

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)

TELEPHARMACY- AUTOMATED PHARMACY SYSTEMS

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)

AUTOMATED PHARMACY SYSTEMS				INSPECTION DATE			
<u>HOME PHARMACY</u>				<u>REMOTE AUTOMATED PHARMACY SYSTEM (RAPS) OR KIOSK</u>			
BUSINESS NAME				BUSINESS NAME			
ADDRESS				ADDRESS			
CITY				CITY			
ZIP CODE				ZIP CODE			
TELEPHONE							
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				NAME			
<input type="checkbox"/> Individual Non-pharmacist							
<input type="checkbox"/> Partnership				TELEPHONE			
<input type="checkbox"/> Corporation				E-MAIL			
<input type="checkbox"/> LLC				<u>PHARMACIST IN CHARGE</u>			
LICENSE NO.				REMOTE LICENSE NO.			
EXPIRES				EXPIRES			
DEA REG. NO.				DEA REG. NO.			
EXPIRES				EXPIRES			
ICSA LICENSE NO.				ICSA LICENSE NO.			
EXPIRES				EXPIRES			
LIST OF PHARMACISTS THAT WILL SUPERVISE THE AUTOMATED PHARMACY SYSTEM				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					
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
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 kiosk, or RAPS 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-charge of the remote site must be licensed in Illinois.					68 Administrative Code Section 1330.510(e)
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)
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SECURITY, SANITATION AND STORAGE	YES	NO	N/A	AUTHORITY
Security provisions are provided for all drugs and devices within the RAPS and Kiosk.				68 Administrative Code Section 1330.600 225 ILCS 85/22b
A pharmacy may use an automated pharmacy system to deliver prescriptions to a patient when the device: A) Is secured against a wall or floor; B) Provides a method to identify the patient and delivers the prescription only to that patient or the patient's authorized agent; C) Has adequate security systems and procedures to prevent unauthorized access, to comply with federal and State regulations, and to maintain patient confidentiality; D) Records the time and date that the patient removed the prescription from the system.				68 Administrative Code Section 1330.510(d)(3)
The RAPS or Kiosk is placed in a clean and sanitary location.				68 Administrative Code Section 1330.630
The RAPS or Kiosk shall be placed in a well-lighted and properly ventilated location.				68 Administrative Code Section 1330.610(c)
No expired medications are stored with active stock within RAPS or Kiosk.				410 ILCS 620/14(b)
All controlled substances are stored securely within the RAPS or Kiosk.				77 Administrative Code Section 3100.340

DISPENSING AND RECORDKEEPING FOR REMOTE AUTOMATED PHARMACY SYSTEMS (RAPS)	YES	NO	N/A	AUTHORITY
Access to and dispensing from an automated pharmacy system shall be limited to pharmacists or personnel who are designated in writing by the pharmacist-in-charge and have completed documented training concerning their duties associated with the automated pharmacy system.				225 ILCS 85/22b(b)
All drugs stored in relation to an automated pharmacy system must be stored in compliance				225 ILCS 85/22b(c)

with this Act and the rules adopted under this Act, including the requirements for temperature, proper storage containers, handling of outdated drugs, prescription dispensing, and delivery.				
An automated pharmacy system operated from a remote site shall be under the continuous supervision of a home pharmacy pharmacist. To qualify as continuous supervision, the pharmacist is not required to be physically present at the site of the automated pharmacy system if the system is supervised electronically by a pharmacist, as defined by rule.				225 ILCS 85/22b(d)
Drugs may only be dispensed at a remote site through an automated pharmacy system after receipt of an original prescription drug order by a pharmacist at the home pharmacy. A pharmacist at the home pharmacy must control all operations of the automated pharmacy system and approve the release of the initial dose of a prescription drug order. Refills from an approved prescription drug order may be removed from the automated medication system after this initial approval.				225 ILCS 85/22b(e)
If an automated pharmacy system uses removable cartridges or containers to store a drug, the stocking or restocking of the cartridges or containers may occur at a licensed wholesale drug distributor and be sent to the home pharmacy to be loaded after pharmacist verification by personnel designated by the pharmacist, provided that the individual cartridge or container is transported to the home pharmacy in a secure, tamper evident container. An automated pharmacy system must use a bar code verification or weight verification or electronic verification or similar process to ensure that the cartridge or container is accurately loaded into the automated pharmacy system. The pharmacist verifying the filling and labeling shall be responsible for ensuring that the cartridge or container is stocked or restocked correctly by personnel designated to load the cartridges or containers. An automated pharmacy system must use a bar code verification, electronic, or similar process, as defined by rule, to ensure that the proper medication is dispensed from the automated system.				225 ILCS 85/22b(f)
These devices shall maintain a prescription drug inventory that is controlled electronically by the home pharmacy or, when operated by a pharmacy contracted with the home pharmacy, by the contracted pharmacy, which shall be utilized to dispense patient specific prescriptions.				68 Administrative Code Section 1330.510(d)(1)(A)
These systems shall have prescription inventory, which must be secured in an automated pharmacy system and electronically connected to and controlled by the home pharmacy.				68 Administrative Code Section 1330.510(d)(1)(B)

A pharmacist must approve all the prescription orders before they are released from the RAPS.				68 Administrative Code Section 1330.510(d)(1)(C)
Dispensing and counseling are performed by a pharmacist employed or contracted by the home pharmacy via audio and video link.				68 Administrative Code Section 1330.510(d)(1)(D)
The pharmacist-in-charge of the home pharmacy, or a designated registrant, shall conduct and complete monthly inspections of the RAPS. Inspection criteria must be included in the policies and procedures for the site. The report must be available to the pharmacy investigators when requested.				68 Administrative Code Section 1330.510(d)(1)(F)
The RAPS must be licensed with the Division as an automated pharmacy system and will be subject to random inspection by pharmacy investigators. Notwithstanding that the RAPS shall possess a license, the home pharmacy shall remain responsible for inventory control and billing. For purposes of random inspections, a pharmacist with access to the system must be available at the site within one hour, or as otherwise approved by the drug compliance investigator. In the event the Department's Chief Pharmacy Coordinator determines that the RAPS poses a significant risk of patient harm, the RAPS must be disabled until such time as the pharmacist with access to the system is available to the site.				68 Administrative Code Section 1330.510(d)(1)(G)
<p>Medication dispensed at the automated pharmacy system site may only be packaged by a licensed manufacturer or repackager, or prepackaged by a licensed pharmacy in compliance with this Section. Prepackaging must occur at the home pharmacy, a pharmacy sharing common ownership with the home pharmacy, or a pharmacy that has contracted with the home pharmacy to perform prepackaging services. The following requirements shall apply whenever medications are prepackaged by a pharmacy other than the home pharmacy:</p> <ul style="list-style-type: none"> <li data-bbox="261 1423 824 1514">i) The prepackaging pharmacy shall be licensed in Illinois as a resident or nonresident pharmacy. <li data-bbox="261 1514 824 1787">ii) The prepackaging pharmacy shall share a common database with the home pharmacy, or have in place an electronic or manual process to ensure that both pharmacies have access to records to verify the identity, lot numbers and expiration dates of the prepackaged medications stocked in the RAPS. <li data-bbox="261 1787 824 1869">iii) The prepackaging pharmacy shall maintain appropriate records to identify the responsible pharmacist 				68 Administrative Code Section 1330.510(d)(1)(H)

who verified the accuracy of the prepackaged medication.				
Written prescriptions may be received at a RAPS. All written prescriptions presented to a RAPS shall be scanned utilizing imaging technology that permits the reviewing pharmacist to determine its authenticity. The sufficiency of the technology shall be determined by the Department. If sufficient technology is not used, the written prescriptions must be delivered to the home pharmacy and reviewed by a pharmacist prior to being dispensed to the patient.				68 Administrative Code Section 1330.510(d)(1)(I)
Controlled drug prescriptions and records must be properly filed and maintained.				21 CFR §1304.04

DISPENSING AND RECORDKEEPING OF KIOSK	YES	NO	N/A	AUTHORITY
A kiosk is a device that maintains individual patient prescription drugs that were verified and labeled at the home pharmacy.				68 Administrative Code Section 1330.510(d)(2)(A)
A home pharmacy may only use the kiosk with prior approval of a patient.				68 Administrative Code Section 1330.510(d)(2)(B)
A kiosk located on the same premises or campus of the home pharmacy shall operate under the same license as the home pharmacy. However, a kiosk must be licensed with the Division if it is not so located.				68 Administrative Code Section 1330.510(d)(2)(C)
A Kiosk shall: i) When located on the same premises or campus as the pharmacy, inform a patient, if using the device when the pharmacy is open, that the patient may address questions and concerns regarding the prescription to a pharmacist at the pharmacy; ii) When not located on the same premises or campus as the pharmacy, inform a patient, if using the device when the pharmacy is closed, that he or she may immediately direct any questions and concerns regarding the prescription to a licensed pharmacist via a pharmacy provided audio/video link; iii) Inform a patient that a prescription is not available to be delivered by the device if the pharmacist desires to counsel the patient in person regarding the prescription.				68 Administrative Code Section 1330.510(d)(2)(D)

DISPENSING AND RECORDKEEPING OF RAPS AND KIOSK	YES	NO	N/A	AUTHORITY
All controlled substances are dispensed in Good Faith.				720 ILCS 570/312(h)
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
Records for returned drugs are properly maintained.				68 Administrative Code Section 1330.750
A record of each transaction with the automated pharmacy system must be maintained for 5 years. A prescription dispensed from an automated pharmacy system shall be deemed to have been approved by the pharmacist.				225 ILCS 85/22b(f)

LABELING	YES	NO	N/A	AUTHORITY
All filled prescription must have a label that meets the requirements of the Act attached to the final drug container.				68 Administrative Code Section 1330.510(d)(1)(E)
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: _____