

BOARDS AND COMMISSIONS
Board of Pharmacy
(Amendment)

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[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. Notwithstanding any USP guidance to the contrary, the addition of flavoring to a drug shall not be considered non-sterile compounding, when such additive:

(a) Is 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.

(2) ~~[Effective January 1, 2018,]~~ All[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) All preparation, compounding, dispensing and repackaging of radiopharmaceuticals shall be pursuant to United States Pharmacopeia (USP) 825, unless specified portions submitted by a pharmacist have been waived by the board.

(4) ~~[After January 1, 2018,]~~ All[all] written waiver requests submitted by a pharmacist shall be considered by the Board at its next regularly scheduled meeting.

(5)~~[(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,~~[-of]~~ 797 or 825.

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 [all] non-sterile preparations that contain hazardous substances shall be compounded pursuant to USP 795.

(2) ~~[Effective January 1, 2018,]~~ All [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; ~~[and]~~ and
- (c) USP 825, Revision Bulletin, Official, Official December 1, 2020.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, [Suite 300, 125 Holmes Street,] Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. through 4:30 p.m. This material is also available on the board's Web site at <https://pharmacy.ky.gov/statutesandregulations/Pages/default.aspx>.

LARRY A. HADLEY, R.Ph., Executive Director

APPROVED BY AGENCY: August 10, 2021

FILED WITH LRC: August 10, 2021 at 12:15 p.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held on October 26, 2021 at 9:00 a.m. Eastern Time at the Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, Frankfort, Kentucky 40601. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to com-

ment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through October 31, 2021. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

CONTACT PERSON: Larry Hadley, 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 Larry.Hadley@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: Larry Hadley

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation sets forth the requirements for compounding non-sterile and sterile preparations.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to set forth the requirements for compounding non-sterile and sterile preparations to promote public health, safety, and welfare.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation, authorized by KRS 315.035(6) and KRS 315.191(1), establishes the requirements for compounding non-sterile and sterile preparations.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: KRS 315.035(6) authorizes the Board of Pharmacy 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.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This amendment will allow adding a flavor to a drug without such addition being considered non-sterile compounding so long as the additive is inert, nonallergenic, produces no effect other than the instillation or modification of flavor, is not greater than five (5) percent of the drug product's total and volume. This amendment also implements USP 825 for radiopharmaceutical governance in the Commonwealth.

(b) The necessity of the amendment to this administrative regulation: This amendment to the administrative regulation is necessary to set forth the requirements for compounding non-sterile and sterile preparations to promote public health, safety and welfare.

(c) How the amendment conforms to the content of the authorizing statutes: This amendment to the administrative regulation, authorized by KRS 315.035(6) and KRS 315.191(1), establishes the requirements for compounding non-sterile and sterile preparations.

(d) How the amendment will assist in the effective administration of the statutes: KRS 315.035(6) authorizes the Board of Pharmacy 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 in the Commonwealth.

(3) List the type and number of individuals, businesses, organizations, or state and local government affected by this administrative regulation: The board anticipates licensees, permit holders and registrants will be minimally impacted by this new regulation.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by ei-

ther the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Licensees, permit holders and registrants will have to familiarize themselves with this new regulation. This regulation provides the requirements for compounding non-sterile and sterile preparations. The board will help educate identified entities of this new regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There are no expected costs for the entities identified to comply with this new regulation.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3). This new regulation will provide licensees, permit holders and registrants with information applicable to the requirements for compounding non-sterile and sterile preparations.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:

(a) Initially: No costs will be incurred.

(b) On a continuing basis: No costs will be incurred.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Board revenues from pre-existing fees provide the funding to enforce the regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding will be required because of this new regulation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation does not establish fees or directly or indirectly increase any fees.

(9) TIERING: Is tiering applied? Tiering is not applied because this new regulation is applicable to all licensees, permit holders and registrants.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? Only the Board of Pharmacy.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 315.035(6), KRS 315.191(1).

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation will not generate revenue for the Board in the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation will not generate revenue for the Board in subsequent years.

(c) How much will it cost to administer this program for the first year? No costs are required to administer this program for the first year.

(d) How much will it cost to administer this program for subsequent years? No costs are required to administer this program for subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain

this fiscal impact of the administrative regulation.

Revenues (+/-): 0

Expenditures (+/-): 0