



# **Illinois Department of Financial and Professional Regulation**

## **Division of Professional Regulation**

### **FAQs for Community Pharmacies**

The following information is provided by the Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation (“Department”) for reference only. Please refer to the specific regulation for an official and complete version of the law.

#### **1. What state and federal laws apply to Illinois-licensed pharmacies?**

- [Pharmacy Practice Act](#) 225 ILCS 85/et seq. and [Administrative Rules](#) 68 IAC 1330/et seq.
- [Illinois Controlled Substances Act](#) 720 ILCS 570/et seq. and [Administrative Rules](#) 77 IAC 3100/et seq.
- [Hypodermic Syringes and Needles Act](#) 720 ILCS 635/et seq.
- DEA – [Title 21 Code of Federal Regulations](#) 21 CFR Section 1300-END
- DEA – [Title 21 USC Controlled Substance Act](#)
- DEA – [DEA Pharmacist’s Manual \(2010\)](#)
- FDA – [Title 21 Code of Federal Regulations](#) 21 CFR Section 100-END
- Compounding – [United States Pharmacopeia](#) (USP)

*Please be aware additional laws may apply and this list is provided for guidance only.*

#### **2. When does the Department inspect or investigate a pharmacy?**

Drug Compliance Officer/Investigators for the Department may inspect/investigate a pharmacy due to, but not limited to, the following reasons:

- New Pharmacy
- Change of Address
- Change of Ownership
- Routine (Unannounced)
- Addition/Change of Designation (Operation)
- Sterile Compounding
- Non-Sterile Compounding
- Complaint
- Follow-up to Theft/Loss Report
- Temporary Pharmacy/Remodel
- Pharmacy Closing

*Please be aware inspections may be required in other instances and this list is provided for guidance only.*

#### **3. What is a Self-Inspection Report and how often must it be completed?**

- Every licensed pharmacy shall conduct an annual self-inspection using forms provided by the Division. Completing the Self-Inspection Report helps pharmacies identify and correct areas of noncompliance. ([Title 68 Administrative Code Section 1330.800](#))

#### **4. When is a pharmacy required to notify the Department?** A pharmacy is required to provide notice to the Department under the following circumstances:

- Additional/Change of Designation to Pharmacy License (For example for Sterile Compounding – Please refer to [Title Administrative Code Section 1330.640](#))
- Change in Hours of Operations – Please refer to [Title 68 Administrative Code Section 1330.400](#)
- Change of Pharmacist-In-Charge (PIC) – Please refer to [Title 68 Administrative Code Section 1330.660](#)
- Closing of Pharmacy – Please refer to [Title 68 Administrative Code Section 1330.790](#)

- Loss/Theft of Controlled Substances Reporting (DEA 106 Form) – Please refer to [Title 68 Administrative Code Section 1330.710](#)
    - i. Pharmacist Personnel Termination Report – Please refer to [225 ILCS 85/30.1](#). Please complete the Pharmacist Personnel Termination Report available on IDFPR’s Pharmacy Page. The pharmacy or pharmacist in charge, pursuant to the policies and procedures of the pharmacy, must file this report with the Department when a pharmacist, registered certified pharmacy technician, or a registered pharmacy technician licensed by the Department is terminated for actions which may have threatened patient safety.
    - ii. This report must be filed within sixty (60) days after a pharmacy’s determination that a report is required under the Act.
  - Remodeling – Please refer to [Title 68 Administrative Code Section 1330.610](#)
- Please be aware additional notifications may be required and this list is provided for guidance only.*

**5. Can I be a pharmacist-in-charge (“PIC”) for multiple pharmacies? How many hours does a PIC need to work in a pharmacy?**

- 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 eight (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 ninety (90) days, a new pharmacist-in-charge must be designated ([Title 68 Administrative Code Section 1330.660](#))

**6. What should I do if I am no longer PIC?**

- You will need to fulfill all the requirements of a departing pharmacist-in-charge as indicated in [Title 68 Administrative Code Section 1330.660](#).

**7. How many days of notice must be given to the Department to close a pharmacy?**

- Provide notice via e-mail to [FPR.DrugComplianceUnit@illinois.gov](mailto:FPR.DrugComplianceUnit@illinois.gov) or via mail to the Drug Compliance Unit of the Division, in writing, at least thirty (30) calendar days in advance of the closing date ([Title 68 Administrative Code Section 1330.790](#)).

**8. Can a pharmacy return dispensed prescriptions from “will call” to stock if the patient never picks up the prescription?**

- Yes, ONLY if the patient’s information is removed from the pharmacy’s label and the Return to Stock Vial is placed in active stock with an expiration date not to exceed twelve (12) months from Fill Date ([Title 68 Administrative Code Section 1330.750](#)).

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*Controlled Substances*

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**9. Can a pharmacist refuse to dispense a controlled substance prescription?**

- Yes. A prescription for a controlled substance must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. ([Title 77 Administrative Code Section 3100.380](#)).

**10. Can I fill or refill a prescription from an out-of-state prescriber?**

- Notwithstanding any other provision of this Part, Illinois pharmacists may fill prescriptions for controlled substances issued by a practitioner actively licensed in another United States jurisdiction and who holds an

active Drug Enforcement Agency (“DEA”) registration in conformance with the Act and this Part ([Title 77 Administrative Code Section 3100.430](#)).

**11. How often does a pharmacy need to report controlled substance dispensing information to the Illinois Prescription Monitoring Program (“ILPMP”)?**

- The information required to be transmitted under 720 ILCS 570/316 must be transmitted no later than the end of the next business day after the date on which a controlled substance is dispensed, or at such other time as may be required by the Department and by administrative rule ([720 ILCS 570/316](#)).

**12. What changes cannot be made by a pharmacist to a Schedule II controlled substance prescription despite consulting with the prescriber?**

- A pharmacist may not change the following components of a prescription for a Schedule II controlled substance:
  - i. Date written, or add the date;
  - ii. Name of the patient;
  - iii. Name of the prescriber, or add a signature; and
  - iv. Name of the drug.
- Any other components of a prescription for a Schedule II controlled substance may be changed after consultation with the prescriber. ([Title 77 Administrative Code Section 3100.400](#))

**13. Can the quantity of the Schedule II controlled substance be only in numeric form?**

- No, all prescriptions issued for Schedule II controlled substances shall include both a written and numerical notation of quantity on the face of the prescription ([720 ILCS 570/309](#)).

**14. How often must a controlled substances inventory be completed? How long do controlled substances inventory records need to be kept?**

- Every licensee shall conduct an annual inventory that includes an actual count of drugs on hand for all Schedule II controlled substances and an approximate count for all Schedule III, IV and V controlled substances. The inventory shall be maintained for a period of no less than five (5) years. ([Title 77 Administrative Code Section 3100.360](#)).

**15. Does a controlled substance inventory have to be completed when there is a change in pharmacist-in-charge?**

- Yes, please refer to [Title 68 Administrative Code Section 1330.660](#).

**16. How many times can a controlled substance be transferred?**

- A prescription for Schedule III, IV and V drugs may be transferred only from the original pharmacy and only one time for the purpose of original fill or refill dispensing and may not be transferred further. However, a pharmacist who is electronically sharing real-time, on-line computerized systems may transfer up to the maximum number of refills permitted by law and the prescriber’s authorization in accordance with CFR 1306.26(a) ([Title 68 Administrative Code Section 1330.720 \(b\)](#)).

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*Patient Counseling*

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**17. When is a pharmacist, or student pharmacist directed and supervised by the pharmacist, required to counsel a patient?**

- A pharmacist, or student pharmacist directed and supervised by the pharmacist, must provide verbal counseling on pertinent medication information ([Title 68 Administrative Code Section 1330.700](#)):
  - i. Prior to dispensing a prescription to a new patient of the pharmacy;

- ii. Prior to dispensing a new prescription to an existing patient of the pharmacy; and
- iii. Prior to dispensing a medication where the dose, strength, route of administration, or directions for use has changed for an existing prescription previously dispensed to an existing patient of the pharmacy.

**18. If an existing patient is having a prescription refilled or reauthorized by a prescriber with no change in dose, strength, route of administration or directions for use, must the patient be offered counseling?**

- Yes. An offer to provide counseling must be made on all prescriptions where counseling is not mandated. Any registrant under the Illinois Pharmacy Practice Act may make the offer to counsel on behalf of a pharmacist, but if the patient requests counseling, only a pharmacist, or student pharmacist directed and supervised by the pharmacist, may provide patient counseling. ([Title 68 Administrative Code Section 1330.700](#)).

**19. Can I dispense a prescription to a patient if the patient declines counseling or simply refuses to be counseled?**

- Yes, but the patient's decision to refuse counseling must be documented in the pharmacy's records ([Title 68 Administrative Code Section 1330.700 \(g\)](#)).
- Be aware that attempting to circumvent patient counseling requirements or otherwise discouraging patients from receiving patient counseling concerning their prescription medications is considered unprofessional and unethical conduct.

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*Pharmacy Working Conditions*

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**20. Can a pharmacist, student pharmacist, or pharmacy technician work more than twelve (12) continuous hours per day?**

- No. A pharmacy shall not require a pharmacist, student pharmacist, or pharmacy technician to work longer than 12 continuous hours per day, inclusive of the required breaks. ([225 ILCS 85/15.1](#)).

**21. Can a pharmacy require a pharmacist to work more than five (5) continuous hours without a break?**

- No. Please refer to [225 ILCS 85/15.1\(b\)](#).

**22. Is a pharmacy required to close while a pharmacist is on break?**

- Sometimes. A pharmacy is not required to close when a pharmacist is on a break. If the pharmacy does not close, the pharmacist must either remain in the pharmacy or in the building to be available for emergencies. Please refer to [225 ILCS 85/15.1\(c\)](#).

**23. Is a pharmacy required to keep break records?**

- Yes. A pharmacy shall keep and maintain a complete and accurate record showing its pharmacists' daily break periods. [225 ILCS 85/15.1\(e\)](#).

*DISCLAIMER: All of the above questions and answers are provided for general information only and may not be completely accurate in every circumstance. The answers do not purport to be legal advice and are not intended to be legally binding on the Department in a particular case. Questions involving interpretation of the law and your legal rights and obligations should be directed to your lawyer.*