**Section 1330.530 Onsite Institutional Pharmacy Services**

a) Onsite Pharmacies. A pharmacy located in facilities licensed under the Nursing Home Care Act, the Hospital Licensing Act, or the University of Illinois Hospital Act, or that are operated by the Department of Human Services or the Department of Corrections, and that provide pharmacy services to residents, patients, employees, prescribers and students of these facilities, shall, in addition to other requirements of the Act and this Part, comply with this Section.

b) Recordkeeping Requirements

1) Every prescription or medication order filled or refilled shall contain the name, initials or other unique identifier of the pharmacist (and pharmacy technician if one is used) who fills or refills the prescription or medication order, or the name, initials or other unique identifier may be recorded on another appropriate, uniformly maintained and readily retrievable record that indicates, at least, the following information:

A) The name and dosage form of the drug;

B) The date of filling or refilling; and

C) The quantity dispensed.

2) No prescription may be dispensed for a period in excess of 15 months from the date of the original issuance of the prescription by the prescriber.

3) The pharmacist-in-charge shall maintain or have access to the following records for at least 5 years or as otherwise required by law:

A) Records of medication orders and medication administration to patients;

B) Procurement records for controlled substances;

C) Records of packaging, bulk compounding or manufacturing; and

D) Records of actions taken pursuant to drug recalls.

c) Labeling Requirements

1) All medication repackaged by the pharmacy for future use inside the institution or facility and not intended for immediate dispensing to a specific patient shall be identified as follows:

A) Single dose or multi-dose drugs, except sterile solutions to which a drug has been added, shall be labeled with:

i) Brand and/or generic name;

ii) Strength (if applicable);

iii) Beyond use date; and

iv) Reference code to identify source and lot number.

B) Sterile solutions to which drugs have been added shall contain on the outer label:

i) Name, concentration and volume of the base sterile solution;

ii) Name and strength of drugs added;

iii) Beyond use date and time of the admixture; and

iv) Reference code to identify source and lot number of drugs added.

2) All medication prepared by the pharmacy for immediate dispensing to a specific patient or resident in the institution or facility shall be identified as follows:

A) Single dose or multi-dose drugs, except parenteral solutions to which a drug has been added, shall be identified with:

i) Brand and/or generic name; and

ii) Strength (if applicable).

B) Sterile solutions to which drugs have been added shall be identified with:

i) Name, concentration and volume of the base sterile solution;

ii) Name and strength of drugs added; and

iii) Beyond use date and time of the admixture.

C) All medication dispensed to a specific patient in the institution shall be dispensed in a container identified with the name of the patient and the patient's location. Those institutions or facilities utilizing a unit-dose and medication cart system may identify the name of the patient and the patient's location on the outside of the bin of the medication cart, when those carts are filled by the pharmacy.

3) Labels on all medications dispensed by the pharmacy for immediate dispensing to a patient being discharged, emergency room patient and/or employee shall contain the following:

A) The name and dosage form of the drug;

B) The date filled;

C) The quantity dispensed; and

D) Directions for use.

4) Investigational new drugs, authorized by the U.S. Food and Drug Administration, shall be dispensed pursuant to a valid prescription order of the principal physician-investigator or the principal physician-investigator's authorized clinician. All investigational drugs shall be stored in and dispensed from the pharmacy and shall be identified with the following information:

A) Name of drug and strength (if applicable);

B) Beyond use date;

C) Reference code to identify source and lot number;

D) A label indicating "For Investigational Use Only"; and

E) Name and location of the patient. Those institutions or facilities utilizing a unit-dose and medication cart system may identify the name of the patient and the patient's location on the outside of the bin of the medication cart, when those carts are filled by the pharmacy.

5) A pharmacist providing a copy of a prescription to an ultimate consumer for the purpose of transfer or any other purpose shall cancel the face of the original prescription and record the date the copy is issued, to whom issued, and the pharmacist's signature on the face of the original prescription. Copies of prescriptions shall be marked "For Information Purposes Only" and require prescriber authorization to fill.

d) Staffing of the Pharmacy

1) The responsibilities of the pharmacist-in-charge shall include:

A) Supervision of all the activities of all employees as they relate to the practice of pharmacy;

B) Establishment and supervision of the method and manner for storage, dispensing and safekeeping of pharmaceuticals in all areas of the institution or facility, including maintenance of security provisions to be used when the pharmacy is closed. The following security provisions shall be utilized:

i) The pharmacy shall be staffed at all times by a registered pharmacist during open hours; and

ii) Only registered, certified, and licensed individuals under this Part shall have access to the pharmacy, except as provided in Section 1330.530(e)(1);

C) Establishment and supervision of the recordkeeping system for the purchase, sale, delivery, possession, storage and safekeeping of drugs;

D) The development and implementation of a procedure to be utilized in the event of a drug recall that can be readily activated to assure that all drugs included on the recall are returned to the pharmacy for proper disposition;

E) Establishment of specifications for the procurement of all drugs that will be dispensed by the pharmacy; and

F) Establishment and supervision of a method of documenting an oral prescription from a practitioner licensed to prescribe to a pharmacist and for transmission of that information to the appropriate members of the nursing staff of the institution or facility.

2) The operations of the pharmacy and the maintenance of security provisions are the responsibility of the pharmacist-in-charge whether the owner is a sole proprietor, partnership, association, corporation or any other entity.

3) Within 30 days after the change of a pharmacist-in-charge, the Division shall be notified in writing by the departing pharmacist-in-charge.

4) The departing pharmacist-in-charge shall, on the effective date of the change, inventory the following controlled substances:

A) All Schedule II drugs, as defined in the Illinois Controlled Substances Act, by actual physical count; and

B) All other scheduled drugs, as defined in the Illinois Controlled Substances Act, by estimated count.

5) The inventory shall constitute, for the purpose of this Section, the closing inventory of the departing pharmacist-in-charge and the initial inventory of the incoming pharmacist-in-charge. This inventory record shall be preserved in the pharmacy for a period of 5 years. An affidavit attesting to the completion and preservation of the inventory record bearing the date of the inventory and the signatures of the departing and incoming pharmacist-in-charge shall be submitted to the Division, at its principal office, within 30 days after the change in the pharmacist-in-charge.

6) Failure on the part of a registrant to provide the affidavit required in subsection (d)(5) shall be grounds for denying an application or renewal application for a pharmacy license or for disciplinary action against a registrant. Denial shall be based on the recommendation of the Board.

7) In the event the departing pharmacist-in-charge refuses to complete the inventory as provided for in subsection (d)(4), or that pharmacist-in-charge is incapacitated or deceased, the initial inventory for the incoming pharmacist-in-charge shall be the inventory as completed by the incoming pharmacist-in-charge. The incoming pharmacist-in-charge will not be responsible for any discrepancy that may exist in the inventory prior to initial inventory.

8) When the accuracy, relevance or completeness of any submitted documentation is reasonably questioned by the Division because of lack of information, discrepancies or conflicts in information given, or a need for clarification, the registrant will be required to:

A) Provide information as may be necessary; and/or

B) Appear for an interview before the Board to explain the relevance or sufficiency, clarify information given or clear up any discrepancies or conflicts in information.

9) Pharmacists and pharmacies are prohibited from accepting from patients or their agents for reuse, reissue or resale dispensed medications, chemicals, poisons or medical devices, except for:

A) Medical devices that can be properly sanitized prior to reuse, resale or re-rent; and

B) Medications that are dispensed and stored under conditions defined and supervised by the pharmacist and are unopened in sealed, intact and unaltered containers that meet the standards for light, moisture and air permeation as defined by a current United States Pharmacopeia − National Formulary published by the United States Pharmacopeial Convention, Inc.

e) Medication Dispensing in the Absence of a Pharmacist. The availability of necessary medications for immediate therapeutic use during those hours when the institutional pharmacy is not open shall be met in the following manner:

1) An after-hour cabinet, which is a locked cabinet or other enclosure located outside of the pharmacy area containing a minimal supply of the most frequently required medication, may be utilized provided that only personnel specifically authorized by the institution in which the pharmacy is located may obtain access and it is sufficiently secure to deny access to unauthorized persons. After-hour cabinets shall only be used in the absence of a pharmacist. When medication is removed from the cabinet or enclosure, written physician's orders authorizing the removal of the medication shall be placed in the cabinet or enclosure. A log shall be maintained within the cabinet or enclosure and authorized personnel removing medication shall indicate on the log the signature of the authorized personnel removing the medication, name of the medication removed, the strength (if applicable), the quantity removed and the time of removal. An automated dispensing and storage system may be used as an after hours cabinet. This use shall be in compliance with Section 1330.680.

2) Emergency kits containing those drugs that may be required to meet the immediate therapeutic needs of the patient, and that are not available from any other source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining the drugs from the other source, may be utilized. Emergency kits shall be supplied and maintained under the supervision of a pharmacist. Drugs shall be removed from emergency kits only by authorized pharmacy personnel, persons authorized to administer medication pursuant to a valid order by a practitioner licensed to prescribe in Illinois. Emergency kits shall be sealed in some manner that will indicate when the kit has been opened. A label shall be affixed to the outside of the emergency kit indicating the beyond use date of the emergency kit. The beyond use date of the emergency kit shall be the earliest beyond use date of any drug contained in the kit. After an emergency kit has been used or upon discovery that the seal has been broken or upon the occurrence of the beyond use date, the kit shall be secured and returned to the pharmacy to be checked and/or restocked by the last authorized user. If the pharmacy is closed at such time, the kit shall be returned when it opens. An automated dispensing and storage system may be used as an emergency kit. This use shall be in compliance with Section 1330.680.

3) Whenever any drug is not available from night cabinets or emergency kits, and the drug is required to treat the immediate needs of a patient, the drug may be obtained from the pharmacy in sufficient quantity to meet the immediate need by an authorized nurse. When medication is removed from the pharmacy by an authorized nurse, a copy of the licensed practitioner's order authorizing the removal of the medication shall be conspicuously placed in the pharmacy with the container from which the drug was removed so that it will be found by a pharmacist and checked promptly. A form shall be available in the pharmacy upon which shall be recorded the signature of the authorized nurse who removed the medication, the name, strength (if applicable) and quantity of medication removed.

4) Drugs may be dispensed from the emergency room only by a practitioner licensed to prescribe and dispense, and only to patients treated in the institution. This shall occur only during hours in which outpatient institutional pharmacy services are not available. The quantity dispensed should be limited to no more than a 72 hour supply, except for antimicrobial drugs and unit of use packages (e.g., inhalers, ophthalmic, otics, etc.), to meet the immediate needs of the patient until pharmacy services are available. Drugs dispensed in this manner must meet all labeling requirements pertaining to community pharmacies as specified in Section 1330.500. There shall be written policies and procedures, approved by the medical staff, regarding the dispensing of drugs from the emergency room.

f) Pharmacies that compound and dispense sterile products shall comply with Section 1330.640.

g) Pharmacies that utilize automated dispensing and storage systems shall comply with Section 1330.680.

(Source: Amended at 47 Ill. Reg. 8352, effective June 2, 2023)