

Illinois Department of Financial and Professional Regulation
Division of Professional Regulation
Drug Compliance Unit
9511 Harrison Street, Suite 300, Des Plaines, IL 60016

Phone: (847) 294-4900

(Read this Page Carefully)

COMMUNITY PHARMACY

Pharmacy Self-Inspection Form

Illinois Law holds the Pharmacist-in-Charge (“PIC”) and all pharmacists on duty responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy.

The primary objective of this report, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. The inspection report also serves as a necessary document used by the Drug Compliance investigators during an inspection to evaluate a pharmacy’s level of compliance. When a Drug Compliance investigator discovers an area of non-compliance, he or she may issue either a Deficiency Notice or a Notice of Non-Compliance. Both require a written response from the PIC. Identifying or correcting an area of non-compliance prior to a Drug Compliance investigator inspection may eliminate the receipt of a Deficiency Notice/Notice of Non-Compliance for that item.

Failure to complete this report by the same month each year may result in Disciplinary Action. (Section 1330.800)

NOTE: Neither the self-inspection nor a Drug Compliance investigator inspection evaluates your complete compliance with all Laws and Rules of the practice of pharmacy. Further, nothing herein shall constitute a waiver of IDFPR enforcement discretion or constitute compliance with all applicable Laws and Rules governing the practice of pharmacy. This report is not final agency action and is intended as guidance. This report is not intended, nor can it be relied upon to create any rights enforceable by any party in litigation or in any enforcement action brought by IDFPR.

STATE OF ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
 DRUG COMPLIANCE UNIT
 9511 HARRISON STREET, SUITE LL 50
 DES PLAINES, IL 60016-1563

PHONE NUMBER: 847-294-4900

(KEEP CURRENT THROUGHOUT THE YEAR, AS NEEDED)

| COMMUNITY PHARMACY | | | | | | |
|--|------------------------------|--------------------------|--------------------------------|----------------|--------------------------------|--|
| BUSINESS NAME | HOURS | | DEA REGISTRATION NUMBER | EXPIRES | DATE OF SELF-INSPECTION | |
| | M | | | | | |
| | T | | | | | |
| | W | | | | | |
| ADDRESS | TH | | ICSA LICENSE NUMBER | EXPIRES | PHARMACY LICENSE NUMBER | |
| | F | | | | | |
| | SAT | | | | | |
| | SUN | | | | | |
| CITY | ZIP CODE | OTHER HOURS EXCEP | TELEPHONE | | | |
| | | | () | | | |
| OWNERSHIP <input type="checkbox"/> Individual pharmacist <input type="checkbox"/> Individual Non-pharmacist <input type="checkbox"/> Partnership <input type="checkbox"/> Corporation <input type="checkbox"/> LLC | OWNERS | | TELEPHONE AFTER HOURS | | PHARMACY E-MAIL ADDRESS | |
| | | | () | | | |
| | PHARMACIST- IN-CHARGE | | OWNER'S E-MAIL ADDRESS | | COUNTY | |
| | | | | | | |
| NAME OF LICENSEE (ALL PHARMACISTS and PHARMACY TECHNICIANS) | | | | | LICENSE NUMBER | |
| R Ph IN CHARGE | | | | | | |
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| If the Pharmacist in charge listed above is the PIC in other pharmacies, list here | | | |
|---|------|---------|--------------|
| | NAME | ADDRESS | PHONE NUMBER |
| 1. | | | |
| 2. | | | |

| QUESTION | YES | NO | N/A | AUTHORITY |
|--|-----|----|-----|---|
| GENERAL | | | | |
| The pharmacy's license is current and posted. | | | | 225 ILCS 85/15 |
| All required current licenses are posted in a conspicuous location in the pharmacy (pocket license or photocopy may be used when registrants are employed at multiple sites). | | | | 225 ILCS 85/15(5) |
| Pharmacy is compliant with Section 1330.500 of the Illinois Pharmacy Practice Act Rules, Community Pharmacy Practice. | | | | 68 Administrative Code Section 1330.500 |
| The PIC has personally reviewed the licenses of all registrants and determined that they are current. | | | | 68 Administrative Code Section 1330.660 |
| Registrants wear proper clean attire and have proper name tags and designations. | | | | 68 Administrative Code Section 1330.30(k) |
| All pharmacy technicians and certified pharmacy technicians have completed the required training set forth in the Act and Rules. | | | | 68 Administrative Code Section 1330.210 |
| Current reference books and copy of laws and rules are maintained in hard copy or readily available in electronic data format. If preparing compounded sterile preparations, then pharmacy shall maintain references listed in Section 1330.640. | | | | 68 Administrative Code Section 1330.610(f), Section 1330.640, and Section 1330.500(h) |
| Meet all the requirements when there is a change in Pharmacist-in-Charge including but not limited to proper notification to the Department and completing Controlled Substance Inventory. | | | | 68 Administrative Code Section 1330.660 |
| The schedule during which pharmacy services are provided is conspicuously displayed. | | | | 68 Administrative Code Section 1330.500(b)(1) |

| QUESTION | YES | NO | N/A | AUTHORITY |
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| SANITATION AND STORAGE | | | | |
| 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. | | | | 68 Administrative Code Section 1330.500(b)(2) |
| Refrigerators for the exclusive use of medications are clean, defrosted and in working order maintaining proper temperature. | | | | 68 Administrative Code Section 1330.610(d) |
| Pharmacy is clean and sanitary. | | | | 68 Administrative Code Section 1330.630 |
| Pharmacy must have a sink with hot and cold running water. | | | | 68 Administrative Code Section 1330.630(c) |
| Food and/or beverages are kept in designated areas away from dispensing activities and stored in refrigerators not used for medications. | | | | 68 Administrative Code Section 1330.630(e) |
| Pharmacy area shall not be used for storage of merchandise that interferes with the practice of pharmacy. | | | | 68 Administrative Code Section 1330.610(e) |
| The pharmacy area and all store rooms shall be well-lighted and properly ventilated. | | | | 68 Administrative Code Section 1330.610(c) |
| All dispensing and drug storage areas of the pharmacy are contiguous. | | | | 68 Administrative Code Section 1330.610(b) |
| Expired medications are stored separately from active medication stock. | | | | 68 Administrative Code Section 1330.630 and 410 ILCS 620/14(b) |

| DISPENSING AND RECORD KEEPING | YES | NO | N/A | AUTHORITY |
|--|------------|-----------|------------|---|
| Every prescription dispensed shall be documented with the name, initials or other unique identifiers of the pharmacist and pharmacy technician if one is used. | | | | 68 Administrative Code Section 1330.500(c) |
| For prescriptions written on or after 1/1/19, a prescription for medication other than controlled substances shall be valid for up to 15 months from the date issued for the purpose of refills, unless the prescription states otherwise. | | | | 225 ILCS 85/3(e) |
| An offer to counsel shall be made on all REFILL prescriptions. Counseling by a registered pharmacist or a student pharmacist under the direct supervision of a registered pharmacist is REQUIRED for all NEW prescriptions. | | | | 68 Administrative Code Section 1330.700 |
| Every licensed pharmacy directly serving patients at a physical location must conspicuously post a sign provided by the Division containing a statement that the patient has the right to counseling, the Division's consumer hotline number, information on how to file a complaint for failure to counsel, and any other information the Division deems appropriate. The sign must be printed in color ink or displayed electronically in color, measure at least 8½ x 11 inches in size, and be posted at either a cashier counter or waiting area clearly visible to patients. The sign is available to download on the Division's website. | | | | 68 Administrative Code Section 1330.700(c) |
| All records are maintained for 5 years and are readily retrievable. | | | | 68 Administrative Code Section 1330.500 |
| Proper transferring of prescriptions and handling of transferred prescriptions. | | | | 68 Administrative Code Section 1330.720 |
| Electronically transmitted prescriptions are only being received directly from the prescribing practitioner or agent. | | | | 225 ILCS 85/3 (z) |
| 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. | | | | 68 Administrative Code Section 1330.500(c)(7) and 21 CFR §1306.22 |
| For every patient who is enrolled in an auto-refill program, records must be maintained showing the patient's or the patient's agent's consent to be enrolled. | | | | 225 ILCS 85/22c(a) |
| The pharmacy keeps and maintains a complete and accurate record showing its pharmacists' daily break periods. | | | | 225 ILCS 85/15.1(e) |
| APRNs must indicate on their prescription orders that they have been granted full practice authority. | | | | 68 Administrative Code Section 1300.466(d) |
| All non-sterile compounded medications are prepared in compliance with Section 1330.640. If preparing compounded non-sterile preparations, the Non-Sterile Compounding Self-Inspection Report must be filled out in addition to this Report. | | | | 68 Administrative Code Section 1330.640 |
| All sterile compounded medications are prepared in compliance with Section 1330.640. If preparing compounded sterile preparations, the Sterile Compounding Self-Inspection Report must be filled out in addition to this Report. | | | | 68 Administrative Code Section 1330.640 |

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| If the pharmacists administer vaccinations/immunizations, they must meet the entire requirements of Section 1330.50. | | | | 68 Administrative Code Section 1330.50 |
| 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. | | | | 68 Administrative Code Section 1330.800 |
| CONTROLLED SUBSTANCES & SECURITY | YES | NO | N/A | AUTHORITY |
| Security provisions are provided for all drugs and devices within the pharmacy when pharmacist is on staff and during the absence of a pharmacist. | | | | 68 Administrative Code Section 1330.600 and 225 ILCS 85/15(1)(b) |
| All applicants and licensees shall provide effective controls and procedures to guard against theft and diversion of controlled substances. | | | | 77 Administrative Code Section 3100.310 |
| A basic alarm system that detects unauthorized entry into the pharmacy area. This does not apply to 24-hour pharmacies that never close. | | | | 77 Administrative Code Section 3100.310(e) |
| Personal bags of any kind, including but not limited to purses, handbags and backpacks, are prohibited in any area where controlled substances are handled and/or stored. | | | | 77 Administrative Code Section 3100.310(d) |
| All pharmacies are required to maintain a key to the licensed pharmacy area held by an employee of the pharmacy who is a licensed pharmacist or a registered pharmacy technician or certified pharmacy technician. | | | | 77 Administrative Code Section 3100.310(f) |
| All Schedule II Controlled Substances shall be stored in a securely locked, substantially constructed cabinet. (Schedule II Controlled Substances should be locked and secure at all times unless actively dispensing. Schedule II Controlled Substances safe keys or combinations is limited to Pharmacist access only.) | | | | 77 Administrative Code Section 3100.340(a) |
| Schedule II Controlled Substances Inventories, Records, and Prescriptions maintained in separate files. | | | | 21 CFR §1304.04(h)(1) & 21 CFR §1304.04(h)(2) |
| Schedule III, IV and V Controlled Substances Inventories, Records, and Prescriptions maintained in separate files or readily retrievable from the ordinary business records of the pharmacy. | | | | 21 CFR §1304.04(h)(3) & 21 CFR §1304.04(h)(4) |
| Controlled Substance Return Records properly maintained in a separate file. (Schedule II Controlled Substances separately filed from Schedule III, IV and V Controlled Substances.) | | | | 21 CFR §1304.21(c) |
| Controlled Substance purchase invoices are signed/dated. | | | | 21 CFR §1304.21(d) and 21 CFR §1304.04 |
| DEA 222 Form properly documented. | | | | 77 Administrative Code Section 3100.500 |
| When using CSOS, only the certificate holder may access or use his or her digital certificate and private key. A certificate holder must ensure that no one else uses the private key. While the private key is activated, the certificate holder must prevent unauthorized use of that private key. | | | | 21 CFR §1311.30 |
| A registrant may authorize one or more individuals to issue orders for Schedule II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained | | | | 21 CFR §1305.05 and 21 CFR §1311.45 |

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| in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records. A registrant must maintain a record that lists each person granted power of attorney to sign controlled substances orders. | | | | |
| Every licensee shall conduct an annual inventory (within 12 months) that includes an inventory with an actual count of the inventory on hand for all Schedule II Controlled Substances and an approximate inventory for all Schedule III, IV and V Controlled Substances. The inventory shall be maintained for a period of not less than 5 years. Inventory requirements are listed in 21 CFR 1304.11. Date of Last Annual Inventory: _____ Signed by: _____ | | | | 77 Administrative Code Section 3100.360(c) |
| All controlled substances are dispensed in Good Faith. | | | | 720 ILCS 570/312(h) |
| Controlled drug prescriptions must contain the following: 1. Name and address of patient 2. Date of Issuance 3. Practitioner's Name/Written Signature and DEA Number 4. Dispensing pharmacist's <u>written</u> signature or initials 5. Date of filling 6. A written prescription for Schedule III, IV or V controlled substances shall not be filled or refilled more than 6 months after the date thereof or refilled more than 5 times unless renewed, in writing, by the prescriber. 7. A prescription for a Schedule II controlled substance shall not be issued for more than a 30-day supply and shall be valid for up to 90 days after the date of issuance. | | | | 720 ILCS 570/312 |
| A prescription for a Schedule II controlled substance must include both a written and numerical notation of quantity on the face of the prescription. | | | | 720 ILCS 570/309 |
| Each refilling of a prescription of a controlled substance listed in Schedules III, IV or V: 1. Be entered on the back of the prescription or in the electronic prescription record; 2. Indicate the date, quantity and name or initials of the dispensing pharmacist for each prescription; 3. Be dated by the pharmacist as of the date of dispensing 4. State the amount dispensed. | | | | 77 Administrative Code Section 3100.410(a) |
| Schedule V Controlled Substances Dispensed in Good Faith 1. Dispensed only by a pharmacist to a person over 21 with two sources of identification. 2. RPH shall record the name and address, name and quantity of the product, the date and time of the sale, and the dispenser's signature. 3. No more than 120 milliliters dispensed in any 96-hour period. | | | | 720 ILCS 570/312(c) |

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| CV sales records are appropriately maintained. | | | | 720 ILCS 570/312(c) |
| All transferred prescriptions for controlled substances in Schedule III, IV and V are transferred only once from the pharmacy which has the original prescription drug order unless the two pharmacies share a common database. | | | | 225 ILCS 85/19(5) |
| Controlled substance data collection must be submitted to the Prescription Monitoring Program as required by the end of the next business day. If no controlled substance is dispensed, the dispenser must transmit a zero report no later than the end of the next business day. | | | | 720 ILCS 570/316 and 77 Administrative Code 2080.100 |
| In every instance that a licensee is required by 21 CFR 1301.76 (April 1, 2014) to file with the DEA a Report of Theft or Loss of Controlled Substances (DEA Form 106), a copy shall be sent to the Division of Professional Regulation directed to the attention of the Drug Compliance Investigator (Drug Compliance Unit) within one business day after submission to the DEA, along with the printed name of the person who signed the form. | | | | 68 Administrative Code Section 1330.710 and 77 Administrative Code 3100.360(e) |

| LABELING | YES | NO | N/A | AUTHORITY |
|--|------------|-----------|------------|---|
| All prescriptions are labeled with: <ol style="list-style-type: none"> 1. Pharmacy name and address; 2. Date and initials of person authorized to dispense; 3. Name of patient; 4. Prescription number; 5. Prescriber's last name; 6. Directions of use, quantity and dosage; and 7. Name of the drug. | | | | 225 ILCS 85/22 |
| Any prepackaged drug must have a label affixed-name and strength of the drug, name of the manufacturer or distributor, beyond use date, lot number on each container. | | | | 68 Administrative Code Section 1330.730 |

| AUTOMATION AND TECHNOLOGY | YES | NO | N/A | AUTHORITY |
|---|------------|-----------|------------|---|
| Pharmacies that utilize automated dispensing and storage systems shall maintain complete and up to date operating policies and procedures and comply with all of the requirements under Section 1330.680. | | | | 68 Administrative Code Section 1330.680 |
| Pharmacies that are part of a health-system with multiple sites and engaged in telepharmacy are compliant with Section 1330.510 of the Illinois Pharmacy Practice Act Rules, Telepharmacy. | | | | 68 Administrative Code Section 1330.510 |

Section 1330.700 Patient Counseling

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 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:

- 1) Name and description of medication;
- 2) Dosage form and dosage;
- 3) Route of administration;
- 4) Duration of therapy;
- 5) Techniques for self-monitoring;
- 6) Proper storage;
- 7) Refill information;
- 8) Actions to be taken in cases of missed doses;
- 9) Special directions and precautions for preparation, administration and use;
- 10) Common severe side effects, adverse effects, or interactions and therapeutic contraindications that may be encountered, including their avoidance and the action required if they occur.

225 ILCS 85/15.1 - Section 15.1 Pharmacy Working Conditions

Except in the case of an emergency, the following restrictions apply to pharmacies:

- The workday for a pharmacist, student pharmacist and pharmacy technician shall not exceed 12 hours including breaks;
- If a pharmacist has to work 6 continuous hours or longer in a day, he or she will be allowed to take one 30-minute uninterrupted meal break and one 15-minute break during the day;
- If a pharmacist has to work 12 continuous hours or longer in a day, he or she will be allowed to take one 30-minute uninterrupted meal break and two 15-minute breaks during the day; and
- A pharmacist who is entitled to a meal break cannot be required to work more than 5 continuous hours (So, a pharmacist who is required to work 6 hours or longer cannot be given a meal break during the last half hour of their shift).

An emergency occurs when a pharmacist, student pharmacist or pharmacy technician is required to work to minimize an immediate health risk to patients, as deemed necessary by the professional judgment of the pharmacist. If a pharmacy is staffed by two or more pharmacists, the pharmacists shall stagger breaks so that at least one pharmacist remains on duty during all times that the pharmacy remains open for the transaction of business. A pharmacy must keep and maintain complete and accurate records, in electronic or paper form, and in sufficient detail to show that, absent an emergency:

- Pharmacists, student pharmacists and pharmacy technicians have not been required to work longer than 12 continuous hours;
- Pharmacists are allowed to take one 30-minute uninterrupted meal break and one 15-minute break during the day, if he or she has to work 6 continuous hours or longer in a day;
- Pharmacists are allowed to take one 30-minute uninterrupted meal break and two 15-minute breaks during the day, if he or she has to work 12 continuous hours or longer in a day; and
- Pharmacists, who are entitled to a meal break, have not worked more than 5 continuous hours prior to being allowed to take the meal break.

If a pharmacy or a building where a pharmacy is located has a private break room, the pharmacist must be given access to the break room and be permitted to have breaks in that room. The pharmacy can close while the pharmacist is on break, but it is not required to do so. If the pharmacy does not close, the pharmacist has to remain in the pharmacy or establishment where the pharmacy is located during the break for any emergencies. If the pharmacy remains open:

- Pharmacy technicians and student pharmacists can continue duties that they are permitted to do;
- Only prescriptions approved by the pharmacist that do not require counseling can be dispensed; and
- If an approved prescription requires counseling, the person picking up the prescription can wait for the return of the pharmacist or can purchase the prescription and then the pharmacist must try to reach the patient or their representative by phone at least twice to provide counseling and must document those attempts to contact the patient.

**DO NOT SEND ANY PART OF THIS REPORT TO THE DEPARTMENT!
KEEP IN THE PHARMACY FOR DRUG COMPLIANCE INVESTIGATOR'S REVIEW.
COPIES SENT TO THE DEPARTMENT WILL BE DISCARDED.**

I hereby certify that I have verified that this pharmacy is in compliance with all laws and rules related to the practice of pharmacy in the State of Illinois and the answers marked on this report are true and correct to the best of my knowledge.

PIC NAME: _____ LICENSE NUMBER: _____

PIC SIGNATURE: _____ DATE: _____