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)***

# 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)**
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 60016-1563
320 W. WASHINGTON STREET, 2ND FLOOR, SPRINGFIELD, IL 62786

Email: fpr.drugcomplianceunit@illinois.gov

**(KEEP CURRENT THROUGHOUT THE YEAR, AS NEEDED)**

## OFFSITE INSTITUTIONAL PHARMACY

| BUSINESS NAME | HOURS | | DEA REGISTRATION NUMBER | EXPIRES | DATE OF 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<br>☐ Individual Non-pharmacist<br>☐ Partnership<br>☐ Corporation<br>☐ LLC | PERSON IN CHARGE | OWNER'S E-MAIL ADDRESS | COUNTY |

| NAME OF LICENSEE<br>R Ph IN CHARGE | LICENSE NUMBER |
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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(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 1330.520 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/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 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) |

| 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 |
| There shall be a sink with hot and cold running water for the purposes of hand washing and drug dispensing. | | | | 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 must be contiguous and have a connecting door for access between the pharmacy and drug storage area. | | | | 68 Administrative Code Section 1330.610(b) |

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| Expired medications are stored separately from active medication stock. | | | | 410 ILCS 620/14(b) |
| 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 student pharmacist or 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 5 years and shall include:<br>1) Name of resident;<br>2) Date of order;<br>3) Name, strength and dosage form of drug, or description of the medical device ordered;<br>4) Quantity dispensed (a separate record should be maintained when the quantity billed differs from the quantity dispensed, e.g., unit dose transfer systems);<br>5) Directions for use;<br>6) Quantity billed;<br>7) Prescriber's name;<br>8) Prescriber's signature and/or DEA number when required for controlled substances; and<br>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:<br>A) computerized pharmaceutical information system that meets the standards of performance required by the regulations of the Drug Enforcement Administration (21 CFR 1306; 2014) and shall include the capability to:<br><br>i) Retrieve the original medication order information for those medication orders that are currently authorized;<br><br>ii) Retrieve the current history of medication orders that shall, at a minimum, include the name of drug, the date of filling, the quantity dispensed, the name and identification code of manufacturer in the case of a generically written prescription or a generic interchange, for each filling, and the total number of refills when read in conjunction with any off-line hard copy of the history of medication orders dispensed to date; and | | | | 68 Administrative Code Section 1330.520(b)(5) |

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| iii) Supply documentation of the correctness of filling information entered into a system must be provided by the pharmacist using the system by way of a hard copy printout of each day's filling data that has been verified, dated and signed by the dispensing pharmacist; or<br><br>B) bound logbook, 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 the individual pharmacist and is correct as shown. The book or file must be maintained at the pharmacy employing the system for a period of 5 years after the date of dispensing the appropriately authorized refill. | | | | |
| No prescription may be filled or refilled for a period in excess of 15 months 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) |
| 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 pharmacy which has the original prescription drug order unless the two pharmacies share a common database. | | | | 225 ILCS 85/19(5) |
| All controlled substances are dispensed in Good Faith. | | | | 720 ILCS 570/312(h)<br>720 ILCS 570/102(u) |
| 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 the end of the business day 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<br>77 Administrative Code 3100.360(e) |
| Controlled substance purchase invoices are signed and kept in a separate file. | | | | 77 Administrative Code Section 3100.510<br>21 CFR §1304.04(h)(3)<br>21 CFR §1304.04(h)(4) |
| 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** | | | | 68 Administrative Code Section 1330.640 |

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| **compounded non-sterile preparations, the Non-Sterile Compounding Self-Inspection Report must be filled out in addition to this Report.** | | | | |
| 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 |
| If a pharmacist or a student pharmacist or a pharmacy technician 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 |
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| **Immediate Dispensing**:<br>• All medication prepared by the pharmacy for immediate dispensing to a specific resident or patient in the facility shall be dispensed in a container identified with:<br>1) Name of the resident;<br>2) Resident's room and bed number;<br>3) Dispensing date;<br>4) Name, strength and dosage form of drug, or description of medical device ordered;<br>5) Quantity dispensed;<br>6) Directions for use;<br>7) Prescriber's name; and<br>8) Beyond use date if less than 60 days from date of dispensing.<br><br>• Pharmacies dispensing medications to a specific resident or patient in facility via ***unit dose*** shall label each order with the following information:<br>1) Name of the resident;<br>2) Resident's room and bed number;<br>3) Date of order;<br>4) Name, strength and dosage form of drug, or description of medical device ordered;<br>5) Directions for use; and<br>6) Prescriber's name. | | | | 68 Administrative Code Section 1330.520(e)(2) |
| **Prepackaging Drug for Future Use**:<br>All medications repackaged by the pharmacy for future use and not intended for immediate dispensing to a specific patient shall be identified as follows:<br>• Single dose or multi-dose drugs, except sterile solutions to which a drug has been added, shall be identified with:<br>1) Brand and/or generic name;<br>2) Strength (if applicable);<br>3) Beyond use date. Unless otherwise specified in the individual monograph, the beyond use date shall be not later than the beyond use date on the manufacturer's container or one year from the date the drug is repackaged, whichever is earlier; and | | | | 68 Administrative Code Section 1330.520(e)(1) and Section 1330.730. |

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| 4) Reference code to identify source and lot number. (Reference code should trace back to specific manufacturer and lot number.)<br><br>• Parenteral solutions to which a drug or diluent has been added or that are not in their original manufacturer's packaging shall contain the following information on the outer label:<br>1) Name, concentration and volume of the base parenteral solution;<br>2) Name and strength of drugs added;<br>3) Beyond use date and date of admixture. Beyond use date, unless otherwise specified in the individual compendia monograph shall be not later than the beyond use date on the manufacturer's container or one year from the date the drug is repackaged, whichever is earlier; and<br>4) Reference code to identify source and lot number of drugs added. (Reference code should trace back to specific manufacturer and lot number.) | | | | |
| **Medication Dispensing in the Absence of a Pharmacist.**<br>The availability of necessary medications for immediate therapeutic use during those hours when the institutional pharmacy is not open shall be met in the following manner:<br>1) An after-hour cabinet, which is a locked cabinet or other enclosure located outside of the pharmacy area containing a minimal supply of the most frequently required medication, may be utilized provided that only personnel specifically authorized by the institution in which the pharmacy is located may obtain access and it is sufficiently secure to deny access to unauthorized persons. After-hour cabinets shall only be used in the absence of a pharmacist. When medication is removed from the cabinet or enclosure, written physician's orders authorizing the removal of the medication shall be placed in the cabinet or enclosure. A log shall be maintained within the cabinet or enclosure and authorized personnel removing medication shall indicate on the log the signature of the authorized personnel removing the medication, the name of the medication removed, the strength (if applicable), the quantity removed and the time of removal. An automated dispensing and storage system may be used as an after hours cabinet. This use shall be in compliance with Section 1330.680.<br><br>2) Emergency kits containing those drugs that may be required to meet the immediate therapeutic needs of the patient, and that are not available from any other source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining the drugs from the other source, may be utilized. Emergency kits shall be supplied and maintained under the supervision of a pharmacist. Drugs shall be removed from emergency | | | | Section 1330.520(g) |

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| kits only by authorized pharmacy personnel or persons authorized to administer medication pursuant to a valid order by a practitioner licensed to prescribe in Illinois. Emergency kits shall be sealed in some manner that will indicate when the kit has been opened. A label shall be affixed to the outside of the emergency kit indicating the beyond use date of the emergency kit. The beyond use date of the emergency kit shall be the earliest beyond use date of any drug contained in the kit. After an emergency kit has been used or upon discovery that the seal has been broken or upon the occurrence of the beyond use date, the kit shall be secured and returned to the pharmacy to be checked and/or 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. This use shall be in compliance with Section 1330.680.<br><br>3) Whenever any drug is not available from night cabinets or emergency kits, and the drug is required to treat the immediate needs of a patient, the drug may be obtained from the pharmacy in sufficient quantity to meet the immediate need by an authorized nurse. When medication is removed from the pharmacy by an authorized nurse, a copy of the licensed practitioner's order authorizing the removal of the medication 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. A form shall be available in the pharmacy upon which shall be recorded the signature of the authorized nurse who removed the medication, the name, strength (if applicable) and quantity of medication removed. | | | | |

| 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: _____