**Section 1330.640 Pharmaceutical Compounding Standards**

All pharmaceutical compounding standards, both sterile and nonsterile, shall be governed by the USP-NF (USP 41-NF 36), as set forth in the United States Pharmacopoeia (USP), 41st Revision and the National Formulary, 36th Edition, Compounding Compendium, with the exception of USP Chapter <800> as it pertains to the handling of hazardous drugs in health care settings. Beginning May 1, 2019, all pharmaceutical compounding standards, both sterile and nonsterile, shall be governed by the USP-NF (USP 42-NF 37), as set forth in the 2019 edition of the USP Compounding Compendium, with the exception of USP Chapter <800> as it pertains to the handling of hazardous drugs in health care settings.

a) A pharmacy may only dispense compounded drugs pursuant to a valid patient-specific prescription, except as provided in this Section.

b) "Office use" means the administration of a non-patient specific compounded drug to a patient by a practitioner in the practitioner's office or by the practitioner in a health care facility or treatment setting. "Office use" does not include a pharmacy's delivery of a compounded drug to a prescribing practitioner's office pursuant to a valid patient-specific prescription.

c) Sterile compounding for office use is prohibited unless the pharmacy is in full compliance with 21 USC 353b, including becoming registered as an outsourcing facility and licensed as a wholesale drug distributor pursuant to the Wholesale Drug Distribution Licensing Act [225 ILCS 120]. However, a sterile compounded drug may be delivered to the prescribing practitioner's office for administration pursuant to a valid patient-specific prescription.

d) A pharmacist may dispense and deliver a reasonable quantity of a nonsterile compounded drug to a practitioner for office use by the practitioner in accordance with this Section, provided:

1) The quantity of compounded drug does not exceed the amount a practitioner anticipates may be used in the practitioner's office before the expiration of the beyond use date of the drug;

2) The quantity of compounded drug is reasonable considering the intended use of the compounded drug and the nature of the practitioner's practice;

3) The quantity of compounded drug for any practitioner, and all practitioners as a whole, is not greater than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality and purity of the compounded drug that are consistent with United States Pharmacopoeia guidelines;

4) The pharmacy maintains readily retrievable records of all compounded drugs ordered by practitioners for office use. The records must be maintained for a minimum of 5 years and shall include:

A) The name, address and phone number of the practitioner ordering the compounded drug for office use and the date of the order;

B) The name, strength, quantity and dosage form of the compounded drug provided, including the number of containers and quantity in each;

C) The date the drug was compounded;

D) The date the compounded drug was provided to the practitioner; and

E) The lot number and beyond-use date.

5) The pharmacy affixes a label to any compounded drug that is provided for office use. The label shall include:

A) The name, address and phone number of the compounding pharmacy;

B) The name, strength and dosage form of the compounded drug and a list of active ingredients and strengths. If the number of active ingredients would prohibit proper labeling, then the pharmacist shall provide to the practitioner a complete list of the active ingredients and strengths (including those on the label);

C) The pharmacy's lot number and beyond-use date;

D) The quantity or amount in the container;

E) The appropriate ancillary instructions, such as storage instructions, cautionary statements, or hazardous drug warning labels when appropriate; and

F) The statement "For Office Use Only – Not for Resale".

e) All pharmacies that compound drugs must maintain, at a minimum, the following standards and equipment:

1) A separate storage area for materials used in compounding;

2) Scales or measuring devices with sufficient accuracy for the products to be compounded;

3) An area of the pharmacy used exclusively for compounding;

4) A logbook or record keeping system to track each compounded drug, which must include the lot number, expiration date of components used, and beyond-use date of compounded drug. This applies to each nonsterile compounded drug and each sterile compounded drug with a beyond-use date greater than 24 hours;

5) The current edition of the USP Compounding Compendium. This publication may be in electronic format and/or available via the internet;

6) If engaged in veterinary drug compounding, "Plumb's Veterinary Drug Handbook" or any other similar publication approved by the Division;

7) Consumable materials, as appropriate to the pharmacy services provided at that specific pharmacy, including but not limited to: filter paper, powder papers, empty capsules, ointment jars, bottles, vials, safety closures, powder boxes, labels and distilled water;

8) Drug Distribution and Control

A) 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:

i) Patient's name;

ii) Date of birth or age;

iii) Gender;

iv) Compounded sterile drugs dispensed;

v) Date dispensed, if off site;

vi) Date compounded;

vii) Drug content and quantity;

viii) Patient directions, if drug is administered off site;

ix) Other drugs or supplements the patient is receiving, if provided by the patient or his or her agent; and

x) Known drug sensitivities and allergies to drugs and foods.

B) Labeling. Each compounded drug dispensed to patients shall be labeled with the following information, using a permanent label:

i) Name, address and telephone number of the licensed pharmacy, if not used within the facility;

ii) Date dispensed and identifying number, if used off site;

iii) Patient's name and room number, if applicable;

iv) Name of each drug component, strength, amount and dosage form;

v) Directions for use and/or infusion rate, if used off site;

vi) Prescriber's name, if used off site;

vii) Required controlled substances transfer warnings, when applicable;

viii) Beyond-use date, and time if appropriate;

ix) If used offsite, identity of compounding and dispensing pharmacist or other authorized individual; and

x) Auxiliary label with storage requirements, if applicable.

C) In addition to labeling requirements on the Pharmacy Practice Act [225 ILCS 85] and this Part, compounded drugs dispensed to patients shall have on the label or an auxiliary label the following: "This prescription was specifically compounded in our pharmacy for you at the direction of your prescriber."

D) The pharmacist-in-charge shall ensure that records are maintained for 5 years, 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:

i) Purchase records; and

ii) Patient profile or medication;

9) Delivery Service. The pharmacist-in-charge shall ensure the environmental control of all preparations shipped or delivered off site. Therefore, any compounded pharmaceutical must be shipped or delivered to a patient in temperature controlled (as defined by USP Standards) delivery containers; and

10) Sales of compounded drugs to other pharmacies not under common ownership, or to clinics, hospitals or manufacturers, other than as provided in subsection (d), 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.

f) For sterile compounding, a pharmacy must comply with the following additional requirements:

1) The following current resource materials and texts shall be maintained in the pharmacy and may be in electronic format:

A) Copies of the Act and this Part, the Illinois Controlled Substances Act [720 ILCS 570] and 77 Ill. Adm. Code 3100, 21 CFR (Food and Drugs), and the Illinois Hypodermic Syringes and Needles Act [720 ILCS 635];

B) One compatibility reference, such as:

i) ASHP's Handbook on Injectable Drugs;

ii) King's Guide to Parenteral Admixtures; or

iii) Any other Division-approved publication; and

C) A file or reference on extended (more than 24 hours) stability data given to finished preparations.

2) Staffing. A pharmacist shall be accessible at all times to enable each licensed facility to respond to patients' and health professionals' questions and needs. A 24-hour telephone number shall be included on the prescription label of compounded drugs and medication infusion devices if used off site.

3) Emergency Medications. Pharmacies that dispense compounded sterile drugs to patients in facilities off site or for administration 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.

g) Notwithstanding any other provision of this Section, a pharmacy may compound a reasonable quantity of sterile and nonsterile drug products for office use by a veterinarian.

h) It shall be the ongoing responsibility of the pharmacist-in-charge to ensure that all pharmacists, student pharmacists, registered certified pharmacy technicians, and registered pharmacy technicians who participate in compounding activities are adequately trained for the type of compounding in which they participate. Documentation of this training shall be maintained by the pharmacy at all times.

i) Any pharmacy that, after initial licensure, chooses to add sterile compounding to the services it provides must be inspected by, and the compounding area must be approved by, the Department. It shall be the responsibility of the pharmacist-in-charge to notify the Department and arrange for the inspection.

j) For the purposes of this Section, "off-site" for all pharmacies, other than an onsite institutional pharmacy, means outside the licensed premises of a pharmacy. "Off-site" for an onsite institutional pharmacy means outside the institution within which the pharmacy is located.

(Source: Amended at 42 Ill. Reg. 20022, effective November 9, 2018)