

**BOARDS AND COMMISSIONS**  
**Board of Pharmacy**  
**(New Administrative Regulation)**

**201 KAR 002:430. Emergency orders and hearings.**

RELATES TO: KRS 13B.050(2), 13B.125, 218A.205, 315.121, 315.131(6)

STATUTORY AUTHORITY: KRS 315.191(1)(a), 218A.205

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.205 and 315.191(1)(a) authorize the board to promulgate administrative regulations, issue subpoenas, schedule and conduct hearings, or appoint hearing officers to schedule and conduct hearings on behalf of the board on any matter under the jurisdiction of the board. This administrative regulation sets forth the requirements and procedures of emergency suspensions and emergency hearings conducted by the board.

**Section 1. Authority to Issue Emergency Order; Timing.**

(1) The case review panel or the president of the board, acting on behalf of the case review panel, may issue an emergency order restricting or suspending a license, permit or registration pursuant to KRS 315.131(3) and 13B.125.

(2) The case review panel shall make this determination following a completed investigation pursuant to KRS 315.191(1)(e) at a regularly scheduled meeting of the case review panel.

(3) (a) The board president may act on behalf of the case review panel and issue an emergency order restricting or suspending a license, permit or registration if the Board President determines that a basis for an emergency order as established in subsection (1) of this section exists and the circumstances of the specific case warrant emergency action prior to the next regularly scheduled meeting of the case review panel.

(b) If an emergency hearing is scheduled prior to the next regularly scheduled meeting of the case review panel, the board president may act on behalf of the case review panel and issue the complaint required to support the continuation of the emergency order.

(c) If the board president acts on behalf of the case review panel pursuant to paragraph (a) or (b) of this subsection, the board president shall report any action to the case review panel at its next regularly scheduled meeting.

**Section 2. Findings of Fact and Conclusions of Law.**

(1) The case review panel, or the board president acting on the panel's behalf, may consider any evidence or information in making a charging decision pursuant to KRS 315.121 or in making the determination to issue an emergency order pursuant to Section 1 of this administrative regulation. The evidence or information may include:

(a) An application for licensing permitting or registration or renewal filed by the individual with any licensing board;

(b) Any prior or current order issued by the board or the case review panel affecting the license, permit or registration;

(c) Any prior or current order issued by another state's licensing authority affecting the license, permit or registration in that state;

(d) The records of any criminal proceeding involving the licensee, permit holder or registrant;

(e) A report by or record of any governmental agency, including a law enforcement agency report;

(f) Patient records maintained by the permit holder or summaries of or references to the contents of those records;

(g) Records or reports issued or maintained by any business;

(h) An investigative report prepared by a board inspector or special investigator, including any summary of a verbal or written statement by a witness or any evidentiary document reviewed by an inspector;

(i) An investigative report prepared by a board inspector or special investigator involving another investigation conducted by the board relating to the licensee, permit holder or registrant;

(j) An oral or written statement by the licensee, registrant or designee for the permit holder, or the agent of licensee, permit holder or registrant, relating to the investigation; or

(k) A physical, mental, or substance abuse evaluation or assessment of the licensee or registrant.

(2) The evidence or information considered by the case review panel or board president, acting on behalf of the case review panel, shall constitute the board's record of proceedings relating to the issuance of an emergency order of restriction or suspension.

(3) If the case review panel or the board president, acting on behalf of the case review panel, issues an emergency order of restriction or suspension against a license, permit or registration, the emergency order shall be a written order and shall include findings of fact and conclusions of law, supported by the board's record of proceedings, upon which the agency bases the emergency order.

(4) Any emergency order shall be served upon the affected licensee, registrant or designee of the permit holder in the manner specified in KRS 13B.050(2). The emergency order shall become effective immediately upon receipt by the affected licensee, registrant or designee of the permit holder.

### Section 3. Authority to Issue Emergency Order of Suspension Upon Felony Indictment.

(1) If a licensee, registrant or designee of the permit holder is indicted in any state for a crime classified as a felony in that state and the conduct charged relates to a controlled substance, the licensee, registrant or designee of the permit holder's practice shall be considered an immediate danger to the public health, safety, or welfare pursuant to KRS 315.131 and 13B.125.

(2) If the board receives verifiable information that a licensee, registrant or designee of a permit holder has been indicted in any state for a crime classified as a felony in the state of indictment and the conduct charged relates to a controlled substance, the case review panel or board president, acting on behalf of the case review panel, shall immediately issue an emergency order suspending or restricting that licensee, registrant or permit holder's license, permit or registration or restricting the licensee, registrant or permit holder from dispensing, administering, or otherwise utilizing a controlled substance in Kentucky, until further order following the final resolution of criminal charges in the indictment.

(3) The emergency order of suspension shall remain in effect for not more than sixty (60) days pursuant to KRS 315.131(6).

### Section 4. Request for the Timing of Emergency Hearing; Waiver.

(1) A licensee, registrant or permit holder required to comply with an emergency order may request an emergency hearing at any time between the effective date of the emergency order and the effective date of an order finally resolving the underlying complaint.

(2) (a) A request for an emergency hearing shall be presented to the board in writing, but may be submitted by facsimile or email.

(b) Upon receipt of a written request for an emergency hearing, the board shall schedule the emergency hearing on one (1) of the ten (10) days following the date of receipt of the written request. The day on which the written request is received by the board shall not be considered one (1) of the ten (10) working days.

(c) A written request shall be considered received on a particular work day if it is received by the board during the board's scheduled operating hours for that day. If the board receives a request for an emergency hearing by facsimile or email received after scheduled operating hours, the request shall be considered to have been received the next scheduled work day of the board.

(3) (a) A written request for an emergency hearing shall be considered a certification by the affected licensee, registrant or permit holder or their attorney, if represented, that the licensee, registrant or designee of the permit holder's counsel, if any, that the licensee, registrant or designee of the permit holder is available to participate in an emergency hearing on any of the ten (10) working days following the date of the board's receipt of the written request for an emergency hearing.

(b) The refusal of the licensee, registrant or designee of the permit holder to accept a hearing date on a date specified by the board within the ten (10) working days shall constitute a waiver of the requirement of KRS 13B.125(3) to conduct the emergency hearing within ten (10) working days of the receipt of a request.

(c) If there is a waiver of the ten (10) working day requirement, the hearing officer and parties shall schedule the emergency hearing to commence at the next date available to the hearing officer and both parties.

(4) (a) Unless there is a waiver of the requirement, the board shall commence the emergency hearing within ten (10) working days of the receipt of the written request for an emergency hearing.

(b) If the parties are unable to conclude the emergency hearing on the initial date assigned, the emergency hearing shall resume on the next date available to the hearing officer and both parties and shall continue on dates available to the hearing officer and both parties until concluded.

#### Section 5. Scope and Conduct of Emergency Hearing; Hearing Officer's Role.

(1) The emergency hearing shall be conducted by the case review panel, its board president, acting on behalf of the case review panel, or by a qualified hearing officer appointed by the board's executive director.

(2) The singular function of the party conducting the emergency hearing shall be to determine whether the findings of fact providing the basis for the emergency order are supported by substantial evidence and, if so, constitute one (1) or more violations of KRS 315.121.

(3) Given the ten (10) working day requirement of KRS 13B.125(3) and the unique nature of the hearing, it shall not be practicable pursuant to:

(a) KRS 13B.125(3) to conduct the emergency hearing in conformity with the provisions of KRS 13B.050;

(b) KRS 13B.060;

(c) KRS 13B.070;

(d) KRS 13B.080(2);

(e) KRS 13B.080(3) {as it relates to discovery orders} or (4) {to the extent it conflicts with this administrative regulation};

(f) KRS 13B.090(1) {to the extent it prohibits consideration of hearsay evidence}, (2) {other than the requirement that all testimony shall be made under oath or affirmation}, (3) or (7);

(g) KRS 13B.110; or

(h) KRS 13B.120.

(4) There shall not be a motion practice, prior to or as a part of the emergency hearing, relating to the legality or validity of the emergency order under consideration or relating to evidentiary issues.

(5) The emergency hearing shall be conducted as required by KRS Chapter 13B and this subsection.

(a) The board shall produce and the hearing officer shall accept the record of the proceedings relating to the issuance of an emergency order under consideration.

(b) 1. The board shall not be required to produce any further evidence to support the emergency order.

2. The board may call the affected licensee, registrant or designee of the permit holder to testify, as if under cross-examination, regarding the factual accuracy of evidence or information cited in the record of proceedings relating to the issuance of the emergency order.

(c) The affected licensee, registrant or designee of the permit holder may testify, produce factual evidence, produce hearsay evidence through documents, or call lay witnesses to the extent that the evidence specifically tends to demonstrate that a factual statement relied upon by the case review panel or board president, acting on behalf of the case review panel, is factually incorrect or false.

(6) (a) Within five (5) working days of completion of the emergency hearing, the hearing officer shall issue a written decision in which the hearing officer shall:

1. Affirm the emergency order if there is substantial evidence of a violation of law and the case review panel has determined that a violation constitutes an immediate danger to the public health, safety, or welfare. If there is substantial evidence of a violation of law, the hearing officer shall not substitute his or her judgment as to the level of public protection necessary for the emergency order;

2. Revoke the emergency order if there is no substantial evidence of a violation of law. The findings of fact shall be found to be supported by substantial evidence if there is a factual basis for the findings, even if there is a conflict in the evidence or information considered by the case review panel or board president, acting on behalf of the case review panel. A finding that there is no substantial evidence to support the findings of fact shall require a finding that there is a complete absence of factual basis for the findings; or

3. Modify the emergency order if the emergency order relied upon multiple violations of law and the hearing officer has determined that there is no substantial evidence to support one (1) or more of the violations. Upon making that finding, the hearing officer may consider each remaining violation for which there is substantial evidence and may modify the level of protection if the modified protection fully protects the public health, safety, or welfare based upon the dangers presented by the licensee, registrant or designee of the permit holder's commission of each remaining violation.

(b) The hearing officer shall not include additional findings of fact or conclusions of law in any written decision affirming the emergency order under consideration. The written decision shall be sufficient if it determines that there was substantial evidence of a violation of law and the panel had determined that the violation constituted an immediate danger to the public health, safety, or welfare.

(c) If the hearing officer issues a written decision revoking or modifying the emergency order under consideration, the hearing officer shall include findings of fact and conclusions of law to support the action.

Section 6. Judicial Review. Judicial review of a final order resulting from an emergency hearing shall comply with KRS 13B.140, 13B.150 and 13B.160.

LARRY A. HADLEY, R.Ph., Executive Director

APPROVED BY AGENCY: August 10, 2021

FILED WITH LRC: August 10, 2021 at 12:15 p.m.

**PUBLIC HEARING AND PUBLIC COMMENT PERIOD:** A public hearing on this administrative regulation shall be held on October 26, 2021 at 9:00 a.m. Eastern Time at the Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, Frankfort, Kentucky 40601. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through October 31, 2021. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

**CONTACT PERSON:** Larry Hadley, 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 Larry.Hadley@ky.gov.

## REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: Larry Hadley

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation sets forth the requirements and procedures of emergency suspensions and emergency hearings conducted by the Board of Pharmacy.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to set forth the requirements and procedures of emergency suspensions and emergency hearings conducted by the Board of Pharmacy.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation, authorized by KRS 315.191(1)(a) and KRS 218A.205, establishes the requirements and procedures of emergency suspensions and hearings conducted by the Board of Pharmacy.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: KRS 315.191 enables the Board of Pharmacy to promulgate an administrative regulation that identifies the appropriate requirements and procedures for emergency suspensions and emergency hearings conducted by the board.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: N/A

(b) The necessity of the amendment to this administrative regulation: N/A

(c) How the amendment conforms to the content of the authorizing statutes: N/A

(d) How the amendment will assist in the effective administration of the statutes: N/A

(3) List the type and number of individuals, businesses, organizations, or state and local government affected by this administrative regulation: The board anticipates licensees, permit holders and registrants will be minimally impacted by this new regulation.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Licensees, permit holders and registrants will have to familiarize themselves with this new regulation. This regulation provides the requirements and procedures of emergency suspensions and emergency hearings conducted by the board. The board will help educate identified entities of this new regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There are no expected costs for the entities identified to comply with this new regulation.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3). This new regulation will provide licensees, permit holders and registrants with information applicable to the requirements and procedures of emergency suspensions and emergency hearings conducted by the board.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:

(a) Initially: No costs will be incurred.

(b) On a continuing basis: No costs will be incurred.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Board revenues from pre-existing fees provide the funding to enforce the regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding will be required because of this new regulation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation does not establish fees or directly or indirectly increase any fees.

(9) Tiering: Is tiering applied? Tiering is not applied because this new regulation is applicable to all licensees, permit holders and registrants.

## FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? Only the Board of Pharmacy.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 315.191(1)(a), KRS 218A.205

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation will not generate revenue for the Board in the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation will not generate revenue for the Board in subsequent years.

(c) How much will it cost to administer this program for the first year? No costs are required to administer this program for the first year.

(d) How much will it cost to administer this program for subsequent years? No costs are required to administer this program for subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain this fiscal impact of the administrative regulation.

Revenues (+/-): 0

Expenditures (+/-): 0

Other Explanation: