

KENTUCKY BOARD OF PHARMACY

via Zoom teleconference

<https://us02web.zoom.us/j/88221014196?pwd=QXRnbjF4WFUyck4rYUULUy9ZZFQydz09>

Meeting ID: 882 2101 4196 Passcode: 0rDYE5

Dial by your location:

+1 312 626 6799 US (Chicago) +1 646 558 8656 US (New York)

Meeting ID: 882 2101 4196 Passcode: 614720

If a closed session is needed,

the teleconference will be suspended while the Board convenes a telephonic closed session.

September 30, 2020

9:00 a.m.

Board Meeting

Agenda

I. CALL TO ORDER

II. MINUTES

- A. *July 29, 2020
- B. *September 8, 2020
- C. *September 15, 2020

III. BOARD REPORTS

- A. Executive Director
 - 1. *eMars – July 2020 and August 2020.
 - 2. HHS COVID-19 Guidance
 - (a) *Access to Childhood Vaccines
 - (b) *COVID-19 Vaccines and Immunity under PREP Act
 - (c) *KYBOP Opinion
 - (d) *KPhA Letter
 - (e) *Executive Order 2020-749
 - (f) *Notes from Travis Mayo
 - 3. *Diversity and Inclusion Task Force
- B. Committee Reports
 - 1. *Regulation Committee – Minutes

IV. CASES

- A. *Fines Report

V. PENDING APPLICATIONS

- A. *Lena Congtang – Request for Pharmacist License Reinstatement – Voluntary surrender

VI. CORRESPONDENCE

- A. *Grant County Drugs – P06853, P06979, P07334– Offsite Storage Request
- B. *Manchester Down Home Pharmacy – P07792 – Offsite Storage Request
- C. *Chewy Pharmacy – CP00118 – Offsite Storage Request
- D. *Non-resident pharmacy permit waiver request – LA2596

VII. LEGISLATION/REGULATION

- A. *201 KAR 2:105 Requirements for wholesalers, medical gas wholesalers, wholesale distributors, and virtual wholesale distributors.
- B. *201 KAR 2:320 Requirements for manufacturers and virtual manufacturers.
- C. *201 KAR 2:225 Special limited pharmacy permit – Medical Gas.
- D. *201 KAR 2:390 Requirements for third-party logistics providers.
- E. *201 KAR 2:205 Pharmacist-in-charge.

VIII. NEW BUSINESS

- A. Protocols
 - 1. *Selfcare Protocol Emergency Contraception
 - 2. *Acute Influenza Infection Antiviral Therapy Protocol update
 - 3. *Acute Group A Streptococcal Pharyngitis Infection Protocol update
- B. *Kit Check – RFID
- C. *Pharmacist role in patient care
- D. *Optometrist Dispensing

*Information included in Board Packet

MINUTES

KENTUCKY BOARD OF PHARMACY

held at

125 Holmes Street

Frankfort KY 40601

via teleconference

BOARD MEETING

September 30, 2020

CALL TO ORDER A regularly scheduled meeting was held via teleconference from the Kentucky Board of Pharmacy, Frankfort, Kentucky. President Poole called the meeting to order on September 30, 2020 at 9:00 a.m.

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

Staff: Larry Hadley, Executive Director; John Romines, Pharmacy and Drug Inspector; Rhonda Hamilton, Pharmacy and Drug Inspector; Jessica Williams, Pharmacy and Drug Inspector, Amanda Harding, Pharmacy and Drug Inspector; Katie Busroe, Pharmacy Inspections and Investigations Supervisor and Darla Sayre, Executive Staff Advisor. Keith Poynter provided legal representation for the Board in the absence of a General Counsel.

MINUTES On motion by Peter Cohron, seconded by Jill Rhodes and passed unanimously, the minutes of the July 29, 2020, September 8, 2020 and September 15, 2020 Board meetings were approved.

APPEARANCES

John Rashidian MD Dr. Rashidian appeared before the Board requesting clarification on the pharmacist role in patient care. He stated that numerous times a pharmacist has questioned his prescriptions for after surgery pain medication, antibiotics for Cesarean Section prophylactics and medications not filled due to out of his scope of practice. Ron Poole responded that many times an individual's insurance will determine that a medication is out of the scope of a physician's practice. Craig Martin identified two issues prevalent today; payer reimbursement and addiction management responsibility. Shannon Stiglitz advised that there have been several lawsuits filed for over dispensing of opioids. Many of the questions asked by pharmacists in the dispensing of opioids are dictated by the DEA. The Board recognized these issues and stated that these should be addressed on a national level.

Emily Messerli DNP, APRN, Immunization Branch Manager, CHFS Dr. Messerli presented COVID-19 Vaccine Planning information to the Board. Providers must sign a COVID-19 Provider agreement and be connected to the KY Immunization Registry to order, receive and document administration of the vaccine. Initial supplies of the vaccine will be limited. Critical healthcare employees and other essential workers will be identified with guidance from the Advisory Committee on Immunization Practices and the National Academy of Medicine. Pharmacies doing mass vaccinations should utilize a drive thru method. Individual immunizations may be

done by appointment in the pharmacy. Dr. Messerli expects pharmacies to play a role when widespread rollout of the vaccine is implemented. Ron Poole questioned Dr. Messerli concerning the use of only chain pharmacies during Phase 1 of the rollout. Dr. Messerli stated that the plan was still being developed with the possibility of including independent pharmacies.

BOARD REPORTS Mr. Hadley advised the Board that the Governor's office stated that current State of Emergency Executive Order allows for pharmacists to dispense drugs as needed to prevent or treat COVID-19 pursuant to protocols established by the CDC or the NIH or determined to be appropriate by the commissioner of public health or his designee to respond to the circumstances causing the emergency. This includes vaccinations. Joel Thornbury asked if a pharmacist was allowed to immunize without being employed at a pharmacy. Katie Busroe advised that a pharmacist cannot possess pharmaceuticals outside of a pharmacy.

Katie Busroe requested clarification on the HHS expansion for pharmacists to order and administer vaccines to children age 3 to 18 under the PREP Act to increase access to lifesaving childhood vaccines and decrease the risk of vaccine-preventable disease outbreaks in children. Larry Hadley will seek guidance from the Governor's office on this issue to determine if this is allowed under the current State of Emergency Executive Order.

Mr. Hadley presented a news alert from CMS regarding the expansion of telehealth. Mr. Hadley advised the comment period for this item ends on October 5, 2020. Jill Rhodes moved to have the Board submit a letter of support once approved by the Executive Director and Board President. Craig Martin seconded, and the motion passed unanimously.

COMMITTEE REPORTS

DIVERSITY AND INCLUSION TASK FORCE Mr. Hadley informed the Board that the task force met for the first time on September 28, 2020. Mr. Hadley assured the Board that the members were excited to discuss and propose changes to promote diversity and inclusion within the pharmaceutical profession.

CORRESPONDENCE

Grant County Drugs, P06853, P06979, P07334 Offsite Storage Request Craig Martin moved to have the inspector, Paul Daniels visit the location and make recommendations at the next Board Meeting. Peter Cohron seconded, and the motion passed unanimously.

Manchester Down Home Pharmacy, P07792 Offsite Storage Request –John Fuller moved to approve this request. Jill Rhodes seconded, and the motion passed unanimously.

Chewy Pharmacy, CP00118 Offsite Storage Request – Craig Martin moved to approve this request. Peter Cohron seconded, and the motion passed unanimously.

Non-resident pharmacy, LA2596 Permit Waiver Request – Jill Rhodes moved to deny this request. Craig Martin seconded, and the motion passed unanimously.

LEGISLATION/REGULATION

201 KAR 2:390, Requirements for third-party logistics providers. Larry Hadley informed the Board that comments were received regarding this regulation amendment from UPS Supply Chain Solutions. The Board reviewed the comments:

- Section 1 and 2 ‘product’ and ‘prescription drugs and related devices’ - Jill Rhodes moved to leave language as is. Peter Cohron seconded, and the motion passed unanimously.
- Section 2 Subsections 7 and 9, Section 5 Subsections 3(a)(b) ‘immediately’ – Craig Martin moved to change the language to ‘readily retrievable within 48 hours’. Peter Cohron seconded, and the motion passed unanimously.
- Section 3 Subsection 4 ‘wholesale distributor’ – Craig Martin moved to leave language as is. Peter Cohron seconded, and the motion passed unanimously.
- Section 4 Subsection 4(c) requires proof of either registration with the FDA or a home state license. Jill Rhodes moved to leave language as is. Peter Cohron seconded, and the motion passed unanimously.
- Section 4 Subsection 4(k) requires a list of states in which the 3PL is licensed. Craig Martin moved to strike this requirement. Peter Cohron seconded, and the motion passed with one nay vote from Jill Rhodes.
- Section 5 Subsection 1(e) ‘apart and separate from any pharmacy permitted by the Board of Pharmacy.’ Jill Rhodes moved to leave language as is. Craig Martin seconded, and the motion passed unanimously.
- Section 5 Subsection 2(b) ‘and reduced to a minimum.’ Craig Martin moved to leave language as is. Peter Cohron seconded, and the motion passed unanimously.
- Section 5 Subsection 3(a) ‘authorized law enforcement officials.’ Peter Cohron moved to change the language to ‘authorized official of any federal, state or local law enforcement agency.’ Jill Rhodes seconded, and the motion passed unanimously.
- Section 5 Subsection 3(c) requires a list of verified persons or businesses to whom they ship. Craig Martin moved to leave language as is. Jill Rhodes seconded, and the motion passed unanimously.
- Section 5 Subsection 3(d) list of authorized recipients may be incomplete. Craig Martin moved to add ‘Any other appropriately licensed or permitted facility in the jurisdiction in which it is located.’ Peter Cohron seconded, and the motion passed unanimously.
- Section 5 Subsection 3(d) language regarding the intended use of the recipient. Craig Martin moved to leave language as is. Jill Rhodes seconded, and the motion passed unanimously.
- Section 4 Subsection 4(f) ‘exercises process control’ - Jill Rhodes moved to strike ‘process’ from this section. Craig Martin seconded, and the motion passed unanimously.

201 KAR 2:105, Requirements for wholesalers, medical gas wholesalers, wholesale distributors, and virtual wholesale distributors. Larry Hadley informed the Board that comments were received regarding this regulation amendment from UPS Supply Chain Solutions and Healthcare Distribution Alliance. The comments from UPS Supply Chain were similar to their comments of 201 KAR 2:390. Craig Martin moved to adopt the actions from 201 KAR 2:390. Peter Cohron seconded, and the motion passed unanimously. The Board reviewed the comments from HDA:

- Section 1: Definitions. ‘Wholesaler’ - Craig Martin moved to leave language as is. Peter Cohron seconded, and the motion passed unanimously.
- Section 2 (5)(a) ‘document proper storage of prescription drugs and related devices’ - Jill Rhodes moved to leave language as is. Peter Cohron seconded, and the motion passed unanimously.
- Section 2 (7) Request to strike this language and reference DSCSA. Craig Martin moved to leave language as is. Peter Cohron seconded, and the motion passed unanimously.
- Section 5(3) and (4) Request to strike this language and reference DSCSA. Craig Martin moved to leave language as is. John Fuller seconded, and the motion passed unanimously.

201 KAR 2:320, Requirements for manufacturers and virtual manufacturers. Larry Hadley informed the Board that comments were received regarding this regulation amendment from UPS Supply Chain Solutions and Hart Consulting Services. The comments from UPS Supply Chain were similar to their comments of 201 KAR 2:390. Craig Martin moved to adopt the actions from 201 KAR 2:390. Jill Rhodes seconded, and the motion passed unanimously. The Board reviewed the comments from Hart Consulting Services:

- Section 6(5) regarding inspections of the facility by the pharmacist-in-charge. In light of COVID-19, request the option of virtual inspections be included. The Board determined that virtual inspections are allowed during the current State of Emergency due to COVID-19. Craig Martin moved to leave language as is. John Fuller seconded, and the motion passed unanimously.

201 KAR 2:225, Special limited pharmacy permit – Medical Gas. Larry Hadley informed the Board that comments were received regarding this regulation amendment from Hart Consulting Services. The Board reviewed the comments from Hart Consulting Services:

- Section 2(b) regarding inspections of the facility by the pharmacist-in-charge. In light of COVID-19, request the option of virtual inspections be included. The Board determined that virtual inspections are allowed during the current State of Emergency due to COVID-19. Craig Martin moved to leave language as is. John Fuller seconded, and the motion passed unanimously.

201 KAR 2:205, Pharmacist-in-Charge. The Regulation Committee recommended this regulation amendment of updated initial permit and renewal applications. Craig Martin moved to approve this amendment and directed staff to submit to LRC. John Fuller seconded, and the motion passed unanimously.

NEW BUSINESS

Selfcare Protocol Emergency Contraception Jill Rhodes moved to approve this protocol. John Fuller seconded, and the motion passed unanimously.

Acute Group A Streptococcal Pharyngitis Infection Protocol and Acute Influenza Infection Antiviral Therapy Protocol Craig Martin moved to approve the revision of these protocols to include COVID testing. John Fuller seconded, and the motion passed unanimously.

Kit Check/RFID After much discussion, 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.

Optometrist Dispensing Larry Hadley presented to the Board a new regulation, 201 KAR 5:140 regarding dispensing by an optometrist. The comment period for this regulation ends October 31, 2020. After much discussion, the Board decided to provide no comments on the regulation allowing the pharmacy associations to provide their comments.

ADJOURNMENT On motion by Jill Rhodes, seconded by Craig Martin and passed unanimously, President Poole adjourned the meeting at 12:23 p.m. The next regularly scheduled meeting begins at 9:00 am on November 5, 2020 at the Kentucky Board of Pharmacy in Frankfort, KY via teleconference.

Larry A. Hadley
Executive Director