

BOARDS AND COMMISSIONS

Board of Pharmacy

(Amended at ARRS Committee)

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 HB 6, Section 8.

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.035(6) authorizes ~~{There is no existing uniform administrative regulation for which}~~ the Kentucky Board of Pharmacy to promulgate administrative regulations to assure reasonable health and sanitation standards for areas within pharmacies that are not subject to the standards established by the Kentucky Cabinet for Health and Family Services or a local health department~~can monitor a pharmacy for cleanliness}~~. KRS 315.191(1) authorizes the board to promulgate administrative regulations to regulate and control all matters relating to the practice of pharmacy, including the establishment of minimum standards for pharmacy sanitation and equipment.~~Existing administrative regulations pertain only to food handling facilities. The purpose of~~ This administrative regulation establishes the minimum sanitation standards for pharmacies in Kentucky~~is to provide the board with the authority to require standards for compliance}~~.

Section 1. The designated pharmacy area or areas~~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 not occur~~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 shall 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.

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