247 CMR 18.00: NON-STERILE COMPOUNDING

Section

18.01: Authority and Purpose

247 CMR 18.00 is promulgated under the authority granted to the Board by M.G.L. c. 112, §§ 39F, 39H, 39J and 42A. The purpose of 247 CMR 18.00 is to establish minimum professional standards for non-sterile compounding in order to safeguard the public health and welfare. 247 CMR 18.00 applies to pharmacies that hold a drug store license, non-resident drug store license, complex non-sterile compounding pharmacy license, and non-resident complex non-sterile compounding pharmacy license.

18:02: Licensure Requirements

(1) A pharmacy that holds a drug store license and conducts complex non-sterile compounding, including hazardous drug (HD) compounding, shall hold a separate license in accordance with M.G.L. c. 112, §§ 39F, 39H and 39J.

(2) Any pharmacy licensed by the Board may not simultaneously hold an outsourcing facility registration issued by the U.S. Food and Drug Administration (FDA) pursuant to 21 U.S.C. § 353b.

18.03: General Requirements

(1) A licensee that performs non-sterile compounding, including veterinary compounding, shall comply with all state and federal laws and regulations and all chapters of the most current United States Pharmacopeia (USP).

(2) A pharmacy shall maintain written policies and procedures on all aspects of the compounding operation based on the type of non-sterile compounding conducted.

(3) A pharmacy that is licensed to conduct complex non-sterile compounding shall maintain a formal, written Quality Assurance Program in accordance with USP <1163>.

(4) A pharmacy shall maintain written policies and procedures requiring the immediate recall of any compounded non-sterile preparation (CNSP) that is contaminated or defective or suspected to be contaminated or defective.

(5) A pharmacy shall maintain a written continuity of care plan that describes how patient needs will be met in the event the pharmacy is unable to compound or dispense CNSPs.

(6) A pharmacy may not prepare CNSPs identified as demonstrably difficult to compound by the FDA or the Board.

18.04: General Facility and Equipment Requirements

(1) A pharmacy shall have a designated non-sterile compounding area that has at least 10 square feet of counter space that is smooth, seamless, impervious, free from cracks and crevices, non-shedding, and resistant to damage by cleaning and sanitizing agents.

(2) A pharmacy licensed to conduct complex non-sterile compounding shall:
   (a) have a room(s) dedicated to non-sterile compounding totaling at least 100 square feet;
   (b) have surfaces that are smooth, seamless, impervious, free from cracks and crevices, non-shedding, and resistant to damage by cleaning and sanitizing agents;
   (c) in addition to the sink requirements of 247 CMR 9.00, have a sink dedicated for non-sterile compounding activities that is located within, or immediately adjacent to the compounding room(s); and
   (d) ensure that water sources and drains are located at least one meter away from any closed-system processing device or Containment Primary Engineering Control (C-PEC).

(3) A pharmacy shall ensure that a designated non-sterile compounding area is separated or otherwise protected from water sources (i.e., sink).

(4) Non-sterile compounding equipment, utensils, and glassware shall be clean, properly maintained, and appropriate for compounding non-sterile preparations. Compounding personnel shall inspect equipment, utensils, and glassware for suitability prior to use.

18.05: Hazardous Drugs (HD)

(1) Non-sterile HD compounding shall adhere to the requirements of USP <800>.

(2) A pharmacy shall utilize a pressure-differential monitoring system to continuously measure the pressure differential of the Containment Secondary Engineering Control (C-SEC) utilized for non-sterile HD compounding.

(3) The quantitative results from the pressure-differential monitoring system must be reviewed and documented at least once daily on all days the pharmacy is open, prior to engaging in compounding for the day, if applicable.

(4) A pharmacy shall respond to out-of-range differential pressures in a timely manner and document the response.

(5) A pharmacy may not compound non-sterile, non-HD preparations in a C-PEC or C-SEC that is used for non-sterile HD preparations.

18:06: Components

(1) Except for Active Pharmaceutical Ingredients (API), a pharmacy shall obtain all other components used in non-sterile compounding from an FDA-registered facility, if available. If obtaining said components from a non-FDA-registered facility, the pharmacist shall verify and document suitability for its intended use.

(2) A pharmacy shall review and maintain a certificate of analysis (COA) for each component to verify that the component has the expected identity, strength, quality, and purity and is suitable for its intended use.

(3) A pharmacy shall ensure each component used in compounding is clearly labeled with the product name, supplier, lot number, strength or concentration, expiration date, and transfer date if the component was transferred out of its original container.

18.07: Beyond Use Date (BUD)

A pharmacy shall assign a BUD in accordance with USP <795> or Board policy, whichever is stricter.

18.08: Master Formulation Records

(1) A pharmacy shall maintain and follow a master formulation record each time it prepares a CNSP.

(2) A pharmacy shall verify that master formulations are based on USP standards, any relevant scientific data, or direct validation testing to ensure that CNSPs prepared according to the master formulation record are stable and have the correct potency for the assigned BUD. This verification must be performed initially and any time there is a change to the master formulation record.

18.09: Compounding Records

(1) Each time it prepares a CNSP, a pharmacy shall complete and maintain a compounding record that includes all elements as specified in the most recent version of USP <795> and in M.G.L. c. 112, § 39D for "accountability documentation".

(2) A pharmacist shall verify the compounding record and master formulation record to ensure that errors did not occur in the compounding process and that the CNSP is suitable for its intended use.

18.10: Packaging and Labeling

(1) A pharmacy shall utilize containers and closures made of suitable and clean material that do not alter the quality, strength, or purity of the CNSP.

(2) A pharmacy shall verify that any packaging and transporting processes do not adversely affect the integrity and stability of the CNSP.

(3) A pharmacy shall label each CNSP with the prescription labeling requirements of M.G.L. c. 94C, § 21 and USP <795>.

18.11: Counseling

(1) In addition to the counseling requirements in 247 CMR 9.00, a pharmacist or pharmacy intern shall instruct the patient or patient's agent to report to the pharmacy any changes in the physical characteristics of the CNSP, or any adverse event resulting from the CNSP.

(2) 247 CMR 18.11 does not apply to any CNSP dispensed for administration in a nursing home or other inpatient or outpatient facility, unless otherwise required by law or regulation.