**Section 1330.520 Offsite Institutional Pharmacy Services**

a) Pharmacies that are not located in the facilities they serve and whose primary purpose is to provide services to patients or residents of facilities licensed under the Nursing Home Care Act, the Hospital Licensing Act, the University of Illinois Hospital Act, or the Illinois Department of Human Services shall, in addition to any other requirements of the Act and this Part, comply with this Section.

b) Recordkeeping Requirements for Dispensing Prescriptions or Orders

1) Every prescription or order dispensed shall be documented with the name, initials or other unique identifiers of the pharmacist (and student pharmacist or pharmacy technician if one is used) authorized to practice pharmacy under the provisions of the Act who dispenses the prescription or order. For purposes of the Act, an authorized person is:

A) A pharmacist licensed in the State of Illinois; or

B) A pharmacy technician, certified pharmacy technician or student pharmacist under the supervision of a pharmacist.

2) Each pharmacy must maintain records for 5 years that contains the information in subsection (b)(3). This information shall be readily retrievable and in a format that provides enforcement agents a concise, accurate and comprehensive method of monitoring drug distribution via an audit trail. This system may require 2 or more documents that, when read together, will provide all the information required by federal (e.g., the regulations of the Drug Enforcement Administration (21 CFR 1300; 2014)) and State (e.g., the Pharmacy Practice Act and the Illinois Controlled Substances Act [720 ILCS 570]) statute.

3) In addition to the recordkeeping requirements of subsection (b)(2), a uniformly maintained, readily retrievable hard copy record or back-up documentation of each prescription or order dispensed shall be maintained by the pharmacy for 5 years and shall include:

A) Name of resident;

B) Date of order;

C) Name, strength and dosage form of drug, or description of the medical device ordered;

D) Quantity dispensed (a separate record should be maintained when the quantity billed differs from the quantity dispensed, e.g., unit dose transfer systems);

E) Directions for use;

F) Quantity billed;

G) Prescriber's name;

H) Prescriber's signature and/or DEA number when required for controlled substances; and

I) The drug name and identification code or the manufacturer in case of a generically ordered medication or a generic interchange.

4) No prescription may be filled or refilled for a period in excess of 15 months from the date of the original issuance of the prescription or order by the prescriber.

5) Subject to Section 18 of the Act, any information required to be kept pursuant to this Section may be recorded and stored in a:

A) computerized pharmaceutical information system that meets the standards of performance required by the regulations of the Drug Enforcement Administration (21 CFR 1306; 2014) and shall include the capability to:

i) Retrieve the original medication order information for those medication orders that are currently authorized;

ii) Retrieve the current history of medication orders that shall, at a minimum, include the name of drug, the date of filling, the quantity dispensed, the name and identification code of manufacturer in the case of a generically written prescription or a generic interchange, for each filling, and the total number of refills when read in conjunction with any off-line hard copy of the history of medication orders dispensed to date; and

iii) Supply documentation of the correctness of filling information entered into a system must be provided by the pharmacist using the system by way of a hard copy printout of each day's filling data that has been verified, dated and signed by the dispensing pharmacist; or

B) bound logbook, or separate file, in which each individual pharmacist involved in dispensing shall sign a statement each day attesting to the fact that the refill information entered into the computer that day has been reviewed by the individual pharmacist and is correct as shown. The book or file must be maintained at the pharmacy employing the system for a period of 5 years after the date of dispensing the appropriately authorized refill.

c) In the event the long-term care facility changes pharmacy provider services, their new provider must obtain the orders from the long-term care facility and verify the authenticity and accuracy of the orders with the prescriber.

d) Staffing of the Pharmacy. When the pharmacy is closed, the public and any employees not registered under the Act are to be prohibited access to the filling and dispensing area.

e) Labeling Requirements

1) Medications for Future Use

A) Parenteral solutions to which a drug or diluent has been added or that are not in their original manufacturer's packaging shall contain the following information on the outer label:

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

ii) Name and strength of drugs added;

iii) Beyond use date and date of the admixture. Beyond use date, unless otherwise specified in the individual compendia monograph shall be not later than the beyond use date on the manufacturer's container or one year from the date the drug is repackaged, whichever is earlier; and

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

B) Non-parenterals repackaged for future use shall be identified with the following information:

i) Brand and/or generic name;

ii) Strength (if applicable);

iii) Beyond use date. Unless otherwise specified in the individual monograph, the beyond use date shall be not later than the beyond use date on the manufacturer's container or one year from the date the drug is repackaged, whichever is earlier; and

iv) Reference code to identify source and lot number.

2) Medications Prepared for Immediate Use

A) All medications prepared by the pharmacy for immediate dispensing to a specific resident or patient in the facility shall be dispensed in a container identified with:

i) Name of the resident;

ii) Resident's room and bed number;

iii) Dispensing date;

iv) Name, strength and dosage form of drug, or description of the medical device ordered;

v) Quantity dispensed;

vi) Directions for use;

vii) Prescriber's name; and

viii) Beyond use date if less than 60 days from date of dispensing.

B) Pharmacies dispensing medications to a specific resident or patient in the facility via unit dose shall label each order with the following information:

i) Name of the resident;

ii) Resident's room and bed number;

iii) Date of order;

iv) Name, strength and dosage form of drug, or description of the medical device ordered;

v) Directions for use; and

vi) Prescriber's name.

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

g) 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, the 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 or 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 that 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.

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