

BOARDS AND COMMISSIONS

Board of Pharmacy

(Amendment)

201 KAR 2:180. Pharmacy ~~{Pharmacies}~~ sanitation.

RELATES TO: KRS Chapter 315

STATUTORY AUTHORITY: KRS 315.035(6), 315.191(1)~~, (5)}~~

CERTIFICATION STATEMENT: This is to certify that this administrative regulation complies with the requirements of 2025 RS HB6, Section 8.

NECESSITY, FUNCTION, AND CONFORMITY: There is no existing uniform administrative regulation for which the Kentucky Board of Pharmacy can monitor a pharmacy for cleanliness. Existing administrative regulations pertain only to food handling facilities. The purpose of this administrative regulation is to provide the board with the authority to require standards for compliance.

Section 1. The designated pharmacy area(s) shall be used exclusively for the compounding and dispensing of drugs and other usual procedures incidental to compounding and dispensing of drugs. This area shall be maintained in a clean and sanitary condition, adequately lighted and ventilated.

Section 2. No compounding or dispensing of drugs shall be carried on in any room used as a dwelling or for usual household purposes.

Section 3. Hot and cold water shall be readily accessible. Adequate facilities, separate and distinct from toilets and washrooms, shall be provided for maintaining clean and sanitary conditions.

Section 4. All equipment used in the storage, compounding, and dispensing of drugs or medicines shall be kept in a clean and sanitary manner.

Section 5. Maintaining Proper Temperature.

(1) Proper temperatures and humidity shall be maintained for compounding and dispensing of drugs and medicines.

(2) Controlled room temperatures shall be fifteen (15) to thirty (30) degrees Centigrade, fifty-nine (59) to eighty-six (86) degrees Fahrenheit. Refrigeration temperatures shall be two (2) to eight (8) degrees Centigrade, thirty-six (36) to forty-six (46) degrees Fahrenheit. Freezer temperatures shall be minus twenty (-20) to minus ten (-10) degrees Centigrade, minus four (-4) to fourteen (14) degrees Fahrenheit.

(3) Absent a United States Pharmacopeia (USP) standard or package insert information for a specific prescription medication, ~~{Under nonspecific conditions, it is to be understood that}~~ the proper storage conditions include protection from moisture, freezing, and excessive heat.

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

CHRISTOPHER HARLOW, PharmD, Executive Director

APPROVED BY AGENCY: December 4, 2025

FILED WITH LRC: December 12, 2025 at 10:45 a.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall be held on February 27, 2026, at 9:00 a.m. EST via a 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 was received by that date, the hearing may be cancelled. 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 February 28, 2026. 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

Subject Headings: Pharmacy; Health and Medical Services; Public Health

(1) Provide a brief summary of:

(a) What this administrative regulation does:

This administrative regulation establishes minimum sanitation and cleanliness standards for pharmacies in Kentucky, including requirements for maintaining a clean, safe and sanitary environment for preparation, storage and dispensing of drugs. The standards include equipment maintenance and hygienic practices to protect patient safety and drug integrity.

(b) The necessity of this administrative regulation:

The regulation is necessary to establish enforceable sanitation standards for pharmacies, ensuring that facilities, equipment, and workflow conditions minimize contamination risks and protect the integrity and safety of drug products dispensed to the public.

(c) How this administrative regulation conforms to the content of the authorizing statutes:

The regulation falls within the authority of KRS 315.191(1) which empowers the Board to promulgate regulations to regulate and control all matters relating to the practice of pharmacy, including the establishment of minimum standards for pharmacy sanitation and equipment.

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

This regulation facilitates effective administration of the authorizing statutes by establishing defined sanitation and facility-maintenance requirements, thereby enabling the Board to consistently evaluate compliance, mitigate risks to drug integrity, and ensure that licensed pharmacies meet the statutory mandate to safeguard patient safety.

(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:

The amendment clarifies the requirements for proper temperature and humidity to address safety concerns that have arisen during inspections of pharmacy facilities recently.

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

An amendment is necessary to address the prior regulation's lack of specificity regarding temperature and humidity controls. By establishing defined standards for moisture, humidity, and temperature, the amendment strengthens sanitation requirements, supports medication integrity, and enhances patient safety.

(c) How the amendment conforms to the content of the authorizing statutes:

The regulation amendment falls within the authority of KRS 315.191(1) which empowers the Board to promulgate regulations to regulate and control all matters relating to the practice of pharmacy, including the establishment of minimum standards for pharmacy sanitation and equipment.

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

The amendment is necessary to address the prior regulation's lack of specificity regarding temperature and humidity controls. By establishing defined standards for moisture, humidity, and temperature, the amendment strengthens sanitation requirements, supports medication integrity, and enhances patient safety.

(3) Does this administrative regulation or amendment implement legislation from the previous five years? No.

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

The Board expects minimal impact, as most facilities already incorporate temperature and moisture control into their sanitation protocols. The amendment codifies a baseline threshold to identify when these conditions compromise medication integrity and public safety.

(5) Provide an analysis of how the entities identified in question (4) 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 (4) will have to take to comply with this administrative regulation or amendment:

Pharmacies and pharmacists will have to familiarize themselves with new amended language in the regulation. However, there has been no significant changes to the sanitation expectations. Temperature and moisture have always been factors that are included in drug inserts and pharmacy sanitation practices.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (4):

There are no additional expected costs for compliance with the amendment.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (4):

Compliance with the amended requirements will help pharmacies maintain appropriate environmental conditions, protect drug stability, minimize sanitation-related risks, and ensure reliable, safe service to the public. (6) Provide an estimate of how much it will cost to implement this administrative regulation:

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

(a) Initially:

No costs will be incurred.

(b) On a continuing basis:

No costs will be incurred.

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

Board revenues from pre-existing fees provide the funding to enforce the regulation.

(8) 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.

(9) 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.

(10) TIERING: Is tiering applied?

Tiering is not applied because the regulation is applicable to all pharmacists and pharmacies.

FISCAL IMPACT STATEMENT

(1) Identify each state statute, federal statute, or federal regulation that requires or authorizes the action taken by the administrative regulation:

The regulation falls within the authority of KRS 315.191(1) which empowers the Board to promulgate regulations to regulate and control all matters relating to the practice of pharmacy, including the establishment of minimum standards for pharmacy sanitation and equipment.

(2) State whether this administrative regulation is expressly authorized by an act of the General Assembly, and if so, identify the act:

No, KRS 315.191.

(3)(a) Identify the promulgating agency and any other affected state units, parts, or divisions:

The Kentucky Board of Pharmacy will be impacted by this administrative regulation.

(b) Estimate the following for each affected state unit, part, or division identified in (3)(a):

1. Expenditures:

For the first year:\$0

For subsequent years:\$0

2. Revenues:

For the first year:\$0

For subsequent years:\$0

3. Cost Savings:

For the first year:\$0

For subsequent years:\$0

(4)(a) Identify affected local entities (for example: cities, counties, fire departments, school districts):

Only the Kentucky Board of Pharmacy will be impacted by this administrative regulation.

(b) Estimate the following for each affected local entity identified in (4)(a):

1. Expenditures:

For the first year:\$0

For subsequent years:\$0

2. Revenues:

For the first year:\$0

For subsequent years:\$0

3. Cost Savings:

For the first year:\$0

For subsequent years:\$0

(5)(a) Identify any affected regulated entities not listed in (3)(a) or (4)(a):

None.

(b) Estimate the following for each regulated entity identified in (5)(a):

1. Expenditures:

For the first year:\$0

For subsequent years:\$0

2. Revenues:

For the first year:\$0

For subsequent years:\$0

3. Cost Savings:

For the first year:\$0

For subsequent years:\$0

(6) Provide a narrative to explain the following for each entity identified in (3)(a), (4)(a), and (5)(a)

(a) Fiscal impact of this administrative regulation:

The regulation does not cost anything for regulated parties to implement nor does it have a cost to the Board to oversee.

(b) Methodology and resources used to reach this conclusion:

None.

(7) Explain, as it relates to the entities identified in (3)(a), (4)(a), and (5)(a):

(a) Whether this administrative regulation will have a "major economic impact", as defined by KRS 13A.010(14):

No, this administrative regulation does not have an overall negative or adverse major economic impact to regulated entities, or those entities identified in questions (2)-(4).

(b) The methodology and resources used to reach this conclusion:

Analysis of the Board's expenditures as well as an assessment regarding cost of compliance for regulated entities.