**Section 1330.680 Automated Dispensing and Storage Systems**

a) This Section sets forth standards for pharmacies whose practice includes the use of automated dispensing and storage systems. Automated dispensing and storage systems shall not be used in nuclear pharmacies.

b) Automated Dispensing and Storage Systems

1) Documentation as to type of equipment, serial numbers, content, policies and procedures, and locations shall be maintained on-site in the pharmacy for review by the Division. Documentation shall include, but not be limited to:

A) Name and address of the pharmacy or facility where the automated dispensing and storage system is operational;

B) Manufacturer's name and model;

C) Quality assurance policy and procedures to determine continued appropriate use and performance of the automated device; and

D) Policies and procedures for system operation, safety, security, accuracy, patient confidentiality, access, controlled substances, data retention or archival, definitions, downtime procedures, emergency or first dose procedures, inspection, installation requirements, maintenance, medication security, quality assurance, medication inventory, staff education and training, system set-up and malfunction.

2) Automated dispensing and storage systems shall be used only in settings that ensure medication orders and prescriptions are reviewed by a pharmacist in accordance with established policies and procedures and good pharmacy practice. This provision shall not apply when used as an after-hours cabinet or emergency kit as provided in Section 1330.530(e).

3) Automated dispensing and storage systems shall have adequate security systems and procedures, evidenced by written pharmacy policies and procedures, to:

A) Prevent unauthorized access or use;

B) Comply with any applicable federal and State regulations; and

C) Maintain patient confidentiality.

4) Records and/or electronic data kept by automated dispensing and storage systems shall meet the following requirements:

A) All events involving access to the contents of the automated dispensing and storage systems must be recorded electronically;

B) Records must be maintained by the pharmacy and must be readily available to the Division. The records shall include:

i) Identity of system accessed;

ii) Identification of the individual accessing the system;

iii) Type of transaction;

iv) Name, strength, dosage form and quantity of the drug accessed;

v) Name of the patient for whom the drug was ordered;

vi) Identification of the registrants stocking or restocking and the pharmacist checking for the accuracy of the medications to be stocked or restocked in the automated dispensing and storage system; and

vii) Such additional information as the pharmacist-in-charge may deem necessary.

5) The stocking or restocking of all medications in the automated dispensing and storage systems shall be accomplished by registrants under the Act or, alternatively, the pharmacist-in-charge may designate a facility's appropriately trained facility employee that is licensed pursuant to the Nurse Practice Act [225 ILCS 65] or Physician Assistant Practice Act of 1987 [225 ILCS 95] to perform the stocking or restocking. A pharmacist-in-charge who delegates stocking/restocking in this manner shall remain responsible for ensuring that the automated dispensing and storage system is stocked/restocked accurately and in accordance with established, written pharmacy policies and procedures.

6) All medications stored in the automated dispensing and storage systems shall be packaged as a unit of use for single patient use (e.g., unit dose tab/cap, tube of ointment, inhaler, etc.) and labeled as specified in thissubsection (b)(6):

A) Sterile 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 sterile solution;

ii) Name and strength of drugs or diluent added;

iii) Date and beyond use date of the admixture. The beyond use date, unless otherwise specified in the individual compendia monograph, shall be no later than the beyond use date on the manufacturer's container or one year from the date the drug is repackaged; and

iv) Reference code to identify source and lot number of drugs or diluent 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 no later than the beyond use date on the manufacturer's container or one year from the date the drug is repackaged; and

iv) Reference code to identify source and lot number.

C) Exceptions to the "unit of use" requirements in this subsection (b)(6) are as follows:

i) Injectable medications stored in their original multi-dose vial (e.g., insulin, heparin) when the medication may be withdrawn into a syringe or other delivery device for single patient use; or

ii) Over-the-counter (OTC) products stored in their original multi-dose container (e.g., antacids, analgesics) when the medication may be withdrawn and placed into an appropriate container for single patient use.

D) The pharmacy providing services to the University of Illinois College of Veterinary Medicine shall be exempt from the requirement that all medications stored in the automated dispensing and storage systems be packaged as a unit for single patient use. This exemption is solely for dispensing medications to animals.

7) For medication removed from the system for on-site patient administration, the system must document the following information:

A) Name of the patient or resident;

B) Patient's or resident's unique and permanent identifier, such as admissions number or medical records number;

C) Date and time medication was removed from the system;

D) Name, initials or other unique identifier of the person removing the drug; and

E) Name, strength and dosage form of the drug or description of the medical device removed. The documentation may be on paper, via electronic media or via any other media or mechanisms as set forth by the Act or this Part or as approved by the Division.

8) The automated dispensing and storage systems shall provide a mechanism for securing and accounting for medications once removed from and subsequently returned to the automated dispensing and storage systems (e.g., return bin). No medication or device shall be returned directly to the system for immediate reissue or reuse by a non-registrant under the Act. Medication or devices once removed shall not be reused or reissued except for:

A) Medical devices that can be properly sanitized prior to reuse or reissue; and

B) Medication that is 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 the current USP/NF, or by the USP Conventions, Inc.

9) The automated dispensing and storage systems shall provide a mechanism for securing and accounting for wasted medications or discarded medications.

10) The quality assurance documentation for the use and performance of the automated dispensing and storage systems shall include at least the following:

A) Safety monitors (e.g., wrong medications removed and administered to patient);

B) Accuracy monitors (e.g., filling errors, wrong medications removed); and

C) Security monitors (e.g., unauthorized access, system security breaches, controlled substance audits).

11) Errors in the use or performance of the automated dispensing and storage systems resulting in patient hospitalization or death shall be reported to the Division by the pharmacist-in-charge within 30 days after acquiring knowledge of the incident.

12) Policy and procedures for the use of the automated dispensing and storage systems shall include a requirement for pharmacist review of the prescription or medication order prior to the system profiling and/or removal of any medication from the system for immediate patient administration. This does not apply to the following situations:

A) The system is being used as an after-hours cabinet for medication dispensing in the absence of a pharmacist (see Section 1330.530(e)(1));

B) The system is being used in place of an emergency kit (see Section 1330.530(e)(2));

C) The system is being used to provide access to medication required to treat the immediate needs of a patient (see Section 1330.530(e)(3)). A sufficient quantity to meet the immediate needs of the patient may be removed until a pharmacist is on duty and available to review the prescription or medication order. A pharmacist shall check the orders promptly once on duty (e.g., floor stock system, emergency department, surgery, ambulatory care or same day surgery, observation unit, etc.).

13) Policies and procedures for the use of the automated dispensing and storage systems shall include the following:

A) List of medications to be stored in each system;

B) List of medications qualifying for emergency or first dose removal without pharmacist prior review of the prescription or medication order.

14) The pharmacist-in-charge shall maintain or have access to all records or documentation specified in this Section for 5 years or as otherwise required by law.

15) A copy of all pharmacy policies and procedures related to the use of an automated dispensing and storage system shall be maintained at all locations where the system is being used.

c) Duties and Responsibilities of the Pharmacist-in-Charge

1) The pharmacist-in-charge shall be responsible for:

A) Assuring that the automated dispensing and storage system is in good working order and accurately provides the correct strength, dosage form and quantity of the drug prescribed while maintaining appropriate recordkeeping and security safeguards;

B) Establishment of a quality assurance program prior to implementation of an automated dispensing and storage system and the supervision of an ongoing quality assurance program that monitors appropriate use and performance of the automated dispensing and storage system, evidenced by written policies and procedures developed by the pharmacy;

C) Providing the Division with written notice 30 days prior to the installation of, or at the time of removal of, an automated storage and dispensing system. The notice must include, but is not limited to:

i) The name and address of the pharmacy;

ii) The address of the location of the automated dispensing and storage system, if different from the address of the pharmacy;

iii) The automated dispensing and storage system's manufacturer and model;

iv) The pharmacist-in-charge; and

v) A written description of how the facility intends to use the automated storage and dispensing system;

D) Determining and monitoring access to and the limits on access (e.g., security levels) to the automated storage and dispensing system. Access shall be defined by policies and procedures of the pharmacy and shall comply with State and federal regulations.

2) Additional responsibilities of the pharmacist-in-charge or pharmacist designated by the pharmacist-in-charge shall include:

A) Authorizing the assigning of access to, discontinuing access to, or changing access to the system;

B) Ensuring that access to the medications complies with State and federal regulations, as applicable; and

C) Ensuring that the automated dispensing and storage system is stocked/restocked accurately and in accordance with established, written pharmacy policies and procedures.

d) An automated dispensing and storage system is authorized for use in any licensed hospital, long-term care facility, or hospice residence ("facility"). For all nonresident pharmacies, the pharmacist-in-charge and all pharmacy personnel who provide services while physically present at a facility located in Illinois must be licensed in Illinois. In addition to compliance with all other provisions in this Section, an automated dispensing and storage system shall comply with the following:

1) Drugs in the automated dispensing and storage system are not considered dispensed until removed from the system by authorized personnel at the facility, after being released by the pharmacy pursuant to a prescription, unless otherwise provided for in this Part.

2) Only the doses of medication needed for contemporaneous administration may be removed from the automated pharmacy system at one time.

3) Automated dispensing and storage systems utilized at a facility shall operate under the same license as the pharmacy utilizing it.

4) All records shall be maintained for a period of 5 years either at the pharmacy providing services to the facility or a central location where records are readily retrievable.

5) Only pharmacies under common ownership may share an automated pharmacy system at a facility.

(Source: Amended at 42 Ill. Reg. 20022, effective November 9, 2018)