201 KAR 2:074. Pharmacy services in hospitals or other organized health care facilities.

RELATES TO: KRS 315.010, 315.020, 315.030, 315.121
STATUTORY AUTHORITY: 315.002, 315.005, KRS 315.191(1)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1) authorizes the Kentucky Board of Pharmacy to establish requirements to regulate and control pharmacies. KRS 315.002 and 315.005 require standards of practice in all settings where drugs are handled and requires the board to ensure the safety of all drug products provided to the citizens of Kentucky. This administrative regulation establishes requirements for pharmacy services in hospitals or other organized health care facilities.

Section 1. Definitions. (1) "Automated pharmacy system" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications, and which collects, controls, and maintains all transaction information and shall be either:
(a) A decentralized automated pharmacy system that is located outside the pharmacy department, but within the same institution, and under the supervision of a pharmacist; or
(b) A centralized automated pharmacy system from which medications are prepared for final distribution that require the approval of a pharmacist.
(2) "Institutional pharmacy" means:
(a) A pharmacy in an acute care hospital licensed pursuant to 902 KAR 20:016;
(b) A pharmacy serving an other organized health care facility; or
(c) An onsite pharmacy serving an infusion center where medication is administered.
(3) "Investigational drug" means a drug that has not been approved for use in the United States, but for which an investigational drug application has been approved by the FDA.
(4) "Other organized health care facility" means a facility:
(a) With a primary purpose to provide medical care and treatment to inpatients; and
(b) That is:
1. An intermediate care facility;
2. A skilled nursing facility;
3. A hospital other than an acute care hospital licensed pursuant to 902 KAR 20:016;
4. A licensed personal care home;
5. A licensed family care home;
6. A nursing home;
7. A nursing facility;
8. An intermediate care facility for mental retardation; or
9. An Alzheimer's nursing home.
(5) "Unit dose distribution" means a system in which drug therapy profiles are maintained in the pharmacy and doses are scheduled, prepared, and delivered in a ready-to-administer form to the patient care area as the doses are needed.

Section 2. Pharmacy Administration. (1) General.
(a) The pharmacy, organized as a separate department or service, shall be directed by a pharmacist, who shall be thoroughly knowledgeable about institutional pharmacy practice and management.
(b) The director of pharmacy services shall be responsible for departmental management and the development and implementation of goals and objectives to meet the needs of the institution and shall be responsible to the chief executive officer of the institution or the chief ex-

ecutive officer’s designee.

(c) If the director of pharmacy services is not employed full time, the institution shall establish an ongoing arrangement in writing with a pharmacist to provide services required by this administrative regulation and KRS 315.020(1).

(d) If a hospital pharmacy is decentralized, each decentralized section or separate organizational element shall be under the immediate supervision of a pharmacist responsible to the director of pharmacy services.

(2) Pharmacy personnel.

(a) The institutional pharmacy shall maintain additional pharmacists in cooperation with the institution's administration, either full time or part time, as required to operate safely and effectively to meet the needs of the patients.

(b) If nonpharmacist personnel are employed, nonpharmacist personnel shall perform all duties under the supervision of a pharmacist and shall not be assigned and shall not perform duties that are to be performed only by a pharmacist.

(3) Responsibilities.

(a)1. Lines of authority and areas of responsibility within the pharmacy shall be clearly defined.

2. Written job descriptions for all categories of pharmacy personnel shall be prepared and revised as necessary.

(b)1. There shall be policies and procedures to provide for selection of drugs as well as a distribution system to serve the needs of the patient.

2. Provision for procurement of drugs in an emergency situation shall be provided for.

(4) Supportive personnel.

(a) Sufficient supportive personnel (technical, clerical, and other) shall be available in order to optimize the participation of pharmacists in activities requiring professional judgment.

(b) The training and supervision of supportive personnel shall be the responsibility of the pharmacist.

(5) Availability.

(a) The services of a pharmacist shall be available continuously. If around-the-clock operation of the pharmacy is not feasible, the pharmacist shall be available on an on-call basis, and an adequate night drug cabinet shall be established. The pharmacy itself shall not be designated as the night drug cabinet.

(b) A hospital not having a full-time pharmacist, but in which drugs are prepackaged or relabeled or transferred from one (1) container to another, shall obtain a pharmacy permit and have at least a part-time pharmacist designated to perform those functions or to provide personal supervision of those functions.

Section 3. Physical Facility. (1) The institutional pharmacy shall have adequate space, equipment, and supplies sufficient to provide for safe and efficient drug storage, preparation, and distribution, patient education and consultation, drug information services, and proper management of the department.

(2) Legal requirements. The physical facility shall meet state and federal regulations and shall be accessible by authorized pharmacy personnel only.

(3)(a) A currently licensed hospital shall be exempt from the provisions of subsection (2) of this section if it:

1. Is authorized by the Department for Health and Human Services to provide pharmacy services; and

2. Does not currently possess a pharmacy permit.

(b) A currently licensed hospital exempt from the provisions of subsection (2) of this section

shall permit access by authorized personnel only.

(4) Location. Locked storage or locked medication carts shall be provided for use in each nursing unit or service area.

(5) Reference materials. The pharmacy shall have current pharmaceutical reference materials in accordance with 201 KAR 2:090. References related to the following subjects shall also be available:

(a) Drug identification;

(b) Toxicology;

(c) Drug interactions;

(d) Parenteral drug compatibility; and

(e) Microbiology.

Section 4. Drug Distribution and Control. (1) General. The institutional pharmacy shall be responsible for the procurement, distribution, and control of all drugs and parenteral solutions used within the institution. Policies and procedures governing these functions shall be developed by the pharmacist with input from other involved hospital, infusion center, or other organized health care facility staff (for example, nurses) and committees (for example, pharmacy and therapeutics committee and patient care committee).

(2) Dispensing. The pharmacist shall dispense medications only on the order of a licensed medical practitioner.

(3) Prescriber's order. The pharmacist shall review the medication order.

(4) Recordkeeping. The pharmacist shall maintain appropriate records of each medication order. The records shall be retained for the time and in the manner prescribed by state and federal law.

(5) Patient medication profile. A medication profile shall be maintained for all inpatients and for those ambulatory patients routinely receiving care at the institution. The pharmacist shall utilize this profile to properly review, schedule, prepare, and distribute medications except in an emergency situation.

(6) Labeling and packaging.

(a) Each licensee shall comply with U.S.P. Standards established pursuant to federal law and all state and federal laws and regulations regarding labeling and packaging.

(b) Labeling and packaging of medications used for outpatients shall meet the requirements of state and federal law.

(7) Dispensing. The pharmacist shall dispense medications by the unit dose distribution system if feasible. If the unit dose distribution system is not utilized, adequate safeguards shall be in place to protect patients.

(8) Stop orders. There shall be established written stop order policies or other methods of assuring that drug orders are not continued inappropriately in accordance with the status of the patient.

(9) Administration.

(a) Drugs shall be administered only upon order of a licensed medical practitioner.

(b) The institutional pharmacy shall participate in the establishment of policies and procedures regarding the administration of medications. Specific procedures shall be developed in cooperation with appropriate hospital, infusion center, or other health care facility personnel and shall include personnel authorized to schedule, prepare, and administer medications.

(10)(a) Unused medication. The institutional pharmacy shall establish policies and procedures for the disposition of patients' unused medications.

(b) Medication in unit dose form may be reissued if package integrity has been maintained and the product has not expired.

(11) Hospital floor stocks.

(a) Floor stocks of drugs shall be kept as small as possible. The pharmacist in charge shall be responsible for authenticating the need for floor stock.

(b) A pharmacist shall review all orders distributed through floor stock.

(c) The pharmacist in charge shall be responsible for defining those areas of the hospital requiring floor stock (for example, emergency room, surgery, critical care, or medical or surgical wards).

(d) All drug storage areas within the hospital shall be routinely inspected by pharmacy personnel at least monthly, and documentation shall be maintained to ensure that:

1. Unusable items shall not be present; and

2. All stock items shall be properly labeled and stored.

(e) This subsection shall not apply to other organized health care facilities.

(f) This subsection shall apply to infusion centers where medications are administered with an onsite pharmacy.

(12) Drug recall. There shall be a system for removing from use a drug that has been recalled.

(13) Sample medications. The institutional pharmacy shall establish policies and procedures regarding medical representatives and the obtaining, storage, and dispensing of complimentary packages of medications.

(14) Emergency drugs.

(a) The institutional pharmacy shall establish policies and procedures for supplying emergency drugs.

(b) For expediency and efficiency, emergency drugs shall be limited in number to include only those whose prompt use and immediate availability are generally regarded by physicians as essential in the proper treatment of sudden and unforeseen patient emergencies.

(c) Emergency stocks shall be routinely inspected by pharmacy personnel on a monthly basis and documentation maintained to determine if contents have become outdated and if the stocks are being maintained at adequate levels.

(15) Investigational drugs.

(a) Policies and procedures controlling the use of investigational drugs (if used in the institution) shall be developed and followed.

(b) The pharmacy shall be responsible for storing, packaging, labeling, distributing, maintaining inventory records (including lot numbers and expiration date), and providing information about investigational drugs (including proper disposal).

(16) Controlled substances. All permit holders shall comply with state and federal laws regarding controlled substances.

Section 5. Assuring Rational Drug Therapy. (1) Appropriate clinical information about patients shall be available and accessible to the pharmacist for use in daily practice activities.

(2) The pharmacist shall be a member of the pharmacy and therapeutics committee and any other committees where input concerning the use of drugs is required.

(3) The pharmacist shall provide a means to ensure that patients receive adequate information about the drugs they receive. Patient education activities shall be in coordination with the nursing and medical staffs and patient education department, if any.

Section 6. Responsibility. The pharmacist-in-charge of a pharmacy utilizing an automated pharmacy system shall be responsible for:

(1) An initial validation of system accuracy prior to use for distribution to patients;

(2) Ensuring the system:

(a) Is properly maintained;
(b) Is in good working order;
(c) Accurately dispenses the correct strength, dosage form, and quantity of drug prescribed; and
(d) Complies with the recordkeeping, access, and security safeguards pursuant to all applicable state and federal laws;
(3) Assuring medications are reviewed prior to loading into an automated pharmacy system and distribution;
(4) Implementing an ongoing quality assurance program that monitors performance of the pharmacy compounding robotics, which is evidenced by written policies and procedures and requires a continued documented validation of doses distributed on a routine basis and annual review of the quality assurance program;
(5) Establishing policies and procedures if there is a system failure of an automated pharmacy system;
(6) Providing the board with prior written notice of installation or removal of an automated pharmacy system. This notification shall include the:
(a) Name and address of the pharmacy; and
(b) Initial location of the automated pharmacy system;
(7) Oversight for assigning, discontinuing, or changing personnel access to the system, including establishment of written policies and procedures for security and control;
(8) Reviewing personnel access on at least an annual basis;
(9) Assuring that the decentralized automated pharmacy system stock is checked at least monthly in accordance with established policies and procedures, including checking for:
(a) Accuracy;
(b) Integrity of packaging; and
(c) Expiration dates;
(10) Maintaining in the pharmacy the following documentation relating to an automated pharmacy system:
(a) The name and address of the pharmacy or inpatient health care facility where the system is being used;
(b) The automated pharmacy system manufacturer's name, model, serial number, and software version;
(c) A description of how the system is used;
(d) Written quality assurance procedures and accompanying documentation of use to determine continued appropriate use of the system as established in subsections (7) and (8) of this section; and
(e) Written policies and procedures for system operation, safety, security, accuracy, emergency medication access, access, and malfunction which includes clearly defined down time and procedures; and
(11) Maintaining adequate security systems and procedures, evidenced by written policies and procedures to:
(a) Prevent unauthorized access;
(b) Maintain patient confidentiality;
(c) Allow user access modification; and
(d) Comply with federal and state laws.

Section 7. Standards. (1)(a) All events involving the contents of the automated pharmacy system shall be recorded electronically.
(b) Records shall be maintained by the pharmacy and be available to the board and shall

include the following:

1. The date, time, and location of the system accessed;
2. Identification of the individual accessing the system;
3. Type of transaction;
4. Name, strength, dosage form, and quantity of drug accessed; and
5. Name of the patient for whom the drug was ordered, if applicable.

(2) All medications to be stocked into the centralized automated pharmacy system shall have been previously validated for bar code accuracy by a pharmacist, pharmacist intern, or certified pharmacy technician. Integrity and accuracy shall be validated by a pharmacist.

(3) The stocking of medications in a decentralized automated pharmacy system utilizing bar code technology shall be done by a pharmacist, pharmacist intern, or a certified pharmacy technician.

(4) The stocking of medications in a decentralized automated pharmacy system without bar code technology shall be done by a pharmacist, pharmacist intern, or a certified pharmacy technician. Integrity and accuracy shall be validated by a pharmacist.

(5) If a hospital licensed pursuant to 902 KAR 20:016 utilizes technology that validates appropriate drug, dose, dosage form, route of administration, time of administration, and patient at the exact time of medication administration, the stocking of the decentralized automated pharmacy system shall be done by a pharmacist, pharmacist intern, or certified pharmacy technician.

(6) A record of medications stocked in an automated pharmacy system shall be maintained for at least five (5) years and shall include:

(a) The name of the person repacking the medications; and

(b) Documentation of the pharmacist checking the medications.

(7) All containers of medications stored in the automated pharmacy system shall be packaged and labeled in accordance with federal and state laws.

(8) The automated pharmacy system shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the automated pharmacy system, in accordance with federal and state laws.

(9) All medications initially received in the pharmacy for use in an automated pharmacy system shall be quarantined until validation of bar code accuracy and existence of the item in the database powering automated pharmacy system by a certified pharmacy technician, pharmacist intern, or pharmacist.

(10) If a medication needs to be repackaged:

(a) A pharmacist, pharmacist intern, or certified pharmacy technician shall:

1. Perform the repackaging and validate the presence of an accurate bar code on the unit dose packaging; and
2. Document the repackaging process including:

a. Manufacturer;
b. Date and time of repackaging;
c. The person repackaging;
d. The lot number or batch number;
e. The expiration date; and
f. The quantity repackaged; and

(b) A pharmacist shall:

1. Validate for accuracy and integrity prior to the addition to the automated pharmacy system; and
2. Document the validation including:

a. The date and time of the validation;

b. The name of the pharmacist validating;

c. The lot number or batch number;

d. The expiration date; and

e. The quantity validated.

(11) A medication returned to the pharmacy from a patient care area shall follow the processes established pursuant to Section 4(10) of this administrative regulation.

(12) A medication distributed by the centralized automated pharmacy system shall be distributed in the delivery device utilized by that system.

(13) A medication distributed by an automated pharmacy system shall be accessed and administered by a professional licensed to administer medications. (16 Ky.R. 1713; Am. 2150; 17 Ky.R. 2175; eff. 12-13-1990; 30 Ky.R. 75; 577; eff. 8-20-2003; 39 Ky.R. 1753; 2175; 2312; eff. 6-19-2013; 44 Ky.R. 15, 447; eff. 7-17-2017.)