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)

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)

STERILE COMPOUNDING

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 ☐ Individual Non-pharmacist ☐ Partnership ☐ Corporation ☐ LLC	PERSON IN CHARGE	OWNER'S E-MAIL ADDRESS	COUNTY

NAME OF LICENSEE R Ph IN CHARGE	LICENSE NUMBER

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

Pharmaceutical Compounding Standards (Section 1330.640)				
REQUIREMENTS	**YES**	**NO**	**N/A**	**AUTHORITY**
The minimum standards and technical equipment considered adequate for compounding drugs shall include:				
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)

Compounded Sterile Preparation Standards (Section 1330.670)				
REQUIREMENT	**YES**	**NO**	**N/A**	**AUTHORITY**
This Section sets forth standards for pharmacies whose practice includes the preparation, labeling and distribution of compounded sterile preparations pursuant to prescriptions or medication orders, as defined in the Act. These activities may include, but are not limited to: 1. Sterile preparation of parenteral therapy and parenteral nutrition; 2. Sterile preparations of cytotoxic or antineoplastic agents; and 3. Other sterile preparations to be used topically or internally by humans or animals.				68 Administrative Code Section 1330.670(a)

PHYSICAL REQUIREMENTS OF PHARMACIES PREPARING COMPOUNDED STERILE PREPARATION	YES	NO	N/A	AUTHORITY
The pharmacy shall have a designated area for preparing compounded sterile preparations. The area shall be designed to minimize outside traffic and airflow disturbances from activity within the facility. It shall be of sufficient size to accommodate a laminar airflow hood (LAF), barrier isolation chamber or BSC and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation and security. It shall be ventilated in a manner so as not to interfere with the equipment specified in this subsection (c)(1).				68 Administrative Code Section 1330.670(c)(1)
The licensed pharmacy preparing compounded sterile preparations shall have the following: A. LAF workstation I. LAF shall be certified annually in accordance with ISO 14644-1; II. In the event the preparation apparatus is moved from its site of certification, recertification shall occur prior to resumption of use for compounding sterile preparations; III. Prefilters shall be inspected, replaced or cleaned per manufacturer specifications monthly and documentation of this maintained; B. Sink with hot and cold running water, which is convenient to, but apart from, the compounding area; C. National Institute for Occupational Safety and Health (NIOSH) approved disposal containers for used needles, syringes, etc., and, if applicable, cytotoxic waste from the preparation of chemotherapy agents; D. Biohazard cabinetry for environment control when cytotoxic compounded sterile preparations are prepared; E. Refrigerator and/or freezer with a thermometer or temperature recording device; and F. Temperature controlled containers for offsite deliveries.				68 Administrative Code Section 1330.670(c)(2)
The following current resource materials and texts shall be maintained in the pharmacy: A. American Hospital Formulary Service; B. Copies of the Act and this Part, the Illinois				68 Administrative Code Section 1330.670(c)(3)

Controlled Substances Act and 77 Ill. Adm. Code 3100, 21 CFR and the Illinois Hypodermic Syringes and Needles Act [720 ILCS 635]; C. One compatibility reference such as: i. Trissel's Handbook on Injectable Drugs; ii. King's Guide to Parenteral Admixtures; or iii. Any other Division approved publication; D. A file or reference on extended (more than 24 hours) stability data given to finished preparations.				

STAFFING	YES	NO	N/A	AUTHORITY
A pharmacist shall be accessible at all times at each licensed facility to respond to patients' and health professionals' questions and needs. A 24-hour telephone number will be included on all labeling of compounded medication and medication infusion devices if used off site.				68 Administrative Code Section 1330.670(d)

DRUG DISTRIBUTION AND CONTROL	YES	NO	N/A	AUTHORITY
Patient Profile or Medication Record System. A pharmacy generated patient profile or medication record system shall be maintained in addition to the prescription file. The patient profile or medication record system shall contain, at a minimum: A. Patient's full name; B. Date of birth or age; C. Gender; D. Compounded sterile preparations dispensed; E. Date dispensed, if off site; F. Drug content and quantity; G. Patient directions, if preparation being administered off site; H. Identifying number; I. Identification of dispensing pharmacist and, if applicable, pharmacy technician; J. Other drugs or supplements the patient is receiving, if provided by the patient or his or her agent; K. Known drug sensitivities and allergies to drugs and foods; L. Diagnosis; and M. Lot numbers of components or individual medicine if the compounded sterile preparation is not used within 48 hours after preparation.				68 Administrative Code Section 1330.670(e)(1)

Labeling. Each compounded sterile preparation dispensed to patients shall be labeled with the following information, using a permanent label: A. Name, address and telephone number of the licensed pharmacy, if not used within facility; B. Administration date and identifying number if used on site, date dispensed, and identifying number if used off site; C. Patient's full name and room number, if applicable; D. Name of each drug, strength and amount; E. Directions for use and/or infusion rate if used off site; F. Prescriber's full name if used off site; G. Required controlled substances transfer warnings, when applicable; H. Beyond use date and time; I. Identity of pharmacist compounding and dispensing, or other authorized individual; and J. Auxiliary labels storage requirements, if applicable.				68 Administrative Code Section 1330.670(e)(2)
The pharmacist-in-charge shall ensure that records are maintained for 5 years and are readily retrievable and in a format that provides enforcement agents an accurate and comprehensive method of monitoring distribution via an audit trail. The records shall include at least the following information: A) Patient profile; B) Medication record system; C) Purchase records; and D) Lot numbers of the components used in compounding sterile prescriptions/orders traceable to a specific patient, if not included on patient profile and if the preparation is not utilized within 48 hours after preparation.				68 Administrative Code Section 1330.670(e)(3)

DELIVERY SERVICE	YES	NO	N/A	AUTHORITY
The pharmacist-in-charge shall assure the environmental control of all preparations shipped or delivered off site. Therefore, any compounded, sterile pharmaceutical must be shipped or delivered to a patient in temperature controlled (as defined by USP Standards) delivery containers.				68 Administrative Code Section 1330.670(f)

CYTOTOXIC DRUGS	YES	NO	N/A	AUTHORITY
Safety and containment techniques or devices for compounding cytotoxic drugs shall be used.				68 Administrative Code Section 1330.670(g)(1)
Disposal of cytotoxic waste shall comply with all applicable local, State and federal requirements.				68 Administrative Code Section 1330.670(g)(2)
Prepared doses of cytotoxic drugs shall be dispensed,				68 Administrative Code

labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.				Section 1330.670(g)(3)
The pharmacy must have as a reference Safe Handling of Hazardous Drugs Video Training Program and Workbook (American Society of Health-System Pharmacists (ASHP), 7272 Wisconsin Avenue, Bethesda MD 20814, (301)657-3000, http://www.ashp.org).				68 Administrative Code Section 1330.670(g)(4)

EMERGENCY MEDICATIONS	YES	NO	N/A	AUTHORITY
Pharmacies that dispense compounded sterile preparations to patients in facilities off site or in the patient's residence shall stock supplies and medications appropriate for treatment of allergic or other common adverse effects, to be dispensed upon the prescription or order of an authorized prescriber.				68 Administrative Code Section 1330.670(h)

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: _____