations.

Commented [GCO(9]: Commission to review?

(2) A registrant must report a theft or significant loss of controlled substances to the Commission.~~to the Commission.~~ A registrant must report the theft or loss on the appropriate DEA form and supply a copy of that form to the Commission on the same day reported to the DEA. ~~a DEA 106 form reporting theft or loss of a controlled substance that includes the information required by federal law.~~

(3) A licensee or registrant must report to the Commission any adulteration or misappropriation of a controlled drug ~~in accordance with RCW 18.130.080(1)(b).~~within 20 days of any closed investigation.

WAC 246-XXX-019 Notifications by health care and pharmaceutical facilities.

(1) All credentialed pharmaceutical facilities shall report in writing to the Commission the occurrence of any of the following changes:

(a) Change of ownership, management, location, or facility remodel.

~~(b) Any and all other matters and occurrences as the commission may require by rules and regulations.~~

(i) No later than fifteen (15) days ~~in advance~~ prior to ~~of~~ closing:

(A) The date the pharmacy will close;

(B) The names and addresses of the persons who shall have custody of the prescription files, the bulk compounding records, the repackaging records, and the controlled substances inventory records of the pharmacy to be closed; and

(C) The names and addresses of any persons who will acquire any of the legend drugs from the pharmacy to be closed, if known at the time the notification is filed.

(ii) No later than fifteen (15) days ~~in~~ after closing:

(A) Return the pharmacy license ; and

(B) 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;

(C) Confirm if controlled substances were transferred, including the date of transfer, names, addresses and a detailed inventory of the drugs transferred;

(D) Confirm return of DEA registration and all unused DEA 222 forms ~~returned~~ to the DEA

(E) Confirm all pharmacy labels and blank prescriptions were destroyed; and

(F) Confirm all signs and symbols indicating the presence of the pharmacy have been removed.

Commented [WTM(10]: Took out 106 in case that form number ever changes.

Commented [WTM(11]: Is this different than (2)? Should it say "adulteration or misappropriation" by an employee? Not sure what we are getting at.

Commented [GCO(12]: Further define

Commented [WTM(13]: We may want to consider adding something about patient notification since we have a policy on it, and we have heard from patients in the past who had no idea their pharmacy closed.

Commented [WTM(14]: Currently inspectors do closing inspections to reaffirm this. Does the Commission want to just require a closing inspection and have these principles in a policy and procedure for the inspection team?

(2) 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.

(3) Any pharmaceutical facility or health care facility license, certificate, registration or other privilege to practice that is denied, revoked, suspended, or restricted by a another state, federal, or foreign authority shall be reported to the commission.

Access Drug Security & Storage (Minimum Facility Requirements)

WAC 246-XXX-XX1 Facilities that Dispense Prescription Drugs: Minimum Facility Standards.

~~(2)~~(1) A ~~resident~~ facility that dispenses prescription drugs to patients in Washington must meet the following minimum requirements:

(a) The facility must be constructed and equipped with adequate security to protect ~~its~~ equipment, records, ~~and~~ supply of drugs, devices and other restricted sale items from unauthorized access, acquisition or use~~...~~. All facilities will be equipped with a system of security that will provide suitable protection.

(b) 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.

~~(b)~~(c) Drug storage areas. Drugs shall be stored under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security.

~~(c)~~(d) The facility must be staffed sufficiently to allow appropriate supervision, to otherwise operate safely and, if applicable, to remain open during ~~the hours posted as open to the public for business~~posted hours of operation.

~~(d)~~(e) Controlled substances must be stored in a securely locked, substantially constructed cabinet or safe. ~~However, a~~A pharmacy may disperse substances listed in Schedules II, III, IV and V, in whole or in part, throughout the stock of non-controlled substances if doing so would ~~be~~ likely ~~to~~ obstruct the theft or diversion of the controlled substances.

~~(e)~~(f) Expired, excess or unwanted controlled substances that are owned by the facility must be properly disposed of through ~~the services of~~ a DEA-registered reverse distributor or by another method permitted by state and federal law.

~~(3)~~(2) A facility must limit access to the restricted drug storage area. Access to the restricted drug storage area can occur only when a pharmacist is on duty.

Commented [WTM(15]: Does the Commission want to limit to these actions taken in other states or all disciplinary actions?

Commented [GCO(16]: Check with Commission on if they want it and if so if there should be a time frame for it to be done.

Commented [BD(17]: Need to define dispensing – hospital verses retail defined 18.64.011

Commented [GCO(18]: Can we fit hospital standards under here?

Commented [GCO(19]: Remove resident to cover all pharmacies

Commented [GCO(20]: Added from hospital standards

Commented [WTM(21]: See comment above – might consolidate the "absence of a pharmacist" dropped in above could be added here as an exception.

(a) Access must be limited to pharmacists, pharmacy interns, pharmacy technicians and pharmacy assistants. A pharmacist may authorize an individual temporary access to the restricted drug storage area to perform a legitimate non-pharmacy function if the individual remains under the supervision of the pharmacist.

(b) An institutional facility that allows non-pharmacist health professionals to enter into the restricted drug storage area ~~of an institutional facility~~ that is otherwise closed, must have a written protocol. The protocol must limit access ~~is pursuant~~ to a valid prescription drug order ~~,~~ to remove a sufficient quantity of non-controlled drugs necessary to meet the immediate needs of a patient.

Commented [BD(22]: Apply the policy language in the absence of a pharmacist as it applies to technicians. Possible Subsection c

Commented [WTM(23]: Exactly!! I think this addresses the absence of a pharmacist piece.

Recordkeeping

WAC 246- XXX-X11 Recordkeeping – Maintenance and Inventory Requirements.

(1) Unless an alternative standard is stated for a specified record type, form, or format, records required ~~to~~ as evidence of compliance with statutes or rules enforced by the ~~C~~commission must be maintained and retained in a readily retrievable form and location for at least two (2) years from the date of the transaction.

(2) A prescription drug order must be retained in a readily retrievable manner by each ~~drug outlet~~facility and maintained as follows:

(a) Schedule II Prescriptions. Paper prescription drug orders for Schedule II controlled substances must be maintained at the registered location in a separate prescription file.

Commented [WTM(24]: Is this current practice/requirement?

(b) Schedule III through V Prescriptions. Paper prescription drug orders for Schedules III, IV and V controlled substances must be maintained at the registered location either in a separate prescription file for Schedules III, IV and V controlled substances only or in a readily retrievable manner separate from other prescription records as required by federal law.

(c) Electronic Prescriptions. Electronic prescription drug orders for controlled substances must be maintained in a system that meets the requirements of federal law. The records may be maintained at another location if readily retrievable at the registered location and must allow the records to be sortable by prescriber name, patient name, drug dispensed, and date filled.

Commented [WTM(25]: I don't know if any of our facility licenses are registrations, pretty sure they are all licensed.

Also we are only allowing electronic prescriptions to be offsite but not paper?

(3) Each pharmacy shall maintain a current, complete and accurate record of each controlled substance manufactured, imported, received, ordered, sold, delivered, exported, dispensed or otherwise disposed of by the registrant.

~~(3)~~(4) Pharmacies shall maintain inventories and records in accordance with federal law. An inventory must be conducted as follows:

(a) Each registrant shall conduct an inventory of controlled substances on hand ~~annually at each registered location no later than seven (7) days after the date of the most recent inventory in a form and manner that satisfies the inventory requirements of federal law.~~once per year within seven (7) days of the anniversary of the last inventory. A separate controlled substances inventory shall be taken and retained at each DEA-registered location.

(b) A complete controlled substance inventory must be conducted by the incoming responsible manager or delegate within thirty days of becoming responsible manager~~on or by the first day of employment of the incoming responsible manager~~.

(c) On the effective date of an addition of a substance to a schedule of controlled substances, each registrant that possesses that substance shall take an inventory of the substance on hand, and thereafter, include the substance in each inventory.

(d) In addition to the annual inventory requirements, the pharmacy shall ~~regularly~~ once a month perform an inventory and inspect drugs stored outside a pharmacy in accordance with these rules to ensure proper storage, security, and accountability of the drugs.

(e) When a pharmacy closes, the pharmacy shall conduct and retain a closing inventory.

(f) Evidence ~~of~~ that shows an amount of a controlled substance ~~that~~ differs from the amount reflected on a record or inventory ~~required by state or federal law~~ creates a ~~rebuttable~~ presumption that the registrant has failed to keep records or maintain inventories in conformance with the recordkeeping and inventory requirements of state and federal law.

(g) Records may be retained at a central location in compliance with federal law.

(h) 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, ~~and if~~provided federal law does not require them to be kept in a hard copy format.

Commented [WTM(26]: Is this only for CS? We should say so.

WAC 246-XXX-X12 Recordkeeping – Electronic System for Patient Medication Records.

(1) A ~~pharmacy, that~~pharmacy that is new or remodeled ~~after the effective date of this rule~~ 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 ~~stored therein~~ for a minimum of twenty-four (24) months from the date of entry.

(3) The electronic recordkeeping system must have functionality that allows refill data to be immediately retrievable and produced upon request~~; for example, a refill-by-refill audit trail for a specified strength and dosage form of a drug~~.

(4) The electronic recordkeeping system ~~shall~~ 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. Systems that automatically generate user identification without requiring an entry by the responsible individual are prohibited. Pharmacies that utilize offsite pharmacy services for product fulfillment or processing must track the identity and location of each individual involved in each step of the offsite pharmacy services.

(5) The electronic recordkeeping system ~~shall~~ must include security features to protect the confidentiality and integrity of patient records including:

(a) Safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription drug order information and patient medication records; and

(b) 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.

(6) The pharmacy must have policies and procedures in place for system downtime, backup and recovery.

(7) Pharmacies are exempt from this section if they fill on average fewer than twenty (20) prescriptions per business day, and paper records are maintained.

Dispensing (Onsite/Offsite)

WAC 246-XXX-XX3 Offsite Pharmacy Services.

Commented [WTM(27]: We'll need to do a cost analysis on this.

Commented [WTM(28]: Seems redundant.

Commented [WTM(29]: What does this mean?

Commented [BD(30]: Add offsite definition – replace remote in place of offsite (shared services – common language) review NABP model act

A pharmacy may provide offsite pharmacy services at one (1) or more locations. When the services being performed are related to prescription fulfillment or processing, the pharmacy 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 share a secure common electronic file 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 246-865-030

Emergency kit & Supplemental Dose Kits~~.~~

(1) The contents and quantity of drugs and supplies in the emergency kit shall be determined by the pharmaceutical services committee as defined in ~~WAC 246-865-010(9)~~RCW 18.64.011 which shall consider the number of residents to be served and their potential need for emergency medications.

(2) A copy of the approved list of contents shall be ~~conspicuously posted on or near the kit~~readily retrievable.

(3) The emergency kit shall be used only for bonafide emergencies and only when medications cannot be obtained from a pharmacy in a timely manner.

(4) Records documenting the receipt and removal of drugs in the emergency kit ~~shall~~ must be maintained by the ~~nursing home~~long-term care facility and the supplying pharmacy, in accordance with [Recordkeeping WAC].

(5) The pharmaceutical services committee shall be responsible for ensuring proper storage, security and accountability of the emergency kit.

(a) The emergency kit shall be stored in a locked area or be locked itself;

(b) Access to the ~~E~~emergency kit drugs ~~shall~~ must be restricted to credentialed personnel acting with their scope of practice.~~be accessible only to licensed nurses as defined in WAC 246-865-010(6).~~

(6) The contents of the emergency kit, the approved list of contents, and all related records shall be made freely available and open for inspection to representatives of the board of pharmacy and the department.

Commented [GCO(31]: Per Doreen's comment should this say remote?

Commented [WTM(32]: Is this going to include compounding which is done in accordance with a Rx?

Commented [WTM(33]: Should we be limiting this to just LTC or all facilities?

Commented [WTM(34]: Don't know if its an issue on posting the list or not.

Commented [WTM(35]: We should maybe look at defining similar to the emergency medical reasons, because we will get asked that question.

Commented [WTM(36]: Can't remember if we state this in the recordkeeping section, e.g. that all records must be open for inspection/investigation.

WAC 246-865-040

Supplemental dose kits.

(1) In addition to an emergency kit, each institution holding a valid Washington state nursing home license, and which employs a unit dose drug distribution system, may maintain a supplemental dose kit for supplemental nonemergency drug therapy if the necessary drug is not available from the pharmacy in a timely manner.

(2) The pharmaceutical services committee shall determine the quantities of drugs in the supplemental dose kit in light of the number of residents in the facility and their potential needs for supplemental doses.

(3) The supplemental dose kit shall remain the property of the supplying pharmacy.

(4) The supplying pharmacy and the facility's pharmaceutical services committee shall be responsible for proper storage, security and accountability of the kit.

Commented [GCO(37]: Added based on Teri's review

WAC 246-XXX-XX2 Facilities That Dispense Prescription Drugs: Minimum Prescription Fulfillment Requirements.

~~Unless exempted by these rules,~~ Each resident facility that dispenses prescription drugs to patients in Washington must meet the following minimum requirements:

(1) Prescription drugs must only be dispensed pursuant to a valid prescription drug order as set forth in ~~Sections 006 through 010 of these rules~~.

Commented [WTM(38]: Should this be deleted or add in chart order, just want to capture all possibilities

Commented [GCO(39]: New section being created in General Provisions to clarify a valid prescription

(2) Prospective drug review, as defined in WAC 246-XXX-200(general provisions), must be provided as set forth in WAC 246-XXX-XXX (professional standards/counseling).

Commented [WTM(40]: What is the purpose of this?

(3) Each drug must bear a complete and accurate label as set forth in ~~Sections 006 through 010~~ of these rules.

Commented [GCO(41]: Reference labeling requirements General Provisions

(4) Facilities must have policies and procedures in place to define the process used for verification of dispensing accuracy. Verification must be performed to compare the drug stock selected to the drug prescribed. If not performed by a pharmacist, an electronic verification system must be used that confirms the drug stock selected to fill the prescription is the same as indicated on the prescription label. A pharmacist verification for all compounded drugs is required.

Commented [BD(42]: Check policy regarding outpatient labeling – reference applicable RCWs. Minimum requirements. Commission consider deviation for specific settings. – Staff provide information to Commission

Commented [BD(43]: This language may imply post-verification. Does this meet the Commission's intent. Review by staff with PQAC direction. Policy and procedure for verification. Staff will draft broad language regarding verification p&P

(5) Counseling, as defined in WAC 246-XXX-200, must be provided as set forth in WAC 246-XXX-XXX (professional standards)

Commented [BD(44]: Language needs to include counseling determined by pharmacist. Note: add language of WAC/RCW reference in the language to relevant RCW/WAC column

~~**WAC 246-XXX-XX6 Prescription Drug Order: Validity.**~~

Commented [GCO(45]: Moved to General Provisions

Offsite Pharmacy Services

WAC 246-XXX-XX7 Prescription Delivery – Restrictions.

(1) A pharmacy that dispenses drugs to patients in Washington state may deliver filled prescriptions, as long as appropriate measures are taken to ensure product integrity, to the following~~, as long as appropriate measures are taken to ensure product integrity~~:

(a) ~~To the~~The patient or the patient's residence, the institutional facility in which the patient is ~~convalescing~~recovering, the correctional facility in which a patient is housed;

(b) ~~To the~~The patient's licensed or registered healthcare provider, as follows:

(i) If the drug is not a controlled substance~~s~~; or

(ii) If the drug is a controlled substance that is intended for direct administration by the prescriber or prescriber's delegate.

(c) To another licensed pharmacy.

(2) Filled prescriptions may be picked up ~~for~~ or returned ~~from~~ 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 ~~that is~~ equipped with adequate security, including an alarm or comparable monitoring system, to prevent unauthorized entry, theft ~~and~~ or diversion under the policies and procedures developed by the responsible pharmacist manager.

~~**WAC 246-XXX-XX8 Prescription Drug Order: Minimum Requirements.**~~

WAC 246-XXX-X10 Repackaging Drug Previously Dispensed.

A pharmacy may repackage a drug previously dispensed to a patient, pursuant to the patient or the patient's agent's request, if:

(1) The repackaging pharmacist verifies the identity of the previously dispensed drugs as matching the label on the container that the drugs were initially dispensed ~~within~~in.

(2) The drugs are never intermingled with the repackaging pharmacy's regular stock.

(3) The repackaging pharmacy affixes to the container of the repackaged drug a label that complies with the standard labeling rule and includes:

(a) The original dispensed prescription's serial number;

(b) The name, address, and phone number of the original dispensing pharmacy; and

(c) A statement that indicates that the drug has been repackaged, such as the words "repackaged by" followed by the name of the repackaging pharmacy.

Destruction/Return of Drugs

WAC 246-XX9 Destruction or Return of Drugs or Devices – Restrictions.

Commented [WTM(48]: May deliver where?

Commented [GCO(49]: Moved to General Provisions

Commented [WTM(50]: Do we define who a patient's agent can be? Is it defined elsewhere in RCW?

Commented [WTM(51]: Do we need to get into cold v. hot sealing?

Commented [GCO(52]: How will new drug take back impact this?

18.64.550
18.64.246

Check

Commented [WTM(53R52]: Do we need to distinguish between drug take back (patients returning drugs for destruction) v. business destruction? That might be the best way to handle this section.

A pharmacy registered with the DEA as a collector may collect controlled and non-controlled drugs for destruction in accordance with applicable state and federal law. Otherwise a dispensed drug or prescription device must only be accepted for return as follows:

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

(2) 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 if product integrity can be assured.

(3) Controlled substances may only be returned from a hospital daily delivery system under which a pharmacy dispenses no more than a twenty-four (24) hour supply for a drug order, or up to a seventy-two (72) hour supply for a drug order if warranted for good patient care.

Commented [GCO(54]: Rewrite for clarification

(4) Those that qualify for return under the provisions of the Washington state Chapter 69.70 RCW Access to Prescription Drugs related to drug donation. Refer to WAC 246-XXX-010.

QA Programs

WAC 246-XXX-X19 Continuous Quality Improvement Program

(1) Compliance with this section may be considered by the ~~Board~~ commission as a factor in the investigation and evaluation of a Quality-Related Event (QRE).

Commented [WTM(55]: Do we need this in rule?

(2) Each ~~P~~pharmacy ~~shall~~ must establish a Continuous Quality Improvement (CQI) Program the purpose of detecting, documenting, assessing, and preventing QREs. At a minimum, a CQI Program shall include provisions to:

(a) Designate an individual or individuals responsible for implementing, maintaining, and monitoring the CQI Program, which is managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form;

(b) Initiate documentation of QREs as soon as possible, but no more than three days, after determining their occurrence;

(c) Analyze data collected in response to QREs to assess causes and any contributing factors such as staffing levels, workflow, and technological support;

(d) Use the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients;

(e) Provide ongoing CQI education at least once per yearannually to all pharmacy personnel;

(f) For those Ppersons utilizing a Ddrug formulary, a periodic review of such formulary shall be undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.

(3) As a component of its CQI Program, each Ppharmacy shall ensure that periodic meetings are held, at least annually, by staff members of the Ppharmacy to consider the effects on quality of the Ppharmacy system due to staffing levels, workflow, and technological support. Such meetings shall review data showing evidence of the quality of care for patients served by the Ppharmacy and shall develop plans for improvements in the system of Pharmacy Practice so as to increase good outcomes for patients.

(4) Appropriately-blinded incidents of QREs shall be reported to a nationally recognized error reporting program designated by the Board commission.

(4) Quality Self-Audit.

3months to determine whether the occurrence of QREs has decreased and whether the occurrence of QREs has decreased and to develop a plan for improved adherence with the CQI Program in the future. Each pharmacy shall conduct a Quality Self-Audit upon change of Pharmacist-in-Charge to familiarize that Pperson with the Pharmacy's CQI Program.

(6) Consumer Survey.

a Consumer Survey of patients who receive pharmaceutical pProducts and services at the Ppharmacy. A Consumer Survey should be conducted at least once per year. A statistically valid sampling technique may be used in lieu of surveying every patient. Each Ppharmacy should use the results of its Consumer Survey to evaluate its own performance at a particular time and over a period of timeafter completion.

(7) Protection from Discovery. All information, communications, or data maintained as a component of a pharmacy CQI Program are privileged and confidential. This shall not prevent review of a pharmacy's CQI Program and records maintained as part of a system by the commission, pursuant to a subpoena, as necessary to protect the public health and safety. All information, communications, or data provided to any Peer Review Committee, and any findings, conclusions, or recommendations resulting from the proceedings of such committee, board, or entity are privileged. The records and proceedings of any Peer Review Committee, are confidential and shall be used by such committee, and the members thereof, only in the exercise of the proper functions of the committee and shall not be public records nor be available for court subpoena or for discovery proceedings. The disclosure of confidential, privileged Peer Review Committee information during advocacy, or as a report to the commission, or to the affected Pharmacist or Pharmacy auxiliary personnel under review does not constitute a waiver of either confidentiality or privilege.

Commented [GCO(56]: Is this a known term?

~~(7) Protection from Discovery~~

the ~~Board~~ commission for documents or information as otherwise authorized by law. disclosure of documents or information under subpoena does not constitute a waiver of the privilege associated with a CQI Program. Failure to comply with the subpoena is grounds for disciplinary action against the Person by the appropriate licensing board.

Advertising

246-881-010

~~**Drug price advertising defined.**~~

Drug price advertising is the dissemination of nonpromotional information pertaining to the prices of legend or prescription drugs.

~~**246-881-020**~~

~~**Drug price advertising conditions.**~~

(1) The advertising complies with all state and federal laws, including regulations of the United States Food and Drug Administration and the Washington State Consumer Protection Act, chapter 19.86 RCW.

(2) The advertising is solely directed towards providing consumers with drug price information and does not promote the use of a prescription drug or drugs to the public.

(3) The drug price advertising shall contain all the following information for all drug products or brand names used in the advertisement:

(a) The proprietary name of the drug product advertised, if any,

(b) The generic name of the drug product advertised, if any,

(c) The strength of the drug product advertised. If the drug product advertised contains more than one active ingredient and a relevant strength can be associated with it without indicating each active ingredient, the generic name and quantity of each active ingredient is not required.

~~(d) The dosage form of the drug product advertised, and~~

(4) Advertising of any generic drug that in any way compares a generic drug to a brand name drug may not in any manner imply that the brand name drug is the product offered for sale.

246-881-030

Prohibition on advertising controlled substances.

No person, partnership, corporation, association or agency shall advertise controlled substances for sale to the general public in any manner that promotes or tends to promote the use or abuse of those drugs. Controlled substances shall not be physically displayed to the public.

Commented [GCO(57]: Added based on Kat's recommendations

Want to find somewhere else within the document to place this.

246-881-040
Drug price disclosure—Required.

No pharmacy shall refuse to disclose the retail price of a prescription drug ~~upon request by a consumer~~.

Commented [WTM(58]: Suggest deletion of by request, so that its not limited what circumstances retail prices could be disclosed.

Registrations

WAC 246-XXX-X52 Animal Control Agencies – Designated Person and Authorized Personnel

(1) The designated responsible person shall be responsible:
  (a) To ensure only authorized trained personnel administer approved legend drugs, and approved controlled substances;
  (b) For ordering and safe storage of all approved drugs;
  (c) 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 another state, local, or 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.

Commented [WTM(59]: This seems to be loose, wouldn't we want those programs to have certain requirements? Is this improper delegation?

(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 designated responsible person.

(4) The department of fish and wildlife's designated responsible person may authorize~~d~~ the following trained individual to possess and administer approved legend drugs and controlled substances. Department of fish and wildlife:
  (a) Officers;
  (b) Biologists; and
  ~~(b)~~(c) Veterinarians

WAC 246-XXX-X54 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:

  (a) Acetylpromazine.
  (b) Dexmedetomidine.
  (c) Medetomidine.
  (d) Xylazine.

(2) Animal Control Agencies and humane societies may not purchase, possess, or administer controlled substances or legend drugs except sodium pentobarbital and approved legend drugs as provided in subsection 1 of this section. Provided, staff may administer legend drugs and controlled substances which have been prescribed by a licensed veterinarian for a specific animal, ~~and~~ which ~~drugs~~ have been dispensed by a pharmacy or a veterinarian and are properly labeled in accordance with either RCW 18.64.246 or 69.41.050. This excludes the department of fish and wildlife chemical capture program.

(3) Sodium pentobarbital shall be labeled "For veterinary use only."

(4) Additional 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:

(a) Atipamezole;
(b) Azaperone;
(c) Detomidine;
(d) Isoflurane;
(e) Naltrexone;
(f) Tolazoline; and
(g) Yohimbine;

(5) Additional controlled substances are approved for use by agents and biologists of the Washington state department of fish and wildlife for chemical capture programs only:

(a) Butorphanol;
(b) Diazepam (Valium);
(c) Diprenorphine;
(d) Carfentanil (Wildnil);
(e) Fentanyl;
(f) Ketamine;
(g) Midazolam; and
(h) Tiletamine and
(i) zolazepam (Telazol).

WAC 246-XXX-X55 Animal Control Agencies - Recordkeeping and reports.

(1) An animal control agency registered for sodium pentobarbital shall use a bound 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.

Commented [WTM(60]: Bound? Should we make electronic an option?

(2) The logbook must have sufficient detail to allow an audit of the drug usage to be performed and must include:

(a) Date and time of administration;
(b) Route of administration;
(c) Identification number or other identifier assigned to the animal;
(d) Estimated weight of the animal;

(e) Estimated age and breed of the animal;
(f) Name of drug used;
(g) Dose of drug administered;
(h) Amount of drug wasted; and
(i) 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. and~~logbook and report~~ed~~ 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. A second member of the staff shall witness the destruction or waste of drugs~~drugs that are destroyed or wasted~~. The destruction of drugs are 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 federal Drug Enforcement Administration, and the department of ecology.

(9) A registered entity ~~shall~~ must maintain a ~~written~~ 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 ~~shall~~ must maintain the logbook and other related records ~~for a minimum of two years.~~in accordance with [Recordkeeping WAC].

WAC 246-xxx-x53 Drug storage and field use.

(1) An animal control agency ~~shall~~ 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:
   (a) Humane officer;
   (b) Animal control enforcement officer;
   (c) Animal control authority;
   (d) Peace officer authorized by the chief of police, sheriff, or county commissioner; or
   (e) 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:
   (a) The drug inventory present at the beginning of a shift and is present or accounted for at the end of each shift.
   (b) Recording all receipts and use of approved legend drugs and controlled substances from the emergency supply.

Distributors

WAC 246-XXX-051 Drug Manufacturers

These rules are applicable to drug manufacturers located within the state of ~~Idaho~~Washington. Non-resident manufacturers engaged in wholesale drug distribution ~~in~~ within or into ~~Idaho~~ Washington must comply with the ~~Idaho Wholesale Drug Distribution Act and rules~~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 production, process control, labeling, packaging, quality control, distribution, complaints, and any information required by state or federal law.

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Commented [WTM(62]: Do we need to make a cross reference to the recordkeeping wac here?

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WAC 246-XXX-045 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-XXX-046 Wholesaler: Facility Requirements

(1) Facilities where drugs are stored, warehoused, handled, held, offered, marketed, or displayed for wholesale distribution must:
   (a) Be of suitable size, construction, and location to accommodate cleaning, maintenance, and proper operations;
   (b) Have adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
   (c) 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;
   (d) Be maintained in a clean and orderly condition;
   (e) Be free from infestation by insects, rodents, birds, or vermin of any kind; and
   (f) Not be part of a home or residential dwelling.

(2) Facilities used for wholesale drug distribution must be secure from unauthorized entry, as follows:
   (a) Access from outside the premises must be kept to a minimum and well controlled;
   (b) The outside perimeter of the premises must be well lit~~lighted~~;
   (c) Entry into areas where drugs are held must be limited to authorized personnel;
   (d) Facilities must be equipped with an alarm system to detect entry after hours; and
   (e) Facilities must be equipped with security systems sufficient to protect against theft, diversion, ~~and~~ 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.
   (a) Used drugs and those whose immediate or sealed outer or sealed secondary containers have been opened are adulterated and must be quarantined.
   (b) 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-XXX-047 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-XXX-048 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.

(a) The records must include at least:

(i) 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;

(ii) The identity and quantity of the drugs received and distributed or disposed of; and

(iii) The dates of receipt and distribution or other disposition of the drugs.

(2) Records ~~may~~ must be maintained in an immediately retrievable manner at the inspection site or in a readily retrievable manner at a central location.

WAC 246-XXX-049 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-XXX-050 Wholesaler –Policies and Procedures

(1) 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~~, and as necessary to ensure compliance with the following:~~.

(2) Policies and procedures must include the following:

~~(1)~~(a) The oldest approved stock of a drug product must be distributed first except if extraordinary circumstances require a temporary deviation.

~~(2)~~(b) Drugs must be recalled or withdrawn upon:

~~(a)~~**i.** A request by the FDA or other local, state, or federal law enforcement or other government agency, including the Commission;

~~(b)~~**ii.** A voluntary action by a manufacturer to remove defective or potentially defective drugs from the market; ~~o~~

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~~(c)~~**iii.** An action undertaken to promote public health and safety by replacing existing merchandise with an improved product or a new package design.

~~(3)~~(c) Wholesalers must prepare for, protect against, and competently handle a crisis affecting the security or operation of a facility, including a fire, flood, or other natural disaster, a strike, or other situations of local, state, or national emergency.

WAC 246-xxx-040 Drug Distribution –Authorized Distributor

The following facilities may distribute legend drugs within or into Washington ~~state~~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 21 U.S.C. Section 353b 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 ~~without being~~is not required to obtain a license~~d or registered~~ as a wholesale distributor ~~according to the following restrictions may distribute~~if engaged in the following activities:

(a) To authorized recipients for an emergency medical purpose in which an alternative source for a drug is not reasonably available in sufficient time to prevent risk of harm to a patient that would result from a delay in obtaining a drug. The amount of the drug distributed in an emergency must not reasonably exceed the amount necessary for immediate use;

(b) Intracompany to any division, subsidiary, parent, affiliated or related company under common ownership and control of a corporate entity;

(c) To another pharmacy or prescriber pursuant to a sale, transfer, merger or consolidation of all or a part of a pharmacy or prescriber's business, whether accomplished as a sale of stock or business assets;

(d) Compounded positron emission tomography drugs or radiopharmaceutics, if in compliance with applicable federal law; and

(e) Minimal quantities of prescription drugs to a prescriber for in-office administration, including the distribution of compounded drug product in the absence of a patient specific prescription drug order in compliance with:

(i) The compounded drug product is not sterile and not intended to be sterile;

(ii) The compounded drug product is not further dispensed or distributed by the practitioner; and

(iii) The quantity of compounded drug product distributed is limited to five percent (5%) of the total number of compounded drug products dispensed and distributed on an annual basis by the dispenser, which may include a

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Commented [WTM(65]: Should check with Chris to make sure this is accurate.

Commented [GCO(66]: Revisit this !

Commented [WTM(67R66]: I do think we need to keep this, because nuclear pharmacies provide this service as a cost saver but also for proper compounding since this is a specialty part of pharmacy.

drug compounded for the purpose of, or incident to, research, teaching or chemical analysis.

WAC 246-XXX-041 Drug Distributor - Distribution

Unless exempted in ~~statute~~state or federal law:~~, an authorized distributor must furnish~~provide~~:~~

(1) An authorized distributor can distribute drug products:

(a) to a person or facility that is credentialed to dispense, conduct research, or independently administer such drugs;

(b) to a person or facility properly credentialed to possess controlled substances by the DEA and the Commission

~~(1)~~ Authorized distributors must maintain and include with each distribution all ~~Drug product only to a person licensed by the appropriate state licensing agency to dispense, conduct research with or independently administer such drugs;~~

~~(4)~~(3) Authorized distributors must deliver ~~D~~drug products ~~only~~ 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.

~~(5)~~(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:

(a) The date of the transaction;

(b) The name, address, and DEA registration number of the distributor;

(c) The name, address, and DEA registration number of the receiving authorized prescriber or entity;

(d) The drug name, strength, and quantity for each product distributed; and

(e) The signature of the person receiving the drugs.

~~**WAC 246-XXX-042 Drug Distributor – Monitoring Purchase Activities**~~

WAC 246-XXX-043 Drug Distributor – Reporting

An authorized distributor must report specified data on controlled substances distributed at least monthly to the Commission in a form and manner prescribed by the Commission, except when distributing intracompany.

WAC 246-XXX-043 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.~~; and~~

Commented [GCO(68]: New word…?

Commented [WTM(69R68]: Possibly "a part of research…" incident to may be the correct term, just reads a little funny to me.

Commented [WTM(70]: This section seems a bit jumbled. We are talking about multiple things.
1.What requirement must be met to distribute to a person/facility.
2.What paperwork must be included with those distributions, and
3.Where delivery can occur, and
4.What has to be included on a specific type of invoice?

Commented [WTM(71R70]: See changes.

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Commented [WTM(75]: Do we need this? Do we also currently require this? What would we do with this information?

(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.

WAC 246-XXX-018 Handling of Hazardous Drug