

Kentucky Board of Pharmacy Advisory Council

Kentucky Board of Pharmacy
via teleconferencing at

<https://us02web.zoom.us/j/84239983405?pwd=bWVtWmh5ZEoxYkF6ZDV5UEpOK0tTdz09>

Meeting ID: 842 3998 3405

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Dial by your location

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Meeting ID: 842 3998 3405

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June 11, 2020

9:00 a.m.

Agenda

- I. Call to Order
- II. Opening remarks by Chair Matt Martin
- III. Approval of Minutes from May 21, 2020
- IV. Discussion items:
 - A. Telepharmacy
 - B. Enhanced Safety Packaging

“Child Fatality and Near Fatality Panel – Request for enhanced safety packaging [blister packs] Larry Hadley and Katie Busroe presented a request from the Program Review and Investigations Committee at LRC for enhanced safety packaging for commonly used prescription drugs. Craig Martin moved to refer this to the Advisory Council. Peter Cohron seconded, and the motion passed unanimously. *The charge to the council is to review and consider the recommendations presented in the request from the Child Fatality and Near Fatality Panel.* John Fuller requested the council also consider the cost involved with the implementation of the enhanced safety packaging.”
- V. Adjournment

KENTUCKY BOARD OF PHARMACY

via teleconference using Zoom

ADVISORY COUNCIL

June 11, 2020

9:00 a.m.

MINUTES

Chairperson Matt Martin called the meeting to order at 9:04a.m. Members present: Shannon Stiglitz; Tony Tagavi; Chris Clifton; Jason Poe [connected at 9:24 a.m.]; Wes Rowe and Mike Wyant. Absent: Tyler Bright and Kelly Whitaker. Staff: Larry Hadley, Executive Director; Katie Busroe, Pharmacy Inspections and Investigations Supervisor; Darla Sayre, Executive Staff Advisor and Anthony Gray, Board Counsel.

There were approximately 25 attendees on the teleconference. The following attendees requested their names be listed: Leon Claywell.

Chris Clifton moved to accept the minutes of the May 21, 2020 meeting. Mike Wyant seconded, and the motion passed unanimously.

Telepharmacy Discussion began with a video clip of Governor Andy Beshear's afternoon COVID-19 briefing dated June 8th regarding the accessibility of healthcare to Kentuckians. Governor Beshear stated that individuals should not be required to take multiple buses in order to obtain healthcare. Those individuals expressing concerns with the proposed regulation were; Shannon Stiglitz, Leon Claywell, Rosemary Smith, Larry Stovall and State Representative Steve Sheldon.

After discussion, the following motions were made to the proposed regulation:

1. Shannon Stiglitz moved to change 'kiosk' to 'Prescription Delivery Locker' throughout the entirety of the proposed regulation. Chris Clifton seconded, and the motion passed unanimously.
2. Tony Tagavi moved to require the managing pharmacy of the prescription delivery locker be located within a 45 mile radius of the device. Jason Poe seconded, and the motion passed with Wes Rowe and Shannon Stiglitz voting no.

Upon the conclusion of the proposed regulation review, Mike Wyant moved to send the proposed regulation [attached] for Board review at its July 29th Board meeting. Chris Clifton seconded, and the motion passed with unanimously.

The next scheduled meeting of the Advisory Council will be June 18, 2020 at 1:00 p.m. via teleconference.

On motion by Chris Clifton, seconded by Shannon Stiglitz and passed unanimously, Chairperson Martin adjourned the meeting at 12:27 p.m.

1 201 KAR 2:???. Telehealth for the provision of pharmacy services

2 RELATES TO:

3 STATUTORY AUTHORITY:

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

8 Section 1. Definitions.

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

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

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

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

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

21 (c) Automated pharmacy system shall have the same definition as KRS 315.295(1)(a).

“Prescription Delivery Locker” 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 shall be located within 45 miles of the remote dispensing site. The managing pharmacy must be physically located in Kentucky. 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 a barcode is not applicable, the pharmacy shall utilize a different verification system that is documented in the prescription record and verified by the pharmacist. The technician shall scan both the stock bottle and the label of the dispensed drug to verify that the drug dispensed is the same as the drug in the stock bottle for each prescription dispensed.

(e) A pharmacist shall counsel on the original prescription that is not a continuation of therapy, and on refills if there are any changes. An offer of counseling shall be required for all refills without any changes. Counseling must be done by a pharmacist via video link and audio link before the drug or drug-related device is dispensed. The pharmacist providing counseling shall be employed and have access to all relevant patient information maintained by the pharmacy.

a) Prescription pickup and counseling pharmacist must be documented.

b) A pharmacist-in-charge or his or her designated pharmacist must complete monthly inspections of the remote dispensing site pharmacy. The inspection report must be available on site for inspection by a designated agent of the Board. A pharmacist employed or contracted by the pharmacy shall be physically

1 available at the remote dispensing site pharmacy given a twelve hour notice at the request of a designated
2 agent of the Board.

3 c) The remote dispensing site pharmacy must maintain a perpetual inventory of all controlled substances
4 at the remote dispensing site pharmacy. A reconciliation of the perpetual inventory shall be done by a
5 pharmacist during the monthly inspection.

6 d) There shall be a working computer link, video link and audio link to a pharmacist at a pharmacy
7 whenever the remote dispensing site pharmacy is open to the public unless a pharmacist is physically present.
8 The communication link must be checked daily and the remote dispensing site pharmacy must be closed if the
9 link malfunctions, unless a pharmacist is physically present at the remote dispensing site pharmacy.

10 1. The remote dispensing site pharmacy shall only be staffed with a pharmacy technician[s] that have a
11 minimum of 2000 hours of pharmacy technician experience and are currently a nationally certified pharmacy
12 technician as defined in 201 KAR 2:045 Section 1 with the knowledge necessary to use computer audio/video
13 link for dispensing and consultation to occur.

14 2. All pharmacy personnel at the remote dispensing site pharmacy must wear a badge with their name
15 and title.

16 3. New prescriptions received at the remote dispensing site pharmacy shall be entered into the pharmacy
17 system with all interpretation, evaluation, implementation of the prescription; responsibility for dispensing;
18 participation of drug and drug-related devices selection; drug evaluation, utilization or regimen review;
19 maintenance of pharmacy records; provision of patient counseling and professional acts, decisions or services
20 being performed by a pharmacist at the pharmacy unless a pharmacist is physically present at the remote
21 dispensing site pharmacy.

22 4. Each pharmacist at the pharmacy shall direct no more than 1 remote dispensing site pharmacy.

23 e) The remote dispensing site pharmacy shall have one or more signs, prominently posted in every
24 prescription pick-up area and clearly visible to the public, informing the public that the location is a remote

dispensing site pharmacy under the direction a pharmacist at another location. Signage shall include the name, location, and telephone number of the managing pharmacy. The remote dispensing site pharmacy shall also prominently post the days and times that the remote dispensing site pharmacy is open for business.

f) The remote dispensing site pharmacy shall have a private, secure area for patient consultation, exclusive of any waiting area with electronic equipment capable for audio and video live feed for patient counseling.

g) The remote dispensing site pharmacy shall not exceed an average of 150 prescriptions per business day based on a one year average. If the site exceeds this average, they shall not be eligible for a remote dispensing site pharmacy permit.

h) There shall be written policies and procedures to provide for the functioning of a remote dispensing site pharmacy. The policies and procedures shall include, at a minimum:

- a. Monthly inspection criteria;
- b. Security; and
- c. System operation.

i) The pharmacist-in-charge of a remote dispensing site pharmacy shall comply with 201 KAR 2:205, except that the pharmacist-in-charge shall be exempt from the requirements of 201 KAR 2:205, Section 2(2).

j) The remote dispensing site pharmacy shall not compound without a pharmacist on site.

k) Surveillance technology shall be video only with the capability of recording. Recordings shall be stored a minimum of 45 days.

(2) Remote Consultation Site Pharmacy

a) A remote consultation site pharmacy shall have no prescription inventory.

b) Only filled prescriptions excluding Schedule II drugs, -from the managing pharmacy, with final patient labeling attached are allowed at a remote consultation site pharmacy.

- c) The remote consultation site pharmacy shall only be staffed with a pharmacy technician[s] that have a minimum of 2000 hours of pharmacy technician experience and are currently a nationally certified pharmacy technician as defined in 201 KAR 2:045 Section 1 with the knowledge necessary to use computer audio/video link for dispensing and consultation to occur.
- d) All pharmacy personnel at the remote consultation site pharmacy must wear a badge with their name and title.
- e) Written prescriptions may be received at a remote consultation site pharmacy for processing at the managing pharmacy. All written prescriptions presented at a remote consultation site pharmacy shall be delivered to the managing pharmacy within 72 hours.
- f) Prescription pickup and counseling pharmacist must be documented.
- g) The remote consultation site pharmacy shall have a private, secure area for patient consultation, exclusive of any waiting area with electronic equipment capable for audio and video live feed for patient counseling.
- h) A pharmacist shall counsel on the original prescription that is not a continuation of therapy, and on refills if there are any changes. An offer of counseling shall be required for all refills without any changes. Counseling must be done by a pharmacist via video link and audio link before the drug or drug-related device is released. The pharmacist providing counseling must be employed with the managing pharmacy and have access to all relevant patient information maintained by the managing pharmacy.
- i) The remote consultation site pharmacy shall have one or more signs, prominently posted in every prescription pick-up area and clearly visible to the public, informing the public that the location is a remote consultation site pharmacy under the direction of a pharmacist at another location. Signage shall include the name, location, and telephone number of the managing pharmacy. The remote consultation site pharmacy shall also prominently post the days and times that the remote consultation site pharmacy is open for business.

- 1 l) There shall be a working computer link, video link and audio link to a pharmacist at a pharmacy
2 whenever the remote consultation site pharmacy is open to the public unless a pharmacist is physically
3 present. The communication link must be checked daily and the remote consultation site pharmacy must be
4 closed if the link malfunctions, unless a pharmacist is physically present at the remote consultation site
5 pharmacy.
- 6 m) Surveillance technology shall be video only with the capability of recording. Recordings shall be stored
7 a minimum of 45 days.
- 8 n) Each pharmacist at the managing pharmacy shall direct no more than 1 remote consultation site
9 pharmacy.
- 10 o) A pharmacist-in-charge or his or her designated pharmacist must complete monthly inspections of the
11 remote consultation site pharmacy. The inspection report must be available on site for inspection by a
12 designated agent of the Board. A pharmacist employed or contracted by the managing pharmacy shall be
13 physically available at the remote consultation site pharmacy given a twelve hour notice at the request of a
14 designated agent of the Board.
- 15 p) There shall be written policies and procedures to provide for the functioning of a remote dispensing
16 site pharmacy. The policies and procedures shall include, at a minimum:
- 17 a. Monthly inspection criteria to include return of prescriptions not picked up to the managing
18 pharmacy;
 - 19 b. Security; and
 - 20 c. System operation.
- 21 q) The pharmacist-in-charge of a remote consultation site pharmacy shall comply with 201 KAR 2:205,
22 except that the pharmacist-in-charge shall be exempt from the requirements of 201 KAR 2:205, Section 2(2).
- 23 (3) Prescription Delivery Locker - A prescription delivery locker is an automated pharmacy device that
24 maintains individual patient prescription drugs that were verified and labeled at the pharmacy. A

pharmacy may only use the prescription delivery locker with prior approval of a patient. A prescription delivery locker shall be located within 45 miles of the managing pharmacy and operate under the same permit as the pharmacy.

A prescription delivery locker shall:

(a) Inform a patient, if he or she is using the device 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;

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

(c) There shall be written policies and procedures to provide for the functioning of a prescription delivery locker. The policies and procedures shall include, at a minimum:

1. Monthly inspection criteria to include return of prescriptions not picked up to the managing pharmacy;
2. Security; and
3. System operation; and
4. Temperature control; and
5. Stocking of prescription delivery locker; and
6. Return of prescription to managing pharmacy.

(d) The pharmacist in charge shall be the pharmacist in charge of the managing pharmacy.

(e) A pharmacist-in-charge or his or her designated pharmacist must complete monthly inspections of the prescription delivery locker. The inspection report must be available on site for inspection by a designated agent of the Board. A pharmacist employed or contracted by the managing pharmacy shall be physically available at the prescription delivery locker given a twelve hour notice at the request of a designated agent of the Board.

(f) The prescription delivery locker shall have one or more signs prominently posted informing the public that the location is a prescription delivery locker under the direction of a pharmacist at another location.

Signage shall include the name, location, and telephone number of the managing pharmacy. The prescription delivery locker shall also prominently post the days and times that the prescription delivery locker is available for pickups.

Section 3. (1) A pharmacy may use a prescription delivery locker to deliver prescriptions to a patient when the prescription delivery locker:

(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 prescription delivery locker.

(2) All pharmacists performing services in support of a remote dispensing site pharmacy or remote consultation site pharmacy 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.