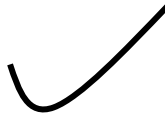


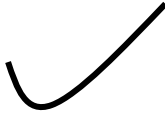
COVID-19 State of Emergency Changes in Board of Pharmacy Regulation and Enforcement

Board of Pharmacy Legal Authority	Suspended During State of Emergency – Guidelines for Suspension Included	Enforcement Discretion During State of Emergency – Guidelines for Discretion Included
<p><u>201 KAR 2:020 Section 8(1):</u> Incorporated by reference the section on page 2 of the “Initial Application for Pharmacist Licensure” that requires the application be notarized.</p> <p>The rest of the 201 KAR 2:020 remained in effect.</p>		
<p><u>201 KAR 2:205 Section 2(3)(d)1:</u> 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.</p>		<p>“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.” <i>April 8, 2020, Board of Pharmacy Declaration Pursuant to Executive Order 2020-243.</i></p>
<p><u>201 KAR 2:205 Section (3)(d)2:</u> 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.</p>		<p>“Pharmacies will not have to provide notice of change in staff pharmacists during the State of Emergency.” <i>April 8, 2020, Board of Pharmacy Declaration Pursuant to Executive Order 2020-243.</i></p>
<p><u>201 KAR 2:205 Section (3)(d)3:</u> 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.</p>		<p>“Pharmacies do not have to notify the Board of a temporary change of hours during the State of Emergency.” <i>Pursuant Special Board Meeting Held on March 18, 2020.</i></p>

Board of Pharmacy Legal Authority	Suspended During State of Emergency – Guidelines for Suspension Included	Enforcement Discretion During State of Emergency – Guidelines for Discretion Included
<p><u>201 KAR 2:280 Section 1(1)(a):</u> 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 2. By checking a "formulary compliance approval" box on a preprinted form.</p>	<p>“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.” <i>April 8, 2020, Board of Pharmacy Declaration Pursuant to Executive Order 2020-243.</i></p>	
<p><u>201 KAR 2:280 Section 1(1)(b):</u> Dispensing. (1) A pharmacist may dispense a therapeutic equivalent drug product under the following conditions: (b) The pharmacist receives a formulary change as a consequence of the patient's third- party plan.</p>	<p>“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.” <i>April 8, 2020, Board of Pharmacy Declaration Pursuant to Executive Order 2020-243.</i></p>	
<p><u>201 KAR 2:280 Section 1(1)(c):</u> Dispensing. (1) A pharmacist may dispense a therapeutic equivalent drug product under the following conditions: (c) The product designated as "preferred" by the third-party formulary is in the same therapeutic class as the prescribed drug.</p>	<p>“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.” <i>April 8, 2020, Board of Pharmacy Declaration Pursuant to Executive Order 2020-243.</i></p>	

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<p><u>201 KAR 2:280 Section 1(2)</u>: The pharmacist, within twenty-four (24) hours of the formulary compliance substitution, shall notify the ordering practitioner, in an original writing or by facsimile:</p> <p>(a) That the pharmacist engaged in formulary compliance; and</p> <p>(b) The therapeutic equivalent drug product that was dispensed.</p>	<p>“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.”</p> <p><i>April 8, 2020, Board of Pharmacy Declaration Pursuant to Executive Order 2020-243.</i></p>	
<p><u>201 KAR 2:280 Section 2</u>: The pharmacist may make adjustments in the quantity and directions to provide for an equivalent dose of the preferred formulary therapeutic alternative.</p>	<p>“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.”</p> <p><i>April 8, 2020, Board of Pharmacy Declaration Pursuant to Executive Order 2020-243.</i></p>	
<p><u>201 KAR 2:370 Section 2(4)(d)2</u>: 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.</p>	<p>“This may be performed by a registered nurse (RN) or a licensed practical nurse (LPN) at the LTCF.”</p> <p><i>April 8, 2020, Board of Pharmacy Declaration Pursuant to Executive Order 2020-243.</i></p>	
<p><u>201 KAR 2:370 Section 2(5)(f)</u>: Requirement that pharmacy personnel inspect the stock of the LTCF Drug Stock for outdated drugs and stock adequacy on a monthly basis.</p>	<p>“This may be performed by a registered nurse (RN) or a licensed practical nurse (LPN) at the LTCF.”</p> <p><i>April 8, 2020, Board of Pharmacy Declaration Pursuant to Executive Order 2020-243.</i></p>	

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<u>201 KAR 2:370 Section 2(5)(g)3:</u> 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.” <i>April 8, 2020, Board of Pharmacy Declaration Pursuant to Executive Order 2020-243.</i>	
<u>201 KAR 2:370 Section 4(5)(a), (b) and (c):</u> 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.” <i>April 8, 2020, Board of Pharmacy Declaration Pursuant to Executive Order 2020-243.</i>	
<u>201 KAR 2:370 Section 4(6):</u> 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.” <i>April 8, 2020, Board of Pharmacy Declaration Pursuant to Executive Order 2020-243.</i>	
<u>201 KAR 2:106:</u> Requirement that a pharmacy shall notify the Board fifteen (15) days prior to an anticipated closure.		Pharmacies are required to notify the Board of temporary closure of a pharmacy during State of Emergency; however, the fifteen-day advanced notice has been waived. Pharmacies are required to submit notification of closure within 72 hours. <i>Pursuant Special Board Meeting Held on March 18, 2020.</i>

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<u>201 KAR 2:076 – USP 797.</u> Minimum garbing requirements (disposable shoe covers, face masks, disposable covers for all facial hair, etc.)		Board allowing the reuse of PPE in sterile compounding due to potential shortages during State of Emergency.
<u>201 KAR 2:380.</u>	Executive order on April 24, 2020, allowing pharmacist may initiate a COVID-19 test without an order from a practitioner during State of Emergency.	
<u>KRS 315.010.</u> “Supervision” means the presence of a pharmacist on the premise to which a pharmacy permit is issued, who is responsible, in whole or in part, for the professional activities occurring in the pharmacy.		
<u>KRS 315.010 Section 22.</u>	<u>201 KAR 2:410E: Ordering and Administering Vaccinations.</u> Allows pharmacists to order and to administer vaccinations and authorizes pharmacist interns and pharmacy technicians to administer vaccinations with certain training requirements. Expires August 20, 2021 or at the expiration of the state of emergency. Can be renewed.	
<u>HB 219. Amends KRS 315.020.</u> Effective June 29, 2021.	Amends <u>KRS 315.020</u> to permit a pharmacist or register pharmacy technician or certified pharmacy intern under supervision to access the electronic database of the pharmacy from inside or outside the pharmacy to perform order entry, verification, or drug regimen review if controls are established. Only for “closed door pharmacies.” Remote location must be within 100 miles of the pharmacy.	

Executive Order: Provisions to KRS 315.500 and 201 KAR 2:330. Renewed Monthly During the State of Emergency.

1. Pharmacists located in any county in the Commonwealth of Kentucky may dispense emergency refills of up to a thirty (30) day supply of any non-scheduled medication for residents of any county in the Commonwealth.
2. Pharmacists may administer immunizations to children pursuant to protocols established by the Center for Disease Control and Prevention, the National Institutes of Health, or the National Advisory Committee on Immunization Practices or determined to be appropriate by the commissioner of public health in his or her designee.
3. Pharmacists may operate temporarily a pharmacy in an area not designated on the pharmacy permit.
4. Pharmacists may dispense drugs as needed to prevent or treat COVID-19 pursuant to protocols established by the CDC or NIH or determined to be appropriate by the commissioner of public health or his designee to respond to the circumstances causing the emergency.

State of Emergency Policy Recommendations:

- Increasing the use of prescription delivery, drive-thru, and curbside services.
- Limiting the number of patients physically entering a pharmacy.
- Enforcing social distancing within a pharmacy.
- Pharmacy staff must wear PPE (facial coverings/masks).