Kentucky Board of Pharmacy

Pharmacy.ky.gov | Phone: 502.564.7910 | Fax: 502.696.3806
125 Holmes Street, Suite 330 | Frankfort, Kentucky 40601
Pharmacy.ky.gov | pharmacy.board@ky.gov

March 3, 2026

Senator Stephen West, Co-Chair
Representative Derek Lewis, Co-Chair
c/o Ange Darnell, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
Room 083, Capitol Annex
Frankfort, Kentucky 40601

Re: 201 KAR 2:050; Licenses and permits; Fees

Dear Co-Chairs West and Lewis:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 201 KAR 2:050, the Kentucky Board of Pharmacy proposes the attached suggested substitute to 201 KAR 2:050.

Sincerely,

Christopher Harlow, PharmD
Executive Director

Final, 3-03-2026

SUGGESTED SUBSTITUTE

BOARDS AND COMMISSIONS
Board of Pharmacy

201 KAR 2:050. Licenses and permits; fees.

RELATES TO: KRS 218A.205(3)(g), 315.035(1), (2), (4), 315.0351(1), 315.036(1), 315.050(5), 315.060, 315.110, 315.120, 315.191, 315.402
STATUTORY AUTHORITY: KRS 218A.205(3)(g), 315.035(1), (2), (4), 315.036(1), 315.050(5), 315.060, 315.110(1), 315.120(4), 315.191(1)(i), 315.402(1)
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)(i) authorizes the board to assess reasonable fees for services rendered to perform its duties and responsibilities. This administrative regulation establishes reasonable fees for the board to perform all the functions for which it is responsible.

Section 1. The following fees shall be paid in connection with pharmacist examinations and licenses, pharmacy permits, intern certificates, and the issuance and renewal of licenses and permits:
(1) Application for initial pharmacist license - $150;
(2) Application and initial license for a pharmacist license by license transfer - $250;
(3) Annual renewal of a pharmacist license - ninety-five (95) dollars;
(4) Delinquent renewal penalty for a pharmacist license - ninety-five (95) dollars;
(5) Annual renewal of an inactive pharmacist license - ten (10) dollars;
(6) Pharmacy intern certificate valid six (6) years - twenty-five (25) dollars;
(7) Duplicate of original pharmacist license wall certificate - seventy-five (75) dollars;
(8) Application for a permit to operate a pharmacy - $200[~~$150~~];
(9) Renewal of a permit to operate a pharmacy - $175[~~$150~~];
(10) Delinquent renewal penalty for a permit to operate a pharmacy - $175[~~$150~~] dollars;
(11) Change of location, name or [~~change of~~]ownership of a pharmacy or manufacturer permit - $175[~~$150~~];
(12) Application for a permit to operate as a manufacturer - $175[~~$150~~];
(13) Renewal of a permit to operate as a manufacturer - $175[~~$150~~];
(14) Delinquent renewal penalty for a permit to operate as a manufacturer - $175[~~$150~~];
(15) Change of location, name or [~~change of~~]ownership of a wholesale distributor license - $175[~~$150~~];
(16) Application for a license to operate as a wholesale distributor - $175[~~$150~~];
(17) Renewal of a license to operate as a wholesale distributor - $175[~~$150~~];
(18) Delinquent renewal penalty for a license to operate as a wholesale distributor - $175[~~$150~~]; and
(19) Query to the National Practitioner Data Bank of the United States Department of Health and Human Services - twenty-five (25) dollars.

Section 2. A pharmacy permit applicant shall submit:
(1) An initial or renewal application for a pharmacy permit on either the:
(a)
1. Application for Permit to Operate a Pharmacy in Kentucky; or
2. Application for Resident Pharmacy Permit Renewal; or
(b)
1. Application for Non-Resident Pharmacy Permit, as incorporated by reference into 201 KAR 2:465; or
2. Application for Non-Resident Pharmacy Permit Renewal, as incorporated by reference into 201 KAR 2:465; and

(2) As appropriate, the:
(a) Initial application fee established by Section 1(8) of this administrative regulation; or
(b) Renewal fee established by Section 1(9) of this administrative regulation.

Section 3. All fees shall be non-refundable.

Section 4. Applications shall expire one (1) year after the date the application is received by the board.

Section 5. Incorporation by Reference.
(1) The following material is incorporated by reference:
(a) "Application for Permit to Operate a Pharmacy in Kentucky", Form 1, ***3/2026[~~6/2023~~]***; and
(b) "Application for Resident Pharmacy Permit Renewal", Form 2, ***3/2026[~~6/2023~~]***.
(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m. This material is also available on the board's ***website[~~Web site~~]*** at ***https://pharmacy.ky.gov/statutesandregulations/Pages/default.aspx [~~https://pharmacy.ky.gov/Businesses/Pages/Pharmacy.aspx~~]***.

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.

MATERIAL INCORPORATED BY REFERENCE

At the time that it files this staff suggested amendment the agency needs to file one (1) clean copy of each of the following:

"Application for Permit to Operate a Pharmacy in Kentucky"
- **With an updated edition date of 3/2026**
- **Updated fee amounts, including the $200 Application for a permit to operate a pharmacy fee**

"Application for Resident Pharmacy Permit Renewal"
- **With an updated edition date of 3/2026**
- **Updated fee amounts, including the $175 Renewal of a permit to operate a pharmacy fee**

KENTUCKY BOARD OF PHARMACY
State Office Building Annex,Suite 300
125 Holmes Street
Frankfort KY 40601
Phone:(502) 564-7910
Fax:(502) 696-3806
Email: pharmacy.board@ky.gov
http://pharmacy.ky.gov

Application For Permit To Operate A Pharmacy In Kentucky

Please print legibly. Make check or money order payable to 'Kentucky State Treasurer' Treasurer' or pay online at https://secure.kentucky.gov/formservices/Pharmacy/VirtualTerminal
Mail to the above address. All applicable entries must be completed. Incomplete applications will be returned. Each permit expires June 30th following the date of issuance.

I. Pharmacy Information:

Name of Pharmacy:
Physical Address of Pharmacy:
CITY: STATE: COUNTY: ZIP:
Email:
Phone number:

Fax number:
Website Address:
Mailing Address of Pharmacy:
CITY: STATE: COUNTY: ZIP:

II. Check and complete one of the following and attach proper fee:

☐ **New Facility** → **$200**

Proposed date of Opening:

(Filed with board 30 days in advance of opening)

☐ **Change of Ownership** → **$175.00**

Proposed date of acquisition:
Name of previous owner(s):

(Please include detailed explanation of the change, including type of transaction, date of transaction and structure of the transfer)

☐ **Change of Address/Location** → **$175.00**

Date of Proposed Relocation:
Previous Address:

☐ **Name Change →$175.00**

Previous Name:

III. Ownership:

How is the pharmacy registered with the Kentucky Secretary of State?

- ☐ Sole Proprietor
- ☐ Partnership
- ☐ LLC
- ☐ Corporation
- ☐ Other

★★ **Name and title for each owner/officer/member, including office and professional designation *(e.g. Pres. John Jones, M.D.)* :**

1.

Name:	Title:

2.

Name:	Title:

3.

Name:	Title:

4.

Name:	Title:

5.

Name:	Title:

(Use supplemental information page if necessary)

IV. Has any owner , member or officer been subject to discipline by any other agency related to the ownership or employment in a pharmacy?

☐ **YES***	☐ **NO**

If yes: Please explain below

:

V. Pharmacist-In-Charge (P.I.C.), Pharmacist(s), Interns and Technicians :

Name	KY License No.:	P.O.A.	Key
P.I.C. :		☐	☐
		☐	☐
		☐	☐

		☐	☐
		☐	☐

(Use supplemental information page if necessary)

(Please indicate by checking the space provided those who have "Power of Attorney" (P.O.A) to order Controlled Substances and/or have been issued keys to the pharmacy.)

Kentucky Pharmacy Regulation 201 KAR 2:205 requires pharmacists-in-charge to notify the Board of all pharmacist personnel changes and changes in pharmacy operating hours.

VI. Name and title of each non-pharmacist with keys to the pharmacy:

Name:	Title:
Name:	Title:
Name:	Title:
Name:	Title:
Name:	Title:
Name:	Title:

(Use supplemental information page if necessary)

VII. Schedule of Hours:

(P.I.C. must notify the Board within fourteen (14) days of any changes in scheduled hours.)

MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	SUNDAY
OPEN:	OPEN:	OPEN:	OPEN:	OPEN:	OPEN:	OPEN:

CLOSE:	CLOSE:	CLOSE:	CLOSE:	CLOSE:	CLOSE:	CLOSE:

★Please indicate if closed for lunch:

_____ until _____

VIII. Name, address and affiliation of all individuals, other than those previously identified in this application, responsible for pharmacy management or staffing (e.g., Pharmacy Services Management Companies or Consultants) :

Name:	Affiliation:
Address:	
CITY: STATE: COUNTY: ZIP:	

Name:	Affiliation:
Address:	
CITY: STATE: COUNTY: ZIP:	

Name:	Affiliation:

Address:			
CITY:	STATE:	COUNTY:	ZIP:

Name:	Affiliation:

Address:			
CITY:	STATE:	COUNTY:	ZIP:

Name:	Affiliation:

Address:			
CITY:	STATE:	COUNTY:	ZIP:

(Use supplemental information page if necessary)

IX. Type of Pharmacy (Check all that apply) :

- ☐ **Retail Independent**
- ☐ **Retail Chain**
- ☐ **Infusion**
- ☐ **Nuclear**
- ☐ **Mail Order**
- ☐ **Nursing Home**
- ☐ **Internet**
- ☐ **Hospital- Ambulatory**
- ☐ **Central Fill**
- ☐ **Compounding**
- ☐ **Veterinary**

X.Does pharmacy currently utilize an automated data processing system?

☐ YES*	☐ NO

If yes: identify the source for:

Hardware: _____

Software: _____

XI.Does the pharmacy plan on obtaining a Digital Pharmacy accreditation or Healthcare Merchant (veterinary) accreditation?

☐ YES	☐ NO

XII. Do you plan on performing sterile compounding?

☐ YES	☐ NO

XIII. Do you plan on performing non-sterile compounding?

☐ YES	☐ NO

XIV. Does this pharmacy stock any emergency medication kits?

☐ YES	☐ NO

XV. Does this pharmacy stock any long-term care facility in Kentucky?

☐ YES	☐ NO

XVI. Does this pharmacy utilize any automation for prescription dispensing?

☐ YES	☐ NO

Supplemental Information Page:

The Board may refuse to issue or renew a permit, or suspend, temporarily suspend, revoke, fine or reasonably restrict any permit holder for knowingly making or causing to be made, any false, fraudulent or forged statement in connection with an application for a permit. KRS 315.121.

I hereby certify that the foregoing is true and correct to the best of my knowledge and that I have read and understand Kentucky Revised Statutes Chapters 217, 218A, and 315 and the regulations of the Kentucky Board of Pharmacy and the Cabinet for Health and Family Services pertaining to the practice of pharmacy and certify that this pharmacy will be conducted in full compliance with all federal and state laws.

Signature of Pharmacist-in-Charge: _____ **Date:** _____

I hereby certify that the above Application for Resident Pharmacy Permit was signed, subscribed and sworn to before me this _____day of _____, 20_____.

By: _____

Signature: _____

My Commission Expires _____ State of _____.

Signature of Owner: _____ **Date:** _____

I hereby certify that the above Application for Resident Pharmacy Permit was signed, subscribed and sworn to before me this _____day of _____, 20_____.

By: _____

Signature: _____

My Commission Expires _____ State of _____.

KENTUCKY BOARD OF PHARMACY
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Application For Resident Pharmacy Renewal

Enclose a check or money order for $175.00 made payable to 'Kentucky State Treasurer' or pay online at https://secure.kentucky.gov/formservices/Pharmacy/VirtualTerminal
Please print legibly and complete this application; including the required original signature and return no later than June 30th. All renewals received after June 30th will be assessed a delinquent fee of $175.00 pursuant to 201 KAR 2:050, Section 1(10).

INCOMPLETE OR UNSIGNED APPLICATIONS WILL BE RETURNED

I. Pharmacy Information:

Name of Pharmacy			
Kentucky Permit Number:			
Address:			
CITY:	STATE:	COUNTY:	ZIP:
Email Address:			

Phone Number:	
Fax Number:	
Website Address:	
Date of last controlled substance inventory:	
DEA Registration No.:	Exp. Date:

II. Ownership:

How are you registered with the Kentucky Secretary of State?

- ☐ Sole Proprietor
- ☐ Partnership
- ☐ Corporation
- ☐ LLC
- ☐ Other

★★ Name and title for each owner/officer/member, including office and professional designation:

1.

Name:	Title:

2.

Name:	Title:

3.

Name:	Title:

4.

Name:	Title:

5.

Name:	Title:

(Use supplemental information page if necessary)

III. Schedule of Hours:

(P.I.C. must notify the Board within fourteen (14) days of any changes in scheduled hours.)

MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	SUNDAY
OPEN:	OPEN:	OPEN:	OPEN:	OPEN:	OPEN:	OPEN:
CLOSE:	CLOSE:	CLOSE:	CLOSE:	CLOSE:	CLOSE:	CLOSE:
☐ 24 HOURS	☐ 24 HOURS	☐ 24 HOURS	☐ 24 HOURS	☐ 24 HOURS	☐ 24 HOURS	☐ 24 HOURS

★Please indicate if closed for lunch:

_____ until _____

IV. Types of Pharmacy (Check all that apply):

- ☐ **Retail Independent**
- ☐ **Retail Chain**
- ☐ **Infusion**
- ☐ **Nuclear**
- ☐ **Mail Order**
- ☐ **Nursing Home**
- ☐ **Internet***
- ☐ **Hospital**
- ☐ **Hospital-Ambulatory**
- ☐ **Central Fill**
- ☐ **Compounding**
- ☐ **Veterinary**

*This must be checked if the pharmacy dispenses any prescriptions to citizens of the Commonwealth of Kentucky, in whole or in part, via the Internet [agent, internet broker or shipper]. If Internet is checked, digital pharmacy accreditation will be verified with the NABP.

V. Does pharmacy ship medications outside of Kentucky?

☐ YES	☐ NO

VI. Do you perform sterile compounding?

☐ YES	☐ NO

VII. Do you perform non-sterile compounding?

☐ YES	☐ NO

VIII. Are you permitted in other states?

☐ YES	☐ NO

If yes: Please list below

:

IX. Have you had a Pharmacy license/permit disciplined by any other agency or has your PIC been disciplined by any other agency which you have not previously reported to this Board?

☐ YES*	☐ NO

*If yes: Please explain below

:

X. For institutional pharmacies, are there decentralized pharmacy services (i.e. oncology satellite, OR satellite, etc.) where drugs are prepared, stored, and/or compounded in the facility?

☐ YES*	☐ NO

*If yes: how many?

:

XI. Does this pharmacy stock any emergency medication kits?

☐ YES	☐ NO

XII. Does this pharmacy stock any long-term care facility in Kentucky?

☐ YES	☐ NO

XIII. Does this pharmacy utilize any automation for prescription dispensing?

☐ YES*	☐ NO

*_If yes:_ Please explain below

:

EMPLOYEE INFORMATION:

1. Pharmacist-In-Charge (PIC):

Name:	KY License Number:

Note: 201 KAR 2:205 requires the pharmacist-in-charge to notify the Board within fourteen [14] calendar days of all pharmacist changes.

2. Please provide a complete list of all employees licensed/registered with the Board:

Name:	License/Registration Number (Pharmacist, Pharmacist Intern or Pharmacy Technician):
1.	

2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	

(Use supplemental information page if necessary)

3. Name, title and address of each non-pharmacist with keys to the pharmacy:

Name:	Title:

Address:			
CITY:	STATE:	COUNTY:	ZIP:

Name:	Title:

Address:			
CITY:	STATE:	COUNTY:	ZIP:

Name:	Title:

Address:			
CITY:	STATE:	COUNTY:	ZIP:

Name:	Title:

Address:			
CITY:	STATE:	COUNTY:	ZIP:

Name:	Title:

Address:			
CITY:	STATE:	COUNTY:	ZIP:

(Use supplemental information page if necessary)

4. Please submit the name, address and affiliation of all individuals, other than those previously identified in this application, responsible for pharmacy operations, management or staffing (eg. Pharmacy Services Management companies or consultants):

Name:	Affiliation:
Address:	
CITY: STATE: COUNTY: ZIP:	

Name:	Affiliation:
Address:	
CITY: STATE: COUNTY: ZIP:	

Name:	Affiliation:
Address:	
CITY: STATE: COUNTY: ZIP:	

Name:	Affiliation:

Address:			
CITY:	STATE:	COUNTY:	ZIP:

Name:	Affiliation:

Address:			
CITY:	STATE:	COUNTY:	ZIP:

(Use supplemental information page if necessary

Supplemental Information Page:

The Board may refuse to issue or renew a permit, or suspend, temporarily suspend, revoke, fine or reasonably restrict any permit holder for knowingly making or causing to be made, any false, fraudulent or forged statement in connection with an application for a permit. KRS 315.121.

I hereby certify that the foregoing is true and correct and that I have read and understand Kentucky Revised Statutes Chapters 217, 218A, and 315 and the regulations of the Kentucky Board of Pharmacy and the Cabinet for Health and Family Services pertaining to the practice of pharmacy and certify that this pharmacy will be conducted in full compliance with all federal and state laws.

Signature of Owner: **Date:**

I hereby certify that the above Renewal Application for Resident Pharmacy Permit was signed, subscribed and sworn to before me this _____day of _____, 20_____.

By: _____

Signature: _____

My Commission Expires _____ State of _____.

Signature of Pharmacist-in-Charge: **Date:**

I hereby certify that the above Renewal Application for Resident Pharmacy Permit was signed, subscribed and sworn to before me this _____day of _____, 20_____.

By: _____

Signature: _____

My Commission Expires _____ State of _____.

Kentucky Board of Pharmacy

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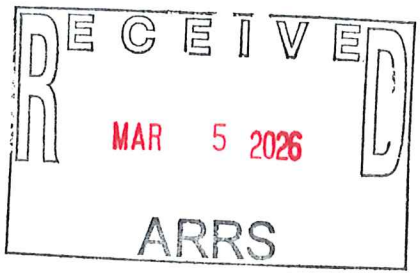
March 3, 2026



Senator Stephen West, Co-Chair
Representative Derek Lewis, Co-Chair
c/o Ange Darnell, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
Room 083, Capitol Annex
Frankfort, Kentucky 40601

Re: 201 KAR 2:160 Licensees; Inactive Status

Dear Co-Chairs West and Lewis:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 201 KAR 2:160 the Kentucky Board of Pharmacy proposes the attached amendment to 201 KAR 2:160.

Sincerely,

Christopher Harlow, PharmD
Executive Director

Final, 3-03-2026

SUGGESTED SUBSTITUTE

BOARDS AND COMMISSIONS
Board of Pharmacy

201 KAR 2:160. Licensees; inactive status.

RELATES TO: KRS Chapter 315
STATUTORY AUTHORITY: KRS 315.065, 315.110, 315.120, 315.191(1)
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) authorizes the board to promulgate administrative regulations to regulate and control all matters set forth in KRS Chapter 315 relating to pharmacists. KRS 315.120(4) authorizes an inactive pharmacist to apply for inactive license upon application provided for by the board in administrative regulations.[~~Senate Bill 241 of the General Assembly, Commonwealth of Kentucky, Regular Session 1982, provided for changes in KRS Chapter 315.~~]*** This ***administrative regulation establishes[~~necessitated~~]*** requirements for licensees to be issued inactive status and for those who desire to apply for renewal of a license to return to active practice.

Section 1. A pharmacist may apply for inactive status by:
(1) Completing ***the*** annual renewal application***, as incorporated by reference in 201 KAR 2:020***; and
(2) Paying ***the*** annual fee for inactive status ***established by 201 KAR 2:050, Section 1(5)***.

Section 2. Pharmacists maintaining an active license to practice in another state or jurisdiction ***shall not be eligible[~~are ineligible~~]*** for inactive status in Kentucky.

Section 3. Pharmacists seeking relicensure from[~~form~~] inactive to active status ***shall[~~must~~]*** fulfill the following requirements:
(1) If the pharmacist has been inactive for no more than five (5) consecutive years, the pharmacist[~~he~~] ***shall[~~must~~]***:
(a) Provide written notice to the board requesting their consideration to active status. The board shall act upon ***the[~~such~~]*** request within sixty (60) days***;[.]***
(b) Satisfy the board's continuing education requirements for each year of inactive status***;[.]***
(c) Successfully complete a jurisprudence examination given by the board***; and[.]***
(d) Pay all cumulative annual renewal fees required for active licensees ***established by 201 KAR 2:050, Section 1(3)***.
(2) If a pharmacist has had inactive status for more than five (5) consecutive years, the pharmacist[~~he~~] ***shall[~~must~~]***:
(a) Provide written notice to the board requesting their consideration to active status. The board shall act upon ***the[~~such~~]*** request within sixty (60) days***;[.]***
(b) Successfully complete any[~~a~~] satisfactory examinations***; and***[~~examination before the board~~]***[.]***
(c) Pay all cumulative annual renewal fees required of active licensees ***established by 201 KAR 2:050, Section 1(3)***.

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.

Kentucky Board of Pharmacy

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March 3, 2026

Senator Stephen West, Co-Chair
Representative Derek Lewis, Co-Chair
c/o Ange Darnell, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
Room 083, Capitol Annex
Frankfort, Kentucky 40601

Re: 201 KAR 2:116 Substitution of Drugs, Biologics and Biosimilar Products

Dear Co-Chairs West and Lewis:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 201 KAR 2:116 the Kentucky Board of Pharmacy proposes the attached amendment to 201 KAR 2:116.

Sincerely,

Christopher Harlow, PharmD
Executive Director

Final, 3-03-2026

SUGGESTED SUBSTITUTE

BOARDS AND COMMISSIONS
Board of Pharmacy

201 KAR 2:116. Substitution of drugs, biologics, and biosimilar products.

RELATES TO: KRS 217.819***, 217.822***
STATUTORY AUTHORITY: KRS 217.814(5), (6), (7), (8), 217.819(1)***, 315.191***
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 217.819(1) requires the Kentucky Board of Pharmacy to prepare by administrative regulation a ***nonequivalent*** drug product formulary of drugs which should not be interchanged by pharmacists. ***KRS 217.822 authorizes pharmacists to dispense interchangeable drug products and biological products.*** This administrative regulation references drug products with active ingredients or dosage forms that are interchangeable***, and[.]*** all other products not referenced as interchangeable are non-interchangeable.

Section 1. The following have been determined by the board to be interchangeable:
(1) Drugs, drug products, or dosage formulations considered by the United States Food and Drug Administration to be therapeutically equivalent as published in the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book);***[~~and~~]***
(2) Biologics drugs, biologics drug products, or biologics dosage formulations considered by the United States Food and Drug Administration to be therapeutically equivalent as published in the ***Database[~~Lists~~]*** of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (Purple Book) ***available at https://purplebooksearch.fda.gov/; and***
(3) Animal drug products considered by the United States Food and Drug Administration to be therapeutically equivalent as published in the Approved Animal Drug Products (Green Book) updated monthly, and available at https://animaldrugsatfda.fda.gov/adafda/views/#/search.

Section 2. Incorporation by Reference.
(1) The following material is incorporated by reference:
(a) "Approved Drug Products with Therapeutic Equivalence Evaluations," (Orange Book), U.S. Food and Drug Administration, ***46th[~~45th~~]*** Edition, ***2026[~~2025~~]***[~~39th Edition, 2019~~];***[~~and~~]***
(b) "***Database[~~Lists~~]*** of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations" (Purple Book), United States Food and Drug Administration, ***2026[~~June 27, 2025~~]; and***[~~June 2019~~]***[.]***
(c) "Approved Animal Drug Products," (Green Book), U.S. Food and Drug Administration, ***2026[~~2025~~]***.
(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, Frankfort, Kentucky 40601-8204, Monday through[~~throught~~] Friday, 8 a.m. to 4:30 p.m. and is available online at http://www.fda.gov.

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.

MATERIAL INCORPORATED BY REFERENCE

At the time the agency files this staff suggested amendment it needs to file one (1) clean copy of the latest version of the:

- **"Approved Drug Products with Therapeutic Equivalence Evaluations", (Orange Book) that is the 46th Edition and includes the 2026 Edition Date.**

Kentucky Board of Pharmacy

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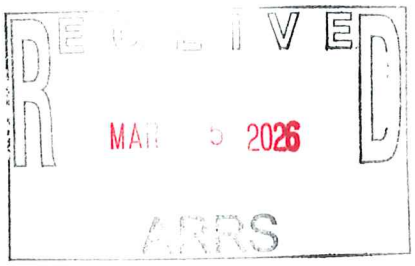
March 3, 2026



Senator Stephen West, Co-Chair
Representative Derek Lewis, Co-Chair
c/o Ange Darnell, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
Room 083, Capitol Annex
Frankfort, Kentucky 40601

Re: 201 KAR 2:180 Pharmacy Sanitation

Dear Co-Chairs West and Lewis:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 201 KAR 2:180 the Kentucky Board of Pharmacy proposes the attached amendment to 201 KAR 2:180.

Sincerely,

Christopher Harlow, PharmD
Executive Director

Final, 3-03-2026

SUGGESTED SUBSTITUTE

BOARDS AND COMMISSIONS
Board of Pharmacy

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.

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.

Kentucky Board of Pharmacy

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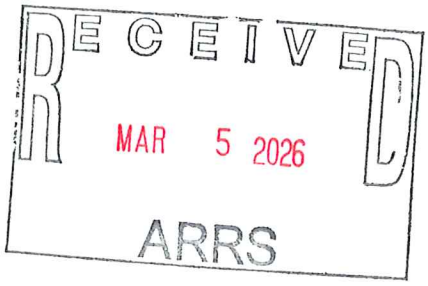
March 3, 2026



Senator Stephen West, Co-Chair
Representative Derek Lewis, Co-Chair
c/o Ange Darnell, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
Room 083, Capitol Annex
Frankfort, Kentucky 40601

Re: 201 KAR 2:190 Return of Prescription Drugs

Dear Co-Chairs West and Lewis:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 201 KAR 2:190 the Kentucky Board of Pharmacy proposes the attached amendment to 201 KAR 2:190.

Sincerely,

Christopher Harlow, PharmD
Executive Director

Final, 3-03-2026

SUGGESTED SUBSTITUTE

BOARDS AND COMMISSIONS
Board of Pharmacy

201 KAR 2:190. Return of prescription drugs[~~, prohibited.~~]

RELATES TO: KRS Chapters 217 and 315
STATUTORY AUTHORITY: KRS 217.055, 217.215,[~~315.010(5),~~] 315.191(1), ***315.404(4)[~~(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 315.191(1) authorizes the board to promulgate administrative regulations to control all matters set forth in KRS Chapter 315 relating to pharmacies and pharmacists. KRS 315.191(1)(f) authorizes the board to promulgate administrative regulations for the retrieval of prescription drugs. KRS 315.404(4) authorizes pharmacies to accept returns of prescription drugs. This administrative regulation establishes procedures for pharmacists accepting returned prescription drugs and prohibits pharmacists from accepting returned prescription drugs for sale or reuse except for in specific circumstances[~~To prevent the dispensing of drugs that have been adulterated, contaminated or misbranded~~]***.

Section 1. ***A[~~No~~]*** pharmacy, pharmacist, or agent thereof shall ***not*** accept ***a prescription drug*** for reuse or resale***[~~, a prescription drug~~]***. This administrative regulation shall not apply to ***sealed or unopened[~~sealed/unopened~~]*** prescription drugs in the original standard unit[~~, dose, unit~~] of dispensing.[~~use or tamper resistant drug packaging.~~]

Section 2. Drug Integrity ***Shall[~~Must~~]*** Be Verified Before Accepting Return.
(1) ***A[~~No~~]*** pharmacist shall ***not*** accept the return of a prescription drug unless:
(a) The drug is in a sealed container by which it ***may[~~can~~]*** be readily determined by a pharmacist employed by the dispensing pharmacy that entry or attempted entry by any means has not been made;
(b) The drug container meets the standards of the United States ***Pharmacopeia[~~Pharmacopoeia~~]*** for storage conditions including temperature, light sensitivity, moisture, chemical, and physical stability;
(c) The drug labeling and packaging has not been altered or defaced and the identity of the drug, its potency, lot number, and expiration date are legible;
(d) The drug does not require refrigeration; and
(e) The drug is returned to a pharmacist employed by the dispensing pharmacy within fourteen (14) days.
(2) Subsection (1)(d) and (e) ***of this section*** shall be waived if all other conditions are met and if:
(a) The drug was dispensed for a patient in a health care facility licensed by the Cabinet for ***Health and Family Services[~~Human Resources~~]***;
(b) The drug has not come into the physical possession of the person for whom it was prescribed;
(c) The drug has been under the continuous control of personnel in the health care facility who are trained and knowledgeable in the storage and administration of drugs;
(d) The drug has been properly stored in an area which is regularly inspected by a pharmacist; and
(e) The drug is not expired.
(3) Drugs dispensed within an acute care facility shall be exempt from the provisions of subsection 1(a), (d), and (e) of this section.
(4) Nothing in this administrative regulation shall be construed to require a pharmacist to accept the return of a prescription drug.

Section 3. Violation of any provision of this administrative regulation constitutes unethical or unprofessional conduct in accordance with KRS 315.121.

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.

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March 3, 2026

Senator Stephen West, Co-Chair
Representative Derek Lewis, Co-Chair
c/o Ange Darnell, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
Room 083, Capitol Annex
Frankfort, Kentucky 40601

Re: 201 KAR 2:205 Pharmacist-in-charge

Dear Co-Chairs West and Lewis:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 201 KAR 2:205 the Kentucky Board of Pharmacy proposes the attached amendment to 201 KAR 2:205.

Sincerely,

Christopher Harlow, PharmD
Executive Director

Final, 3-03-2026

SUGGESTED SUBSTITUTE

BOARDS AND COMMISSIONS
Board of Pharmacy

201 KAR 2:205. Pharmacist-in-charge.

RELATES TO: KRS 315.020, 315.035, 315.0351, 315.191, 315.300, 315.335, 21 C.F.R. 1301.76(b)
STATUTORY AUTHORITY: KRS 315.020(1), 315.0351, 315.191(1)
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) authorizes the board to promulgate administrative regulations pursuant to KRS Chapter 13A necessary to regulate and control all matters relating to pharmacists, pharmacist interns, pharmacy technicians, pharmacies, wholesale distributors, and manufacturers. KRS 315.020(1) and 315.0351(1)(g) require applicants for pharmacy permits to place a pharmacist in charge as a prerequisite to compounding and dispensing privileges granted by the Kentucky Board of Pharmacy. This administrative regulation establishes the requirements relating to a pharmacist-in-charge.

Section 1. Definition. "Pharmacist-in-charge" means a pharmacist licensed in the Commonwealth of Kentucky, who accepts responsibility for the operation of a pharmacy in conformance with all laws and administrative regulations pertinent to the practice of pharmacy and the distribution of prescription drugs and who is personally in full and actual charge of the pharmacy.

Section 2. Duties and Responsibilities.

(1) The pharmacist-in-charge shall be so designated in the Application for Permit to Operate a Pharmacy in Kentucky and in the Application for Non-Resident Pharmacy Permit, and in each Application for Resident Pharmacy Renewal and Application for Non-Resident Pharmacy Permit Renewal, as incorporated by reference in 201 KAR 2:050 ***and 201 KAR 2:465***, and submitted for the renewal of that permit thereafter.

(2) A pharmacist shall not serve as a pharmacist-in-charge:

(a) For more than one (1) pharmacy at a time, except upon written approval from the Kentucky Board of Pharmacy; and

(b) Unless he or she is physically present in that pharmacy for a minimum of ten (10) hours per week or the amount of time appropriate to provide supervision and control.

(3) The pharmacist-in-charge shall be responsible for:

(a) Quality assurance programs for pharmacy services designed to objectively and systematically monitor care***, including:[,]***

1. Pursuing[~~pursue~~] opportunities for improvement***;[,]***

2. Resolving[~~resolve~~] identified problems as ***those*** may exist***;[,]*** and

3. Detecting[~~detect~~] and ***preventing[~~prevent~~]*** drug diversion;

(b) The procurement, storage, security, and disposition of drugs and the provision of pharmacy services;

(c) ***Ensuring[~~Assuring~~]*** that all pharmacists and interns employed by the pharmacy are currently licensed;

(d) Providing notification in writing to the Board of Pharmacy within fourteen (14) calendar days of any change in the:

1. Employment of the pharmacist-in-charge;
2. Employment of staff pharmacists; or
3. Schedule of hours for the pharmacy;

(e) Making or filing of any reports required by state or federal laws and regulations;

(f) Responding to the Kentucky Board of Pharmacy regarding identified violations or deficiencies;***[~~and~~]***

(g) Filing of any report of a theft or loss to:

1. The U. S. Department of Justice Drug Enforcement Administration as required by 21 C.F.R. 1301.76(b);
2. The Department of the Kentucky State Police as required by KRS 315.335;
3. The board by providing a copy to the board of each report submitted; and
4. The Cabinet for Health and Family Services***;[~~,~~]***

(h) Ensuring appropriate equipment is available and in working order ***and allowing[~~to allow~~]*** within the pharmacy area ***equipment[~~,~~]*** such as the following:

1. A prescription balance with sensitivity not less than that of a Class 3 balance;
2. Weights-metric or apothecary-complete set;
3. Graduates capable of accurately measuring from one (1) ml to 250 ml;
4. Mortars and pestles-glass, porcelain, or Wedgewood;
5. Spatulas-steel and nonmetallic;
6. A heating unit;
7. Suitable refrigeration unit for proper storage of drugs; and
8. Ointment slab or ointment papers***; and***

(i) Ensuring proper reference material as required by 201 KAR 2:090 is made available to pharmacy employees.

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.

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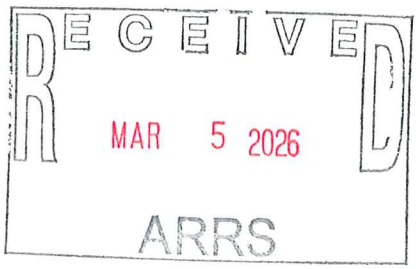
March 3, 2026



Senator Stephen West, Co-Chair
Representative Derek Lewis, Co-Chair
c/o Ange Darnell, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
Room 083, Capitol Annex
Frankfort, Kentucky 40601

Re: 201 KAR 2:250 Pharmacist Recovery Network Committee

Dear Co-Chairs West and Lewis:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 201 KAR 2:250 the Kentucky Board of Pharmacy proposes the attached amendment to 201 KAR 2:250.

Sincerely,

Christopher Harlow, PharmD
Executive Director

Final, 3-03-2026

SUGGESTED SUBSTITUTE

BOARDS AND COMMISSIONS
Board of Pharmacy

201 KAR 2:250. Pharmacist Recovery Network Committee.

RELATES TO: KRS 315.121(1)(d)
STATUTORY AUTHORITY: KRS 61.810(k), 315.126(3), (6), (7), 315.191(1)(a)
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 315.126(1) requires the Board of Pharmacy to establish a pharmacy recovery network committee (PRNC). ***KRS 315.126(3) authorizes the board to promulgate administrative regulations to implement KRS 315.126.*** This administrative regulation establishes minimum requirements for the establishment and operation of the PRNC ***and[. This administrative regulation]*** specifies ***how[the manner by which]*** the board's PRNC consultant works with the board in intervention, evaluating, and treating a pharmacist or ***pharmacist*** intern, and providing for continuing care and monitoring by the consultant through a treatment provider.

Section 1. The Board of Pharmacy's[board's] Pharmacist Recovery Network Committee (PRNC) consultant shall be a pharmacist licensee of the board. The consultant shall assist the Case Review Panel (CRP)[Committee (CRC)] and the PRNC in carrying out their respective responsibilities. This shall include working with the board's inspectors and investigators to determine ***if[whether]*** a pharmacist or pharmacist intern is in fact impaired.

Section 2. If a pharmacist or pharmacist intern self-reports[self-reports] impairment as a result of the misuse or abuse of alcohol or drugs, or both; or if the board receives a legally sufficient complaint alleging that a pharmacist or pharmacist intern is impaired as a result of the misuse or abuse of alcohol or drugs, or both, and ***if[where]*** there is no other alleged violation of state pharmacy law[complaint] against the pharmacist or ***pharmacist*** intern other than impairment exists, the reporting of any impairment information to the board shall be forwarded to the consultant and shall not constitute grounds for discipline, if the PRNC finds the pharmacist or pharmacist intern has:

(1) Acknowledged the impairment problem;
(2) Voluntarily enrolled in an appropriate, approved treatment program;
(3) Voluntarily withdrawn from practice or limited the scope of practice as required by the consultant, in each case, until the PRNC is satisfied the licensee has successfully completed an approved treatment program; and
(4) Executed releases for medical records, authorizing the release of all records of evaluations, diagnoses, and treatment of the licensee, including records of treatment for emotional or mental conditions, to the consultant. The consultant shall not make copies or reports of records that do not regard the issue of the licensee's impairment and his or her participation in a treatment program.

Section 3.

(1) A treatment provider shall disclose to the consultant or board if applicable all information in its possession regarding the issue of a pharmacist's or pharmacist intern's impairment and participation in the treatment program. Failure of the treatment provider to provide information to the consultant shall be a basis for the withdrawal of the use of the program or provider.
(2) If in the opinion of the consultant or PRNC, an impaired pharmacist or pharmacist intern has not progressed satisfactorily in a treatment or recovery program, all information regarding the issue of a pharmacist's or ***pharmacist*** intern's impairment and participation in a treatment or recovery program in the consultant's possession shall be disclosed to the board. That disclosure shall constitute a complaint.

Section 4. All information concerning a pharmacist or ***pharmacist*** intern held by the consultant, PRNC, CRP[~~CRC~~], or board shall remain confidential.

Section 5.

(1) The PRNC shall be comprised of eleven (11) members. The members shall include:

(a) The President of the Board of Pharmacy;

(b) The Chair, who shall be the consultant of the PRNC;

(c) The Executive Director of the Board of Pharmacy; and

(d) Eight (8) other members, of which seven (7) shall be pharmacists and one (1) shall be a citizen member.

(2)

(a) All members shall have the same rights, which include voting privileges.

(b) A member of the PRNC shall not be on the board, except the President of the Board.

(c) Any criminal conviction or disciplinary action by a licensure board against a proposed member shall be reported to the board prior to consideration for appointment.

(d) There may be no more than four (4) members in successful recovery on the PRNC.

(e) A pharmacist under a Pharmacist Recovery Network Agreement shall not serve on the PRNC.

(3)

(a) A ***board-approved[~~board-approved~~]*** PRNC member may be appointed[~~-by the board~~] a maximum of three (3), four (4) year terms or a total of twelve (12) years.

(b) A PRNC member shall not serve more than (2) terms consecutively.

(c) After serving two (2) consecutive terms a PRNC member shall rotate off the PRNC for at least two (2) years.

[~~(d)~~] [~~A committee member shall serve no more than twelve (12) years on the PRNC.~~]

(d)[~~(e)~~] The President of the Board, the PRNC Consultant, and the Executive Director of the Board shall be permanent members of the PRNC[~~membership on the PRNC shall not constitute a twelve (12) year term~~].

(e)[~~(f)~~] Membership of the PRNC shall be selected by the board from a list of qualified candidates submitted by an interested individual or entity.

(4) A member of the PRNC who becomes impaired, relapses, has any criminal conviction, or has any disciplinary action by a licensure board shall immediately resign from the PRNC.

(5) The board by majority vote, with the recusal of the President of the Board, may remove a member of the PRNC for any of the following reasons:

(a) Refusal or inability of a committee member to perform duties as a member of the committee in an efficient, responsible, and professional manner;

(b) Misuse of the committee by a member to obtain personal, pecuniary, or material gain or advantage for the member or others; and

(c) Violation of any provision of KRS Chapter 315.

Section 6.

(1) PRNC meetings are confidential. All PRNC information, interviews, reports, statements, memoranda, or other documents furnished to or produced by the PRNC, all communications to or from the committee, and all proceedings, findings, and conclusions of the committee, including those relating to intervention, treatment, or rehabilitation, that in any way pertain or refer to a pharmacist or pharmacist intern who is or may be impaired shall be privileged and confidential pursuant to KRS 315.126. In accordance with KRS 61.810(k), any meeting which is required by state (or federal) law to be conducted in private is an exception to the open meetings requirements. ***The[~~Thus,~~]*** PRNC ***shall[~~will~~]*** publish its meeting schedule and a redacted meeting agenda, but the meetings ***shall*** remain confidential and ***shall[~~are~~]*** not ***be*** open to the public.

(2) Meeting records are confidential. Pursuant to KRS 315.126(7), all PRNC records and proceedings that pertain or refer to a pharmacist or pharmacist intern who is or may be impaired shall be privileged and confidential, used by the committee and its members only in the exercise of the proper function of ***the*** PRNC, ***shall[~~are~~]*** not ***be*** considered public records and ***shall*** not ***be*** subject to court subpoena,

discovery, or introduction as evidence in any civil, criminal, or administrative hearing, except as required by the ***KRS 315.126(8)[~~statute~~]***.

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.

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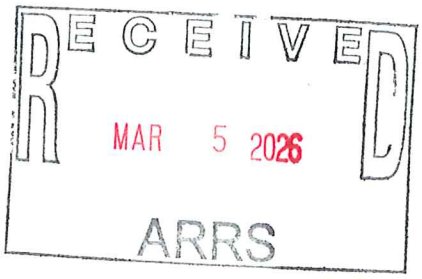
March 3, 2026



Senator Stephen West, Co-Chair
Representative Derek Lewis, Co-Chair
c/o Ange Darnell, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
Room 083, Capitol Annex
Frankfort, Kentucky 40601

Re: 201 KAR 2:260 Automated Pharmacy System in Residential Hospice Facilities

Dear Co-Chairs West and Lewis:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 201 KAR 2:260 the Kentucky Board of Pharmacy proposes the attached amendment to 201 KAR 2:260.

Sincerely,

Christopher Harlow, PharmD
Executive Director

Final, 3-02-2026

SUGGESTED SUBSTITUTE

BOARDS AND COMMISSIONS
Board of Pharmacy

201 KAR 2:260. Automated Pharmacy System in residential hospice facilities.

RELATES TO: KRS 216B.195, 315.010(9), 315.020, 315.035, 315.295, 315.300
STATUTORY AUTHORITY: KRS 315.035, 315.191(1)(a), 315.295***(4)***
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 ***315.020[~~335.020~~]***(1) requires that prescription drugs, medicines, and pharmaceuticals be dispensed or manufactured by a licensed pharmacist. KRS 315.295***(4) requires[~~ authorizes~~]*** the board to ***promulgate administrative regulations to implement requirements relating to[~~regulate~~]*** an automated pharmacy system in a residential hospice facility. This administrative regulation establishes the standards for the operation of this type of system.

Section 1. Definitions.
(1) "Automated Pharmacy System" is defined by KRS 315.295(1)(a).
(2) "Residential Hospice Facility" is defined by KRS 315.295(1)(b).

Section 2. Responsibility. The pharmacist-in-charge of a pharmacy utilizing an automated pharmacy system shall be responsible for***[~~ all of the following~~]***:
(1) ***Ensuring[~~Assuring~~]*** that the automated pharmacy system is in good working order and accurately dispenses the correct strength, dosage form, and quantity of drug prescribed and complying with the recordkeeping and security safeguards pursuant to Section 3 of this administrative regulation;
(2) ***Ensuring[~~Assuring~~]*** medications are reviewed by a pharmacist prior to access;
(3) Implementing an ongoing quality assurance program that monitors performance of the automated system, which is evidenced by written policies and procedures;***[~~ and~~]***
(4) Notifying the board with prior written notice of the installation or removal of an automated pharmacy system. This notification shall include the***[~~ following~~]***:
(a) Name and address of pharmacy;
(b) Initial location of the automated pharmacy system. The automated pharmacy system may thereafter be relocated within the pharmacy or health care facility without providing subsequent notification to the board; and
(c) Pharmacist-in-charge***;[~~.~~]***
(5) Assigning, discontinuing, or changing personnel access to the system;
(6) ***Ensuring[~~Assuring~~]*** that access to the medications comply with state and federal laws; and
(7) ***Ensuring[~~Assuring~~]*** that the automated pharmacy system is stocked accurately and that the automated pharmacy system stock is checked monthly in accordance with established written policies and procedures, including the***[~~ following~~]***:
(a) Accuracy;
(b) Integrity; and
(c) Expiration date.

Section 3. Standards. An automated pharmacy system shall comply with the following provisions:
(1) A pharmacy shall maintain on-site the following documentation relating to an automated pharmacy system:
(a) Name and address of the pharmacy or inpatient health care facility where the system is being used;

(b) The automated pharmacy system manufacturer's name, model, and serial number;
(c) Description of how the system is used;
(d) Written quality assurance procedures to determine continued appropriate use of the system; and
(e) Written policies and procedures for system operation, safety, security, accuracy, access, and malfunction.

(2) All written policies and procedures shall be maintained in the pharmacy responsible for the automated pharmacy system.

(3) An automated pharmacy system shall maintain adequate security systems and procedures, evidenced by written policies and procedures to prevent unauthorized access to maintain patient confidentiality and to comply with federal and state laws.

(4) Records and data kept by the automated pharmacy system shall meet the following requirements:
(a) All events involving the contents of the automated pharmacy system shall be recorded electronically; and
(b) Records shall be maintained by the pharmacy and be available to the board and shall include the ***[~~following~~]***:
1. The time and location of the system accessed;
2. Identification of the individual accessing the system;
3. Type of transaction;
4. Name, strength, dosage form, and quantity of drug accessed;
5. Name of the patient for whom the drug was ordered;
6. The prescription number;
7. The name of the prescriber; and
8. All events involving user database modifications shall be recorded electronically and maintained.

(5) The stocking of all medications in the automated pharmacy system shall be done by a pharmacist, pharmacist intern, or pharmacy technician pursuant to 201 KAR 2:045.[~~, who shall be under the general supervision of a pharmacist on-site.~~]

(6) A record of medications stocked into an automated pharmacy system shall be maintained for five (5) years and shall include identification of the person stocking and pharmacist checking for accuracy.

(7) All containers of medications stored in the automated pharmacy system shall be packaged and labeled in accordance with federal and state laws.

(8) The automated pharmacy system shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the automated pharmacy system, in accordance with federal and state laws.

(9) The automated pharmacy system shall provide a mechanism for securing and accounting for medications returned to the system and accounting for wasted medications in accordance with federal and state laws.

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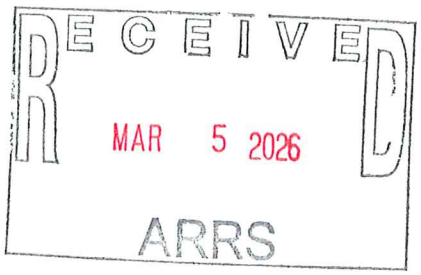
March 3, 2026



Senator Stephen West, Co-Chair
Representative Derek Lewis, Co-Chair
c/o Ange Darnell, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
Room 083, Capitol Annex
Frankfort, Kentucky 40601

Re: 201 KAR 2:330 Emergency Pharmacy Powers

Dear Co-Chairs West and Lewis:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 201 KAR 2:330 the Kentucky Board of Pharmacy proposes the attached amendment to 201 KAR 2:330.

Sincerely,

Christopher Harlow, PharmD
Executive Director

Final, 3-02-2026

SUGGESTED SUBSTITUTE

BOARDS AND COMMISSIONS
Board of Pharmacy

201 KAR 2:330. Emergency pharmacy powers.

RELATES TO: KRS 39A.100, 315.500
STATUTORY AUTHORITY: KRS ***217.215,*** 315.191, ***315.500,*** 315.505***[, 217.215]***
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 315.500 establishes the conditions under which a pharmacy may operate temporarily in an area not designated on the pharmacy permit ***and for pharmacists dispensing emergency supplies of medication*** pursuant to an executive order issued by the Governor ***under[pursuant to]*** KRS 39A.100. ***KRS 315.505 authorizes the Board of Pharmacy to promulgate administrative regulations to allow pharmacists to effectuate the authority granted in KRS 315.500(1). KRS 217.215(3) authorizes pharmacists to dispense prescription refills of medication without prior authorization from the provider during emergency situations as authorized by KRS 315.500 and requires the board to promulgate administrative regulations for implementation. KRS*** 315.191***(1)*** authorizes the board***[of Pharmacy]*** to promulgate administrative regulations governing pharmacists and pharmacies. This administrative regulation ***establishes[sets out]*** the conditions ***that authorize[whereby]*** a prescription ***refill[may be refilled pursuant to an executive order issued by the Governor as authorized by KRS 315.500]*** when the prescriber is unavailable ***and for[. This administrative regulation sets out the conditions whereby]*** a pharmacy ***to[may]*** operate temporarily in an area not designated on the pharmacy permit pursuant to an executive order issued by the Governor ***under[as authorized by]*** KRS 315.500.

Section 1. If a pharmacist receives a request for a prescription refill with no refill authorized and the pharmacist is unable to readily obtain refill authorization from the prescriber, the pharmacist may dispense an emergency refill of up to a thirty (30) day supply of the medication ***pursuant to KRS 217.215*** if:

(1) The Governor has issued an executive order as authorized by KRS 315.500 for the county where the pharmacy is located;
(2) The pharmacist obtains prescription information from:
  (a) A prescription label;
  (b) A prescription record within the pharmacy;
  (c) A prescription record from another pharmacy;
  (d) A common database;
  (e) The patient; or
  (f) Any other healthcare record;
(3) The prescription refill is not for a controlled substance;
(4) The prescription is for a maintenance medication;
(5) In the pharmacist's professional judgment, the interruption of therapy may produce undesirable consequences or may be detrimental to the patient's welfare and cause physical or mental discomfort; and
(6) The pharmacist notes on the prescription record the date, the quantity dispensed, and the pharmacist's name or initials.

Section 2.
(1) A pharmacy may temporarily relocate to and operate at a new location if:
  (a) It is not safe or practicable to operate a pharmacy at the address listed on the permit; and

(b) The Governor has issued an executive order as authorized by KRS 315.500 for the county where the pharmacy is located.

(2) The pharmacy owner shall:

(a) Maintain confidentiality of patient records;

(b) Secure all drugs; and

(c) Notify the board of the temporary address as soon as practicable.

(3) The following regulatory requirements shall not apply for this temporary location:

(a) The requirement to maintain references as listed in 201 KAR 2:090, Section 1;

(b) The requirement to maintain equipment as listed in 201 KAR ***2:205[~~2:090~~]***, Section 2; and

(c) The requirement that the pharmacy be enclosed by a floor to ceiling partition if it is located within a larger establishment which is open to the public for business when a pharmacist is not present.

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