

201 KAR 2:180. Pharmacies sanitation.

RELATES TO: KRS Chapter 315

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

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. Proper temperatures shall be maintained for compounding and dispensing of drugs and medicines. 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. Under nonspecific conditions, it is to be understood that the 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.

(10 Ky.R. 951; eff. 2-1-1984; Crt eff. 4-17-2019.)