

Illinois Department of Financial and Professional Regulation
Division of Professional Regulation
Drug Compliance Unit
9511 Harrison Street, Suite 300, Des Plaines, IL 60016
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Email: fpr.drugcomplianceunit@illinois.gov

(Read this Page Carefully)

TELEPHARMACY- REMOTE DISPENSING SITE

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
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(KEEP CURRENT THROUGHOUT THE YEAR, AS NEEDED)

TELEPHARMACY-REMOTE DISPENSING SITE				INSPECTION DATE			
<u>HOME PHARMACY</u>				<u>REMOTE DISPENSING SITE</u>			
BUSINESS NAME				BUSINESS NAME			
ADDRESS				ADDRESS			
CITY				CITY			
ZIP CODE				ZIP CODE			
TELEPHONE				TELEPHONE			
E-MAIL				E-MAIL			
<u>OPERATING HOURS</u>				<u>OPERATING HOURS</u>			
M-F				M-F			
SAT-SUN				SAT-SUN			
<u>OWNERSHIP</u>				<u>OWNERS</u>			
<input type="checkbox"/> Individual pharmacist <input type="checkbox"/> Individual Non-pharmacist <input type="checkbox"/> Partnership <input type="checkbox"/> Corporation <input type="checkbox"/> LLC				NAME			
				TELEPHONE			
				E-MAIL			
				<u>PHARMACIST IN CHARGE</u>			
LICENSE NO.		EXPIRES		REMOTE LICENSE NO.		EXPIRES	
DEA REG. NO.		EXPIRES		DEA REG. NO.		EXPIRES	
ICSA LICENSE NO.		EXPIRES		ICSA LICENSE NO.		EXPIRES	
LIST OF PHARMACISTS THAT WILL SUPERVISE THE REMOTE DISPENSING SITE		LICENSE NUMBER		CPT AT REMOTE DISPENSING SITE		LICENSE NUMBER	

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 1330.510 of the Illinois Pharmacy Practice Act Rules, Telepharmacy Practice.					68 Administrative Code Section 1330.510
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
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)
Each site where such telepharmacy operations occur shall be a separately licensed pharmacy.					68 Administrative Code Section 1330.510(a)
Each site where such telepharmacy operations occur shall have a home pharmacy.					68 Administrative Code Section 1330.510(a)
Home pharmacies that are located outside of Illinois must be licensed as a nonresident pharmacy. Nonresident pharmacies shall abide by all Illinois laws and rules when filling prescriptions for Illinois residents, except as otherwise provided in the Rules.					68 Administrative Code Section 1330.510(a)
All pharmacists performing services in support of a remote dispensing site must display a copy or electronic image of their licenses at the remote site where they provide services, or shall otherwise make their license visible to the patient, and be licensed in this State, unless employed by a pharmacy licensed in Illinois as a nonresident pharmacy, in which case, the pharmacist providing the services shall hold an active license as a pharmacist in the state in which the nonresident pharmacy is located and only the pharmacist-in-					68 Administrative Code Section 1330.510(e)

charge of the remote site must be licensed in Illinois.				
Each remote site must display a sign, easily viewable by the customer, that states: The facility is a telepharmacy supervised by a pharmacist located at (address) and the pharmacist is required to talk to you, over an audio/visual link, each time you pick up a prescription.				68 Administrative Code Section 1330.510(f)
No remote site may be open when the home pharmacy is closed, unless a pharmacist employed or contracted by the home pharmacy, or by a pharmacy contracted with the home pharmacy, is present at the remote site or is remotely providing supervision and consultation as required under this Section.				68 Administrative Code Section 1330.510(g)

SECURITY, SANITATION AND STORAGE	YES	NO	N/A	AUTHORITY
Security provisions are provided for all drugs and devices within the pharmacy during the absence of a pharmacist.				68 Administrative Code Section 1330.600
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 with connecting door				68 Administrative Code Section 1330.610(b)
Expired medications are stored separately from active medication stock.				410 ILCS 620/14(b)
C-II controlled substances shall be stored in a securely locked within a substantially constructed cabinet within the pharmacy				77 Administrative Code Section 3100.340

DISPENSING AND RECORD KEEPING	YES	NO	N/A	AUTHORITY
Written prescriptions presented to the remote dispensing site shall be scanned into the electronic data processing equipment to ensure initial dispensing and each refill and the original				68 Administrative Code Section 1330.510(b)(1)

prescription may be viewed on the monitor at both the remote dispensing site and home pharmacy site. Records shall be maintained at the remote dispensing site.				
A remote site is considered to be under the supervision of the pharmacist-in-charge of the home pharmacy. Each home pharmacy may supervise no more than 3 remote sites that are simultaneously open.				68 Administrative Code Section 1330.510(b)(2)
The remote site shall use its home pharmacy and pharmacy management system. A) The system shall assign consecutive prescription numbers. B) All records must be maintained at the home pharmacy. C) Prescriptions dispensed at the remote site shall be distinguishable from those dispensed from the home pharmacy. D) Daily reports must be separated for the home and remote site.				68 Administrative Code Section 1330.510(b)(3)
A pharmacist at the home pharmacy must verify each prescription before it leaves the remote site. A) Pharmacist and pharmacy technician initials or unique identifiers must appear on the prescription record and the prescription label. B) A pharmacist shall electronically compare via video link the stock bottle, drug dispensed, the strength and its beyond use date. The entire label must be checked for accuracy on the video link. C) The remote dispensing site shall utilize a barcode system that prints the barcode of the stock bottle on the label of the dispensed drug. If the stock bottle does not have a barcode, the pharmacy shall create one. The technician shall scan both the stock bottle and the label of the dispensed drug to verify that the drug dispensed is the same as the drug in the stock bottle for each prescription dispensed. D) A pharmacy may utilize a different electronic verification system that accomplishes the same purpose after review and approval of the Division.				68 Administrative Code Section 1330.510(b)(4)
Counseling must be done by a pharmacist via video link and audio link. Pursuant to Section 1330.700, the pharmacist providing counseling, pursuant to this subsection, must be employed or contracted by the home pharmacy or by a pharmacy contracted with the home pharmacy and have access to all relevant patient information maintained by the home pharmacy.				68 Administrative Code Section 1330.510(b)(5)

A pharmacist-in-charge or his or her designated pharmacist must complete monthly inspections of the remote site. Inspection criteria must be included in the policies and procedures for the site. The inspection report must be available on site for pharmacy investigator inspection.				68 Administrative Code Section 1330.510(b)(6)
Controlled substances shall be kept at the remote site in accordance with the Act and this Part. All records must be stored at the remote site.				68 Administrative Code Section 1330.510(b)(7)
There shall be a working computer link, video link and audio link to a pharmacist at a home pharmacy whenever the prescription area is open to the public. The communication link must be checked daily and the remote site pharmacy must be closed if the link malfunctions, unless a pharmacist is physically present at the remote site. A) The pharmacy technician located at the remote dispensing site must have one year of experience and be registered as a certified pharmacy technician, or be a student pharmacist. B) New prescriptions received at the remote dispensing site may be entered into the remote computer system with all verification, interaction, checking and profile review by the pharmacist at the home pharmacy. C) Each pharmacist at the home pharmacy may electronically supervise no more than 3 remote sites that are simultaneously open.				68 Administrative Code Section 1330.510(b)(8)
The facility must have a sign clearly identifying it as a remote dispensing site.				68 Administrative Code Section 1330.510(b)(9)
The facility shall have an area for patient consultation, exclusive of any waiting area.				68 Administrative Code Section 1330.510(b)(10)
No prescription may be dispensed after 15 months from the date of the original issuance of the prescription by the prescriber.				68 Administrative Code Section 1330.500(c)(1)
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 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)
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: <ol style="list-style-type: none"> 1. Name and address of patient 2. Date of Issuance 3. Practitioner's name and DEA number 4. Dispensing pharmacist's <u>written</u> signature or initials 5. Date of filling 6. No Schedule III, IV, and V filled or refilled more than 5 times nor more than 6 months 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
Controlled drug prescriptions 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(c)
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 77 Administrative Code 3100.360(e)
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)
In lieu of the printout required by subsection (c)(6), 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 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.				68 Administrative Code Section 1330.500(c)(7)
Proper transferring of prescriptions and handling of transferred prescriptions				68 Administrative Code Section 1330.720
Records for returned drugs are properly maintained.				68 Administrative Code Section 1330.750 21 CFR 1304.21(c)

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
All records are maintained for 5 years and are readily retrievable.				225 ILCS 85/18

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

**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: _____