

Correctional Pharmacy – Discussion Document	Comments
<p>246-874-010 Definitions. For the purpose of these rules and regulations, in addition to the definitions in RCW 18.64.011, the following definitions apply:</p> <p>(1) "Automated drug distribution devices" means automated equipment used for remote storage and distribution of medication for use in patient care. The system is supported by an electronic data base.</p>	
<p>(2) "Authenticated or Authentication authorization of a written entry in a clinical or health record or chart by means of an electronic or handwritten signature which shall include minimally, first initial, last name, date and time.</p>	
<p>(3) "Facility" means any place designated by law for the keeping of persons held in custody under process of law, including state, county or locally owned or contracted facilities primarily used for the purposes of confinement, correction, rehabilitation, or juvenile detention.</p>	
<p>(4) "Correctional pharmacy" means a pharmacy as defined in Chapter 18.64 RCW who provides pharmaceutical services to facilities as defined in this chapter. The pharmacy can be located within or outside of the facility.</p>	
<p>(5) "Immediate supervision" means visual and/or physical proximity to a licensed pharmacist within the same facility to insure adequate safety and controls.</p>	
<p>(6) "Investigational drug" means any article which has not been approved for use in the United States, but for which the FDA has approved an investigational drug application (IND).</p>	
<p>(7) "KOP" mean to "Keep on Person", used in the context to refer to medications that patient inmates may retain on their person.</p>	
<p>(8) "MAR" means medication administration record.</p>	
<p>(9) "Nurse" means a registered nurse or a licensed practical nurse licensed pursuant to chapters 18.88 or 18.78 RCW regulating the practice of nursing in the State of Washington.</p>	
<p>(10) "Patient(s)" means facility inmate or population, clients, offenders or detainees who are receiving medical care or treatment.</p>	
<p>(11) "Perpetual Inventory" means the inventory as recorded or displayed in the pharmacy information system that is updated on a continuous basis with real inventory in stock.</p>	
<p>(12) "Pharmacy Assistant and Pharmacy Technician" means persons credentialed under chapter 18.64A RCW and WAC 246-901.</p>	
<p>(13) "Responsible Facility Practitioner" means a prescriber identified and designated by the facility to work in consultation with the responsible pharmacist in issues related to pharmaceutical care.</p>	
<p>(14) "Self-administration of drugs" means that a patient administers or takes his/her own medication (drug) from a container properly labeled by a Pharmacist or manufacturer.</p>	
<p>(15) "Shall" means that compliance with regulation is mandatory.</p>	
<p>(16) "Should" means that compliance with a regulation or standard is recommended.</p>	
<p>246-874-020 Applicability. The following rules and regulations are applicable to all facilities designated by law for the keeping of persons held in custody under process of law, including state, county or locally owned or contracted facilities primarily for the purposes of confinement, correction, rehabilitation, or juvenile detention.</p>	

<p>246-874-030 Licensure. (1) Facility pharmacists and ancillary personnel working in the pharmacy shall be licensed by the board of pharmacy in accordance with chapter 18.64 RCW & 18.64A RCW.</p>	
<p>(2) Correctional pharmacies shall be licensed by the board of pharmacy in accordance with chapter 18.64 RCW.</p>	
<p>(3) When a correctional pharmacy is decentralized, each decentralized section(s) or separate organizational element(s) shall be licensed separately and under the immediate supervision of a pharmacist.</p>	
<p>246-874-040 Personnel. (1) Each facility under this chapter shall designate a responsible pharmacist who shall have the authority and responsibility to assure that the practice of pharmacy as defined in RCW 18.64 operates in compliance with all applicable state and federal statutes and regulations. This includes licensed correctional pharmacies and those pharmacies supporting facilities without an on-site pharmacy.</p>	
<p>(2) The responsible pharmacist shall be responsible for the safe distribution, control, and accountability of drugs. The responsibilities shall include at a minimum: (a) Participation on the committee(s) or with the practitioner representing the facility to develop a drug formulary and patient care evaluation program that relates to pharmaceutical utilization and effectiveness; (b) Implementing policies and decision of the committee(s) relating to pharmaceutical services of the facility;</p>	
<p>(c) Providing a messenger or delivery service to connect the facility pharmacy with appropriate areas of the facility on a regular basis throughout the normal workday of the facility; (d) To ensure that appropriate levels of pharmaceutical care services are available to patients of the facility; (e) To ensure that drugs and/or devices are prepared for distribution safely and accurately as prescribed;</p>	
<p>(f) To develop and implement written policy and procedures relating to: (i) A system for the purchasing, ordering, storing, compounding, delivering, distributing dispensing, accounting, administering, securing and disposing of pharmaceuticals; (ii) A system to assure that pharmaceuticals are distributed for administration or delivery to patients based on an original or direct copy of the practitioner's medication order. A pharmacist shall review the original order or direct copy thereof prior to the dispensing any drug, except for emergency use or as authorized in WAC 246-874-075. (iii) A system for the filling and labeling of all containers from which drugs are to be distributed or dispensed; (iv) Specifications for the maintenance of a system of accountability for all drugs, records, IV solutions, chemicals, biologicals, patient medication records, and other records required by state and federal regulations, related to the practice of pharmacy; (v) A system assuring the adequate security of controlled substances and legend drugs;</p>	
<p>(vi) A system for completing all forms for the purchase and order of pharmaceuticals; (vii) Monthly inspections of all nursing care units or other areas of the facility where medications will be dispensed, administered, or stored. (viii) Provisions for the dissemination of drug information to practitioners and/or others; and to patients as required by WAC 246-869-220; (ix) Obtaining and recording comprehensive drug histories and when possible participating in discharge planning in order to affect appropriate drug use. (x) Preparation of all sterile products (e.g., IV admixtures, piggybacks, irrigation solutions), except in medical emergencies; (xi) Distribution and control of all radiopharmaceuticals; and</p>	

(xii) Purchase and use of over-the-counter medications	
(3) Written policies and procedures shall meet nationally accredited standards; such as, those established by the National Commission of Correctional Health Care or American Correctional Association. Policies and procedures shall be made available for inspection and review upon request by the Board of Pharmacy.	
(4) Supervision and supportive personnel. All operation of each correctional pharmacy shall be managed by the responsible pharmacist. The practice of pharmacy shall be under the immediate supervision of a pharmacist and shall be performed according to written policies and procedures. There shall be a sufficient number of additional pharmacists, pharmacy ancillary staff and/or clerical personnel required to meet the needs and safety of the patients.	
<p>246-874-050 Physical Requirements</p> <p>(1) All areas occupied by the correctional pharmacy shall be secured by key, combination or electronic means in order to prevent access by unauthorized personnel and shall be under the control of the responsible pharmacist.</p> <p>(a) The responsible pharmacist shall designate in writing, by title and/or position those licensed health care providers who shall be authorized access to medication areas outside of the pharmacy, including authorization to keys or access devices.</p> <p>(b) Ancillary pharmacy personnel shall only access the pharmacy when a pharmacist is present and shall not remove keys or access device to the pharmacy from the facility's premises.</p> <p>(c) All pharmacy personnel, while on duty, are responsible for the security of the pharmacy and shall provide adequate safeguards against the theft or diversion of drugs, and/or pharmacy records.</p>	
(2) Physical standards - A pharmacy shall have an adequate environment necessary for the storage, compounding, labeling, dispensing, distribution and sterile preparation of drugs prepared in the pharmacy and administrative functions.	
(3) Flammable storage. All flammable material shall be stored and handled in accordance with applicable local and state fire regulations, and there shall be written policies and procedures for the destruction of these flammable materials.	
(4) Adequate equipment. All pharmacies shall have in their possession the equipment and supplies necessary to compound, dispense, label, administer and distribute drugs and devices. The equipment shall be in good repair and shall be available in sufficient quantity to meet the needs of the pharmacy. There shall be a sink with hot and cold running water.	
(5) All correctional pharmacies must have access to:	
<p>(a) Washington State statutes and rules governing the practice of pharmacy; and</p> <p>(b) Current drug references to provide information to practitioners or patients concerning medications.</p>	
<p>246-874-070 Drug procurement, distribution and control.</p> <p>(1) A facility shall store medication to be dispensed to a patient pursuant to the following requirements:</p> <p>(a) The responsible pharmacist in consultation with the responsible facility practitioner shall develop written policies and procedures for the secure storage, control, administration and disposal of all drugs. Such policies and procedures must include, but are not limited to:</p>	
<p>(i) Policies prohibiting the administration, distribution, delivery or dispensing of drugs by other patients and/or residents of the facility;</p> <p>(ii) Policies shall only permit administration and/or dispensing of drugs by licensed health care personnel within the scope of their practice;</p> <p>(iii) Procedures for administration or delivery of medications to patients as prescribed;</p> <p>(iv) Procedures for confirming that the patient has ingested the medication;</p> <p>(v) Procedures for recording that the prescribed medication has or has not been administered, by whom the medication was administered, and if the medication was not administered, the reason it was not administered;</p> <p>(vi) Policies limiting the length of time medications may be administered without further</p>	

<p>medical evaluation; (vii) Procedures describing the circumstances and methods for contacting the pharmacist; (viii) Policies to provide medication to patients upon their release; and (ix) Self-administration of medications and “keep on person” (KOP) medications shall occur only within approved guidelines in accordance with a program of self-care or rehabilitation.</p>	
<p>(b) All drugs shall be stored, packaged, labeled and compounded in accordance with USP standards and under the security and control of the responsible pharmacist. (i) Locked storage and/or locked medication carts, to include refrigerated areas when appropriate, shall be provided for all areas where drugs are stored or used; (ii) All drugs which have exceeded its expiration date must be removed from stock; (iii) Drug recall procedures must be established to assure prevention of potential harm to patients of the facility and to verify that all drugs included on the recall are returned to the pharmacy for proper disposition; (iv) Pharmaceuticals shall be stored separately from all food products; and (v) Pharmaceuticals used for external use shall be stored apart from pharmaceuticals for internal use, on a separate shelf or in a separate compartment or cabinet.</p>	
<p>(2) Drug procurement: (a) Emergency Procurement. If drugs and /or pharmaceutical services are not available from the correctional pharmacy, the facility may obtain patient prescriptions from an outside pharmacy. Written policies and procedures shall assure that such outside pharmacy provides services of sufficient quality to protect the safety of the patients and serve the needs of the facility.</p>	
<p>(b) Patient’s Own Medication. Medications brought into the facility by or for the patient shall only be administered when authorized by the attending practitioner. Prior to administration, the medication must be authenticated and the quality reasonably assessed. Authentication shall be restricted to health care professionals as designated in written pharmacy policies and procedures. (i) The responsible pharmacist shall have policies and procedures for the return of patient medication when the patient is discharged from the facility. Medications not returned to the patient or the patient’s family may be disposed of within a reasonable number of days following release or death; (ii) Medications brought into the facility by an inmate which are not used shall be packaged, sealed and stored as per written policy and returned to the patient at time of release; and (iii) If returning the medication may endanger the patient’s health, the responsible pharmacist shall confer with the facility’s legal counsel or the patient’s prescriber.</p>	
<p>(3) Distribution and Records: A drug distribution system is the complete process by which a practitioner’s prescription drug order is executed to the time the ordered drug is administered to the patient or delivered to the patient for self administration. (a) The responsible pharmacist shall be responsible for establishing written policies and procedures to assure the safe and efficient distribution control and accountability of drugs. Policies and procedures shall include, but are not limited to:</p>	
<p>(i) Identification of drugs up to the point of administration or delivery to the patient for self administration; (ii) Administration or delivery of drugs based on a direct copy or original medication order issued by an authorized practitioner, except as defined by policies and procedures regarding supplemental dose kits; and (iii) Utilization of an official record of medications (MAR) dispensed to the patient. If the medication is administered or delivered, the patient profile shall be generated by the pharmacy and shall include, at a minimum: A. Patient’s name and any other assigned identification number; B. Date of Birth; C. Gender;</p>	

<p>D. Housing assignment; E. Pharmaceutical product dispensed, to include KOPs, date dispensed, strength, dose form, quantity and directions, and identification of dispensing pharmacist; F. Chronic conditions; and G. Any patient allergies which may relate to drug utilization.</p>	
<p>(b) The responsible pharmacist shall be responsible for the appropriate security and control of the pharmacy managed patient medication record system, whether manual or electronic. The medication record system shall have appropriate user tracking in-place to identify the generator of each record and track who modified each order in succession.</p> <p>(4) Labeling. All drugs dispensed, administered, or delivered shall be labeled with adequate identifiers to assure the right drug for the right patient. All drugs shall be stored in appropriate containers, and legibly labeled to identify at a minimum, brand name or generic name, strength, lot number and expiration date.</p>	
<p>(a) Accessory and/or cautionary statements and the expiration date shall be applied to the label of all medication containers.</p> <p>(b) All drugs dispensed for use by the patient to be released from the facility shall be labeled in accordance with RCW 18.64.246 and WAC 246-869-210 and shall include any precautionary information as may be required for proper use and safety to the patient.</p>	
<p>(c) For all suitable label shall be affixed to all parenteral and irrigation solutions. At a minimum the label shall indicate:</p> <ul style="list-style-type: none"> (i) Name and location of the patient; (ii) Prescriber's name; (iii) Drug name and the amount of drug(s) added to the solution; (iv) Directions for use, administration, and storage; (v) Cautionary information; (vi) Beyond use dating, and; (vii) Initials of the personnel who prepared and checked the solution. 	
<p>(5) The responsible pharmacist shall establish:</p> <ul style="list-style-type: none"> (a) A process for conducting an annual review and update of comprehensive written policies and procedures governing the responsibilities and functions of pharmaceutical services; and (b) Policies affecting patient care and treatment involving drug use in consultation and with input from the medical staff, nursing service and facility administration. Pertinent policies affecting other medical staff, nursing service and administration shall be made readily available for appropriate reference. 	
<p>246-874-075 Supplemental Dose Kit.</p> <p>(1) General. Pharmaceutical services shall be available on a 24-hour basis. Written policies and procedures shall address the use of a supplemental dose kit when the pharmacist is not available.</p>	
<p>(2) Automated drug distribution devices or supplemental dose kit. Access to drugs, in the absence of a licensed pharmacist, shall be by substantially secured devices located outside of the pharmacy area. Access shall be authorized to nurses or practitioners, as specified by written policies and procedures. The device shall be sufficiently secure to deny access to unauthorized personnel.</p> <p>(a)The responsible manager shall, in conjunction with the appropriate committee(s) of the facility, develop inventory of those drugs to be included in such devices.</p>	
<p>(b)The responsible pharmacist shall establish and implement written policies and procedures to include, at a minimum:</p> <ul style="list-style-type: none"> (i) All drugs removed from the device shall be labeled in accordance with written policies and procedures that shall establish full accountability for the drugs and comply with state and federal rules and regulations; (ii) Drugs shall be packaged using unit dose or a modified unit dose packaging system in amounts sufficient for the immediate therapeutic requirements until the pharmacy opens; (iii)Drug shall be removed in amounts equal to a single prescribed dose at the time of 	

<p>administration or delivery and the drugs must remain in the original packaging until administration;</p> <p>(iv)When doses for multiple patients are removed simultaneously each patient’s medication must be placed in separate containers identifying the patient;</p> <p>(v)Removal of any drug shall be properly documented, to include practitioner’s order and proof of use; and</p> <p>(vi)A system for accountability of access, use and stocking of drug inventory shall comply with Chapter 246-872 WAC.</p>	
<p>RCW 246-874-080 Controlled Substances.</p> <p>(1) Controlled substance accountability. The responsible pharmacist shall establish written procedures for maintaining adequate records regarding use and accountability of controlled substances, and other drugs as deemed appropriate by the responsible pharmacist, in compliance with state and federal laws and regulations.</p>	
<p>(a) The pharmacy shall maintain records of controlled substances issued from the pharmacy to each facility location. The records shall include, at a minimum:</p> <ul style="list-style-type: none"> (i) Date; (ii) Name of the Drug; (iii) Amount of the drug issued; (iv) Name and/or initials of the pharmacist who issued the drug; and (v) Name of the patient and/or unit to which the drug was issued. 	
<p>(b) Records shall be maintained by all units of the facility that possess controlled substances and other drugs as designated by the responsible pharmacist indicating:</p> <ul style="list-style-type: none"> (i) Date of administration; (ii) Time of administration; (iii) Name of the drug (if not already indicated on the records); (iv) Dosage of the drug to include the amount administered, and any amount destroyed. (v) Name of the patient to whom the drug was administered; (vi) Name of the practitioner who authorized the drug; and (vii) Signature or unique identifier of the licensed individual who administered the drug. 	
<p>(2) Perpetual inventories shall be maintained for all controlled substances.</p>	
<p>(3) The responsible pharmacist shall develop written procedures for the proper destruction of controlled substances to include at a minimum the following:</p> <ul style="list-style-type: none"> (a) Return all solid dosages to the pharmacy. When it is necessary to destroy parenteral controlled substances following the administration of a dose by a nurse, the destruction shall be witnessed by a second nurse, pharmacist, or practitioner who shall countersign the records of destruction. (b) All drug destructions shall render the drugs unrecoverable. 	
<p>(4) Periodic monitoring of controlled substances records shall be performed by a nurse or a pharmacist to determine whether the drugs recorded on usage records have also been recorded on the patient's chart.</p>	
<p>(5) Use of multiple dose vials of controlled substances shall be discouraged.</p>	
<p>(6) All controlled substances stored outside of the pharmacy shall be locked in a substantially constructed storage container approved by the responsible pharmacist.</p>	
<p>(7) Controlled substances stored in any facility’s patient or nursing service area shall be counted by two authorized persons licensed to administer drugs when transfer of accountability occurs. If an automated dispensing device is utilized, the procedures for the automated dispensing device shall be used.</p>	
<p>(8) All controlled substance records shall be kept for two years.</p>	
<p>(9) Facilities using record systems other than that described above shall make application and receive written approval from the board of pharmacy prior to implementation.</p>	
<p>(10) Losses, disappearances and unaccounted discrepancies of controlled substances shall be reported to the board of pharmacy, the federal drug enforcement administration, the facility manager/administrator and other appropriate authorities.</p>	

<p>246-874-090 Administration of Medications.</p> <p>(1) Medications shall be administered only upon the order of a practitioner who has been granted clinical privileges to write such orders. The facility shall maintain policies for the granting of practitioner clinical privileges. Verbal orders for drugs shall only be issued in emergency or unusual circumstances and shall be accepted only by a licensed nurse, pharmacist, or physician, and shall be immediately recorded and signed as a verbal order by the person receiving the order. Such orders shall be authenticated by the prescribing practitioner in a timely manner as defined in policy. The following methods maybe used for authentication:</p> <ul style="list-style-type: none"> (a) Authorization by the facility prescriber; or (b) Receipt of written medication order from patient's prescriber. 	
<p>(2) Drugs shall be administered only by appropriately licensed personnel in accordance with state and federal laws and regulations governing such acts and in accordance with facility policies as approved by medical staff.</p>	
<p>246-874-100 Investigational drugs.</p> <p>(1) Distribution. Storage, distribution, and control of approved investigational drugs used in the facility shall be the responsibility of the responsible pharmacist or his designee. The pharmacy shall be responsible for maintaining and providing information on approved investigational drugs.</p>	
<p>(2) General. Investigational drugs shall be properly labeled and stored for use only under the explicit direction of the authorized principal investigator or co-investigator(s). Such drugs shall be approved by an appropriate medical staff committee.</p>	
<p>(3) Administration. On approval of the principal investigator or co-investigator(s), those authorized to administer drugs may administer these drugs after they have been given basic pharmacological information about the drug. Investigational drugs shall be administered in accordance with approved written guidelines that include any requirements for the patient's appropriate informed consent.</p>	
<p>246-874-110 Medication drug therapy monitoring.</p> <p>(1)The Pharmacist shall review the appropriateness of the choice of medications for the patient and the patient's therapeutic regimen. The pharmacist shall have timely access to the following:</p> <ul style="list-style-type: none"> (a)Admission diagnosis; (b)Age, weight, height and sex; (c) History of allergies and/or previous adverse drug reactions; (d) Current and discontinued medications; (e) Co-Morbid disease states; and (f) Pertinent laboratory information. 	
<p>(2) The pharmacist shall review each medication order and in the case of an identified significant problem or opportunity for improvement, the pharmacist shall contact the prescribing practitioner. All such significant communications shall be documented in the patient record. Pharmacy interventions shall be reviewed with appropriate staff committees on a routine basis.</p>	
<p>246-874-120 Continuous quality improvement and quality assurance.</p> <p>(1) Each correctional pharmacy shall establish a continuous quality improvement program organized under RCW 43.70.510. The purpose of a continuous quality improvement program is to improve the quality of health care services by identifying and preventing health care malpractice. The quality improvement plans should at a minimum include an ongoing plan to monitor, evaluate, and reduce medication incidents and reduce adverse drug events and raise the quality of the pharmaceutical services provided.</p>	
<p>(2)Plans should include:</p> <ul style="list-style-type: none"> (a) Organizational quality assurance policies that meet the requirements of national accrediting organizations where applicable; (b) Use of electronic order systems/ information records system; (c) Drug utilization review; 	

<ul style="list-style-type: none"> (d) Medication error tracking and root cause analysis; (e) Adverse event tracking and trends; (f) Use of information for institutional quality improvement; and (g) Staff training and orientation. 	
<p>(3) All medication errors and adverse drug events upon discovery shall be recorded in an incident report that is routed to the pharmacy and the prescribing practitioner.</p>	
<p>(4) The responsible pharmacist shall:</p> <ul style="list-style-type: none"> (a) Monitor drug therapy; (b) Provide drug information to patients, practitioners and others; (c) Conduct surveillance and report adverse drug reactions and drug product defect(s); and (d) Prepare a written report, at least every three months, addressing CQI activities. 	
<p>246-874-130 Additional responsibilities.</p> <p>(1) General. The correctional pharmacy shall participate in other activities and committees within the facility affecting pharmaceutical services, drug administration, and drug use.</p>	
<p>(2) Clinical activities. The responsible pharmacist should develop clinically oriented programs, including but not limited to obtaining and recording comprehensive drug histories and participation in inmate discharge planning, to affect appropriate drug use, a formal drug information service, prescribing, and administration of drugs.</p>	
<p>(3) Additional pharmaceutical services shall include the following with appropriate written policies and procedures:</p> <ul style="list-style-type: none"> (a) The use of pharmaceutical samples if used within the facility; and (b) Collaborative drug therapy agreements. 	

General Comments