

ILLINOIS REGISTER

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF PROPOSED RULES

The Department of Financial and Professional Regulation is posting these proposed rules in an effort to make the public aware of possible changes that may have an impact on the profession.

The general public may submit written comments to the Division during the first 45 day public comment period. Any suggested changes will be considered by the Division and the appropriate Board.

These proposed rules were published in the September 25, 2009 Illinois Register. The 45 day comment period will end November 9, 2009.

Please submit written comments to Craig Cellini as stated in the attached notice.

THESE PROPOSED CHANGES ARE NOT IN EFFECT AT THIS TIME AND THE ADOPTED RULES MAY DIFFER FROM THOSE ORIGINALLY PUBLISHED.

1) Heading of the Part: Pharmacy Practice Act

2) Code Citation: 68 Ill. Adm. Code 1330

3) Section Numbers: Proposed Action:

1330.10	New Section
1330.20	New Section
1330.30	New Section
1330.40	New Section
1330.50	New Section
1330.60	New Section
1330.70	New Section
1330.80	New Section
1330.90	New Section
1330.100	New Section
1330.200	New Section
1330.210	New Section
1330.220	New Section
1330.300	New Section
1330.310	New Section
1330.320	New Section
1330.330	New Section
1330.340	New Section

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1330.350	New Section
1330.400	New Section
1330.410	New Section
1330.420	New Section
1330.500	New Section
1330.510	New Section
1330.520	New Section
1330.530	New Section
1330.540	New Section
1330.550	New Section
1330.560	New Section
1330.600	New Section
1330.610	New Section
1330.620	New Section
1330.630	New Section
1330.640	New Section
1330.650	New Section
1330.660	New Section
1330.670	New Section
1330.680	New Section
1330.700	New Section
1330.710	New Section
1330.720	New Section
1330.730	New Section
1330.740	New Section
1330.750	New Section
1330.760	New Section
1330.770	New Section
1330.780	New Section
1330.790	New Section

4) Statutory Authority: Pharmacy Practice Act [225 ILCS 85/11(a)]

5) A Complete Description of the Subjects and Issues Involved: As a result of the sunset review process, PA 95-689 completely rewrote the Act regulating the licensure of pharmacists and pharmacies in Illinois, including changing the name to the Pharmacy Practice Act. As a result of the extensive changes this entails, the current Part 1330 is being repealed, to be replaced with a new Part 1330 encompassing all aspects of pharmacy regulation in Illinois. Probably the most significant changes are eliminating the divisions of pharmacy and adding which pharmacy services any licensed pharmacy, regardless of

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previous division, may provide. The current rules have also been overhauled to allow greater use of current technology in the course of recordkeeping and for the dispensing of prescription drugs remotely, while ensuring that the computer systems utilized protect private healthcare information. Section 1330.40 implements the registration of certified pharmacy technicians, including passage of an examination, while 1330.60 streamlines the application and acceptance process for pharmacists educated outside the United States, bringing us in line with the process utilized by most other states. Section 1330.270 sets the parameters under which telepharmacies are permitted, including remote automated pharmacy systems; pharmacy facility equipment and security requirements have also been updated. Section 1330.330 has been created to regulate the administration of vaccinations by pharmacists pursuant to standing orders. The Department has substituted the so-called “Plan B” rules with language modeled after rules promulgated in Washington State in 2007. The Washington rules are content neutral, apply to all FDA-approved drugs, and have survived constitutional challenge. *See Stormans, Inc. v. Selecky*, 571 F.3d 960 (9th Cir. 2009). The overall effect of the rewrite of this Part is to enhance licensed pharmacists’ role in providing pharmacy services to the public.

- 6) Published studies or reports, and sources of underlying data, used to compose this rulemaking: None
- 7) Will this rulemaking replace any emergency rulemaking currently in effect? No
- 8) Does this rulemaking contain an automatic repeal date? No
- 9) Does this rulemaking contain incorporations by reference? No
- 10) Are there any other proposed rulemakings pending on this Part? No
- 11) Statement of Statewide Policy Objectives: This rulemaking has no impact on local government.
- 12) Time, Place and Manner in which interested persons may comment on this proposed rulemaking: Interested persons may submit written comments within 45 days of this issue of the *Illinois Register* to:

Department of Financial and Professional Regulation
Attention: Craig Cellini
320 West Washington, 3rd Floor
Springfield, IL 62786
217/785-0813 Fax #: 217/557-4451

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- 13) Initial Regulatory Flexibility Analysis:
- A) Types of small businesses, small municipalities and not for profit corporations affected: Licensed pharmacists, pharmacy technicians, and pharmacies may be affected.
 - B) Reporting, bookkeeping or other procedures required for compliance: None
 - C) Types of professional skills necessary for compliance: Licensure pursuant to the Pharmacy Practice Act.
- 14) Regulatory Agenda on which this rulemaking was summarized: July 2009

The full text of the Proposed Rules begins on the next page:

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TITLE 68: PROFESSIONS AND OCCUPATIONS

CHAPTER VII: DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

SUBCHAPTER b: PROFESSIONS AND OCCUPATIONS

PART 1330

PHARMACY PRACTICE ACT

SUBPART A: GENERAL PROVISIONS

Section	
1330.10	Definitions
1330.20	Fees
1330.30	Unprofessional/Unethical Conduct
1330.40	Violations
1330.50	Vaccinations/Immunizations
1330.60	Internet Pharmacies
1330.70	Granting Variances
1330.80	Renewals
1330.90	Restoration
1330.100	Continuing Education

SUBPART B: PHARMACY TECHNICIAN

Section	
1330.200	Application for Certificate of Registration as a Pharmacy Technician
1330.210	Pharmacy Technician Training
1330.220	Certified Pharmacy Technician

SUBPART C: PHARMACIST

Section	
1330.300	Approval of Pharmacy Programs
1330.310	Graduates of Programs Outside the United States
1330.320	Application for Examination
1330.330	Examination for Licensure
1330.340	Application for Licensure on the Basis of Examination
1330.350	Endorsement

SUBPART D: PHARMACY LICENSURE

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Section

- 1330.400 Application for a Pharmacy License
- 1330.410 Pharmacy Licenses
- 1330.420 Emergency Remote Temporary Pharmacy License

SUBPART E: TYPES OF PHARMACIES

Section

- 1330.500 Community Pharmacy Services
- 1330.510 Telepharmacy
- 1330.520 Offsite Institutional Pharmacy Services
- 1330.530 Onsite Institutional Pharmacy Services
- 1330.540 Nuclear Pharmacy Services
- 1330.550 Nonresident Pharmacies
- 1330.560 Remote Prescription/Medication Order Processing

SUBPART F: PHARMACY STANDARDS

Section

- 1330.600 Security Requirements
- 1330.610 Pharmacy Structural/Equipment Standards
- 1330.620 Electronic Equipment Requirements
- 1330.630 Sanitary Standards
- 1330.640 Pharmaceutical Compounding Standards
- 1330.650 Pharmacy Computer Regulations
- 1330.660 Pharmacist-in-Charge
- 1330.670 Compounded Sterile Preparation Standards
- 1330.680 Automated Dispensing and Storage Systems

SUBPART G: PHARMACY OPERATIONS

Section

- 1330.700 Patient Counseling
- 1330.710 Reporting Theft or Loss of Controlled Substances
- 1330.720 Transfer of Prescription
- 1330.730 Drug Prepackaging
- 1330.740 Multi-Med Dispensing Standards for Community Pharmacies
- 1330.750 Return of Drugs
- 1330.760 Electronic Transmission of Prescriptions
- 1330.770 Centralized Prescription Filling
- 1330.780 Change of Ownership of a Pharmacy

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1330.790 Closing a Pharmacy

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

SOURCE: Adopted at 33 Ill. Reg. _____, effective _____.

SUBPART A: GENERAL PROVISIONS

Section 1330.10 Definitions

"Act" means the Pharmacy Practice Act [225 ILCS 85].

"Automated Dispensing and Storage Systems" include, but are not limited to, mechanical systems that perform operations or activities, other than counting, compounding or administration, relative to the storage, packaging or dispensing of medications, and that collect, control and maintain all transaction information.

"Board" means the State Board of Pharmacy.

"Community Pharmacy" means any pharmacy that engages in general community pharmacy practice and that is open to, or offers pharmacy service to, the general public.

"Deliver" means the actual, constructive or attempted transfer of possession of a prescription medication.

"Department" means the Department of Financial and Professional Regulation.

"Direct Supervision" means in the immediate physical presence of the person supervised.

"Director" means the Director of the Division of Professional Regulation with the authority delegated by the Secretary.

"Dispense" means to interpret, verify computer entry of, select the prescribed product for, prepare and/or deliver a prescription medication to an ultimate consumer or to a person authorized to receive the prescription medication by or pursuant to the lawful order of a practitioner, including the compounding,

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packaging and/or labeling necessary for delivery and any recommending, advising and counseling concerning the contents, therapeutic values, uses and any precautions, warnings and/or advice concerning consumption. Dispense does not mean the physical delivery to a patient or a patient's representative in a home or institution by a designee of a pharmacist or by common carrier or the physical delivery of a drug or medical device to a patient or patient's representative by a pharmacist's designee within a pharmacy or drugstore while the pharmacist is on duty and the pharmacy is open.

"Distribute" means to deliver, other than by dispensing, a prescription medication.

"Division" means the Department of Financial and Professional Regulation-Division of Professional Regulation.

"Drug Regimen Review" means *and includes the evaluation of prescription drug orders and patient records for known allergies; drug or potential therapy contraindications; reasonable dose, duration of use, and route of administration, taking into consideration factors such as age, gender, and contraindications; reasonable directions for use; potential or actual adverse drug reactions; drug-drug interactions; drug-food interactions; drug-disease contraindications; therapeutic duplication; patient laboratory values when authorized and available; proper utilization (including over or under utilization) and optimum therapeutic outcomes; and abuse and misuse* [225 ILCS 85/3(y)].

"Electronic Transmission of Prescriptions" and "electronically transmitted prescriptions" means the communication of original prescriptions, refill authorizations, or medication orders, including controlled substances to the extent permitted by federal law, from an authorized licensed prescriber, or his or her authorized agent, to the pharmacy of the patient's choice by electronic means, including, but not limited to, telephone, facsimile machine, computer, computer modem or any other electronic device or authorized means.

"Institutional Pharmacy" means any pharmacy that is located in or outside a facility licensed under the Nursing Home Care Act, [210 ILCS 45] the Hospital Licensing Act [225 ILCS 85], or the University of Illinois Hospital Act [110 ILCS 330] or a facility that is operated by the Department of Human Services or the Department of Corrections, and that provides pharmacy services to residents or patients of the facility, as well as employees, prescribers and students of the facility.

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"Medication Order" means a prescription issued by a physician or other authorized prescriber for a resident or patient of a facility served by an institutional pharmacy.

"Nonresident Pharmacy" means a pharmacy that is located outside this State that ships, delivers, dispenses or distributes into Illinois by any means any drugs, medicines, pharmaceutical services or devices requiring a prescription.

"Nuclear Pharmacist" means a pharmacist who provides radiopharmaceutical services and has satisfied the requirements of Section 1330.540(i).

"Nuclear Pharmacy" means any pharmacy that provides and/or offers for sale radiopharmaceuticals.

"On File" as used in Section 19 of the Act and this Part means the maintenance at the transferor pharmacy of the transferred prescription, whether previously filled or unfilled. For previously filled prescriptions at a transferor pharmacy located in Illinois, the prescriptions shall be maintained pursuant to the recordkeeping requirements of Section 18 of the Act. For previously unfilled prescriptions at a transferor pharmacy located in Illinois, the prescriptions shall be maintained in a readily retrievable format in a suitable book, file or recordkeeping system for a period of not less than 5 years. For previously filled and unfilled prescriptions at a transferor pharmacy located in a state other than Illinois, the prescriptions shall be maintained pursuant to the recordkeeping requirements of that state.

"Patient Counseling" means the communication between a pharmacist or a student pharmacist under the supervision of a pharmacist and a patient or the patient's representative about the patient's medication or device for the purpose of optimizing proper use of prescription medications or devices. *"Patient counseling" may include without limitation: obtaining a medication history; acquiring a patient's allergies and health conditions; facilitation of the patient's understanding of the intended use of the medication; proper directions for use; significant potential adverse events; potential food-drug interactions; and the need to be compliant with the medication therapy. A pharmacy technician may only participate in the following aspects of patient counseling under the supervision of a pharmacist: obtaining medication history; providing the offer for counseling by a pharmacist or intern; and acquiring a patient's allergies and health conditions.* [225 ILCS 85/3(r)]

"Patient Profiles" or "Patient Drug Therapy Record" means the obtaining,

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recording and maintenance of patient prescription and personal information.

"Pharmacist" means a currently licensed pharmacist or registered assistant pharmacist.

"Pharmacy Services" means the provision of any services listed within the definition of the "practice of pharmacy" found in Section 3(d) of the Act.

"Radiopharmaceutical" means any substance defined as a drug in Section 3(b) of the Act that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or nuclide generator that is intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds of potassium-containing salts that contain trace quantities of naturally occurring radionuclides. Radiopharmaceuticals include radioactive biological products as defined in the Federal Food, Drug and Cosmetic Act (21 USC 301 et seq.) and regulations promulgated under that Act.

"Radiopharmaceutical Quality Assurance" means, but is not limited to, the performance of appropriate chemical, biological and physical tests on potential radiopharmaceuticals, and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history and the keeping of proper records in these regards.

"Radiopharmaceutical Service" means the compounding, dispensing, labeling and delivery of radiopharmaceuticals; the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals as determined by the Illinois Emergency Management Agency; the maintenance of radiopharmaceutical quality assurance; the responsibility for advising, where necessary or required, of diagnostic and therapeutic values, hazards and use of radioactive pharmaceuticals; and the offering or performance of those acts, services, operations or transactions necessary in the conduct, operation, management and control of a nuclear pharmacy.

"Registrant" means a licensed pharmacist, registered assistant pharmacist, certified pharmacy technician, student pharmacist, or registered pharmacy technician.

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"Remote Medication Order Processing" means receiving, interpreting or clarifying medication orders; data entry and transferring of medication order information; performing drug utilization review; interpreting clinical data; performing therapeutic interventions; and providing drug information concerning medication orders or drugs from a remote pharmacy.

"Remote Pharmacy" means any pharmacy that provides pharmacy services at a location other than the home pharmacy.

"Secretary" means the Secretary of the Department of Financial and Professional Regulation.

"Student Pharmacist" means a person registered as a pharmacy technician who is enrolled in a pharmacy program and is designated as a "student pharmacist" pursuant to Section 9 of the Act.

"Ultimate Consumer" means the person for whom a drug is intended.

"Unique Identifier" means an electronic signature, handwritten signature or initials, thumb print or other acceptable individual biometric or electronic identification process approved by the Division.

"Unprofessional Conduct" under Section 30 of the Act shall include, but not be limited to, any act or practice related to the practice of pharmacy that is willful, wanton, repeated or flagrant and likely to result in harm to an individual. In determining what constitutes unprofessional conduct, the Board shall consider, but shall not be limited to, the following standards as they relate to the person who is the subject of the proposed disciplinary action:

Violations set forth in Section 30(a) of the Act;

Repeated commission of 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;

Repeated commission of an act or acts in a relationship with a patient so as to violate common standards of decency or propriety;

Willful violation or knowing assistance in the violation of any law relating to the use of habit-forming drugs;

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Willful preparation or signing false statements in order to induce payment for pharmacy services by the Department of Healthcare and Family Services, or any other local, state or federal department, agency or governmental body, or any private insurance program; and

Violating the practice standards of the American Pharmaceutical Association (American Association of Colleges of Pharmacy Standards of Practice for the Profession of Pharmacy (March 1979)) and the Principles of Practice for Pharmaceutical Care (1996), which include no later editions or amendments, and which are herein incorporated by reference; however, non-compliance with these professional standards shall not alone be considered an act of unprofessional conduct unless these acts are of a flagrant, glaringly obvious nature constituting a substantial departure from these professional standards.

Section 1330.20 Fees

The following fees are not refundable

- a) Certificate of Pharmacy Technician.
 - 1) The fee for application for a certificate of registration as a pharmacy technician is \$40.
 - 2) The fee for the renewal of a certificate of registration as a pharmacy technician shall be calculated at the rate of \$25 per year.

- b) License as a Pharmacist.
 - 1) The fee for application for a license as a pharmacist is \$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.

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- 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 \$200.
 - 4) The fee for the renewal of a license shall be calculated at the rate of \$75 per year.
 - 5) The fee for the restoration of a license other than from inactive status is \$20 plus all lapsed renewal fees.
 - 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.
 - 7) The fee to have the scoring of an examination authorized by the Division reviewed and verified is \$20 plus any fee charged by the applicable testing service.
- c) License as a Pharmacy.
- 1) The fee for application for a license for a pharmacy under the Act is \$100.
 - 2) The fee for the renewal of a license for a pharmacy under the Act shall be calculated at the rate of \$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 duplicate license, for the issuance of a replacement license for a license that has been lost or destroyed or 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.
 - 2) The fee for a certification of a registrant's record for any purpose is \$20.

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- 3) The fee to have the scoring of an examination administered by the Division reviewed and verified is \$20.
- 4) The fee for a wall certificate showing licensure or registration shall be the actual cost of producing the certificate.
- 5) The fee for a roster of persons registered as pharmacists or registered pharmacies in this State shall be the actual cost of producing the roster.
- 6) The fee for pharmacy licensing, disciplinary or investigative records obtained pursuant to a subpoena is \$1 per page.

Section 1330.30 Unprofessional/Unethical Conduct

Unprofessional and Unethical conduct shall include but not be limited to:

- a) Failing to establish and maintain effective controls against diversion of prescription drugs.
- b) 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.
- c) Knowingly dispensing a prescription drug after the death of the person for whom the prescription was written.
- d) 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.
- e) Submitting fraudulent billing or reports to a third party payer.
- f) Filling a prescription when a pharmacist knows, or reasonably should know, that no valid physician-patient relationship exists.
- g) Failing to ensure that patient counseling is offered or refusing to respond to requests for patient counseling.
- h) Failing to use appropriate professional judgment when dispensing drugs.

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- i) Unreasonably refusing to compound a valid prescription.
- j) 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.
- k) Knowingly selling a prescription drug without a valid prescription.
- l) Failing to exercise sound professional judgment with respect to the accuracy and authenticity of any prescription drug order dispensed.
- m) Failure of a licensee or registrant to keep himself or herself and his or her apparel clean or to wear identification bearing his or her name and designation.
- n) Directly or indirectly furnishing to a medical practitioner prescription order-blanks that refer to a specific pharmacist or pharmacy in any manner.
- o) 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.
- p) Claiming a fee for a service that is not performed or earned.
- q) 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.

Section 1330.40 Violations

- a) A registrant shall not:
 - 1) Engage in a professional association, with any place defined as a drug store or pharmacy in the Act where the practice of pharmacy is engaged in by any person who is not authorized to practice under the Act or that is not operated and conducted in compliance with the Act.
 - 2) Compound, sell or offer for sale, or cause to be compounded, sold or offered for sale, any drug, medicine, poison, chemical or pharmaceutical preparation, under or by a name recognized in the United States Pharmacopeia/National Formulary for internal or external use that differs

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from standard of strength, quality, purity or bioavailability as determined by the tests specified in the United States Pharmacopeia/National Formulary that is official at the time of the compounding, sale or offering for sale.

- 3) Compound, sell or offer for sale, or willfully cause to be compounded, sold or offered for sale, any drug, medicine, poison, chemical or pharmaceutical preparation the strength or purity of which falls below the professed standard of strength or purity under which it is sold.
 - 4) Purchase prescription drugs from any source that fails to meet provisions of the Wholesale Drug Distribution Licensing Act [225 ILCS 120].
- b) No registrant shall violate any of the following laws, or the rules or regulations promulgated pursuant to these laws, which relate to the practice of pharmacy:
- 1) Illinois Food, Drug and Cosmetic Act [410 ILCS 620].
 - 2) Hypodermic Syringes and Needles Act [720 ILCS 635].
 - 3) Federal Food, Drug and Cosmetic Act (21 USC 301 et seq.).
 - 4) Federal Controlled Substances Act (21 USC 801 et seq.).
 - 5) Illinois Controlled Substances Act [720 ILCS 570].
 - 6) Cannabis Control Act [720 ILCS 550].
 - 7) Illinois Poison Prevention Packaging Act [430 ILCS 40].
 - 8) Poison Prevention Packaging Act of 1970 (15 USC 1471 et seq.).
 - 9) Wholesale Drug Distribution Licensing Act [225 ILCS 120].
- c) If a licensee or registrant is disciplined in another state he or she must inform the Division.

Section 1330.50 Vaccinations / Immunizations

- a) Qualifications

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- 1) A pharmacist, or student pharmacist under the direct supervision of a pharmacist, may administer vaccinations/immunizations to persons who are 14 years of age or older pursuant to a valid patient specific prescription or a standing order by a physician licensed to practice medicine in all of its branches under the Medical Practice Act of 1987 [225 ILCS 60].
 - 2) The pharmacist shall successfully complete a course of training accredited by the Accreditation Council on Pharmacy Education, or a similar health authority or professional body approved by the Division.
 - 3) The pharmacist shall maintain a current Basic Life Support Certification for Healthcare Providers issued by the American Heart Association or the American Red Cross.
 - 4) Each pharmacy or pharmacist functioning outside of a pharmacy shall have available a current copy or electronic version of the CDC reference “Epidemiology and Prevention of Vaccine – Preventable Diseases” at the location where vaccinations are administered.
 - 5) The administration of vaccines shall be done by a pharmacist or student pharmacist under the direct supervision of a pharmacist.
- b) Protocols, Policies and Procedures
- 1) Prior to administering vaccinations/immunizations to persons who are 14 years of age or older, a pharmacist or student pharmacist under the direct supervision of a pharmacist must follow protocols written by a physician licensed to practice medicine in all of its branches for the administration of vaccines and treatment of severe adverse events following administration of vaccines.
 - 2) The pharmacy must maintain written policies and procedures for handling and disposal of all used supplies or contaminated equipment.
 - 3) The pharmacist or student pharmacist under the direct supervision of a pharmacist must give the appropriate vaccine information statement (VIS) to the patient or legal representative prior to each vaccination. The pharmacist or student pharmacist under the direct supervision of a pharmacist must ensure that the adult patient or minor (age 14 or older)

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patient's parent or legal representative is available and has the vaccine information statement.

- 4) The pharmacy must report adverse events as required by the Vaccine Adverse Events Reporting System (VAERS) and to the primary care provider named by the patient.

c) Record Keeping and Reporting

- 1) All records regarding each administration of a vaccine must be kept for 5 years. These records shall include:
 - A) The name, address and date of birth of the patient.
 - B) Date of administration and site of injection of the vaccine.
 - C) Name, dose, manufacturer, lot number and beyond use date of the vaccine.
 - D) Name and address of the patient's primary health care provider named by the patient.
 - E) The name or unique identifier of the administering pharmacist.
 - F) Which vaccine information statement (VIS) was provided.
- 2) A pharmacist who administers any vaccine must report that administration, within 30 days after the date of administration, to the patient's primary healthcare provider named by the patient.

Section 1330.60 Internet Pharmacies

The provisions of the federal Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act) (21 USC 801/*et seq.*) and all federal regulations adopted under that Act, are expressly adopted by this Part.

Section 1330.70 Granting Variances

- a) The Director may grant variances from this Part in individual cases when he or she finds that:

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- 1) The provision from which the variance is granted is not statutorily mandated;
 - 2) No party will be injured by the granting of the variance; and
 - 3) The rule from which the variance is granted would, in the particular case, be unreasonable or unnecessarily burdensome.
- b) The Director shall notify the Board of the granting of the variance, and the reasons for granting the variance, at the next meeting of the Board.

Section 1330.80 Renewals

- a) Every license issued under the Act, except the certificate of registration as a pharmacy technician, shall expire on March 31 of each even-numbered year. Every certificate of registration as a 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. Failure to receive a renewal form from the Division shall not constitute an excuse for failure to 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.

Section 1330.90 Restoration

- a) A registrant 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 continuing education (e.g., certificate of attendance or completion) in accordance with Section 1330.100 of this Part.
- b) A registrant 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 continuing education (e.g.,

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certificate of attendance or completion) in accordance with Section 1330.100 of this Part.

- c) A registrant 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 continuing education (e.g., certificate of attendance or completion) in accordance with Section 1330.100 of this Part.
 - 1) The registrant 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 registrant who is unable to submit proof of satisfaction of either subsection (c)(1)(A) or (B) shall submit proof of completion of:
 - A) 15 clock hours of refresher courses or continuing education for each year the license was expired; or
 - B) Up to 400 hours of clinical practice under the supervision of a pharmacist.
 - 3) The course work or clinical training described in subsections (c)(2)(A) and (B) must have the prior approval of the Board.
- 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

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sufficiency, clarify information given, or clear up any discrepancies in information.

Section 1330.100 Continuing Education

- a) Continuing Education Requirements
 - 1) Each person who applies for renewal of a license as a pharmacist shall complete 30 hours of continuing education (CE) during the 24 months preceding the expiration date of the license, in accordance with Section 12 of the Act.
 - 2) A renewal applicant is not required to comply with CE requirements for the first renewal after original licensure.
- b) Approved Continuing Education
 - 1) CE credit shall be based upon the completion of courses offered by providers approved by the Accreditation Council for Pharmacy Education. These courses may be completed outside the State of Illinois.
 - 2) Undergraduate Coursework
 - A) Undergraduate coursework taken after completion of a first professional degree in pharmacy through a recognized college or approved school of pharmacy (in accordance with Section 1330.300 of this Part) may be used to fulfill the CE requirement if:
 - i) Evidence of course completion through an official transcript and other documentation (e.g., certificate of completion or degree) of the university or college is submitted that indicates the number of course content hours completed; and
 - ii) These courses are completed for college credit.
 - B) CE credit will be earned for each undergraduate course completed.
- c) Certification of CE Requirements

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- 1) Each renewal applicant shall certify on the renewal application full compliance with CE requirements set forth in subsection (a).
 - 2) The Division may require additional evidence demonstrating compliance with the CE requirements. It is the responsibility of each renewal applicant to retain or otherwise produce evidence of the compliance (e.g., certificate of attendance or completion). Evidence shall be required in the context of the Division's random audit in accordance with Section 12 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 renewal of a 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 on the basis of these facts. 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; or
 - ii) Physical inability to travel to the sites of approved programs, as documented by a currently licensed physician;

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or

- iii) Any other similar extenuating circumstances (e.g., illness of family member).
- 3) An interview before the Board with respect to a request for waiver shall be granted only if the interview is requested at the time the request for the waiver is filed with the Division. 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 certified mail, return receipt requested.
- 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.

SUBPART B: PHARMACY TECHNICIAN

Section 1330.200 Application for Certificate of Registration as a Pharmacy Technician

- a) An applicant for registration as a pharmacy technician shall file an application on forms supplied by the Division, together with:
 - 1) A copy of his or her high school diploma or its equivalent, or proof of current enrollment in a high school program; and
 - 2) The fee required by Section 1330.20 of this Part.
- b) Pursuant to Section 9 of the Act, an applicant may assist a registered pharmacist for 60 days upon submission of an application, or submission for reinstatement not due to disciplinary action, to the Division in accordance with subsection (a). A copy of the application must be maintained by the applicant at the site of employment during and until notice of registration or disqualification is received by the applicant and must be readily retrievable for review by the Drug Compliance Investigator.
- c) A pharmacy technician must renew his or her registration with the Division on an annual basis.
- d) Technician certificate of registration must be displayed and visible to the public in the pharmacy where the pharmacy technician is employed.

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- e) Every registered pharmacy technician shall notify the Division of any change in the address on record within 30 days after the change.
- f) No pharmacist whose license has been denied, revoked, suspended or restricted for disciplinary purposes is eligible to be registered as a 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) Record keeping requirements.
 - 6) The ability to perform and apply arithmetic calculations.
- 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.

Section 1330.220 Certified Pharmacy Technician

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- a) An individual may receive certification as a certified pharmacy technician if he or she:
 - 1) Has submitted a written application in the form and manner prescribed;
 - 2) Has attained the age of 18;
 - 3) Is of good moral character, as determined by the Division;
 - 4) Graduated from a pharmacy technician training program approved by a nationally recognized accrediting body or obtained documentation from the pharmacist-in-charge of the pharmacy where the applicant is employed verifying that he or she has successfully completed a training program as provided for in Section 1330.210(a);
 - 5) Has successfully passed an examination accredited by the National Organization for Competency Assurance (NOCA), as approved and required by the Board. The Division, upon the recommendation of the Board, has determined that the Exam for the Certification of Pharmacy Technicians offered by the Institute for the Certification of Pharmacy Technicians, and the Pharmacy Technician Certification Examination offered by the Pharmacy Technician Certification Board, are accredited by NOCA and are, therefore, approved examinations for certification; and
 - 6) Has paid the required certification fees.
- b) No pharmacist whose license has been denied, revoked, suspended or restricted for disciplinary purposes may be eligible to be registered as a certified pharmacy technician.

SUBPART C: PHARMACIST

Section 1330.300 Approval of Pharmacy Programs

- a) The Division shall, upon the recommendation of the Board, approve a pharmacy program in a school or college or department of pharmacy of a university or other institution as reputable and in good standing if it meets the following minimum criteria:
 - 1) Is legally recognized and authorized, through appropriate agencies such as

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a ministry of education or higher education governing board, by the jurisdiction in which it is located to confer a first professional degree in pharmacy;

- 2) Has a faculty comprised of a sufficient number of full-time instructors to make certain that the educational obligations to the student are fulfilled. Their facility must have demonstrated competence in their area of teaching as evidenced by appropriate degrees from professional colleges or institutions in disciplines reflective of the curricular requirements. (All of the pharmacist members of the clinical faculty and a majority of the faculty in the pharmaceutical sciences should be licensed pharmacists in that jurisdiction. The clinical faculty should be active practitioners.);
- 3) Has a curricular offering of post-secondary instruction totaling at least 5 academic years, including any preprofessional education requirements, and requiring a minimum of the following subject areas:
 - A) General Education (a minimum of 30 semester hours or its equivalent in courses in the humanities and behavioral and social sciences);
 - B) Preclinical Sciences (courses in the physical and biological sciences and mathematics that are prerequisites to professional studies and training; course work should include general chemistry, organic chemistry, general biology, microbiology and mathematics);
 - C) Professional Studies and Training (in the following areas):
 - i) Biomedical sciences, which include anatomy, physiology, immunology, biological chemistry, pathology and biostatistics;
 - ii) Pharmaceutical sciences, which include pharmaceutical or medicinal chemistry, pharmaceuticals or dosage form design and evaluation, pharmacokinetics, synthetic and natural drug product chemistry, pharmacology, pharmaceutical administration and the social and behavioral sciences in pharmacy;

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- iii) Clinical sciences and practice, which include clinically applied courses based on the biomedical and pharmaceutical sciences, such as didactic courses in clinical foundations, disease processes and diagnoses, clinical pharmacology and therapeutics, and drug information research and literature retrieval; and
 - iv) Externship and clerkship, which include a minimum of 400 direct contact hours in clerkship and externship experience. These experiences should minimally include supervised training in inpatient environments providing for interdisciplinary experiences with other health professionals and distributive aspects of pharmacy practice.
 - 4) Has essential facilities including, but not limited to, administrative and faculty offices, teaching and research laboratories, lecture rooms, conference rooms, student activities areas, service areas and other programmatic support areas;
 - 5) Has a comprehensive library that contains a contemporary collection of periodicals, texts and reference books relevant to the biomedical, pharmaceutical and clinical aspects of health care and its systems of delivery;
 - 6) Has clinical facilities adequate in number and quality and with appropriate supervision to deliver the clinical clerkships and externships of the curriculum. The facilities shall be available in inpatient and outpatient environments, including patient care areas of health care institutions, hospital pharmacies and community pharmacies; and
 - 7) Maintains permanent retrievable and auditable student records that summarize the credentials for admission, attendance, grades and other records of performance for each student enrolled in the program.
- b) In determining whether a school or college should be approved, the Division shall take into consideration, but not be bound by, accreditation standards established by the Accreditation Council on Pharmacy Education.
 - c) An applicant from a pharmacy program that has not been evaluated shall cause to be forwarded to the Division documentation concerning the criteria in this

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Section. If the documentation is insufficient to evaluate the program, the applicant will be required to provide such additional information as necessary. Once the Division has received the documentation or after 6 months have elapsed from the date of application, whichever is first, the Board will evaluate the program based on all documentation received from the school and any additional information the Division has received that will enable the Board to evaluate the program based on the criteria specified in this Section. In the event the program is not approved as reputable and in good standing by the Division, applicants from the program must successfully complete the preliminary diagnostic examination and all other requirements set forth in the Act and this Part.

- d) The Director shall, upon written recommendation of the Board, withdraw, suspend or place on probation the approval of a pharmacy program when the Director determines, based upon the report of the Board, the quality of the program has been materially affected. In determining the existence of a material effect, the Board and the Director shall consider:
 - 1) Gross or repeated violations of any provision of the Act;
 - 2) Gross or repeated violations of any provision of this Part;
 - 3) Fraud or dishonesty in furnishing documentation for evaluation of the pharmacy program; or
 - 4) Failure to continue to meet the established criteria for an approved pharmacy program set out in this Section.
- e) When approval of a pharmacy program is being reconsidered by the Division, written notice shall be given at least 15 days prior to any recommendation by the Board, and the officials in charge may either submit written comments or request an interview before the Board.
- f) The Division, upon the recommendation of the Board, has determined that all pharmacy programs accredited by the Accreditation Council on Pharmacy Education as of July 1, 1998 meet the minimum criteria set forth in subsection (a) and are, therefore, approved. The Board shall review the list of accredited programs published each year on July 1 by the Accreditation Council on Pharmacy Education in order to determine whether the programs continue to meet the minimum criteria.

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Section 1330.310 Graduates of Programs Outside the United States

Applicants who are graduates of a first professional degree program in pharmacy located outside the United States or its territories that is not approved pursuant to the provisions of Section 1330.300 shall submit proof of:

- a) Submission of a Foreign Pharmacy Graduate Examination Committee (FPGEC) Certificate;
- b) Passage of the preliminary diagnostic examination (Foreign Pharmacy Graduate Equivalency Exam (FPGEE)) designed to determine equivalence of education to programs approved pursuant to Section 1330.300;
- c) Passage of the Test of English as a Foreign Language (TOEFL) examination with a score of at least 550;
- d) Passage of the Test of Spoken English (TSE) examination with a score of 50; and
- e) Either:
 - 1) Completion of a course of clinical instruction totaling 1,200 clinical hours approved by the Board as required by Section 7 of the Act. The course of clinical instruction shall be conducted under the supervision of a pharmacist registered in the State of Illinois. The applicant shall obtain prior approval of the Board before enrolling in the course of clinical instruction. In approving a course of clinical instruction, the Board shall consider, but not be limited to, whether the course:
 - A) Enhances development of effective communication skills by enabling consultation among the applicant, the prescriber and the patient;
 - B) Promotes development of medical data retrieval skills through exposure to patient medical charts, patient medication profiles and other similar sources of patient information;
 - C) Promotes development of the applicant's ability to research and analyze drug information literature; and
 - D) Promotes development of the applicant's ability to interpret

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laboratory test and physical examination results; or

- 2) Have been licensed in a U.S. jurisdiction or territory for at least 1 year with no disciplinary actions or encumbrances on their license or pending license.

Section 1330.320 Application for Examination

- a) An applicant for examination shall apply, on forms approved by the Division, at least 30 days prior to an examination date. The application shall include:
 - 1) One of the following:
 - A) Certification of graduation from a first professional degree program in pharmacy. The program must be approved by the Division upon recommendation of the Board of Pharmacy under the provisions of Section 1330.300; or
 - B) Certification, in the case of an applicant applying in the last half-year of the curriculum, from the dean of an approved pharmacy program indicating the applicant is expected to graduate. It is the responsibility of the individual school to notify the Division of all the students who do not graduate; or
 - C) Proof of compliance with Section 1330.310 if the applicant is a graduate of a program located outside the United States.
 - 2) The fee required by Section 1330.20.
- b) An applicant whose application is complete shall be scheduled for the next available examination.
- c) If the applicant has successfully completed the in another jurisdiction the examinations required by Section 1330.330(a)(1) and (2)(B), the applicant may have examination scores submitted to the Division from the reporting entity.

Section 1330.330 Examination for Licensure

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

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- 1) Theoretical and Applied Pharmaceutical Sciences portion, which shall test the following subjects:
 - A) Medicinal Chemistry;
 - B) Pharmacology;
 - C) Pharmacy;
 - D) Pharmaceutical Calculations;
 - E) Interpreting and Dispensing Prescription Orders;
 - F) Compounding Prescription Orders; and
 - G) Monitoring Drug Therapy.
 - 2) Pharmaceutical Jurisprudence portion, which consists of 2 parts and shall test:
 - A) Illinois Law related to pharmacy practice; and
 - B) Federal Law related to pharmacy practice.
- b) An applicant must score a minimum of 75 on the Theoretical and Applied Pharmaceutical Sciences portion and a minimum of 75 on the combined Pharmaceutical Jurisprudence portion in order to successfully pass the examination for licensure. An applicant who scores 75 or greater in either the Theoretical and Applied Pharmaceutical Sciences portion or on either of the combined Pharmaceutical Jurisprudence portions will not be required to retake that portion of the examination. The reporting of scores to the candidates shall include the score obtained on the Theoretical and Applied Pharmaceutical Sciences, the score obtained on the Federal Law portion, a pass or fail score on the Illinois Law portion and the combined score consisting of the Federal Law portion and the State Law portion.
- c) Any applicant who fails any portion or all portions of the registered pharmacist examination 3 times in any jurisdiction will be required to furnish proof of remedial education in an approved program on the subjects of the portion failed in

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the third examination. Proof of additional remedial education in an approved program shall also be furnished each time the applicant fails any portion of the examination 3 times after undergoing remedial education (i.e., after the sixth exam, ninth exam, etc.).

- d) Pursuant to Section 7 of the Act, an applicant may work as a registered pharmacist for up to 60 days prior to the issuance of a certificate of registration upon receipt of a notice from the Division that the examination was successfully completed.
- e) For the purposes of this Section remedial training shall be defined as:
 - 1) A course of study of at least 30 classroom hours in an approved pharmacy college in the subjects of the portions failed 3 times; or
 - 2) A tutorial or preceptorship with a faculty member in an approved pharmacy college or another pharmacist as a preceptor. The course of instruction must be deemed by the Board to be substantially equivalent to subsection (e)(1) and approved by the Division. Any remedial training must be approved by the Board and the Division prior to commencement.
- f) The provisions of this Section shall apply to all applicants upon adoption without regard to where the applicant is in the application process.

Section 1330.340 Application for Licensure on the Basis of Examination

- a) An applicant for licensure on the basis of examination shall submit to the Division a properly completed application on forms provided by the Division, along with the following:
 - 1) The fee required by Section 1330.20;
 - 2) Certification of graduation from an approved program of pharmacy (see Section 1330.300); and
 - 3) Proof of successful completion of the examination approved by the Division (see Section 1330.330).
- b) Upon receipt of the items required in subsection (a), and upon verification by the Division that the candidate meets all of the requirements for licensure as a

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Registered Pharmacist, the Division shall issue a license to practice pharmacy or notify the applicant of the reason for denial.

Section 1330.350 Endorsement

- a) An applicant who is currently licensed by examination under the laws of another U.S. jurisdiction or another country shall file an application with the Division, together with:
 - 1) Certification of graduation from a pharmacy program approved pursuant to Section 6 of the Act and Section 1330.300 of this Part;
 - 2) For individuals licensed in another state prior to January 1, 1983, proof of having completed the hours of apprenticeship, or, if at least 1500 hours of apprenticeship were not required, an affidavit attesting to the period of the applicant's active experience as a pharmacist;
 - 3) A certification by the state or territory of original licensure stating:
 - A) The time during which the applicant was licensed in that state;
 - B) Whether the file on the applicant contains any record of any disciplinary actions taken or pending; and
 - C) A brief description of the examination and the applicant's grades.
 - 4) Proof of successful passage of the Illinois multi-state jurisprudence examination; and
 - 5) The fee as required by Section 1330.20.
- b) The Division shall examine each application to determine whether the requirements, at the time of licensure in the state where the applicant was licensed by examination, were substantially equivalent to the requirements then in force in this State.
- c) If the requirements are found to be substantially equivalent and the applicant graduated from an approved college of pharmacy and meets all other requirements of the Act, the Division will notify the applicant of approval and/or denial and the reasons for the approval or denial within 30 days after receipt of

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the application and supporting documentation.

SUBPART D: PHARMACY LICENSURE

Section 1330.400 Application for a Pharmacy License

- a) Establishing, Relocating or Changing Ownership
 - 1) Any person who desires to establish, relocate or change the ownership of a pharmacy shall file an application on forms supplied by the Division, together with the fee required by Section 1330.20, and specify the types of pharmacy services to be provided as described in Sections 1330.500, 1330.510, 1330.520, 1330.530, 1330.540, 1330.550 and 1330.560.
 - 2) Upon determination that the application is in good order, an inspection of the premises will be conducted to determine compliance with Sections 1330.610, 1330.630, 1330.640 and 1330.670. An application shall be in good order when it is signed and notarized and the license of the pharmacist-in-charge has been verified to be in good standing with the Division.
 - 3) Upon recommendation of the Drug Compliance Coordinator, the Board may request the owner of the pharmacy and the pharmacist-in-charge to appear for an interview with the Board.
- b) For a change of name of pharmacist-in-charge only, the owner shall be required to file an application on forms supplied by the Division, together with the required fee, and submit the present license. The Division shall evaluate the application and, if satisfactory, issue a new license.
- c) Within 30 days after issuance of a pharmacy license, the pharmacy for which the licensure was requested shall be open to the public for pharmaceutical services.

Section 1330.410 Pharmacy Licenses

- a) Each individual, partnership, corporation or any other applicant for a pharmacy license shall indicate, on forms supplied by the Division, the type of pharmacy services to be provided by the licensee.
- b) The Board may review and make recommendations to the Director regarding

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pharmacy applications filed with the Division.

- c) A pharmacy who provides more than one type of pharmacy service shall be issued one pharmacy license and shall be charged the appropriate fee, as set forth in Section 1330.20.
- d) A pharmacy shall designate a pharmacist-in-charge as provided for in Section 1330.660.
- e) When a management company is hired to run a pharmacy, that management company shall be the license holder; however, the license may be issued in the name of the pharmacy or of the management company. The Illinois Controlled Substance license shall be issued in the name of the management company unless the management company and the pharmacy or hospital cosigns a pharmacy service agreement that assigns overall responsibility for controlled substances to the management company.

Section 1330.420 Emergency Remote Temporary Pharmacy License

- a) Definitions:
 - 1) “Emergency remote temporary pharmacy” means a pharmacy not located at the same location as a home pharmacy at which pharmacy services are provided during an emergency situation.
 - 2) “Emergency situation” means an emergency caused by a natural or manmade disaster or any other exceptional situation that causes an extraordinary demand for pharmacy services.
- b) The following is applicable for the emergency remote temporary pharmacy:
 - 1) The emergency remote temporary pharmacy will not be issued a separate pharmacy license but shall operate under the license of the home pharmacy. To qualify for an emergency remote temporary pharmacy license, the applicant must submit an application including the following information:
 - A) license number, name, address and phone number of the home pharmacy;

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- B) names, address and phone number of the emergency remote temporary pharmacy;
 - C) name and pharmacist license number of the pharmacist-in-charge of the home pharmacy and of the pharmacist-in-charge of the emergency remote temporary pharmacy; and
 - D) any other information required by the Board.
- 2) The Division will notify the home pharmacy of the approval of an emergency remote temporary pharmacy license.
 - 3) The emergency remote temporary pharmacy license shall be valid for a period determined by the Director not to exceed 6 months. The Director, in his or her discretion, may renew the emergency remote temporary pharmacy license for an additional 6 months if the emergency situation still exists and the holder of the license shows good cause for the emergency remote temporary pharmacy to continue operation.
 - 4) The emergency remote temporary pharmacy shall have a written contract or agreement with the home pharmacy that outlines the services to be provided and the responsibilities and accountabilities of the remote and home pharmacy in fulfilling the terms of the contract or agreement in compliance with federal and State laws and regulations.
 - 5) The home pharmacy shall designate a pharmacist to serve as the pharmacist-in-charge of the emergency remote temporary pharmacy.
 - 6) The equipment and facility of the pharmacy must enable prescriptions to be filled accurately and properly compounded; it must be operated and maintained in a manner that will not endanger the health and safety of the public.
 - 7) An onsite pharmacy can only provide service to patients, staff or families of that institution.

SUBPART E: TYPES OF PHARMACIES

Section 1330.500 Community Pharmacy Services

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- 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 and on duty.
- c) Record Keeping 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 one year 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 registered 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 who dispenses the prescription.
 - 3) 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:

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- 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 for the prescription.
- B) If the pharmacist doesn't otherwise indicate in a uniformly maintained record, he/she shall be deemed to have dispensed a refill for the full face amount of the prescription.
- 4) 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.
- 5) Copies of prescriptions given to an ultimate consumer shall be marked "For Information Purposes Only".
- 6) Subject to Section 18 of the Act, any information required to be kept pursuant to this 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; 1998, no further amendments or editions, except as provide 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;

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- 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; or
- 7) 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 by him/her 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.
- 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) 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:

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- 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 the pharmacy.
- e) All pharmacies that dispense drugs must maintain at all times a representative assortment of drugs in order to meet the pharmaceutical needs of their patients.
- f) Pharmacies have a duty to deliver lawfully prescribed drugs or devices to patients and to distribute drugs and devices approved by the U.S. Food and Drug Administration for restricted distribution by pharmacies, or provide a therapeutically equivalent drug or device 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 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 subsection 3(aa) of the Act, she or he 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 or devices;
 - 3) Lack of specialized equipment or expertise needed to safely produce, store or dispense drugs or devices, such as certain drug compounding or storage for nuclear medicine;
 - 4) Potentially fraudulent prescriptions; or
 - 5) Unavailability of drug or device despite good faith compliance with subsection (e).
- g) Nothing in this Section requires pharmacies to deliver a drug or device without payment of their usual and customary or contracted charge.

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- h) If, despite good faith compliance with subsection (e), the lawfully prescribed drug or device is not in stock, or the prescription cannot be filled pursuant to subsection (f)(1), 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 or device. These alternatives include but are not limited to:
 - 1) Contact the prescriber to address concerns such as those identified in subsection (f)(1) or to obtain authorization to provide a therapeutically equivalent product;
 - 2) If requested by the patient or his or her agent, return unfilled lawful prescriptions to the patient or agent; or
 - 3) If requested by the patient or his or her 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.
- i) Engaging in or permitting any of the following shall constitute grounds for discipline or other enforcement actions:
 - 1) 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.

Section 1330.510 Telepharmacy

- a) Telepharmacy shall be limited to the following types of operations. Each site where such operations occur shall be a separately licensed pharmacy.
- b) Operations

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- 1) Remote Dispensing Site
 - A) 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. All written prescriptions shall be delivered to the home pharmacy for filing within 72 hours. Records shall be maintained at the home pharmacy in files separate from the home pharmacy files.
 - B) A remote site is considered to be under the supervision of the pharmacist-in-charge of the home pharmacy.
 - C) The remote site shall use its home pharmacy and pharmacy management system.
 - i) The system shall assign consecutive prescription numbers.
 - ii) All records must be maintained at the home pharmacy.
 - iii) Prescriptions dispensed at the remote site shall be distinguishable from those dispensed from the home pharmacy.
 - iv) Daily reports must be separated for the home and remote site.
 - D) A pharmacist at the home pharmacy must verify each prescription before it leaves the remote site.
 - i) Pharmacist and pharmacy technician initials or unique identifiers must appear on the prescription record and the prescription label.
 - ii) 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.

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- iii) The remote dispensing site shall utilize a barcode system that prints the barcode of the stock bottle on the label of the dispensed drug. 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.
- iv) A pharmacy may utilize a different electronic verification system that accomplishes the same purpose after review and approval of the Division.
- E) Counseling must be done by a pharmacist via video link and audio link before the script is released. The pharmacist must counsel the patient or the patient's agent on all new prescriptions and refills.
- F) A pharmacist-in-charge or his or her 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.
- G) Controlled substances shall be kept at the remote site in accordance with the Act and this Part. All records must be stored at the home pharmacy and at the remote site.
- H) 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.
 - i) The pharmacy technician must have one year experience after certification by a nationally recognized certification organization to work in a remote facility.
 - ii) New prescriptions received at the remote dispensing site may be entered into the remote computer system with all

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verification, interaction, checking and profile review by the pharmacist at the home pharmacy.

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

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

2) Remote Consultation Site

A) These sites have no prescription inventory.

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

C) 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.

D) 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.

E) Security of filled prescriptions must be maintained by a separate lock drawer or cabinet.

F) Record keeping shall be conducted by the pharmacist (time/date) when dispensing and counseling occurred.

G) The facility shall have a room for patient consultation exclusive of any waiting area.

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

3) Remote Automated Pharmacy Systems (RAPS)

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- A) These sites have prescription inventory, which must be secured in an automated dispensing device connected to the home pharmacy.
 - B) A pharmacist, or prescriber when the RAPS is located on the same premises as the prescriber, must approve all the prescription orders before they are released from the automated dispensing device.
 - C) Dispensing and counseling are performed by a pharmacist employed by the home pharmacy via audio link and video link or by the prescriber when the RAPS is located on the same premises as the prescriber.
 - D) All filled prescription must have a label that meets the requirements of the Act attached to the final drug container.
 - E) The pharmacist-in-charge of the home pharmacy, or a designated registrant, shall conduct and complete monthly inspections of the remote telepharmacy dispensing machine site. Inspection criteria must be included in the policies and procedures for the site. The report must be available to the pharmacy investigators when requested.
 - F) The RAPS must be licensed with the Division and will be subject to random inspection by pharmacy investigators. For purposes of random inspections, a pharmacist with access to the system must be available at the site within one hour.
 - G) No controlled substances shall be stocked in the automatic dispensing unit.
- 4) Medication dispensed at the automated pharmacy system site may only be packaged by a licensed manufacturer or repackager. Prepackaging must occur at the home pharmacy in compliance with Section 1330.730.
- c) All pharmacists performing services in support of the remote sites must display a copy of their licenses in any remote site where they provide services.
 - d) Each remote site must display a sign, easily viewable by the customer, that states:

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- 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 prescription.
- e) No remote site may be open when the home pharmacy is closed, unless the pharmacist is present at the remote site. No employees are allowed access to the remote site when the home pharmacy is closed. The security system must allow for tracking of entries into a pharmacy. The pharmacist-in-charge must review the log of entries when conducting the weekly inspection.

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 purpose services to patients or residents of facilities licensed under the Nursing Home Care Act, the Hospital Licensing Act, or the University of Illinois Hospital Act 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 identifies of the pharmacist (and 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 registered 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 two 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 et

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seq.; 1998) and State statute (e.g., the Pharmacy Practice Act and the Illinois Controlled Substances Act [720 ILCS 570]).

- 3) In addition to the record keeping 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 one year 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

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Enforcement Administration (21 CFR 1306; 1998) 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 log book, 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 him/her 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

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- 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 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;

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- 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 Sections 1330.640 and 1330.670.

Section 1330.530 Onsite Institutional Pharmacy Services

- a) Pharmacies located in facilities licensed under the Nursing Home Care Act, the

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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 one year 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

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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:

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- 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; and
 - C) The quantity dispensed.
- 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 his 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

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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 registrants and licensees 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;

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- 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 licensed physician 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 subsections (d)(4) and (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.

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- 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 his or her initial inventory.
- 8) When the accuracy, relevance or completeness of any submitted documentation is reasonably questioned by the Division because of lack of information, discrepancies or conflicts in information given, or a need for clarification, the registrant will be required to:
 - A) Provide information as may be necessary; and/or
 - B) Appear for an interview before the Board to explain the relevance or sufficiency, clarify information given or clear up any discrepancies or conflicts in information.
- 9) Pharmacists and pharmacies are prohibited from accepting from patients or their agents for reuse, reissue or resale dispensed medications, chemicals, poisons or medical devices, except for:
 - A) Medical devices that can be properly sanitized prior to reuse, resale or re-rent; and
 - B) Medications that are dispensed and stored under conditions defined and supervised by the pharmacist and are unopened in sealed, intact and unaltered containers that meet the standards for light, moisture and air permeation as defined by a current United States Pharmacopoeia/National Formulary published by the United States Pharmacopoeial 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

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personnel specifically authorized by the institution in which the pharmacy is located may obtain access and it is sufficiently secure to deny access to unauthorized persons. After-hour cabinets shall only be used in the absence of a pharmacist. When medication is removed from the cabinet or enclosure, written physician's orders authorizing the removal of the medication shall be placed in the cabinet or enclosure. A log shall be maintained within the cabinet or enclosure and authorized personnel removing medication shall indicate on the log the signature of the authorized personnel removing the medication, name of the medication removed, the strength (if applicable), the quantity removed and the time of removal.

- 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 physician's order of a physician licensed to practice medicine in all of its branches 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.
- 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 physician'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

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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 unit use packages (e.g., inhalers, ophthalmic, otics, etc., or as provided for in Section 1330.510(b)(3)) 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 Sections 1330.640 and 1330.670 of this Part.
- g) Pharmacies that utilize automated dispensing and storage systems shall comply with Section 1330.680 of this Part.

Section 1330.540 Nuclear Pharmacy Services

- a) Pharmacies that provide and/or offer for sale radiopharmaceuticals shall, in addition to any other requirements of the Act and this Part, comply with this Section.
- b) Prior to issuance of a pharmacy license to practice as a nuclear pharmacy:
 - 1) The pharmacy shall provide a copy of its Illinois Radioactive Material License issued by the Illinois Emergency Management Agency in accordance with the Radiation Protection Act [420 ILCS 40].
 - 2) The Division shall conduct an on-site inspection of the facility.
- c) The pharmacy shall have:
 - 1) Space commensurate with the scope of services provided, but at least 300 square feet; and

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- 2) A radioactive storage and product decay facility separate from and exclusive of the "hot" laboratory, compounding, dispensing, quality assurance and office areas.
- d) Each nuclear pharmacy shall have the following equipment:
- 1) Laminar flow hood;
 - 2) Fume hood – minimum of 30 inches in height, which shall be vented through a filter with a direct outlet to the outside;
 - 3) Dose calibrator;
 - 4) Refrigerator;
 - 5) Class A prescription balance or a balance of greater sensitivity;
 - 6) Single-channel or multi-channel gamma scintillation counter;
 - 7) Microscope;
 - 8) Low level, thin-window portable radiation survey meter;
 - 9) Drawing station – lead glass and lead lined;
 - 10) Syringe shields; and
 - 11) Energy Compensated Geiger Mueller (GM) Probe or ion chamber.
- e) Each nuclear pharmacy shall have the following reference texts available:
- 1) The current edition or revision of the United States Pharmacopoeia – Dispensing Information;
 - 2) The current edition or revision of the United States Pharmacopoeia/National Formulary;
 - 3) State and federal regulations governing the use of applicable radioactive material; and

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- 4) U.S. Public Health Service Radiological Health Handbook.
- f) Pharmacist-in-Charge
 - 1) The pharmacist-in-charge for a nuclear pharmacy shall meet the requirements set forth in subsection (i). 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 nuclear pharmacy;
 - B) Establishment and supervision of the record keeping system for the purchase, acquisition, disposition, sale, delivery, possession, storage and safekeeping of radiopharmaceuticals; and
 - C) Establishment and maintenance of security provisions, which shall include the following:
 - i) There shall be no public access to the pharmacy hot lab/dispensing area; and
 - ii) In the absence of a nuclear pharmacist, all radiopharmaceuticals shall be locked and accessible only to a nuclear pharmacist or an individual under direct supervision of the pharmacist; except, a licensed medical practitioner authorized to possess, use and administer radiopharmaceuticals may have access to radiopharmaceuticals in the absence of a nuclear pharmacist.
 - 2) Within 30 days after the change of a pharmacist-in-charge, the Division shall be notified in writing by the departing pharmacist-in-charge.
- g) Dispensing Radiopharmaceuticals
 - 1) A radiopharmaceutical shall be dispensed only upon a prescription order from a licensed medical practitioner authorized to possess, use and administer radiopharmaceuticals.

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- 2) No radiopharmaceutical shall be dispensed in the absence of a nuclear pharmacist except, a licensed medical practitioner authorized to possess, use, dispense and administer radiopharmaceuticals may dispense in the absence of a nuclear pharmacist.
 - 3) The amount of radioactivity in a preparation for dispensing shall be determined by radiometric methods for each individual preparation at the time of preparation, and calibrated for the anticipated time of administration.
- h) Labeling Requirements
- 1) In addition to the labeling requirements of pharmaceuticals, as stipulated in the Act, the immediate outer container of a radioactive drug, diagnostic agent or device to be dispensed shall also be labeled to include:
 - A) The standard radiation symbol;
 - B) The words "Caution-Radioactive Material";
 - C) The name of the radionuclide;
 - D) The name of the chemical form;
 - E) The amount of radioactive material contained, in milliCuries or microCuries, in the container contents at the time of calibration;
 - F) If the container contents are in liquid form, the volume in milliliters;
 - G) The requested calibration time for the amount of radioactivity contained;
 - H) The prescription number; and
 - I) The name or initials of the nuclear pharmacist filling the prescription.
 - 2) The immediate container shall be labeled with:

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- A) The standard radiation symbol;
 - B) The words "Caution-Radioactive Material";
 - C) The name and address of the pharmacy;
 - D) The prescription number;
 - E) Name of radionuclide; and
 - F) Name of chemical form.
- i) Nuclear Pharmacist Requirements. A nuclear pharmacist who serves as the pharmacist-in-charge of a nuclear pharmacy and all other pharmacists employed in the pharmacy shall provide evidence to the Division of the following:
- 1) Licensure as a pharmacist in the State of Illinois; and
 - 2) That he/she is named as an authorized user, or works under the supervision of a pharmacist who is named as an authorized user, on a commercial nuclear pharmacy license issued by the Illinois Emergency Management Agency(IEMA) or, when a nuclear pharmacist who works under a broad medical license at a university or research hospital has been approved as a user by that institution's radiation safety committee in accordance with conditions of the license issued by the IEMA.
- j) Nothing in this Part shall prohibit the operation of a nuclear medicine laboratory or any other department that is operated under the direct supervision of a licensed medical practitioner authorized to possess, use and administer radiopharmaceuticals.

Section 1330.550 Nonresident Pharmacies

- a) The Division shall require and provide for an annual nonresident special pharmacy registration for all pharmacies located outside of this State that dispense medications for Illinois residents and mail, ship or deliver prescription medications into this State. Nonresident special pharmacy registration shall be granted by the Division upon the disclosure and certification by a pharmacy:
 - 1) That it is licensed in the state in which the dispensing facility is located

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and from which the drugs are dispensed;

- 2) Of the location, names and titles of all principal corporate officers and all pharmacists who are dispensing drugs to residents of this State;
 - 3) That it complies with all lawful directions and requests for information from the board of pharmacy of each state in which it is licensed or registered, except that it shall respond directly to all communications from the Division concerning emergency circumstances arising from the dispensing of drugs to residents of this State;
 - 4) That it maintains its records of drugs dispensed to residents of this State so that the records are readily retrievable from the records of other drugs dispensed;
 - 5) That it cooperates with the Division in providing information to the board of pharmacy of the state in which it is licensed concerning matters related to the dispensing of drugs to residents of this State; and
 - 6) That, during its regular hours of operation, but not less than 6 days per week for a minimum of 40 hours per week, a toll-free telephone service is provided to facilitate communication between patients in this State and a pharmacist at the pharmacy who has access to the patients' records. The toll-free number must be disclosed on the label affixed to each container of drugs dispensed to residents of this State.
- b) To obtain nonresident special pharmacy registration in Illinois, an applicant shall file an application with the Division, on forms provided by the Division, that includes:
- 1) Disclosure and certification of information required in subsection (a); and
 - 2) The fee required fee by Section 1330.20.
- c) Nonresident special pharmacy registration shall expire on March 31 of each even-numbered year and may be renewed during the 60 days preceding the expiration date by paying the fee required by Section 1330.20.

Section 1330.560 Remote Prescription/Medication Order Processing

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- a) Any pharmacy may provide remote prescription/medication order processing services to any other pharmacy as provided in Section 25.10 of the Act and the following further requirements:
 - 1) Any nonresident pharmacy remote prescription /medication order processing services shall first be registered in its resident state.
 - 2) There shall be a secure, HIPAA compliant, electronic communication system that shall include but not be limited to computer, telephone and facsimile connections.
 - 3) The communication system shall give remote access to all relevant patient information to allow the pharmacist of the remote pharmacy to perform remote medication order processing that shall include all laboratory results and every patient's or resident's medication profile, if appropriate.
 - 4) The secure electronic communication system shall be maintained on a daily basis. If this system malfunctions, the remote processing pharmacy shall cease operations related to the institution affected.
 - 5) Nothing in this Section shall relieve the pharmacist-in-charge of dispensing pharmacies of compliance with Sections 1330.520 and 1330.530.

- b) Record Keeping Requirements
 - 1) A policy and procedure manual shall be maintained by the remote prescription/medication order processing pharmacy pertaining to the pharmacy's operations. The manual shall:
 - A) Be accessible to the remote prescription/medication order processing pharmacy staff and the staff at the dispensing pharmacy;
 - B) Be available for inspection by the Division;
 - C) Outline the responsibilities of the remote prescription/medication order processing pharmacy staff and the staff at the dispensing pharmacy;

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- D) Include a current list of the name, address, telephone number and license number of each pharmacist involved in remote prescription/medication order processing;
- E) Include policies and procedures for:
 - i) Protecting the confidentiality and integrity of patient information;
 - ii) Ensuring that pharmacists performing remote prescription /medication order processing have access to appropriate drug information resources;
 - iii) Ensuring that medical and nursing staff when appropriate, understand how to contact a pharmacist;
 - iv) Maintaining records to identify the name, initials, or identification code of each pharmacist who performs any processing function;
 - v) Complying with federal and State laws and regulations;
 - vi) Operating or participating in 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;
 - vii) Reviewing the written policies and procedures and documenting the review annually.
- 2) Every pharmacist providing remote prescription/medication order processing services shall record on the order, in the computer system, or on another appropriate, unalterable, uniformly maintained and readily retrievable record the following information for every medication order or prescription processed on behalf of a dispensing pharmacy:
 - A) The name, initials or other unique identifier of the pharmacist who verifies the medication order or prescription;

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- B) The name of the patient or resident;
 - C) The name, dose, dosage form, route of administration and dosing frequency of the drug;
 - D) The date and time of verification;
 - E) The name of the prescribing/ordering practitioner;
 - F) Any other information that is required by the dispensing pharmacy being served for use in its own records.
- 3) The records for medications entered at the remote prescription/medication order processing pharmacy must be distinguishable and readily retrievable from those entered at the institution being served.
 - 4) The pharmacist-in-charge of the remote prescription /medication order processing pharmacy shall maintain and have access to the following records for a minimum of 5 years:
 - A) Records of medication orders processed;
 - B) Records of the electronic communication system maintenance.
 - 5) The remote prescription/medication order processing pharmacy shall maintain a record containing the names and license numbers of all pharmacies to which they are providing services and the number of hours per day the services are being provided.
- c) All pharmacists practicing at a remote pharmacy shall be licensed in Illinois. However, when pharmacists are providing remote prescription/medication order processing for a community pharmacy licensed in Illinois from a community pharmacy licensed in Illinois but located out-of-state, only the pharmacist-in-charge of the remote pharmacy must be licensed in Illinois.
 - d) Only licensed pharmacists at the pharmacy providing remote pharmacy services shall conduct the drug utilization evaluation or review and validation of any order processed within the remote pharmacy, except as provided for in subsection (c).

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SUBPART F: PHARMACY STANDARDS

Section 1330.600 Security Requirements

- a) Whenever the pharmacy (prescription area) is not occupied by a registrant, the pharmacy (prescription area) must be secured and inaccessible to non-licensed persons (employees and public). This may be accomplished by measures such as walling off, locking doors or electronic security equipment, as approved by the Division.
- b) Schedule II drugs shall be secured in rooms, vaults, safes, cabinets, etc., under lock, whether by key, combination or electronically.
- c) Schedule II drugs shall not be distributed among regular stock.
- d) All secured Schedule II drugs shall be accessible only when a pharmacist is physically present, except as provided for in Section 1330.530(e).
- e) A pharmacist shall be physically present whenever Schedule II drugs are not secured and are to be dispensed, except as provided for in Section 1330.530(e).

Section 1330.610 Pharmacy Structural/Equipment Standards

Any new pharmacy or any existing pharmacy that is remodeled, other than institutional pharmacies, must comply with the following provisions:

- a) Notification shall be submitted to the Division that an existing pharmacy will be remodeled.
- b) All dispensing and drug storage areas of the pharmacy must be contiguous.
- 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

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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 the United States Pharmacopedia/National Formulary, the United States Pharmacopeia Dispensing Information, Facts and Comparisons, or other suitable references determined by the Division that are 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.

Section 1330.620 Electronic Equipment Requirements

All remote pharmacies operating in Illinois shall meet the following equipment requirements:

- a) The pharmacy shall have a computer, scanner, fax capability and printer.
- b) All prescriptions shall be scanned and sequentially numbered, and the prescription labels shall be produced on site and viewed at the home pharmacy.
- c) Scanned prescriptions shall be displayable on a computer terminal at both the remote pharmacy and home pharmacy.
- d) All patient's demographic and prescription information shall be viewable at both the remote and home pharmacy in real time.
- e) Prescriptions dispensed at the remote pharmacy site must be distinguishable from those dispensed at the home pharmacy.
- f) In all cases in which electronic data processing equipment is used, the original prescription (either hard copy or an exact, unalterable image) shall be retained on file according to law to assure access to the information contained on the prescription in the event of a computer malfunction.

Section 1330.630 Sanitary Standards

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- a) All pharmacies and equipment in the pharmacy shall be maintained in a clean condition and in good repair.
- b) All waste material shall be immediately deposited in an appropriate waste receptacle.
- c) There shall be a sink with hot and cold running water for the purposes of hand washing and drug dispensing. No sink shall be required for pharmacies that do not maintain drug inventory.
- d) The pharmacy area shall be dry and free from vermin.
- e) Food and/or beverages shall only be placed in a designated area away from dispensing activities.
- f) Personal items shall not be placed in an area where they will interfere with dispensing activities.

Section 1330.640 Pharmaceutical Compounding Standards

The minimum standards and technical equipment considered adequate for compounding drugs shall include:

- a) A storage area separate for materials used in compounding.
- b) Scales and balances for the compounding done in the pharmacy.
- c) An area of the pharmacy used for compounding activities.
- d) A heating apparatus.
- e) A logbook or record keeping system to track each compounded prescription and the components used.
- f) A book or reference containing formulas with directions for compounding. The books and references may be in electronic format and/or available via the Internet.
- g) The pharmacy operations manual shall contain the policies and procedures pertinent to the level of complexity and the size of the compounding operations of the practice at that specific pharmacy. Electronic versions are acceptable.

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- h) Consumable materials, as appropriate to the pharmacy services provided at that specific pharmacy, such as filter paper, powder papers, empty capsules, ointment jars, bottles, vials, safety closures, powder boxes, labels and distilled water.
- i) The pharmacy may compound drug products to be used by practitioners in their office for administration to patients.
- j) Sales of compounded drugs to other pharmacies not under common ownership, or to clinics, hospitals or manufacturers are not allowed, except for sales provided by pharmacies contracted to provide centralized prescription filling services pursuant to Section 25.5 of the Act, including compounding in anticipation of receiving a prescription or order based on routine, readily observed dispensing patterns.

Section 1330.650 Pharmacy Computer Regulations

- a) When electronic data processing equipment is employed by a pharmacy, input of drug information shall be performed by a pharmacist, or by a pharmacy technician or a certified pharmacy technician under the supervision of a pharmacist. When orders are entered by pharmacy technicians or certified pharmacy technicians, the supervising pharmacist must verify the accuracy of the information entered. The identity of the supervising pharmacist and the technician shall be maintained in the prescription record.
- b) Electronic data processing equipment or media, when used to store or process prescription information, shall meet the following requirements:
 - 1) Must guarantee the confidentiality of the information contained in the database.
 - 2) Must require that the transmission of electronic prescriptions from prescriber to pharmacist not be compromised by interventions, control or manipulation of the prescription by any other party.

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.

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- c) A pharmacist may be the pharmacist-in-charge for more than one pharmacy however, the pharmacist-in-charge must work an average of at least 8 hours per week at each location where he or she is the pharmacist-in-charge.
- 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 record keeping system for the purchase, sale, delivery, possession, storage and safekeeping of drugs.
- e) The operations of the pharmacy and the establishment and maintenance of security provisions are the dual responsibility of the pharmacist-in-charge and the owner of the pharmacy.
- f) Within 30 days after a change of a pharmacist-in-charge, the Division shall be notified in writing by the departing pharmacist-in-charge.
- g) In addition to notifying the Division within 30 days, the departing pharmacist-in-charge shall, on the effective date of the change, inventory the following controlled substances:
 - 1) All Schedule II drugs, as defined in the Illinois Controlled Substances Act, by actual physical count; and
 - 2) All other scheduled drugs, as defined in the Illinois Controlled Substances Act, by estimated count.
- h) The inventory described in subsection (g)(1) of this Section 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

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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 registrant to provide the information required in subsections (g) and (h) shall be grounds for denying an application or renewal application for a pharmacy license by that registrant or for disciplinary action against the registrant. Disciplinary action shall be based on the recommendation of the Board.
- j) 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) 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) Records shall be retained as provided for in Section 18 of the Act. Invoices for all legend drugs shall be maintained for a period of 5 years either on site or at a central location where records are readily retrievable. Invoices shall be maintained on site for at least one year from the date of the invoice.
- m) 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 and 1330.560, it shall notify the Division no less than 30 days prior to the change or addition.

Section 1330.670 Compounded Sterile Preparation Standards

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- a) This Section sets forth standards for pharmacies whose practice includes the preparation, labeling and distribution of compounded sterile preparations pursuant to prescriptions or medication orders, as defined in the Act. These activities may include, but are not limited to:
 - 1) Sterile preparation of parenteral therapy and parenteral nutrition;
 - 2) Sterile preparations of cytotoxic or antineoplastic agents; and
 - 3) Other sterile preparations to be used topically or internally by humans or animals.

- b) Definitions
 - 1) “Barrier Isolation Chamber” means an apparatus designed to provide a Class 5, 6, or 7 environment, as spelled out in ISO (International Organization for Standardization) 14644-1, for preparation of sterile preparations using solid walls rather than air movement (laminar air flow) to create a critical zone for preparation handling, a high efficiency particular air (HEPA) filtration system that conditions the air flowing through the unit to remove initial particles and particles generated within the controlled environment, and a means by which preparations are introduced and people interact with the preparation being prepared within the unit.
 - 2) “Biological Safety Cabinet” or “BSC” means a containment unit suitable for the preparation of low to moderate risk agents when there is a need for protection of the preparation, personnel and environment, according to ISO 14644-1.
 - 3) “Compounded Sterile Preparation” or “CSP” means a sterile pharmaceutical that has been prepared by a pharmacist, or under the supervision of a pharmacist. It shall be a preparation prepared for or in anticipation of a specific patient prescription or medication order issued by a prescribing practitioner. The preparation may include commercially available dosage forms that may need to be altered by the pharmacist to meet a specific patient’s need.
 - 4) “Cytotoxic” means a pharmaceutical that has the capability of killing living cells. These agents shall include, but are not limited to, agents

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classified as cancer chemotherapeutic, carcinogenic, mutagenic and antineoplastic.

- 5) “Laminar Airflow Hood” means an apparatus designed to provide a Class 5, 6 or 7 environment, as spelled out in ISO 14644-1 for preparation of sterile products using air circulation in a defined direction that passes through a HEPA filter to remove the initial particles and particles generated within the controlled environment.
- 6) “Parenteral” means sterile preparations of drugs for injection through one or more layers of the skin.
- 7) “Terminal” means a patient whose medical condition indicates his or her life expectancy to be 6 months or less.

c) Physical Requirements of Pharmacies Preparing Compounded Sterile Preparations

- 1) The pharmacy shall have a designated area for preparing compounded sterile preparations. The area shall be designed to minimize outside traffic and airflow disturbances from activity within the facility. It shall be of sufficient size to accommodate a laminar airflow hood (LAF), barrier isolation chamber or BSC and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation and security. It shall be ventilated in a manner not interfering with the proper operation of the compounded sterile preparations.
- 2) The licensed pharmacy preparing compounded sterile preparations shall have the following:
 - A) workstation
 - i) LAF shall be certified annually in accordance with ISO 14644-1;
 - ii) In the event the preparation apparatus is moved from its site of certification, recertification shall occur prior to resumption of use for compounding sterile preparations;

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- iii) Prefilters shall be inspected, replaced or cleaned per manufacturer specifications monthly and documentation of this maintained;
 - B) Sink with hot and cold running water, which is convenient to, but apart from, the compounding area;
 - C) National Institute for Occupational Safety and Health (NIOSH) approved disposal containers for used needles, syringes, etc., and, if applicable, cytotoxic waste from the preparation of chemotherapy agents;
 - D) Biohazard cabinetry for environment control when cytotoxic compounded sterile preparations are prepared;
 - E) Refrigerator and/or freezer with a thermometer or temperature recording device; and
 - F) Temperature controlled containers for off site deliveries.
- 3) The following current resource materials and texts shall be maintained in the pharmacy:
- A) United States Pharmacopoeia/National Formulary (USP/NF);
 - B) American Hospital Formulary Service;
 - C) Copies of the Act and this Part, the Illinois Controlled Substances Act and rules adopted under that Act, 21 CFR and the Illinois Hypodermic Syringes and Needles Act [720 ILCS 635];
 - D) One compatibility reference such as:
 - i) Trissel's Handbook on Injectable Drugs;
 - ii) King's Guide to Parenteral Admixtures; or
 - iii) Any other Division approved publication;
 - E) A file or reference on extended (more than 24 hours) stability data

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given to finished preparations.

- d) Staffing. A pharmacist shall be accessible at all times at each licensed facility to respond to patients' and health professionals' questions and needs. A 24-hour telephone number will be included on all labeling of compounded medication and medication infusion devices if used off site.
- e) Drug Distribution and Control
 - 1) Patient Profile or Medication Record System. A pharmacy generated patient profile or medication record system shall be maintained in addition to the prescription file. The patient profile or medication record system shall contain, at a minimum:
 - A) Patient's full name;
 - B) Date of birth or age;
 - C) Gender;
 - D) Compounded sterile preparations dispensed;
 - E) Date dispensed, if off site;
 - F) Drug content and quantity;
 - G) Patient directions, if preparation being administered off site;
 - H) Identifying number;
 - I) Identification of dispensing pharmacist and, if applicable, pharmacy technician;
 - J) Other drugs or supplements the patient is receiving, if provided by the patient or his or her agent;
 - K) Known drug sensitivities and allergies to drugs and foods;
 - L) Diagnosis; and

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- M) Lot numbers of components or individual medicine if the compounded sterile preparation is not used within 48 hours after preparation.
- 2) Labeling. Each compounded sterile preparation dispensed to patients shall be labeled with the following information using a permanent label:
- A) Name, address and telephone number of the licensed pharmacy, if not used within facility;
 - B) Administration date and identifying number if used on site, date dispensed, and identifying number if used off site;
 - C) Patient's full name and room number, if applicable;
 - D) Name of each drug, strength and amount;
 - E) Directions for use and/or infusion rate if used off site;
 - F) Prescriber's full last name if used off site;
 - G) Required controlled substances transfer warnings, when applicable;
 - H) Beyond use date and time;
 - I) Identity of pharmacist compounding and dispensing, or other authorized individual; and
 - J) Auxiliary labels storage requirements, if applicable.
- 3) The pharmacist-in-charge shall ensure that records are maintained for 5 years and are readily retrievable and in a format that provides enforcement agents an accurate and comprehensive method of monitoring distribution via an audit trail. The records shall include at least the following information:
- A) Patient profile;
 - B) Medication record system;

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- C) Purchase records; and
 - D) Lot numbers of the components used in compounding sterile prescriptions/orders traceable to a specific patient, if not included on patient profile and if the preparation is not utilized within 48 hours after preparation.
- f) **Delivery Service.** The pharmacist-in-charge shall assure the environmental control of all preparations shipped or delivered off site. Therefore, any compounded, sterile pharmaceutical must be shipped or delivered to a patient in temperature controlled (as defined by USP Standards) delivery containers.
- g) **Cytotoxic Drugs.** The following additional requirements are necessary for those licensed pharmacies that prepare cytotoxic drugs:
- 1) Safety and containment techniques or devices for compounding cytotoxic drugs shall be used.
 - 2) Disposal of cytotoxic waste shall comply with all applicable local, State and federal requirements.
 - 3) Prepared doses of cytotoxic drugs shall be dispensed, labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.
 - 4) The pharmacy must have as a reference Procedures for Handling Cytotoxic Drugs (American Society of Hospital Pharmacists (ASHP)).
- h) **Emergency Medications.** Pharmacies that dispense compounded sterile preparations to patients in facilities off site or in the patient's residence shall stock supplies and medications appropriate for treatment of allergic or other common adverse effects, to be dispensed upon the prescription or order of an authorized prescriber.

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.

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- b) Automated Dispensing and Storage Systems
 - 1) Automated dispensing and storage systems may be utilized in licensed community or institutional pharmacies.
 - 2) 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.
 - 3) 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.
 - 4) 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

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- C) Maintain patient confidentiality.
- 5) 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.
- 6) The stocking or restocking of all medications in the automated dispensing and storage systems shall be accomplished by registrants under the Act.
- 7) All containers of 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)(7):
- 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

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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 subsections (b)(7) are as follows:
- i) Injectable medications stored in their original multi-dose vial (e.g., insulin, heparin) when the medication may be withdrawn into a syringe or other delivery device for single patient use; or
 - ii) Over-the-counter (OTC) products stored in their original multi-dose container (e.g., antacids, analgesics) when the

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medication may be withdrawn and placed into an appropriate container for single patient use.

- 8) 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.
- 9) 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.
- 10) The automated dispensing and storage systems shall provide a mechanism for securing and accounting for wasted medications or discarded

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medications.

- 11) 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).
- 12) Errors in the use or performance of the automated dispensing and storage systems resulting in patient or resident death shall be reported to the Division by the pharmacist-in-charge within 30 days after acquiring knowledge of the incident.
- 13) 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

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care or same day surgery, observation unit, etc.).

- 14) 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; and
 - C) List of medications qualifying for control purposes.
 - 15) 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.
 - 16) 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 record keeping 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

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to:

- i) the name and address of the pharmacy;
 - ii) the address of the location of the automated dispensing and storage system, if different from the address of the pharmacy;
 - iii) the automated dispensing and storage system's manufacturer and model;
 - iv) the pharmacist-in-charge; and
 - v) a written description of how the facility intends to use the automated storage and dispensing system;
- D) Determining and monitoring access to and the limits on access (e.g., security levels) to the automated storage and dispensing system. Access shall be defined by policies and procedures of the pharmacy and shall comply with State and federal regulations.
- 2) Additional responsibilities of the pharmacist-in-charge or pharmacist designated by the pharmacist-in-charge shall include:
- A) Authorizing the assigning of access to, discontinuing access to, or changing access to the system;
 - B) Ensuring that access to the medications complies with State and federal regulations, as applicable; and
 - C) Ensuring that the automated dispensing and storage system is stocked/restocked accurately and in accordance with established, written pharmacy policies and procedures.
- d) Kiosk
- 1) A pharmacy may use automated dispensing and storage systems to deliver prescriptions to a patient when the device:
 - A) Allows a patient to choose whether or not to use the system;

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- B) Is located within the physical premises at which the licensed pharmacy is located. The automated dispensing and storage system shall be secured against a wall or floor in such a manner as to prevent the unauthorized removal of the system;
 - C) Contains only prescriptions that have been processed, verified and completed in the same manner as if the prescriptions were going to be delivered manually by the pharmacy;
 - D) Can deliver any one, any combination of, or all of the prescriptions available to a patient at the option of the patient at the time the patient picks up his prescriptions;
 - E) Provides a method to identify the patient and delivers the prescription only to that patient or the patient's authorized agent;
 - F) Has adequate security systems and procedures to prevent unauthorized access, to comply with federal and State regulations, and to maintain patient confidentiality;
 - G) Records the time and date that the patient removed the prescription from the system;
 - H) Informs a patient, if he or she is 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;
 - I) Informs a patient, if he or she is using the device when the pharmacy is closed, that he or she may direct any questions and concerns regarding the prescription to a licensed pharmacist via a pharmacy provided audio/video link;
 - J) Informs a patient that a prescription is not available to be delivered by the device if the pharmacist has determined that he or she desires to counsel the patient in person regarding the prescription.
- 2) The system must be approved by the Board prior to its operation.

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- 3) The Board may prohibit a pharmacy from using an automated dispensing and storage system to deliver prescriptions to a patient if the board determines that the device does not comply with this Section or that the pharmacy's use of the device does not comply with this Section.

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. An offer to counsel shall be made on all prescriptions. If the offer to counsel is accepted, the pharmacist or the student pharmacist, as directed and supervised by the pharmacist, shall counsel the patient or patient's agent using his or her professional judgment. Counseling shall include, 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

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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) 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.
- d) 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.
- e) A pharmacist at an institutional pharmacy shall provide patient counseling as required in this Section when drugs are dispensed by the pharmacy upon a patient's discharge from the institution.
- f) When a patient or patient's agent refuses to accept patient counseling as provided in this Section, that refusal shall be documented. The absence of any record of a refusal to accept the offer to counsel shall be presumed to signify that the offer was accepted and that counseling was provided.
- g) 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.

Section 1330.710 Reporting Theft or Loss of Controlled Substances

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In every instance that a pharmacy is required by federal regulation (21 CFR 1301.76) to file with the U.S. Drug Enforcement Agency a Report of Theft or Loss of Controlled Substances (Form 106) a copy shall be sent to the Division, along with the printed name of the person who signed the form. Failure to do so may result in discipline of the pharmacy.

Section 1330.720 Transfer of Prescription

- a) A prescription may be transferred between pharmacies for the purpose of original fill or refill dispensing, provided that:
 - 1) The pharmacist transferring the prescription invalidates the prescription on file and records to which pharmacy the prescription was transferred, the date of issuance of the copy and the name of the pharmacist issuing the transferred prescription order; and
 - 2) The pharmacist receiving the transferred prescription directly from the other pharmacist records the following:
 - A) The name, address and original prescription number of the pharmacy from which the prescription was transferred;
 - B) All information constituting a prescription order, including the following: name of the drug, original amount dispensed, date of original issuance of the prescription, and number of valid refills remaining; and
 - C) The pharmacist receiving the transferred prescription informs the patient that the original prescription has been cancelled at the pharmacy from which it has been transferred.
- b) A prescription for Schedule III, IV and V drugs may be transferred only from the original pharmacy and only one time for the purpose of original fill or refill dispensing and may not be transferred further. However, a pharmacist who is electronically sharing real-time on-line computerized systems may transfer up to the maximum refills permitted by law and the prescriber's authorization in accordance with CFR 1306.26(a).
- c) Computerized systems must satisfy all information requirements of this Section, including invalidation of the original prescription when transferred between pharmacies accessing the same prescription records or between pharmacies of the

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

- d) When prescription information is transferred to another pharmacy for the purposes of original fill, the transferring pharmacy must enter a prescription into its system as if that prescription were filled at that pharmacy.
- e) Nothing in this Section shall apply to transactions described in Section 20 of the Act.
- f) A prescription shall only be transferred upon the request or authorization of the person for whom the prescription was issued, except upon closure of a pharmacy, in which case notice shall be made to that person, orally or in writing, of the closure and location where the prescription is transferred.

Section 1330.730 Drug Prepackaging

- a) The term prepackaged, as used in this Section, is defined as any drug being removed from the original manufacturer container and placed in a dispensing container for other than immediate dispensing to a patient.
- b) Any prepackaged drugs must have a label affixed that contains, at a minimum, the name and strength of the drug, the name of manufacturer or distributor, beyond use date, and lot number. Maximum beyond use date allowed for prepackaged drugs shall be the manufactured beyond use date or 12 months, whichever is less. Pharmacies that store drugs with an automated counting device may, in place of the required labels, maintain records of lot numbers and beyond use dates that are required on the label as long as it is fully traceable and is readily retrievable during an inspection.
- c) Automatic counting cassettes must have a label affixed to the cassette containing the information required in subsection (b).

Section 1330.740 Multi-Med Dispensing Standards for Community Pharmacies

- a) In lieu of dispensing 2 or more prescribed drug products in separate containers, a pharmacist may, with the consent of the patient, the patient's caregiver, or a

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prescriber, provide a customized patient medication package (patient med pak).

- b) A patient med pak is a package prepared by a pharmacist for a specific patient comprising a series of containers and containing 2 or more prescribed solid oral dosage forms. The patient med pak is designed, or each container is labeled, to indicate the day and time or period of time when the contents within each container are to be taken.
- 1) The patient med pak shall include information stating:
 - A) The name of the patient;
 - B) A serial number for the patient med pak itself and a separate identifying serial number for each of the prescription orders for each of the drug products contained the med pak;
 - C) The name, strength, physical description or identification, and total quantity of each drug product contained in the med pak;
 - D) The directions for use and cautionary statements, if any, contained in the prescription order for each drug product contained in the med pak;
 - E) Any storage instructions;
 - F) The name of the prescriber of each drug product;
 - G) The date of preparation of the patient med pak; and
 - H) The name, address and telephone number of the pharmacist and any other registrant involved in dispensing.
 - 2) Once a patient med pak has been delivered to an institution or to a patient, the drugs dispensed in the med pak shall not be accepted for return to the pharmacy.
 - 3) A pharmacy is prohibited from creating a patient med pak utilizing drugs dispensed from a different pharmacy.

Section 1330.750 Return of Drugs

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- a) Once a dispensed drug is removed from the premises by a patient or the patient's agent, that drug shall not be accepted for return or exchange by a pharmacy or pharmacist.
- b) The provision of subsection (a) shall not apply to a drug dispensed to a patient of an institutional healthcare facility where a licensed healthcare professional administers the drug and the pharmacist ensures that:
 - 1) the drugs were stored in compliance with Sections 1330.610 and 1330.630;
 - 2) the drugs are not contaminated, deteriorated or beyond their use date; and
 - 3) the returns are properly documented.
- c) The provisions of subsection (a) shall not apply to drugs returned for purposes of destruction. The returned drugs must be stored separately from the pharmacy's active stock.

Section 1330.760 Electronic Transmission of Prescriptions

Electronic transmission of prescriptions shall be allowed, provided the following conditions are met:

- a) The prescription shall be transmitted directly, or through an intermediary, from the authorized licensed prescriber to the pharmacy of the patient's choice. No intermediary shall alter the prescription information or content of the prescription.
- b) The prescriptions shall comply with all applicable statutes and rules regarding the form, content, record keeping and processing of a prescription drug.
- c) The electronically transmitted prescription shall include the following:
 - 1) The transmitting prescriber's facsimile number, if applicable;
 - 2) The time and date of the transmission;
 - 3) The identity of the person sending the prescription;

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- 4) The address and contact information of the person transmitting the prescription.
- d) The electronic device in the pharmacy that receives the electronically transmitted prescription shall be located within the pharmacy area.
- e) A facsimile of an electronically transmitted prescription shall be non-fading and remain legible.
- f) The facsimile of the electronically transmitted prescription shall be stored in the pharmacy as required by State and federal laws or rules and may serve as the record of the prescription.
- g) The electronically transmitted prescription shall serve as the record of the prescription so long as the electronically submitted prescription can be stored and is readily retrievable so as to comply with federal and State record keeping requirements.
- h) To maintain confidentiality, adequate security and systems safeguards designed to prevent and detect unauthorized access, modification or manipulation of electronically transmitted prescriptions is required.
- i) A pharmacy or pharmacist shall not enter into an agreement with a practitioner or healthcare facility concerning the provision of any means for the electronic transmission of prescriptions that would adversely affect a patient's freedom to select the pharmacy or pharmacy department of his or her choice.
- j) Electronically transmitted prescriptions for controlled substances may be dispensed only as provided by federal law.

Section 1330.770 Centralized Prescription Filling

Pharmacies providing centralized prescription filling 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.

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

Section 1330.780 Change of Ownership of a Pharmacy

A new pharmacy application must be filed whenever:

- a) 10% or more of the ownership of the business, other than a publicly traded business, to which the pharmacy licensee was issued is sold or otherwise transferred to a person or entity that does not hold any interest in the business issued the pharmacy license prior to the sale or transfer; or
- b) more than half the board of directors or executive officers of a business issued a pharmacy license change.

Section 1330.790 Closing a Pharmacy

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

- a) Notify the Division in writing 30 days in advance of the closing date.
- b) Notify customers of the closure at least 15 days in advance of the closing date and where the customer's records will be maintained.
- c) Comply with all DEA requirements for closing a pharmacy.
- d) On the day the pharmacy closes:
 - 1) Conduct an inventory of the pharmacy's controlled substances and maintain the inventory record for inspection by the Division for 5 years.
 - 2) Return the pharmacy license to the Division's drug compliance investigator or other authorized Division personnel.
 - 3) Notify the Division in writing as to where the controlled substances inventory and records will be kept and how the controlled substances were transferred or destroyed. Records involving controlled substances must be kept available for 5 years for inspection by the Division.
 - 4) Notify the Division in writing of the name of the person responsible for

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and the location where the closing pharmacy's prescription files and patient profiles will be maintained. These records shall be kept for a minimum of 5 years from the date the last original or refill prescription was dispensed.

- e) The pharmacy acquiring prescription records from a closing pharmacy must inform the Division prior to the date when the transaction is going to take place.
- f) After the closing date, only the pharmacist-in-charge, or other designated pharmacist, of the pharmacy discontinuing business shall have access to the prescription drugs until those drugs are transferred to the new owner or other purchaser or are properly destroyed.
- g) Cover all signage indicating "Drug Store" or "Pharmacy" as soon as practicable. The signage shall be removed in a timely manner. A sign shall be prominently posted that the pharmacy is closed.