KENTUCKY BOARD OF PHARMACY

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Agenda for Regulation Committee
March 19, 2021
9:00 a.m.

I. Call to Order

II. Minutes – February 18, 2021

III. Old Business:

A. **201 KAR 2:061, Procedures followed by the Kentucky Board of Pharmacy in the investigation and hearing of complaints.**
'The Board requested the Regulation Committee provided amended language to remove the inspector from the voting process and add the Vice President of the Board as a voting member.'

B. **KRS 315.0351 Non-resident Pharmacy Permit Questions**
"After discussion, Jill Rhodes moved to direct the Regulation Committee to review these issues and provide recommendations to the Board for regulation amendments or implementing Board policy."
- Staff to provide information from other states for committee review.

C. **201 KAR 2:074 Decentralized Pharmacies**
"After discussion, Jill Rhodes moved to direct the Regulation Committee to review these issues and provide recommendations to the Board for regulation amendments or implementing Board policy."
- Staff to provide information from other states and Larry Hadley to provide input from KSHP for committee review.

D. **KitCheck/RFID**
'Jill Rhodes moved to send this item to the Regulation Committee for evaluation and amendment of technology terminology. Craig Martin seconded, and the motion passed unanimously.'
- Excerpt from November 5, 2020 minutes – *"Ralph Bouvette requested clarification on the issue or RFID tagging sent to the committee. Current regulation allows for barcode scanning. Mr. Poole stated the Board's intent was to modernize language in regulations to include advanced technology. Craig Martin suggested the language include future advances in technology.''*

E. **Repository Regulation**
"Jill Rhodes moved to send the draft versions to the Regulation Committee. Peter Cohron seconded, and the motion passed unanimously. The charge to the committee is to review and consider the establishment of repository regulation."
- Report from Katie Busroe on the NABP Task Force.

IV. Next meeting date

V. Adjournment

KENTUCKY BOARD OF PHARMACY
REGULATION COMMITTEE
via teleconference
March 19, 2021
9:00 a.m.

MINUTES

Chairperson Ralph Bouvette called the meeting to order at 9:10 a.m. Members present via teleconference: Larry Hadley, Ralph Bouvette, Katie Busroe, Chris Palutis, Elisha Bischoff; Cathy Hanna, Jennifer Grove and Mike Burleson. Joel Thornbury was absent. Staff: Eden Davis, General Counsel; Paul Daniels, Pharmacy and Drug Inspector; Amanda Harding, Pharmacy and Drug Inspector; John Romines, Pharmacy and Drug Inspector and Darla Sayre, Executive Staff Advisor.

Cathy Hanna moved to accept the minutes of the February 18, 2021 meeting with corrections. Mike Burleson seconded, and the motion passed unanimously.

201 KAR 2:061, Procedures followed by the Kentucky Board of Pharmacy in the investigation and hearing of complaints. Eden Davis gave an overview of the proposed draft of 201 KAR 2:061. Ms. Davis addressed concerns of constitutionality vs. standardization and the current backlog of cases. These amendments include the adoption of grievance in lieu of complaint to avoid confusion of 'formal complaint' and 'consumer/entity complaint'. The committee made the following changes to the proposed draft:

- Section 2. (3) – add language 'accepted by the Executive Director or the Executive Director's designee;' On motion by Chris Palutis and seconded by Katie Busroe, the motion passed unanimously.
- Section 3. (1)(b) – add language 'shall be notified via written letter via the United States Postal Service' On motion by Katie Busroe and seconded by Cathy Hanna, the motion passed unanimously.
- Section 4. (4) – change 'shall' to 'may' On motion by Cathy Hanna and seconded by Mike Burleson, the motion passed unanimously.

Katie Busroe stated concern over the lack of deadlines to provide case resolution and the omission of the National Association of Boards of Pharmacy as the reporting agent for disciplinary actions.

Cathy Hanna moved to approve the draft revised during the meeting [attached] and present to the Board at the March 30th Board meeting. Chris Palutis seconded and the motion passed with Katie Busroe voting nay.

201 KAR 2:074, Decentralized Pharmacies. The committee resumed discussion on offsite locations dispensing under a main pharmacy permit. Chairperson Bouvette suggested going forward to utilize the term 'decentralized pharmacy' in reference to this practice. The committee moved to recommend to the Board:

- A location not located on the campus of the main pharmacy is required to have a separate pharmacy permit.
- Campus is defined as a location that is not separated by other commercial property or residential property.

Mike Burleson seconded, and the motion passed unanimously.

Katie Busroe requested additional clarification of decentralized pharmacies without a pharmacist present. This practice involves the use of an automated dispensing system at an offsite location. These systems are

maintained under the main pharmacy permit. Concerns were raised on the stocking and maintenance of the systems. Katie Busroe suggested drafting a special limited pharmacy permit – automated dispensing system regulation to address this practice. Cathy Hanna moved to table this discussion until the next meeting. Elisha Bischoff seconded, and the motion passed unanimously. 201 KAR 2:370, 201 KAR 2:225, 201 KAR 2:230, 201 KAR 2:240 and 201 KAR 2:340 will be provided for review.

KitCheck/RFID The committee discussed drafting language to allow for various forms of advanced technology without specific language. Jennifer Symon volunteered to provide that language at the next meeting.

On motion by Chris Palutis, seconded by Mike Burleson and passed unanimously, Chairperson Ralph Bouvette adjourned the meeting at 11:55 p.m.

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

RELATES TO: KRS 218A.205, 315.131, 315.191(4)
STATUTORY AUTHORITY: KRS 218A.205(3)(e), (f), (5), 315.191(1), (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~~ subject matters governed by Chapter 315. 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) “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.
(2) “Board” means the Kentucky Board of Pharmacy;
(3) "Charge" means a specific allegation alleging a violation of a specified provision of this chapter;
(4) "Complaint" means a formal administrative pleading that sets forth charges against a licensee, permit holder or registrant and commences a formal disciplinary proceeding;
(5) “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. At the conclusion of the time period, the case review panel may dismiss the grievance, issue a complaint, issue a letter of concern or reprimand, modify the terms of the diversion agreement or enter into an agreed order with the licensee, permit holder or registrant.
(6) "Executive director" means the executive director of the Kentucky Board of Pharmacy;
(7) “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;
(8) "Grievance" means any allegation in whatever form alleging misconduct by a licensee, permit holder or registrant;
(9) “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 should modify or eliminate certain practices and that the continuation of those practices may result in action against the license, permit or registration;
(10) “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;
(11) “Pharmacy Law” means any provision of law in KRS Chapter 315 and 201 KAR Chapter 2 or any provision of law in KRS 217 or KRS 218A relating to prescription drugs.

Section 2. Grievances (1) A grievance ~~complaint~~ against a licensee may:
(a) Be submitted orally or in writing;
(b) Originate from a consumer, competitor, health professional, government or provider agency, or other interested party.
(2) A grievance ~~complaint shall~~ can be ~~accepted~~ submitted anonymously, and if the grievance ~~complaint~~ is accompanied by sufficient corroborating evidence ~~as would allow the board to believe, based upon a totality of the circumstances,~~ that there is a reasonable probability that there has been a violation of pharmacy law, the grievance shall be accepted by the executive director or the executive director's designee; ~~exists that the complaint is meritorious~~.
(3) A grievance ~~complaint~~ shall not be required to be sworn to or notarized.

Section 3 ~~2~~. Investigations (1) Except as provided by subsection (2) of this section, upon ~~receipt~~ acceptance of a grievance ~~complaint~~, the executive director ~~board~~ shall instruct its staff or a special investigator to:
(a) Conduct an investigation; and
(b) ~~Report the conclusions and recommendations of the investigation to the:~~
~~1. Executive director; and~~
~~2. Board member assigned by the board to review conclusions and recommendations relating to an investigation~~. Except as provided by subsection (d), notify the licensee, permit holder or registrant via written letter 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 via 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; and
(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 of the extension of time. An extension cannot be granted for a period exceeding 120 days. Multiple extensions are 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.
(~~d~~)(2) If the grievance ~~complaint~~ 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 ~~complaint~~; and
(c) Produce a charging decision within 120 days of the grievance ~~complaint~~, unless an extension for a definite time period is requested in writing by a law enforcement agency due to an ongoing criminal investigation.
(3) A special investigator shall only be utilized when a conflict of interest exists that prevents any board inspector from being assigned to investigate the grievance.

Section 4~~3~~. Case Review Panel (1) A panel consisting of ~~the~~ three assigned board members, ~~the executive director~~, ~~and the pharmacy drug inspector~~ shall review the findings ~~conclusions and recommendation~~ 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 shall be empowered to request the attendance of any person, including the assigned inspector, at any meeting of the case review panel in regard to the investigation of any grievance or consideration of any disciplinary matter.

(4) The executive director and general counsel may attend all 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: (a) dismiss the case with or without prejudice; or (b) 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 ~~recommend~~ adopt one (1) of the following dispositions ~~options to the board~~:
(a) Non-adverse action against the licensee, permit holder or registrant. Non-adverse action includes:
1. Issuance of a letter of reprimand ~~restricting the licensee, permit or certificate holder~~; or
2. Entry into a diversion agreement;
(b) Attempt resolution of the case through an agreed order; or
(c) Issuance of a formal complaint, order, and notice of hearing; or
(d) Return~~ing~~ the case to the inspector or special investigator for further investigation.
(7) (~~3~~) Documentation of a letter of ~~board~~ reprimand, letter of concern or diversion agreement shall be maintained in ~~the appropriate~~ board records for three years ~~files~~.
(8) Within thirty (30) days of the case review panel decision, the licensee, permit holder, or registrant shall be informed in writing via 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.

~~Section 4.(1) With the approval of the board, the executive director shall notify the licensee, permittee, or certificate holder, in writing, that he or she may request an administrative conference before the executive director and the pharmacy drug inspector to be held prior to the hearing.~~
~~(2) The licensee, permit or certificate holder shall be notified that he or she may appear with counsel.~~ Counsel ~~for the board shall be in attendance as an adviser to the executive director.~~
~~(3) An administrative conference shall be held to determine whether an agreement may be reached to resolve the complaint that is acceptable to all parties.~~
~~(4) If an agreement is reached, it shall be submitted to the board for approval and board order.~~

Section 5. Settlement. At any time after notice of a grievance or filing of a complaint, A-settlement conference may be requested by the licensee, permit ~~or certificate~~ holder, registrant, or ~~the~~ their attorney ~~for that person~~ to resolve a grievance or complaint.
(2) If a settlement conference is requested, it shall be scheduled. The settlement conference shall include the board's attorney, the licensee, permit ~~or certificate~~ holder or registrant, ~~and~~ the attorney for that licensee, permit holder or registrant ~~person.~~, and anyone else at the request of the licensee, permit holder or registrant.
(3) Except as provided in subsection (4), if the parties to a settlement conference ~~agree on stipulations, proposed terms, and conditions for an agreed order~~ reach an agreement, general counsel, with the consent of the executive director, shall be authorized to 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 ~~agreed order is~~ shall be approved by the case review panel. If the settlement agreement is approved, ~~board~~, the ~~complaint~~ grievance or complaint shall be considered resolved ~~and a hearing shall not be held~~.

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. ~~Post-hearing Proceedings~~. (1) The board shall deliberate on issuance of a final order ~~on all cases~~ in closed session. Board members that voted on the disposition of the case for the case review panel shall recuse themselves. In the event of 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 Pursuant to KRS 218A.(1) Pursuant to KRS 218A.205(3)(e)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)(e)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)(e)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)(f), 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.