BOARDS AND COMMISSIONS
Board of Pharmacy
(Amended at ARRS Committee)

201 KAR 2:076. Compounding.

RELATES TO: KRS 217.055(1), 217.065(7), 315.020(1), 315.035(6), 315.0351, 315.121, 315.191(1)(a), (g), 21 U.S.C. 353A, 21 C.F.R. 216.23

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 that proper equipment and reference material is on hand considering the nature of the pharmacy practice conducted at the particular pharmacy and to assure reasonable health and safety standards for areas within the pharmacies, which are not subject to these standards under CHFS. 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, and the preparation, compounding, dispensing, and repackaging of radiopharmaceuticals in accordance with 21 U.S.C. 353A.

Section 1. Definitions.

(1) "API" means active pharmaceutical ingredient.

(2) "Designated person" means one (1) or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of compounded non-sterile or sterile preparations or the preparation, compounding, dispensing, and repackaging of radiopharmaceuticals.

(3) "Essential copy of a commercially available drug product" is a compounded preparation in which:

(a) The compounded preparation has the same API as the commercially available drug product;

(b) The APIs have the same, similar, or an easily substitutable dosage strength; and

(c) The commercially available drug product can be used by the same route of administration as prescribed for the compounded preparations, unless a prescriber determines that there is a change, made for an identified individual patient, which produces, for that patient, a significant difference from the commercially available drug product.

(4) "Hazardous Drug" means any drug identified by the National Institute for Occupational Safety and Health with at least one (1) of the following criteria:

(a) Carcinogenicity, teratogenicity, or developmental toxicity;

(b) Reproductive toxicity in humans;

(c) Organ toxicity at low dose in humans or animals;

(d) Genotoxicity; or

(e) New drugs that mimic existing hazardous drugs in structure or toxicity.

(5) "USP" means United States Pharmacopeia.

Section 2. Policies and Procedures.

(1) A policy and procedure manual for non-sterile and sterile compounding shall be readily available at a pharmacy for inspection purposes.

(2) The policy and procedure manual shall be made available to the board upon request.

(3) The manual shall be reviewed and revised on an annual basis.

Section 3. Standards.

(1) All non-sterile compounded preparations shall be compounded pursuant to USP 795.

(2) All sterile compounded preparations shall be compounded pursuant to USP 797.

(3) All preparation, compounding, dispensing, and repackaging of radiopharmaceuticals shall be pursuant to USP 825.

(4) All non-sterile or sterile compounded preparations containing hazardous drugs shall be compounded pursuant to USP 800, unless specified portions submitted by a pharmacy have been waived by the board.

(5) Non-sterile and sterile preparations compounded for human use shall:[

(a)

1. Comply with the standards of an applicable USP or National Formulary monograph;

2. Be compounded from a component of a human drug approved by the United States Food and Drug Administration (FDA); or

3. Be compounded from a component that appears on the FDA's list of bulk drug substances established in 21 C.F.R. 216.23 that can be used in compounding; and

(b) Not be essential copies of a commercially available drug product unless authorized by 21 U.S.C. 353(a).

Section 4. Designated Person.

(1) The designated person of a facility that compounds non-sterile or sterile preparations or prepares, compounds, dispenses, or repackages radiopharmaceuticals shall be knowledgeable in the specialized requirements of preparing and dispensing compounded preparations.

(2) The PIC shall serve or appoint any designated person.

(3) The PIC shall ensure any compounded preparation leaving the premises is shipped or delivered in a manner that maintains the integrity and stability of the preparation.

Section 5. Dispensing and Labeling.

(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 pharmacist dispensing compounded preparations for veterinary use shall follow the order requirements of 201 KAR 2:311.

(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 preparation 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 warning, if applicable;

(h) Beyond use date;
(i) Identity of dispensing pharmacist;
(j) Storage requirements, if applicable; and
(k) Auxiliary labels, if applicable.

(4) Verification of a compounded preparation shall be completed by a pharmacist after the preparation is compounded and prior to dispensing to the patient. Documentation of the verification shall include notation of each pharmacist who performs verification.

Section 6. Recordkeeping.

(1) The PIC shall maintain access to and provide records and reports to the board or its agents upon request. Records shall be maintained and readily available for no less than five (5) years.

(2) Records. Records shall include the following:
(a) Prescriptions, medical orders, or requests for compounded preparations;
(b) Purchase records;
(c) Verification records; and
(d) Other records and reports as required by USP 795, 797, 800, and 825.

Section 7. Violations. Violation of any provision of this administrative regulation shall constitute unethical or unprofessional conduct in accordance with KRS 315.121.

Section 8. Waivers.

(1) All written waiver requests submitted by a pharmacy shall be considered by the board at its next regularly scheduled meeting.

(2) 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, 797, 800 or 825 or any provision of this administrative regulation. Any waiver issued shall identify with specificity the pharmacy to which is applies and the provisions of law for which the waiver is applied.

Section 9. Enforcement Discretion.

(1) Effective January 1, 2026, the board shall enforce the 2022 revisions to USP Chapters USP 795, 797, and 800. Until January 1, 2026, the board shall enforce the 2014 revision of USP 795 and the 2008 revision of USP 797, and the board shall not enforce USP 800. Until January 1, 2026, at the request of a permit holder, the board may inspect pursuant to the 2022 revision of the USP Chapters 795, 797, and 800.

(2) The board shall not enforce the USP 795 standard that the addition of flavoring to a commercially available drug is compounding, if the additive:
(a) Is non-expired, inert, nonallergenic, and produces no effect other than the instillation or modification of flavor; and
(b) Is not greater than five (5) percent of the drug product's total volume.

Section 10. Incorporation by Reference.

(1) The following material is incorporated by reference:
(a) "USP 795, Revision Bulletin, Official", November 1, 2022;
(b) "USP 795, Revision Bulletin, Official", January 1, 2014;
(c) "USP 797, Revision Bulletin, Official", November 1, 2022;
(d) "USP 797, Revision Bulletin Official", June 1, 2008;
(e) "USP 825, Revision Bulletin, Official, Official", December 1, 2020; and
(f) "USP 800, Revision Bulletin", December 1, 2020.

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(16 Ky.R. 1716; Am. 2152; 2652; eff. 6-10-1990; 43 Ky.R. 2184; 44 Ky.R. 510; eff. 9-20-2017; 48 Ky.R. 879, 1726; eff. 12-15-2021; 50 Ky.R. 91, 802; eff. 10-25-2023.)

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CONTACT PERSON: Christopher Harlow, Executive Director, Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, Frankfort, Kentucky 40601, phone (502) 564-7910, fax (502) 696-3806, email Christopher.harlow@ky.gov.