BOARDS AND COMMISSIONS

Kentucky Board of Pharmacy

(Amendment)

201 KAR 2:076. Compounding.

RELATES TO: KRS 217.055(1)~~(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, and the preparation, compounding, dispensing and repackaging of radiopharmaceuticals.

Section 1. Definitions.

(1) API means active pharmaceutical ingredient.

(2) Designated person means one 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 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)~~1~~. 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 ~~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 (3)~~2~~. Standards

(1) All non-sterile compounded preparations shall be compounded pursuant to ~~United States Pharmacopeia (USP)~~ USP 795, unless specified portions submitted by a pharmacy ~~pharmacist~~ have been waived by the board. ~~Notwithstanding any USP guidance to the contrary,~~

(2)The addition of flavoring to a commercially available drug shall not be considered non-sterile 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.

(3) ~~(2)~~ All sterile compounded preparations shall be compounded pursuant to USP 797, unless specified portions submitted by a pharmacy ~~pharmacist~~ have been waived by the board.

(4)~~(3)~~ All preparation, compounding, dispensing and repackaging of radiopharmaceuticals shall be pursuant to USP ~~United States Pharmacopeia (USP)~~ 825, unless specified portions submitted by a pharmacy ~~pharmacist~~ have been waived by the board.

(5) 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.

(6)~~(4)~~ All written waiver requests submitted by a pharmacy ~~pharmacist~~ shall be

considered by the Board at its next regularly scheduled meeting.

(6) ~~(5)~~ 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. Any waiver issued shall identify with specificity the pharmacy to which it applies.

(7) Non-sterile and sterile preparations compounded for human use must:

(a) Comply with the standards of an applicable USP or National Formulary monograph; or

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

(c) Be compounded from a component that appears on the FDA's list of bulk drug substances that can be used in compounding.

(d) Not be essential copies of a commercially available drug product.

Section 4~~3~~. Pharmacist-in-Charge

(1) The pharmacist-in-charge (PIC) of a ~~A~~ facility that compounds non-sterile or sterile preparations or prepares, compounds, dispenses or repackages radiopharmaceuticals shall be ~~managed by a pharmacist-in-charge (PIC) licensed to practice pharmacy in the Commonwealth and who is~~ knowledgeable in the specialized requirements ~~functions~~ of preparing and dispensing compounded ~~non- sterile and sterile~~ preparations~~, including the principles of aseptic technique and quality assurance~~.

(2) The PIC shall serve as the primary designated person and shall be responsible for the appointment for any additional designated persons. ~~The PIC shall be responsible for the: purchasing, storage, compounding, repackaging, dispensing, of 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 shall be responsible to ensure any compounded product leaving the premises is shipped or delivered in a manner that maintains the integrity and stability of the preparation ~~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 5 4. 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 must follow the order requirements of 201 KAR 2:311 ~~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) 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 each pharmacist who performs verification.

Section 6. Recordkeeping

(1) ~~(4)~~ The PIC shall maintain access to and provide ~~submit, as appropriate, such~~ records and reports to the board or its agents upon request. ~~as are required to ensure the patient's health, safety, and welfare~~. Records shall be maintained and readily available for no less than five (5) years~~, 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~~.

(2) Records ~~These~~ shall include the following:

(a) Prescriptions or medical orders or requests for compounded preparations ~~Patient profile~~;

(b) Purchase records

(c) Verification records ~~Biennial controlled substances inventories~~;

(d) ~~Policy and procedures manual;~~

(e) ~~Policies and procedures for hazardous wastes, if applicable~~;

(~~f) Quality assurance records;~~

(g)Other records and reports as ~~may be~~ required by USP 795, 797, 800 and 825, state and federal law, and administrative regulations of the Kentucky Board of Pharmacy ~~KRS 217 or 315 and 201 KAR Chapter 2~~.

~~(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) All non-sterile preparations that contain hazardous substances shall be compounded pursuant to USP 795.~~

~~(2) All sterile compounded preparations that contain hazardous substances shall be compounded pursuant to USP 797.~~

Section 7~~6~~. Violations.

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

Section 8~~7~~. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) USP 795, Revision Bulletin, Official November 1, 2022 ~~January 1, 2014~~; ~~and~~

(b) USP 797, Revision Bulletin, Official November 1, 2022 ~~June 1, 2008;~~ and

(c) USP 825, Revision Bulletin, Official, Official December 1, 2020

(d) USP 800, Revision Bulletin, Official DATE

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