201 KAR 2:061. Procedures followed by the Kentucky Board of Pharmacy in the investigation and hearing of complaints.

RELATES TO: KRS 218A.205, 315.121, 315.131, 315.191, 21 C.F.R. 310.305(b)

STATUTORY AUTHORITY: KRS 218A.205(3)(e), (f), (5), 315.191(1), (2), (3), (4)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations relating to the practice of pharmacy, including a process for complaints and hearings. KRS 315.191(2) authorizes the board to enforce pharmacy laws and administrative regulations. KRS 218A.205(3)(e), (f) and (5) require the board to promulgate administrative regulations relating to complaints, licensure standards, and disciplinary actions. The administrative regulation establishes board procedure for investigations, the administrative hearings process, and the penalties for violations.

Section 1. Definitions.

(1) "Adverse drug experience" means any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following:

(a) An adverse event occurring in the course of the use of a drug product in professional practice;

(b) An adverse event occurring from drug overdose, whether accidental or intentional;

(c) An adverse event occurring from drug abuse;

(d) An adverse event occurring from drug withdrawal; and

(e) Any failure of expected pharmacological action.

(2) "Agreed order" means a formal written agreement between the board and the licensee, permit holder, or registrant that stipulates that a violation of pharmacy law may have occurred and specifies the disciplinary terms and conditions imposed on the licensee, permit holder, or registrant.

(3) "Board" is defined by KRS 315.010(4).

(4) "Charge" means a specific allegation alleging a violation of a specified provision of KRS Chapter 315, the provisions of KRS Chapters 217 and 218A pertaining to prescription drugs, or 201 KAR Chapter 2.

(5) "Complaint" means a formal administrative pleading that sets forth charges against a licensee, permit holder, or registrant and commences a formal disciplinary proceeding pursuant to KRS Chapter 13B.

(6) "Diversion agreement" means an interim agreement between the board and the licensee, permit holder, or registrant that is utilized as a method of ensuring patient safety during a time mutually agreed upon.

(7) "Executive director" means the executive director of the Kentucky Board of Pharmacy.

(8) "FDA" is defined by KRS 315.400(10).

(9) "General counsel" means the general counsel of the Kentucky Board of Pharmacy or any attorney hired or contracted with the Kentucky Board of Pharmacy to provide legal services.

(10) "Grievance" means any allegation alleging misconduct by a licensee, permit holder, or registrant.

(11) "Inordinate amount of compounded human drug products" means when a pharmacy has distributed interstate during any calendar year more than fifty (50) percent of the sum of the number of prescription orders for compounded human drug products that the pharmacy sent out of the facility in which the drug products were compounded during that same calendar year plus the number of prescription orders for compounded human drug products that were dispensed at the facility in which they were compounded during that same calendar year.

(12) "Letter of concern" means an advisory letter to notify a licensee, permit holder, or registrant that, although there is insufficient evidence to support disciplinary action, the board believes the licensee, permit holder, or registrant needs to modify or eliminate certain practices and that the continuation of those practices may result in action against the license, permit, or registration.

(13) "Letter of reprimand" means a letter admonishing a licensee, permit holder, or registrant for violating pharmacy law, but notifying the licensee, permit holder, or registrant that in consideration of mitigating evidence, the board has determined that disciplinary action is not appropriate.

(14) "Pharmacy Law" means any law in KRS Chapter 315 and 201 KAR Chapter 2 or any law in KRS Chapter 217 or 218A relating to prescription drugs.

(15) "Product quality issue" means any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article, any contamination, any significant chemical, physical, or other change or deterioration in the distributed drug product, or any failure of one (1) or more distributed batches of the drug product to meet the applicable specifications.

(16) "Serious adverse drug experience" means:

(a) Any adverse drug experience occurring at any dose that results in death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability of incapacity, or a congenital anomaly or birth defect; or

(b) Important medical events that do not result in death, are not life-threatening, or do not require hospitalization that are considered as a serious adverse drug experience if, based upon appropriate medical judgment, these events may jeopardize the patient or subject and may require medical or surgical intervention to prevent results of a serious adverse drug experience.

(17) "Serious product quality issue" means any product quality issue that may have the potential to cause a serious adverse drug experience.

Section 2. Grievances.

(1) A grievance against a licensee may:

(a) Be submitted orally or in writing; and

(b) Originate from a consumer, competitor, health professional, government or provider agency, or other interested party.

(2) A grievance may be submitted anonymously, and if the grievance is accompanied by sufficient corroborating evidence that there is a reasonable probability of a violation of pharmacy law, the grievance shall be accepted by the executive director or the general counsel.

(3) A grievance shall not be required to be sworn to or notarized.

(4) A grievance that alleges an adverse drug experience or a product quality issue from human drug products compounded in Kentucky and distributed outside the state shall be reviewed, and if the grievance is accepted and involves an alleged serious adverse drug experience or serious product quality issue, the grievance shall be reported to the FDA within five (5) business days from receipt of the grievance.

(5) A grievance that alleges an adverse drug experience or a product quality issue from a compounded human drug product that was compounded in Kentucky by a physician and distributed outside the state shall be reported to the Kentucky Board of Medical Licensure and the FDA within five (5) business days from receipt of the grievance.

Section 3. Investigations.

(1) Except as established in subsection (2) of this section, upon acceptance of a grievance, the executive director shall instruct its staff or a special investigator to:

(a) Conduct an investigation;

(b) Except as established in paragraph (d) of this subsection, notify the licensee, permit holder, or registrant via written letter sent through the United States Postal Service that a grievance has been filed, and that the board is investigating the merits of the grievance. If during the investigation, it is alleged that another licensee, permit holder, or registrant may have violated pharmacy law, that licensee, permit holder, or registrant shall also be notified via written letter sent through the United States Postal Service that a grievance has been filed and the board is investigating the grievance. Any licensee, permit holder, or registrant under investigation shall be given the opportunity to provide a written statement to the executive director;

(c) Report the case to the case review panel within 120 days of the receipt of the grievance. If an extension of time is requested, the case shall be brought before the case review panel to approve or deny the extension of time. If an extension of time is approved, the licensee, permit holder, or registrant that is the subject of the investigation shall be notified via written letter sent through the United States Postal Service of the extension of time. An extension shall not be granted for a period exceeding 120 days. Multiple extensions shall be permitted; and

(d) The executive director may hold an investigation in abeyance for a reasonable period of time or approve of a delay in notice to the licensee, permit holder, or registrant in order to permit law enforcement or a government agency to perform or complete essential investigative tasks, following a request by law enforcement or a government agency.

(2) If the grievance pertains to the improper, inappropriate, or illegal dispensing of controlled substances, the board shall:

(a) File a report with the Attorney General's office, the Office of Inspector General's office, and the Department of the Kentucky State Police within three (3) business days;

(b) Commence an investigation within seven (7) days of the grievance; and

(c) Produce a charging decision within 120 days of the receipt of the grievance, unless an extension for a definite time period is requested in writing by a law enforcement agency due to an ongoing criminal investigation.

(3) If the grievance pertains to human drug products compounded in Kentucky and distributed outside of Kentucky, the investigation shall include assessing if there is a public health risk associated with the compounded drug product and if any public health risk associated with the product is adequately contained.

(4) A special investigator shall only be utilized if a conflict of interest exists that prevents any board inspector from being assigned to investigate the grievance.

Section 4. Case Review Panel

(1) A panel consisting of three (3) assigned board members, shall review the findings relating to an investigation.

(2) Board staff or a special investigator shall provide the written findings and evidence from each investigation to the case review panel, executive director, and general counsel at least seven (7) days prior to the meeting of the case review panel.

(3) The case review panel may request the attendance of any person, including the assigned inspector, at any meeting of the case review panel for the investigation of any grievance or consideration of any disciplinary matter.

(4) The executive director and general counsel shall attend case review panel meetings in a non-voting, ex-officio capacity.

(5) The panel shall determine if a preponderance of the evidence exists or does not exist that the licensee, permit holder, or registrant violated pharmacy law. If the panel determines that the preponderance of the evidence indicates that the licensee, permit holder, or registrant did not violate the law, the case review panel shall dismiss the case with or without prejudice or issue a letter of concern.

(6) After reviewing the evidence, if the case review panel determines that a preponderance of the evidence indicates that the licensee, permit holder, or registrant violated pharmacy law, the case review panel, shall adopt one (1) of the following dispositions:

(a) Non-adverse action against the licensee, permit holder, or registrant. Non-adverse action includes:

1. Issuance of a letter of reprimand; or
2. Entry into a diversion agreement;

(b) Attempting resolution of the case through an agreed order;

(c) The issuance of a formal complaint, order, and notice of hearing; or

(d) Returning the case to the inspector or special investigator for further investigation.

(7) Documentation of a letter of reprimand, letter of concern, or diversion agreement shall be maintained in board records for three (3) years.

(8) Within thirty (30) days of the case review panel decision, the licensee, permit holder, or registrant shall be informed via letter sent through the United States Postal Service of the decision of the case review panel.

(9) In the case of recusal by a member of the case review panel, the executive director shall replace the recused board member as a voting member of the case review panel.

(10) If the case review panel determines by a preponderance of the evidence that a grievance involving human drug products compounded in Kentucky and distributed to another state did violate pharmacy law, the board shall take action to ensure that the relevant pharmacy investigates the root cause of the problem that is the subject of the grievance and undertakes sufficient corrective action to address any identified public health risk related to the problem, including the risk that future similar problems may occur. A sufficient corrective action plan may include tasks such as locating expired components, finding record-keeping errors, and ensuring proper temperature and sterility controls.

Section 5. Settlement.

(1) At any time after notice of a grievance or the filing of a complaint, a settlement conference may be requested by the licensee, permit holder, registrant, or their attorney to resolve a grievance or a complaint.

(2) If a settlement conference is requested, it shall be scheduled. The settlement conference shall include the general counsel, the licensee, permit holder, registrant, the attorney for the licensee, permit holder, or registrant, and anyone else at the request of the licensee, permit holder, or registrant.

(3) Except as established in subsection (4) of this section, if the parties to a settlement conference reach an agreement, general counsel, with the consent of the executive director, may resolve the case with a settlement agreement.

(4) If the case involves harm to any member of the public, diversion of controlled substances, proposed probation, suspension or revocation, the proposed settlement agreement shall be reviewed by the case review panel. If the settlement agreement is approved by the case review panel, the grievance or complaint shall be considered resolved.

Section 6. Hearings. All hearings shall be conducted in accordance with the provisions of KRS 315.131(1) and KRS Chapter 13B.

Section 7. Final Order.

(1) The board shall deliberate on issuance of a final order in closed session. Board members that voted on the disposition of the case for the case review panel shall recuse themselves. If board member recusal and the need for a tie-breaking vote, the executive director shall be available to deliberate and vote on issuance of the final order.

(2) Board counsel shall not attend, or be involved in any manner with, the closed session.
(3) The specific findings of the board shall be made in open session following the board's deliberation.

Section 8. Required Penalties for Violations of KRS Chapter 218A.
(1) Pursuant to KRS 218A.205(3)(f)1., a licensee convicted of a felony offense related to dispensing a controlled substance shall, at a minimum, be permanently banned from dispensing any controlled substance.
(2) Pursuant to KRS 218A.205(3)(f)2., the board shall impose restrictions short of a permanent ban from dispensing controlled substances on a licensee convicted of a misdemeanor offense relating to the dispensing of a controlled substance.
(3) Pursuant to KRS 218A.205(3)(f)3., a licensee disciplined by the licensing board of another state relating to the improper, inappropriate, or illegal dispensing of a controlled substance shall, at a minimum, have the same disciplinary action imposed in Kentucky as the disciplinary action imposed by the licensing board of the other state.
(4) Pursuant to KRS 218A.205(3)(g), the board shall submit all disciplinary actions to the National Practitioner Data Bank of the United States Department of Health and Human Services either directly or through a reporting agent.

Section 9. Required Reporting of Investigative Findings to the FDA.
(1) At the conclusion of an investigation of a grievance involving a serious adverse drug experience or a serious product quality issue relating to a drug product compounded at a pharmacy in Kentucky, but distributed outside the state, the board shall share, as permitted by state law, the findings of the investigation with the FDA.
(2) The board shall maintain records of grievances involving adverse drug experiences or product quality issues relating to human drug products compounded at a pharmacy, the investigations of the grievances, and any response to or action taken as a result of the grievance beginning when the board receives notice of the grievance. The board shall maintain these records for at least three (3) years. The three (3) year period begins on the date of final action on a grievance, or the date of a decision that the grievance requires no action.

Section 10. Information Sharing with the FDA.
(1) On an annual basis, the board shall identify pharmacies that distribute inordinate amounts of compounded human drug products interstate and within thirty (30) days of identifying the pharmacy, notify FDA of the pharmacy.
(2) For pharmacies that have been identified as distributing inordinate amounts of compounded human drug products interstate during any calendar year, the board shall identify during the same calendar year:
(a) The total number of prescription orders for sterile compounded human drugs distributed interstate;
(b) The names of states in which the pharmacy is licensed;
(c) The names of states into which the pharmacy distributed compounded human drug products; and
(d) If the state inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid prescription orders for individually identified patients.
(3) If the board becomes aware of a physician who is distributing any amount of compounded human drug products interstate, the board shall notify the Kentucky Board of Medical Licensure and within thirty (30) business days of identifying the physician, notify the FDA.

(18 Ky.R. 2449; Am. 2773; eff. 3-4-92; 39 Ky.R. 506; 1374; eff. 2-1-2013; 47 Ky.R. 2421; 48 Ky.R. 310; eff. 8-26-2021.)