BOARDS AND COMMISSIONS
Board of Pharmacy
(Amendment)

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

RELATES TO: KRS 217.822~~[217.814]~~, 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.

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; Drugs and Medicines; Medical and Health Services

(1) Provide a brief summary of:

(a) What this administrative regulation does:

This administrative regulation establishes the conditions under which a pharmacist may dispense a therapeutic equivalent drug product when a prescriber has authorized "formulary compliance approval" and a patient's third-party plan requires a formulary change. It sets procedural requirements for such medication substitutions.

(b) The necessity of this administrative regulation:

The regulation is necessary to implement KRS 217.822 by establishing the procedure that pharmacists must follow when dispensing a therapeutic equivalent under "formulary compliance approval." The framework ensures that substitutions required by insurance plans occur safety, consistently and with the appropriate prescriber notification, therefore protecting patients while allowing pharmacists to comply with statutory authority and third-party formulary requirements.

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

This regulation conforms with KRS 315.191 and KRS 217.822 by establishing the procedures and oversight framework under which a pharmacist may make a formulary-driven therapeutic substitution. The regulation directly implements the statutory grant of authority by defining how substitutions must occur, including prescriber authorization and notice, ensuring the practice aligns with the scope and safeguards required by the statute.

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

The regulation assists in the effective administration of the statutes by providing clear, enforceable procedures for therapeutic substitutions made under formulary compliance approval. These standards ensure consistent pharmacist practices, proper prescriber notification, and safe patient care, enabling the Board to oversee and enforce the statutory framework established in KRS 217.822.

(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 does not change the content of the original regulation but rather strengthens its applicability in modern medicine by providing explicit provisions to allow a prescriber to leave a comment or note or designation within an electronic prescription system to require "formulary compliance approval."

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

This amendment is necessary because it modernizes the formulary compliance provisions to account for electronic prescription systems that may not have a "check box" for "formulary compliance approval."

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

The amendment is consistent with the intention of KRS 217.822 and enhances the procedures and conditions under which a pharmacist may make a formulary driven therapeutic substitution. Allowing electronic communication of this substitution creates efficiency for the prescriber, pharmacists and the patient.

(d) How the amendment will assist in the effective administration of the statutes:
The amendment provides a modern way for all parties involved in the prescription cycle to communicate formulary compliance approval as is required by KRS 217.822.

(3) Does this administrative regulation or amendment implement legislation from the previous five years?Yes, KRS 217.822.

(4) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:
The board anticipates no one will be affected by the administrative regulation amendment as this is already practiced within electronic prescription systems.

(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.

(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 expected costs for the identities to comply with the amendment.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (4):
Allowing electronic prescription system notes or designations for formulary compliance will streamline workflow for pharmacists, reduce administrative burden, and minimize delays in patient care. It also provides prescribers with a more efficient and consistent method of granting formulary compliance approval, increases accuracy by reducing handwritten or verbal ambiguity, and facilitates clearer documentation and auditing for both pharmacies and insurers. (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:
KRS 217.822

(2) State whether this administrative regulation is expressly authorized by an act of the General Assembly, and if so, identify the act:
Yes, KRS 217.822 (2016)

(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.