January 26, 2022

Pursuant to the General Assembly's Declaration of a State of Emergency for COVID-19, the Kentucky Board of Pharmacy is exercising enforcement discretion for the following regulations.

I. 201 KAR 2:020 Examination

Due to the prohibition of in-person work that is not necessary to protect or sustain life in Executive Order 2020-257 and pursuant to Executive Order 2020-243, the Kentucky Board of Pharmacy is not enforcing the following part of 201 KAR 2:020:

- Section 8(1) Incorporated by reference the section on page 2 of the "Initial Application for Pharmacist Licensure" that requires the application be notarized.

The rest of the 201 KAR 2:020 is in effect.

Please Note:

- The Board of Pharmacy has posted "KY Fingerprint Guide During COVID-19" on the Board's website:
  - www.pharmacy.ky.gov
  - On the left hand side of the home page: click "Professionals"
  - Click "Pharmacist Information"
  - Under the second question, "How do I . . . Apply for Initial Licensure?" click on "Initial Pharmacist Licensure"
- A photograph is no longer required.

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

Due to the difficulty that may be encountered during the COVID-19 pandemic in staffing pharmacies, including naming a pharmacist-in-charge (PIC), the Kentucky Board of Pharmacy is exercising enforcement discretion regarding the following parts of 201 KAR 2:205:

- **Section 2(3)(d)1:** the requirement that the PIC provide notification in writing to the Board of Pharmacy within fourteen (14) calendar days of any change in the employment of the pharmacist in charge. If a pharmacy cannot name a PIC within fourteen (14) calendar days please contact the Board of Pharmacy office or the Inspector for guidance. The Board staff will work with each pharmacy permit holder and pharmacy staff on an individual basis to determine an appropriate solution.

- **Section 2(3)(d)2:** the requirement that the PIC provide notification in writing to the Board of Pharmacy within fourteen (14) calendar days of any change in employment of staff pharmacists. Pharmacies will not have to provide notice of change in staff pharmacists during the State of Emergency.
- **Section 2(3)(d)3:** the requirement that the PIC provide notification in writing to the Board of Pharmacy within fourteen (14) calendar days of any change in schedule of hours for the pharmacy. Pharmacies do not have to notify the Board of a temporary change of hours during the State of Emergency.

The rest of 201 KAR 2:205 is in effect.

The requirement in KRS 315.020 (1) for a pharmacy to name a PIC is in effect.

Please contact the Board of Pharmacy office or the Inspector for guidance should this become an issue. The Board staff will work with each pharmacy permit holder and pharmacy staff on an individual basis to determine an appropriate solution.

III. 201 KAR 2:280 Prescription Dispensing for Formulary Compliance

Due to the shortage of critical medications during the COVID-19 pandemic, the Kentucky Board of Pharmacy is suspending the following parts of 201 KAR 2:280:

- **Section 1(1)(a):** the prescriber does not have to indicate "formulary compliance approval" on the prescription. If the drug is on the FDA Drug Shortage List, the pharmacist may automatically substitute a therapeutically equivalent drug. For example, substituting albuterol inhalers that are not A/B rated by the FDA Orange Book.
- **Section 1(1)(b):** the pharmacist does not have to receive a formulary change as a consequence of the patient's third party plan. If the drug is on the FDA Drug Shortage List, the pharmacist may automatically substitute a therapeutically equivalent drug. For example, substituting albuterol inhalers that are not A/B rated by the FDA Orange Book.
- **Section 1(1)(c):** the drug does not have to be designated as "preferred" by the third-party formulary, however, the drug must be in the same therapeutic class. If the drug is on the FDA Drug Shortage List, the pharmacist may automatically substitute a therapeutically equivalent drug. For example, substituting albuterol inhalers that are not A/B rated by the FDA Orange Book.
- **Section 1(2):** the 24-hour notification window for the pharmacist to notify the prescriber of the therapeutically equivalent substitution is extended to 2 business days or the next day the prescriber can be reached.
- **Section 2:** the drug dispensed does not have to be the preferred formulary therapeutic alternative, however, it must be on the FDA Drug Shortage List. The pharmacist may make adjustments in the quantity and directions of the alternative drug dispensed to provide for an equivalent dose of the drug that is on the FDA Drug Shortage List.

The following parts of 201 KAR 2:280 are **being enforced**:

- **Section 1(2)(a):** the pharmacist must notify the prescriber in an original writing or by facsimile that the pharmacist substituted a drug because of the FDA Drug Shortage List.
- **Section 1(2)(b):** the pharmacist must notify the prescriber in an original writing or by facsimile which therapeutically equivalent product was dispensed.

Please Note:

- The drug must be on the FDA Drug Shortage List, not any other group or association's drug shortage list.
- This does not apply to biological products.

IV. 201 KAR 2:370 Pharmacy Services in long-term care facility (LTCF)

In an effort to limit the number of people entering long term care facilities, the Kentucky Board of Pharmacy is suspending the following parts of 201 KAR 2:370:

- **Section 2(4)(d)2:** the requirement that a pharmacist, pharmacist intern, or certified pharmacy technician review the Emergency Medication Kit (EMK) for outdated, damaged or adulterated drugs and stock adequacy of non-controlled drugs on a monthly basis. This may be performed by a registered nurse (RN) or a licensed practical nurse (LPN) at the LTCF.
- **Section 2(5)(f):** the requirement that pharmacy personnel inspect the stock of the LTCF Drug Stock for outdated drugs and stock adequacy on a monthly basis. This may be performed by a registered nurse (RN) or a licensed practical nurse (LPN) at the LTCF.
- **Section 2(5)(g)(3):** the requirement that LTCF Drug Stock be replenished by a pharmacist, pharmacist intern, or a certified pharmacy technician who shall be under the immediate supervision of a pharmacist on-site, if there is no pharmacy on-site. This may be performed by a registered nurse (RN) or a licensed practical nurse (LPN) at the LTCF.
- **Section 4(5)(a), (b) and (c):** The requirement that the stocking of an automated dispensing system (ADS) be done by a pharmacist, pharmacist intern, or certified pharmacy technician under the supervision of a pharmacist on-site. This may be performed by a registered nurse (RN) or a licensed practical nurse (LPN) at the LTCF.
- **Section 4(6)**: the requirement that if the pharmacy utilizes a tamper resistant barcoding technology, microchip, or other equivalent tamper-resistant ADS, a pharmacist-verified drug may then be loaded by a pharmacist-in-charge trained pharmacist, pharmacist intern, or certified pharmacy technician. The loading of the pharmacist-verified drug into the ADS may be performed by a registered nurse (RN) or a licensed practical nurse (LPN) at the LTCF.

The rest of the 201 KAR 2:370 is **being enforced**, including, but not limited to:

- **Section 2(4)(d)1:** the requirement that a pharmacist or any lawful person as stated in 902 KAR 55:070 review the EMK for outdated, damaged or adulterated drugs and stock adequacy of controlled substance on a monthly basis. 902 KAR 55:070 Section 2(4)(d) requires the pharmacy provider to document completion of a physical inventory of the controlled substances in an EMK no less than 1 time per month. This must be done by the pharmacy provider.
- **Section 2(2)(a):** the requirement that a prescription drug order from a licensed practitioner is obtained prior to the administration of a controlled substance from the EMK.
- **Section 2(2)(b):** the requirement that a prescription drug order or medical order from a licensed practitioner is obtained prior to the administration of a non-controlled substance from the EMK.
- **Section 2(5)(e):** the requirement a pharmacist must review the prescription drug or medical order before the release of medication from LTCF Drug Stock.