

KENTUCKY BOARD OF PHARMACY
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**Special Called Board Meeting
March 25, 2020
9:00 a.m.**

Agenda

- I. Call to Order
- II. Medication Limitations
 - a) Prescriptions for chloroquine, hydroxychloroquine, mefloquine, or azithromycin may not be dispensed or distributed unless all the following apply:
 - (a) the prescription or medication order bears a written diagnosis from the prescriber consistent with the evidence for its use;
 - (b) the prescription or medication order is limited to no more than a ten (10) day supply, unless the patient was previously established on the medication prior to the effective date of this rule;
 - (c) no refills may be permitted unless a new prescription or medication order is furnished with established written diagnosis and indication for continuation;
 - (d) the Board of Pharmacy shall have the authority to set limitations on any medications found to be therapeutic in the treatment of the COVID-19 coronavirus
 - (e) statement from Public Health
- III. Temporary Licensure/Registration - Temporary license/registration for bordering state pharmacists and technicians to practice in the Commonwealth of Kentucky should the need arise.
 - a) A temporary license/registration may be granted providing the following requirements are met;
 - 1. the pharmacist/technician be in good standing in his or her original state;
 - 2. state of licensure/registration borders Kentucky; and
 - 3. temporary license/registration shall be good for a period of 60-90 days, though renewable if the emergency continues.

- IV. Executive Director - Authority under KRS 315.160 of the Board to allow Executive Director to handle future issues pursuant to Executive Order.
- V. Miscellaneous
 - a) How much can pharmacies compound if required PPE is unavailable?
 - b) Graduates and reciprocals unable to test due to Pearson Vue testing center closures.
 - c) The Board of Pharmacy needs a regulation based on the proposed executive order above to be able to have some area of control over the dispensing of medications in emergencies like the current one.
 - d) Limiting retail pharmacies to drive thru or curbside pickup only unless barriers have been constructed inside the store for pick-up and drop-off only.
 - e) Requiring pharmacists and staff to use PPE for any in person contact with customers.
 - f) Pharmacist off-site testing for COVID-19.
- VI. Correspondence
 - a) Riley-White, Off-site Storage Request
 - b) SEMC Medical Village, Off-site Storage Request
 - c) Plaza Drug, Dual PIC
 - d) Methodist Hospital Inc, Dual PIC
 - e) U of L Request for waiver during downtime.
 - f) University of Kentucky Specialty Pharmacy and Infusion Services
- VII. Adjournment

**KENTUCKY BOARD OF PHARMACY
SPECIAL CALLED BOARD MEETING
via teleconference using Go to Meeting**

**March 25, 2020
9:00 a.m.**

CALL TO ORDER A special called meeting was held by the Kentucky Board of Pharmacy via video teleconference using Go To Meeting. President Ron Poole called the meeting to order at 9:00 a.m.

Members present via video teleconference: Ron Poole; Peter Cohron; Craig Martin; Jill Rhodes and John Fuller. Absent: Jody Forgy.

Staff present via video teleconference: Larry Hadley, Executive Director; Anthony Gray, Board Counsel; Katie Busroe, Inspections and Investigations Supervisor; Amanda Harding, Pharmacy and Drug inspector; Paul Daniels, Pharmacy and Drug inspector; Jessica Williams, Pharmacy and Drug inspector; Rhonda Hamilton, Pharmacy and Drug inspector; John Romines, Pharmacy and Drug inspector and Darla Sayre, Executive Staff Advisor. The meeting was recorded using Go To Meeting.

Guest present via video teleconference: Shannon Stiglitz, Kentucky Retail Federation; Steve Hart; Mark Glasper, KPhA; Lauren Adams, Walgreens; Debbie Duckworth, University of Kentucky Specialty Pharmacy; Samantha Bochenak, University of Kentucky Specialty Pharmacy; David Roy; Misty Stutz, Sullivan University College Of Pharmacy; William Cover, NABP; Joan Haltom; Jonathan Van Lear; and Spencer Bolton.

President Poole opened the meeting advising participants of the meeting process and actions. He informed the audience that all discussions were restricted to only the Agenda items because this is a special called meeting.

Medication Limitations President Poole read the proposed language restricting the quantity dispensed of chloroquine, hydroxychloroquine, mefloquine and azithromycin. After much discussion, Craig Martin moved to approve the language below:

Prescriptions for chloroquine, hydroxychloroquine, mefloquine, or azithromycin may not be dispensed or distributed unless all the following apply:

- a) the prescription or medication order bears a written diagnosis from the prescriber consistent with the evidence for its use;
- b) the prescription or medication order is limited to no more than a ten (10) day supply, unless the patient was previously established on the medication prior to the effective date of this rule;
- c) no refills may be permitted unless a new prescription or medication order is

furnished with established written diagnosis and indication for continuation; and
d) the Board of Pharmacy shall have the authority to set limitations on any medications for the use in treatment of the COVID-19 coronavirus.

Jill Rhodes seconded, and the motion passed unanimously.

Temporary Licensure/Registration President Poole read the proposed language for temporary licensure of pharmacists and registration of pharmacy technicians due to a possible shortage of pharmacy personnel due to COVID-19. After discussion, Peter Cohron moved to approve the language below:

Temporary license/registration for pharmacists and technicians to practice in the Commonwealth of Kentucky should the need arise during the current State of Emergency. A temporary license/registration may be granted providing the following requirements are met;

- a) the pharmacist/technician be in good standing in his or her original state; and
- b) temporary license/registration shall be valid for a period of 90 days, though renewable if the emergency continues.

Craig Martin seconded, and the motion passed unanimously.

Authority of Executive Director President Poole read the proposed language to grant the Executive Director the authority to authorize changes or amendments made based on the Governor's Executive Order. Anthony Gray stated the Board has this authority to do so under KRS 315.160 but a statement on record specifying this authority during the current state of emergency may be beneficial. Larry Hadley informed the Board that any decisions made would be implemented after consultation with the Board President. Craig Martin moved to grant the Executive Director the authority under KRS 315.160 to allow the Executive Director to handle future issues pursuant to Executive Order 20-243 during the current state of emergency. Peter Cohron seconded, and the motion passed unanimously.

Miscellaneous

Compounding PPE - The Board discussed how much pharmacists may compound if required PPE is unavailable. Jill Rhodes advised that guidance was available from USP. This guidance document is available on the website.

Testing Centers - The Board discussed the issue of testing with the closure of Pearson Vue testing centers. President Poole advised that the veterinary profession utilized Honor Lock allowing for remote testing. Misty Shultz, Dean of Sullivan University College of Pharmacy stated that remote testing should be considered due to the upcoming influx of graduates this spring. Both Misty Shultz and Craig Martin assured the Board that remote testing could be accommodated at both Sullivan and the University of Kentucky, if needed. These accommodations would follow the required social distancing with applicant scheduling.

William Cover, National Association of Boards of Pharmacy (NABP), joined the meeting via teleconferencing. He informed the Board that on March 26, 2020, NABP will launch NABP Passport, a companion to the Electronic Licensure Transfer Program (e-LTP). NABP Passport includes screening and tracking that assists and supports states as they seek to quickly and accurately manage requests for temporary or emergency licensure in response to the COVID-19 pandemic. This program should help with the temporary licensure of pharmacists during the state of emergency.

President Poole inquired if NABP were considering remote testing during the COVID-19 pandemic. Mr. Cover advised that this was a big concern of NABP. NABP is currently working with testing centers for how best to proceed and still maintain the integrity of the exams.

Emergency Regulation - President Poole suggested establishing a committee at a later date to evaluate and write and/or amend regulations for future events as the COVID-19 pandemic. Jill Rhodes requested the committee also look at guidance during drug shortages.

Pharmacy Operations - The Board discussed limiting retail pharmacies to drive-thru or curbside pickup only unless barriers have been constructed inside the facility for pickup and drop-off only. Multiple parties have raised this issue to Board Members. President Poole stated this is difficult to mandate due to the many different pharmacy layouts. Shannon Stiglitz advised that store fronts are critical to customers. The in-store services are necessary in some areas of the state where this is their source of food supplies. The Kentucky Retail Federation is not in favor of this due to privacy concerns and the lack of PPE. Anthony Gray stated that he is not sure the Board should be making business decisions for companies. Peter Cohron stated that this is not a business decision but a method to allow pharmacists to use professional judgement in the safety of staff and customers. Jill Rhodes recommended that PPE should be provided to pharmacy staff in accordance with proper risk assessment and guidance provided by OSHA and CDC. Jill Rhodes recommended that our board should consider adopting a statement to distribute reinforcing the existing regulations and requirements for sanitary pharmacy conditions, citing the North Carolina board of pharmacy statement recently released. The Board directed Board staff to distribute via email and post on the website the following notice:

Kentucky law requires that “all pharmacies shall comply with all sanitation laws and administrative regulations” inclusive of, but not limited to provision of “adequate facilities, separate and distinct from toilets and washrooms, shall be provided for maintaining clean and sanitary conditions” in accordance with 201 KAR 2:090 and 201 KAR 2:180.

“Sanitary” conditions include those sufficient to minimize risk of transmission of a communicable disease within a pharmacy, in accordance with nationally published standards such as the CDC and OSHA. Violation of any provision of these administrative regulations constitutes unethical or unprofessional conduct in accordance with KRS 315.121.

The Board strongly supports efforts by pharmacies and pharmacists to adjust work flows and processes within a pharmacy to reduce the risk of person-to-person coronavirus transmission. Such efforts might include, but are not limited to: not physically handling patient identifications at the point of dispensing; not requiring a physical signature for pick-up of a prescription; increasing use of prescription delivery, drive-thru, and curbside services; limiting the number of patients physically entering a pharmacy; encouraging patients to wait in their vehicles; encouraging the use of an appointment system for patients to conduct business; placing physical barriers inside the pharmacy and drive thru; encouraging employees to wear PPE and how often to change PPE; adhering to consistent store cleaning regimens.

The Board emphasizes that the pharmacist-in-charge is the person authorized by law to ensure compliance with our pharmacy practice standards. Improper interference with a pharmacist-in-charge carrying out these duties and responsibilities subjects a pharmacy permit holder to potential disciplinary action, up to and including revocation. Likewise, a person licensed by, or registered with, the Board who improperly interferes with a pharmacist-in-charge carrying out these duties and responsibilities, is subject to potential disciplinary action, up to and including revocation. Pharmacist professional judgement is encouraged and depended on during these times of crisis to mitigate the possibilities for both employee and customer COVID-19 exposure. Permit holders shall cooperate with their PIC's and staff to ensure protection for both their staff and customers.

Pharmacy PPE - The Board discussed requiring pharmacy personnel to use PPE for any in-person contact with customers. Jill Rhodes and Peter Cohron stated that pharmacies should follow the CDC and OSHA guidelines.

COVID-19 Testing -The Board discussed COVID-19 testing. Craig Martin stated that the Board supported pharmacist involvement with testing. Joan Haltom advised that they would utilize pharmacy personnel when testing becomes available.

CORRESPONDENCE

Riley-White, Off-site Storage Request Craig Martin moved to approve this request for Clinic Pharmacy P02386 and Clinic Pharmacy Franklin P07819 to store pharmacy records greater than 2 years old at Riley-White Drugs P06574. All pharmacies are under common ownership. Peter Cohron seconded, and the motion passed unanimously.

SEMC Medical Village, Off-site Storage Request Peter Cohron moved to approve this request for SEMC Medical Village Pharmacy P07065 to store pharmacy records greater than 2 years old at the St. Elizabeth Mount Zion Record Center. Craig Martin seconded, and the motion passed unanimously.

Plaza Drug, Dual PIC Peter Cohron moved to approve this request for one pharmacist to serve as pharmacist-in-charge both of Plaza Drug (retail) P07794 and Plaza Drug (long term care) P07438, both located at the same address. Craig Martin seconded, and the motion passed unanimously.

Peter Cohron recused himself from the teleconference.

Methodist Hospital, Dual PIC Craig Martin moved to approve this request for one pharmacist to service as pharmacist-in-charge of both Methodist Health Hospital Pharmacy in Owensboro P05007 and Methodist Health Inc. Union County Hospital Pharmacy P05172, a critical access hospital in Union County thirty miles from Methodist Health Hospital Pharmacy in Owensboro. Jill Rhodes seconded, and the motion passed unanimously.

Peter Cohron returned to the teleconference.

Jill Rhodes recused herself from the teleconference.

U of L Waiver Request during downtime Craig Martin moved to approve this request from University of Louisville Hospital Pharmacy for a waiver from full compliance with sterile compounding of hazardous drugs while renovating the sterile compounding clean room suite. A detailed Assessment of Risk document was submitted and did not include any Table 1 hazardous drugs. Peter Cohron seconded, and the motion passed unanimously.

Jill Rhodes returned to the teleconference. Peter Cohron and Craig Martin recused themselves from the teleconference. Jody Forgy joined the meeting via telephone to establish a quorum.

University of Kentucky Specialty Pharmacy and Infusion Services Debbie Duckworth and Samantha Bochenek, University of Kentucky Specialty Pharmacy and Infusion Services, appeared via teleconference requesting a waiver exempting the second floor from the permit, off-site storage request for records to be stored on the second floor and a waiver allowing for non-pharmacist staff such as environmental services disinfecting patient care spaces, or finance and administrative staff to be in spaces where there is not access to either medications or patient records after hours, without a pharmacist being present.

After much discussion, John Fuller moved to approve the storage of pharmacy records on the second floor in a locked area. Jill Rhodes seconded, and the motion passed unanimously.

Jill Rhodes moved to allow appropriate environmental services personnel access when a pharmacist was not present to areas that have no protected patient health information or prescription drugs present. John Fuller seconded, and the motion passed unanimously.

The Board discussed the necessity of the second floor of the building to be permitted pharmacy space. Due to the presence of a Pyxis, it was determined that a second permit was required for the second floor. Due to that determination, Debbie Duckworth stated they would not place a Pyxis on the second floor. Medications for infusion patients would be obtained from the first

floor pharmacy. Jill Rhodes moved to direct the Regulation Committee to review the issue of a Pyxis system in an infusion area. John Fuller seconded, and the motion passed unanimously.

Jill Rhodes moved to exempt the second floor from the pharmacy permit. John Fuller seconded, and the motion passed unanimously.

Peter Cohron and Craig Martin returned to the teleconference.

ADJOURNMENT On motion by Jody Forgy, seconded by Craig Martin and passed unanimously, President Poole adjourned the meeting at 12:00 p.m.