

KENTUCKY BOARD OF PHARMACY

125 Holmes Street

Frankfort KY 40601

October 17, 2018

9:00 AM

Agenda

I. CALL TO ORDER

II. MINUTES

- A. *September 12, 2018

III. INTERAGENCY

IV. BOARD REPORTS

A. Executive Director

- 1. *eMars – September 2018
 - 2. Travel Requests
 - i. NABP Interactive Member Forum – November 28-30, 2018
 - ii. APhA Annual Meeting, Seattle WA – March 22-25, 2019
 - iii. 2019 National Drug Abuse & Heroin Summit, Atlanta GA – April 22-25, 2019
 - iv. NABP Annual Meeting, Minneapolis MN – May 16-18, 2019
 - 3. *Board Calendar 2019
- B. Diabetes Medical Emergency Response Task Force
- C. Jessica Williams
- 1. FDA Intergovernmental Working Meeting on Drug Compounding
 - 2. MALTAGON Meeting

V. CURRENT/PENDING CASES

- A. *Case Update and Fines Report

VI. RECIPROCITY/RELICENSURE/INTERNSHIP/PHARMACY TECHNICIANS

- A. *Reciprocal Application

VII. CORRESPONDENCE/COMMUNICATION

- A. *St. Elizabeth Pharmacy Space Approval Request
- B. *Chewy Pharmacy Off-site Storage Request

VIII. LEGISLATION/REGULATION

- A. *201 KAR 2:370
 - 1. *CVS Health
 - 2. *Ascribe RX
 - 3. *Joe Mashni

B. *201 KAR 2:074

IX. CONTINUING EDUCATION

A. *CE Programs – 18-40 through 18-49

X. OLD BUSINESS

- A. *Board Authorized Protocol for Epinephrine
- B. *Hazardous Drug Compounding Task Force Report
- C. Regulation Committee Report

XI. NEW BUSINESS

- A. Advisory Board Appointments – 4 openings beginning January 1, 2019
 - 1. *Brian Hancock
 - 2. *Chris Clifton
 - 3. *Cindy Cummings
 - 4. *Elizabeth Lovell
 - 5. *Jason Poe
 - 6. *Stephanie Blandford
 - 7. *Thomas Kaye
 - 8. *Tyler Bright
 - 9. *Vikram Patel

XII. FYI

- A. Expungement
 - 1. 15-0231
 - 2. 13-0064
 - 3. 15-0174
 - 4. 14-0050
 - 5. 15-0183

- B. Open Meeting Decisions
 - 1. Case # 18-OMD-162
 - 2. Case # 18-OMD-163

*Information enclosed with this agenda.

MINUTES

KENTUCKY BOARD OF PHARMACY Board Meeting

125 Holmes Street
Frankfort KY 40601

October 17, 2018

CALL TO ORDER A regularly scheduled meeting was held at the Kentucky Board of Pharmacy in Frankfort, Kentucky. President Hanna called the meeting to order on October 17, 2018 at 9:00 a.m.

Members present: Cathy Hanna, Ron Poole, Peter P. Cohron, Jill Rhodes and Craig Martin. Jody Forgy was absent.

Staff: Larry Hadley, Executive Director; Cheryl Lalonde, General Counsel; Paul Daniels, Pharmacy and Drug Inspector; Jessica Williams, Pharmacy and Drug Inspector and Darla Sayre, Executive Staff Advisor. Court Reporter Terri Pelosi recorded the meeting.

Guests: Cindy Stowe, Sullivan College of Pharmacy; Chris Killmeier, Walgreens; Mark Glasper, KPhA; Chris Palutis, KPhA; Angela Brunemann, St. Elizabeth Healthcare; Adam Parrish, Walmart; Kevin McGinnis, Baptist Health; Scott Dilley, PharMerica; Deanne Timmering; Darren Parks, Omnicare; Brenda Shafer, Quarles and Brady; Lavanya Peter, Park Duvalle; Emma Hatfield, St. Elizabeth Healthcare; John Long, CVS Health and Helen Thompson, UK College of Pharmacy.

MINUTES On motion by Dr. Martin, seconded by Dr. Cohron and passed unanimously, the minutes of the September 12, 2018 Board Meeting were approved with corrections.

INTERAGENCY Mark Glasper, KPhA invited everyone to attend the Legislative Conference held at the Marriott Louisville Downtown on November 2, 2018.

UPDATE ON HAZARDOUS DRUG COMPOUNDING TASK FORCE Matt Martin, Chair presented the recommendations of the committee to the Board. The recommendations are:

Option 1, Proposed Changes

- We recommend a one year delayed implementation of USP <800> from the filing date.
- We recommend the Board consider waivers for low-volume chemotherapy generator facilities.
- We recommend the Board consider waivers for discrepancies between USP <800> and USP <797>.
- Section 2. Box 1. Add '[except Section 5.3.1]' after –Any HD API

- Section 5.3.1. Third paragraph. Add ‘for all NIOSH Table 1 API. An assessment of risk can be conducted for NIOSH Tables 2 and 3 APIs and manipulated dosage forms.’ after at least 12 ACPH.
- Section 15.2. Second paragraph. Add ‘unless a CSTD is used. When a CSTD is utilized a SOP must be established by the facility to outline the decontamination process during compounding.’ after must be decontaminated between compounding of different HDs.

Option 2, Waiver Process

- We recommend a one year delayed implementation of USP <800> from the filing date.
- We recommend a waiver process be considered for the following:
 1. Pharmacies should be able to conduct an assessment of risk for requiring a CSEC for manipulation of any dosage form including APIs on Tables 2 and 3 NIOSH list drugs.
 2. Pharmacies should be able to decontaminate based upon SOPs rather than after a different product is compounding IF CSTDs are used.
 3. Low-volume chemotherapy generator facilities.
 4. Discrepancies between USP <800> and USP <797>.
 5. Other

After much discussion, Mr. Poole moved to vet both options to interested parties for comments or alternative suggestions with a deadline for submission of March 31, 2019. Comments or suggestions will be given to the task force for their consideration and recommendations to the Board. Dr. Martin seconded, and the motion passed unanimously.

ST. ELIZABETH PHARMACY SPACE APPROVAL REQUEST Dr. Martin moved to approve this request for eighteen months with this stipulation; dispensing process must remain the same, if process changes Board approval is required. Mr. Poole seconded, and the motion passed unanimously.

BOARD REPORTS

Mr. Hadley presented the eMars reports for September 2018 to the Board. Mr. Hadley gave a report of the Executive Director meeting of the NABP. The most relevant issue for all Boards of pharmacy is unused permits/licenses. Entities seek a permit/license with the Board but never officially open for business. NABP identified this practice as a means for fraudulent billing. Dr. Hanna inquired if this could be addressed by Board policy or regulation. Ms. Lalonde stated that the Board must have statutory or regulatory basis to proceed with disciplinary action or revocation of permit/license. After much discussion, the Board directed Mr. Hadley to provide additional information from other states and present those findings at the December meeting.

Dr. Hanna presented the following travel requests to the Board:

1. NABP Interactive Member Forum – November 28-30, 2018: There is no cost to the Board for this meeting. Mr. Poole moved to approve one member to attend. Dr. Martin seconded, and the motion passed unanimously.
2. APhA Annual Meeting – March 22-25, 2019: Mr. Poole moved to approve one member and the Executive Director to attend. Dr. Martin seconded, and the motion passed unanimously.
3. 2019 National Drug Abuse & Heroin Summit – April 22-25, 2019: Mr. Poole moved to approve one member and the Executive Director to attend. Dr. Martin seconded, and the motion passed unanimously.
4. NABP Annual Meeting – May 16-18, 2019: Mr. Poole moved to approve the Board members, Executive Director, Board Counsel and the inspectors to attend. Dr. Martin seconded, and the motion passed unanimously.

Mr. Hadley presented a proposed 2019 Board calendar to the Board for discussion. He suggested the Board begin meeting on a monthly basis. Ms. Lalonde said monthly meetings held at the end of the month could be combined with Public Hearings for proposed regulations eliminating the need for special meetings. Mr. Hadley requested the addition of a February meeting due to the Legislative calendar. He also proposed a deadline of one week prior to the meeting for information to be presented to the Board. Dr. Martin agreed with the deadline but disagreed with monthly meetings. Dr. Hanna requested Mr. Hadley to provide calendar options at the December meeting. Dr. Hanna will discuss with the Sullivan College of Pharmacy and the UK College of Pharmacy the best month for them to host the Board meeting.

Dr. Cohron moved to accept the date of January 30, 2019 for the January Board meeting. Mr. Poole seconded, and the motion passed unanimously.

Dr. Hanna called for a ten-minute break at 10:50 a.m. and the meeting resumed at 11:00 a.m.

Dr. Hanna attended the Diabetes Medical Emergency Response Task Force. She stated that the Board's concerns over emergency dispensing of unit of use packaging will be addressed in a future bill. This bill will allow for emergency dispensing of the smallest package size available. The Board will draft a letter of support once the bill has been filed.

Jessica Williams, Pharmacy and Drug Inspector gave presentation on her attendance at the 2018 Intergovernmental Working Meeting and the 2018 MALTAGON meeting.

During the 2018 Intergovernmental Working Meeting on Drug Compounding, FDA presented the revised draft Memorandum of Understanding (MOU) under Section 503A of the FD&C Act, which addresses interstate distribution and investigation by a state agency of complaints related to compounded drugs. FDA also discussed mechanisms to facilitate information sharing with state

agencies and coordination of enforcement efforts. Presenters from FDA and state agencies provided additional information for discussion of the following compounding topics: oversight of outsourcing facilities, bulk drug substances, compounding “copies” of commercially available products, Drug Supply Chain Security Act, and veterinary compounding.

The 2018 MALTAGON Meeting was held October 11th-14th. Kentucky BOP inspectors presented information on USP 795 enforcement and compliance in Kentucky, including changes to compounding regulation, inspection findings, and corrective action for deficiencies. Attendees from other states led discussions related to sterile compounding, licensure requirements, drug diversion, and the opioid crisis. The Arkansas Board of Pharmacy shared a promotional music video parody for Arkansas Prescription Drug Take Back Day as an example of the state’s drug prevention initiative.

In reference to the presentation of the Intergovernmental Working Meeting, Matt Martin inquired who is the legal authority to sign the MOU for Kentucky. Ms. Lalonde stated that the Governor’s Office signs agreements with federal agencies. Mr. Poole directed Mr. Hadley to consult with KBML regarding physician compounding. Ohio Board of Pharmacy has a model in which the pharmacy inspectors inspect physician offices who compound pharmaceuticals. Ms. Lalonde stated that the Kentucky Board of Pharmacy does not regulate physicians. If this model were adopted in Kentucky, the inspectors would only inspect and provide their findings to the KBML. Funding for these inspections should be provided by the KBML. Mr. Daniels suggested the Board look at ‘hydration centers’ as a type of facility conducting compounding without a pharmacist on staff.

CURRENT/PENDING CASES Mr. Poole moved to accept the Case Review Recommendations for:

Case 18-0291A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 300 dosage units of Suboxone 8mg-2mg sublingual films. Alleged Violation of Law: 201 KAR 2:100 Section 1. **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

Case 18-0291B. Pharmacist in charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 300 dosage units of Suboxone 8mg-2mg sublingual films. Alleged Violation of Law: 201 KAR 2:205. Section 2. (3) (b). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

Case 18-0291C. Registered Pharmacy Technician allegedly engaged in unprofessional or unethical conduct by selling, transferring, dispensing, ingesting, or administering a drug for which a prescription drug order is required, without first receiving a prescription drug order for the drug. Alleged Violation of Law: KRS 315.121 (2) (f). **CRC Recommendation: There is sufficient**

evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and revocation.

Case 18-0309. Pharmacist allegedly violated his Agreed Order by testing positive for a controlled substance, which he was not prescribed. Alleged Violation of Law: KRS 315.121(1)(i). **CRC Recommendation:** There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Approve terms of proposed Agreed Order.

Case 18-0341 A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. The pharmacy reported the loss of 4 oxycodone/apap 10/325mg tablets due to employee pilferage. Alleged Violation of Law: 201 KAR 2:100 Section 1 **CRC Recommendation:** There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case 18-0341 B. Pharmacist-in-charge allegedly failed to provide adequate security and control of drugs. The pharmacy reported the loss of 4 oxycodone/apap 10/325mg tablets due to employee pilferage. Alleged Violation of Law: 201 KAR 2:205 Section 2 (3)(b). **CRC Recommendation:** There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case 18-0341 C. Pharmacy technician allegedly engaged in unprofessional or unethical conduct by selling, transferring, dispensing, ingesting, or administering a drug for which a prescription drug order is required, without first receiving a prescription drug order for the drug. Alleged Violation of Law: KRS 315.121 (2)(f). **CRC Recommendation:** There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and revocation.

Case 18-0357 Revisit. Licensee allegedly provided false information on application for registration as a pharmacy technician. Alleged Violation of Law: KRS 315.121 (1)(e). **CRC Recommendation:** There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and revocation.

Case 18-360A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 4,694 ml of promethazine with codeine liquid. Alleged Violation of Law: 201 KAR 2:100 Section 1. **CRC Recommendation:** There is sufficient

evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$1000 administrative fine, approved corrective action plan to prevent future occurrences involving the PIC.

Case 18-360B. Pharmacist in charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 4,694 ml of promethazine with codeine liquid. Alleged Violation of Law: 201 KAR 2:205. Section 2. (3) (b). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine, additional 6 hours of continuing education on quality assurance, quality control, pharmacy law or diversion.**

Case 18-360C. Registered Pharmacy Technician allegedly engaged in unprofessional or unethical conduct by selling, transferring, dispensing, ingesting, or administering a drug for which a prescription drug order is required, without first receiving a prescription drug order for the drug. Alleged Violation of Law: KRS 315.121 (2) (f). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and revocation.**

Case 18-0361 A Revisit. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by failing to comply with applicable requirements for compounding sterile preparations and failing to maintain complete and accurate records of drugs compounded by the pharmacy, and violating terms of Agreed Order. Alleged Violations of Law: 201 KAR 2:076 Section 2 (2); KRS 217.055; KRS 217.065; 201 KAR 2:170; KRS 315.121 (1)(i); KRS 315.121 (1)(h). **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.**

Case 18-0361 B Revisit. Pharmacist-in-charge allegedly engaged in unprofessional or unethical conduct likely to harm the public with or without established proof of actual injury by failing to comply with applicable requirements to ensure quality of sterile preparations compounded by the pharmacy. Alleged Violations of Law: KRS 315.121 (2)(d); 201 KAR 2:076 Section 2 (2); 201 KAR 2:076 Section 3 (2); KRS 315.121 (1)(h). **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.**

Case 18-0361 C Revisit. Pharmacist allegedly engaged in unprofessional or unethical conduct likely to harm the public with or without established proof of actual injury by failing to comply with applicable requirements for compounding sterile preparations. Alleged Violations of Law: KRS 315.121 (2)(d); 201 KAR 2:076 Section 2 (2); KRS 315.121 (1)(h). **CRC Recommendation:**

There is sufficient evidence developed and the investigator is directed to conduct further investigation.

Case 18-0368A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Alleged Violation of Law: 201 KAR 2:100 Section 1. **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.**

Case 18-0368B. Pharmacist in charge allegedly failed to provide adequate security and control of drugs. Alleged Violation of Law: 201 KAR 2:205. Section 2. (3) (b). **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.**

Case 18-0368C. Registered Pharmacy Technician allegedly engaged in unprofessional or unethical conduct by selling, transferring, dispensing, ingesting, or administering a drug for which a prescription drug order is required, without first receiving a prescription drug order for the drug. Alleged Violation of Law: KRS 315.121 (2) (f). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and revocation.**

Dr. Martin seconded, and the motion passed unanimously.

RECIPROCAL APPLICATION Dr. Martin moved to table this request until the December meeting for a more detailed explanation. Dr. Rhodes seconded, and the motion passed unanimously.

CHEWY PHARMACY OFF-SITE STORAGE REQUEST Dr. Martin moved to approve this request. Mr. Poole seconded, and the motion passed unanimously.

CONTINUING EDUCATION Dr. Hanna recused herself from the meeting. Dr. Martin noted that there were multiple requests within 18-40. Mr. Poole moved to approve these requests once numbers are assigned. Dr. Rhodes seconded, and the motion passed unanimously. Mr. Poole moved to approve the New Drug Update request for 1 hour. Dr. Cohron seconded, and the motion passed unanimously. Dr. Hanna returned to the meeting. Dr. Martin moved to deny 18-41 due to the presenter being an employee of the sponsor. Dr. Cohron seconded, and the motion passed unanimously. Dr. Martin moved to approve 18-49 for 3 hours. The remaining requested hours were not pharmacy related. Mr. Poole seconded, and the motion passed unanimously.

BOARD AUTHORIZED PROTOCOL FOR EPINEPHRINE Dr. Hanna tabled this issue until the December meeting.

Ms. Lalonde brought a concern of a Board policy approved at the September meeting involving protocols. This policy may broaden the intent of the Board and suggested alternative wording to be more indicative of the Board's intent.

ADVISORY COUNCIL APPOINTMENTS The Board voted to fill the vacancies on the Advisory Council by ballot. Larry Hadley and Cheryl Lalonde counted the ballots. The applicants appointed for a four-year term are Chris Clifton, Jason Poe, Tyler Bright and Elizabeth Lovell. Their terms will begin January 1, 2019.

Dr. Hanna called for a lunch break at 12:00 p.m. The meeting resumed at 12:55 p.m.

Mr. Poole moved to approve the following wording to amend the Board policy regarding protocols from the September meeting:

Although the KBOP approves protocols that are written comprehensively for content and aim, it is not necessary to have a protocol brought back before the Board for additional approval if the prescriber wishes to limit the medications initiated under a board approved protocol by removing a drug or class of drugs from the medications authorized to be dispensed, as long as no other alterations are made.

Dr. Rhodes seconded, and the motion passed unanimously. Ms. Lalonde requested that a footnote be included in the September 12, 2018 minutes reflecting this amendment.

LEGISLATION/REGULATION The Board received public comments from three organizations regarding the proposed changes to 201 KAR 2:370. After much discussion, Dr. Rhodes moved to hold a special called meeting on November 8, 2018 at 9:00 a.m. to discuss these changes and proposed changes to 201 KAR 2:074 after a meeting with CHFS and OIG. Dr. Martin seconded, and the motion passed unanimously.

The Board were given hard copies of the Open Meetings Decisions on Case Numbers 18-OMD-162 and 18-OMD-163 allowing sufficient time for each member to read the material.

18-OMD-162[attached] Mr. Hadley informed the Board of an appeal made to him of the closed session at the June 6, 2018 special meeting. He denied this appeal based on the fact that the Board acted under the guidance and direction of the Finance Cabinet. This appeal was then made to the Attorney General's office. The Attorney General's office determined that the Board was in violation of the Open Meetings Act. Ms. Lalonde stated that because the Board had acted in good faith based on the advice of the Finance Cabinet, there were no punitive consequences since the violation was unintentional.

18-OMD-163[attached] Mr. Hadley informed the Board of an appeal made to him of the July 3, 2018 meeting of case review. Ms. Busroe had argued that there was not a proper quorum. Mr. Hadley denied the appeal based on the fact that a quorum was established under 201 KAR 2:061. The appeal was then made to the Attorney General's office. The Attorney General's office determined that the Board was not in violation of the Open Meetings Act since the three member panel required by 201 KAR 2:061 Section 3 was present at the July 3rd meeting.

CASE REVIEW In consideration of 18-OMD-163, Ms. Lalonde asked the Board for direction in future meetings of Case Review. The Board may propose changes to 201 KAR 2:061 to reflect

the current process of Case Review, or direct Board staff to conduct Case Review to conform to the current regulation. Dr. Martin moved to conduct future Case Review meetings in line with the current regulation. Mr. Poole seconded, and the motion passed unanimously.

Mr. Poole moved to address this group as the Case Review Panel, consisting of the Board President, Executive Director and the Pharmacy and Drug Inspector (with the attorney permitted for legal consideration). Dr. Cohron seconded, and the motion passed unanimously.

ADJOURNMENT On motion by Dr. Cohron, seconded by Mr. Poole and passed unanimously, President Hanna adjourned the meeting at 3:37 p.m. The next regularly scheduled meeting begins at 9:00 a.m. on December 12, 2018 at the Board Office in Frankfort, Kentucky.

Larry A. Hadley

Executive Director

18-OMD-162

August 21, 2018

In re: Katie Busroe/Board of Pharmacy

Summary: Evaluation Committee of the Kentucky Board of Pharmacy violated the Open Meetings Act by citing an exception to the Act to go into closed session that was not yet in effect at the time the committee invoked the exception. Board's response to Open Meetings complaint was late by two days and so constituted a procedural violation of the Act.

Open Meetings Decision

The issue presented in this appeal is whether an Evaluation Committee of the Kentucky Board of Pharmacy ("Board") violated the Open Meetings Act on June 6, 2018, when the Evaluation Committee went into closed session pursuant to KRS 61.810(1)(n), an exception to the Act that did not become effective until July 14, 2018. For the reasons that follow, we find that the Evaluation Committee violated the Open Meetings Act.

Katie Busroe ("Appellant"), filed an appeal with this office stating that the Evaluation Committee violated the Act by going into closed session at its June 6, 2018, meeting. Her complaint was that the Evaluation Committee cited KRS 61.810(1)(n)¹ as the statutory exception under which it was going into closed

¹ KRS 61.810(1) states, in pertinent part:

session when that exception did not become effective until July 14, 2018. For the reasons stated below, we find that the Evaluation Committee violated the Act.

Appellant filed a complaint² with the Board on July 25, 2018, stating that the Evaluation Committee went into closed session at a “Special Called Board Meeting” on June 6, 2018, pursuant to KRS 61.810(1)(n). Appellant stated that the minutes of the June 6, 2018, Board meeting reflect that the President of the Board, Cathy Hanna, selected three members of the Board (Ron Poole, Craig Martin, and Jody Forgy) as members of the “Evaluation Committee for RFP 2701800000341” (the “Evaluation Committee”). After appointing the Evaluation Committee members, President Hanna recused herself, and then, according to the minutes of the meeting:

Mr. Poole moved to go into closed session pursuant to KRS 61.810(1)(n) which allows an exemption of public meeting for the purpose of an evaluation committee to select a successful bidder for award of a state contract. Mr. Forgy seconded and the motion passed unanimously.

Mr. Poole moved to go back to open session. Mr. Forgy seconded and the motion passed unanimously.

President Hanna returned to the meeting.

All meetings of a quorum of the members of any public agency at which any public business is discussed or at which any action is taken by the agency, shall be public meetings, open to the public at all times, except for the following:

...

(n) Meetings of any selection committee, evaluation committee, or other similar group established under KRS Chapter 45A or 56 to select a successful bidder for award of a state contract.

² Ms. Busroe submitted her complaint via electronic mail. Although KRS 61.846(1) provides that a “person shall submit a written complaint to the presiding officer of the public agency suspected of” the violation, a public agency can waive this requirement expressly or by a course of conduct, and the Board did so here (assuming that Executive Director Hadley is the “presiding officer”) by responding via e-mail without objection. Accordingly, further discussion of this procedural requirement is unwarranted.

Larry Hadley, Executive Director of the Board, responded to Ms. Busroe's complaint on August 1, 2018, in part, as follows:

Having consulted counsel, I have learned that, historically, open meeting rules do not apply to evaluation committees formed to make a recommendation to the Secretary of the Finance Cabinet. In fact, KRS 45A.695(4) expressly prohibits disclosure of information contained in proposals to competing vendors, which would necessarily occur if the evaluation committee's deliberations are considered a meeting for purposes of the Open Meetings Act.

Appellant filed her appeal with this office August 7, 2018. Cheryl Lalonde, Board attorney, responded to the appeal on August 9, 2018. Ms. Lalonde stated that the three board members were appointed to a committee for the purpose of considering RFP 180000341.³ Each committee member had to submit a Confidentiality Statement, indicating they would not divulge information pertaining to the bid proposals, and an Evaluation Committee Member Agreement that only allowed them to discuss procurement with other committee members and Darla Sayre, Executive Staff Advisor, who served as the sole point of contact for the committee. As Ms. Sayre was the sole point of contact, the Board's General Counsel did not assist the committee during its meeting. Mr. Poole moved for the Evaluation Committee to go into closed session pursuant to KRS 61.810(l)(n), which Mr. Forgy seconded, and the motion passed unanimously. The meeting was closed, and upon return to open session, there was no final action announced since the Board does not make an award of a state contract. Ms. Sayre subsequently submitted the evaluation criteria to the Finance Cabinet, who chose the successful bidder and awarded the state contract.

Ms. Lalonde provided an email exchange between Ms. Sayre and Tracy Gritton, Executive Staff Advisor, Finance and Administration Cabinet. In the email Ms. Sayre explained that "Board Counsel" had advised that the evaluation of the bids must take place during an open meeting, unless there is an exception. Ms. Gritton responded with a reference to HB 302, passed in the 2018 General Session, which amended KRS 61.810 to allow: "Meetings of any selection committee, evaluation committee, or other similar group established under KRS

³ "RFP" stands for "Request for Proposal."

Chapter 45A or 56 to select a successful bidder for award of a state contract.” The Board’s response stated that:

The closed session citation had an enactment date of July 14, 2018, and was not in effect at the time of the Board's special meeting, so the Board reconvened on August 9, 2018 to hold another meeting. The Minutes of that meeting will be available after they are approved at the Board's next meeting on September 12, 2018.

Late Response by the Board. Appellant stated that she sent her complaint letter to Executive Director Larry Hadley at 2:21 p.m. on July 25, but did not receive a written reply until August 1, at 9:49 a.m. Pursuant to KRS 61.880(1)⁴, a public agency must notify the complainant of its decision regarding the complaint, in writing, within three business days after receipt of the complaint. As the Board received the complaint on Wednesday, July 25, it was obligated to respond no later than Monday, July 30, 2018. The Board’s response of August 1st was two days late and constituted a procedural violation of KRS 61.880(1).

KRS 61.810(1)(n). In the 2018 General Session, House Bill 302 amended KRS 61.810(1) to add a new exception to the Open Meetings Act:

(n) Meetings of any selection committee, evaluation committee, or other similar group established under KRS Chapter 45A or 56 to select a successful bidder for award of a state contract.

The legislature passed the bill and the Governor signed it on April 26, 2018.⁵ The effective date of legislation, other than general appropriation bills and acts containing emergency or delayed effective date provisions, passed during the 2018 Regular Session of the Kentucky General Assembly, was Saturday, July

⁴ KRS 61.880(1), in pertinent part, states: “The public agency shall determine within three (3) days, excepting Saturdays, Sundays, and legal holidays, after the receipt of the complaint whether to remedy the alleged violation pursuant to the complaint and shall notify in writing the person making the complaint, within the three (3) day period, of its decision.”

⁵ <http://www.lrc.ky.gov/record/18RS/HB302.htm> (Last visited Aug. 21, 2018).

14, 2018.⁶ The copies of KRS 61.810, prior to July 14, 2018, and copies of KRS 61.810 after July 14, 2018, provided by Appellant in her appeal, are copies from the Kentucky Legislative Research Commission website⁷ and also reflect an effective date of July 14, 2018, for the amendment to the statute.

KRS 61.815(1)(a)⁸ requires that “[n]otice shall be given in regular open meeting of the general nature of the business to be discussed in closed session, the reason for the closed session, and the *specific provision of KRS 61.810 authorizing the closed session.*” (Emphasis added). As KRS 61.878(1)(n) was not yet effective on June 6, 2018, the Committee erred in citing it as the “specific provision of KRS 61.810 authorizing the closed session” for the Committee.^{9, 10, 11}

⁶ See, OAG 18-007, an advisory opinion of the Attorney General, determining the effective date of legislation passed by the 2018 Regular Session of the Kentucky General Assembly to be July 14, 2018, except for general appropriation measures and those containing emergency or delayed effective date provisions.

⁷ Legislative Research Commission website, <http://www.lrc.ky.gov/statutes/statute.aspx?id=48229> (Last visited Aug. 9, 2018).

⁸ KRS 61.815 states, in pertinent part:

(1) Except as provided in subsection (2) of this section, the following requirements shall be met as a condition for conducting closed sessions authorized by KRS 61.810:

(a) Notice shall be given in regular open meeting of the general nature of the business to be discussed in closed session, the reason for the closed session, and the specific provision of KRS 61.810 authorizing the closed session...

⁹ The Board did not contest whether the Evaluation Committee was a “public agency” for the purposes of the Open Meetings Act, and it is clear from the facts of the appeal, that the Committee qualifies as a “public agency” for the purposes of the Act pursuant to KRS 61.805(2)(f) and (g) which state that a “public agency” means:

(f) Any entity when the majority of its governing body is appointed by a "public agency" as defined in paragraph (a), (b), (c), (d), (e), (g), or (h) of this subsection, a member or employee of a "public agency," a state or local officer, or any combination thereof;

(g) Any board, commission, committee, subcommittee, ad hoc committee, advisory committee, council, or agency, except for a committee of a hospital medical staff or a committee formed for the purpose of evaluating the qualifications of public agency employees, established, created, and controlled by a "public agency" as defined in paragraph (a), (b), (c), (d), (e), (f), or (h) of this subsection[.]

¹⁰ KRS 61.815(1)(a) also required the Evaluation Committee to give notice “in regular open meeting of the general nature of the business to be discussed in closed session, the reason for the

From the Board's response to the appeal, it appears that it attempted to correct the Evaluation Committee's error at its meeting of August 9, 2018, but, as we do not have the approved minutes of that meeting, we decline to speculate on whether the Board has corrected its error.

A party aggrieved by this decision may appeal it by initiating action in the appropriate circuit court pursuant to KRS 61.846(4)(a). The Attorney General shall be notified of any action in circuit court, but shall not be named as a party in that action or in any subsequent proceedings.

Andy Beshear
Attorney General

Gordon Slone
Assistant Attorney General

#328

Distributed to:

Katie Busroe
Larry Hadley
Cheryl Lalonde

closed session, and the specific provision of KRS 61.810 authorizing the closed session[.]” The June 6, 2018, meeting minutes do not disclose whether the Evaluation Committee provided notice in open meeting of the general nature of the business to be discussed in closed session, or the reason for the closed session. Neither the Appellant's complaint to the Board, nor her appeal of the Board's response, assert that the Evaluation Committee failed to give notice of the general nature of the business to be discussed in closed session, or the reason for the closed session. As such, we decline to decide if the Evaluation Committee violated these requirements of the Act.

¹¹ The Court of Appeals, in *Bd. of Regents for Western Kentucky Normal School v. Engle*, 224 Ky. 184, 5 S.W.2d 1062, 1063 (Ky. 1928), pointed out that the courts would not consider a statute in any way where the statute was not yet in effect. As the courts would not consider a statute that was not yet in effect, neither can the Evaluation Committee.

18-OMD-163

August 21, 2018

In re: Katie Busroe/Kentucky Board of Pharmacy, Case Review Committee

Summary: Case Review Committee (“CRC”) of the Kentucky Board of Pharmacy did not violate the Open Meetings Act when it held a special meeting on July 3, 2018. The undisputed facts establish that all three members of the “panel,” or CRC, as identified at 201 KAR 2:061 Section 3, were present and the complainant did not allege the CRC failed to comply with notice requirements for special meetings codified at KRS 61.823 or notice requirements for closed sessions codified at KRS 61.815.

Open Meetings Decision

The question presented in this appeal is whether the Case Review Committee (“CRC”) of the Kentucky Board of Pharmacy (“Board”) violated the Open Meetings Act in holding a special meeting on July 3, 2018, to allow the assigned pharmacy drug inspector to present his report concerning his investigation of Cases 18-0225A and 18A-0225B.¹ By written complaint directed to Executive Director of the Board, Larry Hadley, on July 26, 2018, per KRS 61.846(1), Pharmacy Inspections and Investigations Supervisor Katie J. Busroe

¹ In 04-OMD-148 (copy enclosed), the Attorney General conclusively resolved the question of whether the CRC is a “public agency” for purposes of the Open Meetings Act, finding that because the Kentucky Board of Pharmacy is a public agency within the meaning of KRS 61.805(2)(a), any committee established, created, and controlled by the Board is a public agency pursuant to KRS 61.805(2)(g). 04-OMD-148, p. 6. Because the CRC is grounded in a regulation, 201 KAR 2:061 Section 3, it may also be properly characterized as a “public agency” within the meaning of KRS 61.805(2)(d) and (e). *See* 04-OMD-148, p. 6, n. 1.

alleged the CRC “consists of nine members: the Board President, the Executive Director, the Board Attorney and the six members of the inspection staff.”² However, Ms. Busroe also noted that 201 KAR [2:061] Section 3, states that a panel consisting of the assigned Board Member, the Executive Director and the Inspector “shall make a recommendation to the Board regarding any disciplinary action.” Ms. Busroe premised her complaint on the assumption that a meeting of the Board President, the Executive Director, the Board Attorney, and the Inspector, “four members of the [CRC],” did “not constitute a quorum of a committee of the Board.”³ She further questioned why a quorum of the CRC was not required in order to hold the July 3, 2018, special meeting, but was required on July 10, 2018, during the Board’s regularly scheduled meeting to approve the minutes of the CRC’s July 3, 2018, special meeting.⁴

² Ms. Busroe submitted her complaint via electronic mail. Although KRS 61.846(1) provides that a “person shall submit a written complaint to the presiding officer of the public agency suspected of” the violation, a public agency can waive this requirement expressly or by a course of conduct, and the CRC did so here (assuming that Executive Director Hadley is the “presiding officer”) by responding via e-mail without objection. Accordingly, further discussion of this procedural requirement is unwarranted.

³ If a quorum of the CRC had actually not been present on July 3 when a discussion of public business occurred, Ms. Busroe’s complaint would have failed to “state the circumstances which constituted an alleged violation” of the Act per KRS 61.846(1). In the absence of a quorum of a public agency such as the CRC at a single meeting, or collectively at a series of meetings, there “was not a public meeting under the Open Meetings Act.” 00-OMD-200, p. 6 (quoting 93-OMD-63; 13-OMD-166; 10-OMD-210; 16-OMD-065. *Compare* 13-OMD-057. Ms. Busroe did not challenge the propriety of the closed session held on July 3, 2018, nor did she allege the CRC failed to comply with all of the notice requirements codified at KRS 61.815(1)(closed sessions) and 61.823(3) and (4)(special meetings). Accordingly, this office makes no finding relative to either of those provisions.

⁴ This allegation implicates KRS 61.835, pursuant to which minutes of “action taken” at every meeting (as defined at KRS 61.805(1)) of any public agency (as defined at KRS 61.805(2)), “setting forth an accurate record of votes and actions taken at such meetings, shall be promptly recorded and such records shall be open to public inspection at reasonable times no later than immediately following the next meeting of the body.” However, it does not state circumstances that constitute a violation. In addressing KRS 61.835 relative to ad-hoc committees that were serving a strictly advisory function, the Attorney General determined that minutes must be maintained, even if those minutes reflect only that the public agency convened, approved the minutes of the last meeting, and adjourned. *See* 00-OMD-96; 95-OMD-64.

The record establishes the CRC complied with KRS 61.835 in recording minutes of its July 3, 2018, special meeting and ultimately made necessary corrections to reflect what actually occurred. *Compare* 10-OMD-017. A quorum of the CRC later voted to approve the minutes; Ms. Busroe did not contend the CRC failed to make the minutes publicly available.

To remedy the perceived violations of the Act, Ms. Busroe requested that Cases 18-0255A and 18-0255B “be handled the same as every other case with a quorum of the [CRC] present for discussion and the decision be made in the form of a motion in the open meeting session on September 1, 2018.” On August 1, 2018, Executive Director Hadley informed Ms. Busroe, “There is no action to challenge pertaining to the meeting on 7/3/18 – no final decision was made.”⁵ Dissatisfied with Executive Director Hadley’s brief response, Ms. Busroe initiated this appeal. Ms. Busroe acknowledged, “the Attorney General’s Investigator had a conflict with the regularly scheduled [CRC meeting] on July 10, 2018, but this should not negate the requirement of a quorum.”

Upon receiving notification of Ms. Busroe’s appeal from this office, Executive Director Hadley responded on behalf of the CRC. Referencing 201 KAR 2:061 Section 3, regarding the composition of the “panel”⁶ known as the CRC, Director Hadley explained that approximately twenty years ago, the Board had a total of three inspectors. “Over time, the number of inspectors increased to six. Presumably, for the sake of efficiency, consistency, and education, all the inspectors were permitted to attend the panel discussion/meeting which became known as the CRC, even though decisions are always, and only, made by the required panel members.” Executive Director Hadley noted that Ms. Busroe did not cite any minutes or legal authorities in support of her contention that the CRC is comprised of nine individuals (or six when the Board employed three inspectors, or seven when the Board employed four inspectors, or eight when the

⁵ Executive Director Hadley’s position that no violation was committed merely because “no final decision was made” is contrary to KRS 61.810(1). This office rejected a similar argument in 98-OMD-94 as follows:

KRS 61.810(1) requires that any meeting at which public business is discussed *or* action is taken must be open to the public. We attach significance to the use of the disjunctive particle “or” rather than the conjunction “and.” Since a quorum of the members of the [agency] was apparently present and public business was discussed, the [agency] violated the Open Meetings Act by failing to notify the public about the meeting and by excluding the public from that meeting. 98-OMD-94, p. 5. *See also* 99-OMD-117; 02-OMD-153; 03-OMD-187; 05-OMD-117; 13-OMD-057. Here, Ms. Busroe did not allege the CRC failed to give proper notice of the special meeting and this office makes no finding in that regard.

⁶ *Taylor v. Bowling Green Municipal Utilities*, No. 2011-CA-00592, 2012 WL 5371994 (Ky. App. Nov. 2, 2012 (citing 95-OMD-71)) (“It is not the name which a group is given that is determinative, but its function.”).

Board employed five inspectors).” He further clarified that its attorney has “never acted as a member of the CRC; rather, the attorney has always attended CRC meetings to provide guidance with probable cause determinations.”

In summary, the CRC consists of the panel members identified at 201 KAR 2:061 Section 3 “with the Board’s other inspectors who are able to participate in discussion; however, the ‘additional’ inspectors have no vote in the options that the panel recommends to the Board.” Executive Director Hadley stated “the number of individuals who convened on July 3, 2018,” was adequate to make a final decision pursuant to 201 KAR 2:061 Section 3 or, in other words, a quorum of the CRC was present. In deference to a “process that has been developed over time,” the CRC adjourned the special meeting “with the expectation that the matter would be considered at the regularly scheduled CRC meeting on July 10, 2018.” Because Ms. Hamilton was unable to acquire the necessary additional information prior to July 10, 2018, the case was not presented on July 10, 2018, but will be presented at the next regularly scheduled CRC meeting on September 11, 2018. If Ms. Busroe is challenging whether a quorum was present on July 3, 2018, Executive Director Hadley stated, then 201 KAR 2:061 Section 3 is the only legal authority that provides guidance and there was no violation pursuant to it. Executive Director Hadley stated that insofar as Ms. Busroe is challenging the disciplinary process itself, her complaint is beyond the scope of the Open Meetings Act.⁷ When viewed in light of existing legal authority, the record on appeal does not substantiate Ms. Busroe’s complaint.

Insofar as the CRC, “standing alone, constituted a public agency for purposes of the Open Meetings Act, this office considers the total composition of the [CRC] itself, rather than the total composition of the [Board], in determining whether a quorum of the [CRC] was present.” 06-OMD-211, pp. 4-5; 15-OMD-155. A quorum is the “minimum number of members (usu. a majority of all the

⁷ The Attorney General is not empowered to “adjudicate a dispute relating to interpretation of, and compliance with, a public agency’s bylaws [or city ordinances, unrelated statutory provisions, etc.]” in this forum. 02-OMD-22, p. 4; 12-OMD-080. Rather, the role of this office in adjudicating disputes arising under the Open Meetings Act, is defined at KRS 61.846(2), pursuant to which the Attorney General “shall review the complaint and denial and issue within ten (10) days, excluding Saturdays, Sundays, and legal holidays, a written decision which states whether the agency violated the provisions of KRS 61.805 to 61.850.” This office has declined, for example, to “decide whether the procedures relative to the termination of a [public] employee were properly interpreted or administered.” 10-OMD-023, p. 5.

members) who must be present for a deliberative assembly to legally transact business.” Black’s Law Dictionary (9th ed. 2009). Pursuant to 201 KAR 2:061 Section 3(1), “A panel consisting of the assigned board member [Board President Cathy Hanna], the executive director [Director Hadley], and the pharmacy drug inspector [Ms. Rhonda Hamilton] shall review the conclusions and recommendation relating to an investigation.” The undisputed facts establish that all three of these individuals, or the CRC in its entirety attended the July 3, 2018, special meeting and, therefore, a quorum was, by definition, present.

When a quorum of the CRC came together to discuss public business, a meeting occurred within the meaning of KRS 61.805(1). 06-OMD-211, p. 5. “At a minimum,” on any such occasion “there [should have been] a determination that a quorum [was] present and a commencement of proceedings prior to the beginning” of any discussions properly held in closed session. 12-OMD-140, p. 7; 15-OMD-155. The minutes of the July 3, 2018, special meeting indicate that a quorum of the CRC was present and Ms. Hanna, Board President (the “assigned member” of the CRC) commenced the proceedings. Ms. Busroe’s complaint is premised on the flawed assumption that a quorum of the CRC was not present (which, if true, would not have constituted a violation of the Act). See KRS 61.810(1); 16-ORD-065. The presence of Cheryl Lalonde, General Counsel, Detective Michael Koenig (exited the closed session after giving his report), and Shan Dutta, Office of the Attorney General (did not attend the closed session), does not change that determinative fact.

The fundamental mandate of the Open Meetings Act, codified at KRS 61.810(1), provides that “[a]ll meetings of a quorum of the members of any public agency at which any public business is discussed or at which any action is taken by the agency, shall be public meetings, open to the public at all times[.]” This provision reflects the legislative statement of policy, codified at KRS 61.800, which declares, “The formation of public policy is public business and shall not be conducted in secret” Accordingly, in a series of decisions dating back to 1978 the Attorney General has recognized that even a casual gathering of a quorum of the members of a public agency triggers the requirements of the Open Meetings Act *if* a quorum discusses public business⁸ *or* takes action.⁹ 01-OMD-30

⁸ In *Yeoman v. Comm. of Ky., Health Policy Bd.*, 983 S.W.2d 459, 474 (Ky. 1998), the Kentucky Supreme Court defined the term “public business” as “the discussion of the various alternatives to a given issue about which the [agency] has the option to take action.”

(gathering of a quorum of the agency held for the purpose of discussing public business violated the Act even though it was informational and informal)(citing OAG 78-411). *Compare* OAG 78-634; 00-OMD-147; 14-OMD-183.

KRS 61.820 provides that all meetings of all public agencies, “and any committees or subcommittees thereof, shall be held at specified times and places which are convenient to the public.” It further mandates that all public agencies “provide for a schedule of regular meetings by ordinance, order, resolution, bylaws, or by whatever other means may be required for the conduct of business of that public agency.” The term “meeting” is broadly defined at KRS 61.805(1) as “all gatherings of every kind . . . regardless of where the meeting is held, and whether regular or special and informational or casual gatherings held in anticipation of or in conjunction with a regular or special meeting.”¹⁰ Thus, all gatherings of a quorum of the CRC at which it discussed public business *or* took action, such as the special meeting it held on July 3, 2018, were meetings of a public agency subject to provisions of the Open Meetings Act, including KRS 61.820 and 61.823, regardless of whether the CRC took action. *See* 99-OMD-77; 06-OMD-068; 11-OMD-060; 14-OMD-246; 15-OMD-142. However, “[i]n the absence of any evidence that a quorum of the members of the [CRC] was present at a single meeting *from which the public was excluded*, or that the members engaged in a series of less than quorum meetings for the purpose of avoiding the requirements of the Act, this office has no basis upon which to conclude that the [CRC] violated the Open Meetings Act.” 13-OMD-142, p. 4; 16-OMD-030.

A party aggrieved by this decision may appeal it by initiating action in the appropriate circuit court pursuant to KRS 61.846(4)(a). The Attorney General shall be notified of any action in circuit court, but shall not be named as a party in that action or in any subsequent proceedings.

⁹ KRS 61.805(3) defines “Action taken” as “a collective decision, a commitment or promise to make a positive or negative decision, or an actual vote by a majority of the members of the governmental body[.]”

¹⁰ On many occasions, the Attorney General has recognized that “[t]here are only two kinds of meetings – regular meetings and special meetings.” 94-OMD-50, p. 4. Accordingly, “[t]he public has a right to expect a public agency . . . to follow its regular schedule or to call special meetings following the required notice, delivery, and posting provisions pursuant to KRS 61.823.” 92-OMD-1677, p. 3.

18-OMD-163

Page 7

Andy Beshear
Attorney General

Michelle D. Harrison
Assistant Attorney General

#329

Distributed to:

Katie Busroe
Larry Hadley
Cheryl Lalonde