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

PART 1330
PHARMACY PRACTICE ACT

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AUTHORITY: Implementing the Pharmacy Practice Act [225 ILCS 85] and authorized by Section 2105-15 of the Civil Administrative Code of Illinois (Department of Professional Regulation Law) [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 Reg. 7116, effective April 16, 2008; old Part repealed at 34 Ill.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. 10225, effective June 28, 2024; amended at 49 Ill. Reg. _____, effective _____.

SUBPART A: GENERAL PROVISIONS

Section 1330.20 Fees

The following fees are not refundable:

a) Registration as a Pharmacy Technician, Student Pharmacist or Certified Pharmacy Technician

1) The fee for application for a certificate of registration as a pharmacy technician, student pharmacist, or certified pharmacy technician is $50~~$40~~.

2) The fee for the renewal of a certificate of registration as a pharmacy technician, student pharmacist or certified pharmacy technician shall be calculated at the rate of $35~~$25~~ per year.

b) License as a Pharmacist

1) The fee for application for a license as a pharmacist is $400~~$75~~.

2) In addition, applicants for any examination as a registered pharmacist shall be required to pay, either to the Division or to the designated testing service, a fee covering the cost of determining an applicant's eligibility and providing the examination. Failure to appear for the examination on the scheduled date, at the time and place specified, after the applicant's application for examination has been received and acknowledged by the Division or the designated testing service, shall result in the forfeiture of the examination fee.

3) The fee for a license as a registered pharmacist, registered or licensed under the laws of another state or territory of the United States, is $400~~$200~~.

4) The fee for the renewal of a license shall be calculated at the rate of $175~~$75~~ per year.

5) The fee for the restoration of a license other than from inactive status is $50 plus all lapsed renewal fees, not to exceed $450.

6) Applicants for the preliminary diagnostic examination shall be required to pay, either to the Division or to the designated testing service, a fee covering the cost of determining an applicant's eligibility and providing the examination. Failure to appear for the examination on the scheduled date, at the time and place specified, after the application for examination has been received and acknowledged by the Division or the designated testing service, shall result in the forfeiture of the examination fee.

c) License as a Pharmacy

1) The fee for application for a license for a pharmacy under the Act is $600~~$100~~.

2) The fee for the renewal of a license for a pharmacy under the Act shall be calculated at the rate of $250~~$100~~ per year.

3) The fee for the change of a pharmacist-in-charge is $25.

d) General Fees

~~1)~~ ~~The fee for the issuance of a license with a change of name or address other than during the renewal period is $20. No fee is required for name and address changes on Division records when no duplicate certification is issued.~~

1~~2~~) The fee for a certification of a registrant's record for any purpose is $20.

2~~3~~) The fee to have the scoring of an examination administered by the Division reviewed and verified is $20.

(Source: Amended at 49 Ill. Reg. _____, effective _____)

Section 1330.30 Unprofessional and Unethical Conduct

Unprofessional and unethical conduct by a licensee or registrant shall include, but not be limited to:

a) Failing to establish and maintain effective controls against diversion of prescription drugs.

b) Committing theft or diversion, or attempting to commit theft or diversion, by a registrant or licensee.

c) Making or filing a report or record that a pharmacist or pharmacy knows to be false or intentionally or negligently failing to file a report or keep records as required by the Act or this Part.

d) Knowingly dispensing a prescription drug after the death of the person for whom the prescription was written.

e) Billing or charging for quantities of drugs greater than that which was delivered or charging patients for a brand drug when a generic is dispensed.

f) Submitting fraudulent billing or reports to a third party payer or claiming a fee for a service that is not performed or earned.

g) Filling a prescription when a pharmacist knows, or reasonably should know, that no valid physician-patient relationship exists or failing to exercise sound professional judgment with respect to the accuracy and authenticity of any prescription/drug order dispensed.

h) Failing to provide patient counseling in accordance with this Part, failing to respond to requests for patient counseling, attempting to circumvent patient counseling requirements, or otherwise discouraging patients from receiving patient counseling concerning their prescription medications.

i) Discriminating in any manner against a person or group based upon that person or group's religion, race, creed, color, gender, sexual orientation, age or national origin.

j) Knowingly dispensing a prescription drug without a valid prescription. Dispensing or offering to dispense any drug not approved by the Food and Drug Administration (FDA), found in the USP-NF, or found on the list promulgated by the FDA for bulk drug substances that may be used to compound drug products.

k) Failing to keep one's self and one's apparel clean or to wear identification bearing name and designation.

l) Directly or indirectly furnishing to a medical practitioner prescription order-blanks that refer to a specific pharmacist or pharmacy in any manner.

m) Actively or passively participating in any arrangement or agreement in which a prescription order-blank is prepared, written, or issued in a manner that refers to a specific pharmacist or pharmacy. Pharmacy-branded enrollment forms, when a patient requests his or her prescriptions be filled at a specific pharmacy, and Risk Evaluation and Mitigation Strategies documents containing prescription information are not prohibited by this subsection.

n) Dividing a prescription order unless directed by the prescriber, payer or patient or when the full quantity of that prescription medication is not available at that location.

o) Committing dispensing errors that result in hospitalization of a patient or demonstrating a pattern and practice of dispensing errors.

p) Committing an act or acts that are of a flagrant and obvious nature so as to constitute conduct of such a distasteful nature that accepted codes of behavior or codes of ethics are breached.

q) Committing an act or acts in a relationship with a patient that violate common standards of decency or propriety.

r) Willfully violating, or knowingly assisting in the violation of, any law relating to the use of habit-forming controlled substances.

s) Failing to full comply or respond to a Department subpoena within 60 days.

t) Committing any other act or omission that breaches the pharmacist's responsibility to a patient according to the accepted standard of care in pharmacy practice.

(Source: Amended at 49 Ill. Reg. _____, effective _____)

Section 1330.80 Renewals

a) Every license issued under the Act, except the certificate of registration as a student pharmacist~~pharmacy technician~~, shall expire on March 31 of each even-numbered year. Every certificate of registration as a student pharmacist~~pharmacy technician~~ issued under the Act shall expire annually on March 31. The holder of a license or certificate of registration may renew the license or certificate during the 60 days preceding the expiration date by paying the required fee.

b) It is the responsibility of each registrant to notify the Division of any change of address or email address. Failure to receive a renewal form from the Division shall not constitute an excuse for failure to renew~~pay the renewal fee~~.

c) Practicing or operating on a license or certificate that has expired shall be considered unlicensed activity and shall be grounds for discipline pursuant to Section 30 of the Act.

d) As provided in Section 9 of the Act, registered pharmacy~~Pharmacy~~ technicians shall be required to submit ~~with their second renewal~~ proof of certification as a certified pharmacy technician, proof of enrollment in a first professional degree program in pharmacy, or proof of enrollment in clinical training by a graduate of a foreign pharmacy program for the first renewal or restoration that occurs after the license has been issued for at least 2 years, regardless of whether or not the license has been active, inactive, or not renewed~~, as provided in Section 9 of the Act~~. This requirement does not apply to pharmacy technicians licensed prior to

January 1, 2008. Failure to provide proof of certification results in non-renewal of the pharmacy technician's registration.

e) Certified pharmacy technicians must certify to having completed the continuing education requirements of Section 1330.230.

(Source: Amended at 49 Ill. Reg. _____, effective _____)

Section 1330.90 Restoration ~~of a Pharmacist License~~

a) A pharmacist seeking restoration of a certificate of registration that has expired for 5 years or less shall have the license restored upon payment of all lapsed renewal fees required by Section 1330.20 and proof of 30 hours of CE (e.g., certificate of attendance or completion) in accordance with Section 1330.100.

b) A pharmacist seeking restoration of a certificate of registration that has been placed on inactive status for 5 years or less shall have the license restored upon payment of the current renewal fee and proof of 30 hours of CE (e.g., certificate of attendance or completion) in accordance with Section 1330.100.

c) A pharmacist seeking restoration of a certificate of registration after it has expired or been placed on inactive status for more than 5 years shall file an application, on forms supplied by the Division, together with the fee required by Section 1330.20 and proof of 30 hours of CE (e.g., certificate of attendance or completion) in accordance with Section 1330.100.

1) The pharmacist shall also submit either:

A) Certification of active practice in another jurisdiction. Evidence shall include a statement from the appropriate board or licensing authority in the other jurisdiction that the registrant was authorized to practice during the term of active practice; or

B) An affidavit attesting to military service as specified in Section 12 of the Act. The applicant restoring a license shall be excused from the payment of any lapsed fee or any restoration fees.

2) A pharmacist who is unable to submit proof of satisfaction of either subsection (c)(1)(A) or (B) shall submit proof of completion of:

A) 30 hours of CE; and

B) Either:

i) 600 hours of clinical practice under the supervision of a licensed pharmacist completed within 2 years prior to restoration; or

ii) Successful completion of the North American Pharmacist Licensure Examination (NAPLEX). To be successful, an applicant must receive a passing score of 75 on the NAPLEX.

3) The course work or clinical training described in subsections (c)(2)(A) and (c)(2)(B)(i) must have the prior approval of the Board.

d) A pharmacy technician seeking restoration of a license that is inactive or not renewed shall file an application for restoration including payment of the renewal fee and evidence of meeting the renewal requirements of Section 1330.80.

e) A pharmacy whose license has been expired for one year or more may not have its license restored but must apply for a new license and meet all requirements for licensure.

f~~d~~) When the accuracy of any submitted documentation, or the relevance or sufficiency of the course work or experience, is questioned by the Division because of lack of information, discrepancies or conflicts in information given, or a need for clarification, the registrant will be requested 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 in information.

(Source: Amended at 49 Ill. Reg. _____, effective _____)

Section 1330.120 Administration of Tests and Therapeutics

a) Requirements

1) A pharmacist may administer and order tests or therapeutics to persons for the following conditions:

A) Influenza;

B) SARS-CoV-2;

C) Group A Streptococcus;

D) Respiratory syncytial virus;

E) Adult-stage head louse;

F) Health conditions identified by a statewide public health emergency, as defined in the Illinois Emergency Management Agency Act; and

G) Any other health condition authorized by the Act.

2) *A pharmacist may delegate the administrative and technical tasks of performing a test for the health conditions described in this Section to a pharmacy technician or student pharmacist acting under the supervision of the pharmacist.* (Section 3(d)(17) of the Act).

3) Pharmacists shall practice in accordance with the professional standard of care, consistent with their education and training. When assuming new clinical responsibilities or engaging in specialized areas of practice, pharmacists shall possess the necessary knowledge and skills to provide safe, effective, and evidence-based care. Pharmacists may complete a course of training accredited by the Accreditation Council of Pharmacy Education (ACPE) to meet this requirement.

4) The pharmacist who is responsible for supervising the pharmacy student or pharmacy technician has the sole responsibility of evaluating the appropriateness of each test prior to its administration and shall maintain oversight of the process.

5) The pharmacist shall maintain a current Basic Life Support Certification for Healthcare Providers issued by the American Heart Association, the American Red Cross, the Health and Safety Institute, or an equivalent as determined by the Division.

6) Each pharmacy shall have available a current copy or electronic version of the current version of the guidelines of the Centers for Disease Control and Prevention, guidelines of the United States Preventive Services Task Force, or generally recognized evidence-based clinical guidelines.

7) The pharmacist shall ensure that any pharmacy technician or student pharmacist performing administration of testing, under their direct supervision, has been appropriately trained and is competent to perform the test safely and accurately, consistent with the standard of care and manufacturer instructions.

b) Patient Health History Intake Form

1) Prior to administering testing or therapeutics, a pharmacist shall have the patient complete a patient health history intake form for the purpose of performing a patient assessment.

A) The patient health history intake form shall include, at a minimum, basic patient information, including patient contact information, emergency contact information, history of past and present illness, current medications, allergies, and patient consent.

B) Based upon the results of the patient assessment, the pharmacist shall use their professional and clinical judgment to determine when a patient should be referred to the patient's physician or other appropriate health care provider in lieu of providing testing or therapeutics.

2) Based on the pharmacists professional and clinical judgment, a referral may be issued following an initial or follow-up assessment, directing the patient to a qualified health care provider for further evaluation, diagnosis, or treatment. All referrals under this subsection must be provided in writing and include information advising the patient to seek follow-up care from a health care provider.

3) Pharmacists shall advise patients to consult with the patient's physician or other appropriate health care provider if their symptoms persist, worsen, or involve physical manifestations, or if a test comes back as inconclusive or the treatment plan is unclear. This disclosure must be documented and signed by the patient or guardian.

4) "Therapeutics" are limited to medications approved by the Food and Drug Administration for the treatment of health conditions as described in subsection (a)(1) as established in generally recognized evidence-based clinical guidelines. "Therapeutics" does not include controlled substances.

c) Recordkeeping and Reporting

1) The pharmacist shall maintain appropriate records related to the administration of a test or prescribed therapeutics, including but not limited to the information collected under subsection (b), the name of the test or therapeutic administered and the date administered, and the name or unique identifier of the administering pharmacist, pharmacy technician, or student pharmacist.

2) The pharmacist should make a reasonable effort to notify the patient's healthcare provider, if known, within a timely manner after a therapeutic has been dispensed, in accordance with professional judgment and patient care needs.

(Source: Added at 49 Ill. Reg. _____, effective _____)

SUBPART B: PHARMACY TECHNICIAN

Section 1330.210 Pharmacy Technician Training

a) It shall be the joint responsibility of a pharmacy and its pharmacist-in-charge to have trained all of its pharmacy technicians or obtain proof of prior training in all of the following topics as they relate to the practice site:

1) The duties and responsibilities of the technicians and pharmacists.

2) Tasks and technical skills, policies and procedures.

3) Compounding, packaging, labeling and storage.

4) Pharmaceutical and medical terminology.

5) Recordkeeping requirements.

6) The ability to perform and apply arithmetic calculations.

7) The administrative and technical tasks of performing a test as provided Section 3(d)(17) of the Act.

b) Within 6 months after initial employment or changing the duties and responsibilities of a pharmacy technician, it shall be the joint responsibility of the pharmacy and the pharmacist-in-charge to train the pharmacy technician or obtain proof of prior training in the areas listed in subsection (a) as they relate to the practice site or to document that the pharmacy technician is making appropriate progress.

c) All pharmacies shall maintain an up to date training program describing the duties and responsibilities of a pharmacy technician.

d) All pharmacies shall create and maintain retrievable records of training or proof of training as required in this Section.

e) Ensuring registered pharmacy technicians and certified pharmacy technicians are properly trained shall be the responsibility of the pharmacy, the pharmacist-in-charge, and the pharmacy technician.

(Source: Amended at 49 Ill. Reg. _____, effective _____)

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 licensed beginning January 1, 2024.

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

c) The work experience training under subsection (b) must be completed by the pharmacy technician's 2nd renewal.

d) Curriculum must include didactic and practical experience for each area of instruction. At minimum of 100 hours must be applied toward the didactic portion of the training.

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; and

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

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

1) Knowledge and 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, personal protection equipment (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 Joint Commission of Pharmacy Practitioners' 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, and 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) Occupational Safety and Health Administration (OSHA) requirements;

D) USP requirements, including 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: Amended at 49 Ill. Reg. _____, effective _____)

Section 1330.230 Continuing Education ("CE") for Certified Pharmacy Technicians

a) CE Requirements

1) Number of Hours of CE Required

A) Each person who applies for renewal of a license as a certified pharmacy technician shall complete 20~~10~~ hours of CE during the 24~~12~~ months preceding the expiration date of the license, in accordance with Section 9.5 of the Act.

B) A renewal applicant is not required to comply with CE requirements for the first renewal after original licensure.

2) Required Topics for CE

A) At least one hour of continuing pharmacy education must be on the subject of pharmacy laws, pharmacy rules and ethics;

B) At least one hour of continuing pharmacy education must be on the subject of patient safety; and

C) Any other applicable CE requirements under 68 Ill. Adm. Code 1130.

b) Approved CE

1) The completion of courses offered by providers approved by the Accreditation Council on Pharmacy Education or another standardized nationally approved education program approved by the Department, may be completed outside the State of Illinois are approved CE courses.

2) The pharmacist-in-charge and the certified pharmacy technician must maintain records showing proof of training that constituted the pharmacy technician's CE.

c) Certification of CE Requirements

1) Each renewal applicant shall certify on the renewal application full compliance with CE requirements set forth in this Part.

2) The Division may require additional evidence demonstrating compliance with the CE requirements (e.g., certificates of attendance, certificates of completion, course registration). It is the responsibility of each renewal applicant to retain or otherwise produce evidence of the compliance. Evidence shall be required in the context of the Division's random audit in accordance with Section 9.5 of the Act.

d) The same CE hours cannot be used to fulfill the CE requirement for more than one renewal period.

e) Waiver of CE Requirements

1) Any renewal applicant seeking to renew their license without having fully complied with these CE requirements shall file with the Division a renewal application, along with the required fee, a statement setting forth the facts concerning noncompliance and a request for waiver of the CE requirements with facts explaining the basis of the request. A request for waiver shall be made prior to the renewal date. If the Division, upon the written recommendation of the Board, finds from the affidavit or any other evidence submitted that good cause has been shown for granting a waiver, the Division shall waive enforcement of the CE requirements for the renewal period for which the applicant has applied.

2) Good cause shall be defined as an inability to fulfill the CE requirements during the applicable period because of:

A) Full-time service in the armed forces of the United States of America during the applicable period; or

B) Extreme hardship, which shall be determined on an individual basis by the Board and shall be limited to documentation of:

i) An incapacitating illness, documented by a currently licensed physician;

ii) Physical inability to travel to the sites of approved programs, as documented by a currently licensed physician; or

iii) Any other similar extenuating circumstances (e.g., illness of a family member).

3) If a renewal applicant requests an interview before the Board at the time the waiver request is submitted, the Board shall not deny the waiver request before an interview is conducted. The renewal applicant requesting a waiver shall be given at least 20 days written notice of the date, time, and place of the interview by mail or email.

4) Any renewal applicant who submits a request for waiver pursuant to subsection (e)(1) shall be deemed to be in good standing until the final Division decision on the application has been made.

(Source: Amended at 49 Ill. Reg. _____, effective _____)

SUBPART E: TYPES OF PHARMACIES

Section 1330.500 Community Pharmacy Services

a) Pharmacies that engage in general or specialty community pharmacy practice and are open to, or offer pharmacy service to, the general public shall, in addition to any other requirements of the Act and this Part, comply with this Section. A community pharmacy that, in addition to offering pharmacy services to the general public, provides institutional services shall also comply with Section 1330.520.

b) Staffing of the Pharmacy

1) Whenever the hours of the pharmacy differ from those of the establishment in which the pharmacy is located, the schedule during which pharmacy services are provided shall be conspicuously displayed.

2) Whenever a pharmacy is open and a pharmacist is not present and available to provide pharmacy services, a sign stating that situation shall be conspicuously displayed.

3) No prescription may be dispensed when a pharmacist is not physically present in the establishment.

c) Recordkeeping Requirements for Dispensing Prescription Drugs

1) For every prescription dispensed, the prescription record shall contain the name, initials or other unique identifier of the pharmacist who dispenses the prescription drugs. No prescription may be dispensed after 15 months from the date of the original issuance of the prescription by the prescriber.

2) Whenever a prescription is dispensed by a registered pharmacy technician or certified pharmacy technician under the supervision of a pharmacist, the prescription record shall contain the names, initials or other unique identifier of both the supervising pharmacist and the registered pharmacy technician or certified pharmacy technician who dispenses the prescription.

3) An invoice is required for all pharmacy to pharmacy drug transfers.

43) Refilling a Prescription

A) Each refilling of a prescription shall be entered on the prescription or on another appropriate, uniformly maintained, readily retrievable record that indicates, by the number of the prescription, the following information:

i) The name and dosage form of the drug;

ii) The date of each refilling;

iii) The quantity dispensed;

iv) The name or initials of the pharmacist and the pharmacy technician, if applicable, in each refilling; and

v) The total number of refills remaining for the prescription.

B) If the pharmacist does not otherwise indicate in a uniformly maintained record, the pharmacist shall be deemed to have dispensed a refill for the full face amount of the prescription.

54) Presentation of a written prescription copy or prescription label shall be for information purposes only and has no legal status as a valid prescription order. The recipient pharmacist of the copy or prescription label shall contact the prescribing practitioner to obtain a new prescription order.

65) Copies of prescriptions given to an ultimate consumer shall be marked "For Information Purposes Only".

76) Subject to Section 18 of the Act, any information required to be kept pursuant to that Section may be recorded and stored in a computerized pharmaceutical information system that meets the standards of performance stated in the regulations of the Drug Enforcement Administration (21 CFR 1306; 2014), except as provided in subsection (c)(7), and shall include the capability to:

A) Retrieve the original prescription order information for those prescription orders currently authorized for refilling;

B) Retrieve the current prescription orders, including, at a minimum, name of drug, date of refill, quantity dispensed, name and identification code of the manufacturer in the case of a generically written prescription or a generic interchange, name or initials of the dispensing pharmacist and technician for each refill, and the total number of refills dispensed to date;

C) Supply documentation of refill information entered by the pharmacist using the system through a hard copy printout of each day's refill data that has been verified for correctness. This printout must include for each prescription filled at least the following information:

i) The name and dosage form of the drug;

ii) The date of each refilling;

iii) The quantity dispensed;

iv) The name or initials of the pharmacist in each refilling and the pharmacy technician, if applicable;

v) The patient's name;

vi) The prescriber's name; and

vii) The prescription number for the prescription.

87) In lieu of the printout required by subsection (c)(6), the pharmacy shall maintain a bound log book, or separate file, in which each individual

pharmacist involved in the dispensing shall sign a statement each day, attesting to the fact that the refill information entered into the computer that day has been reviewed 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.

9~~8~~) All refill data shall be maintained by the pharmacy on the premises for 5 years, in accordance with Section 18 of the Act. The pharmacy shall have the appropriate equipment on the premises to provide readily retrievable information in the course of an on-site inspection. A hard copy printout shall be provided to the Division, upon request, within 48 hours.

d) Any drug that is dispensed pursuant to prescription, other than vaccinations administered in the pharmacy, shall have affixed to its container a label as provided in Section 22 of the Act.

e) No person shall establish or move to a new location any pharmacy unless the pharmacy is licensed with the Division and has on file with the Division a verified statement that:

1) The pharmacy is or will be engaged in the practice of pharmacy; and

2) The pharmacy will have in stock and will maintain sufficient prescription drugs and materials to protect the public it serves within 30 days after opening of the pharmacy.

f) Pharmacies have a duty to deliver lawfully prescribed drugs to patients and to distribute nonprescription drugs approved by the U.S. Food and Drug Administration for restricted distribution by pharmacies, or to substitute a generic drug as permitted in Section 25 of the Act in a timely manner, or to contact the prescriber to obtain authorization to dispense a different drug that produces a similar clinical effect in a timely manner, except for the following or substantially similar circumstances:

1) When, in the pharmacist's professional judgment, after screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including, but not limited to, serious interactions with nonprescription or over-the-counter drugs), drug-food interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, or clinical abuse or misuse, pursuant to Section 3(aa) of the Act, the pharmacist determines that the drug should not be dispensed due to one of the foregoing clinical reasons;

2) National or State emergencies or guidelines affecting availability, usage or supplies of drugs;

3) Lack of specialized equipment or expertise needed to safely produce, store or dispense drugs, such as certain drug compounding or storage for nuclear medicine;

4) Potentially fraudulent prescriptions;

5) Unavailability of drug; or

6) The drug is not typically carried in similar practice settings in the State.

g) Nothing in this Section requires pharmacies to dispense a drug without payment of their usual and customary or contracted charge.

h) All pharmacies shall be required to maintain the following current resource materials, either in hard copy or electronic format:

1) Copies of the Act and this Part;

2) Illinois Controlled Substances Act and 77 Ill. Adm. Code 3100;

3) Title 21 of the United States Code of Federal Regulations (Food and Drugs); and

4) Hypodermic Syringes and Needles Act [720 ILCS 635].

i) If the lawfully prescribed drug or nonprescription drug approved by the U.S. Food and Drug Administration for restricted distribution by pharmacies is not in stock or is otherwise unavailable, or the prescription cannot be filled pursuant to subsection (f)(1) or (f)(6), the pharmacy shall provide the patient or agent a timely alternative for appropriate therapy that, consistent with customary pharmacy practice, may include obtaining the drug. These alternatives include but are not limited to:

1) Contact the prescriber to address concerns such as those identified in subsection (f)(1);

2) If requested by the patient or the patient's agent, return unfilled lawful prescriptions to the patient or agent; or

3) If requested by the patient or the patient's agent, communicate or transmit, as permitted by law, the original prescription information to a pharmacy of the patient's choice that will fill the prescription in a timely manner.

j) Any mail order pharmacy that provides services in Illinois shall provide, 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 to facilitate communication between patients in this State and a pharmacist retained by the mail order pharmacy who has access to the patient's records. The toll free number must be disclosed on the label affixed to each container of drugs dispensed to residents of the State.

k) Engaging in or permitting any of the following shall constitute grounds for discipline or other enforcement actions:

1) Intentionally destroying unfilled lawful prescriptions;

2) Refusing to return unfilled lawful prescriptions;

3) Violating a patient's privacy;

4) Discriminating against patients or their agents in a manner prohibited by State or federal laws;

5) Intimidating or harassing a patient; or

6) Failing to comply with the requirements of this Section.

(Source: Amended at 49 Ill. Reg. _____, effective _____)

Section 1330.510 Telepharmacy

a) Telepharmacy shall be limited to the types of operations described in this Section. Each site where such operations occur shall be a separately licensed pharmacy. Home pharmacies that are located outside of Illinois must be licensed as a nonresident pharmacy. Nonresident pharmacies shall abide by all Illinois laws and rules when filling prescriptions for Illinois residents, except that the dispensing pharmacist and the pharmacist-in-charge shall not be required to be licensed in Illinois, except as otherwise provided in this Part.

b) Remote Dispensing Site

1) Written prescriptions presented to the remote dispensing site shall be scanned into the electronic data processing equipment to ensure initial dispensing and each refill and the original prescription may be viewed on the monitor at both the remote dispensing site and home pharmacy site. Records shall be maintained at the remote dispensing site.

2) A remote site is considered to be under the supervision of the pharmacist-in-charge of the home pharmacy. Each home pharmacy may supervise no more than 3 remote sites that are simultaneously open.

3) The remote site shall use its home pharmacy and pharmacy management system.

A) The system shall assign consecutive prescription numbers.

B) Prescriptions dispensed at the remote site shall be distinguishable from those dispensed from the home pharmacy.

C) Daily reports must be separated for the home and remote site.

4) Unless staffed by an onsite pharmacist, a~~A~~ pharmacist at the home pharmacy must verify each prescription before it leaves the remote site.

A) Pharmacist and pharmacy technician initials or unique identifiers must appear on the prescription record and the prescription label.

B) A pharmacist shall electronically compare via video link the stock bottle, drug dispensed, the strength and its beyond use date. The entire label must be checked for accuracy on the video link.

C) The remote dispensing site shall utilize a barcode system that prints the barcode of the stock bottle on the label of the dispensed drug. If the stock bottle does not have a barcode, the pharmacy shall create one. The technician shall scan both the stock bottle and the label of the dispensed drug to verify that the drug dispensed is the same as the drug in the stock bottle for each prescription dispensed.

D) A pharmacy may utilize a different electronic verification system that accomplishes the same purpose after review and approval of the Division.

5) Counseling must be done by a pharmacist via video link and audio link. Pursuant to Section 1330.700, the pharmacist providing counseling, pursuant to this subsection, must be employed or contracted by the home pharmacy or by a pharmacy contracted with the home pharmacy and have access to all relevant patient information maintained by the home pharmacy.

6) A pharmacist-in-charge or a designated pharmacist must complete monthly inspections of the remote site. Inspection criteria must be included in the policies and procedures for the site. The inspection report must be available on site for pharmacy investigator inspection.

7) Controlled substances shall be kept at the remote site in accordance with the Act and this Part. All records must be stored at the remote site.

8) There shall be a working computer link, video link and audio link to a pharmacist at a home pharmacy whenever the prescription area is open to the public. The communication link must be checked daily and the remote site pharmacy must be closed if the link malfunctions, unless a pharmacist is physically present at the remote site.

A) The pharmacy technician located at the remote dispensing site must have one year of experience and be registered as a certified pharmacy technician, or be a student pharmacist.

B) New prescriptions received at the remote dispensing site may be entered into the remote computer system with all verification, interaction, checking and profile review by the pharmacist at the home pharmacy.

C) Each pharmacist at the home pharmacy may electronically supervise no more than 3 remote sites that are simultaneously open.

9) The facility must have a sign clearly identifying it as a remote dispensing site.

10) The facility shall have an area for patient consultation, exclusive of any waiting area.

11) A remote dispensing site must maintain a log with the date and time when a pharmacist is working onsite.

c) Remote Consultation Site

1) These sites have no prescription inventory.

2) Only filled prescriptions, filled at the home pharmacy, with final patient labeling attached are allowed at these sites.

3) These sites must be staffed with a pharmacy technician or certified pharmacy technician who has the knowledge necessary to use computer audio/video link for dispensing and consultation to occur. Pharmacist and pharmacy technician initials or unique identifiers must appear on the prescription record and the prescription label.

4) Written prescriptions may be received at a remote consultation site. All written prescriptions presented at a remote consultation site shall be delivered to the home pharmacy within 72 hours.

5) Security of filled prescriptions must be maintained by storing them in a separate lock drawer or cabinet.

6) Recordkeeping shall be conducted by the pharmacist (time/date) when dispensing and counseling occurred.

7) The site shall have an area~~a room~~ for patient consultation exclusive of any waiting area.

8) The site must have a sign clearly identifying it as a remote consultation site.

d) Automated Pharmacy Systems (Section 22(b) of the Act)

1) Remote Automated Pharmacy Systems (RAPS)

A) These devices shall maintain a prescription drug inventory that is controlled electronically by the home pharmacy or, when operated by a pharmacy contracted with the home pharmacy, by the contracted pharmacy, which shall be utilized to dispense patient specific prescriptions.

B) These systems shall have prescription inventory, which must be secured in an automated pharmacy system and electronically connected to and controlled by the home pharmacy.

C) A pharmacist must approve all the prescription orders before they are released from the RAPS.

D) Dispensing and counseling are performed by a pharmacist employed or contracted by the home pharmacy via audio and video link.

E) All filled prescriptions must have a label that meets the requirements of the Act attached to the final drug container.

F) The pharmacist-in-charge of the home pharmacy, or a designated registrant, shall conduct and complete monthly inspections of the RAPS. Inspection criteria must be included in the policies and procedures for the site. The report must be available to the pharmacy investigators when requested.

G) The RAPS must be licensed with the Division as an automated pharmacy system and will be subject to random inspection by pharmacy investigators. Notwithstanding that the RAPS shall possess a license, the home pharmacy shall remain responsible for inventory control and billing. For purposes of random inspections, a pharmacist with access to the system must be available at the site within one hour, or as otherwise approved by the drug compliance investigator. In the event the Department's Chief Pharmacy Coordinator determines that the RAPS poses a significant risk of patient harm, the RAPS must be disabled until such time as the pharmacist with access to the system is available to the site.

H) Medication dispensed at the automated pharmacy system site may only be packaged by a licensed manufacturer or repackager, or prepackaged by a licensed pharmacy in compliance with this Section. Prepackaging must occur at the home pharmacy, a pharmacy sharing common ownership with the home pharmacy, or a pharmacy that has contracted with the home pharmacy to perform prepackaging services. The following requirements shall apply whenever medications are prepackaged by a pharmacy other than the home pharmacy:

i) The prepackaging pharmacy shall be licensed in Illinois as a resident or nonresident pharmacy.

ii) The prepackaging pharmacy shall share a common database with the home pharmacy, or have in place an

electronic or manual process to ensure that both pharmacies have access to records to verify the identity, lot numbers and expiration dates of the prepackaged medications stocked in the RAPS.

iii) The prepackaging pharmacy shall maintain appropriate records to identify the responsible pharmacist who verified the accuracy of the prepackaged medication.

I) Written prescriptions may be received at a RAPS. All written prescriptions presented to a RAPS shall be scanned utilizing imaging technology that permits the reviewing pharmacist to determine its authenticity. The sufficiency of the technology shall be determined by the Department. If sufficient technology is not used, the written prescriptions must be delivered to the home pharmacy and reviewed by a pharmacist prior to being dispensed to the patient.

2) Kiosk

A) A kiosk is a device that maintains individual patient prescription drugs that were verified and labeled at the home pharmacy.

B) A home pharmacy may only use the kiosk with prior approval of a patient.

C) A kiosk located on the same premises or campus of the home pharmacy shall operate under the same license as the home pharmacy. However, a kiosk must be licensed with the Division if it is not so located.

D) A kiosk shall:

i) When located on the same premises or campus as the pharmacy, inform a patient, if using the device when the pharmacy is open, that the patient may address questions and concerns regarding the prescription to a pharmacist at the pharmacy;

ii) When not located on the same premises or campus as the pharmacy, inform a patient, if using the device when the pharmacy is closed, that he or she may immediately direct any questions and concerns regarding the prescription to a

licensed pharmacist via a pharmacy provided audio/video link;

iii) Inform a patient that a prescription is not available to be delivered by the device if the pharmacist desires to counsel the patient in person regarding the prescription.

3) A pharmacy may use an automated pharmacy system to deliver prescriptions to a patient when the device:

A) Is secured against a wall or floor;

B) Provides a method to identify the patient and delivers the prescription only to that patient or the patient's authorized agent;

C) Has adequate security systems and procedures to prevent unauthorized access, to comply with federal and State regulations, and to maintain patient confidentiality;

D) Records the time and date that the patient removed the prescription from the system.

4) A licensed automated pharmacy system shall not be utilized by prescribers. Nothing in this Section shall prevent a prescriber from utilizing an automated pharmacy system in connection with his or her own dispensing. However, a prescriber may not utilize or access an automated pharmacy system licensed pursuant to this Section.

e) All pharmacists performing services in support of a remote dispensing site, remote consultation site, kiosk, or RAPS must display a copy or electronic image of their licenses at the remote site where they provide services, or shall otherwise make their license visible to the patient, and be licensed in this State, unless employed by a pharmacy licensed in Illinois as a nonresident pharmacy, in which case, the pharmacist providing the services shall hold an active license as a pharmacist in the state in which the nonresident pharmacy is located and only the pharmacist-in-charge of the remote site must be licensed in Illinois.

f) Each remote site must display a sign, easily viewable by the customer, that states:

1) The facility is a telepharmacy supervised by a pharmacist located at (address); and

2) The pharmacist is required to talk to you, over an audio/visual link, each time you pick up a new prescription.

g) No remote site may be open when the home pharmacy is closed, unless a pharmacist employed or contracted by the home pharmacy, or by a pharmacy contracted with the home pharmacy, is present at the remote site or is remotely providing supervision and consultation as required under this Section.

(Source: Amended at 49 Ill. Reg. _____, effective _____)

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, the Ambulatory Surgical Treatment Center 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, a valid practitioner's order ~~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.

(Source: Amended at 49 Ill. Reg. _____, effective _____)

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.~~

3~~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.

4~~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, a valid practitioner's order~~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 49 Ill. Reg. _____, effective _____)

Section 1330.570 Outpatient Clinic Pharmacy Services

a) Outpatient Clinic Pharmacies are defined as those pharmacies not located in or servicing patients of a facility licensed as defined in Section 1330.520(a), whether located in a health care facility or another location that provides outpatient treatment or care.

1) An outpatient is an ambulatory patient who comes to an outpatient clinic to receive health care services related to the objectives of the outpatient clinic and departs within 24 hours.

2) An outpatient drug order is defined as an order written by a medical practitioner engaged in the practice of that clinic and ordered for services received in that clinic in conjunction with health care services related to the objectives of that clinic.

b) Contracting Services. Outpatient clinic pharmacies may contract with outpatient clinics to provide pharmacy services. The contract must define the scope of pharmacy services to be provided and delineate the specific duties and responsibilities of each party.

c) Investigational new drugs, authorized by the U.S. Food and Drug Administration, shall be dispensed pursuant to a valid drug 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:

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

2) Beyond use date;

3) Reference code to identify source and lot number;

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

5) 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.

d) The pharmacist-in-charge of the outpatient clinic pharmacy or his/her pharmacist designee may, in the best interest of the patients served, establish one or more lists of the kind and quantity of drugs to be kept in one or more automatic dispensing machines at all times within the outpatient clinic. A copy of the list of items stored in automatic dispensing machines must be kept by the pharmacist-in-charge or his/her pharmacist designee.

e) Staffing of the Pharmacy

1) Each outpatient clinic pharmacy shall be directed by a pharmacist-in-charge, who is knowledgeable in and thoroughly familiar with the specialized functions of outpatient clinic pharmacy.

2) The pharmacist-in-charge shall ensure that all staff shall be adequately trained. The pharmacist-in-charge shall develop and implement written policies and procedures to specify the duties to be performed by each employee.

3) All functions and activities of pharmacy technicians shall be personally and directly supervised by an adequate number of licensed pharmacists to ensure that all such functions and activities are performed competently.

4) The pharmacist-in-charge shall meet the requirements of 1330.660 in addition to the following:

A) The pharmacist-in-charge of an outpatient clinic pharmacy shall be assisted by a sufficient number of additional pharmacists and personnel, as may be required to operate such pharmacy competently, safely, and to meet the needs of the patients of the clinic facility.

B) Establishment and supervision of the method and manner for storage, dispensing and safekeeping of pharmaceuticals in all areas of the outpatient clinic, including maintenance of security provisions to be used when the pharmacy is closed.

C) 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.

f) Recordkeeping Requirements

1) Every drug order filled shall contain the name, initials or other unique identifier of the pharmacist (and pharmacy technician if one is used) who fills or refills the drug 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) 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 drug orders;

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

C) Records of actions taken pursuant to drug recalls.

g) 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.

3) 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 outpatient clinics 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.

h) Storage. Pharmacies licensed under this Part shall comply with Sections 1330.600, 1330.610, 1330.630, and 1330.680.

(Source: Added at 49 Ill. Reg. _____, effective _____)

SUBPART F: PHARMACY STANDARDS

Section 1330.610 Pharmacy Structural/Equipment Standards

All pharmacies must comply with the following provisions:

a) Notification shall be submitted to the Division that an existing pharmacy will be remodeled. Approval is required prior to initiation of any remodel.

b) Other than on-site institutional pharmacies, all dispensing, and drug storage areas of the pharmacy must be contiguous and have a connecting door for access between the pharmacy and drug storage area.

c) The pharmacy area and all store rooms shall be well-lighted and properly ventilated.

d) Refrigerators shall be for the exclusive use of prescription drugs. No personal or food items shall be stored in the refrigerator. Refrigeration shall be capable of maintaining temperature within a range compatible with the proper storage of drugs requiring refrigeration or freezing.

e) The pharmacy area shall not be used for storage of merchandise that interferes with the practice of pharmacy.

f) Suitable current reference sources, either in book or electronic data form (available in the pharmacy or on-line), which shall include Facts and Comparisons www.factsandcomparisons.com or other suitable references determined by the Division to be pertinent to the practice carried on in the licensed pharmacy.

g) A telephone shall be immediately accessible in the pharmacy area.

h) These requirements are in addition to any other requirements found in this Part.

i) At a minimum, the equipment and references listed in Section 1330.640 must be maintained at all dispensing pharmacies.

(Source: Amended at 49 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 the pharmacist 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 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 and the pharmacy license holder.

g) In addition to notifying the Division within 30 days, the incoming~~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.

3) The pharmacy license holder is equally responsible for ensuring that such inventory is completed.

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) Failure on the part of a pharmacy to provide notification of a change in pharmacist-in-charge required in subsection (f) shall be grounds for denying an application or renewal application for a pharmacy license or for disciplinary action against a pharmacy.

j~~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.

k~~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.

l~~k~~) Records shall be retained as provided for in Section 18 of the Act. Invoices for all legend drugs and controlled substances 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.

m~~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 49 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;

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; or

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 any applicable 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, facilities serviced by an outpatient clinic pharmacy, 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 49 Ill. Reg. _____, effective _____)

SUBPART G: PHARMACY OPERATIONS

Section 1330.700 Patient Counseling

a) Upon receipt of a new or refill prescription, a prospective drug regimen review or drug utilization evaluation shall be performed. Prior to dispensing a prescription to a new patient, a new drug~~prescription~~ to an existing patient, or a medication that has had a change in the dose, strength, route of administration or directions for use, the pharmacist, or a student pharmacist directed and supervised by the pharmacist, shall provide verbal counseling to the patient or patient's agent on pertinent medication information. An offer to counsel shall be made on all other prescriptions. Counseling may~~shall~~ include without limitation~~, but is not limited to~~:

1) Name and description of medication;

2) Dosage form and dosage;

3) Route of administration;

4) Duration of therapy;

5) Techniques for self-monitoring;

6) Proper storage;

7) Refill information;

8) Actions to be taken in cases of missed doses;

9) Special directions and precautions for preparation, administration and use;

10) Common severe side effects, adverse effects, or interactions and therapeutic contraindications that may be encountered, including their avoidance and the action required if they occur.

b) If, in the pharmacist's professional judgment, oral counseling is not practicable for the patient or patient's agent, the pharmacist shall use alternative forms of patient

information. When used in place of oral counseling, alternative forms of patient information shall advise the patient or agent that the pharmacist may be contacted for consultation in person at the pharmacy or by toll-free or collect telephone service.

c) Every licensed pharmacy directly serving patients at a physical location must conspicuously post a sign provided by the Division containing a statement that the patient has the right to counseling, the Division's consumer hotline number, information on how to file a complaint for failure to counsel, and any other information the Division deems appropriate. The sign must be printed in color ink or displayed electronically in color, measure at least 8½ x 11 inches in size, and be posted at either a cashier counter or waiting area clearly visible to patients. Licensed pharmacies that do not maintain a physical location directly serving patients must include a copy of the sign within any dispensed prescriptions. The sign will be available to download on the Division's website.

d) The pharmacist is responsible for maintaining patient profiles as defined in Section 3(s) of the Act. A reasonable effort shall be made to obtain information, including, but not limited to, the following:

1) Name, date of birth (age), gender, address and telephone number;

2) Individual history, when significant, including disease state, known allergies, drug interactions, and a comprehensive list of medications and relevant devices; and

3) Pharmacist's comments relevant to the individual's therapy.

e) Patient identifiable information obtained by the pharmacist or the pharmacist's designee for the purpose of patient record maintenance, prospective drug review, drug utilization review and patient counseling shall be considered protected health information, as defined in Section 3(cc) of the Act. A pharmacist shall provide counseling related to protected health information in a discreet, supportive and informative manner.

f) A pharmacist at an on-site or off-site institutional pharmacy shall not be required to provide patient counseling as required in this Section unless drugs are dispensed by the pharmacy upon a patient's discharge from the institution.

g) Nothing in this Section shall be construed as requiring a pharmacist to provide counseling when a patient or patient's agent refuses such counseling. When a patient or patient's agent refuses to accept patient counseling as provided in this Section, that refusal shall be documented.

h) A pharmacist operating a remote pharmacy shall comply with the requirements of this Section. Counseling in those circumstances shall be done by both video and audio means.

(Source: Amended at 49 Ill. Reg. _____, effective _____)

Section 1330.770 Centralized Prescription Filling

Pharmacies providing centralized prescription filling, as provided in Section 25.5 of the Act, shall:

a) Share a common electronic file to allow access to sufficient information necessary or required to fill or refill a prescription order.

b) Maintain appropriate records to identify the responsible pharmacist in the dispensing process.

c) Maintain a mechanism for tracking the prescription drug order during each step in the process.

d) Pharmacies that engage in central fill pharmacy practice shall, in addition to any other requirements of the Act and this Part, comply with this Section.

e) For the purpose of this Section, the following definitions apply:

1) Central Fill Pharmacy – A pharmacy that prepares prescription drug orders for dispensing for one or more originating pharmacies.

2) Originating Pharmacy – A pharmacy wherein the prescription which will be filled by the central fill pharmacy is initially presented, entered into a computer system, data reviewed, and drug utilization review is completed.

f) A pharmacy may outsource prescription drug order dispensing to a central fill pharmacy provided the pharmacies:

1) Have the same owner or have a written contract which outlines the services to be provided, the responsibilities and accountabilities of each pharmacy, and the manner in which the pharmacies will comply with federal and state laws, rules, and regulations; and

2) Share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to dispense or

process a prescription drug order.

g) Policies and Procedures. A policy and procedure manual as it relates to centralized filling shall be maintained at both the originating and central fill pharmacies and be available for inspection. The manual shall:

1) Outline the responsibilities of each of the pharmacies;

2) Include a list of the names, addresses, telephone numbers, and all license/registration numbers of the pharmacies involved in centralized prescription dispensing;

3) Designate the types of medications that may and may not be filled by the central fill pharmacy; and

4) Include policies and procedures for:

A) Notification to patients;

B) Protecting the confidentiality and integrity of patient information;

C) Communicating orders from the originating pharmacy to the central fill pharmacy;

D) Dispensing prescription drug orders when the dispensed order is not received or the patient comes in before the order is received;

E) Complying with federal and state laws and regulations;

F) Operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems;

G) Annually reviewing the written policies and procedures and documenting such review; and

H) Process and documentation for return of product to the central fill pharmacy from the originating pharmacy. No drug delivered directly to the patient may be returned except in cases where a medication error has occurred.

h) Recordkeeping

1) Each pharmacy shall comply with all the laws and rules relating to the maintenance of records and be able to produce an audit trail identifying the responsible pharmacist in the dispensing process and all prescriptions dispensed by the pharmacy.

2) The originating pharmacy shall maintain records, in addition to the prescription drug order, which indicate:

A) The date the request for dispensing was transmitted to the central fill pharmacy;

B) The date the dispensed prescription was received by the originating pharmacy, including the method of delivery and the name of the person accepting delivery;

C) Name, address, license number, and the unique identifier of the central fill pharmacy;

D) Date prescription was returned to the central fill pharmacy.

3) The central fill pharmacy shall maintain records, in addition to the prescription drug order, which indicate:

A) The date the prescription was shipped to the originating pharmacy or the patient;

B) Name and address where the prescription was shipped;

C) Method of delivery;

D) Name, address, and license number of originating pharmacy;

E) Date of receipt of returned product.

i) Delivery of Medications

1) A community central fill pharmacy may deliver medications for an originating pharmacy to the patient or patient's agent under the following conditions:

A) The pharmacies are under the same ownership or have a written

contract specifying the services to be provided by each pharmacy, including delivery services to the patient or patient's agent;

B) The pharmacies shall have a pharmacist available a minimum of 40 hours per week, either in person or via telephone, to provide patient counseling. The telephone number shall not incur a cost to the caller; and

C) The pharmacies shall include a telephone number that allows the patient to reach a pharmacist for the purposes of counseling; and

D) The central fill pharmacy shall only deliver via carrier to the patient or patient's agent those medications which could have been delivered via carrier by the originating pharmacy;

2) An institutional central fill pharmacy may only deliver medications to the originating pharmacy.

j) The originating pharmacy is responsible for the patient consultation and transfer requirements.

k) Nothing in this Section shall be construed as requiring a nonresident pharmacy that outsources drug order dispensing to a central fill pharmacy to hold an Illinois pharmacy license, provided that the nonresident pharmacy does not physically ship, mail or deliver prescription drugs or device directly to a patient or patient's agent in this state.

(Source: Amended at 49 Ill. Reg. _____, effective _____)