

Illinois Department of Financial and Professional Regulation
Division of Professional Regulation
Drug Compliance Unit
9511 Harrison Street, Suite LL 50, Des Plaines, IL 60016

Phone: (847) 294-4900

(Read this Page Carefully)

OFFSITE 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)

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.

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 1330.520 of the Illinois Pharmacy Practice Act Rules, Offsite Institutional Practice.				68 Administrative Code Section 1330.520
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 1330.670(c)(3).				68 Administrative Code Section 1330.610(f) and Section 1330.670(c)(3)
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 1330.660
The schedule during which pharmacy services are provided is conspicuously displayed.				68 Administrative Code Section 1330.500(b)(1)

SECURITY, SANITATION AND STORAGE	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
Staffing of the Pharmacy: When the pharmacy is closed, the public and any employees not registered under the Act are to be prohibited access to the filling and dispensing area.				68 Administrative Code Section 1330.520(d)
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
All C-II controlled substances are stored securely within the pharmacy and a perpetual inventory is maintained.				77 Administrative Code Section 3100.340

DISPENSING AND RECORD KEEPING	YES	NO	N/A	AUTHORITY
Every prescription or order 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 1330.520(b)(1)
Uniformly maintained, readily retrievable hard copy record or back-up documentation of each prescription or order dispensed shall be maintained by the pharmacy for <u>5</u> years and shall include: 1) Name of resident; 2) Date of order; 3) Name, strength and dosage form of drug, or description of the medical device ordered; 4) Quantity dispensed (a separate record should be maintained when the quantity billed differs from the quantity dispensed, e.g., unit dose transfer systems); 5) Directions for use; 6) Quantity billed; 7) Prescriber's name; 8) Prescriber's signature and/or DEA number when required for controlled substances; and 9) The drug name and identification code or the manufacturer in case of a generically ordered medication or a generic interchange.				68 Administrative Code Section 1330.520(b)(3)
Subject to Section 18 of the Act, any information required to be kept pursuant to this Section may be recorded and stored in a: A) Computerized pharmaceutical information system that meets the requirements outlined in 1330.520(b)5Ai-iii; and B) Bound log book, or separate file, in which each individual pharmacist involved in 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 1330.520(b)(5)(A)
No prescription or order may be filled or refilled for a period in excess of one year from the date of the original issuance of the prescription or order by the prescriber.				68 Administrative Code Section 1330.520(b)(4)
In the event the long term care facility changes pharmacy provider services, their new provider must obtain the orders from the long term care facility and verify the authenticity and accuracy of the orders with the prescriber.				68 Administrative Code Section 1330.520(c)
Procedure to ensure proper drug recall process				
Proper transferring of prescriptions and handling of transferred prescriptions				68 Administrative Code Section 1330.720
All transferred prescriptions for controlled substances in Schedule III, IV and V are transferred only once from the				225 ILCS 85/19(5)

pharmacy which has the original prescription drug order unless the two pharmacies share a common database.				
All controlled substances are dispensed in Good Faith.				720 ILCS 570/312(h)
Controlled drug prescriptions/medication orders and records must be properly filed and maintained.				21 CFR §1304.04
Annual inventory of controlled substances are properly recorded, dated and signed.				77 Administrative Code Section 3100.360
Controlled substance data collection is submitted to the Prescription Monitoring program as required at least once a week if appropriate.				720 ILCS 570/316
Any theft or significant loss of controlled substances are immediately filed using the DEA form 106 with the Drug Enforcement Administration, with a copy to the Division of Professional Regulation directed to the attention of the Drug Compliance investigator.				68 Administrative Code Section 1330.710
Controlled substance purchase invoices are signed and kept in a separate file.				77 Administrative Code Section 3100.510
DEA 222 Form properly documented.				77 Administrative Code Section 3100.500
Electronically transmitted prescriptions are only being received directly from the prescribing practitioner or agent.				225 ILCS 85/3 (z)
Records for returned drugs are properly maintained.				68 Administrative Code Section 1330.750
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 and 1330.670. 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 and Section 1330.670
If the pharmacists administer vaccinations/immunizations, they must meet the entire requirements of Section 1330.50.				68 Administrative Code Section 1330.50

LABELING	YES	NO	N/A	AUTHORITY
Immediate Dispensing: <ul style="list-style-type: none"> • All medication prepared by the pharmacy for immediate dispensing to a specific patient or resident in the facility shall be dispensed in a container identified with: <ol style="list-style-type: none"> 1) Name of the resident; 2) Resident's room and bed number; 3) Dispensing date; 4) Name, strength and dosage form of drug, or description of medical device; 5) Quantity dispensed; 6) Directions for use; 7) Prescriber's name; and 8) Beyond use date if less than 60 days from date of dispensing. 				68 Administrative Code Section 1330.520(e)(2)

<ul style="list-style-type: none"> • Pharmacies dispensing medications to a specific resident or patient in facility via unit dose shall label each container with following: <ol style="list-style-type: none"> 1) Name of the resident; 2) Resident's room and bed number; 3) Date of order; 4) Name, strength and dosage form of drug, or description of medical device; 5) Directions for use; and 6) Prescriber's name. 				
<p>Prepackaging Drug for Future Use: All medications repackaged by the pharmacy for future use and not intended for immediate dispensing to a specific patient shall be identified as follows:</p> <ul style="list-style-type: none"> • Single dose or multi-dose drugs, except sterile solutions to which a drug has been added, shall be identified with: <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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.) 				<p>68 Administrative Code Section 1330.520(e)(1) and Section 1330.730.</p>

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: _____