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)

ONSITE INSTITUTIONAL 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 December 31st of 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.

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

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(KEEP CURRENT THROUGHOUT THE YEAR, AS NEEDED)

ONSITE INSTITUTIONAL 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	OWNERS	TELEPHONE AFTER HOURS	PHARMACY E-MAIL ADDRESS
☐ Individual pharmacist ☐ Individual Non-pharmacist ☐ Partnership ☐ Corporation ☐ LLC	PHARMACIST IN CHARGE	OWNER'S EMAIL 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 1330.530 of the Illinois Pharmacy Practice Act Rules, Onsite Institutional Practice.				68 Administrative Code Section 1330.530
The PIC has personally reviewed the licenses of all registrants and determined that they are current.				68 Administrative Code Section 1330.530(d)(1)
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)
Meet all the requirements when there is a change in Pharmacist-in-Charge including but limited to proper notification to the Department and completing Controlled Substance Inventory.				68 Administrative Code Section 1330.530(d)(3) thru Section 1330.530(d)(7) and Section 1330.660

STAFFING, SANITATION AND STORAGE	YES	NO	N/A	AUTHORITY
The pharmacy shall be staffed at all times by a registered pharmacist during open hours.				68 Administrative Code Section 1330.530(d)(1)(B)
Pharmacies dispensing necessary medications in the absence of a pharmacist must maintain methods/records for the nursing staff to obtain emergency medications.				68 Administrative Code Section 1330.530(e)
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. Dispensing and drug storage areas are not required to be contiguous nor connecting.				68 Administrative Code Section 1330.610(c) 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
The pharmacist-in-charge shall maintain or have access to the following records for at least 5 years **in a readily retrievable file** or as otherwise required by law. Records including but not limited to the following: 1) Records of medication orders and medication administration to patients; 2) Procurement records for controlled substances; 3) Records of packaging, bulk compounding or manufacturing; and 4) Records of actions taken pursuant to drug recalls.				68 Administrative Code Section 1330.530(b)(3)
Records for every prescription or medication order filled or refilled shall contain the name, initials or other unique identifier of the pharmacist (and pharmacy technician if one is used) who fills or refills the prescription or medication order, or the name, initials or other unique identifier may be recorded on another appropriate, uniformly maintained and readily retrievable record that indicates, at least, the following information: 1) The name and dosage form of the drug; 2) The date of filling or refilling; and 3) The quantity dispensed.				68 Administrative Code Section 1330.530(b)(1)
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 (b)(2)
Procedure to ensure proper drug recall process				68 Administrative Code Section 1330.530(d)(1)(D)
Proper transferring of prescriptions and handling of transferred prescriptions				68 Administrative Code Section 1330.530(c)(5)
Medication Dispensed in Absence of a Pharmacist: 1. After Hour Cabinet: a. Written physician's orders authorizing the removal of the medication shall be placed in the cabinet or enclosure; and b. Log shall be maintained within the cabinet or enclosure indicating name of the authorized person removing drug, name of medication, the strength (if applicable), the quantity, and time of removal. 2. Emergency Kits a. Drugs shall be removed from emergency kits only by authorized pharmacy personnel, persons authorized to administer medication pursuant to a valid practitioner order licensed to prescribe in Illinois; b. Sealed in some manner that will indicate when the kit has been opened; c. Label shall be affixed to the outside of the emergency kit indicating the beyond use date of the emergency kit; and				68 Administrative Code Section 1330.530(e)

d. After an emergency kit has been used or seal has been broken or upon the occurrence of the beyond use date, the kit shall be secured and then returned to the pharmacy to be checked and restocked by the last authorized user. If the pharmacy is closed at that time, the kit shall be returned when it opens. An automated dispensing and storage system may be used as an emergency kit. 3. Not available from Night Cabinet or Emergency Kit: a. Only an authorized nurse has access to the pharmacy; b. A copy of the licensed practitioner's order authorizing the removal of the drug shall be conspicuously placed in the pharmacy with the container from which the drug was removed so that it will be found by a pharmacist and checked promptly; and c. A form shall be available, which shall be recorded the signature of the authorized nurse who removed the medication, the name, strength (if applicable) and quantity of medication removed. 4. Drugs may be dispensed from the emergency room: a. Only by a practitioner licensed to prescribe and dispense, and only to patients treated in the institution; b. The practitioner shall dispense only when the outpatient institutional pharmacy services are not available; c. Drugs dispensed must meet all labeling requirements pertaining to community pharmacies as specified in Section 1330.500; d. The quantity dispensed should be limited to no more than 72 hours supply unless packaging does not permit. e. There shall be written policies and procedures, approved by the medical staff, regarding the dispensing of drugs from the emergency room.				
Investigational new drugs, authorized by the U.S. Food and Drug Administration, shall be dispensed pursuant to a valid prescription order of the principal physician-investigator or the principal physician-investigator's authorized clinician. All investigational drugs shall be stored in and dispensed from the pharmacy and shall be identified with the following information: A) Name of drug and strength (if applicable); B) Beyond use date; C) Reference code to identify source and lot number;				68 Administrative Code Section 1330.530(c)(4)

D) A label indicating "For Investigational Use Only"; and E) Name and location of the patient. Those institutions or facilities utilizing a unit-dose and medication cart system may identify the name of the patient and the patient's location on the outside of the bin of the medication cart, when those carts are filled by the pharmacy.				
A pharmacist at an on-site or off-site institutional pharmacy shall not be required to provide patient counseling as required in Section 1330.700 unless drugs are dispensed by the pharmacy upon a patient's discharge from the institution.				68 Administrative Code Section 1330.700(f)
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
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
The pharmacy maintains proper pharmacy staff working conditions.				225 ILCS 85/15.1

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.				225 ILCS 85/15(1)(b) 68 Administrative Code Section 1330.600, Section 1330.530(d)
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
Only registered pharmacy technicians, student pharmacists and licensed nurses authorized by the pharmacist in charge have access to the pharmacy when a pharmacist is not present.				68 Administrative Code Section 1330.530(d)(1)(B)
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				77 Administrative Code Section 3100.310(d)

area where controlled substances are handled and/or stored.				
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.)				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 records of electronic prescription shall be maintained in an application that meets the requirements of 21 CFR part 1311 of this chapter. The computers on which the records are maintained may be located at another location, but the records must be readily retrievable at the registered location if requested by the Department. The electronic application must be capable of printing out or transferring the records in a format that is readily understandable to by the Department at the registered location. Electronic copies of prescription records must be sortable by prescriber name, patient name, drug dispensed, and date filled.				21 CFR §1304.04(h)(5) 21 CFR §1311
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 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 and 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)
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**
Immediate Dispensing: All medication prepared by the pharmacy for immediate dispensing to a specific patient or resident in the institution or facility shall be identified as follows: • Single dose or multi-dose drugs, except parenteral solutions to which a drug has been added, shall be identified with: 1) Brand and/or generic name; and 2) Strength (if applicable). • Sterile solutions to which drugs have been added shall be identified with: 1) Name, concentration and volume of the base sterile solution; 2) Name and strength of drugs added; and 3) Beyond use date and time of the admixture. • All medication dispensed to a specific patient in the institution shall be dispensed in a container identified with the name of the patient and the patient's location. Those institutions or facilities utilizing a unit-dose and medication cart system may identify the name of the patient and the patient's location on the outside of the bin of the medication cart, when those carts are filled by the pharmacy.				68 Administrative Code Section 1330.530(c)(2)
Prepackaging Drug for Future Use: All medications repackaged by the pharmacy for future use inside the institution or facility and not intended for immediate dispensing to a specific patient shall be identified as follows:				68 Administrative Code Section 1330.530(c)(1) and Section 1330.730.

• Single dose or multi-dose drugs, except sterile solutions to which a drug has been added, shall be identified with: 1) Brand and/or generic name; 2) Strength (if applicable); 3) Beyond use date; and 4) Reference code to identify source and lot number. (Reference code should trace back to specific manufacturer and lot number.) • Sterile solutions to which drugs have been added shall be identified with: 1) Name, concentration and volume of the base sterile solution; 2) Name and strength of drugs added; 3) Beyond use date and time of the admixture; and 4) Reference code to identify source and lot number of drugs added. (Reference code should trace back to specific manufacturer and lot number.)				
Immediate dispensing to a patient being discharged, emergency room patient and/or employee, the label shall contain the following: 1) The name and dosage form of the drug; 2) The date filled; 3) The quantity dispensed; and 4) Directions for use.				68 Administrative Code Section 1330.530(c)(3)
Investigational new drugs, authorized by the U.S. Food and Drug Administration, shall be dispensed pursuant to a valid prescription order of the principal physician-investigator or the principal physician-investigator's authorized clinician. All investigational drugs shall be stored in and dispensed from the pharmacy and shall be identified with the following information: 1) Name of drug and strength (if applicable); 2) Beyond use date; 3) Reference code to identify source and lot number; 4) A label indicating “For Investigational Use Only”; 5) Name and location of the patient. Those institutions or facilities utilizing a unit-dose and medication cart system may identify the name of the patient’s location on the outside of the bin of the medication cart, when those carts are filled by the pharmacy.				68 Administrative Code Section 1330.530(c)(4)

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: _____