

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)*

## **NON-STERILE COMPOUNDING**

### **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.

STATE OF ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION  
 DRUG COMPLIANCE UNIT  
 9511 HARRISON STREET, SUITE LL 50  
 DES PLAINES, IL 60016-1563

PHONE NUMBER: 847-294-4900

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

<b>NON-STERILE COMPOUNDING</b>					
<b>BUSINESS NAME</b>	<b>HOURS</b>		<b>DEA REGISTRATION NUMBER</b>	<b>EXPIRES</b>	<b>DATE OF INSPECTION</b>
	M				
	T				
	W				
<b>ADDRESS</b>	TH		<b>ICSA LICENSE NUMBER</b>	<b>EXPIRES</b>	<b>PHARMACY LICENSE NUMBER</b>
	F				
	SAT				
	SUN				
<b>CITY</b>	<b>ZIP CODE</b>	<b>OTHER HOURS EXCEP</b>	<b>TELEPHONE</b>		
			(      )		
<b>OWNERSHIP</b> <input type="checkbox"/> Individual pharmacist <input type="checkbox"/> Individual Non-pharmacist <input type="checkbox"/> Partnership <input type="checkbox"/> Corporation <input type="checkbox"/> LLC	<b>OWNERS</b>		<b>TELEPHONE AFTER HOURS</b>	<b>PHARMACY E-MAIL ADDRESS</b>	
			(      )		
	<b>PERSON IN CHARGE</b>		<b>OWNER'S E-MAIL ADDRESS</b>	<b>COUNTY</b>	
<b>NAME OF LICENSEE</b>				<b>LICENSE NUMBER</b>	
<b>R Ph IN CHARGE</b>					

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

<b>Pharmaceutical Compounding Standards (Section 1330.640)</b>				
<b>REQUIREMENTS</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>AUTHORITY</b>
<b>The minimum standards and technical equipment considered adequate for compounding drugs shall include:</b>				
A storage area separate for materials used in compounding.				68 Administrative Code Section 1330.640(a)
Scales and balances for the compounding done in the pharmacy.				68 Administrative Code Section 1330.640(b)
An area of the pharmacy used for compounding activities.				68 Administrative Code Section 1330.640(c)
A heating apparatus.				68 Administrative Code Section 1330.640(d)
A logbook or record keeping system to track each compounded prescription and the components used.				68 Administrative Code Section 1330.640(e)
A book or reference containing formulas with directions for compounding. The books and references may be in electronic format and/or available via the Internet.				68 Administrative Code Section 1330.640(f)
The pharmacy operations manual shall contain the policies and procedures pertinent to the level of complexity and the size of the compounding operations of the practice at that specific pharmacy. Electronic versions are acceptable.				68 Administrative Code Section 1330.640(g)
Consumable materials, as appropriate to the pharmacy services provided at that specific pharmacy, such as filter paper, powder papers, empty capsules, ointment jars, bottles, vials, safety closures, powder boxes, labels and distilled water.				68 Administrative Code Section 1330.640(h)
The pharmacy may compound drug products to be used by practitioners in their office for administration to patients.				68 Administrative Code Section 1330.640(i)
Sales of compounded drugs to other pharmacies not under common ownership, or to clinics, hospitals or manufacturers are not allowed, except for sales provided by pharmacies contracted to provide centralized prescription filling services pursuant to Section 25.5 of the Act, including compounding in anticipation of receiving a prescription or order based on routine, readily observed dispensing patterns.				68 Administrative Code Section 1330.640(j)

**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: \_\_\_\_\_