

2015

ILLINOIS

REGISTER

Rules of
Governmental Agencies



Volume 39, Issue 19

May 8, 2015

Pages 6,073 - 6,729

Index Department
Administrative Code Division
111 E. Monroe St.
Springfield, IL 62756
217-782-7017

Printed by authority of the State of Illinois. May — 90

PUBLISHED BY JESSE WHITE • SECRETARY OF STATE

TABLE OF CONTENTS

May 8, 2015 Volume 39, Issue 19

PROPOSED RULES

CHILDREN AND FAMILY SERVICES, DEPARTMENT OF	
Intercountry Adoption Services	
89 Ill. Adm. Code 333.....	6073
Appeal of Child Abuse and Neglect Investigation Findings	
89 Ill. Adm. Code 336.....	6093
COMMERCE COMMISSION, ILLINOIS	
Net Metering	
83 Ill. Adm. Code 465.....	6134
HUMAN SERVICES, DEPARTMENT OF	
Early Intervention Program	
89 Ill. Adm. Code 500.....	6153
POLLUTION CONTROL BOARD	
Sound Emission Standards and Limitations for Property Line	
Noise-Sources	
35 Ill. Adm. Code 901.....	6179
PUBLIC HEALTH, DEPARTMENT OF	
Hospital Licensing Requirements	
77 Ill. Adm. Code 250.....	6184
Emergency Medical Services, Trauma Center, Primary Stroke Center	
and Emergent Stroke Ready Hospital Code	
77 Ill. Adm. Code 515.....	6217

ADOPTED RULES

FINANCIAL AND PROFESSIONAL REGULATION, DEPARTMENT OF	
Pharmacy Practice Act	
68 Ill. Adm. Code 1330.....	6267
HEALTH FACILITIES AND SERVICES REVIEW BOARD	
Health Facilities and Services Review Operational Rules	
77 Ill. Adm. Code 1130.....	6347
HUMAN SERVICES, DEPARTMENT OF	
Electronic Prescription Monitoring Program	
77 Ill. Adm. Code 2080.....	6421
Electronic Prescription Monitoring Program - Long Term Care	
77 Ill. Adm. Code 2081.....	6444
Supplemental Nutrition Assistance Program (SNAP)	
89 Ill. Adm. Code 121.....	6470
INSURANCE, DEPARTMENT OF	
Annual Financial Reporting	
50 Ill. Adm. Code 925.....	6485
Health Maintenance Organization	

50 Ill. Adm. Code 5421.....	6505
NATURAL RESOURCES, DEPARTMENT OF	
Sport Fishing Regulations for the Waters of Illinois	
17 Ill. Adm. Code 810.....	6517
PURCHASED CARE REVIEW BOARD	
Public Information, Rulemaking and Organization	
2 Ill. Adm. Code 1850.....	6640
STATE BOARD OF EDUCATION	
Educator Licensure	
23 Ill. Adm. Code 25.....	6649
Programs for the Preparation of Superintendents in Illinois	
23 Ill. Adm. Code 33.....	6668
Early Childhood Block Grant	
23 Ill. Adm. Code 235.....	6674
Driver Education	
23 Ill. Adm. Code 252.....	6705
STATE BOARD OF ELECTIONS	
Personnel	
26 Ill. Adm. Code 212.....	6712
AGENCY WITHDRAWAL IN RESPONSE TO A STATEMENT OF OBJECTION	
INSURANCE, DEPARTMENT OF	
Confidential Supervisory Information (Withdrawal)	
50 Ill. Adm. Code 870.....	6721
JOINT COMMITTEE ON ADMINISTRATIVE RULES AGENDA	
JOINT COMMITTEE ON ADMINISTRATIVE RULES	
May Agenda.....	6722
SECOND NOTICES RECEIVED	
JOINT COMMITTEE ON ADMINISTRATIVE RULES	
Second Notices Received.....	6728

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- 1) Heading of the Part: Pharmacy Practice Act
- 2) Code Citation: 68 Ill. Adm. Code 1330
- 3)

<u>Section Numbers:</u>	<u>Adopted Action:</u>
1330.10	Amendment
1330.20	Amendment
1330.30	Amendment
1330.40	Amendment
1330.50	Amendment
1330.80	Amendment
1330.90	Amendment
1330.110	New Section
1330.200	Amendment
1330.210	Amendment
1330.220	Amendment
1330.400	Amendment
1330.410	Amendment
1330.500	Amendment
1330.510	Amendment
1330.520	Amendment
1330.530	Amendment
1330.550	Amendment
1330.560	Amendment
1330.600	Amendment
1330.610	Amendment
1330.620	Amendment
1330.660	Amendment
1330.680	Amendment
1330.710	Amendment
1330.740	Amendment
1330.750	Amendment
1330.770	Amendment
1330.780	Amendment
1330.790	Amendment
1330.800	New Section

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- 4) Statutory 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]
- 5) Effective Date of Rule: April 23, 2015
- 6) Does this rulemaking contain an automatic repeal date? No
- 7) Does this rulemaking contain incorporations by reference? No
- 8) A copy of the adopted rule, including any material incorporated by reference, is on file in the principal office of the Department of Financial and Professional Regulation and is available for public inspection.
- 9) Notice of Proposal published in the *Illinois Register*: 38 Ill. Reg. 10534; May 16, 2014
- 10) Has JCAR issued a Statement of Objection to this rulemaking? No
- 11) Differences between Proposal and Final Version: The changes to Section 1330.640 regarding compounding have been removed, as has the repeal of Section 1330.670; they will be considered in a subsequent rulemaking. Several wording or technical types of changes, many of them as a result of the several comments received during First Notice, were accepted by the Department and are included in this adopted version.
- 12) Have all changes agreed upon by the Agency and JCAR been made as indicated in the agreements issued by JCAR? Yes
- 13) Will this rulemaking replace an emergency rule currently in effect? No
- 14) Are there any rulemakings pending on this Part? No
- 15) Summary and Purpose of Rulemaking: In 2007, the Pharmacy Practice Act was completely overhauled (PA 95-689, effective October 29, 2007). It put into place, among its many changes, a framework for remote pharmacy and telepharmacy and resulted in a complete rewrite of this Part in 2010. Those changes were a best guess at how new technology would be used in the practice of pharmacy and how best to regulate it to protect the public. Now, with five years of experience, the amendments contained in this adopted rulemaking are meant to adjust the regulations to the reality of what technology is being implemented and how it is being utilized. A new provision was also added to

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

implement PA 97-1043, permitting pharmacists to administer influenza and Tdap immunizations.

- 16) Information and questions regarding this adopted rule shall be directed 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

The full text of the Adopted Amendments begins on the next page:

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

TITLE 68: PROFESSIONS AND OCCUPATIONS
CHAPTER VII: DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
SUBCHAPTER b: PROFESSIONS AND OCCUPATIONSPART 1330
PHARMACY PRACTICE ACT

SUBPART A: GENERAL PROVISIONS

Section	
1330.10	Definitions
1330.20	Fees
1330.30	Unprofessional <u>and</u> Unethical Conduct
1330.40	Violations
1330.50	Vaccinations/Immunizations
1330.60	Internet Pharmacies
1330.70	Granting Variances
1330.80	Renewals
1330.90	Restoration <u>of a Pharmacist License</u>
1330.100	Continuing Education
<u>1330.110</u>	<u>Confidentiality</u>

SUBPART B: PHARMACY TECHNICIAN

Section	
1330.200	Application for Certificate of Registration as a Pharmacy Technician
1330.210	Pharmacy Technician Training
1330.220	<u>Application for Certificate of Registration as a</u> 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

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

SUBPART D: PHARMACY LICENSURE

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 [for Remote Pharmacies](#)
- 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

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- 1330.760 Electronic Transmission of Prescriptions
1330.770 Centralized Prescription Filling
1330.780 Change of Ownership of a Pharmacy
1330.790 Closing a Pharmacy
[1330.800 Pharmacy Self-Inspection](#)

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

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

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,

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

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.

"Beyond Use Date" means a drug's expiration date.

"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, 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.

"Dispensing Error" means any preventable event that may cause or lead to inappropriate medication use or patient harm. Such events may be related to professional practice, health care products, procedures and systems, including:

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

prescribing; order communication; product labeling, packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

"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 Compliance Coordinator" means the chief pharmacy coordinator, appointed by the Secretary, who shall serve as the executive administrator and the chief enforcement officer of the Act, pursuant to Section 11(d) of the Pharmacy Practice Act.

"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;

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

proper utilization (including over or under utilization) and optimum therapeutic outcomes; and

abuse and misuse [225 ILCS 85/3(y)].

"Electronic Format" includes, but is not limited to, information obtained via the Internet or stored on personal digital assistant, smart phone, tablet, etc.

"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.

"Home Pharmacy" means the location of a pharmacy's primary operations.

"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.

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

"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 [student](#)

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

~~pharmacist~~~~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, 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

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

pharmacy.

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

"Remote Consultation Site" means a location, other than that of the home pharmacy, where prescriptions filled at the home pharmacy are stored and dispensed by a pharmacy technician, certified pharmacy technician and/or student pharmacist under the direct, remote supervision of a pharmacist located at, or contracted with, the home pharmacy.

"Remote Dispensing Site" means a location other than that of the home pharmacy where a supply of prescription drugs is maintained and prescriptions are filled and dispensed by a certified pharmacy technician and/or student pharmacist under the direct, remote supervision of a pharmacist located at, or contracted with, the home pharmacy.

"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.

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

~~"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;~~

~~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, noncompliance 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.~~

(Source: Amended at 39 Ill. Reg. 6267, effective April 23, 2015)

Section 1330.20 Fees

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

The following fees are not refundable:

- a) Registration as a Pharmacy Technician, Student Pharmacist or Certified~~Certificate of Pharmacy Technician~~
 - 1) The fee for application for a certificate of registration as a pharmacy technician or certified pharmacy technician is \$40.
 - 2) The fee for the renewal of a certificate of registration as a pharmacy technician, student pharmacist or certified pharmacy technician shall be calculated at the rate of \$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.
 - 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 \$50~~\$20~~ plus all lapsed renewal fees, not to exceed \$450.
 - 6) Applicants for the preliminary diagnostic examination shall be required to pay, either to the Division or to the designated testing service, a fee covering the cost of determining an applicant's eligibility and providing the examination. Failure to appear for the examination on the scheduled date, at the time and place specified, after the application for examination

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

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.
 - 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.

(Source: Amended at 39 Ill. Reg. 6267, effective April 23, 2015)

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

Section 1330.30 Unprofessional ~~and~~ Unethical Conduct

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

- a) Failing to establish and maintain effective controls against diversion of prescription drugs.
- b) Committing theft or diversion, or attempting to commit theft or diversion, by a registrant or licensee.
- ~~c)~~ Making or filing a report or record that a pharmacist or pharmacy knows to be false or intentionally or negligently failing to file a report or keep records as required by the Act or this Part.
- ~~d)~~ Knowingly dispensing a prescription drug after the death of the person for whom the prescription was written.
- ~~e)~~ Billing or charging for quantities of drugs greater than that which was delivered or charging patients for a brand drug when a generic is dispensed.
- ~~f)~~ Submitting fraudulent billing or reports to a third party payer or claiming a fee for a service that is not performed or earned.
- ~~g)~~ Filling a prescription when a pharmacist knows, or reasonably should know, that no valid physician-patient relationship exists or failing to exercise sound professional judgment with respect to the accuracy and authenticity of any prescription/drug order dispensed.
- ~~h)~~ Failing to 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.
- ~~i)~~ Unreasonably refusing to compound a valid prescription.
- ~~i)~~ Discriminating in any manner against a person or group based upon that person or group's religion, race, creed, color, gender, sexual orientation, age or national

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

origin.

- ~~j)~~k) Knowingly ~~dispensing~~selling a prescription drug without a valid prescription. Dispensing or offering to dispense any drug not approved by the Food and Drug Administration (FDA), found in the USP-NF, or found on the list promulgated by the FDA for bulk drug substances that may be used to compound drug products.
- ~~l)~~ Failing to exercise sound professional judgment with respect to the accuracy and authenticity of any prescription drug order dispensed.
- ~~k)~~m) Failing~~Failure of a licensee or registrant~~ to keep one's self~~himself or herself~~ and one's~~his or her~~ apparel clean or to wear identification bearing his or her~~his or her~~ name and designation.
- ~~l)~~n) Directly or indirectly furnishing to a medical practitioner prescription order-blanks that refer to a specific pharmacist or pharmacy in any manner.
- ~~m)~~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. Pharmacy-branded enrollment forms, when a patient requests his or her prescriptions be filled at a specific pharmacy, and Risk Evaluation and Mitigation Strategies documents containing prescription information are not prohibited by this subsection.
- ~~p)~~ Claiming a fee for a service that is not performed or earned.
- ~~n)~~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.
- ~~o)~~ Committing dispensing errors that result in hospitalization of a patient or demonstrating a pattern and practice of dispensing errors.
- ~~p)~~ Committing an act or acts that are of a flagrant and obvious nature so as to constitute conduct of such a distasteful nature that accepted codes of behavior or codes of ethics are breached.
- ~~q)~~ Committing an act or acts in a relationship with a patient that violate common standards of decency or propriety.

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

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

(Source: Amended at 39 Ill. Reg. 6267, effective April 23, 2015)

Section 1330.40 Violations

- a) A registrant shall not:
- 1) Engage in a ~~business relationship~~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 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].

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- 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 [within 60 days](#).

(Source: Amended at 39 Ill. Reg. 6267, effective April 23, 2015)

Section 1330.50 Vaccinations/Immunizations

- a) Qualifications
 - 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) [A pharmacist, or student pharmacist under the direct supervision of a pharmacist, may administer influenza \(inactivated influenza vaccine and live attenuated influenza intranasal vaccine\) and Tdap \(tetanus, diphtheria, acellular pertussis\) vaccines/immunizations to persons who are 10 to 13 years of age 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.](#)
 - 3)2) The pharmacist shall successfully complete a course of training accredited

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

by the Accreditation Council on Pharmacy Education, or a similar health authority or professional body approved by the Division.

- 4)3) The pharmacist shall maintain a current Basic Life Support Certification for Healthcare Providers issued by the American Heart Association, the American Red Cross, the American Safety and Health Institute, or an equivalent as determined by the ~~Division~~Department.
- 5)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.
- 6)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 administrating 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 10 and older for influenza and Tdap, age 14 and older for all other vaccines~~ ~~age 14 or older~~) 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

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

provider named by the patient.

- c) ~~Recordkeeping~~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.

(Source: Amended at 39 Ill. Reg. 6267, effective April 23, 2015)

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.

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- c) Practicing or operating on a license or certificate that has expired shall be considered unlicensed activity and shall be grounds for discipline pursuant to Section 30 of the Act.
- d) Pharmacy technicians shall be required to submit with their second renewal proof of certification as a certified pharmacy technician, proof of enrollment in a first professional degree program in pharmacy, or proof of enrollment in clinical training by a graduate a foreign pharmacy program, as provided in Section 9 of the Act. This requirement does not apply to pharmacy technicians licensed prior to January 1, 2008. Failure to provide proof of certification results in non-renewal of the pharmacy technician's registration.

(Source: Amended at 39 Ill. Reg. 6267, effective April 23, 2015)

Section 1330.90 Restoration of a Pharmacist License

- a) A pharmacistregistrant 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 pharmacistregistrant 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., certificate of attendance or completion) in accordance with Section 1330.100 ~~of this Part~~.
- c) A pharmacistregistrant 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 pharmacistregistrant shall also submit either:
 - A) Certification of active practice in another jurisdiction. Evidence shall include a statement from the appropriate board or licensing

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

authority in the other jurisdiction that the registrant was authorized to practice during the term of active practice; or

- B) An affidavit attesting to military service as specified in Section 12 of the Act. The applicant restoring a license shall be excused from the payment of any lapsed fee or any restoration fees.
- 2) A ~~pharmacist~~~~registrant~~ who is unable to submit proof of satisfaction of either subsection (c)(1)(A) or (B) shall submit proof of completion of:
- A) ~~3015 clock~~ hours of ~~refresher courses or~~ continuing education ~~for each year the license was expired; and/or~~
- B) Either:
- i) ~~600~~~~Up to 400~~ hours of clinical practice under the supervision of a licensed pharmacist completed within 2 years prior to restoration; or-
- ii) Successful completion of the Pharmacist Assessment for Remediation Evaluation (PARE) examination. To be successful, an applicant must receive an overall score of 80 or higher, as well as a minimum score of 75 in each of the 3 content areas on the PARE examination.
- 3) The course work or clinical training described in subsections (c)(2)(A) and (c)(2)(B)(i) must have the prior approval of the Board.
- d) When the accuracy of any submitted documentation, or the relevance or sufficiency of the course work or experience, is questioned by the Division because of lack of information, discrepancies or conflicts in information given, or a need for clarification, the registrant will be requested to:
- 1) Provide information as may be necessary; and/or
- 2) Appear for an interview before the Board to explain the relevance or sufficiency, clarify information given, or clear up any discrepancies in information.

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

(Source: Amended at 39 Ill. Reg. 6267, effective April 23, 2015)

Section 1330.110 Confidentiality

All information collected by the Department in the course of an examination or investigation of a licensee or applicant, including, but not limited to, any complaint against a licensee filed with the Department and information collected to investigate any such complaint, shall be maintained for the confidential use of the Department and shall not be disclosed. The Department shall not disclose the information to anyone other than law enforcement officials, regulatory agencies that have an appropriate regulatory interest as determined by the Secretary, or a party presenting a lawful subpoena to the Department. Information and documents disclosed to a federal, State, county or local law enforcement agency shall not be disclosed by the agency for any purpose to any other agency or person. A formal complaint filed against a licensee by the Department or any order issued by the Department against a licensee or applicant shall be a public record, except as otherwise prohibited by law.

(Source: Added at 39 Ill. Reg. 6267, effective April 23, 2015)

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

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

annual basis.

- d) Technician certificate of registration must be displayed and visible to the public in the pharmacy where the pharmacy technician is employed.
- 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](#)~~Pharmacist~~.
- g) No person who holds an active Illinois pharmacist's license may concurrently hold an active Illinois pharmacy technician registration.
- h) Any pharmacy technician who is permitted to use the title "student pharmacist" pursuant to Section 9 of the Act shall notify the Division within 10 days if he or she has permanently separated from or been expelled from an ACPE accredited college or school of pharmacy; failed to complete his or her 1,200 hours of Board approved clinical training within 24 months; or failed the pharmacist licensure examination 3 times. When this occurs, the technician shall have 90 days to obtain a certified pharmacy technician license as provided in Section 1330.220, unless that certified pharmacy technician was registered prior to January 1, 2008. During the period prior to registering as a pharmacy technician, the individual is not permitted to use the title "student pharmacist". If the individual does not become registered as a certified pharmacy technician within 90 days, the pharmacy technician registration shall expire.

(Source: Amended at 39 Ill. Reg. 6267, effective April 23, 2015)

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.

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- 3) Compounding, packaging, labeling and storage.
 - 4) Pharmaceutical and medical terminology.
 - 5) Recordkeeping 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.
- e) Ensuring registered pharmacy technicians and certified pharmacy technicians are properly trained shall be the responsibility of the pharmacy, the pharmacist-in-charge, and the pharmacy technician.

(Source: Amended at 39 Ill. Reg. 6267, effective April 23, 2015)

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

- a) An individual may receive certification as a certified pharmacy technician if he or she:
- 1) Has submitted a written application in the form and manner prescribed;
 - 2) Has attained the age of 18;
 - 3) Is of good moral character, as determined by the Division;

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- 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 Commission for Certifying Agencies of the Institute for Credentialing Excellence \(NCCA\)](#)~~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 [National Healthcareer Association \(or its successor\)](#)~~Certification of Pharmacy Technicians~~, and the Pharmacy Technician Certification Examination offered by the Pharmacy Technician Certification Board [\(or its successor\)](#), are accredited by [NCCANOCA](#) and are, therefore, approved examinations for certification; and
 - 6) Has paid the required certification fees.
- b) No pharmacist whose license has been denied, revoked, suspended or restricted for disciplinary purposes may be eligible to be registered as a certified pharmacy technician. [No person who holds an active Illinois pharmacist license may concurrently hold an active Illinois certified pharmacy technician registration.](#)

(Source: Amended at 39 Ill. Reg. 6267, effective April 23, 2015)

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.

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- 2) Upon determination that the application is in good order, an inspection of the premises will be conducted to determine compliance with Sections 1330.610, 1330.620, 1330.630, 1330.640, ~~1330.670~~ and 1330.680. An application shall be in good order when it is signed and notarized and the license of the pharmacist-in-charge has been verified to be in good standing with the Division.
- 3) Upon recommendation of the Drug Compliance Coordinator, the Board may request the owner of the pharmacy and the pharmacist-in-charge to appear for an interview with the Board.
- b) For a change of name of pharmacist-in-charge only, the owner shall be required to file an application on forms supplied by the Division, together with the required fee, and submit the present license. The Division shall evaluate the application and, if satisfactory, issue a new license.
- c) Within 30 days after issuance of a pharmacy license, the pharmacy for which the licensure was requested shall be open to the public for pharmaceutical services.
- d) Any reduction in hours of operation shall be reported to the Division within 30 days.
- e) Upon receipt by the Division of a change of ownership application, the purchaser may begin operations prior to the issuance of a new pharmacy license only when the purchaser and seller have a written power of attorney agreement. This agreement shall provide, among other things, that violations during the pendency of the application process shall be the sole responsibility of the seller. This agreement shall be provided to the Division upon request.
- f) No pharmacy shall relocate prior to the inspection of the premises. All drugs shall be transferred within 24 hours after issuance of the license unless otherwise approved by the Department.

(Source: Amended at 39 Ill. Reg. 6267, effective April 23, 2015)

Section 1330.410 Pharmacy Licenses

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- a) Each individual, partnership, corporation or any other applicant for a pharmacy license shall indicate, on forms supplied by the Division, the type of pharmacy services to be provided by the licensee.
- b) The Board may review and make recommendations to the Director regarding pharmacy applications filed with the Division.
- c) A pharmacy who provides more than one type of pharmacy service shall be issued one pharmacy license and shall be charged the appropriate fee, as set forth in Section 1330.20.
- d) A pharmacy shall designate a pharmacist-in-charge as provided for in Section 1330.660.
- e) When a management company is hired to run a pharmacy, that management company shall be the license holder; however, the license may be issued ~~with~~ the name of the pharmacy, ~~as a d/b/a,~~ or ~~with the name~~ of the management company. The Illinois Controlled Substance license shall be issued ~~to~~ ~~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 hospital or pharmacy.

(Source: Amended at 39 Ill. Reg. 6267, effective April 23, 2015)

SUBPART E: TYPES OF PHARMACIES

Section 1330.500 Community Pharmacy Services

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

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- 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) Recordkeeping~~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 pharmacy technician under the supervision of a pharmacist, the prescription record shall contain the names, initials or other unique identifier of both the supervising pharmacist and the registered pharmacy technician or certified pharmacy technician who dispenses the prescription.
 - 3) Refilling a Prescription
 - A) Each refilling of a prescription shall be entered on the prescription or on another appropriate, uniformly maintained, readily retrievable record that indicates, by the number of the prescription, the following information:
 - i) The name and dosage form of the drug;
 - ii) The date of each refilling;
 - iii) The quantity dispensed;

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- iv) The name or initials of the pharmacist and the pharmacy technician, if applicable, in each refilling; and
 - v) The total number of refills remaining for the prescription.
- B) If the pharmacist ~~does not~~^{doesn't} otherwise indicate in a uniformly maintained record, ~~he or she~~^{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; ~~20141998~~), except as provided in subsection (c)(7), and shall include the capability to:
- A) Retrieve the original prescription order information for those prescription orders currently authorized for refilling;
 - B) Retrieve the current prescription orders, including, at a minimum, name of drug, date of refill, quantity dispensed, name and identification code of the manufacturer in the case of a generically written prescription or a generic interchange, name or initials of the dispensing pharmacist and technician for each refill, and the total number of refills dispensed to date;
 - C) Supply documentation of refill information entered by the pharmacist using the system through a hard copy printout of each day's refill data that has been verified for correctness. This printout

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

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

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

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

- 1) The pharmacy is or will be engaged in the practice of pharmacy; and
- 2) The pharmacy will have in stock and will maintain sufficient prescription drugs and materials to protect the public it serves within 30 days after opening of the pharmacy.

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

- 1) When, in the pharmacist's professional judgment, after screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including, but not limited to, serious interactions with nonprescription or over-the-counter drugs), drug-food interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, or clinical abuse or misuse, pursuant to ~~Section~~ 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;
- 3) Lack of specialized equipment or expertise needed to safely produce, store or dispense drugs, such as certain drug compounding or storage for nuclear medicine;
- 4) Potentially fraudulent prescriptions;
- 5) Unavailability of drug; or
- 6) The drug is not typically carried in similar practice settings in the State.

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- ~~g)~~ Nothing in this Section requires pharmacies to dispense a drug without payment of their usual and customary or contracted charge.
- h) All pharmacies shall be required to maintain the following current resource materials, either in hard copy or electronic format:
- 1) Copies of the Act and this Part;
 - 2) The Illinois Controlled Substances Act and 77 Ill. Adm. Code 3100;
 - 3) 21 CFR (Food and Drugs; 2014); and
 - 4) The Illinois Hypodermic Syringes and Needles Act [720 ILCS 635].
- ~~i)~~ If the lawfully prescribed drug or nonprescription drug approved by the U.S. Food and Drug Administration for restricted distribution by pharmacies is not in stock or is otherwise unavailable, or the prescription cannot be filled pursuant to subsection ~~(f)~~(1) or ~~(f)~~(6), the pharmacy shall provide the patient or agent a timely alternative for appropriate therapy that, consistent with customary pharmacy practice, may include obtaining the drug. These alternatives include but are not limited to:
- 1) Contact the prescriber to address concerns such as those identified in subsection ~~(f)~~(1);
 - 2) If requested by the patient or 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.
- j) Any mail order pharmacy that provides services in Illinois shall provide, during its regular hours of operation, but not less than 6 days per week for a minimum of 40 hours per week, a toll-free telephone service to facilitate communication between patients in this State and a pharmacist retained by the mail order pharmacy who has access to the patient's records. The toll free number must be

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

disclosed on the label affixed to each container of drugs dispensed to residents of the State.

- ~~k)h)~~ Engaging in or permitting any of the following shall constitute grounds for discipline or other enforcement actions:
- 1) Intentionally destroying unfilled lawful prescriptions;
 - 2) Refusing to return unfilled lawful prescriptions;
 - 3) Violating a patient's privacy;
 - 4) Discriminating against patients or their agents in a manner prohibited by State or federal laws;
 - 5) Intimidating or harassing a patient; or
 - 6) Failing to comply with the requirements of this Section.

(Source: Amended at 39 Ill. Reg. 6267, effective April 23, 2015)

Section 1330.510 Telepharmacy

- a) Telepharmacy shall be limited to the ~~following~~ types of operations described in this Section. Each site where such operations occur shall be a separately licensed pharmacy. Home pharmacies that are located outside of Illinois must be licensed as a nonresident pharmacy. Nonresident pharmacies shall abide by all Illinois laws and rules when filling prescriptions for Illinois residents, except that the dispensing pharmacist and the pharmacist-in-charge shall not be required to be licensed in Illinois, except as otherwise provided in this Part.
- b) ~~Operations~~¹⁾ Remote Dispensing Site
- ~~1)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

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

filing within 72 hours. Records shall be maintained at the home pharmacy in files separate from the home pharmacy files.

- ~~2)B)~~ A remote site is considered to be under the supervision of the pharmacist-in-charge of the home pharmacy.
- ~~3)C)~~ The remote site shall use its home pharmacy and pharmacy management system.
 - ~~A)i)~~ The system shall assign consecutive prescription numbers.
 - ~~B)ii)~~ All records must be maintained at the home pharmacy.
 - ~~C)iii)~~ Prescriptions dispensed at the remote site shall be distinguishable from those dispensed from the home pharmacy.
 - ~~D)iv)~~ Daily reports must be separated for the home and remote site.
- ~~4)D)~~ A pharmacist at the home pharmacy must verify each prescription before it leaves the remote site.
 - ~~A)i)~~ Pharmacist and pharmacy technician initials or unique identifiers must appear on the prescription record and the prescription label.
 - ~~B)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.
 - ~~C)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. If the stock bottle does not have a barcode, the pharmacy shall create one. The technician shall scan both the stock bottle and the label of the dispensed drug to verify that the drug dispensed is the same as the drug in the stock bottle for each prescription dispensed.
 - ~~D)iv)~~ A pharmacy may utilize a different electronic verification system that accomplishes the same purpose after review and approval of the Division.

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- ~~5)E)~~ Counseling must be done by a pharmacist via video link and audio link before the drug or medical devicescript is released. ~~The pharmacist must counsel the patient or the patient's agent on all new prescriptions and refills. The pharmacist providing counseling, pursuant to this subsection, must be employed or contracted by the home pharmacy or by a pharmacy contracted with the home pharmacy and have access to all relevant patient information maintained by the home pharmacy.~~
- ~~6)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.
- ~~7)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.
- ~~8)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.
- ~~A)ii)~~ The pharmacy technician located at the remote dispensing site must have one year of experience and be registered as a certified pharmacy technician, or be a student pharmacist.
- ~~B)iii)~~ New prescriptions received at the remote dispensing site may be entered into the remote computer system with all verification, interaction, checking and profile review by the pharmacist at the home pharmacy.
- ~~C)iii)~~ Each pharmacist at the home pharmacy may electronically supervise no more than 3 remote sites that are simultaneously open.
- ~~9)I)~~ The facility must have a sign clearly identifying it as a remote dispensing site.

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

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

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

c)2) Remote Consultation Site

1)A) These sites have no prescription inventory.

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

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

4)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.

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

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

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

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

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

1)3) Remote Automated Pharmacy Systems (RAPS)

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- A) ~~These devices shall maintain a prescription drug inventory that is controlled electronically by the home pharmacy or, when operated by a pharmacy contracted with the home pharmacy, by the contracted pharmacy, which shall be utilized to dispense patient specific prescriptions.~~
- B)A) These ~~systems shall~~ sites have prescription inventory, which must be secured in an automated pharmacy system and electronically dispensing device connected to and controlled by the home pharmacy.
- C)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 RAPS automated dispensing device.
- D)C) Dispensing and counseling are performed by a pharmacist employed or contracted 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.~~
- E)D) All filled prescription must have a label that meets the requirements of the Act attached to the final drug container.
- F)E) The pharmacist-in-charge of the home pharmacy, or a designated registrant, shall conduct and complete monthly inspections of the RAPS 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.
- G)F) The RAPS must be licensed with the Division as an automated pharmacy system and will be subject to random inspection by pharmacy investigators. Notwithstanding that the RAPS shall possess a license, the home pharmacy shall remain responsible for inventory control and billing. For purposes of random inspections, a pharmacist with access to the system must be available at the site within one hour, or as otherwise approved by the drug compliance

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

investigator. In the event the Chief Pharmacy Coordinator determines that the RAPS poses a significant risk of patient harm, the RAPS must be disabled until such time as the pharmacist with access to the system is available to the site.

- H)4) Medication dispensed at the automated pharmacy system site may only be packaged by a licensed manufacturer or repackager, or prepackaged by a licensed pharmacy in compliance with this Section. Prepackaging must occur at the home pharmacy, a pharmacy sharing common ownership with the home pharmacy, or a pharmacy that has contracted with the home pharmacy to perform prepackaging services in compliance with Section 1330.730. The following requirements shall apply whenever medications are prepackaged by a pharmacy other than the home pharmacy:
- i) The prepackaging pharmacy shall be licensed in Illinois as a resident or nonresident pharmacy.
 - ii) The prepackaging pharmacy shall share a common database with the home pharmacy, or have in place an electronic or manual process to ensure that both pharmacies have access to records to verify the identity, lot numbers and expiration dates of the prepackaged medications stocked in the RAPS.
 - iii) The prepackaging pharmacy shall maintain appropriate records to identify the responsible pharmacist who verified the accuracy of the prepackaged medication.
- D) Written prescriptions may be received at an RAPS. All written prescriptions presented to an RAPS shall be scanned utilizing imaging technology that permits the reviewing pharmacist to determine its authenticity. The sufficiency of the technology shall be determined by the Department. If sufficient technology is not used, the written prescriptions must be delivered to the home pharmacy and reviewed by a pharmacist prior to being dispensed to the patient.

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- 2) Kiosk
- A) A kiosk is a device that maintains individual patient prescription drugs that were verified and labeled at the home pharmacy.
- B) A home pharmacy may only use the kiosk with prior approval of a patient.
- C) A kiosk located on the same premises or campus of the home pharmacy shall operate under the same license as the home pharmacy. However, a kiosk must be licensed with the Division if it is not so located.
- D) A kiosk shall:
- i) When located on the same premises or campus as the pharmacy, inform a patient, if 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;
- ii) When not located on the same premises or campus as the pharmacy, inform a patient, if he is using the device when the pharmacy is closed, that he or she may immediately direct any questions and concerns regarding the prescription to a licensed pharmacist via a pharmacy provided audio/video link;
- iii) Inform a patient that a prescription is not available to be delivered by the device if the pharmacist has determined that he or she desires to counsel the patient in person regarding the prescription.
- 3) A pharmacy may use an automated pharmacy system to deliver prescriptions to a patient when the device:
- A) Is secured against a wall or floor;

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- B) Provides a method to identify the patient and delivers the prescription only to that patient or the patient's authorized agent;
 - C) Has adequate security systems and procedures to prevent unauthorized access, to comply with federal and State regulations, and to maintain patient confidentiality;
 - D) Records the time and date that the patient removed the prescription from the system.
- 4) A licensed automated pharmacy system shall not be utilized by prescribers. Nothing in this Section shall prevent a prescriber from utilizing an automated pharmacy system in connection with his or her own dispensing. However, a prescriber may not utilize or access an automated pharmacy system licensed pursuant to this Section.
- e)e) All pharmacists performing services in support of ~~at~~ the remote dispensing site, remote consultation site, kiosk, or RAPS sites must display a copy or electronic image of their licenses at the ~~in any~~ remote site where they provide services, or shall otherwise make their license visible to the patient, and be licensed in this State, unless employed by a pharmacy licensed in Illinois as a nonresident pharmacy, in which case, the pharmacist providing the services shall hold an active license as a pharmacist in the state in which the nonresident pharmacy is located and only the pharmacist-in-charge of the remote site must be licensed in Illinois.
- f)⊕) Each remote site must display a sign, easily viewable by the customer, that states:
- 1) The facility is a telepharmacy supervised by a pharmacist located at (address); and
 - 2) The pharmacist is required to talk to you, over an audio/visual link, each time you pick up a prescription.
- g)e) No remote site may be open when the home pharmacy is closed, unless ~~at~~ the pharmacist employed or contracted by the home pharmacy, or by a pharmacy contracted with the home pharmacy, is present at the remote site or is remotely providing supervision and consultation as required under this Section. ~~No employees are allowed access to the remote site when the home pharmacy is~~

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

~~closed. The security system must allow for tracking of entries into a pharmacy. The pharmacist in charge must review the log of entries weekly.~~

(Source: Amended at 39 Ill. Reg. 6267, effective April 23, 2015)

Section 1330.520 Offsite Institutional Pharmacy Services

- a) Pharmacies that are not located in the facilities they serve and whose primary purpose is to provide services to patients or residents of facilities licensed under the Nursing Home Care Act, the Hospital Licensing Act, 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 ~~identifiers~~~~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 seq.; ~~20141998~~)) and State (e.g., the Pharmacy Practice Act and the Illinois Controlled Substances Act [720 ILCS 570]) statute.
 - 3) In addition to the recordkeeping requirements of subsection (b)(2), a uniformly maintained, readily retrievable hard copy record or back-up

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

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 Enforcement Administration (21 CFR 1306; [20141998](#)) and shall include the capability to:

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- 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

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- A) Parenteral solutions to which a drug or diluent has been added or that are not in their original manufacturer's packaging shall contain the following information on the outer label:
 - i) Name, concentration and volume of the base parenteral solution;
 - ii) Name and strength of drugs added;
 - iii) Beyond use date and date of the admixture. Beyond use date, unless otherwise specified in the individual compendia monograph shall be not later than the beyond use date on the manufacturer's container or one year from the date the drug is repackaged, whichever is earlier; and
 - iv) Reference code to identify source and lot number of drugs added.
 - B) Non-parenterals repackaged for future use shall be identified with the following information:
 - i) Brand and/or generic name;
 - ii) Strength (if applicable);
 - iii) Beyond use date. Unless otherwise specified in the individual monograph, the beyond use date shall be not later than the beyond use date on the manufacturer's container or one year from the date the drug is repackaged, whichever is earlier; and
 - iv) Reference code to identify source and lot number.
- 2) Medications Prepared for Immediate Use
- A) All medications prepared by the pharmacy for immediate dispensing to a specific resident or patient in the facility shall be dispensed in a container identified with:

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- i) Name of the resident;
 - ii) Resident's room and bed number;
 - iii) Dispensing date;
 - iv) Name, strength and dosage form of drug, or description of the medical device ordered;
 - v) Quantity dispensed;
 - vi) Directions for use;
 - vii) Prescriber's name; and
 - viii) Beyond use date if less than 60 days from date of dispensing.
- B) Pharmacies dispensing medications to a specific resident or patient in the facility via unit dose shall label each order with the following information:
- i) Name of the resident;
 - ii) Resident's room and bed number;
 - iii) Date of order;
 - iv) Name, strength and dosage form of drug, or description of the medical device ordered;
 - v) Directions for use; and
 - vi) Prescriber's name.
- f) Pharmacies that compound and dispense sterile products shall comply with [SectionSections 1330.640 and 1330.670](#).

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- g) Medication Dispensing in the Absence of a Pharmacist. The availability of necessary medications for immediate therapeutic use during those hours when the institutional pharmacy is not open shall be met in the following manner:
- 1) An after-hour cabinet, which is a locked cabinet or other enclosure located outside of the pharmacy area containing a minimal supply of the most frequently required medication, may be utilized provided that only personnel specifically authorized by the institution in which the pharmacy is located may obtain access and it is sufficiently secure to deny access to unauthorized persons. After-hour cabinets shall only be used in the absence of a pharmacist. When medication is removed from the cabinet or enclosure, written physician's orders authorizing the removal of the medication shall be placed in the cabinet or enclosure. A log shall be maintained within the cabinet or enclosure and authorized personnel removing medication shall indicate on the log the signature of the authorized personnel removing the medication, the name of the medication removed, the strength (if applicable), the quantity removed and the time of removal. An automated dispensing and storage system may be used as an after hours cabinet. This use shall be in compliance with Section 1330.680.
 - 2) Emergency kits containing those drugs that may be required to meet the immediate therapeutic needs of the patient, and that are not available from any other source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining the drugs from the other source, may be utilized. Emergency kits shall be supplied and maintained under the supervision of a pharmacist. Drugs shall be removed from emergency kits only by authorized pharmacy personnel or persons authorized to administer medication pursuant to a valid 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 that time, the kit shall be returned when it opens. An automated

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

dispensing and storage system may be used as an emergency kit. This use shall be in compliance with Section 1330.680.

- 3) Whenever any drug is not available from night cabinets or emergency kits, and the drug is required to treat the immediate needs of a patient, the drug may be obtained from the pharmacy in sufficient quantity to meet the immediate need by an authorized nurse. When medication is removed from the pharmacy by an authorized nurse, a copy of the 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 the authorized nurse who removed the medication, the name, strength (if applicable) and quantity of medication removed.

(Source: Amended at 39 Ill. Reg. 6267, effective April 23, 2015)

Section 1330.530 Onsite Institutional Pharmacy Services

- a) Pharmacies located in facilities licensed under the Nursing Home Care Act, the Hospital Licensing Act, or the University of Illinois Hospital Act, or that are operated by the Department of Human Services or the Department of Corrections, and that provide pharmacy services to residents, patients, employees, prescribers and students of these facilities, shall, in addition to other requirements of the Act and this Part, comply with this Section.
- b) Recordkeeping Requirements
- 1) Every prescription or medication order filled or refilled shall contain the name, initials or other unique identifier of the pharmacist (and pharmacy technician if one is used) who fills or refills the prescription or medication order, or the name, initials or other unique identifier may be recorded on another appropriate, uniformly maintained and readily retrievable record that indicates, at least, the following information:
- A) The name and dosage form of the drug;
- B) The date of filling or refilling; and

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- 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 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;

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- ii) Name and strength of drugs added;
 - iii) Beyond use date and time of the admixture; and
 - iv) Reference code to identify source and lot number of drugs added.
- 2) All medication prepared by the pharmacy for immediate dispensing to a specific patient or resident in the institution or facility shall be identified as follows:
- A) Single dose or multi-dose drugs, except parenteral solutions to which a drug has been added, shall be identified with:
 - i) Brand and/or generic name; and
 - ii) Strength (if applicable).
 - B) Sterile solutions to which drugs have been added shall be identified with:
 - i) Name, concentration and volume of the base sterile solution;
 - ii) Name and strength of drugs added; and
 - iii) Beyond use date and time of the admixture.
 - C) All medication dispensed to a specific patient in the institution shall be dispensed in a container identified with the name of the patient and the patient's location. Those institutions or facilities utilizing a unit-dose and medication cart system may identify the name of the patient and the patient's location on the outside of the bin of the medication cart, when those carts are filled by the pharmacy.

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- 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; ~~and~~;
 - D) Directions for use.
- 4) Investigational new drugs, authorized by the U.S. Food and Drug Administration, shall be dispensed pursuant to a valid prescription order of the principal physician-investigator or 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 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.

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- 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;
 - 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

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

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.
- 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.

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- 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 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

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

removing medication shall indicate on the log the signature of the authorized personnel removing the medication, name of the medication removed, the strength (if applicable), the quantity removed and the time of removal. [An automated dispensing and storage system may be used as an after hours cabinet. This use shall be in compliance with Section 1330.680.](#)

- 2) Emergency kits containing those drugs that may be required to meet the immediate therapeutic needs of the patient, and that are not available from any other source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining the drugs from the other source, may be utilized. Emergency kits shall be supplied and maintained under the supervision of a pharmacist. Drugs shall be removed from emergency kits only by authorized pharmacy personnel, persons authorized to administer medication pursuant to a valid 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. [An automated dispensing and storage system may be used as an emergency kit. This use shall be in compliance with Section 1330.680.](#)
- 3) Whenever any drug is not available from night cabinets or emergency kits, and the drug is required to treat the immediate needs of a patient, the drug may be obtained from the pharmacy in sufficient quantity to meet the immediate need by an authorized nurse. When medication is removed from the pharmacy by an authorized nurse, a copy of the 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 the authorized nurse who removed the medication, the name, strength (if applicable) and quantity of medication removed.

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- 4) Drugs may be dispensed from the emergency room only by a practitioner licensed to prescribe and dispense, and only to patients treated in the institution. This shall occur only during hours in which outpatient institutional pharmacy services are not available. The quantity dispensed should be limited to no more than a 72 hour supply, except for antimicrobial drugs and unit of use packages (e.g., inhalers, ophthalmic, otics, etc., ~~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 ~~Section~~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.~~

(Source: Amended at 39 Ill. Reg. 6267, effective April 23, 2015)

Section 1330.550 Nonresident Pharmacies

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

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

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

(Source: Amended at 39 Ill. Reg. 6267, effective April 23, 2015)

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

Section 1330.560 Remote Prescription/Medication Order Processing

- 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 [and registered in this 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) [Recordkeeping](#)~~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;

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- C) Outline the responsibilities of the remote prescription/medication order processing pharmacy staff and the staff at the dispensing pharmacy;
 - 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

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

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;
 - 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 [providing remote prescription/medication order processing](#) 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

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

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).

(Source: Amended at 39 Ill. Reg. 6267, effective April 23, 2015)

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).~~

(Source: Amended at 39 Ill. Reg. 6267, effective April 23, 2015)

Section 1330.610 Pharmacy Structural/Equipment Standards

~~All pharmacies~~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.

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- b) Other than on-site institutional pharmacies, 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 with the practice of pharmacy.
- f) Suitable current reference sources, either in book or electronic data form (available in the pharmacy or on-line), which shall include Facts and Comparisons (<http://www.factsandcomparisons.com>) or other suitable references determined by the Division to be pertinent to the practice carried on in the licensed pharmacy.
- g) A telephone shall be immediately accessible in the pharmacy area.
- h) These requirements are in addition to any other requirements found in this Part.
- i) At a minimum, the equipment and references listed in Section 1330.640 must be maintained at all dispensing pharmacies.

(Source: Amended at 39 Ill. Reg. 6267, effective April 23, 2015)

Section 1330.620 Electronic Equipment Requirements for Remote Pharmacies

All remote pharmacies operating in Illinois shall meet the following equipment requirements, except that subsections (a) through (d) shall not apply to RAPS:

- 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.

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- 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.

(Source: Amended at 39 Ill. Reg. 6267, effective April 23, 2015)

Section 1330.660 Pharmacist-in-Charge

- a) No pharmacy shall be granted a license without a pharmacist being designated on the pharmacy license as pharmacist-in-charge.
- b) A pharmacy shall have one pharmacist-in-charge who shall be routinely and actively involved in the operation of the pharmacy.
- c) A pharmacist may be the pharmacist-in-charge for more than one pharmacy; however, the pharmacist-in-charge must work an average of at least 8 hours per week at each location where he or she is the pharmacist-in-charge. If a pharmacist in charge is on a leave of more than 90 days, a new pharmacist-in-charge must be designated.
- d) The responsibilities of the pharmacist-in-charge shall include:
 - 1) Supervision of all activities of all employees as they relate to the practice of pharmacy;
 - 2) Establishment and supervision of the method and manner for storage and safekeeping of pharmaceuticals, including maintenance of security provisions to be used when the pharmacy is closed (see Section 1330.600); and

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- 3) Establishment and supervision of the recordkeeping system for the purchase, sale, delivery, possession, storage and safekeeping of drugs.
- e) The operations of the pharmacy and the establishment and maintenance of security provisions are the dual responsibility of the pharmacist-in-charge and the owner of the pharmacy.
- f) Within 30 days after a change of a pharmacist-in-charge, the Division shall be notified in writing by the departing pharmacist-in-charge.
- g) In addition to notifying the Division within 30 days, the departing pharmacist-in-charge shall, on the effective date of the change, inventory the following controlled substances:
 - 1) All Schedule II drugs, as defined in the Illinois Controlled Substances Act, by actual physical count; and
 - 2) All other scheduled drugs, as defined in the Illinois Controlled Substances Act, by estimated count.
- h) The inventory described in subsection (g) ~~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 the departing and the incoming pharmacist-in-charge, shall be submitted to the Division at its principal office within 30 days after the change in the pharmacist-in-charge.
- i) In the event the departing pharmacist-in-charge refuses to complete the inventory as provided for in subsection (g), or that pharmacist-in-charge is incapacitated or deceased, the initial inventory for the incoming pharmacist-in-charge shall be the inventory as completed by the incoming pharmacist-in-charge. The incoming pharmacist-in-charge will not be responsible for any discrepancy that may exist in the inventory prior to his or her initial inventory.

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- j) When the accuracy, relevance or completeness of any submitted documentation is questioned by the Division, because of a lack of information, discrepancies or conflicts in information given, or a need for clarification, the registrant will be required to:
- 1) Provide information as may be necessary; and/or
 - 2) Appear for an interview before the Board to explain the relevance or sufficiency, clarify information given, or clear up any discrepancies or conflict of information.
- k) Records shall be retained as provided for in Section 18 of the Act. Invoices for all legend drugs shall be maintained for a period of 5 years either on site or at a central location where records are readily retrievable. Invoices shall be maintained on site for at least one year from the date of the invoice.
- l) Whenever a pharmacy intends on changing or adding to the type of pharmacy services it offers, as listed in Sections 1330.500, 1330.510, 1330.520, 1330.530, 1330.540 and 1330.560, it shall notify the Division no less than 30 days prior to the change or addition.

(Source: Amended at 39 Ill. Reg. 6267, effective April 23, 2015)

Section 1330.680 Automated Dispensing and Storage Systems

- a) This Section sets forth standards for pharmacies whose practice includes the use of automated dispensing and storage systems. Automated dispensing and storage systems shall not be used in nuclear pharmacies.
- b) Automated Dispensing and Storage Systems
- ~~1) Automated dispensing and storage systems may be utilized in licensed community or institutional pharmacies.~~
- 1)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:

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- A) Name and address of the pharmacy or facility where the automated dispensing and storage system is operational;
 - B) Manufacturer's name and model;
 - C) Quality assurance policy and procedures to determine continued appropriate use and performance of the automated device; and
 - D) Policies and procedures for system operation, safety, security, accuracy, patient confidentiality, access, controlled substances, data retention or archival, definitions, downtime procedures, emergency or first dose procedures, inspection, installation requirements, maintenance, medication security, quality assurance, medication inventory, staff education and training, system set-up and malfunction.
- ~~2)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. This provision shall not apply when used as an after hours cabinet or emergency kit as provided in Section 1330.530(e).
- ~~3)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
 - C) Maintain patient confidentiality.
- ~~4)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;

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- B) Records must be maintained by the pharmacy and must be readily available to the Division. The records shall include:
- i) ~~Identity~~identity of system accessed;
 - ii) ~~Identification~~identification of the individual accessing the system;
 - iii) ~~Type~~type of transaction;
 - iv) ~~Name~~name, strength, dosage form and quantity of the drug accessed;
 - v) ~~Name~~name of the patient for whom the drug was ordered;
 - vi) ~~Identification~~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~~such additional information as the pharmacist-in-charge may deem necessary.
- ~~5)6)~~ The stocking or restocking of all medications in the automated dispensing and storage systems shall be accomplished by registrants under the Act.
- ~~6)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)(~~67~~):
- A) Sterile solutions to which a drug or diluent has been added, or that are not in their original manufacturer's packaging, shall contain the following information on the outer label:
- i) Name, concentration and volume of the base sterile solution;
 - ii) Name and strength of drugs or diluent added;

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- iii) Date and beyond use date of the admixture. The beyond use date, unless otherwise specified in the individual compendia monograph, shall be no later than the beyond use date on the manufacturer's container or one year from the date the drug is repackaged; and
 - iv) Reference code to identify source and lot number of drugs or diluent added.
- B) Non-parenterals repackaged for future use shall be identified with the following information:
- i) Brand and/or generic name;
 - ii) Strength (if applicable);
 - iii) Beyond use date. Unless otherwise specified in the individual monograph, the beyond use date shall be no later than the beyond use date on the manufacturer's container or one year from the date the drug is repackaged; and
 - iv) Reference code to identify source and lot number.
- C) Exceptions to the "unit of use" requirements in this subsection (b)(67) are as follows:
- i) Injectable medications stored in their original multi-dose vial (e.g., insulin, heparin) when the medication may be withdrawn into a syringe or other delivery device for single patient use; or
 - ii) Over-the-counter (OTC) products stored in their original multi-dose container (e.g., antacids, analgesics) when the medication may be withdrawn and placed into an appropriate container for single patient use.
- D) [The pharmacy providing services to the University of Illinois College of Veterinary Medicine shall be exempt from the](#)

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

requirement that all medications stored in the automated dispensing and storage systems be packaged as a unit for single patient use. This exemption is solely for dispensing medications to animals.

- ~~7)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.
- ~~8)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.

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- ~~9)10)~~ The automated dispensing and storage systems shall provide a mechanism for securing and accounting for wasted medications or discarded medications.
- ~~10)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).
- ~~11)12)~~ Errors in the use or performance of the automated dispensing and storage systems resulting in patient hospitalization or ~~resident~~ death shall be reported to the Division by the pharmacist-in-charge within 30 days after acquiring knowledge of the incident.
- ~~12)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

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

needs of the patient may be removed until a pharmacist is on duty and available to review the prescription or medication order. A pharmacist shall check the orders promptly once on duty (e.g., floor stock system, emergency department, surgery, ambulatory care or same day surgery, observation unit, etc.).

~~13)~~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.~~

~~14)~~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.

~~15)~~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 recordkeeping and security safeguards;
 - B) Establishment of a quality assurance program prior to implementation of an automated dispensing and storage system and the supervision of an ongoing quality assurance program that monitors appropriate use and performance of the automated

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- dispensing and storage system, evidenced by written policies and procedures developed by the pharmacy;
- C) Providing the Division with written notice 30 days prior to the installation of, or at the time of removal of, an automated storage and dispensing system. The notice must include, but is not limited to:
- i) ~~The~~ name and address of the pharmacy;
 - ii) ~~The~~ address of the location of the automated dispensing and storage system, if different from the address of the pharmacy;
 - iii) ~~The~~ automated dispensing and storage system's manufacturer and model;
 - iv) ~~The~~ pharmacist-in-charge; and
 - v) ~~A~~ written description of how the facility intends to use the automated storage and dispensing system;
- D) Determining and monitoring access to and the limits on access (e.g., security levels) to the automated storage and dispensing system. Access shall be defined by policies and procedures of the pharmacy and shall comply with State and federal regulations.
- 2) Additional responsibilities of the pharmacist-in-charge or pharmacist designated by the pharmacist-in-charge shall include:
- A) Authorizing the assigning of access to, discontinuing access to, or changing access to the system;
 - B) Ensuring that access to the medications complies with State and federal regulations, as applicable; and
 - C) Ensuring that the automated dispensing and storage system is stocked/restocked accurately and in accordance with established, written pharmacy ~~policies~~ policies and procedures.

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- d) An automated dispensing and storage system is authorized for use in any licensed hospital, long-term care facility, or hospice residence ("facility"). For all nonresident pharmacies, the pharmacist-in-charge and all pharmacy personnel who provide services while physically present at a facility located in Illinois must be licensed in Illinois. In addition to compliance with all other provisions in this Section, an automated dispensing and storage system shall comply with the following:
- 1) Drugs in the automated dispensing and storage system are not considered dispensed until removed from the system by authorized personnel at the facility, after being released by the pharmacy pursuant to a prescription, unless otherwise provided for in this Part.
 - 2) Only the doses of medication needed for contemporaneous administration may be removed from the automated pharmacy system at one time.
 - 3) Automated dispensing and storage systems utilized at a facility shall operate under the same license as the pharmacy utilizing it.
 - 4) All records shall be maintained for a period of 5 years either at the pharmacy providing services to the facility or a central location where records are readily retrievable.
 - 5) Only pharmacies under common ownership may share an automated pharmacy system at a facility.
- 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;~~
 - 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;~~

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- ~~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 is using the device when the pharmacy is closed, that he or she may immediately direct any questions and concerns regarding the prescription to a licensed pharmacist via a pharmacy provided audio/video link;~~
 - ~~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.~~
 - ~~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.~~

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

(Source: Amended at 39 Ill. Reg. 6267, effective April 23, 2015)

SUBPART G: PHARMACY OPERATIONS

Section 1330.710 Reporting Theft or Loss of Controlled Substances

In every instance that a pharmacy is required by federal regulation (21 CFR 1301.76; [2014](#)) to file with the U.S. Drug Enforcement Agency a Report of Theft or Loss of Controlled Substances (Form 106), a copy shall concurrently be sent to the Division, Attention of the Drug Compliance Unit, along with the printed name of the person who signed the form. Failure to do so may result in discipline of the pharmacy or the pharmacist-in-charge.

(Source: Amended at 39 Ill. Reg. 6267, effective April 23, 2015)

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 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 in 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

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

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 med pak has been delivered to an institution, a patient, or a patient's agent, the drugs in the med pak can be accepted for return by the pharmacy only when a medication must be added or removed, or when drug therapy is discontinued. Med paks returned to the pharmacy can only be re-dispensed for the same patient. Medications removed from the med pak shall not be reused and must be disposed of properly. The revised med pak shall be given a new serial number. ~~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) When a pharmacist utilizes drugs dispensed from another pharmacy in creating an initial med pack, that pharmacist shall bear full responsibility for the drugs as if dispensed from that pharmacy; otherwise, a pharmacy is prohibited from creating a patient med pak utilizing drugs dispensed from a different pharmacy.

(Source: Amended at 39 Ill. Reg. 6267, effective April 23, 2015)

Section 1330.750 Return of Drugs

- 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:

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- 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;
 - 3) ~~The~~ returns are properly documented; and
 - 4) ~~Obtaining~~ payment twice for the same drug is prohibited.
- 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.
- d) The provisions of subsection (a) shall not apply to drugs returned when the wrong medication was dispensed to the patient or in the instance of a drug recall. In no instance may returned drugs be reused or returned to active stock.

(Source: Amended at 39 Ill. Reg. 6267, effective April 23, 2015)

Section 1330.770 Centralized Prescription Filling

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

- a) Share a common electronic file to allow access to sufficient information necessary or required to fill or refill a prescription order.
- b) Maintain appropriate records to identify the responsible pharmacist in the dispensing process.
- c) Maintain a mechanism for tracking the prescription drug order during each step in the process.

(Source: Amended at 39 Ill. Reg. 6267, effective April 23, 2015)

Section 1330.780 Change of Ownership of a Pharmacy

- a) A new pharmacy application must be filed whenever:

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- ~~1)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
- ~~2)b)~~ ~~More~~ ~~more~~ than half the board of directors or executive officers of a business issued a pharmacy license change.
- b) Any change of ownership of a parent company that owns a pharmacy shall not be considered a change of ownership of the pharmacy.

(Source: Amended at 39 Ill. Reg. 6267, effective April 23, 2015)

Section 1330.790 Closing a Pharmacy

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

- a) Provide notice to the Drug Compliance Unit of ~~Notify~~ the Division, in writing, postmarked at least 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

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

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.

(Source: Amended at 39 Ill. Reg. 6267, effective April 23, 2015)

Section 1330.800 Pharmacy Self-Inspection

Every licensed pharmacy shall conduct an annual self-inspection using forms provided by the Division. The annual self-inspection shall be conducted during the same month, annually, as determined by the pharmacy. Documentation of the self-inspection shall be maintained at the pharmacy for 5 years. The primary objective of the self-inspection is to create an opportunity for a pharmacy to identify and correct areas of noncompliance with State and federal law. This includes, but is not limited to, recordkeeping, inventory, labeling and sanitation requirements.

(Source: Added at 39 Ill. Reg. 6267, effective April 23, 2015)