

# **Kentucky Board of Pharmacy Advisory Council**

Kentucky Board of Pharmacy  
125 Holmes St. Suite 300  
Frankfort KY 40601

March 5, 2020  
9:00 am

## **Agenda**

- I. Call to Order
- II. Opening remarks by Chair Matt Martin
- III. Approval of Minutes from January 30, 2020
- IV. Discussion items:
  - A. Telepharmacy
- V. Adjournment

**MINUTES**  
KENTUCKY BOARD OF PHARMACY  
ADVISORY COUNCIL  
125 Holmes St. Suite 300  
Frankfort KY 40601  
March 5, 2020

Present: Chair Matt Martin; Jason Poe; Michael Wyant; Tyler Bright; Chris Clifton and Anthony Tagavi. Staff present were Executive Director Larry Hadley, Anthony Gray, Board Counsel; Katie Busroe, Pharmacy Inspection and Investigation Supervisor and Darla Sayre, Executive Staff Advisor. Absent: Kelly Whitaker and Shannon Stiglitz.

Guests included: Lavanya Peter, Park Duvalle; Hope Maniyar, U of L Health; Tina Claypool, U of L Health; Cathy Hanna, APSC; Will Sharp, Student; Mark Glasper, KPHA; Chris Killmeier and Ron Poole, Board President.

The meeting was called to order by Chairman Martin at 9:01 am.

After introductions from all present, Chairman Martin informed the Council of the resignation of Elizabeth Lovell. She tendered her resignation due to an upcoming move out of state. The Board will vote on the vacancy at the March 25<sup>th</sup> meeting. Chairman Martin welcomed Ron Poole, President of the Kentucky Board of Pharmacy.

Mr. Poole thanked the Advisory Council for their work on the issue of telepharmacy. He expressed concerns over the initial request for this regulation coming from a corporation with a vested business interest in the implementation of remote sites. He requested the Council upon submitting the regulation to the Board provide a summary of the discussions that led to the proposed regulation. Mr. Poole expressed concern that the Board had not been informed on the progress of this issue. In addition, he requested a report from each individual member on their thoughts or concerns for the proposed regulation. This will provide the Board with information to make a more informed determination of the regulation. If requested, he will provide a list of the items that should be addressed in the reports and summary. His concern is that members would have a vested interest in the implementation of a new pharmacy business model that would undermine existing pharmacies. Mr. Poole indicated he could not speak on behalf of the Board but he personally had concerns about the motivation of the telepharmacy regulation.

Chairman Martin responded with an assurance that the Council made decisions that best served the public rather than a business. Both parties, those in favor of and those opposed have been present during the meetings. The Council proceeded with the understanding that they were charged by the Board to draft a proposed regulation to allow telepharmacy in Kentucky. Chairman Martin objected to having each member provide a personal statement. He stated the Council proceeds on majority vote and personal feelings are insignificant to the charge of the Council.

Mr. Poole stated that the charge to the Council was to provide a recommendation to the Board on telepharmacy in Kentucky not to draft a regulation. He questioned the motivating factors for this regulation and the removal of 'proof of need' provisions.

Chairman Martin stated that there was interest from other parties for this regulation. Rural hospitals were represented with the need for after hour access to pharmacy services in an emergency room. Mental health facilities located in Jefferson County expressed interest in these services to meet the needs of patients in a

clinic setting. Anthony Tagavi echoed Chairman Martin regarding the need for telepharmacy in rural and urban hospital settings. The Council is responding to the needs of the public not business interest.

Chairman Martin reiterated that the Council was acting on what they believed to be the charge from the Board – draft a regulation allowing for telepharmacy in Kentucky. Chris Killmeier informed the Council that this charge was received by the Council in 2017 when he was Chairman. His understanding of the charge was to draft a regulation. The ‘proof of need’ provisions were discussed multiple times. The term pharmacy desert was used to indicate areas in Kentucky where patient access to pharmacies would be improved with telepharmacy. These locations cannot be determined by a specified mileage but rather all aspects of the patient mobility and locality must be considered. Mr. Killmeier stated that Cardinal Health was allowed to present at a meeting due to their national expertise regarding telepharmacy.

Mr. Killmeier read a portion of the minutes from the September 6, 2017 Board meeting:

Dr. Michael Mone`, Cardinal Health, made a presentation on telepharmacy to the Board. At the completion of the presentation, he offered his services to the Board in developing and implementing legislation regarding telepharmacy in Kentucky. He assured the Board that no solicitation of potential customers had been done by Cardinal Health. Mr. Poole expressed a concern regarding the potential for abuse by investors. Ms. Lalonde stated that there is a statute in place for telehealth but no healthcare Board has submitted any regulations as of yet.

Seema Siddiqui, MedAvail, made a presentation on their MedAvail MedCenter, an automated dispensing system currently allowed in five states with another two states with pending regulations. This system dispenses unit of use or specific count pharmaceuticals. Maintenance includes a 10 minute battery in case of power failure and maintenance personnel onsite within hours. The system is partnered with a home pharmacy which is local for stocking and record keeping. Mr. Poole moved to send this to the Advisory Council for further action. Ms. Brewer seconded, and the motion passed unanimously.

Tina Claypool asked if Council minutes are available to review. Darla Sayre indicated all Council minutes are posted on the Board of Pharmacy website once approved at the next meeting.

Larry Hadley stated that the charge to the Council was not specific. Cathy Hanna agreed with Mr. Poole that the charge was to evaluate telepharmacy and provide a recommendation to the Board not to draft a regulation. Mr. Killmeier stated that the charge to the Council was presented to him to move forward with telepharmacy.

Mr. Hadley proposed proceeding with the regulation for submission to the Board.

Chairman Martin agreed but once again stated that the Council acted under the guidance of the Board in drafting the regulation. He was gravely concerned by the allegation that the Council acted outside of the charge. He did not appreciate the interpretation the Council acted without the charge of the Board.

At 9:48 a.m., on motion by Chris Clifton, seconded by Michael Wyant, and passed unanimously, the minutes from the January 30, 2020 meeting were approved.

Chairman Martin thanked the inspection staff for the input provided on the proposed regulation. He proposed working through the inspection staff version line by line. Katie Busroe was available to provide additional information for the changes made. After much discussion the proposed regulation was amended as follows:

NECESSITY, FUNCTION, AND CONFORMITY: KRS 325.020(1) requires that prescription drugs, medicines, and pharmaceuticals be dispensed or manufactured by a licensed pharmacist. KRS 315.310 authorizes the board to regulate telehealth. This administrative regulation establishes the standards for the operation of this type of practice.

#### Section 1. Definitions.

(1) Telehealth shall have the same definition as KRS 315.310(3).

(2) Pharmacy shall have the same definition as KRS 315.010(19).

(3) "Telepharmacy" means the provision of pharmacy services using telehealth. There are 4 types of telepharmacy.

(a) "Remote Dispensing Site Pharmacy" means a permitted pharmacy, other than that of the managing pharmacy, that may receive written and electronic prescriptions and store and dispense prescription drugs and drug-related devices, excluding Schedule II controlled substances. A remote dispensing site pharmacy is not required to have a pharmacist onsite if it is providing pharmacy services using telehealth.

(b) "Remote Consultation Site Pharmacy" means a permitted pharmacy, other than that of the managing pharmacy, where prescriptions dispensed at the managing pharmacy, excluding Schedule II controlled substances, are stored and provided by a nationally certified pharmacy technician under the direction of a pharmacist located at, or contracted with, the managing pharmacy.

(c) Automated pharmacy system shall have the same definition as KRS 315.295(1)(a). There are two types of automated pharmacy systems used for telehealth:

1. Automated dispensing system means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications and which collects, controls, and maintains all transaction information, and

2. "Kiosk" means an automated pharmacy system that maintains individual patient prescriptions that were verified and labeled at the managing pharmacy.

(4) "Pharmacy Records" means all prescription records, patient records, prescription claims and payment records, and drug inventory records.

(5) Managing pharmacy means a pharmacy permitted pursuant to KRS 315.035 or KRS 315.351 that provides pharmacy services through a telepharmacy.

Section 2. Each remote dispensing site pharmacy and remote consultation site pharmacy shall be a separately permitted telepharmacy. Each managing pharmacy with an automated pharmacy system shall notify the Board prior to each installation or removal of an automated pharmacy system. Managing pharmacies that are located outside of

Kentucky must be permitted as a nonresident pharmacy. All pharmacists providing telehealth services in Kentucky shall be Kentucky licensed pharmacists.

(1) Remote Dispensing Pharmacy Site

(a) The managing pharmacy and the remote dispensing site pharmacy must utilize computerized recordkeeping.

1. All pharmacy records shall be maintained at the remote dispensing site pharmacy.
2. Prescriptions dispensed at the remote dispensing site pharmacy shall be distinguishable from those dispensed from the managing pharmacy.
3. Daily reports must be separated for the managing pharmacy and remote dispensing site pharmacy.

(b) Written prescriptions presented to the remote dispensing site pharmacy shall be entered into the pharmacy system and coordinated with an image of the written prescription that is accessible to the pharmacist for eighteen months.

(c) A remote dispensing site pharmacy is considered to be under the direction of a pharmacist at the managing pharmacy.

(d) Prior to dispensing, a pharmacist at the managing pharmacy shall compare via electronic media the stock bottle, drug dispensed, strength and expiration date. The entire label and packaging shall be verified for accuracy via electronic media.

1. Pharmacist and pharmacy technician initials or unique identifiers must appear on the prescription record and the prescription label.
2. The prescription label shall bear the name and address of the managing pharmacy and the name and address of the remote dispensing site pharmacy.
3. The remote dispensing site pharmacy shall utilize a barcode system for electronic verification. If the stock bottle does not have a barcode, the pharmacy shall utilize a different...**to be continued at the next meeting.**

Chris Clifton moved to retain the requirement of barcode scanning for electronic verification. Tyler Bright seconded, and the motion passed with Tony Tagavi and Jason Poe opposing.

Chairman Martin polled the council for a preferred date of the next meeting. The next meeting will be April 6, 2020 at the Board office.

The meeting was adjourned at 12:05 p.m. by motion of Chris Clifton and seconded by Tyler Bright. The vote was unanimous.

Matt Martin, Chair