Illinois Department of Financial and Professional Regulation
Division of Professional Regulation
Drug Compliance Unit
9511 Harrison Street, Suite 300, Des Plaines, IL 60016
320 W. Washington Street, 2nd Floor, Springfield, IL 62786

Email: fpr.drugcomplianceunit@illinois.gov

(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)
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. Documentation of the self-inspection shall be maintained at the pharmacy for 5 years. The primary objective of the self-inspection is to create an opportunity for a pharmacy to identify and correct areas of noncompliance with State and federal law. This includes, but is not limited to, recordkeeping, inventory, labeling and sanitation requirements.

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.

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STATE OF ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
DRUG COMPLIANCE UNIT
9511 HARRISON STREET, SUITE 300, DES PLAINES, IL 60016
320 W. WASHINGTON STREET, 2ND FLOOR, SPRINGFIELD, IL 62786

Email: fpr.drugcomplianceunit@illinois.gov

(KEEP CURRENT THROUGHOUT THE YEAR, AS NEEDED)

COMMUNITY PHARMACY

BUSINESS NAME	HOURS	DEA REGISTRATION NUMBER	EXPIRES	DATE OF SELF-INSPECTION
	M ☐ T ☐ W ☐ TH ☐ F ☐ SAT ☐ SUN ☐			
ADDRESS		ICSA LICENSE NUMBER	EXPIRES	PHARMACY LICENSE NUMBER
CITY ZIP CODE	OTHER HOURS EXCEP	TELEPHONE		

OWNERSHIP	OWNERS	TELEPHONE AFTER HOURS	PHARMACY E-MAIL ADDRESS
☐ Individual pharmacist ☐ Individual Non-pharmacist ☐ Partnership ☐ Corporation ☐ LLC	PHARMACIST- IN-CHARGE	OWNER'S E-MAIL ADDRESS	COUNTY

NAME OF LICENSEE (ALL PHARMACISTS and PHARMACY TECHNICIANS)	LICENSE NUMBER
R Ph IN CHARGE	

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(5)
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/work experience set forth in the Act and Rules.	☐	☐	☐	68 Administrative Code Section 1330.210 Section 1330.215
Current reference books and copy of laws and rules are maintained in hard copy or readily available in electronic data format.	☐	☐	☐	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 a 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)

SANITATION AND STORAGE	YES	NO	N/A	AUTHORITY
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 storerooms 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 with connecting door.	☐	☐	☐	68 Administrative Code Section 1330.610(b)
Expired medications are stored separately from active medication stock.	☐	☐	☐	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 applicable).	☐	☐	☐	68 Administrative Code Section 1330.500(c)
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) 68 Administrative Code Section 1330.500(c)(1)
Prior to dispensing a prescription to a new patient, a new prescription 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.**	☐	☐	☐	68 Administrative Code Section 1330.700 Section 1330.30(h)
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 prescription records are maintained for 5 years and are readily retrievable.	☐	☐	☐	68 Administrative Code Section 1330.500 225 ILCS 85/18
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) 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) 68 Administrative Code Section 1330.765
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

Vaccinations/Immunizations 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 Section 1330.50.	☐	☐	☐	68 Administrative Code Section 1330.50
Dispensing opioid antagonists. (b) A licensed pharmacist shall dispense an opioid antagonist in accordance with written, standardized procedures or protocols developed by the Department with the Department of Public Health and the Department of Human Services and filed at the pharmacy before implementation and are available to the Department upon request. (c) **Before dispensing an opioid a pharmacist shall inform patients that opioids are addictive and offer to dispense an opioid antagonist.** (d) "opioid antagonist" means a drug that binds to opioid receptors and blocks or inhibits the effect of opioids acting on those receptors, including, but not limited to, naloxone hydrochloride or any other similarly acting and equally safe drug approved by the U.S. Food and Drug Administration for the treatment of drug overdose. ***Illinois Naloxone Standardized Procedure***	☐	☐	☐	225 ILCS 85/19.1
Dispensation of hormonal contraceptives. The dispensing of hormonal contraceptives to a patient shall be pursuant to a valid prescription, or pursuant to a standing order by a physician licensed to practice medicine in all its branches, a standing order by the medical director of a local health department, or a standing order by the Department of Public Health pursuant to the following: (1) A pharmacist may dispense no more than a 12-month supply of hormonal contraceptives to a patient; (2) A pharmacist must complete an educational training program accredited by the Accreditation Council for Pharmacy Education and approved by the Department that is related to the patient self-screening risk assessment, patient assessment contraceptive counseling and education, and dispensation of hormonal contraceptives; (3) A pharmacist shall have the patient complete the self-screening risk assessment tool; the self-screening risk assessment tool is to be based on the most current version of the United Stated Medical Eligibility Criteria for Contraceptive Use published by the federal Centers for Disease Control and Prevention; (4) Based upon the results of the self-screening risk assessment and the patient assessment, the pharmacist shall use their professional and clinical judgment as to when a patient should be	☐	☐	☐	225 ILCS 85/43

referred to the patient's physician or another health care provider; (5) A pharmacist shall provide, during the patient assessment and consultation, counseling and education about all methods of contraception, including methods not covered under the standing order, and their proper use and effectiveness; (6) The patient consultation shall take place in a private manner; (7) A pharmacist and pharmacy must maintain appropriate records ***Illinois Hormonal Contraception Standing Order***	☐	☐	☐	
Dispensation of HIV prophylaxis. In accordance with a standing order by a physician licensed to practice medicine in all its branches or the medical director of a county or local health department or a standing order by the Department of Public Health, a pharmacist may provide patients with prophylaxis drugs for human immunodeficiency virus pre-exposure prophylaxis or post-exposure prophylaxis. • A pharmacist may provide initial assessment and dispensing of prophylaxis drugs for human immunodeficiency virus pre-exposure prophylaxis or post-exposure prophylaxis. If a patient's HIV test results are reactive, the pharmacist shall refer the patient to an appropriate health care professional or clinic. If the patient's HIV test results are nonreactive, the pharmacist may initiate human immunodeficiency virus pre-exposure prophylaxis or post-exposure prophylaxis to eligible patients. • The standing order must be consistent with the current version of the guidelines of the Centers for Disease Control and Prevention, guidelines of the United States Preventive Services Task Force, or generally recognized evidence-based clinical guidelines. • A pharmacist must communicate the services provided under this Section to the patient and the patient's primary health care provider or other health care professional or clinic, if known. If there is no primary health care provider provided by the patient, then the pharmacist shall give the patient a list of primary health care providers, other health care professionals, and clinics in the area. • The services provided under this Section shall be appropriately documented and retained in a confidential manner consistent with State HIV confidentiality requirements. • The services provided under this Section shall take place in a private manner.	☐	☐	☐	225 ILCS 85/43.5

• A pharmacist shall complete an educational training program accredited by the Accreditation Council for Pharmacy Education and approved by the Department that is related to the initiation, dispensing, or administration of drugs, laboratory tests, assessments, referrals, and consultations for human immunodeficiency virus pre-exposure prophylaxis and human immunodeficiency virus post-exposure prophylaxis.	☐	☐	☐	
Pharmacy Personnel Termination Report As set forth in 225 ILCS 85/30 1. The pharmacy or pharmacist in charge must file this report with the Department anytime 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. 2. This report must be fi led within sixty (60) days after a pharmacy's determination that a report is required under the Act. 3. Email this completed signed form to FPR.PharmacyAdverse@Illinois.gov	☐	☐	☐	225 ILCS 85/30.1
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)
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.)	☐	☐	☐	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) 21 CFR §1304.04
DEA 222 form(s) properly documented. A copy of DEA 222 form(s) shall be maintained by the pharmacy for a period of two years.	☐	☐	☐	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 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.	☐	☐	☐	21 CFR §1305.05 21 CFR §1311.45
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) 720 ILCS 570/102(u)
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 written 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	☐	☐	☐	720 ILCS 570/312

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.	☐	☐	☐	
All nonelectronic 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
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)
CV sales records are appropriately maintained.	☐	☐	☐	720 ILCS 570/312(c)
Prescriptions for drugs in Schedules III, IV, and V of the Illinois Controlled Substances Act may be transferred only once and may not be further transferred. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by the law and the prescriber's authorization.	☐	☐	☐	225 ILCS 85/19(5)
The pharmacy's controlled substance data collection must be transmitted electronically to the Prescription Monitoring Program not later than the end of the business day on which a controlled substance is dispensed.	☐	☐	☐	720 ILCS 570/316
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 77 Administrative Code 3100.360(e)
LABELING	**YES**	**NO**	**N/A**	**AUTHORITY**
All prescriptions are labeled with: 1. Pharmacy name and address; 2. Date and initials of person authorized to dispense; 3. Name of patient;	☐	☐	☐	225 ILCS 85/22

4. Prescription number; 5. Prescriber's last name; 6. Directions of use, quantity and dosage; and 7. Name of the drug(s)	☐	☐	☐	
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

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: _____