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)

REMOTE PRESCRIPTION/MEDICATION ORDER PROCESSING

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 <u>all</u> 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)

BUSINESS NAME	HOURS		EXPIRES	DATE OF INSPECTION
	м	NUMBER		
	т			
	w			
ADDRESS	тн	ICSA LICENSE NUMB	ER EXPIRES	PHARMACY LICENSE NUMBER
	F			
	SAT			
	SUN			
CITY ZIP	CODE OTHER HOURS EXCEP	TELEPHONE ()		
 Individual pharmacist Individual Non-pharmacist Partnership Corporation 	NERS	TELEPHONE AFTER H		Y E-MAIL ADDRESS
				2
R Ph IN CHARGE				

	If the Pharmacist in charge listed above is the PIC in other pharmacies, list here				
	NAME		PHONE NUMBER		
1.					
2.					
		1			

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				225 ILCS 85/15(5)
may be used when registrants are employed at multiple				
sites).				
Pharmacy is compliant with Section 1330.560 of the				68 Administrative Code
Illinois Pharmacy Practice Act Rules, Remote				Section 1330.560
Prescription/Medication Order Processing.				
The PIC has personally reviewed the licenses of all				68 Administrative Code
registrants and determined that they are current.				Section 1330.660
All pharmacy technicians and certified pharmacy				68 Administrative Code
technicians have completed the required training set forth				Section 1330.210
in the Act and Rules.				
Meet all the requirements when there is a change in				
Pharmacist-in-Charge including but not limited to proper				68 Administrative Code
notification to the Department.				Section 1330.660
The facility must have a sign clearly identifying it as a				68 Administrative Code
Remote Prescription/Medication Order Processing site.				Section 1330.510

SECURITY AND SANITATION	YES	NO	N/A	AUTHORITY
Security provisions are provided during the absence of a pharmacist.				68 Administrative Code Section 1330.600 and 225 ILCS 85/15(1)(b)
Facility is clean and sanitary.				68 Administrative Code Section 1330.630
Facility area shall not be used for storage of merchandise that interferes with the practice of pharmacy.				68 Administrative Code Section 1330.610(e)
The facility area and all store rooms shall be well-lighted and properly ventilated.				68 Administrative Code Section 1330.610(c)

REMOTE ORDER PROCESSING REQUIREMTENTS	YES	NO	N/A	AUTHORITY
The pharmacies shall either have the same owner or have a written contract describing the scope of services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with all federal and State laws and regulations related to the practice of pharmacy.				225 ILCS 85/25.10(b)(1)
The pharmacies shall share a common electronic file or have technology that allows sufficient information necessary to process a non-dispensing function.				225 ILCS 85/25.10(b)(2)
 Any pharmacy may provide remote prescription/medication order processing services to any other pharmacy as provided in Section 25.10 of the Act and the following further requirements: 1) Any nonresident pharmacy remote prescription/medication order processing services 				68 Administrative Code Section 1330.560(a)

	shall first be registered in its resident state and	
	registered in this State.	
2)	There shall be a secure, HIPAA compliant,	
_/	electronic communication system that shall	
	include but not be limited to computer, telephone	
	and facsimile connections.	
2)	The communication system shall give remote	
3)		
	access to all relevant patient information to allow	
	the pharmacist of the remote pharmacy to	
	perform remote medication order processing that	
	shall include all laboratory results and every	
	patient's or resident's medication profile, if	
	appropriate.	
4)	The secure electronic communication system	
	shall be maintained on a daily basis. If this	
	system malfunctions, the remote processing	
	pharmacy shall cease operations related to the	
	institution affected.	
5)	Nothing in this Section shall relieve the	
	pharmacist-in-charge of dispensing pharmacies	
	of compliance with Sections 1330.520 and	
	1330.530.	
Policy	and Procedure Manual:	68 Administrative Code
_	and procedure manual shall be maintained by	Section 1330.560(b)(1)
	note prescription/medication order processing	225 ILCS 85/25.10(b)(3)
	acy pertaining to the pharmacy's operations. The	
manual		
	Be accessible to the remote	
73.	prescription/medication order processing	
	pharmacy staff and the staff at the dispensing	
	pharmacy;	
Б	Be available for inspection by the Division;	
D.	Outline the responsibilities of the remote	
0.		
	prescription/medication order processing	
	pharmacy staff and the staff at the dispensing	
_	pharmacy;	
D.	Include a current list of the name, address,	
	telephone number and license number of each	
	pharmacist involved in remote	
	prescription/medication order processing;	
E.	Include policies and procedures for:	
	i. Protecting the confidentiality and integrity	
	of patient information;	
	ii. Ensuring that pharmacists performing	
	remote prescription /medication order	
	processing have access to appropriate	
	drug information resources;	
	iii. Ensuring that medical and nursing staff	
	when appropriate, understand how to	
	contact a pharmacist;	
1		

iy Moi	ntaining records to identify the name	
	ntaining records to identify the name,	
	als or identification code of each	
	rmacist who performs any processing	
	ction;	
	nplying with federal and State laws	
and	regulations;	
vi. Ope	erating or participating in a continuous	
qua	lity improvement program for	
pha	rmacy services designed to	
obje	ectively and systematically monitor	
and	evaluate the quality and	
app	ropriateness of patient care, pursue	
	ortunities to improve patient care, and	
	blve identified problems;	
	viewing the written policies and	
	cedures and documenting the review	
	ually.	
Every pharmacist pr		68 Administrative Code
	ion order processing services shall	Section 1330.560(b)(2)
• •	in the computer system, or on	
	, unalterable, uniformly maintained	
-	ble record the following information for	
-	der or prescription processed on	
behalf of a dispensi		
	nitials or other unique identifier of the	
pharmacist	who verifies the medication order or	
prescription	,	
B. The name of	f the patient or resident;	
C. The name, o	dose, dosage form, route of	
administrati	on and dosing frequency of the drug;	
D. The date an	d time of verification;	
E. The name of	f the prescribing/ordering practitioner;	
F. Any other in	formation that is required by the	
dispensing	pharmacy being served for use in its	
own records		
	lications entered at the remote	68 Administrative Code
	ion order processing pharmacy must	Section 1330.560(b)(3)
	nd readily retrievable from those	- ()(-)
entered at the institu	-	
The pharmacist-in-c	-	68 Administrative Code
•	ion order processing pharmacy shall	Section 1330.560(b)(4)
	iccess to the following records for a	
	-	
minimum of 5 years		
	medication orders processed;	
	the electronic communication system	
maintenanc		
	tion/medication order processing	68 Administrative Code
-	ntain a record containing the names	Section 1330.560(b)(5)
	s of all pharmacies to which they are	
providing services a	nd the number of hours per day the	

services are being provided.	
All pharmacists providing remote prescription/medication order processing at a remote pharmacy shall be licensed in Illinois. However, when pharmacists are providing remote prescription/medication order processing for a community pharmacy licensed in Illinois from a community pharmacy licensed in Illinois but located out- of-state, only the pharmacist-in-charge of the remote pharmacy must be licensed in Illinois.	68 Administrative Code Section 1330.560(c)
Only licensed pharmacists at the pharmacy providing remote pharmacy services shall conduct the drug utilization evaluation or review and validation of any order processed within the remote pharmacy, except as provided for in subsection (c).	68 Administrative Code Section 1330.560(d)

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: _____