

BOARDS AND COMMISSIONS

Board of Pharmacy (Amendment)

201 KAR 2:280. Prescription dispensing for formulary Compliance.

RELATES TO: KRS 217.822, 315.191

STATUTORY AUTHORITY: KRS 315.191(1)(a), (f)

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 315.191(1)(a) authorizes the board to promulgate administrative regulations necessary to regulate and control all matters set forth in KRS Chapter 315 relating to pharmacists. KRS 315.191(1)(f) authorizes the board to promulgate administrative regulations to control the storage, retrieval, dispensing, refilling, and transfer of prescription drug orders within and between qualifying pharmacists and pharmacies. This administrative regulation establishes procedural and substantive requirements for dispensing an equivalent drug product pursuant to a practitioner declaration of formulary compliance approval.

Section 1. Dispensing.

(1) A pharmacist may dispense a therapeutic equivalent drug product under the following conditions:

(a) The ordering practitioner has indicated "formulary compliance approval" on the prescription, in one of the following ways:

1. In the practitioner's own handwriting or an equivalent designation within an electronic system; or
2. By checking a "formulary compliance approval" box on a preprinted form; or
3. By indicating a "formulary compliance approval" through a note, prescriber comment or other designation within an electronic prescription system.

(b) The pharmacist receives a formulary change as a consequence of the patient's third-party plan; and

(c) The product designated as "preferred" by the third-party formulary is in the same therapeutic class as the prescribed drug.

(2) The pharmacist, within twenty-four (24) hours of the formulary compliance substitution, shall notify the ordering practitioner, in an original writing or by facsimile:

- (a) That the pharmacist engaged in formulary compliance; and
- (b) The therapeutic equivalent drug product that was dispensed.

Section 2. The pharmacist may make adjustments in the quantity and directions to provide for an equivalent dose of the preferred formulary therapeutic alternative.

(201 KAR 002:280. 29 Ky.R. 2197; 2447; eff. 4-11-2003; Crt eff. 4-17-2019; 52 Ky.R. 1184; eff. 6-16-2026.)

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.