

BOARDS AND COMMISSIONS

Board of Pharmacy

(Amendment)

201 KAR 2:300. Common database.

RELATES TO: KRS 315.020, 315.035, 315.0351

STATUTORY AUTHORITY: KRS 315.035, ~~[315.0351,]~~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 315.035 and 315.0351 require that prescription drugs, medicines, and pharmaceuticals be dispensed or manufactured by a licensed pharmacist. KRS 315.191(1)(a) and (f) authorize the Kentucky Board of Pharmacy to promulgate administrative regulations pertaining to pharmacies; pharmacists; and the storage, retrieval, dispensing, refilling, and transfer of prescription drug orders. This administrative regulation establishes minimum requirements for prescription drug orders within and between pharmacists and pharmacies.

Section 1. Definition. "Common Database" means information shared among pharmacists and pharmacies for the purpose of dispensing medications or providing other forms of pharmacist care to a patient.

Section 2. The use of a common database shall not constitute a transfer as established in 201 KAR 2:165, provided that the following conditions are met:

(1) All pharmacies involved in the transactions pursuant to which the prescription is dispensed shall be under common ownership and utilize a common database;

(2) All pharmacies involved in the transactions pursuant to which the prescription is dispensed and all pharmacies engaging in dispensing functions shall be properly permitted in Kentucky pursuant to KRS 315.035 or 315.0351;

~~[(3)] [A pharmacist who provides a pharmacy service on a prescription dispensed in Kentucky shall be licensed in Kentucky.]~~

~~[(4)]~~ (3) The common database shall maintain a record of all pharmacists, pharmacist interns, and pharmacy technicians involved in the process of dispensing a prescription;

~~[(5)]~~ (4) The owner of the common database shall maintain a policy and procedure manual that governs its participating pharmacies, pharmacists, and pharmacy employees and that is available to the board or its agents upon request within five (5) business days and which shall include:

(a) A procedure detailing how each pharmacy and each pharmacist accessing the common database shall comply with applicable federal and state laws, rules, and regulations;

(b) The procedure for maintaining appropriate records for regulatory oversight for tracking a prescription during each stage of the filling and dispensing process, identifying the pharmacists involved in filling and dispensing the prescription and counseling the patient, and responding to any requests for information made by the board;

(c) The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information; and

(d) A quality assurance program designed to objectively and systemically monitor, evaluate, and improve the quality and appropriateness of patient care through the use of a common database; and

~~[(6)]~~ (5) A pharmacist dispensing a prescription shall at all times exercise independent professional judgment and shall be responsible for his or her actions and the professional actions of those individuals the pharmacist is required to supervise.

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 defines the rules for shared "common databases" used by pharmacies under common ownership so that using a shared database does not count as a formal prescription transfer. It sets requirements for licensing, record-keeping, security, and quality assurance to ensure prescriptions and related care remain properly documented, secure, and under pharmacist control.

(b) The necessity of this administrative regulation:

The regulation is necessary to set clear standards for pharmacies sharing a common database, ensuring secure, accurate prescription information and maintaining pharmacist accountability. This framework allows the Board to regulate shared-data operations in a way that protects patient safety and supports compliant dispensing practices.

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

This regulation conforms with KRS 315.191 by establishing the controls and oversight needed to regulate how pharmacies store, access and share prescription information through a common database. The regulation directly implements the Board's statutory duty to ensure safe pharmacy practice and protect the public by defining standards for security, documentation and pharmacist responsibility.

(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 standards for shared pharmacy databases, allowing the Board to consistently monitor compliance, ensure proper record-keeping, and maintain patient safety. These requirements give the Board a uniform framework for oversight, supporting its statutory responsibility under KRS 315.191 to regulate the safe practice of pharmacy.

(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 make substantive changes to the regulation but rather clarifies a point of confusion around resident and non-resident pharmacists.

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

This amendment clarifies to ensure understanding related to common databases.

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

This regulation amendment conforms with KRS 315.191 by establishing the controls and oversight needed to regulate how pharmacies store, access and share prescription information through a common database.

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

The amendment provides additional clarification for use of a common database.

(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 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 315.020; KRS 315.191(1)(a), (f)

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

Yes, 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.