

BOARDS AND COMMISSIONS

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, 315.121, 315.191(1)(a), (g), 21 U.S.C. 353A

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 utilized~~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 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 ~~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. ~~[Section 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 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, if the 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) 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 ~~USP~~~~[United States Pharmacopeia (USP)]~~ 825~~[, unless specified portions submitted by a pharmacist have been waived by the board].~~

(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.

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

~~[(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 or 825.]~~

(5) 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 unless authorized by 21 U.S.C. 353(a).

Section 4. ~~[Section 3.] Designated Person.~~

(1) The designated person 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 be responsible for the appointment for any designated persons. [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 shall be responsible to ensure any compounded preparation 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. ~~[Section 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 preparation~~[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 warning~~[warnings]~~, 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) ~~[(4)]~~ The PIC shall maintain access to and provide~~[submit, as appropriate, these]~~ 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. ~~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}; and~~
- (d) ~~{Policy and procedures manual;}~~
- ~~{(e)} {Policies and procedures for hazardous wastes, if applicable;}~~
- ~~{(f)} {Quality assurance records; and}~~
- ~~{(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. ~~{Section 6.}~~ 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 regulation. Any waiver issued shall identify with specificity the pharmacy to which it applies and the provisions of law for which the waiver is applied.

Section 9. Enforcement Discretion.

(1) The Board shall not enforce the provisions of this regulatory amendment requiring compliance with the 2022 revisions to USP Chapters USP 795 and 797 until January 1, 2026. Until January 1, 2026, the 2014 revision of USP 795 will be enforced and the 2008 revision of USP 797 will be enforced. USP 800 will not be enforced until January 1, 2026.

(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.

Section 10. ~~{Section 7.}~~ Incorporation by Reference.

(1) The following material is incorporated by reference:

- (a) "USP 795, Revision Bulletin, Official", November 1, 2022~~{January 1, 2014}~~;

- (b) "USP 797, Revision Bulletin, Official", November 1, 2022~~[June 1, 2008]; [and]~~
(c) "USP 825, Revision Bulletin, Official, Official", December 1, 2020~~[-]; and~~
(d) "USP 800, Revision Bulletin", 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, 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>.

CHRISTOPHER HARLOW, Executive Director

APPROVED BY AGENCY: June 7, 2023

FILED WITH LRC: June 7, 2023 at 1:45 p.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall be held on August 30, 2023, at 10:00 a.m. Eastern Time via zoom teleconference. 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 comment on the proposed administrative regulation. 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 August 31, 2023. 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: 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.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Christopher Harlow

(1) Provide a brief summary of:

(a) What this administrative regulation does:

This administrative regulation establishes the requirements for compounding non-sterile and sterile preparations, and the preparation, compounding, dispensing and repackaging of radiopharmaceuticals.

(b) The necessity of this administrative regulation:

This administrative regulation is necessary to comply with federal regulation and to establish the requirements for compounding non-sterile and sterile preparations, and the preparation, compounding, dispensing and repackaging of radiopharmaceuticals.

(c) How this administrative regulation conforms to the content of the authorizing 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. This administrative regulation relates to the requirements for compounding non-sterile and sterile preparations, and the preparation, compounding, dispensing and repackaging of radiopharmaceuticals.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:

This administrative regulation establishes the requirements for compounding non-sterile and sterile preparations, and the preparation, compounding, dispensing and repackaging of radiopharmaceuticals. This administrative regulation assures minimum standards of practice of compounding by pharmacies and pharmacists are established and assures the safety of all products provided to 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 conforms to the updated USP chapters, which are required under federal regulation.

(b) The necessity of the amendment to this administrative regulation:

This amendment is necessary to comply with federal regulation.

(c) How the amendment conforms to the content of the authorizing 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. This amendment assures minimum standards of practice of compounding by pharmacies and pharmacists are established.

(d) How the amendment will assist in the effective administration of the statutes:

This administrative regulation assures minimum standards of practice of compounding by pharmacies and pharmacists are established.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:

This administrative regulation impacts pharmacists and pharmacies.

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

This administrative regulation provides pharmacists and pharmacies with the requirements for compounding non-sterile and sterile preparations, and the preparation, compounding, dispensing and repackaging of radiopharmaceuticals. If engaging in the practice of compounding, pharmacists and pharmacies shall meet the requirements set forth in this administrative regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):

Pharmacists and pharmacies will incur no costs in complying with this administrative regulation.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):

. The ability to engage in the practice of compounding in a manner that assures the safety of all products provided to the citizens of the Commonwealth. (5) Provide an estimate of how much it will cost to implement this administrative regulation:

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

(a) Initially:

No cost to the administrative body.

(b) On a continuing basis:

No cost to the administrative body.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation:

The Board of Pharmacy will inspect pharmacies and pharmacist practice to ensure compliance with this administrative regulation. The Board of Pharmacy already employs inspectors, and this regulation will not increase any cost of enforcement for the Board of Pharmacy.

(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:

There will be no increase in fees or funding necessary to implement this 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 any fees directly or indirectly.

(9) TIERING: Is tiering applied?

No. Tiering is not applied, as this administrative regulation establishes the minimum standards the requirements for compounding non-sterile and sterile preparations, and the preparation, compounding, dispensing and repackaging of radiopharmaceuticals, it simply provides the requirements for the practice of compounding.

FISCAL NOTE

(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?

There will be no impact on local or state government outside of the Board of Pharmacy's enforcement of the regulation.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation.

KRS 315.020(1), 315.035(6), 315.0351, 315.191(1)(a) and (g), and 21 U.S.C 353(a).

(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.

There will be no effect on the expenditures and revenue of a state or local government agency.

(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 any revenue for the state or local government.

(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.

(c) How much will it cost to administer this program for the first year?

There will be no cost to administer this administrative regulation. The cost of educating pharmacists and having pharmacist inspectors provide guidance is built into the employment cost for those staff members.

(d) How much will it cost to administer this program for subsequent years?

This administrative regulation will not generate costs. Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain this fiscal impact of the administrative regulation.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):0

Expenditures (+/-):0

Other Explanation:

This regulation will not create additional costs for the agency.

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

? There will be no impact on the expenditures or cost savings of the regulated entities. Pharmacies will have to come into compliance with USP 795, 797 and 800 respectively. This can take significant time and expenditure, and that is why the Board has built in a period of enforcement discretion.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year?

There will be no impact on the expenditures or cost savings of regulated entities.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years?

There will be no impact on the expenditures or cost savings of regulated entities.

(c) How much will it cost the regulated entities for the first year?

Regulated entities that are not in compliance with the federal standard will need to come into compliance, and installing the appropriate mechanisms to be in compliance could cost regulated entities a significant sum, and that is why the Board is building in a period of enforcement discretion. During that period, the state will not enforce to the new standard, but the FDA could still come in and they will be inspecting to the new standard despite the state's exercise of enforcement discretion.

(d) How much will it cost the regulated entities for subsequent years?

There will be no impact on the expenditures or cost savings of regulated entities. Once regulated entities come into compliance, there will be no further cost for regulated entities.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Cost Savings (+/-):0

Expenditures (+/-):not uniform, cannot be quantified.

Other Explanation:

This regulation does require pharmacies to come into compliance with USP 795, 797 and 800, depending on the type of compounding they are performing. It is our understanding that for some pharmacies, this will be costly. This is why the Board does not plan on enforcing the standards until 2026.

(5) Explain whether this administrative regulation will have a major economic impact, as defined below.

"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars (\$500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)] This administrative regulation will not have a major economic impact.

FEDERAL MANDATE ANALYSIS COMPARISON

(1) Federal statute or regulation constituting the federal mandate.

21 U.S.C. 353A.

(2) State compliance standards.

21 U.S.C. 353A is section 503A of the federal Food, Drug and Cosmetic Act. This section of law creates federal floor requirements for pharmacies that are compounding drugs. This regulatory amendment ensures congruence with 21 U.S.C. 353A.

(3) Minimum or uniform standards contained in the federal mandate.

21 U.S.C. 353A requires non-sterile compounding to follow USP Chapter 795, sterile compounding to follow USP Chapter 797 and hazardous drug compounding to follow USP 800. Moreover, 21 U.S.C. 353A prohibits the compounding of a commercially available drug unless certain requirements are met. This amendment includes the same regulatory language as 21 U.S.C. 353A.

(4) Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate?

No, this regulatory amendment only imposes the floor requirement of the federal rule.

(5) Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements.

Not applicable because we have only adopted the federal minimum standard.