TITLE 68: PROFESSIONS AND OCCUPATIONS
CHAPTER VII: DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
SUBCHAPTER b: PROFESSIONS AND OCCUPATIONS

PART 1330
PHARMACY PRACTICE ACT

SUBPART A: GENERAL PROVISIONS

SUBPART B: PHARMACY TECHNICIAN

SUBPART C: PHARMACIST

1330.790 Closing a Pharmacy
1330.800 Pharmacy Self-Inspection

AUTHORITY: Implementing the Pharmacy Practice Act [225 ILCS 85] and authorized by Section 2105-15 of the Civil Administrative Code of Illinois [20 ILCS 2105/2105-15].

SOURCE: Rules and Regulations Promulgated for the Administration of the Illinois Pharmacy Practice Act, effective August 20, 1975; amended March 8, 1977; amended at 4 Ill. Reg. 1234, effective July 11, 1980; amended at 5 Ill. Reg. 2997, effective March 11, 1981; codified at 5 Ill. Reg. 11049; emergency amendment at 6 Ill. Reg. 916, effective January 6, 1982, for a maximum of 150 days; amended at 6 Ill. Reg. 7448, effective June 15, 1982; amended at 7 Ill. Reg. 6496, effective June 30, 1983; amended at 9 Ill. Reg. 16918, effective October 23, 1985; amended at 10 Ill. Reg. 21913, effective December 17, 1986; transferred from Chapter I, 68 Ill. Adm. Code 330 (Department of Registration and Education) to Chapter VII, 68 Ill. Adm. Code 1330 (Department of Professional Regulation) pursuant to P.A. 85-225, effective January 1, 1988, at 12 Ill. Reg. 2957; amended at 12 Ill. Reg. 17394, effective October 14, 1988; amended at 16 Ill. Reg. 19811, effective December 7, 1992; amended at 21 Ill. Reg. 12600, effective August 29, 1997; amended at 22 Ill. Reg. 21959, effective December 1, 1998; amended at 23 Ill. Reg. 14131, effective November 18, 1999; amended at 24 Ill. Reg. 8548, effective June 9, 2000; amended at 26 Ill. Reg. 18338, effective December 13, 2002; amended at 27 Ill. Reg. 19389, effective December 11, 2003; emergency amendment at 29 Ill. Reg. 5586, effective April 1, 2005, for a maximum of 150 days; amended at 29 Ill. Reg. 13639, effective August 25, 2005; amended at 30 Ill. Reg. 14267, effective August 21, 2006; amended at 30 Ill. Reg. 16930, effective October 12, 2006; emergency amendment at 31 Ill. Reg. 16045, effective November 19, 2007, for a maximum of 150 days; amended at 32 Ill. Reg. 3262, effective February 21, 2008; amended at 32 Ill. Reg. 7116, effective April 16, 2008; old Part repealed at 34 Ill. Reg. 6688, effective April 29, 2010; new Part adopted at 34 Ill. Reg. 6690, effective April 29, 2010; amended at 39 Ill. Reg. 6267, effective April 23, 2015; amended at 41 Ill. Reg. 10643, effective August 18, 2017; amended at 42 Ill. Reg. 20022, effective November 9, 2018; amended at 47 Ill. Reg. 8352, effective June 2, 2023; amended at 48 Ill. Reg. _____, effective _____.

SUBPART B: PHARMACY TECHNICIAN

Section 1330.215 Minimum Standards for Approved Work Experience Pharmacy Technician Certification

A pharmacy technician certification program shall meet the following requirements:

a) This Section applies to pharmacy technicians registered beginning January 1, 2024.

b) The curriculum must include at least 500 hours of instruction.

c) The training must be completed by the pharmacy technician's 2nd renewal.

d) Curriculum must include didactic and practical experience for each area of instruction.

e) A graduate shall be competent in:

1) The knowledge, skills, abilities, and behaviors beyond those of a pharmacy technician.

2) Functioning in a variety of pharmacy practice settings.

3) Self-management and the management of the pharmacy.

f) The curriculum must include the following areas of instruction:

1) Knowledge/Skills:

A) Ethics;

B) Conflict resolution;

C) Customer service;

D) Communication with individuals, staff, and other healthcare professionals;

E) Self-management skills; and

F) Problem solving.

2) Continuing competency:

A) Continuing education;

B) Pharmacy technician's role and other occupations' roles in the healthcare environment;

C) Basics in anatomy, pharmacology, and physiology relevant to pharmacy technician role;

D) Pharmacy technician's role in the medication-use process;

E) Infection control procedures;

F) Protocols for vaccine administration;

G) Common allergies; and

H) Hygiene, PPE, cleaning and maintaining equipment.

3) Medication Orders:

A) Medication storage;

B) Medication ordering;

C) Recordkeeping;

D) Medication labeling;

E) Special handling procedures;

F) Prescription entry and interpretation;

G) Generic/brand names;

H) Compounding sterile preparations per applicable, current USP Chapters;

I) Moderate and high level non-sterile compounding as defined by USP (e.g., suppositories, tablets, complex creams);

J) Chemotherapy/hazardous drug preparations per applicable, current USP Chapters;

K) Billing for complex and/or specialized pharmacy services and goods;

L) Purchasing pharmaceuticals, devices, and supplies;

M) Inventory control of medications, equipment, and devices;

N) Administration of immunizations and other injectable medications;

O) Current technology/automation related to safety and accuracy of medication dispensing; and

P) Dosage forms.

4) Patient Care:

A) Pharmacy technicians' role under the Pharmacists' Patient Care Process;

B) Patient and medication safety practices;

C) Emergency patient situations;

D) Medication reconciliation process;

E) Medication management services;

F) Measurements, preparation, and packaging;

G) Point of care testing;

H) Patient confidentiality;

I) Error prevention;

J) Safety event reporting; and

K) Different insurance plan types/coupons/prior authorizations.

5) Regulatory Knowledge:

A) Review of state and federal laws pertaining to processing, handling, and dispensing of medications, including controlled substances;

B) Review of state and federal laws pertaining to pharmacy technicians;

C) OSHA requirements;

D) USP requirements – USP 795 and 797 training;

E) The Institute for Safe Medication Practices (ISMP);

F) The Joint Commission;

G) Risk Evaluation and Mitigation Strategies (REMS);

H) Look-Alike/Sound-Alike (LASA) High Alert;

I) Health Insurance Portability and Accountability Act (HIPAA);

J) Facility maintenance; and

K) Medication disposal.

g) Graduates must be competent in providing appropriate life support measures including Basic Life Support (BLS) and automated external defibrillators (AED), for medical emergencies that may be encountered in pharmacy practice.

h) All programs accredited by the Accreditation Council for Pharmacy Education (ACPE) and the American Society of Health System Pharmacists (ASHP) meet the minimum curriculum criteria set forth in this Section and are, therefore, approved.

(Source: Added at 48 Ill. Reg. _____, effective _____)

Section 1330.220 Application for Certificate of Registration as a Certified Pharmacy Technician

a) An individual may receive certification as a certified pharmacy technician if he or she:

1) Has submitted a written application in the form and manner prescribed;

2) Has attained the age of 18;

3) Is of good moral character, as determined by the Division;

4) Graduated from a pharmacy technician training program approved by the Accreditation Council for Pharmacy Education (ACPE or the American Society of Health System Pharmacists (ASHP)~~a nationally recognized accrediting body~~ or obtained documentation from the pharmacist-in-charge of the pharmacy where the applicant is employed verifying that he or she has successfully completed equivalent work experience of 500

hours as a pharmacy technician covering the practice areas set forth in items (1) through (6) of Section 17.1(a) of the Act, or successfully completed work experience ~~a training program~~ as provided for in Section 1330.215~~210(a)~~;

5) Has successfully passed an examination accredited by the National Commission for Certifying Agencies of the Institute for Credentialing Excellence (NCCA), as approved and required by the Board. The Division, upon the recommendation of the Board, has determined that the Exam for the Certification of Pharmacy Technicians offered by the Institute for the National Healthcareer Association (or its successor), and the Pharmacy Technician Certification Examination offered by the Pharmacy Technician Certification Board (or its successor), are accredited by NCCA and are, therefore, approved examinations for certification; and

6) Has paid the required certification fees.

b) No pharmacist whose license has been denied, revoked, suspended or restricted for disciplinary purposes may be eligible to be registered as a certified pharmacy technician. No person who holds an active Illinois pharmacist license may concurrently hold an active Illinois certified pharmacy technician registration.

(Source: Amended at 48 Ill. Reg. _____, effective _____)

SUBPART C: PHARMACIST

Section 1330.330 Examination for Licensure

a) The examination for licensure as a registered pharmacist shall be divided into two portions:

1) Theoretical and Applied Pharmaceutical Sciences portion, which shall test the following subjects:

A) Medicinal Chemistry;

B) Pharmacology;

C) Pharmacy;

D) Pharmaceutical Calculations;

E) Interpreting and Dispensing Prescription Orders;

F) Compounding Prescription Orders; and

G) Monitoring Drug Therapy; and

2) Pharmaceutical Jurisprudence portion, which consists of 2 parts and shall test:

A) Illinois Law related to pharmacy practice; and

B) Federal Law related to pharmacy practice.

b) An applicant must score a minimum of 75 on the Theoretical and Applied Pharmaceutical Sciences portion and a minimum of 75 on the combined Pharmaceutical Jurisprudence portion in order to successfully pass the examination for licensure. An applicant who scores 75 or greater in either the Theoretical and Applied Pharmaceutical Sciences portion or on either of the combined Pharmaceutical Jurisprudence portions will not be required to retake that portion of the examination. The reporting of scores to the candidates shall include the score obtained on the Theoretical and Applied Pharmaceutical Sciences, the score obtained on the Federal Law portion, a pass or fail score on the Illinois Law portion and the combined score consisting of the Federal Law portion and the State Law portion.

c) Any applicant who fails the NAPLEX~~any~~ portion three times or the MPJE portion ~~all portions~~ of the registered pharmacist examination three~~3~~ times in any jurisdiction will be required to furnish proof of remedial education in an approved program on the subjects of the portion failed. Proof of additional remedial education in an approved program shall also be furnished each time the applicant fails each~~any~~ portion of the examination three~~3~~ times after undergoing remedial education (i.e., after the sixth exam, ninth exam, etc.).

~~d) Pursuant to Section 7 of the Act, an applicant may work as a registered pharmacist for up to 60 days prior to the issuance of a certificate of registration upon receipt of a notice from the Division that the examination was successfully completed.~~

d~~e~~) For the purposes of this Section remedial training shall be defined as:

1) A course of study of at least 30 classroom hours in an approved pharmacy college in the subjects of the portions failed three~~3~~ times; or

2) A tutorial or preceptorship with a faculty member in an approved

pharmacy college or another pharmacist as a preceptor. The course of instruction must be deemed by the Board to be substantially equivalent to subsection (e)(1) and approved by the Division. Any remedial training must be approved by the Board and the Division prior to commencement.

e~~f~~) The provisions of this Section shall apply to all applicants upon adoption without regard to where the applicant is in the application process.

(Source: Amended at 48 Ill. Reg. _____, effective _____)

SUBPART D: PHARMACY LICENSURE

Section 1330.400 Application for a Pharmacy License

a) Establishing, Relocating or Changing Ownership

1) Any person who desires to establish, relocate or change the ownership of a pharmacy shall file an application on forms supplied by the Division, together with the fee required by Section 1330.20, and specify the types of pharmacy services to be provided as described in Sections 1330.500, 1330.510, 1330.520, 1330.530, 1330.540, 1330.550 and 1330.560.

2) Upon determination that the application is in good order, an inspection of the premises will be conducted to determine compliance with Sections 1330.610, 1330.620, 1330.630, 1330.640 and 1330.680. An application shall be in good order when it is signed and notarized and the license of the pharmacist-in-charge has been verified to be in good standing with the Division.

3) Upon recommendation of the Drug Compliance Coordinator, the Board may request the owner of the pharmacy and the pharmacist-in-charge to appear for an interview with the Board.

b) For a change of name of pharmacist-in-charge only, the owner shall be required to file an application on forms supplied by the Division, together with the required fee, and submit the present license. The Division shall evaluate the application and, if satisfactory, issue a new license.

c) Within 180~~30~~ days after issuance of a pharmacy license, the pharmacy for which the licensure was requested shall be open to the public for pharmaceutical services.

d) Any reduction in hours of operation shall be reported to the Division within 30 days.

e) Upon receipt by the Division of a change of ownership application, the purchaser may begin operations prior to the issuance of a new pharmacy license only when the purchaser and seller have a written power of attorney agreement. This agreement shall provide, among other things, that violations during the pendency of the application process shall be the sole responsibility of the seller. This agreement shall be provided to the Division upon request.

f) No pharmacy shall relocate prior to the inspection of the premises. All drugs shall be transferred within 24 hours after issuance of the license unless otherwise approved by the Department.

(Source: Amended at 48 Ill. Reg. _____, effective _____)

Section 1330.410 Pharmacy Licenses

a) Each individual, partnership, corporation or any other applicant for a pharmacy license shall indicate, on forms supplied by the Division, the type of pharmacy services to be provided by the licensee.

b) The Board may review and make recommendations to the Director regarding pharmacy applications filed with the Division.

c) A pharmacy who provides more than one type of pharmacy service shall be issued one pharmacy license and shall be charged the appropriate fee, as set forth in Section 1330.20.

d) A pharmacy shall designate a pharmacist-in-charge as provided for in Section 1330.660.

e) When a third-party~~management~~ company is hired to run a pharmacy, that third-party~~management~~ company shall be the license holder; however, the license may be issued with the name of the pharmacy, as a d/b/a, or with the name of the third-party~~management~~ company. The Illinois Controlled Substance license shall be issued to the third-party ~~management~~ company unless the third-party ~~management~~ company and the pharmacy or hospital cosigns a pharmacy service agreement that assigns overall responsibility for controlled substances to the hospital or pharmacy.

(Source: Amended at 48 Ill. Reg. _____, effective _____)

SUBPART E: TYPES OF PHARMACIES

Section 1330.550 Nonresident Pharmacies

a) The Division shall require and provide for an annual nonresident special pharmacy registration for all pharmacies located outside of this State that dispense medications for Illinois residents and mail, ship or deliver prescription medications into this State, including home pharmacies of remote pharmacies located in Illinois that are located outside of Illinois. Unless there is a direct conflict between Illinois pharmacy law and the pharmacy laws of the state in which the nonresident pharmacy is located, nonresident pharmacies shall abide by all Illinois laws and rules when filling prescriptions for Illinois residents, except that pharmacists employed at those pharmacies ~~and the pharmacist-in-charge of those pharmacies~~ shall not be required to be licensed in Illinois except as otherwise provided in this Part. Beginning January 1, 2026, pharmacists-in-charge of nonresident pharmacies shall be licensed in Illinois. Nonresident special pharmacy registration shall be granted by the Division upon the disclosure and certification by a pharmacy:

1) That it is licensed in the state in which the dispensing facility is located and from which the drugs are dispensed;

2) Of the location, names and titles of all principal corporate officers and all pharmacists who are dispensing drugs to residents of this State;

3) That it complies with all lawful directions and requests for information from the board of pharmacy of each state in which it is licensed or registered, except that it shall respond directly to all communications from the Division concerning emergency circumstances arising from the dispensing of drugs to residents of this State;

4) That it maintains its records of drugs dispensed to residents of this State so that the records are readily retrievable from the records of other drugs dispensed;

5) That it cooperates with the Division in providing information to the board of pharmacy of the state in which it is licensed concerning matters related to the dispensing of drugs to residents of this State; and

6) That, during its regular hours of operation, but not less than 6 days per week for a minimum of 40 hours per week, a toll-free telephone service is provided to facilitate communication between patients in this State and a pharmacist retained by the nonresident pharmacy who has access to the

patients' records. The toll-free number must be disclosed on the label affixed to each container of drugs dispensed to residents of this State.

b) To obtain nonresident special pharmacy registration in Illinois, an applicant shall file an application with the Division, on forms provided by the Division, that includes:

1) Disclosure and certification of information required in subsection (a); and

2) The fee required by Section 1330.20.

c) Nonresident special pharmacy registration shall expire on March 31 of each even-numbered year and may be renewed during the 60 days preceding the expiration date by paying the fee required by Section 1330.20.

(Source: Amended at 48 Ill. Reg. _____, effective _____)

SUBPART F: PHARMACY STANDARDS

Section 1330.640 Pharmaceutical Compounding Standards

All pharmaceutical compounding standards, both sterile and nonsterile, shall be governed by the current edition of USP-NF ~~(USP 41-NF 36)~~, as set forth in the United States Pharmacopoeia (USP), ~~41st Revision~~ and the National Formulary, ~~36th Edition,~~ Compounding Compendium~~, with the exception of USP Chapter <800> as it pertains to the handling of hazardous drugs in health care settings. Beginning May 1, 2019, all pharmaceutical compounding standards, both sterile and nonsterile, shall be governed by the USP-NF (USP 42-NF 37), as set forth in the 2019 edition of the USP Compounding Compendium, with the exception of USP Chapter <800> as it pertains to the handling of hazardous drugs in health care settings~~.

a) A pharmacy may only dispense compounded drugs pursuant to a valid patient-specific prescription, except as provided in this Section.

b) "Office use" means the administration of a non-patient specific compounded drug to a patient by a practitioner in the practitioner's office or by the practitioner in a health care facility or treatment setting. "Office use" does not include a pharmacy's delivery of a compounded drug to a prescribing practitioner's office pursuant to a valid patient-specific prescription.

c) Sterile compounding for office use is prohibited unless the pharmacy is in full compliance with 21 USC 353b, including becoming registered as an outsourcing facility and licensed as a wholesale drug distributor pursuant to the Wholesale Drug Distribution Licensing Act [225 ILCS 120]. However, a sterile

compounded drug may be delivered to the prescribing practitioner's office for administration pursuant to a valid patient-specific prescription.

d) A pharmacist may dispense and deliver a reasonable quantity of a nonsterile compounded drug to a practitioner for office use by the practitioner in accordance with this Section, provided:

1) The quantity of compounded drug does not exceed the amount a practitioner anticipates may be used in the practitioner's office before the expiration of the beyond use date of the drug;

2) The quantity of compounded drug is reasonable considering the intended use of the compounded drug and the nature of the practitioner's practice;

3) The quantity of compounded drug for any practitioner, and all practitioners as a whole, is not greater than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality and purity of the compounded drug that are consistent with United States Pharmacopoeia guidelines;

4) The pharmacy maintains readily retrievable records of all compounded drugs ordered by practitioners for office use. The records must be maintained for a minimum of five~~5~~ years and shall include:

A) The name, address and phone number of the practitioner ordering the compounded drug for office use and the date of the order;

B) The name, strength, quantity and dosage form of the compounded drug provided, including the number of containers and quantity in each;

C) The date the drug was compounded;

D) The date the compounded drug was provided to the practitioner; and

E) The lot number and beyond-use date.

5) The pharmacy affixes a label to any compounded drug that is provided for office use. The label shall include:

A) The name, address and phone number of the compounding pharmacy;

B) The name, strength and dosage form of the compounded drug and a list of active ingredients and strengths. If the number of active ingredients would prohibit proper labeling, then the pharmacist shall provide to the practitioner a complete list of the active ingredients and strengths (including those on the label);

C) The pharmacy's lot number and beyond-use date;

D) The quantity or amount in the container;

E) The appropriate ancillary instructions, such as storage instructions, cautionary statements, or hazardous drug warning labels when appropriate; and

F) The statement "For Office Use Only – Not for Resale".

e) All pharmacies that compound drugs must maintain, at a minimum, the following standards and equipment:

1) A separate storage area for materials used in compounding;

2) Scales or measuring devices with sufficient accuracy for the products to be compounded;

3) An area of the pharmacy used exclusively for compounding;

4) A logbook or record keeping system to track each compounded drug, which must include the lot number, expiration date of components used, and beyond-use date of compounded drug. This applies to each nonsterile compounded drug and each sterile compounded drug with a beyond-use date greater than 24 hours;

5) The current edition of the USP Compounding Compendium. This publication may be in electronic format and/or available via the internet;

6) If engaged in veterinary drug compounding, "Plumb's Veterinary Drug Handbook" or any other similar publication approved by the Division;

7) Consumable materials, as appropriate to the pharmacy services provided at that specific pharmacy, including but not limited to: filter paper, powder papers, empty capsules, ointment jars, bottles, vials, safety closures, powder boxes, labels and distilled water;

8) Drug Distribution and Control

A) Patient Profile or Medication Record System. A pharmacy generated patient profile or medication record system shall be maintained, in addition to the prescription file. The patient profile or medication record system shall contain, at a minimum:

i) Patient's name;

ii) Date of birth or age;

iii) Gender;

iv) Compounded sterile drugs dispensed;

v) Date dispensed, if off site;

vi) Date compounded;

vii) Drug content and quantity;

viii) Patient directions, if drug is administered off site;

ix) Other drugs or supplements the patient is receiving, if provided by the patient or his or her agent; and

x) Known drug sensitivities and allergies to drugs and foods.

B) Labeling. Each compounded drug dispensed to patients shall be labeled with the following information, using a permanent label:

i) Name, address and telephone number of the licensed pharmacy, if not used within the facility;

ii) Date dispensed and identifying number, if used off site;

iii) Patient's name and room number, if applicable;

iv) Name of each drug component, strength, amount and dosage form;

v) Directions for use and/or infusion rate, if used off site;

vi) Prescriber's name, if used off site;

vii) Required controlled substances transfer warnings, when applicable;

viii) Beyond-use date, and time if appropriate;

ix) If used offsite, identity of compounding and dispensing pharmacist or other authorized individual; and

x) Auxiliary label with storage requirements, if applicable.

C) In addition to labeling requirements on the Pharmacy Practice Act [225 ILCS 85] and this Part, compounded drugs dispensed to patients shall have on the label or an auxiliary label the following: "This prescription was specifically compounded in our pharmacy for you at the direction of your prescriber."

D) The pharmacist-in-charge shall ensure that records are maintained for five~~5~~ years, are readily retrievable and in a format that provides enforcement agents an accurate and comprehensive method of monitoring distribution via an audit trail. The records shall include at least the following information:

i) Purchase records; and

ii) Patient profile or medication;

9) Delivery Service. The pharmacist-in-charge shall ensure the environmental control of all preparations shipped or delivered off site. Therefore, any compounded pharmaceutical must be shipped or delivered to a patient in temperature controlled (as defined by USP Standards) delivery containers; and

10) Sales of compounded drugs to other pharmacies not under common ownership, or to clinics, hospitals or manufacturers, other than as provided in subsection (d), are not allowed, except for sales provided by pharmacies contracted to provide centralized prescription filling services pursuant to Section 25.5 of the Act, including compounding in anticipation of receiving a prescription or order based on routine, readily observed dispensing patterns.

f) For sterile compounding, a pharmacy must comply with the following additional requirements:

1) The following current resource materials and texts shall be maintained in the pharmacy and may be in electronic format:

A) Copies of the Act and this Part, the Illinois Controlled Substances Act [720 ILCS 570] and 77 Ill. Adm. Code 3100, 21 CFR (Food and Drugs), and the Illinois Hypodermic Syringes and Needles Act [720 ILCS 635];

B) One compatibility reference, such as:

i) ASHP's Handbook on Injectable Drugs;

ii) King's Guide to Parenteral Admixtures; or

iii) Any other Division-approved publication; and

C) A file or reference on extended (more than 24 hours) stability data given to finished preparations.

2) Staffing. A pharmacist shall be accessible at all times to enable each licensed facility to respond to patients' and health professionals' questions and needs. A 24-hour telephone number shall be included on the prescription label of compounded drugs and medication infusion devices if used off site.

3) Emergency Medications. Pharmacies that dispense compounded sterile drugs to patients in facilities off site or for administration in the patient's residence shall stock supplies and medications appropriate for treatment of allergic or other common adverse effects, to be dispensed upon the prescription or order of an authorized prescriber.

g) Notwithstanding any other provision of this Section, a pharmacy may compound a reasonable quantity of sterile and nonsterile drug products for office use by a veterinarian.

h) It shall be the ongoing responsibility of the pharmacist-in-charge to ensure that all pharmacists, student pharmacists, registered certified pharmacy technicians, and registered pharmacy technicians who participate in compounding activities are adequately trained for the type of compounding in which they participate. Documentation of this training shall be maintained by the pharmacy at all times.

i) Any pharmacy that, after initial licensure, chooses to add sterile compounding to the services it provides must be inspected by, and the compounding area must be approved by, the Department. It shall be the responsibility of the pharmacist-in-charge to notify the Department and arrange for the inspection.

j) For the purposes of this Section, "off-site" for all pharmacies, other than an onsite institutional pharmacy, means outside the licensed premises of a pharmacy. "Off-site" for an onsite institutional pharmacy means outside the institution within which the pharmacy is located.

(Source: Amended at 48 Ill. Reg. _____, effective _____)

Section 1330.660 Pharmacist-in-Charge

a) No pharmacy shall be granted a license without a pharmacist being designated on the pharmacy license as pharmacist-in-charge.

b) A pharmacy shall have one pharmacist-in-charge who shall be routinely and actively involved in the operation of the pharmacy.

c) A pharmacist may be the pharmacist-in-charge for more than one pharmacy; however, the pharmacist-in-charge must work an average of at least 8 hours per week at each location where he or she is the pharmacist-in-charge. If the pharmacist-in-charge is not involved in verifying or dispensing prescriptions, the hours worked in the pharmacy must be documented. If a pharmacist-in-charge~~pharmacist in charge~~ is on a leave of more than 90 days, a new pharmacist-in-charge must be designated.

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

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

2) Establishment and supervision of the method and manner for storage and safekeeping of pharmaceuticals, including maintenance of security provisions to be used when the pharmacy is closed (see Section 1330.600); and

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

e) The operations of the pharmacy and the establishment and maintenance of security provisions are the dual responsibility of the pharmacist-in-charge and the owner of the pharmacy.

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

g) In addition to notifying the Division within 30 days, the departing pharmacist-in-charge shall, on the effective date of the change, inventory the following controlled substances:

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

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

h) The inventory described in subsection (g) 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 of the inventory and preservation of the inventory record, bearing the date of the inventory and the name and signatures of the departing and the 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.

i) In the event the departing pharmacist-in-charge refuses to complete the inventory as provided for in subsection (g), 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 his or her initial inventory.

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

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

2) Appear for an interview before the Board to explain the relevance or sufficiency, clarify information given, or clear up any discrepancies or conflict of information.

k) Records shall be retained as provided for in Section 18 of the Act. Invoices for all legend drugs shall be maintained for a period of 5 years either on site or at a central location where records are readily retrievable. Invoices shall be maintained on site for at least one year from the date of the invoice.

l) Whenever a pharmacy intends on changing or adding to the type of pharmacy services it offers, as listed in Sections 1330.500, 1330.510, 1330.520, 1330.530, 1330.540, 1330.560 and 1330.640, it shall notify the Division no less than 30 days prior to the change or addition.

(Source: Amended at 48 Ill. Reg. _____, effective _____)

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 this subsection (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.

iii) Topical preserved surgical facility medications, such as eyedrops, eardrops, creams and ointments, when properly stored in their original multidose containers, applied and handled per Centers for Disease Control and Prevention and Institute for Safe Medication Practices infection control guidelines and best practices, which include mandatory training and regular competency and monitoring protocols, provided multidose and in compliance with manufacturer labeling, and used, then discarded, within the manufacturer's expiration date or facility's "beyond use" date.

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 48 Ill. Reg. _____, effective _____)

SUBPART G: PHARMACY OPERATIONS

Section 1330.720 Transfer of Prescription

a) A prescription may be transferred between pharmacies for the purpose of original fill or refill dispensing, provided that:

1) The transferring pharmacy must invalidate the original prescription on file and record the name of the receiving pharmacy, the date of issuance of the copy, and the name of the pharmacist, student pharmacist, or pharmacy technician issuing the transferred prescription order; and

2) The pharmacy~~pharmacist~~ receiving the transferred prescription directly from another pharmacy records the following:

A) The name, address and original prescription number of the pharmacy from which the prescription was transferred;

B) All information constituting a prescription order, including the following: name of the drug, original amount dispensed, date of original issuance of the prescription, and number of valid refills remaining; and

C) The pharmacist, student pharmacist, or pharmacy technician receiving the transferred prescription informs the patient that the original prescription has been cancelled at the pharmacy from which it has been transferred.

b) A prescription for Schedule II, III, IV and V drugs may be transferred only from the original pharmacy and only one time for the purpose of original fill~~ or refill dispensing and may not be transferred further~~. A prescription for Schedule III, IV, and V drugs may be transferred only from the original pharmacy and only one time for the purpose of a refill and may not be transferred further. However, a pharmacist who is electronically sharing real-time on-line computerized systems may transfer up to the maximum refills permitted by law and the prescriber's authorization in accordance with 21 CFR 1306.26(a).

c) Computerized systems must satisfy all information requirements of this Section, including invalidation of the original prescription when transferred between pharmacies accessing the same prescription records or between pharmacies of the

same ownership. If those systems that access the same prescription records have the capability of cancelling the original prescription, pharmacies using such a system are exempt from the requirements of this subsection if the transferred prescription can always be tracked to the original prescription order from the prescribing practitioner and the original prescription can be produced.

d) When prescription information is transferred to another pharmacy for the purposes of original fill, the transferring pharmacy must enter a prescription into its system as if that prescription were filled at that pharmacy.

e) Nothing in this Section shall apply to transactions described in Section 20 of the Act.

f) A prescription shall only be transferred upon the request or authorization of the person for whom the prescription was issued, except upon closure of a pharmacy, in which case notice shall be made to that person, orally or in writing, of the closure and the location where the prescription is transferred.

(Source: Amended at 48 Ill. Reg. _____, effective _____)

Section 1330.765 Requirements for Enrollment in Automated Prescription Refill Programs

Pharmacies providing automated prescription refills, whether prescribed through electronic or paper prescriptions as provided in Section 22c(a) of the Act, must:

a) Require that the patient or patient's agent agree to be enrolled in the automated refill program for each prescription medication that the patient has been prescribed.

b) Ensure that only prescriptions with valid refills are~~which include an instruction from the prescribing health care provider that the medication can be refilled and be~~ eligible for the pharmacy's automatic refill program.

c) Ensure prescriptions enrolled in the pharmacy's automatic refill program do not conflict with any other Federal or State regulations.

d~~c~~) Require that the patient or the patient's agent sign a statement that they consent to the enrollment in an automated prescription refill program for each medication for which they enroll.

e~~d~~) Maintain a record of the patient's or the patient's agent's signatures showing that they consented to be enrolled in the automated refill program for each prescription in which they are enrolled.

fe) Maintain policies and procedures which require that upon the pharmacy's receipt of a notice that the medication has been discontinued, the pharmacy staff take prompt action to ensure that discontinued medications are not dispensed to the patient under the automated refill program and that the patient's medication is removed from enrollment in the automated refill program.

(Source: Amended at 48 Ill. Reg. _____, effective _____)

Section 1330.780 Changes of Ownership, Name, Location, or Operations of a Pharmacy

a) A pharmacy application must be filed whenever any of the following occur:

1) 50% or more of the ownership of the business, other than a publicly traded business, to which the pharmacy license was issued is sold or otherwise transferred to a person or entity that does not hold any interest in the business issued the pharmacy license prior to the sale or transfer;

2) More than half the board of directors or executive officers of a business issued a pharmacy license changes;

3) Any change in the legal status of an entity (e.g., individual, partnership, corporation, limited liability company);

~~4)~~ Any change in location of a pharmacy~~, including remodel of the pharmacy or drug storage area~~;

5) Any change in the name of a pharmacy; or

6) Any addition to~~change in~~ the pharmacy operations~~ pursuant to Subpart E of this Part or the Act~~.

b) Any change of ownership of a parent company that owns a pharmacy shall not be considered a change of ownership of the pharmacy.

c) The application required by subsection (a) must be filed:

1) At least 90 days prior to occurrence of the change requiring the application for pharmacies located in Illinois.

2) No later than 30 days after the occurrence of the change requiring the application for pharmacies located outside of Illinois.

d) The Division must be notified no later than 30 days after any change in owners, partners, members, officers, directors, or shareholders owning 5% or more of the outstanding shares occurs, or any other change in the information provided on the application not specified in subsection (a).

(Source: Amended at 48 Ill. Reg. _____, effective _____)

Section 1330.790 Closing a Pharmacy

Whenever a pharmacy intends to close permanently, the following procedures must be followed:

a) Provide notice to the Drug Compliance Unit of the Division, in writing, no later than~~postmarked at least~~ 30 days after closure of the pharmacy~~in advance of the closing date~~.

b) Notify customers of the closure at least 15 days in advance of the closing date and where the customer's records will be maintained.

c) Comply with all DEA requirements for closing a pharmacy.

d) On the day the pharmacy closes:

1) Conduct an inventory of the pharmacy's controlled substances and maintain the inventory record for inspection by the Division for five~~5~~ years.

2) Return the pharmacy license to the Division's drug compliance investigator or other authorized Division personnel.

3) Notify the Division in writing as to where the controlled substances inventory and records will be kept and how the controlled substances were transferred or destroyed. Records involving controlled substances must be kept available for five~~5~~ years for inspection by the Division.

4) Notify the Division in writing of the name of the person responsible for and the location where the closing pharmacy's prescription files and patient profiles will be maintained. These records shall be kept for a minimum of five~~5~~ years from the date the last original or refill prescription was dispensed.

e) The pharmacy acquiring prescription records from a closing pharmacy must inform the Division prior to the date when the transaction is going to take place.

f) After the closing date, only the pharmacist in-charge, or other designated pharmacist, of the pharmacy discontinuing business shall have access to the prescription drugs until those drugs are transferred to the new owner or other purchaser or are properly destroyed.

g) Cover all signage indicating "Drug Store" or "Pharmacy" as soon as practicable. The signage shall be removed in a timely manner. A sign shall be prominently posted that the pharmacy is closed.

h) If a pharmacy intends to close temporarily for more than 72 hours, the following procedures must be followed:

1) The owner of the pharmacy must provide notice to the Drug Compliance Unit of the Division, in writing, within 72 hours in advance of the temporary closing date.

2) Notify customers of the closure at least 72 hours in advance of the closing date and where the customer's records will be maintained.

3) Post signage on the front door or window of the pharmacy in a manner clearly legible.

4) A pharmacy may remain temporarily closed for no longer than six months.

(Source: Amended at 48 Ill. Reg. _____, effective _____)