KENTUCKY BOARD OF PHARMACY

Justice and Public Safety Building
125 Holmes Street, 1st Floor Conference Room
Frankfort, KY 40601

November 19, 2025
10:00 a.m.

Zoom Registration Link
https://us02web.zoom.us/j/86850416557?pwd=6LfZtneqJLPIhM8anyz3atwbnsZpCq.1

Board Meeting Agenda

I. CALL TO ORDER

II. MINUTES
- A. September 17, 2025

III. APPEARANCES
- A. Pharmacists
  - i. License Transfer
    1. Campbell, Zachary (MPJE Request)
    2. Swanstrom, Kasey Ann (SWAN-BO51BF)
- B. Pharmacy Technicians
  - i. Cox, Brettany (COX4-0FBPRS)
  - ii. Hamilton, Hayden (HAMI-XLUYP8)
  - iii. Hebdon, Ashley (HEBD-TB40PS)
  - iv. Kessel, Corry (KESS-H8FMC7)
- C. Exception to 201 KAR 2:020 Request
  - i. Nkwanwo, Minette (I15442)

IV. CORRESPONDENCE
- A. Dual PIC Requests
  - i. Crabtree, Kevin (008709) for P08405 & P06475
  - ii. Mcintosh, Aaron (012005) for P01908 & P07746
  - iii. Turner, James Ryan (014196) for P07724 & P06302
  - iv. Smith, Sandra Foster (012554) for P05029 & Pending Permit WCH Service LLC #SMIT-65CQBX
- B. Off-Site Storage Requests
  - i. P07352
  - ii. P07632
  - iii. P07753

iv. Primary Plus
    1. P08020, P07999, P07461, P08140, P07233, P08143, P08254, P07791, P06782, P07030

V. INTERAGENCY/PROFESSIONAL ASSOCIATIONS

A. KSHP Petition

VI. BOARD REPORTS

A. Executive Director
    a. eMars
    b. 201 KAR 2:050 Fee Increase Proposal
    c. Continuing Education Advisory Committee Proposal
    d. Letter of Support- Dr. Dustin Miracle University of Kentucky College of Pharmacy
    e. Department of Insurance Inquiry
    f. Delegation Document Annual Review
    g. 2026 Board Meeting Dates
B. General Counsel
    a. Expungements
        i. 21-0269A
        ii. 21-0269B
    b. Regulation Status Update
    c. Board Authorized Protocol Issue Discussion (OIG Report)

VII. COMMITTEE REPORTS

A. KYPRN
B. Protocol Review Committee
    i. Tuberculin Skin Testing Protocol- NEW
C. Advisory Council
    i. 201 KAR 2:190
    ii. 201 KAR 2:280
D. Regulation Committee
    i. 201 KAR 2:260

VIII. NEW BUSINESS

A. 201 KAR 2:440- Legend Drug Repository
B. Regulation Committee Appointment (5 Appointments)
    i. Adams, Nathaniel
    ii. Ahmed, Yahya
    iii. Arnold, Jordan
    iv. Bartlet, Jenny
    v. Bouvette, Ralph
    vi. Bunde, Michaela
    vii. France, Kimberly

viii. Fredrick, Tyler
ix. Davis, Gary
x. Hanna, Cathy
xi. Holbrook Green, Emily
xii. Jones, Joshua
xiii. Nguyen, John
xiv. Shweta, Desai
xv. Thornbury, Joel
xvi. Toney, Warren
xvii. Waibel, Andrew
xviii. Wick, Jennifer

C. Pharmacist Recovery Network Committee (2 appointments- 1 pharmacist 1 consumer)
i. Adams, Nathaniel
ii. Balcerzak, Amanda
iii. Blair, Amanda
iv. Durran, Taylor
v. Ferguson, Scott
vi. Fields, Chelsea
vii. Foree, Sarah
viii. Jones, Avery
ix. Lemarr, Stuart (consumer applicant)
x. Sheehan, Taylor
xi. Shweta, Desai
xii. Thompson, Natasha
xiii. Toney, Warren

D. Election of 2026 Officers and Case Review Panel Members

IX. OLD BUSINESS

A. 201 KAR 2:076 Compounding (1:00 p.m. EST)

X. CLOSED SESSION DISCUSSION REQUIRED

A. Current or Pending Litigation

ATTENTION: A portion of the meeting may be held in closed/executive session for the purpose of discussing and deliberating upon open investigations or the review of information required to be conducted in private according to federal and state law. The specific statutory sections authorizing closed session are KRS 61.810(1)(c) KRS 61.878(1)(a) KRS 61.810(1)(j) KRS 61.878(1)(h) KRS 61.810(1)(k). Following discussion and deliberation, any and all action will be taken in open/public session.

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

RELATES TO: KRS Chapters 217 and 315
STATUTORY AUTHORITY: KRS 217.055, KRS 217.215 [~~315.010(5), 315.191(1), (5)~~]
CERTIFICATION STATEMENT:
NECESSITY, FUNCTION, AND CONFORMITY: To prevent the dispensing of drugs that have been adulterated, contaminated or misbranded.

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

Section 2. Drug Integrity must be verified before accepting return.

1. No pharmacist, practitioner or agent thereof shall accept the return of a prescription drug unless:
   (a) The drug is in a sealed container by which it can be readily determined by a pharmacist employed by the dispensing pharmacy or by the dispensing practitioner that entry or attempted entry by any means has not been made;
   (b) The drug container meets the standards of the United States 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 or to the dispensing practitioner within fourteen (14) days.
2. Subsection (1)(d) and (e) 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 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 or practitioner to accept the return of a prescription drug.

Section 2. Violation of any provision of this administrative regulation constitutes unethical or unprofessional conduct in accordance with KRS 315.121.

(10 Ky.R. 952; eff. 2-1-1984; 11 Ky.R. 1126; eff. 3-12-1985; 16 Ky.R. 799; eff. 1-12-1990; Crt eff. 4-17-2019.)

Commented [JB1]: AC recommended removing "prohibited" from title to reduce confusion.

Commented [JB2]: Suggested change to language to be consistent with 201 KAR 2:175 language of "standard unit of dispensing."

Suggestion to remove tamper resistant packaging (per CH).

Commented [JB3]: AC suggested adding requirements of 902 KAR 55:065 to add guidance and clarification.

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

RELATES TO: KRS 315.010(9), 315.020, 315.035, 315.295, 315.300, 216B3195
STATUTORY AUTHORITY: KRS 315.035, 315.191(1)(a), 315.295
CERTIFICATION STATEMENT:
NECESSITY, FUNCTION, AND CONFORMITY: KRS 335.020(1) requires that prescription drugs, medicines, and pharmaceuticals be dispensed or manufactured by a licensed pharmacist. KRS 315.295 authorizes the board 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) 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) 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) Assuring that access to the medications comply with state and federal laws; and
(7) 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.

(33 Ky.R. 3305; 3602; eff. 6-20-2007; Crt eff. 4-17-2019.)

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

RELATES TO: KRS 217.814, 315.191
STATUTORY AUTHORITY: KRS 315.191(1)(a), (f)
CERTIFICATION STATEMENT:
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 (such as Escripts or similar).
(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.

(29 Ky.R. 2197; 2447; eff. 4-11-2003; Crt eff. 4-17-2019.)

Commented [JB1]: AC suggested adapting the language within regulation to accommodate electronic prescription. This was done throughout.