COMPLIANCE CAPSULE *with* IDFPR

Quarterly Newsletter

Illinois Department of Financial and Professional Regulation

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UPDATES TO THE ADMINISTRATIVE CODE

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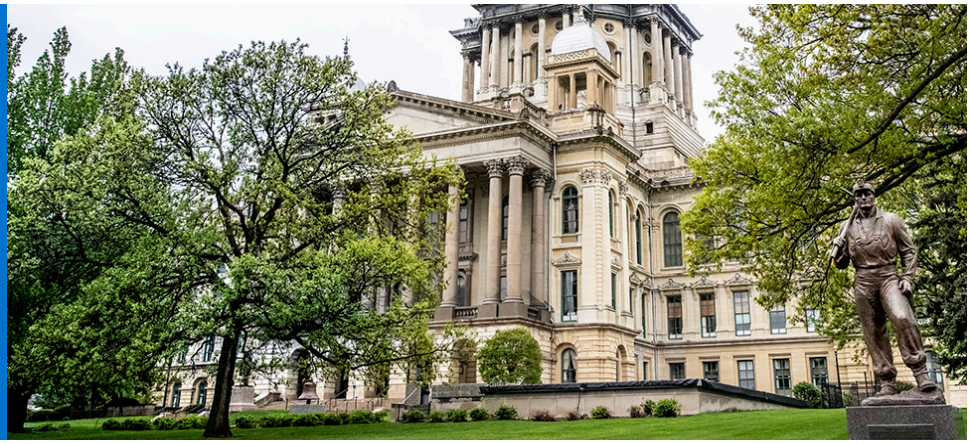
UPDATES TO THE ADMINISTRATIVE CODE



Effective June 2, 2023, the following sections have been updated to the Administrative Code (1330) to the Pharmacy Practice Act.

Bolded text has been added or amended. Strikethrough sections have been eliminated.

Section 1330.50 Vaccinations/Immunizations

a) Qualifications

1) A pharmacist, or a student pharmacist **or a pharmacy technician** under the direct supervision of a pharmacist, may administer vaccinations/immunizations to persons who are **7** ~~14~~ years of age or older pursuant to a valid patient specific prescription or a standing order by a physician licensed to practice medicine in all of its branches under the Medical Practice Act of 1987 [225 ILCS 60].

2) The pharmacist, **student pharmacist, or pharmacy technician** shall successfully complete a course of training accredited by the Accreditation Council on Pharmacy Education, or a similar health authority or professional body approved by the Division. **The pharmacist who is responsible for supervising the pharmacy student or pharmacy technician has the sole responsibility of evaluating the appropriateness of each vaccination prior to its administration and maintains full responsibility and oversight of the process.**

5) The administration of vaccines shall be done by a pharmacist, or a student pharmacist or **pharmacy technician** under the direct supervision of a pharmacist, **who has completed training as described in this Section.**

b) Protocols, Policies and Procedures

1) Prior to administrating vaccinations/immunizations, a pharmacist, or a student pharmacist or **a pharmacy technician** 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.

3) The pharmacist, student pharmacist, **or pharmacy technician** 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 **7** ~~10 and older for influenza and Tdap, age 14 and older for all other vaccines~~) patient's parent or legal representative is available and has the vaccine information statement

c) Recordkeeping and Reporting

2) A pharmacist who administers or **oversees the administration** of any vaccine must **ensure**

that the report of that administration, **is made** ~~within 30 days after the date of administration~~ **to the Illinois Comprehensive Automated Immunization Registry Exchange (I-CARE)** or to the primary healthcare provider named by the patient **within 30 days of administration**

1330.230 Continuing Education (CE) for Certified Pharmacy Technicians

a) CE Requirements

1) Number of Hours of CE Required

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

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

2) Required Topics for CE

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

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

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

b) Approved CE

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

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

c) Certification of CE Requirements

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

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

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

e) Waiver of CE Requirements

1) Any renewal applicant seeking to renew their license without having fully complied with these CE requirements shall file with the Division a renewal application, along with the

required fee, a statement setting forth the facts concerning noncompliance and a request for waiver of the CE requirements with facts explaining the basis of the request. A request for waiver shall be made prior to the renewal date. If the Division, upon the written recommendation of the Board, finds from the affidavit or any other evidence submitted that good cause has been shown for granting a waiver, the Division shall waive enforcement of the CE requirements for the renewal period for which the applicant has applied.

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

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

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

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

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

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

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

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

Section 1330.360 Pharmacy Residents

A pharmacy resident participating in a nationally accredited residency program is exempt from Section 15.1(a) of the Act to the extent the provision conflicts with the requirements of the nationally accredited residency program.

Section 1330.500 Community Pharmacy Services

b) Staffing of the Pharmacy

3) No prescription may be dispensed when a pharmacist is not physically present in the establishment ~~and on duty~~

c) Recordkeeping Requirements for Dispensing Prescription Drugs

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

Section 1330.510 Telepharmacy

b) Remote Dispensing Site

1) Written prescriptions presented to the remote dispensing site shall be scanned into the electronic data processing equipment to ensure initial dispensing and each refill and the original prescription may be viewed on the monitor at both the remote dispensing site and home pharmacy site. ~~Unless otherwise provided by federal law, written prescriptions shall be delivered to the home pharmacy for filing within 72 hours,~~ Records shall be maintained at **the remote dispensing site**

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

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

~~B) All records must be maintained at the home pharmacy~~

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

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

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

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

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

Section 1330.520 Offsite Institutional Pharmacy Services

a) Pharmacies that are not located in the facilities they serve and whose primary purpose is to provide services to patients or residents of facilities licensed under the Nursing Home Care Act, the Hospital Licensing Act, the University of Illinois Hospital Act, **or the Illinois Department of Human Services** shall, in addition to any other requirements of the Act and this Part, comply with this Section.

b) Recordkeeping Requirements for Dispensing Prescriptions or Orders

1) Every prescription or order dispensed shall be documented with the name, initials or other unique identifiers of the pharmacist (and **student pharmacist or** pharmacy technician if one is used) authorized to practice pharmacy under the provisions of the Act who dispenses the prescription or order. For purposes of the Act, an authorized person is

4) No prescription may be filled or refilled for a period in excess of **15 months** ~~one year~~ from the date of the original issuance of the prescription or order by the prescriber

Section 1330.530 Onsite Institutional Pharmacy Services

a) **Onsite Pharmacies. A pharmacy** located in facilities licensed under the Nursing Home Care Act, the Hospital Licensing Act, or the University of Illinois Hospital Act, or that are operated by the Department of Human Services or the Department of Corrections, and that provide pharmacy services to residents, patients, employees, prescribers and students of these facilities, shall, in addition to other requirements of the Act and this Part, comply with this Section.

b) Recordkeeping Requirements

2) No prescription may be dispensed for a period in excess of **15 months** ~~one year~~ from the date of the original issuance of the prescription by the prescriber

d) Staffing the Pharmacy

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

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:

ii) Only **registered, certified, and licensed individuals under this Part** ~~registrants and licensees~~ shall have access to the pharmacy, except as provided in Section 1330.530(e)(1);

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:

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 ~~physicians~~ order **by a practitioner** ~~of a physician~~ **licensed to prescribe** ~~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 **licensed practitioner's** ~~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.

Section 1330.610 Pharmacy Structural/Equipment Standards

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

Section 1330.700 Patient Counseling

a) Upon receipt of a new or refill prescription, a prospective drug regimen review or drug utilization evaluation shall be performed. Prior to dispensing a prescription to a new patient, a new prescription ~~medication~~ to an existing patient, or a medication that has had a change in the dose, strength, route of administration or directions for use, the pharmacist, or a student pharmacist directed and supervised by the pharmacist, shall provide verbal counseling to the patient or patient's agent on pertinent medication information. An offer to counsel shall be made on all other prescriptions. Counseling shall include, but is not limited to:

Section 1330.720 Transfer of Prescription

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

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

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

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

Section 1330.760 Electronic Transfer of Prescriptions

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

e) The pharmacy has procedures in place for the cancellation of electronically transmitted prescriptions including the following:

1) A pharmacy using the National Council for Prescription Drug Program's SCRIPT standard for receiving electronic prescriptions must enable, activate, and maintain the ability to receive transmissions of electronic prescription cancellations and to transmit cancellation response transactions.

2) As soon as possible after the receipt of a prescription cancellation notification, no later than two business days after receipt of the notification, pharmacy staff must either review the cancellation transaction to ensure that the prescription has been deactivated or ensure that deactivation occurred automatically.

3) Policies and procedures to ensure that the discontinued medications are not dispensed to a patient by a pharmacist

Section 1330.765 Requirements for Enrollment in Automated Prescription Refill Program

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

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

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

c) Require that the patient or the patient's agent sign a statement that they consent to the enrollment in an automated prescription refill program for each medication for which they enroll.
d) Maintain a record of the patient's or the patient's agent's signatures showing that they consented to be enrolled in the automated refill program for each prescription in which they are enrolled.

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

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

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

1) **50%** ~~10%~~ or more of the ownership of the business, other than a publicly traded business, to which the pharmacy license ~~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;

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

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

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

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

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

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

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

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

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

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

CHANGING LOCATION OF A FACILITY

The Department continues to discover licensees (including Pharmacy, Wholesale Drug Distributor, and Controlled Substance) that have moved to the new location after submitting an application, but prior to an inspection of the new facility. An inspection of the new facility ***is required*** prior to moving per the following:

Pharmacies: Per 1330.400 a) 2) provides; Upon determination that the application is in good order, an inspection of the premises will be conducted to determine compliance with Sections 1330.610, 1330.620, 1330.630, 1330.640 and 1330.680. An application shall be in good order when it is signed and notarized, and the license of the pharmacist-in-charge has been verified to be in good standing with the Division.

Wholesale Drug Distributors: Per 225 ILCS 120/25 (d) (1); (d) The Department may not issue a wholesale distributor license to an applicant, unless the Department first:

(1) ensures that a physical inspection of the facility satisfactory to the Department has occurred at the address provided by the applicant, as required under item (1) of subsection (b) of this Section;

Controlled Substance Licenses: Per 720 ILCS 570/303 (a) The Department of Financial and Professional Regulation shall license an applicant to manufacture, distribute or dispense controlled substances included in Sections 202, 204, 206, 208, 210 and 212 of this Act or purchase, store, or administer euthanasia drugs unless it determines that the issuance of that license would be inconsistent with the public interest. In determining the public interest, the Department of Financial and Professional Regulation shall consider the following:

(1) maintenance of effective controls against diversion of controlled substances into other than lawful medical, scientific, or industrial channels;

(2) compliance with applicable Federal, State and local law;

(7) whether the applicant is suitably equipped with the facilities appropriate to carry on the operation described in his or her application;

(9) any other factors relevant to and consistent with the public health and safety; and

CLOSING A PHARMACY

The Drug Compliance Unit must be notified by a licensee 30 days prior to the closure of a pharmacy. Per 1330.790, when a pharmacy intends to close, the following procedures must be followed:

a) Provide notice to the Drug Compliance Unit of 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 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.

All notifications for closing a pharmacy may be made utilizing the reporting tab found on the IDFPR Pharmacy webpage at https://idfpr.illinois.gov/profs/pharm.html

OPENING A NEW PHARMACY

The Drug Compliance Unit has conducted many new community pharmacy inspections where deficiencies were discovered. When this occurs, it can significantly delay issuance of the new license. Once the Drug Compliance Unit receives the approved application the pharmacy will be sent a questionnaire. The applicant needs to thoroughly review the questionnaire to assure the facility is compliant with all the identified requirements. In preparing your community pharmacy, please assure compliance with the following rules:

1330.30 (k), 1330.700 (c), 3100.310 (e), 1330.610 (d), 1330.610 (f), 1330.500 (h), 1330.630 (c), 1330.640 (e), 1330.610 (b), 3100.310 (d), 3100.340 (a)

The provided list may not be inclusive of all the requirements necessary to open a new pharmacy. Each applicant should take the time to review all pharmacy regulations to assure compliance.

REPORTING THEFT OR LOSS OF CONTROLLED SUBSTANCES

The U.S. Drug Enforcement Administration ("DEA") published the final rule for reporting theft or loss of controlled substances and became effective on 7/24/2023. The following are the highlights:

1) The initial notification of any theft or significant loss to the local DEA Field Office within one (1) business day remains in effect.

2) As of the effective date paper 106 forms will no longer be accepted. All reports must be filed electronically through the DEA's online portal.

3) DEA 106 forms must be submitted to the DEA within 45 days after discovering the theft or loss.

Reporting to the Illinois Drug Compliance Unit should follow 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 a Report of Theft or Loss of Controlled Substances (Form 106) with the DEA, a copy must also be sent be sent to the Illinois Division of Professional Regulation, 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.

The initial and completed DEA 106 form notification may be made utilizing the reporting tab found on the IDFPR Pharmacy webpage at https://idfpr.illinois.gov/profs/pharm.html

PHARMACY BURGLARIES

The Drug Compliance Unit would like to make licensees aware of recent community pharmacy burglaries over the last few months. Each community pharmacy should assess the overall facility security, alarm systems, and secure storage locations.

A review of the reported 106 forms demonstrates safes have been a significant deterrent to significant CII controlled substance losses in these recent burglaries. The Drug Compliance Unit strongly urges the use of safes for CII storage.

NEW CITATION FORM COMING

The Drug Compliance Unit will be rolling out a new citation form. Violations identified during an inspection or investigation may result in a pharmacist or pharmacy receiving a citation. A corrective action plan will also be required for all violations resulting in a citation.

The Drug Compliance Unit recommends that pharmacy owners and the pharmacist-in-charge of each pharmacy review the pharmacy statutes and rules to assure compliance.

CONTACT US

Have questions about Pharmacy professions in Illinois? Contact us by going here:

https://idfpr.illinois.gov/profs/email/prfgrp10.html

State of Illinois
Illinois Department of Financial and Professional Regulation

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