

# **Kentucky Board of Pharmacy Advisory Council**

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

January 30, 2020  
9:00 am

## **Agenda**

- I. Call to Order
- II. Opening remarks by Chair Matt Martin
- III. Approval of Minutes from December 5, 2019
- IV. Discussion items:
  - A. RX Adaptation
  - B. Telepharmacy
    1. \*Definitions
    2. \*Telepharmacy working document
- V. Adjournment

**MINUTES**  
KENTUCKY BOARD OF PHARMACY  
ADVISORY COUNCIL  
125 Holmes St. Suite 300  
Frankfort KY 40601  
January 30, 2020

Present: Chair Matt Martin; Jason Poe; Michael Wyant, Tyler Bright and Anthony Tagavi. Staff present were Executive Director Larry Hadley, Anthony Gray, Board Counsel and Darla Sayre, Executive Staff Advisor.  
Absent: Elizabeth Lowell and Shannon Stiglitz.

Guests included: Lavanya Peter, Park Duvalle; Hope Maniyar, U of L Health; Tina Claypool, U of L Health; Jessica Adams, Telepharm and Spencer Bolton, St. Elizabeth Healthcare.

The meeting was called to order by Chairman Martin at 9:00 am.

On motion by Michael Wyant, seconded by Jason Poe, and passed unanimously, the minutes from the December 5, 2019 meeting were approved.

**RX ADAPTATION**

Larry Hadley reported on comments from the Kentucky Board of Medical Licensure. There was no interest from KBML on allowing RX Adaptation. Mr. Hadley presented proposed language adapted from Idaho language. After much discussion, Jason Poe moved to send the proposed language [below] to the Board. Tyler Bright seconded, and the motion passed unanimously.

Upon patient consent, a pharmacist may adapt non-controlled drugs as specified in this rule, provided that the prescriber has not indicated that adaptation is not permitted.

- 1) Change Quantity. A pharmacist may change the quantity of medication prescribed if:
  - a. The prescribed quantity or package size is not commercially available;
  - b. The change in quantity is related to a change in dosage form or therapeutic interchange;
  - c. The change is intended to dispense up to the total amount authorized by the prescriber including refills; or
  - d. The change extends a maintenance drug for the limited quantity necessary to coordinate a patient's refills in a medication synchronization program.
- 2) Change Dosage Form. A pharmacist may change the dosage form of the prescription if it is in the best interest of patient care, so long as the prescriber's directions are also modified to equate to an equivalent amount of drug dispensed as prescribed.
- 3) Complete Missing Information. A pharmacist may complete missing information on a prescription if there is evidence to support the change.
- 4) Documentation. A pharmacist who adapts a prescription in accordance with these rules must document the evidence for the adaptation in the patient's record. Adaptation shall be reported to the prescriber within 72 hours.

## TELEPHARMACY

Chairperson Martin gave a brief overview of the proposed telepharmacy regulation. The council began with the Automated Dispensing Section. After much discussion, the council made the following changes to the proposed language.

(3) Automated Pharmacy System is defined by KRS 315.295(1)(a) shall be located at only 24 hour urgent care or emergency departments.

a) These devices shall maintain a prescription drug inventory that is controlled electronically by the home pharmacy or, when operated by a pharmacy contracted with the home pharmacy, by the contracted pharmacy, which shall be utilized to dispense patient specific prescriptions.

b) These systems shall have prescription inventory, which shall be secured in an automated pharmacy system and electronically connected to and controlled by the home pharmacy.

c) A pharmacist shall approve all the prescription orders before they are released from the automated pharmacy system.

d) Dispensing and counseling are performed by a pharmacist employed or contracted by the home pharmacy via audio and video link.

e) All filled prescriptions shall have a label that meets the requirements of this section attached to the final drug container.

f) The pharmacist-in-charge of the home pharmacy, or a designated registrant, shall conduct and complete monthly inspections of the automated pharmacy system. Inspection criteria shall be included in the policies and procedures for the site. The report shall be available to the pharmacy investigators when requested.

g) The automated pharmacy system shall be permitted with the Board as an automated pharmacy system and will be subject to inspection by pharmacy investigators. Notwithstanding that the automated pharmacy system shall possess a license, the home pharmacy shall remain responsible for inventory control and billing. For purposes of inspections, a pharmacist with access to the system shall be available at the site within twelve hours. In the event the Board determines that the automated pharmacy system poses a significant risk of patient harm, the automated pharmacy system shall be disabled until such time as the pharmacist with access to the system is available to the site.

h) Medication dispensed at the automated pharmacy system site may only be packaged by a licensed manufacturer or repackager, or prepackaged by a licensed pharmacy in compliance with this Section. Prepackaging shall occur at the home pharmacy, a pharmacy sharing common ownership with the home pharmacy, or a pharmacy that has contracted with the home pharmacy to perform prepackaging services. The following requirements shall apply whenever medications are prepackaged by a pharmacy other than the home pharmacy:

1. The prepackaging pharmacy shall be licensed in Kentucky as a resident or nonresident pharmacy.

2. The prepackaging pharmacy shall share a common database with the home pharmacy, or have in place an electronic or manual process to ensure that both pharmacies have access to records to verify the identity, lot numbers and expiration dates of the prepackaged medications stocked in the automated pharmacy system.

3. The prepackaging pharmacy shall maintain appropriate records to identify the responsible pharmacist who verified the accuracy of the prepackaged medication.

i) Written prescriptions may be received at an automated pharmacy system. All written prescriptions presented to an automated pharmacy system shall be scanned utilizing imaging technology that permits the reviewing pharmacist to determine its authenticity. The sufficiency of the technology shall be determined by the Board. If sufficient technology is not used, the written prescriptions shall be delivered to the home pharmacy and reviewed by a pharmacist prior to being dispensed to the patient.

j) A pharmacist shall counsel on the initial prescription, and on refills if there are any medication therapy changes. An offer of counseling shall be required for all refills. Counseling must be done by a pharmacist via video link and audio link before the drug or medical device is released. The pharmacist providing counseling, pursuant to this subsection, must be employed or contracted by the home pharmacy or by a pharmacy contracted with the home pharmacy and have access to all relevant patient information maintained by the home pharmacy.

k) There shall be a working computer link, video link and audio link to a pharmacist at a home pharmacy whenever the prescription area is open to the public unless a pharmacist is physically present. The communication link must be checked daily and the remote site pharmacy must be closed if the link malfunctions, unless a pharmacist is physically present at the remote site. The technology used for pharmacist supervision be both video and audio with the capability of recording video only. Recordings shall be stored a minimum of 45 days. The audio of any interaction with patient will not be recorded due to HIPAA.

(4) Kiosk - A kiosk is a device that maintains individual patient prescription drugs that were verified and labeled at the home pharmacy. A home pharmacy may only use the kiosk with prior approval of a patient. A kiosk located on the same premises or campus of the home pharmacy shall operate under the same license as the home pharmacy. However, a kiosk must be permitted with the Board if it is located elsewhere.

A kiosk shall:

a) When located on the same premises or campus as the pharmacy, inform a patient, if he or she is using the device when the pharmacy is open, that the patient may address questions and concerns regarding the prescription to a pharmacist at the pharmacy;

b) When not located on the same premises or campus as the pharmacy, inform a patient, if he or she is using the device when the pharmacy is closed, that he or she may immediately direct any questions and concerns regarding the prescription to a licensed pharmacist via a pharmacy provided audio/video link;

c) Inform a patient that a prescription is not available to be delivered by the device if the pharmacist has determined that he or she desires to counsel the patient in person regarding the prescription.

Section 3. (1) A pharmacy may use an automated pharmacy system or kiosk to deliver prescriptions to a patient when the device:

a) Is secured against a wall or floor;

b) Provides a method to identify the patient and delivers the prescription only to that patient or the patient's authorized agent;

c) Has adequate security systems and procedures to prevent unauthorized access, to comply with federal and State regulations, and to maintain patient confidentiality;

d) Records the time and date that the patient removed the prescription from the system.

(2) A licensed automated pharmacy system shall not be utilized by prescribers. Nothing in this Section shall prevent a prescriber from utilizing an automated pharmacy system in connection with his or her own dispensing. However, a prescriber may not utilize or access an automated pharmacy system permitted pursuant to this Section.

(3) All pharmacists performing services in support of a remote dispensing pharmacy site, remote consultation site, automated pharmacy system or kiosk must display a copy or electronic image of their permits at the remote site where they provide services, or shall otherwise make their permit visible to the patient, and be permitted in this State, unless employed by a pharmacy permitted in Kentucky as a nonresident pharmacy, in which case, the pharmacist providing the services shall hold an active license as a pharmacist in the state in which the nonresident pharmacy is located and only the pharmacist-in-charge of the remote site must be licensed in Kentucky.

(4) No remote site may be open when the home pharmacy is closed, unless a pharmacist employed or contracted by the home pharmacy, or by a pharmacy contracted with the home pharmacy, is present at the remote site or is remotely providing supervision and consultation as required under this Section.

The council approved and added the proposed definitions to the regulation. They directed Anthony Gray, Board Counsel to provide a definition for remote consultation site. Michael Wyant moved to approve the document with the proposed changes. Tony Tagavi seconded, and the motion passed unanimously. Michael Wyant moved to send the proposed regulation to the inspection staff for comments. These comments will be reviewed at the next meeting of the Advisory Council. Tony Tagavi moved to add and approve the following definitions:

“Remote Consultation Site” means a location, other than that of the home pharmacy, where prescriptions filled at the home pharmacy are stored and dispensed by a certified pharmacy technician under the direct, remote supervision of a pharmacist located at, or contracted with, the home pharmacy.

“Store and forward” means a video or still image record which is saved electronically for future review.

Tyler Bright seconded, and the motion passed unanimously.

Chairperson Martin polled the council for a preferred date of the next meeting. The next meeting will be March 5, 2020 at the Board office.

The meeting was adjourned at 1:17 p.m. by motion of Mike Wyant and seconded by Tyler Bright. The vote was unanimous.

Matt Martin, Chair