



COMPLIANCE CAPSULE *with* **IDFPR**

Quarterly Newsletter

Illinois Department of Financial and Professional Regulation

WINTER 2024

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INTRODUCING IDFPR'S NEW DEPUTY SECRETARY

Ericka Johnson serves as the Deputy Secretary of the Illinois Department of Financial and Professional Regulation (“IDFPR”). She is a principal advisor to the Secretary, where she assists in developing and implementing policies, goals, and strategies for the agency’s four divisions.

Prior to this role, Johnson served as Deputy Director of the Division of Real Estate at IDFPR, where she managed and led multiple executive-level projects. Johnson spearheaded the creation of the Division of Real Estate’s “How to Series,” an interactive workshop that tours the state to teach new and diverse candidates how to enter the appraisal profession with the goal of fostering diversity and reducing barriers to licensure.

Johnson also previously served as the Chief of Real Estate Prosecutions at IDFPR, where she led a team of talented attorneys, resulting in a sharp reduction in pending license law violation cases by more than 65%.

Prior to her arrival at IDFPR in 2018, Johnson was a career litigator with over a decade and a half of experience in the courtroom, representing the People of the State of Illinois at the Cook County State’s Attorney’s Office.

Johnson earned her Juris Doctor from Northwestern University, Pritzker School of Law (2003) and her Bachelor of Arts in Government, with honors, from The University of Texas at Austin (2000), where she was on the trial team. Johnson is a member of the Illinois State Bar (2003) and the United States District Court, Northern District of Illinois, General Bar (2003). She is also a member of the Association of Real Estate License Law Officials (“ARELLO”), where she currently serves on the Fair Housing Committee, and is a member of the Association of Appraisal Regulatory Officials (“AARO”).



INTRODUCING IDFPF'S NEW DIRECTOR OF PROFESSIONAL REGULATION

Camile Lindsay was appointed Acting Director of the Division of Professional Regulation (DPR) for the Illinois Department of Financial and Professional Regulation effective October 16, 2023. In this role, Lindsay manages the licensing, enforcement, and oversight of more than a million professionals over 70 professions and more than 200 license types.

Before joining IDFPF, Lindsay served as First Assistant Deputy Governor for infrastructure, public safety, environment, and energy in the Pritzker Administration. Her portfolio included overseeing several Illinois state agencies, including the Department of Transportation, State Police, Department of Corrections, Emergency Management Agency, and the Capital Development Board. Prior to joining the Governor's office, Lindsay served as Chief of Staff and Chief Legal Counsel for the Illinois Department of Corrections. Earlier in her career, she worked as Supervisory Regional Counsel for the Illinois Department of Children and Family Services, Assistant Attorney General for the Illinois Attorney General's office, and Assistant State's Attorney for the Cook County State's Attorney's office.



Lindsay has also completed multiple leadership programs, including Edgar Fellows, Leadership Greater Chicago, Chicago Urban League's Impact Leadership Development Program, and the Chicago Foundation for Women Willie's Warriors program. She is currently Vice-President of the board of directors for Housing Forward, an organization dedicated to eradicating homelessness and is a member of several bar associations.

Lindsay earned her Bachelors and Masters degrees from the University of Illinois at Chicago and her Juris Doctor degree from the University of Illinois Urbana-Champaign College of Law. In 2022, Lindsay was recognized by the University of Illinois at Chicago Department of Criminology, Law, and Justice as Alumni of the Year.



NEW ELECTRONIC PRESCRIBING REQUIREMENT

The Illinois Controlled Substance Act (720 ILCS 570/311.6) has been amended to include requirements and exceptions for mandatory electronic prescriptions that became effective January 1, 2024. See Public Act 103-0425. Learn more here: <https://ilga.gov/legislation/publicacts/103/PDF/103-0425.pdf>.

The Department has learned that there are pharmacies that are rejecting written prescriptions from prescribers and requesting copies of prescribers' "E-Prescription" waiver. IDFP is not issuing such waivers. IDFP is not issuing such waivers and pharmacies are not required to keep track of written prescriptions from prescribers.

Important points in the rule include:

- An electronic prescription is not required when:
 - Prescribers have obtained a hardship waiver from the mandatory electronic prescription requirements.
 - There is a temporary technological or electrical failure that prevents an electronic prescription from being issued.
 - The prescription is for a drug that the practitioner reasonably determines would be impractical for the patient to obtain in a timely manner if prescribed by an electronic data transmission prescription and the delay would adversely impact the patient's medical condition.
 - The prescription is for an individual who:
 - Resides in a nursing or assisted living facility.
 - Is receiving hospice or palliative care.
 - Is receiving care at an outpatient renal dialysis facility and the prescription is related to the care provided.

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- Is receiving care through the United States Department of Veterans Affairs.
- Is incarcerated in a state, detained, or confined in a correctional facility.
- o The prescription prescribes a drug under a research protocol.
- o The prescription is a non-patient specific prescription dispensed under a standing order, approved protocol for drug therapy, collaborative drug management, or comprehensive medication management, or in response to a public health emergency or other circumstance in which the practitioner may issue a non-patient specific prescription.
- o The prescription is issued when the prescriber and dispenser are the same entity.
- o The prescription is issued for a compound prescription containing two or more compounds.
- o The prescription is issued by a licensed veterinarian within two years after the effective date of this amendatory Act of the 103rd General Assembly.
- o Prior to January 1, 2029, the practitioner does not prescribe more than 150 controlled substance prescriptions during a 12-month period. After January 1, 2029, the practitioner prescribes not prescribe more than 50 controlled substance prescriptions in a 12-month period.

Pharmacists' Responsibility:

- 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) of 720 ILCS 570/311.6, nor may any other entity or organization require a pharmacist to ensure the prescriber's compliance with that subsection.
- If a pharmacist believes that a paper prescription is valid and written in good faith the pharmacist may fill the paper prescription.

Continuing Education Reminder

Remember, two (2) hours of continuing education for the administration of vaccines must be completed within each State licensing period.

Pharmacist requirements for required vaccine specific continuing education can be found under 225 ILCS 85/3 (15) (E) of the Act:

the pharmacist must complete, during each State licensing period, a minimum of 2 hours of immunization-related continuing pharmacy education approved by the Accreditation Council on Pharmacy Education;

Pharmacy technician and Student Pharmacist requirements for vaccine specific continuing education can be found under ILCS 85/9.6 (a) (5) of the Act:

the pharmacy technician or student pharmacist must complete, during the relevant licensing period, a minimum of 2 hours of immunization-related continuing pharmacy education that is approved by the Accreditation Council for Pharmacy Education;

Additional information may be found on IDFPR's Pharmacy profession webpage [here](#).

UPDATED PHARMACY TECHNICIAN TRAINING REQUIREMENTS



225 ILCS 85.9.5 has been published, updating the training requirements of a pharmacy technician. The statute became effective January 1, 2023. The rule, 1330.215, supporting the change in the Act has been drafted and it is moving through the approval process.

Proposed rules for the new statute are now being considered. The proposed rules may be found in the Illinois Register with the Secretary of States Office issued December 15, 2023 by going here: https://www.ilsos.gov/departments/index/register/volume47/register_volume47_50.pdf.

CONTROLLED SUBSTANCE TRANSFER FOR PURPOSE OF INITIAL FILL

The U.S. Drug Enforcement Administration's published final rule (21 CFR 1306.08) became effective on August 28, 2023 and allows for the transfer, for the purpose of initial fill, of electronic prescriptions for Schedule II-V controlled substances. The rule applies to the transfer for initial fill on a one-time transfer basis upon request from the patient.

Rule 1330.720 currently allows for the transfer of schedule III-V controlled substances for purpose of initial fill. An updated version of the rule has been drafted to include schedule II drugs. The proposed rule can be found in the Illinois Register with the Secretary of States Office issued December 15, 2023.

The Department defers to the DEA for specific security requirements to allow transfers of scheduled medication for purpose of original fill.



REMINDER OF DSCSA REQUIREMENT FOR PHARMACIES

The Department would like to assure all pharmacies are following Drug Supply Chain Security Act (DSCSA) requirements for the receipt and distribution of drugs. Dispenser requirements can be found under Title II of the DQSA Section 202 (d) by going here: <https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act>.

Pharmacies should only distribute or receive FDA approved drugs to/from Authorized Trading Partners.

Upon receipt, pharmacies must receive all required transaction information from the authorized trading partner providing the drugs. The pharmacy may enter into an agreement with a third party under which the third party confidentially maintains all the required transaction information on behalf of the pharmacy. If the pharmacy enters into such an agreement, the dispenser shall maintain a copy of the written agreement, however this does not relieve the dispenser of the obligation to comply with this requirement.

A pharmacy distributing legend drugs must provide the required transaction information to the receiving Authorized Trading Partner unless the drug is transferred to another pharmacy for a specific patient need.

Pharmacy should also be familiar with the process for reporting suspect product to the FDA.

CONTRACTED PHARMACY SERVICES



When pharmacy owners contract out pharmacy services to third party vendors to operate and run the day-to-day activities of the pharmacy, rule 1330.410 e) provides:

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 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.

You may find the link online by going here: <https://www.ilga.gov/commission/jcar/admincode/068/068013300D04100R.html>.

SELF-INSPECTION FORMS

The Self-inspection forms must be completed on the same month annually. Always download the self-inspection form from the Department's website at the time of inspection to ensure the is utilizing the most up to date form. All self-inspection forms for each pharmacy profession may be found here: <https://idfpr.illinois.gov/profs/pharm.html>.

A compliance issue has been identified where pharmacies are not completing all the necessary self-inspection forms. Pharmacies must complete a self-inspection form for each type of pharmacy operation conducted at the licensed location. An example would be if a retail pharmacy conducting non-sterile compounding needing to complete the community and non-sterile compounding self-inspection forms.

CONTACT US

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

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

