



Kentucky Board of Pharmacy

2021 Update

Larry A. Hadley, R.Ph.
Executive Director

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Kentucky Board of Pharmacy

Disclosure

In accordance with policies of the Accreditation Council for Continuing Medical Education (ACCME) and the Accreditation Council for Pharmacy Education (ACPE), I certify that my spouse, significant other, or I have not had any relevant financial relationships during the past 12 months with commercial interests.

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Kentucky Board of Pharmacy

Mission Statement

The Kentucky Board of Pharmacy serves the Commonwealth to promote, preserve, and protect the public health, safety, and welfare through effective regulation of the practice of Pharmacy. The Board of Pharmacy accomplishes this mission through examination, testing and credentialing of prospective pharmacists, regulation and discipline of all licensed pharmacists, and through appropriate communication of information and laws pertaining to the practice of Pharmacy in Kentucky.

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Current Work of the Board of Pharmacy

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Kentucky Board of Pharmacy

Case Review Panel: Hears All Disciplinary Cases

Upcoming Meetings:

- June 10, 2021
- July 20, 2021
- August 24, 2021
- September 21, 2021
- October 12, 2021
- November 16, 2021

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Kentucky Board of Pharmacy Medication Safety Committee

Next Meeting, June 9th at 9 a.m.

July 29, 2020 – Initial Charge -- advise the board on medication error matters that include:

1. Considering application of a tool to assign harm level for medication errors that occur and are investigated by the board.
2. Categorize the types of errors that occur and develop a standardized remediation plan/assignment for the board to employ with a disciplinary action for a medication error.
3. Provide an opinion on the disciplinary action recommended for first time medication error offense that causes no harm v. medication errors that cause harm.
4. Consider the idea of developing a repository database for Kentucky pharmacists to safely and anonymously report medication errors and concerns for patient welfare (no specific pharmacies or pharmacists would be reported – data collected would be categorized to type of practice setting, etc.) •
5. For med error review and discussion by the ad hoc committee to identify patterns of concern for our state and recommend corresponding corrective action plans / remediation support for the board to consider for the profession • potential disciplinary action in the process.

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Kentucky Board of Pharmacy Medication Safety Committee, Further Charge

- January 28, 2021 Charge--Consider the utilization of the ISMP Medication Safety Self-Assessment for resolution in medication error disciplinary cases.

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Kentucky Board of Pharmacy Pharmacy Technician Committee

May 27, 2020 Charge: Explore if Kentucky would like to consider specific pharmacy technician categories. If so, determine the job description, duties that may be performed and education requirements for each category.

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Kentucky Board of Pharmacy Diversity and Inclusion Task Force Next Meeting: June 17th at 2:30 p.m.

July 29, 2020 Charge

- a) Gather/evaluate/collect data to determine need for strategic plan to address diversity and inclusion in the Kentucky pharmacy community.
- b) Develop a clear cultural competency plan that addresses diversity and inclusion in the Kentucky pharmacy community.
- c) Implement ways to spearhead access to pharmacy services to reach those in underrepresented/underserved demographics by evaluating the disparity amongst rural and urban populations.
- d) Provide diversity and cultural competency trainings (CE) pharmacists/technicians and encourage various pharmacy organizations to provide the same courses to members.
- e) Work with Colleges of Pharmacy to continue to recruit and retain a more diverse student body and the pool of pharmacists serving as preceptors.
- f) Determine methods to engage women and minorities in leadership and professional advocacy activities.

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Kentucky Board of Pharmacy Advisory Council Current Charges Next Meeting, June 8th at 9:00 a.m.

February 23, 2021 Charge - Related to Pandemics, Epidemics, Natural Disasters, Terroristic Disasters and Biologic Disasters: 1) Evaluate pharmacy practice changes due to COVID-19 – short-term additions with long-term plans or implications, that include but are not limited to remote order entry.

- 2) Review current law in KY to determine if they are sufficient to allow potential response and change in work practice to meet patient care needs immediately; evaluate other state laws to determine if other changes should be adopted to ensure pharmacists may practice legally.
- 3) Evaluate and recommend permanent practice changes that are temporarily being done at this time to meet the demands of the pandemic.
- 4) Evaluate the opioid epidemic and make recommendations to the board for any necessary regulatory changes that would improve the health of the Commonwealth / and reduce opioid OD and addiction.
- 5) Simulate a recovery exercise for each type of emergency and outline the legal restraints and allowances that impact operations – provide a list of these and whether other changes should be invoked in an emergency pharmacy powers regulation.
- 6) Determine the role that the KY Board of Pharmacy Executive Director, staff and inspection staff can serve in emergency/disaster response. Determine if the KY Board of Pharmacy office and staff could/should serve as a command center or coordination center.
- 7) Seek input and coordination with KPhA and KSHP.

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Advisory Council Current Charges
Next Meeting, June 8th at 9:00 a.m.

- February 23, 2021 Charge - NABP Passport Program / Development of a State Pharmacist Database for response: 1) Create a readily usable and UTD robust pharmacy / pharmacist database to recognize the pharmacists who can be called upon to assist based on their capacity, i.e. certifications, job expertise and work location. 2) Create a process to allow no-practicing retirees of the pharmacy practice to re-enter work to meet the patient care demands of various types of emergencies.
- May 25, 2021 Charge – Prescription integrity during transit: 1) Study the issue of shipped medications for temperature excursions/integrity during transit until received by the ultimate consumer.

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Regulation Committee

- July 29, 2020 Charge- KRS 315.0351 Non-resident Pharmacy Permit Questions: review KRS 315.0351 and provide recommendations to the Board for regulation amendments or implementing Board policy.
- July 29, 2020 Charge - 201 KAR 2:074 Decentralized Pharmacies: Review issues presented and provide recommendations to the Board for regulation amendments or implementing Board policy.
- September 30, 2020 Charge - KitCheck/RFID: Evaluate and consider amendment to technology terminology.
- May 27, 2020 Charge - Repository Regulation: Review and consider the establishment of repository regulation.
- May 25, 2021 Charge - Central Fill: Evaluate 201 KAR 2:230 for a broader scope of practice allowing for modern business models.

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Kentucky Board of Pharmacy Kentucky Professionals Recovery Network Committee

- March 30, 2021 Charge –Review by the Professional Recovery Network Committee for an interpretation of current practices and concerns that have been raised and an evaluation of 201 2:250 for amendments to address these concerns.
- May 25, 2021 Charge–Review and suggest recommendations to the Board regarding participation of individuals without a substance abuse disorder to include insight from the colleges of pharmacy.

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Kentucky Board of Pharmacy Recent Finalized Amendments to Regulation

On February 4, 2021, the following contained amendments that became effective:

201 KAR 2:050 Licenses and permits; fees

201 KAR 2:205 Requirements for wholesalers, medical gas wholesalers, wholesaler distributors, and virtual wholesale distributors

201 KAR 2:106 Licensed or permitted facility closures

201 KAR 2:225 Special limited pharmacy permit - Medical gas

201 KAR 2:240 Special limited pharmacy permit - Charitable

201 KAR 2:320 Requirements for manufacturers and virtual manufacturers

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Kentucky Board of Pharmacy

Regulations with Amendments Pending ARRS Committee Review

Tentative June 8th ARRS Committee Meeting:

- 201 KAR 2:040 Registration of Pharmacist Interns
- 201 KAR 2:171 Computerized Recordkeeping
- 201 KAR 2:205 Pharmacist-in-Charge
- 201 KAR 2:390 Requirements for Third Party Logistics Providers

Tentative July 9th ARRS Committee Meeting:

- 201 KAR 2:061 Procedures followed in the investigation and hearing of complaints

*Will be automatically continued to following month's ARRS meeting if written comments received.

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Board-Approved Amendments to be Filed by June 15, 2021

- 201 KAR 2:270 Expungement
- 201 KAR 2: 360 Naloxone Dispensing

NEW REGULATION ON ADMINISTERING VACCINATIONS:

- 201 KAR 2:420

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Kentucky Board of Pharmacy

Proposed Administration of Vaccines Regulation

201 KAR 2:420

Section 1. Definitions.

- (1) "Administer" is defined by KRS 315.010(1).
- (2) "Pharmacist" is defined by KRS 315.010(17).
- (3) "Pharmacist intern" is defined by KRS 315.010(18).
- (4) "Pharmacy technician" is defined by KRS 315.010(21).

Section 2. Pharmacist Requirements. A pharmacist may administer a vaccine to an individual in accordance with KRS 315.010(22).

Section 3. Pharmacist Intern Requirements. A pharmacist intern under the general supervision of a pharmacist may administer a vaccine to an individual if the pharmacist intern:

- (1) Completes, or has completed as part of pharmacy school curriculum, a practical training program accredited by the Accreditation Council for Pharmacy Education (ACPE) that includes hands-on injection technique and the recognition and treatment of emergency reactions to vaccines; and
- (2) Possesses a current certificate in basic cardiopulmonary resuscitation.

Section 4. Pharmacy Technician Requirements. A pharmacy technician may administer a vaccine under the general supervision of a pharmacist to an individual if the pharmacy technician:

- (1) Completes a minimum of two (2) hours of immunization-related continuing education accredited by the Accreditation Council for Pharmacy Education (ACPE) per each state registration period;
- (2) Completes, or has completed, a practical training program accredited by the Accreditation Council for Pharmacy Education (ACPE) that includes hands-on injection technique and the recognition and treatment of emergency reactions to vaccines; and
- (3) Possesses a current certificate in basic cardiopulmonary resuscitation.

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FDA Memorandum of Understanding on Compounding

- Board voted to sign the FDA Memorandum of Understanding.
- Currently including regulatory language from MOU into 201 KAR 2:061, as required by the MOU.
- Once 201 KAR 2:061 is effective, official signature of the Board will be placed on the MOU.
- Purpose: For states to communicate with each other regarding compounding violations to protect distribution of compounding substances across state lines.

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Kentucky Board of Pharmacy When the State of Emergency Ends...

POSSIBLE CHANGES TO:

- Limitations on in-person pharmacy contact
- Administration of Vaccinations (default to PREP Act Rule)
- Payer contract
- Remote order entry (HB219 impact on KRS 315.020)
- COVID-19 Testing (No longer authorized)
- Notifications to Board
- Garbing Requirements

*Board of Pharmacy may choose to exercise enforcement discretion to provide a buffer period for licensees and permit holders to return their practices to the non-emergency rule.

*Board of Pharmacy may exercise enforcement discretion if they wish to make a regulatory amendment and do not wish to enforce the regulation until the amendment is made.

*Board of Pharmacy will call a special meeting when/if the state of emergency ends to determine enforcement status.

**The Board is in regular contact with the Governor’s Office regarding the State of Emergency status.

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Thank You

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