

BOARD OF PHARMACY

DIVISION 41

OPERATION OF PHARMACIES (RETAIL AND INSTITUTIONAL DRUG OUTLETS) CONSULTING PHARMACISTS AND OPERATION OF DRUG ROOMS

Hospitals with Pharmacies

855-041-6050

Definitions

(1) In these rules, OAR 855-041-6000 through 855-041-6999, the terms below have these meanings:

(a) “Automated Distribution Cabinet” (ADC) means a computerized drug storage device or cabinet that allows a drug to be stored and dispensed near the point-of-care, while controlling and tracking drug distribution;

(b) “Drug” means a drug, a prescription device, a biological medication, a chemical or any combination of these terms;

(c) “Central pharmacy” means a pharmacy within a licensed hospital with a single location and inventory, which prepares and distributes drugs to secondary storage areas in the facility, and remote locations;

(d) “Chief Pharmacy Officer” (CPO) means an Oregon licensed pharmacist who supervises the pharmacy operations in a hospital. The CPO may hold the title of Pharmacy Manager, Pharmacy Director, Director of Pharmacy, Pharmacy Administrator or other pharmacy supervisory management title within the organization. The PIC may also be the CPO if there is only one pharmacy in the hospital;

(e) “Drug profile” means a complete and comprehensive summary of a patient’s current drugs and details of each drug including information such as active ingredient, strength and form, dose and directions for use, and other supplementary information;

(f) “Licensed Independent Practitioner” (LIP) means an individual permitted by law and by the organization to provide care and services, without direction or supervision, within the scope of the individual's license;

(g) “Out-patient” means a person who is not residing in the facility but who is registered with the facility and is using the facility for treatment or diagnostic services;

(h) "Remote storage area" means a patient care area which is part of the hospital that is under the supervision and control of the hospital's central pharmacy but is not located in the same building as the central pharmacy;

(i) "Secondary drug storage area" means an area in a hospital or licensed residential facility, which is supplied by a central pharmacy and may include facilities such as a drug room, a distribution cabinet or a hospital department;

(j) "Unit-dose" means a quantity of a drug designed to be administered to a patient, such as:

(A) An oral solid individually packaged or re-packaged;

(B) An oral liquid drawn up in a labeled oral syringe;

(C) An injectable product; or

(D) A pre-mixed IV product.

(2) Notwithstanding 855-006-0005 and 855-019-0200(2) and (3), for the purpose of these rules, OAR 855-041-6000 through 855-041-6999, verification or final verification means the confirmation by a pharmacist of the correctness, exactness and accuracy of the act, tasks, or function as specified elsewhere in this Division of rules.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

855-041-6100

Registration

(1) Each central pharmacy must be registered with the Board. In a hospital with multiple central pharmacies, each pharmacy location must be registered with the Board.

(2) A secondary drug storage area within the hospital or in a structure physically attached to the hospital does not require a separate registration.

(3) A registered pharmacy in a hospital may use additional locations within the hospital, supervised by a pharmacist, without acquiring separate registrations for each additional location.

(4) A secondary drug storage area in a separate location must be registered as a drug room and must follow all rules that apply to secondary storage areas in the hospital.

(5) A residential healthcare facility that is licensed by DHS and that has a central pharmacy must register the pharmacy with the Board.

(6) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public health or safety or the health and safety of a patient. A waiver granted under this section shall only be effective when it is issued by the Board in writing. A waiver is not valid for more than five years.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155, 689.305

855-041-6150

General Pharmacy Requirements

- (1) Each hospital pharmacy must have an Oregon licensed pharmacist designated as Pharmacist-in-Charge (PIC).
- (2) A hospital that has more than one pharmacy must designate an Oregon licensed pharmacist as CPO or an equivalent position who has responsibility for directing pharmacy services in the hospital. The CPO may also be the PIC of one of the pharmacies.
- (3) A hospital pharmacy may only be operated when under the direct supervision of an Oregon licensed pharmacist. The pharmacist shall be responsible for all areas of the hospital where drugs are stored, including remote storage areas
- (4) The pharmacy must be operated at least part-time, five days a week.
- (5) The hospital pharmacy must have adequate space so that drugs can be prepared in sanitary, well-lit, enclosed places. Space and equipment must be adequate for the pharmaceutical services provided including compounding, distributing, and storage of drugs and parenteral preparations.
- (6) As a minimum, the pharmacy must have the following:
 - (a) Equipment listed in OAR 855-041-0040, except that a pharmacy that is only registered as an institutional drug outlet does not need to have an Official Poison and Exempt Narcotic Register;
 - (b) A drug formulary approved by the appropriate hospital committee;
 - (c) Pharmacy policy and procedures.
- (7) All areas occupied by a hospital pharmacy must be secured to prevent access by unauthorized personnel.
 - (a) Whenever any area of a hospital pharmacy is not under direct supervision of a pharmacist, the area must be secured;

(b) The CPO shall designate in writing, by title and specific area, those persons who may have access to specific areas within the pharmacy;

(c) Unless otherwise permitted by these rules, a non-pharmacist may not have access to the pharmacy unless a pharmacist is on duty and present in the hospital.

(8) A residential healthcare facility that has a central pharmacy must comply with these rules.

(9) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public health or safety or the health and safety of a patient. A waiver granted under this section shall only be effective when it is in writing. A waiver is not valid for more than five years.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

Drug Distribution and Control

855-041-6200

Chief Pharmacy Officer and Pharmacist in Charge

(1) The CPO must specify the respective responsibilities of the CPO and the PIC if separate individuals hold these positions.

(2) In addition to the duties listed in this rule, the PIC has the responsibilities listed in OAR 855-019-0300.

(3) The CPO must establish policies and procedures that include:

(a) Procedures for general distribution of drugs throughout the hospital;

(b) A procedure for review and revision of the policies and procedures not less than every three years;

(c) Procedures for the supervision of pharmacy services including storage, distribution, control and accountability for drugs including controlled drugs;

(d) Procedures to ensure that all areas of the hospital where drugs are stored are inspected not less than every two months to verify proper drug storage, documentation of distribution and administration of controlled substances, absence of outdated drugs, and the integrity of the emergency drug supplies;

(e) Policies and procedures that govern the preparation, verification and sterilization of parenteral drugs compounded within the hospital. Procedures must comply with OARs 855-045-0200 through 855-045-0270 and these rules;

- (f) Procedures for administration of drugs, including self-administration;
- (g) Procedures for labeling drugs;
- (h) Policies and procedures that govern the filling and labeling of containers from which drugs are to be administered;
- (i) Procedures for a Quality Assurance program to ensure that there is a planned, ongoing and systematic process for the monitoring and evaluation of the quality and appropriateness of pharmacy services, and for identifying and resolving problems. Such monitoring and evaluation must be accomplished through ongoing collection of information and periodic assessment of the collected information;
- (j) Emergency drug distribution;
- (k) Procedures for procurement of all drugs subject to approval of the appropriate committee of the hospital;
- (L) Procedures to ensure that discontinued, outdated, adulterated or misbranded drugs are returned to the pharmacy for proper disposition, or that the PIC makes proper disposition or disposal of such drugs at the storage site;
- (m) A recall procedure that can be quickly activated to assure the CPO and pharmacy staff, and the medical staff that all drugs included in the recall have been returned to the pharmacy for proper disposition;
- (n) Policies and procedures for the use of investigational drugs;
- (o) Procedures to be followed in the absence of the pharmacist.
- (4) The CPO must:
 - (a) Participate in the development and revisions of a hospital formulary;
 - (b) Maintain an emergency and disaster plan for pharmacy services, and participate in the facility's emergency and disaster plan;
 - (c) Ensure that records of all transactions of the hospital pharmacy that are required by state and federal laws and regulations are maintained, and maintain accurate control and accountability for all pharmaceutical materials;
 - (d) Participate in the hospital's Quality Assurance program related to drugs;
 - (e) Comply with all inspection and other requirements of the pharmacy in accordance with all applicable state and federal laws and regulations.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155

855-041-6220

Records

(1) Unless specified otherwise, all records and documentation required by these rules, OAR 855-041-6000 through 855-041-6999 must be retained for three years and made available to the Board for inspection upon request. Records must be stored onsite for at least one year and may be stored in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.

(2) The PIC must ensure maintenance of written or electronic records and reports as necessary to ensure patient health, safety and welfare. Records must include:

- (a) Patient profiles and drug administration records;
- (b) Reports of suspected adverse drug reactions;
- (c) Inspections of drug storage areas;
- (d) Annual controlled substance inventories;
- (e) Controlled drug accountability reports;
- (f) Collaborative Drug Therapy agreements;
- (g) Current hospital drug formulary;
- (h) Any other records and reports required by state and federal laws and regulations.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.508

855-041-6240

Drug Administration

(1) In a hospital, a drug may only be administered upon an order initiated by:

- (a) A member of the medical staff who has been granted clinical privileges;

(b) An authorized member of the house staff; or

(c) An authorized licensed practitioner.

(2) Each administration of a drug must be in accordance with policies and procedures approved by the appropriate committee of the hospital, must comply with all applicable laws, rules and regulations, and must follow usual and customary standards of good medical practice.

(3) Self-administration. A patient may only be permitted to self-administer a drug when specifically authorized by the treating or ordering practitioner, and when the patient has been educated and trained in the proper self-administration of the drug.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

855-041-6250

Patient's Own Drugs and Other Drugs from Outside Sources

When a patient or a patient's agent brings a drug into the hospital, the drug may only be administered to the patient if:

(1) The practitioner or pharmacist has identified it and it is in a pharmacy labeled container; and

(2) Any administration is pursuant to a practitioner's order; or

(3) In the pharmacist's professional judgment, withholding the drug would be detrimental to the patient's health. In such a case, the pharmacist may authorize administration of the drug pursuant to a practitioner's order.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

855-041-6260

Investigational Drugs

(1) All in-patient investigational drugs must be stored in the pharmacy and may only be distributed from the pharmacy when properly labeled.

(2) Information concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions and symptoms of toxicity of such drugs must be available in the pharmacy.

(3) Investigational drugs may only be ordered by a designated physician-investigator or their authorized clinician, subject to the prior approval of the appropriate hospital committee.

(4) Each order must include the appropriate protocol number.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

855-041-6270

Labeling

(1) Each pharmacy record keeping system must identify and document the pharmacist who verifies the drug.

(2) Each pre-packed drug, including a unit-dosed drug, prepared by the pharmacy and intended for use within the facility shall be in an appropriate container with a label that contains:

(a) The brand or generic name and expiration date;

(b) The manufacturer and lot number, or an internal pharmacy code that references manufacturer and lot number;

(c) The strength of the drug.

(3) In-patient: Each drug dispensed to an in-patient other than in a unit-dose or manufacturer's unit-of-use packaging must be labeled with the following information:

(a) Name and location of patient;

(b) Name and strength of drug;

(c) Route of administration, when necessary for clarification;

(d) Manufacturer and lot number, or internal pharmacy code;

(e) Auxiliary labels as needed, and

(f) Expiration date.

(4) A drug that is to be sent with the patient upon discharge must be labeled in accordance with ORS 689.505(5) and other rules in this Division. Drug counseling information must be provided to the patient or patient's agent.

(5) A label for an outpatient prescription must comply with ORS 689.505(5) and other rules in this Division.

(6) New bar coding or electronic label: When a new barcode or electronic label is used to identify a drug the pharmacist must verify and document the accuracy of the identification with all electronic verification systems prior to distribution.

(7) Whenever a drug is added to a parenteral solution under the direct supervision of a pharmacist, the admixture must be labeled with a distinctive supplementary label that contains

(a) The name, quantity and concentration of the drug added and the primary solution;

(b) The date and time of addition;

(c) The expiration date;

(d) The scheduled time for administration;

(e) The infusion rate, when applicable;

(f) The name or initials of person performing admixture;

(g) The identification of the pharmacy where the admixture was performed; and

(h) The name or initials of the verifying pharmacist.

(8) The label applied at a secondary storage or remote storage area by a nurse or physician must include: the patient name or patient identifier, quantity and concentration of the drug added and the primary IV solution; the date and time of addition and the initials of the nurse or physician adding the drug.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155, 689.505

Absence of a Pharmacist

855-041-6300

The CPO must make appropriate arrangements for provision of drugs to the medical staff and other authorized personnel by use of a night cabinet or by access to the pharmacy, or both, for situations when hospital pharmacy services are not available.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.605

855-041-6305

Night Cabinet

(1) If a night cabinet is used, the following procedures must be followed:

(a) The cabinet or other enclosure located outside the pharmacy must be secure from unauthorized access;

(b) Only one authorized registered nurse on a shift may have access to the night cabinet and may remove drugs. Such nurse must be designated in writing by the appropriate committee of the hospital and prior to being given access to the night cabinet, must receive appropriate training in the proper procedures for access, removal of drugs, and recordkeeping;

(c) The PIC or designee must give this training, and must require, at a minimum, the following procedures:

(A) A drug may only be removed from the night cabinet on a practitioner's written order or a verbal order that has been reduced to writing;

(B) A copy of the practitioner's order must be left in the night cabinet for the pharmacist to verify for accuracy. Both the nurse supervisor and the verifying pharmacist must initial the order.

(2) In conjunction with the appropriate hospital committee, the CPO must develop an inventory of those drugs to be included in each cabinet and establish procedures to ensure that:

(a) Drugs are available and labeled as required by these rules;

(b) Only prepackaged drugs are placed in the cabinet;

(c) Quantities do not exceed those reasonable for immediate therapeutic requirements;

(d) Whenever a cabinet has been accessed, a written record is kept of the drug order and certification of the drug use;

(e) Controlled substances are kept securely and are accounted for using a reconciled perpetual inventory;

(f) An audit of controlled substances in the cabinet is conducted at least once per month. If a tamper-evident seal system is not used, a quality assurance program must be in place to identify any diversion.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.605

855-041-6310

After hours access to pharmacy

When a drug required to treat the immediate needs of a patient is not available from floor-stock or a night cabinet, it may be obtained from the pharmacy in accordance with the following procedures:

- (1) Only one registered nurse supervisor on a shift may have access to the pharmacy and may remove drugs. The nurse supervisor must be designated in writing by the appropriate hospital committee and prior to being permitted to obtain access to the pharmacy, must receive appropriate training in the proper procedures for access, removal of drugs, and recordkeeping;
- (2) The PIC or designee must give such education and training, and must require, at a minimum, the following procedures:
 - (a) A drug may only be removed from the pharmacy on a practitioner's order that has been posted to the patient's medical record;
 - (b) A copy of the practitioner's order must be left either with the container from which the drug was removed or with an identical unit-dose, and must be placed conspicuously for a pharmacist to verify for accuracy;
 - (c) A record of each drug removed from the pharmacy by the nurse supervisor must include:
 - (A) Name and hospital location of the patient;
 - (B) Name and strength of drug distributed;
 - (C) Units used;
 - (D) Date and time of distribution;
 - (E) Initials of the nurse supervisor distributing the drug;
 - (F) Date and initials of the pharmacist who confirmed the accuracy of the transaction.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.605

Outpatient Drug Distribution

855-041-6400

Emergency Dispensing by a Nurse

A hospital may provide for the emergency dispensing of a drug to an outpatient who is under the care of a practitioner who is a member of the hospital medical staff, when there is a legitimate medical need as described in hospital policies and procedures.

(1) A designated registered nurse may dispense a drug to an outpatient subject to the following:

(a) There is a prescription from a practitioner authorized to prescribe the drug or a verbal order that the nurse has reduced to writing. A practitioner who issues a verbal order or prescription must send a written prescription to the hospital pharmacy within seven days;

(b) The drug is in a manufacturer's bulk unit-of-use, such as an inhaler, or hospital pre-pack that has been labeled by the pharmacy with;

(A) Name of drug, strength, and number of units. When a generic name is used, the label must also contain the name of the manufacturer or distributor;

(B) Accessory cautionary information as required for patient safety;

(C) Product identification label if the drug is not in unit-of-use packaging;

(D) An expiration date after which the patient should not use the drug;

(E) Name, address and phone number of the hospital pharmacy.

(c) The following information must be added to the drug container by the nurse before dispensing to the patient:

(A) Name of patient;

(B) Directions for use by the patient;

(C) Date of issue;

(D) Unique identifying number;

(E) Name of prescribing practitioner;

(F) Initials of the dispensing nurse or practitioner.

(d) The patient must be given instructions on the use and precautions for taking the drug;

(e) A prescription must be completed by the practitioner or nurse. This prescription must contain:

(A) Name of patient;

(B) Date of issuance;

(C) Name and strength of drug distributed;

(D) Units issued;

(E) Name of practitioner and initials of dispensing nurse;

(F) Instructions given to the patient.

(f) Any additional information required by state and federal laws and regulations for the distribution of a drug to an outpatient.

(2) The patient may not be given more than an emergency supply, as that is defined in the hospital policy and procedures.

(3) The pharmacist must verify, document and date the original prescription.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155, 689.505

855-041-6410

Emergency Department Distribution

(1) A practitioner who is a member of the hospital's medical staff may dispense an emergency supply of drugs to a patient examined by them or by an associate practitioner subject to the following requirements:

(a) There is an order from a practitioner authorized to prescribe the drug in the patient's medical record;

(b) The drug is in a manufacturer's bulk unit-of-use, such as an inhaler, or hospital pre-pack that has been labeled by the pharmacy with:

(A) Name of drug, strength, and number of units. When a generic name is used, the label must also contain the name of the manufacturer or distributor;

(B) Accessory cautionary information as required for patient safety;

- (C) Product identification label if the drug is not in unit-of-use packaging;
 - (D) An expiration date after which the patient should not use the drug;
 - (E) Name, address and phone number of the hospital pharmacy.
- (c) The following information must be added to the drug container by the practitioner or nurse before dispensing to the patient:
- (A) Name of patient;
 - (B) Directions for use by the patient;
 - (C) Date of issue;
 - (D) Unique identifying number as determined by policy and procedure;
 - (E) Name of prescribing practitioner;
 - (F) Initials of the dispensing nurse or practitioner.
- (d) The patient must be given instructions on the use and precautions for taking the drug;
- (e) A prescription or record of the distribution must be completed by the practitioner or nurse. This record must contain:
- (A) Name of patient;
 - (B) Date of issuance;
 - (C) Drug name and strength distributed;
 - (D) Units issued;
 - (E) Name of practitioner;
 - (F) Initials of the dispensing nurse or practitioner; and
 - (G) Instructions given to the patient.
- (f) Any additional information required by state and federal laws and regulations for the distribution of a drug to an outpatient;
- (g) The record must be reviewed and documented by a pharmacist for accuracy and completeness.

(2) A controlled substance may only be distributed or dispensed to an outpatient by the examining practitioner after the patient has been examined by the practitioner and a legitimate medical purpose for a controlled substance has been determined. Distribution of a controlled substance must comply with all applicable state and federal laws and regulations.

(3) The pharmacy must determine the amount of each drug that constitutes an emergency supply. That amount may not exceed a four-day supply except for;

a) A drug in the manufacturer's unit-of-use packaging such as an inhalant or a topical drug;

b) A full course of therapy that may be dispensed if in the professional judgment of the pharmacist or practitioner this would be in the patient's best interest.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155, 689.505

In-patient Drug Distribution

855-041-6420

Emergency Kit and Code Cart

An emergency kit consists of those drugs which may be required to meet the immediate therapeutic needs of in-patients and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients.

(1) An emergency kit may be placed in a code cart or as a stand-alone emergency kit.

(2) A pharmacist must verify and document the contents of each emergency kit.

(3) The CPO in cooperation with the appropriate hospital committee shall determine the list and quantity of drugs to be included in an emergency kit. The CPO must ensure that this list is reviewed annually.

(4) An emergency drug kit must use a tamper-evident system and be stored to prevent unauthorized access.

(5) All drugs in emergency kits and code carts must be labeled in accordance with OAR 855-041-6270.

(6) An emergency kit or code cart must be labeled to indicate that it is a drug supply for emergency use. A label must also contain the name, strength, quantity of all drugs in the kit or code cart and the expiration date of the kit. The label shall be affixed to or be available on the exterior of the code cart.

(7) The expiration date of an emergency kit or code cart must be the same as the earliest expiration date of any drug in the kit or cart. Prior to the expiration date, the pharmacist must replace expired drugs.

(8) Only an authorized person may remove a drug from an emergency kit or code cart. Any removal must be pursuant to a valid order or approved protocol.

(9) The pharmacy must be notified when an emergency kit or code cart has been opened or has expired and the pharmacist must restock or replace the emergency kit within a reasonable time.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

855-041-6500

Practitioner's Drug Order

(1) An order for a drug for an in-patient must be transmitted to the pharmacy using a system that produces a direct or an electronic copy.

(2) A pharmacist must review the drug order before the initial dose is dispensed, and must document the review and DUR except:

(a) When a drug is dispensed under OAR 855-041-6310;

(b) In an emergency;

(c) When pharmacy services are not available; or

(d) When a LIP is present.

(3) An order for a drug must contain:

(a) The patient's name and location;

(b) The drug name and strength;

(c) Route of administration;

(d) Directions for use;

(e) The date and time; and

(f) The practitioner's written or electronic signature, or the signature of the practitioner's agent.

(4) The hospital must follow the following procedures for verbal drug orders:

(a) A verbal drug order should be used infrequently;

(b) A verbal drug order of an authorized individual may be accepted and transcribed only by a qualified person who has been identified by title or category in the hospital policies and procedures;

(c) A verbal order must be reduced to writing and read back to the prescribing practitioner to verify accuracy;

(d) A verbal order must be signed or initialed by the prescribing practitioner as soon as possible.

(5) A drug administered to a patient must be ordered by an authorized prescribing practitioner or otherwise allowed by these rules.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

855-041-6510

In-patient Drug Profile

(1) Each pharmacist must ensure that a drug order for a patient requiring continuous drug therapy is entered into the patient's drug profile. The profile must contain:

(a) The patient's name, location and important clinical data such as age, height, weight, sex, chronic disease states, problem list and allergies;

(b) The drug name, strength, dosage form, route of administration and directions for administration;

(c) The drug therapy start and end date as applicable;

(d) The name or ID of the pharmacist responsible for entry or verification of the drug order.

(2) Prior to the drug being released for access by the nurse, a pharmacist must enter the drug order into a drug profile and perform a DUR except when:

(a) The drug is being dispensed from an after-hours cabinet in the absence of a pharmacist;

(b) The drug is from an emergency drug kit; or

(c) A system override is being used by a LIP or nurse to treat the emergency needs of a patient. Subject to a prescriber's order, a sufficient quantity to meet the emergency needs of the patient may be used until a pharmacist is available to review and confirm the drug order.

(3) The pharmacist must continue to monitor the appropriateness of the patient's drug utilization throughout the patient's stay in the hospital.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

855-041-6520

Cart-fill

(1) A unit-dose cart-fill system is a pharmacy controlled unit-of-use drug distribution system.

(a) A unit-dose cart-fill system must provide for separation of drugs by patient name and location, and must be designed to record in an individual patient's record:

(A) The drug, dose strength, and dosing regimen of those drugs dispensed by the pharmacy;

(B) The number of doses dispensed;

(C) The date of the original order, and the date the order is discontinued.

(b) The system must:

(A) Provide a means for the pharmacist to verify the prescriber's original order;

(B) Provide a means for the pharmacist to verify the accuracy of the selected drug before the dose is delivered for administration to the patient; and

(C) Provide a mechanism to identify controlled substances.

(c) The pharmacist must verify the prescriber's original order and the accuracy of the selected drug.

(2) Controlled substances may be included in the unit-dose system if the system complies with all applicable state and federal laws and regulations.

(3) Each drug must be in unit-dose packaging when dispensed except when this is impracticable.

(4) A drug not dispensed in unit-dose packaging must be labeled in accordance with other rules in this Division.

(5) A drug in a single container multiple-dose package such as an inhaler or a topical drug must be labeled with the patient's name and location within the facility.

(6) A pharmacy technician, certified pharmacy technician, intern or pharmacist may fill daily unit-dose drug supplies for a hospital in-patient or a nursing home patient.

(7) The pharmacist must verify the accuracy of a unit-dose package before the dose is delivered for administration to the patient.

(8) Each drug must be stored in a locked area or locked cart.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

855-041-6530

Robotic Distribution Systems

(1) A robotic drug distribution system used in a central pharmacy must be in a secure area under the control of the PIC and must be connected with the system that contains the patient's drug profile.

(2) The pharmacy must maintain the following documentation for each system:

(a) Details of the equipment including manufacturer's name, model and serial number;

(b) A description of how the system is used;

(c) Policies and procedures that include:

(A) Quality assurance performed at least quarterly including a requirement that a pharmacist visually verifies the accuracy of the electronic or bar code labeling using an audit procedure that includes random sampling;

(B) Procedures for training personnel in safe system operation, security, accuracy, patient confidentiality, access and downtime procedures.

(3) All distribution records must be recorded electronically and retained for 3 years or as approved by the Board. Records must include:

(a) Identity of robotic drug distribution system accessed;

(b) Type of transaction;

- (c) Date and time of transaction;
 - (d) Name, strength, dosage form, and quantity of the drug accessed;
 - (e) Identity of the patient for whom the drug was ordered;
 - (f) Any other information the PIC may deem necessary.
- (4) Only a pharmacy technician, certified pharmacy technician, intern, pharmacist or a person designated by the PIC may have access to the system.
- (5) Only a pharmacy technician, certified pharmacy technician, intern or pharmacist may stock drugs in the system.
- (6) All drugs in the system must be packaged and labeled in accordance with state and federal laws and regulations.
- (7) Controlled Substances:
- (a) Controlled substances must be handled in accordance with all applicable state and federal laws and regulations;
 - (b) Schedule III, IV and V drugs may be stocked in a robotic drug distribution system provided there is adequate security to limit access to those personnel designated by the PIC;
 - (c) Schedule II drugs may not be stocked in any robotic drug distribution system.
- (8) Drugs prepared by a robotic system must be packaged and separated by patient or as approved by hospital protocol, prior to distribution for administration.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155, 689.508

855-041-6540

Automated Distribution Cabinets

- (1) Each ADC must be under the control of the pharmacy. The PIC must establish policies and procedures to meet the requirements of all applicable state and federal laws and regulations.
- (2) Policies and procedures addressing the operation of the ADC must be maintained in the pharmacy. They must include:
 - (a) Training of personnel granted access to the ADC;

- (b) System operation, safety, security, access, accuracy and patient confidentiality;
 - (c) Cabinet replenishment procedures;
 - (d) Downtime procedures;
 - (e) A procedure for securing and accounting for any wasted, discarded or unused drug in accordance with existing state and federal laws and regulations.
- (3) All events involving the contents of the ADC must be recorded and must include:
- (a) Identity of ADC accessed;
 - (b) Identification of the individual accessing the ADC;
 - (c) Type of transaction;
 - (d) Date and time of transaction;
 - (e) Name, strength, dosage form and quantity of the drug accessed;
 - (f) Name of the patient or patient identifier for whom the drug was ordered;
 - (g) Such additional information as the PIC may deem necessary.
- (4) Only a pharmacist, pharmacy technician, certified pharmacy technician, intern or other person designated by the PIC may have access to the ADC.
- (5) Stocking drugs in an ADC:
- (a) Only a pharmacy technician, certified pharmacy technician, intern, pharmacist or other licensed healthcare personnel designated by the PIC may stock drugs in the ADC;
 - (b) A pharmacist must visually or electronically verify the name, strength and accuracy of the drug to be released from the central pharmacy for restocking;
 - (c) When a barcode or other electronic system is used to confirm the accuracy of the replenishment of the stock in an ADC, the system must receive an initial quality assurance validation;
 - (d) When all drug doses for an individual storage unit or bin have been packaged in one container, a single barcode verification may be used;
 - (e) The PIC must monitor the accuracy of the replenishment of drugs with a quality assurance process that includes:

(A) Reconciling the ADC fill list with established unit specific drugs using the drug profile, ADC discrepancy and inventory reports; and

(B) Monitoring the accuracy of the restocking and withdrawal procedures used by all hospital staff approved for drug administration.

(f) The PIC may permit medical supplies and devices to be included in the ADC.

(6) All drugs stored in the ADC must be packaged and labeled in accordance with state and federal laws and regulations.

(7) A drug that has been removed from the ADC for any purpose may not be returned to the system unless:

(a) A pharmacist has examined the drug, the packaging, and the labeling and determined that reuse of the drug is appropriate; or

(b) It is a drug, such as a multi-dose vial, which has been exempted by the appropriate hospital committee.

(8) At the time of loading, unloading, inventorying, removing or accessing any controlled substance from the ADC, a blind count or confirmation of the correct count must be conducted. Any discrepancy must be reported immediately to the PIC or pharmacist on duty who is responsible for reconciliation of the unresolved discrepancy or proper reporting of the loss.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

855-041-6550

Secondary and Remote Storage

(1) All drugs must be stored in designated areas to ensure proper sanitation, temperature, light, ventilation, moisture control, and security.

(2) Drugs may only be stored in nursing units when space is available for the storage, security, and preparation of drug doses. Such space must include:

(a) A locked drug cabinet or room that is equipped so that each patient's drugs are separated physically or electronically. Drugs may be stored in secured individual patient storage areas or individually labeled for each patient;

(b) A container or compartment that is permanently attached to a storage cart or the drug room in which controlled substances can be secured;

(c) Alcohol and other flammables must be stored in areas that meet local building code requirements for the storage of volatiles, and such other laws and regulations that apply.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

Floor-stock and Non-emergency Trays and Kits

855-041-6560

Floor-stock

- (1) A minimal quantity of drugs may be stocked in patient care areas to meet the immediate therapeutic needs of a patient where delay would interrupt the continuity of, or compromise the care of the patient.
- (2) A hospital pharmacy must not use a floor-stock drug distribution system as its primary system of drug distribution except in departments staffed with a LIP such as the Emergency Room, Operating Rooms and Radiology.
- (3) The CPO, in consultation with nursing staff, must prepare a list of drugs by identity and quantity for each area where such supplies are stocked. This list must be kept in the pharmacy.
- (4) Floor-stock drug supplies must be stored in a secure area only accessible to pharmacy-authorized personnel.
- (5) All drugs in floor-stock must be labeled in accordance with other rules in this Division.
- (6) Drugs may only be removed from floor-stock by personnel authorized by the appropriate hospital committee. A drug may only be removed pursuant to a valid prescriber's order. Removal from stock must be recorded in accordance with policy and in the patient's medical record.
- (7) The CPO may permit medical supplies and devices to be included in the floor-stock.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

855-041-6570

Trays and Kits

(1) All drug trays and kits must be prepared by the pharmacy prior to release from the central pharmacy except that trays and kits may be prepared from floor-stock by an LIP who administers the drug or by authorized hospital staff in the case of emergency use if:

(a) The pharmacy and appropriate hospital departments jointly develop guidelines for the proper use, preparation, and security for the trays or kits; and

(b) The pharmacy has a quality assurance program for monitoring the proper use, preparation and security of the kits.

(2) A pharmacist must verify the accuracy and secure the contents of each tray or kit prepared in the pharmacy prior to release from the central pharmacy.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

Controlled Substances

855-041-6600

Controlled Drug Accountability

(1) The hospital must establish procedures and maintain records to account for all controlled substances and any other drugs designated by the appropriate hospital committee. Records must include:

(a) Name of drug;

(b) Dose ordered, dose dispensed, and dose administered;

(c) Identity of patient;

(d) Date and time of administration;

(e) Person administering the drug;

(f) Verification and documentation of any wasted drug including partial doses.

(2) The pharmacy must provide separately locked, securely affixed compartments for storage of controlled drugs and other drugs subject to abuse, except when the facility uses single-unit packaged drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

(3) The pharmacy must obtain a delivery receipt for all controlled drugs supplied as floor-stock. This record must include the date, drug name and strength, quantity, hospital unit receiving drug and the signatures of the distributing pharmacist and the receiving nurse.

(4) A record must be kept of each administration of a controlled drug from floor-stock. The record must be returned to the pharmacy monthly and the PIC or designee must:

- (a) Match returned records with delivery receipts to verify that all records are returned;
- (b) Periodically audit administration records for completeness;
- (c) Reconcile administration records with inventory and verify that sums carried from one record to the next are correctly recorded;
- (d) Periodically verify that doses documented on administration records are reflected in the medical record; and
- (e) Initial the returned record and file by date of issue.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 475.165, 689.155

855-041-6610

Schedule II Drugs

(1) In addition to the requirements above, Schedule II record keeping must include:

- (a) A perpetual inventory system for all Schedule II drugs received, stored and distributed by the pharmacy. The perpetual inventory must be reconciled with an actual inventory at least monthly and the results and any discrepancies must be noted;
- (b) Schedule II drugs stored as floor-stock in patient-care areas must be controlled with a perpetual inventory system that includes an actual inventory count and reconciliation when the department or nursing unit is open. The CPO must develop policies and procedure to ensure a regular audit of the inventory;
- (c) Quality assurance procedures for the random sample of perpetual inventory sheets including sign-out sheets or other dose-by-dose documentation, must be performed at least quarterly and must be used to determine the accuracy and effectiveness of Schedule II floor-stock drug control;
- (d) All Schedule II drugs stored in the pharmacy must be kept in a locked area or secured storage system that tracks the identity of each person making entry into and out of the system whenever a pharmacist is not physically present in the department.

(2) Policies and Procedures must specify the conditions under which Schedule II controlled substances can be transferred into or removed from an ADC.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.165, 689.155

855-041-6620

Electronic Safe Systems

(1) The pharmacy must maintain policies and procedures that address the operation of any electronic safe system. These policies must include:

- (a) Training of personnel granted access to the electronic safe system;
- (b) System operation, safety, security, access, accuracy and patient confidentiality;
- (c) Downtime procedures.

(2) All events involving the contents of the electronic safe system must be recorded electronically. Such records must include:

- (a) Identity of electronic safe system accessed;
- (b) Identification of the individual accessing the electronic safe system;
- (c) Type of transaction;
- (d) Date and time of transaction;
- (e) Name, strength, dosage form, and quantity of the drug accessed;
- (f) Name of the patient for whom the drug was ordered when applicable;
- (g) Any additional information that the CPO requires.

(3) Only a pharmacist, pharmacy technician, certified pharmacy technician or intern may have access to the electronic safe system.

(4) Only a pharmacist, pharmacy technician, certified pharmacy technician or intern may stock drugs in the electronic safe system.

(5) All activities involving the electronic safe system must comply with all applicable state and federal laws and regulations.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.165, 689.155