

201 KAR 2:076. Compounding.

RELATES TO: KRS 217.055(2), 217.065(7), 315.020(1), 315.035(6), 315.0351, 315.191(1)(a), (g)

STATUTORY AUTHORITY: KRS 315.020(1), 315.035(6), 315.0351, 315.191(1)(a), (g)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.020(1) requires the owner of a pharmacy who is not a pharmacist to place a pharmacist in charge of the owner's pharmacy. KRS 315.035(6) authorizes the board to promulgate administrative regulations to assure minimum standards of practice of compounding by pharmacies and pharmacists, and to assure the safety of all products provided to the citizens of the Commonwealth. KRS 315.191(1) authorizes the board to promulgate administrative regulations necessary to regulate and control all matters relating to pharmacists, pharmacist interns, pharmacy technicians, pharmacies, wholesale distributors, and manufacturers. This administrative regulation establishes the requirements for compounding non-sterile and sterile preparations.

Section 1.

- (1) A policy and procedure manual for non-sterile and sterile compounding shall be readily available at a pharmacy for inspection purposes.
- (2) A copy of the manual shall be made available to the board upon request.
- (3) The manual shall be reviewed and revised on an annual basis.

Section 2.

- (1) Effective January 1, 2018, all non-sterile compounded preparations shall be compounded pursuant to United States Pharmacopeia (USP) 795, unless specified portions submitted by a pharmacist have been waived by the board.
- (2) Effective January 1, 2018, all sterile compounded preparations shall be compounded pursuant to USP 797, unless specified portions submitted by a pharmacist have been waived by the board.
- (3) After January 1, 2018, all written waiver requests submitted by a pharmacist shall be considered by the Board at its next regularly scheduled meeting.
- (4) The board, upon a showing of good cause and in balancing the best interest of the public health, safety and welfare, may waive the requirement of any specified portion of USP 795 or 797.

Section 3.

- (1) A facility that compounds non-sterile or sterile preparations shall be managed by a pharmacist-in-charge (PIC) licensed to practice pharmacy in the Commonwealth and who is knowledgeable in the specialized functions of preparing and dispensing compounded non-sterile and sterile preparations, including the principles of aseptic technique and quality assurance.
- (2) The PIC shall be responsible for the: purchasing, storage, compounding, repackaging, dispensing, distribution of all drugs and preparations, development and continuing review of all policies and procedures, training manuals, quality assurance programs, and participation in those aspects of the facility's patient care evaluation program relating to pharmaceutical material utilization and effectiveness.
- (3) The PIC may be assisted by additional pharmacy personnel adequately trained, to the satisfaction of the PIC, in this area of practice and for each product they will be compounding.

Section 4.

- (1) The pharmacist shall receive a written, electronic, facsimile, or verbal prescription, or medical order from a prescriber before dispensing any compounded, non-sterile or sterile preparation. These prescriptions or medical orders shall contain the following:

- (a) Patient's name, and species if not human;
 - (b) Patient's address on controlled substances prescriptions or location (room number);
 - (c) Drug name and strength;
 - (d) Directions for use;
 - (e) Date;
 - (f) Authorized prescriber's name;
 - (g) Prescriber's address and DEA number, if applicable;
 - (h) Refill or end date instructions, if applicable; and
 - (i) Dispensing quantity, if applicable.
- (2) A pharmacy generated patient profile shall be maintained separate from the prescription file. The patient profile shall be maintained under the control of the PIC for a period of two (2) years following the last dispensing activity. In addition, a medication administration record (MAR) as part of the institutional record shall be retained for a period of five (5) years from date of the patient's discharge from the facility, or in the case of a minor, three (3) years after the patient reaches the age of majority under state law, whichever is the longer. Supplemental records may also be employed as necessary. The patient profile shall contain:
- (a) Patient's name;
 - (b) Name of compounded preparation dispensed;
 - (c) Date dispensed;
 - (d) Drug content and quantity; and
 - (e) Patient's directions.
- (3) Each compounded preparation dispensed to patients shall be labeled with the following information:
- (a) Name, address, and telephone number of the licensed pharmacy, if product will leave the premises;
 - (b) Date;
 - (c) Identifying number;
 - (d) Patient's full name;
 - (e) Name of each drug, strength, and amount;
 - (f) Directions for use, including infusion rate;
 - (g) Required controlled substances transfer warnings, where applicable;
 - (h) Beyond use date;
 - (i) Identity of dispensing pharmacist;
 - (j) Storage requirements, when applicable; and
 - (k) Auxiliary labels, when applicable.
- (4) The PIC shall maintain access to and submit, as appropriate, such records and reports as are required to ensure the patient's health, safety, and welfare. Records shall be readily available, maintained for two (2) years at a facility not computerized, but for five (5) years at a facility utilizing computerized recordkeeping, and subject to inspection by the Board of Pharmacy or its agents. These shall include the following:
- (a) Patient profile;
 - (b) Purchase records;
 - (c) Biennial controlled substances inventories;
 - (d) Policy and procedures manual;
 - (e) Policies and procedures for hazardous wastes, if applicable;
 - (f) Quality assurance records; and
 - (g) Such other records and reports as may be required by law and rules and administrative regulations of the Kentucky Board of Pharmacy.
- (5) Information regarding individual patients shall be maintained in a manner to assure confidentiality of the patient's records. Release of this information shall be in accordance with federal and state laws.

(6) The PIC shall be responsible for the environmental control of all products shipped. Any compounded product that is frozen or requires refrigeration shall be shipped or delivered to a patient in appropriate temperature controlled delivery containers, if the product leaves the premises.

(7) The PIC shall be responsible for assuring that there is a system for the disposal of hazardous waste in a manner that does not endanger the public health.

Section 5. Hazardous Drugs.

(1) Effective January 1, 2018, all non-sterile preparations that contain hazardous substances shall be compounded pursuant to USP 795.

(2) Effective January 1, 2018, all sterile compounded preparations that contain hazardous substances shall be compounded pursuant to USP 797.

Section 6. Violation of any provision of this administrative regulation shall constitute unethical or unprofessional conduct in accordance with KRS 315.121.

Section 7. Incorporation by Reference.

(1) The following material is incorporated by reference:

(a) USP 795, Revision Bulletin, Official January 1, 2014; and

(b) USP 797, Revision Bulletin, Official June 1, 2008.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. through 4:30 p.m.

(16 Ky.R. 1716; Am. 2152; 2652; eff. 6-10-1990; 43 Ky.R. 2184; 44 Ky.R. 510; eff. 9-20-2017.)