COMPLIANCE CAPSULE *with* IDFPR

Quarterly Newsletter

Illinois Department of Financial and Professional Regulation



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IDFPR LAUNCHES NEW ONLINE PROFESSIONAL LICENSING SYSTEM

CORE
Comprehensive Online Regulatory Environment

On October 30, the Illinois Department of Financial and Professional Regulation (IDFPR) announced the launch of the Comprehensive Online Regulatory Environment (CORE), its new online licensing system, for the first set of IDFPR-licensed professionals. The new online process eliminates the need for paper applications, gives applicants more control over their application materials, and helps prevent deficient applications from being submitted. In addition to creating a streamlined online application process, CORE features a simplified review process for all license applications received by IDFPR.

The launch of CORE marks the first completed step of a planned, multiphase approach by IDFPR over the next two years that will ensure applications for more than 300 license types and records for more than 1.2 million professionals are properly transitioned. CORE is a result of IDFPR's work with Tyler Technologies, a leading provider of integrated software and technology services for the public sector. CORE is built on their State Regulatory Platform Suite, which allows regulatory agencies like IDFPR to oversee professional and occupational licenses.

New applicants seeking initial licensure for three license types (clinical psychologists, nail technicians, and music therapists) can now submit their applications online using CORE. IDFPR selected these three license types to test and ensure CORE's functionality, while preparing to add all other professions licensed by IDFPR across five additional phases over the next two years. The next phases are:

Phase 1	Three pilot professions added to test system functionality. New applications only for clinical psychologists, nail technicians, and music therapists. This phase was completed on ***October 30, 2024.***
Phase 2	Add all remaining Division of Professional Regulation (DPR) professions with manual or paper processes, with a priority on healthcare professions. This phase will be for new applications only.
Phase 3	Full regulatory transition for DPR.
Phase 4	Full regulatory transition for the Division of Real Estate.
Phase 5	Full regulatory transition for the Division of Banking.
Phase 6	Full regulatory transition for the Division of Financial Institutions.

To create a streamlined review process, CORE features a user-friendly interface with improved communications. Prospective licensees will be notified directly within the system when applications are received, reviewed, and licenses are issued by the Department—eliminating the need for paper mail and email responses from the Department. In addition, enforcement services (including complaint intake and review, document tracking, and investigations) will be transitioned to CORE. IDFPR will make user guides available online as more services are added to CORE, while continuing its diligent work in reviewing and issuing licenses to qualified applicants under its current processes.

IDFPR will make an announcement when each CORE implementation phase is completed. More information about professional licensing in Illinois may be found on IDFPR's website: idfpr.illinois.gov.



RULES UPDATE 2024

New rules for the Illinois Pharmacy Practice Act became effective on June 28, 2024. These rules were adopted in order to allow for the Department, applicants, and licensees to properly function under the Act. The addition of certified pharmacy technician programs to these rules were added per statutory requirement. The remaining updates and clarifications made within these amendments help to reduce regulatory burdens by simplifying the application and renewal processes for both the Department and the professionals it serves. The updates are provided below, with the shaded portions identifying the changes.

Section 1330.215 Minimum Standards for Approved Work Experience Pharmacy Technician Certification

A pharmacy technician certification program shall meet the following requirements:

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

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

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

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

e) A graduate shall be competent in:

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

2) Functioning in a variety of pharmacy practice settings; and

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

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

1) Knowledge and Skills:

A) Ethics;

B) Conflict resolution;

C) Customer service;

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

E) Self-management skills; and

F) Problem solving.

2) Continuing Competency:

A) Continuing education;

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

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

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

E) Infection control procedures;

F) Protocols for vaccine administration;

G) Common allergies; and

H) Hygiene, personal protection equipment (PPE), cleaning and maintaining equipment.

3) Medication Orders:

A) Medication storage;

B) Medication ordering;

C) Recordkeeping;

D) Medication labeling;

E) Special handling procedures;

F) Prescription entry and interpretation;

G) Generic/brand names;

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

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

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

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

L) Purchasing pharmaceuticals, devices, and supplies;

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

N) Administration of immunizations and other injectable medications;

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

P) Dosage forms.

4) Patient Care:

A) Pharmacy technicians' role under the Joint Commission of Pharmacy Practitioners' Pharmacists' Patient Care Process;

B) Patient and medication safety practices;

C) Emergency patient situations;

D) Medication reconciliation process;

E) Medication management services;

F) Measurements, preparation, and packaging;

G) Point of care testing;

H) Patient confidentiality;

I) Error prevention;

J) Safety event reporting; and

K) Different insurance plan types, coupons, and prior authorizations.

5) Regulatory Knowledge:

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

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

C) Occupational Safety and Health Administration (OSHA) requirements;

D) USP requirements, including USP 795 and 797 training;

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

F) The Joint Commission;

G) Risk Evaluation and Mitigation Strategies (REMS);

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

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

J) Facility maintenance; and

K) Medication disposal.

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

h) All programs accredited by the Accreditation Council for Pharmacy Education (ACPE) and the American Society of Health System Pharmacists (ASHP) meet

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 the individual:

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

2) Has attained the age of 18;

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

4) Graduated from a pharmacy technician training program approved by the Accreditation Council for Pharmacy Education (ACPE) or the American Society of Health System Pharmacists (ASHP) or obtained documentation from the pharmacist-in-charge of the pharmacy where the applicant is employed verifying that the applicant has successfully completed equivalent work experience of 500 hours as a pharmacy technician covering the practice areas set forth in Sections 17.1(a)(1) through (6) of the Act, or successfully completed work experience as provided for in Section 1330.215;

Section 1330.330 Examination for Licensure

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

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

Section 1330.400 Application for a Pharmacy License

c) Within 180 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 after the reduction in hours take effect.

Section 1330.410 Pharmacy Licenses

e) When a third-party company is hired to run a pharmacy, that third-party company shall be the license holder; however, the license may be issued with the name of the pharmacy, as a d/b/a, or with the name of the third-

party company. The Illinois Controlled Substance license shall be issued to the third-party company unless the third-party company and the pharmacy or hospital cosigns a pharmacy service agreement that assigns overall responsibility for controlled substances to the hospital or pharmacy.

Section 1330.550 Nonresident Pharmacies

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

Section 1330.640 Pharmaceutical Compounding Standards

No person shall compound, or sell or offer for sale, or cause to be compounded, sold or offered for sale any medicine or preparation under or by a name recognized in the United States Pharmacopoeia National Formulary, for internal or external use, which differs from the standard of strength, quality or purity as determined by the test laid down in the United States Pharmacopoeia National Formulary official at the time of such compounding, sale or offering for sale. (Section 25 of the Act) All pharmaceutical compounding standards, both sterile and nonsterile, shall be governed by the official USP-NF (USP 47-NF 42), as set forth in the 2024 edition of United States Pharmacopoeia (USP), 47th Revision and the National Formulary, 42nd Edition, Compounding Compendium, with the exception of USP Chapter <800> as it pertains to the handling of hazardous drugs in health care settings. ~~Beginning May 1, 2019, all pharmaceutical compounding standards, both sterile and nonsterile, shall be governed by the USP-NF (USP 42-NF 37), as set forth in the 2019 edition of the USP Compounding Compendium, with the exception of USP Chapter <800> as it pertains to the handling of hazardous drugs in health care settings.~~

Section 1330.660 Pharmacist-in-Charge

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

Section 1330.680 Automated Dispensing and Storage Systems

b) Automated Dispensing and Storage Systems

6) All medications stored in the automated dispensing and storage systems shall be packaged as a unit of use for single patient use (e.g., unit dose tab/cap, tube of ointment, inhaler, etc.) and labeled as specified in this subsection (b)(6):

C) Exceptions to the “unit of use” requirements in this subsection (b)(6) are as follows:

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

Section 1330.720 Transfer of Prescription

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

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

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

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

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

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

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

Section 1330.765 Requirements for Enrollment in Automated Prescription Refill Programs

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

a) Require that the patient or patient's agent agree to be enrolled in the automated refill program for each prescription medication that the patient has been prescribed.
b) Ensure that only prescriptions with valid refills are ~~which include an instruction from the prescribing health care provider that the medication can be refilled and be~~ eligible for the pharmacy's automatic refill program.
c) Ensure prescriptions enrolled in the pharmacy's automatic refill program do not conflict with any other applicable federal or State regulations.

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

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

1) 50% or more of the ownership of the business, other than a publicly traded business, to which the pharmacy license was issued is sold or otherwise transferred to a person or entity that does not hold any interest in the business issued the pharmacy license prior to the sale or transfer;
2) More than half the board of directors or executive officers of a business issued a pharmacy license changes;
3) Any change in the legal status of an entity (e.g., individual, partnership, corporation, limited liability company);
4) Any change in location of a pharmacy, ~~including remodel of the pharmacy or drug storage area;~~
5) Any change in the name of a pharmacy; or
6) Any addition to ~~change in~~ the pharmacy operations ~~pursuant to Subpart E of this Part or the Act.~~

Section 1330.790 Closing a Pharmacy

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

a) Provide notice to the Drug Compliance Unit of the Division, in writing, no later than ~~postmarked at least~~ 30 days after closure of the pharmacy ~~in advance of the closing date.~~
h) If a pharmacy intends to close temporarily for more than 72 hours, the following procedures must be followed:

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

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

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

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

STATUTE UPDATE

Effective August 2, 2024, it will be a violation of the Illinois Controlled Substance Act for a pharmacist to refuse a controlled substance prescription solely because it is not prescribed electronically. 720 ILCS 570/311.6 has been amended as follows (shaded portion):

(e) Any pharmacist who dispenses in good faith based upon a valid prescription that is not prescribed electronically may be exempt from any disciplinary action. A pharmacist is not required to ensure or responsible for ensuring the prescriber's compliance under subsection (b), nor may any other entity or organization require a pharmacist to ensure the prescriber's compliance with that subsection. A pharmacist may not refuse to fill a valid prescription solely because it is not prescribed electronically.

REMOTE PRESCRIPTION/ MEDICATION ORDER PROCESSING



IDFPR has learned that pharmacies are performing Remote Prescription/Medication Order Processing without proper licensure.

Administrative Code 1330.400 a) 1) provides: 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.

Any pharmacy performing functions described in 1330.560 must maintain a Remote Prescription/ Medication Order Processing license.

WEBSITE UPDATES



Self-Inspection Forms

IDFPR recently completed a review and update of the Self-Inspection Forms found on our website. The process of adding the forms to the website is underway and will be completed over the next few weeks. The Department recommends you download the form(s) you need at the time of inspection to ensure the pharmacy is utilizing the most current form(s).

Pharmacy Closure Form

A pharmacy closure form has been added to the Department's website to assist licensees through the pharmacy closure process. Although not required, IDFPR encourages use of this form.

Pharmacy Services Provided by Third-Party Company

The Department discovered pharmacy owners are contracting out pharmacy operations to third-party companies where the pharmacy owner remains the license holder. Section 1330.410 e) provides:

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

Please ensure your pharmacy is compliant with this regulation.

CONTACT US

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

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