

# Kentucky Board of Pharmacy Advisory Council

Kentucky Board of Pharmacy  
via teleconferencing at  
<https://zoom.us/j/753792891>  
Meeting ID: 753 792 891

April 6, 2020  
9:00 am

## Agenda

- I. Call to Order
- II. Opening remarks by Chair Matt Martin
- III. Approval of Minutes from March 5, 2020
- IV. Discussion items:
  - A. Telepharmacy
- V. Adjournment

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,  
5 medicines, and pharmaceuticals be dispensed or manufactured by a licensed pharmacist. KRS  
6 315.310 authorizes the board to regulate telehealth. This administrative regulation establishes  
7 the standards for the operation of this type of 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 4  
12 types of telepharmacy.

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

18 (b) "Remote Consultation Site Pharmacy" means a permitted pharmacy; other than that of the  
19 managing pharmacy, where prescriptions dispensed at the managing pharmacy, excluding  
20 Schedule II controlled substances, are stored and provided by a nationally certified pharmacy

1 technician under the direction of a pharmacist located at, or contracted with, the managing  
2 pharmacy.

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

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

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

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

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

15 Section 2. Each remote dispensing site pharmacy and remote consultation site pharmacy shall  
16 be a separately permitted telepharmacy. Each managing pharmacy with an automated  
17 pharmacy system shall notify the Board prior to each installation or removal of an automated  
18 pharmacy system. Managing pharmacies that are located outside of Kentucky must be  
19 permitted as a nonresident pharmacy. All pharmacists providing telehealth services in Kentucky  
20 shall be Kentucky licensed pharmacists.

1 (1) Remote Dispensing Pharmacy Site

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

4 1. All pharmacy records shall be maintained at the remote dispensing site pharmacy.

5 2. Prescriptions dispensed at the remote dispensing site pharmacy shall be distinguishable  
6 from those dispensed from the managing pharmacy.

7 3. Daily reports must be separated for the managing pharmacy and remote dispensing site  
8 pharmacy.

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

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

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

17 1. Pharmacist and pharmacy technician initials or unique identifiers must appear on the  
18 prescription record and the prescription label.

19 2. The prescription label shall bear the name and address of the managing pharmacy and  
20 the name and address of the remote dispensing site pharmacy.

21 3. The remote dispensing site pharmacy shall utilize a barcode system for electronic  
22 verification. If the stock bottle does not have a barcode, the pharmacy shall utilize a different

1 electronic verification system **that is documented in the prescription record.** The technician  
2 shall scan both the stock bottle and the label of the dispensed drug to verify that the drug  
3 dispensed is the same as the drug in the stock bottle for each prescription dispensed.

4 (e) A pharmacist shall counsel on the initial **original** prescription **that is not a continuation of**  
5 **therapy**, and on refills if there are any medication therapy changes. An offer of counseling shall  
6 be required for all refills **without any changes**. Counseling must be done by a pharmacist via  
7 video link and audio link before the drug or medical **drug-related** device is released **dispensed**.  
8 The pharmacist providing counseling, pursuant to this subsection, must be employed or  
9 contracted by the managing pharmacy or by a pharmacy contracted with the managing  
10 pharmacy and have access to all relevant patient information maintained by the managing  
11 pharmacy. **(or: require a pharmacist at the managing pharmacy to counsel and not let this be**  
12 **a contracted pharmacist).**

13 **a) Prescription pickup and counseling must be documented.**

14 **b)** A pharmacist-in-charge or his or her designated pharmacist must complete monthly  
15 inspections of the remote **dispensing site pharmacy**. ~~Inspection criteria must be included in the~~  
16 ~~policies and procedures for the site.~~ **(Moved this to the PnP section).** The inspection report  
17 must be available on site for pharmacy investigator inspection **by a designated agent of the**  
18 **Board**. A pharmacist employed or contracted by the managing pharmacy shall be physically  
19 available at the remote **dispensing site pharmacy** given a twelve hour notice. **(Is this in**  
20 **reference to the inspection or at any time? If it is at any time, it needs to be a new point and**  
21 **not in with the inspection item).**

- 1 c) ~~Controlled substances excluding CII shall be kept at the remote site with a perpetual~~  
2 ~~inventory reviewed onsite monthly by a pharmacist. The remote dispensing site pharmacy~~  
3 ~~must maintain a perpetual inventory of all controlled substances at the remote dispensing~~  
4 ~~site pharmacy.~~ A reconciliation of the perpetual inventory shall be done by a pharmacist  
5 during ~~at~~ the monthly inspection.
- 6 d) There shall be a working computer link, video link and audio link to a pharmacist at a  
7 ~~managing pharmacy whenever the prescription area~~ remote dispensing site pharmacy is open  
8 to the public unless a pharmacist is physically present. The communication link must be  
9 checked daily and the remote dispensing site pharmacy must be closed if the link malfunctions,  
10 unless a pharmacist is physically present at the remote dispensing site pharmacy. The  
11 ~~technology used for pharmacist supervision be both video and audio with the capability of~~  
12 ~~recording video only. Recordings shall be stored a minimum of 45 days. The audio of any~~  
13 ~~interaction with patient will not be recorded due to HIPAA. (Not sure this is necessary or what~~  
14 ~~exactly is being recorded)~~
- 15 1. The pharmacy technician located at the remote dispensing site pharmacy shall have a  
16 minimum of 2000 hours of pharmacy work experience as a nationally certified pharmacy  
17 technician as defined in 201 KAR 2:045 Section 1 with the knowledge necessary to use  
18 computer audio/video link for dispensing and consultation to occur.
- 19 2. All pharmacy personnel at the remote dispensing site pharmacy must wear a badge with  
20 their name and title. (Is there a limit to the number of people that can work at a remote  
21 dispensing pharmacy site? Do they all have to be certified technicians?)

- 1 3. New prescriptions received at the remote dispensing site pharmacy shall be entered  
2 into the remote computer **pharmacy** system with all verification, interaction, checking and  
3 profile review **all interpretation, evaluation, implementation of the prescription; responsibility**  
4 **for dispensing; participation of drug and drug-related devices selection; drug evaluation,**  
5 **utilization or regimen review; maintenance of pharmacy records; provision of patient**  
6 **counseling and professional acts, decisions or services being performed (this is the definition**  
7 **of the practice of pharmacy from KRS 315.010)** by the **a** pharmacist at the managing pharmacy  
8 unless a pharmacist is physically present **at the remote dispensing site pharmacy.**
- 9 4. Each pharmacist at the managing pharmacy may electronically supervise **direct** no more  
10 than 1 remote **dispensing site pharmacy.**
- 11 e) The facility **remote dispensing site pharmacy** ~~must~~ **shall** have one or more signs,  
12 prominently posted in every prescription pick-up area and clearly visible to the public, ~~shall~~  
13 informing the public that the location is a remote dispensing site pharmacy supervised by  
14 **under the direction** a pharmacist at a remote **another** location. Signage shall include the name,  
15 location, and telephone number of the managing pharmacy. The remote dispensing site  
16 pharmacy shall also prominently post the days and times that the remote dispensing site  
17 pharmacy is open for business.
- 18 f) The facility **remote dispensing site pharmacy** shall have an **a private, secure** area for  
19 patient consultation, exclusive of any waiting area ~~that is private, secure and HIPAA compliant~~  
20 with electronic equipment capable for audio and video live feed for patient counseling.

- 1 g) The remote dispensing site pharmacy shall not exceed an average of 150 prescriptions  
2 per business day based on a one year average. If the site exceeds this average, they shall obtain  
3 a pharmacy permit. **Not be eligible for a remote dispensing site pharmacy permit.**
- 4 h) **There shall be written policies and procedures to provide for the functioning of a**  
5 **remote dispensing site pharmacy. The policies and procedures shall include, at a minimum:**
- 6 a. **Monthly inspection criteria;**
- 7 b. **Security; and**
- 8 c. **System operation.**
- 9 i) **The pharmacist-in-charge of a remote dispensing site pharmacy shall comply with 201**  
10 **KAR 2:205, except that the pharmacist-in-charge shall be exempt from the**  
11 **requirements of 201 KAR 2:205, Section 2(2).**

12 j) **Can the technician at the remote dispensing site pharmacy compound prescriptions?**

13 **This is not addressed.**

14 (2) Remote Consultation Site **Pharmacy**

- 15 a) These sites **A remote consultation site pharmacy shall** have no prescription inventory.
- 16 b) Only filled prescriptions excluding Schedule II drugs, filled at the home **from the**  
17 **managing** pharmacy, with final patient labeling attached are allowed at these sites **a remote**  
18 **consultation site pharmacy.**
- 19 c) **These sites must be staffed with a certified pharmacy technician who shall have a** **The**  
20 **pharmacy technician located at the remote consultation site pharmacy shall have a** minimum  
21 of 2000 hours of pharmacy work experience as a nationally certified pharmacy technician, **as**  
22 **defined in 201 KAR 2:045 Section 1,** with the knowledge necessary to use computer audio/video

1 link for dispensing and consultation to occur. ~~Pharmacist and pharmacy technician initials or~~  
2 ~~unique identifiers must appear on the prescription record and the prescription label.~~ Not sure  
3 how this would work or if necessary since the prescription is being filled at the managing  
4 pharmacy and this tech is only handing it out.

5 **d) All pharmacy personnel at the remote dispensing site pharmacy must wear a badge with**  
6 **their name and title.** (Is there a limit to the number of people that can work at a remote  
7 dispensing pharmacy site? Do they all have to be certified technicians?)

8 d) Written prescriptions may be received at a remote consultation site **pharmacy for**  
9 **processing at the managing pharmacy.** All written prescriptions presented at a remote  
10 consultation site **pharmacy** shall be delivered to the ~~managing~~ pharmacy within 72 hours.

11 e) ~~Records of~~ **P**rescription pickup and counseling must be documented.

12 f) The facility **remote consultation site pharmacy** shall have an **private, secure** area for  
13 patient consultation, exclusive of any waiting area ~~that is private, secure and HIPAA compliant~~  
14 with electronic equipment capable for audio and video live feed for patient counseling.

15 g) A pharmacist shall counsel on the initial **original** prescription **that is not a continuation**  
16 **of therapy,** and on refills if there are any ~~medication therapy~~ changes. An offer of counseling  
17 shall be required for all refills **without any changes.** Counseling must be done by a pharmacist  
18 via video link and audio link before the drug or ~~medical~~ **drug-related** device is released. The  
19 pharmacist providing counseling, ~~pursuant to this subsection,~~ must be employed or contracted  
20 by the ~~managing~~ pharmacy or by a pharmacy contracted with the managing pharmacy and have  
21 access to all relevant patient information maintained by the managing pharmacy.

- 1 h) The facility must **remote consultation site pharmacy shall** have one or more signs,  
2 prominently posted in every prescription pick-up area and clearly visible to the public, ~~shall~~  
3 **informing** the public that the location is a remote consultation site **pharmacy supervised by**  
4 **under the direction of** a pharmacist at a remote **another** location. Signage shall include the  
5 name, location, and telephone number of the managing pharmacy. The remote consultation  
6 site **pharmacy** shall also prominently post the days and times that the remote consultation site  
7 **pharmacy** is open for business.
- 8 k) There shall be a working computer link, video link and audio link to a pharmacist at a  
9 managing pharmacy whenever the prescription area **remote consultation site pharmacy** is  
10 open to the public unless a pharmacist is physically present. The communication link must be  
11 checked daily and the remote **consultation** site pharmacy must be closed if the link  
12 malfunctions, unless a pharmacist is physically present at the remote **consultation** site  
13 **pharmacy**. ~~The technology used for pharmacist supervision be both video and audio with the~~  
14 ~~capability of recording video only. Recordings shall be stored a minimum of 45 days. The audio~~  
15 ~~of any interaction with patient will not be recorded due to HIPAA. (Not sure this is necessary or~~  
16 ~~what exactly is being recorded)~~
- 17 l) **Is there a limit to the number of remote consultation site pharmacies a managing**  
18 **pharmacy may direct like there is for the remote dispensing site pharmacy?**
- 19 m) **A pharmacist-in-charge or his or her designated pharmacist must complete monthly**  
20 **inspections of the remote consultation site pharmacy. The inspection report must be available**  
21 **on site for inspection by a designated agent of the Board.**

- 1 n) **There shall be written policies and procedures to provide for the functioning of a**  
2 **remote dispensing site pharmacy. The policies and procedures shall include, at a minimum:**
- 3     a. **Monthly inspection criteria to include return of prescriptions not picked up to the**  
4 **managing pharmacy;**
- 5     b. **Security; and**
- 6     c. **System operation.**
- 7o) **The pharmacist-in-charge of a remote consultation site pharmacy shall comply with 201 KAR**  
8 **2:205, except that the pharmacist-in-charge shall be exempt from the requirements of 201**  
9 **KAR 2:205, Section 2(2).**
- 10 (3) Automated ~~Pharmacy~~ **Dispensing** System is defined by ~~KRS 315.295(1)(a)~~ **201 KAR 2:370**  
11 **Section 1(1)** shall be located at only 24 hour urgent care or **24 hour** emergency departments.
- 12 a) These devices shall maintain a prescription drug inventory that is controlled electronically  
13 by the ~~managing~~ pharmacy or, when operated by a pharmacy contracted with the ~~managing~~  
14 pharmacy, by the contracted pharmacy, which shall be utilized to dispense patient specific  
15 prescriptions.
- 16 b) These systems shall have prescription inventory, which shall be secured in an automated  
17 ~~pharmacy~~ **dispensing** system and electronically connected to and controlled by the  
18 ~~managing~~ pharmacy.
- 19 c) A pharmacist shall approve all the prescriptions ~~orders~~ before they are released from the  
20 automated ~~pharmacy~~ **dispensing** system.
- 21 d) Dispensing and counseling are performed by a pharmacist employed or contracted by the  
22 ~~managing~~ pharmacy via audio and video link.

- 1 ~~e) All filled prescription shall have a label that meets the requirements of the ? attached to the~~  
2 ~~final drug container.~~ **All prescriptions shall be appropriately labeled, including patient**  
3 **specific information, prior to being released from the automated dispensing system.**
- 4 f) The pharmacist-in-charge of the ~~managing~~ pharmacy, or a designated ~~registrant~~  
5 **pharmacist**, shall conduct and complete monthly inspections of the automated pharmacy  
6 system. ~~Inspection criteria shall be included in the policies and procedures for the site.~~  
7 **(Moved to PnP section)** The report shall be available to the pharmacy investigators **for**  
8 **inspection by a designated agent of the Board** when requested.
- 9 ~~g) The automated pharmacy system shall be permitted with the Board as an automated~~  
10 ~~pharmacy system and will be subject to inspection by pharmacy investigators.~~  
11 ~~Notwithstanding that the automated pharmacy system shall possess a license, the home~~  
12 ~~pharmacy shall remain responsible for inventory control and billing. For purposes of~~  
13 ~~inspections, a pharmacist with access to the system shall be available at the site within~~  
14 ~~twelve hours. In the event the Board determines that the automated pharmacy system~~  
15 ~~poses a significant risk of patient harm, the automated pharmacy system shall be disabled~~  
16 ~~until such time as the pharmacist with access to the system is available to the site.~~
- 17 **h) Medication dispensed at the automated pharmacy system site may only be packaged by a**  
18 **licensed manufacturer or repackager, or prepackaged by a licensed pharmacy in compliance**  
19 **with this Section. Prepackaging shall occur at the home pharmacy, a pharmacy sharing**  
20 **common ownership with the home pharmacy, or a pharmacy that has contracted with the**  
21 **home pharmacy to perform prepackaging services. The following requirements shall apply**  
22 **whenever medications are prepackaged by a pharmacy other than the home pharmacy:**

- 1 1. The prepackaging pharmacy shall be licensed in Kentucky as a resident or nonresident  
2 pharmacy.
- 3 2. The prepackaging pharmacy shall share a common database with the home pharmacy,  
4 or have in place an electronic or manual process to ensure that both pharmacies have  
5 access to records to verify the identity, lot numbers and expiration dates of the  
6 prepackaged medications stocked in the automated pharmacy system.
- 7 3. The prepackaging pharmacy shall maintain appropriate records to identify the  
8 responsible pharmacist who verified the accuracy of the prepackaged medication. **Not**  
9 **sure this is allowed by FDA.**
- 10 i) Written prescriptions may be received at an automated pharmacy system. All written  
11 prescriptions presented to an automated pharmacy system shall be scanned utilizing  
12 imaging technology that permits the reviewing pharmacist to determine its authenticity.  
13 The sufficiency of the technology shall be determined by the Board. If sufficient technology  
14 is not used, the written prescriptions shall be delivered to the home pharmacy and  
15 reviewed by a pharmacist prior to being dispensed to the patient.
- 16 j) A pharmacist shall counsel on the initial **original** prescription **that is not a change of**  
17 **therapy**, and on refills **(are there going to be refills ever in the ADS at an urgent care or**  
18 **ED?)** if there are any medication therapy changes. An offer of counseling shall be required  
19 for all refills **without changes**. Counseling must be done by a pharmacist via video link and  
20 audio link before the drug or medical device is released. The pharmacist providing  
21 counseling, pursuant to this subsection, must be employed or contracted by the managing

1 pharmacy or by a pharmacy contracted with the ~~managing~~ pharmacy and have access to all  
2 relevant patient information maintained by the ~~managing~~ pharmacy.

3 ↵ There shall be a working computer link, video link and audio link to a pharmacist at a ~~home~~  
4 the managing pharmacy whenever the ~~prescription area~~ automated dispensing device is  
5 open to the public unless a pharmacist is physically present. The communication link must  
6 be checked daily and the ~~remote site pharmacy must be closed~~ automated dispensing  
7 device must not be used if the link malfunctions, unless a pharmacist is physically present at  
8 the remote site automated dispensing device. The technology used for pharmacist  
9 supervision be both video and audio with the capability of recording video only. Recordings  
10 shall be stored a minimum of 45 days. The audio of any interaction with patient will not be  
11 recorded due to HIPAA. Not sure this is necessary or what would be recorded. Also, if the  
12 ADS isn't working, not sure having a pharmacist stand beside the ADS is any help.

13 ↵ Who can and how is the ADS to be stocked? Only by a pharmacist? Look at 201 KAR 2:370

14 ↵ Need a PnP sections. Look at 201 KAR 2:370.

15 ↵ Is there a limit to the number of ADSs a managing pharmacy may oversee?

16 (4) Kiosk - A kiosk is a automated pharmacy device that maintains individual patient  
17 prescription drugs that were verified and labeled at the ~~managing~~ pharmacy. A ~~managing~~  
18 pharmacy may only use the kiosk with prior approval of a patient. A kiosk located on the  
19 same premises or campus of the ~~managing~~ pharmacy shall operate under the same ~~license~~  
20 permit as the ~~managing~~ pharmacy. However, a kiosk must be permitted with the Board if it  
21 is not located elsewhere on the same premises or campus.

22 A kiosk shall:

- 1 a) When located on the same premises or campus as the managing pharmacy, inform a  
2 patient, if he or she is using the ~~device~~ kiosk when the pharmacy is open, that the patient  
3 may address questions and concerns regarding the prescription to a pharmacist at the  
4 pharmacy;
- 5 b) When not located on the same premises or campus as the pharmacy, inform a patient, if he  
6 or she is using the device when the pharmacy is closed, that he or she may immediately  
7 direct any questions and concerns regarding the prescription to a licensed pharmacist via a  
8 pharmacy provided audio/video link; **What about when the pharmacy is open? How does  
9 this work? Should it be if the pharmacy is opened or closed? Can the kiosk be used on the  
10 same premises as the managing pharmacy if the managing pharmacy is closed? What is  
11 that signage?**
- 12 c) Inform a patient that a prescription is not available to be delivered by the ~~device~~ kiosk if the  
13 pharmacist has determined that he or she desires to counsel the patient in person regarding  
14 the prescription.
- 15 d) **Need a policy and procedure section**
- 16 e) **Need a PIC section**
- 17 f) **Need an inspection of the kiosk section**
- 18 Section 3. (1) A pharmacy may use an automated ~~pharmacy~~ dispensing system or kiosk to  
19 deliver prescriptions to a patient when the ~~device~~ **automated pharmacy system:**
- 20 a) Is secured against a wall or floor;
- 21 b) Provides a method to identify the patient and delivers the prescription only to that patient  
22 or the patient's authorized agent;

- 1 c) Has adequate security systems and procedures to prevent unauthorized access, to comply  
2 with federal and State regulations, and to maintain patient confidentiality;
- 3 d) Records the time and date that the patient removed the prescription from the automated  
4 pharmacy system.

5 (2) A licensed automated pharmacy system shall not be utilized by prescribers. Nothing in this  
6 Section shall prevent a prescriber from utilizing an automated pharmacy system in connection  
7 with his or her own dispensing. However, a prescriber may not utilize or access an automated  
8 pharmacy system permitted pursuant to this Section. **Not sure what this means? Needs to be**  
9 **clearer. Does this mean a prescriber can't label the prescription from the ADS?**

10 (3) All pharmacists performing services in support of a remote dispensing site pharmacy site,  
11 remote consultation site pharmacy, ~~automated pharmacy system or kiosk~~ **(Not sure how this**  
12 **would work because there may be multiple pharmacist involved. Are the licenses going to**  
13 **hang on the machine?)** must display a copy or electronic image of their permits at the remote  
14 site where they provide services, or shall otherwise make their permit visible to the patient,  
15 and ~~be permitted in this State, unless employed by a pharmacy permitted in Kentucky as a~~  
16 ~~nonresident pharmacy, in which case, the pharmacist providing the services shall hold an active~~  
17 ~~license as a pharmacist in the state in which the nonresident pharmacy is located and only the~~  
18 ~~pharmacist in charge of the remote site must be licensed in Kentucky.~~ **(This contradicts Section**  
19 **2 which says a pharmacist performing telehealth in Kentucky has to have a Kentucky pharmacist**  
20 **license.)**

21 (4) ~~No remote site may be open when the home pharmacy is closed, unless a pharmacist~~  
22 ~~employed or contracted by the home pharmacy, or by a pharmacy contracted with the home~~

- 1 ~~pharmacy, is present at the remote site or is remotely providing supervision and consultation as~~
- 2 ~~required under this Section.~~ **(This is addressed elsewhere)**