

STATE OF KANSAS
KANSAS PHARMACY BOARD

**NOTICE OF PUBLIC HEARING ON
ADMINISTRATIVE REGULATIONS**

A public hearing will be conducted at 9:00 a.m., on the 10th day of March, 2011, at the University of Kansas School of Pharmacy, 2010 Becker Drive, Lawrence, Kansas 66045, to consider the proposed adoption of K.A.R. 68-17-1 through 68-17-9 by the Kansas Pharmacy Board.

This 60-day notice of the public hearing shall constitute a public comment period for the purpose of receiving written public comments on the proposed adoption of K.A.R. 68-17-1 through 68-17-9. All parties may submit written comments prior to the hearing to the Executive Secretary of the Kansas Pharmacy Board, Debra Billingsley, pharmacy@pharmacy.ks.gov or 800 SW Jackson, Suite 1414, Topeka, Kansas 66612. All interested parties will be given a reasonable opportunity to present their views orally on the regulations during the hearing. In order to give all parties an opportunity to present their views, it may be necessary to request each participant to limit any oral presentation to five minutes.

Any individual with a disability may request accommodation in order to participate in the public hearing and may request the regulation and economic impact statement in an accessible format. Requests for accommodation to participate in the hearing should be made at least five working days in advance of the hearing by contacting the Kansas Pharmacy Board, 800 SW Jackson, Suite 1414, Topeka, Kansas 66612, (785) 296-4056. Handicapped parking is located in the parking lot at the University of Kansas School of Pharmacy at 2010 Becker Drive, Lawrence, Kansas.



Proposed

K.A.R. 68-17-1 through 68-17-9 is a set of new regulations to address telepharmacy branch pharmacies. The following is a summary of the new regulations.

K.A.R. 68-17-1. Definitions. This regulation defines terms used in the telepharmacy branch pharmacy regulations.

K.A.R. 68-17-2. Status of telepharmacy branch pharmacy. This regulation addresses the status of the telepharmacy branch pharmacy and limits the number of such branch pharmacies a retail pharmacy may have.

K.A.R. 68-17-3. Requirements for approval of location. This regulation establishes the requirement that each location of a telepharmacy branch pharmacy must be approved by the Pharmacy Board and establishes criteria for approval.

K.A.R. 68-17-4. Application for approval of a telepharmacy branch pharmacy. This regulation establishes the requirement of an application for a registration of a proposed telepharmacy branch pharmacy and establishes the required content of the application.

K.A.R. 68-17-5. Equipment requirements. This regulation establishes requirements for equipment in a telepharmacy branch pharmacy and its use.

K.A.R. 68-17-6. Minimum operating requirements. This regulation establishes operating requirements which must be met when a telepharmacy branch pharmacy is open for operations and dispensing drugs.

K.A.R. 68-17-7. Minimum security requirements. This regulation establishes minimum security requirements for the physical location of the telepharmacy branch pharmacy.

K.A.R. 68-17-8. Renewal registration. This regulation establishes the requirement that the registration of a telepharmacy branch pharmacy be renewed with the renewal application of the parent pharmacy by application to the Pharmacy Board.



K.A.R. 68-17-9. Fees. This regulation establishes the fees for the registration and renewal of a registration for a telepharmacy branch pharmacy.

Copies of the regulations and the economic impact statements may be obtained from the Kansas Pharmacy Board, 800 SW Jackson, Suite 1414, Topeka, Kansas 66612, (785) 296-4056, or by accessing the Board's website at <http://www.accesskansas.org/pharmacy/leg.html>.

Debra Billingsley
Executive Secretary



Proposed

Article 17 – TELEPHARMACY BRANCH PHARMACY

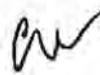
68-17-1. Definitions. (a) "Electronically verified" means that the national drug code on a manufacturer's container from which a drug is taken and on a prescription label are electronically read before dispensing to verify that the manufacturer's container and the prescription label bear the same number.

(b) "Parent pharmacy" means a retail pharmacy located in Kansas and registered by the board that is authorized by the board to operate a telepharmacy branch pharmacy using real-time data, video, and audio links.

(c) "Pharmacy counting and verification system" means a mechanical system that is capable of counting orally administered solid drugs and has a bidirectional interfacing with the parent pharmacy's electronic pharmacy management system.

(d) "Real-time," when used to describe the transmission of information through data, video, and audio links, means that the transmission is sufficiently rapid that the information is available simultaneously to the parent pharmacy and the telepharmacy branch pharmacy.

(e) "Telepharmacy branch pharmacy" means a pharmacy or other facility used for the storage and dispensing of prescription drugs that is dependent upon, stocked by, and supervised by a pharmacist in charge in another licensed Kansas retail pharmacy designated and approved by the board as the parent pharmacy. (Authorized by K.S.A. 65-1630; implementing K.S.A. 2009 Supp. 65-1642 and K.S.A. 2009 Supp. 65-1643; effective P-_____.)

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68-17-2. Status of telepharmacy branch pharmacy. Each telepharmacy branch pharmacy shall be registered as a retail pharmacy branch of an existing retail pharmacy located in the state of Kansas. Any retail pharmacy may have only one telepharmacy branch pharmacy. (Authorized by K.S.A. 65-1630; implementing K.S.A. 2009 Supp. 65-1636 and K.S.A. 2009 Supp. 65-1643; effective P- _____.)

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68-17-3. Requirements for approval of location. (a) The location of each telepharmacy branch pharmacy shall be approved by the board. Each application for location approval shall be submitted on a form provided by the board before the application specified in K.A.R. 68-17-4 is submitted.

(b) To be approved, the proposed location for a telepharmacy branch pharmacy shall meet all of the following requirements:

(1) The proposed location shall be no greater than 100 miles from the location of the parent pharmacy.

(2) The proposed location shall be at least 20 miles from a retail pharmacy.

(3) The proposed location shall have physical facilities sufficient to permit the telepharmacy branch pharmacy to meet the equipment and security requirements of these regulations.

(c) The requirements of paragraphs (b)(1) and (2) may be waived by the board for good cause. In determining whether good cause exists, the following shall be considered by the board:

(1) The extent to which pharmacy services are available to the people who would be served from the proposed location; and

(2) the difficulties those people experience in obtaining those services. (Authorized by K.S.A. 65-1630; implementing K.S.A. 2009 Supp. 65-1643; effective P-_____.)



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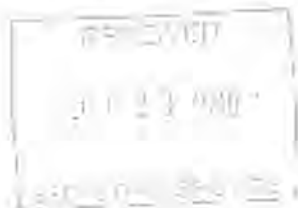
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68-17-4. Application for approval of a telepharmacy branch pharmacy. The pharmacist in charge of any retail pharmacy located in Kansas and registered by the board who wants to operate a telepharmacy branch pharmacy shall submit an application for registration of the proposed telepharmacy branch pharmacy. Each application shall be submitted on a form provided by the board and shall include the following:

- (a) Identifying information concerning the applying parent pharmacy;
- (b) identifying information concerning the designated supervising pharmacist employed at the parent pharmacy;
- (c) the address and a description of the facility in which the telepharmacy branch pharmacy is to be located;
- (d) the specific formulary to be stocked at the telepharmacy branch pharmacy, indicating for each prescription drug the name and dosage strength;
- (e) identifying information for each person located at the telepharmacy branch pharmacy who will dispense prescription drugs in accordance with the approved protocol;
- (f) protocols regarding how the telepharmacy branch pharmacy will operate and its relationship with the parent pharmacy, which shall include the following:
 - (1) The conditions under which prescription drugs will be stored, used, and accounted for;
 - (2) the method by which the drugs will be transported to the telepharmacy branch pharmacy and accounted for by the telepharmacy branch pharmacy; and
 - (3) a description of how records will be kept with respect to the following:



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- (A) The formulary;
- (B) changes in the formulary;
- (C) a record of the drugs sent by the parent pharmacy;
- (D) a record of the drugs received by the telepharmacy branch pharmacy;
- (E) a record of the drugs dispensed;
- (F) periodic inventories; and
- (G) any other record contributing to an effective audit trail with respect to the prescription drugs provided to the telepharmacy branch pharmacy;
- (g) the type of computer, video, and communication systems to be used at the telepharmacy branch pharmacy and the parent pharmacy;
- (h) written confirmation that the parent pharmacy and the pharmacist in charge assume responsibility for the telepharmacy branch pharmacy; and
- (i) a copy of the board's approval of the location for the telepharmacy branch pharmacy.

(Authorized by K.S.A. 65-1630; implementing K.S.A. 2009 Supp. 65-1643; effective

P-_____.)



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68-17-5. Equipment requirements. (a) Each telepharmacy branch pharmacy shall have the following equipment located on site:

- (1) A computer;
- (2) a scanner;
- (3) a printer;
- (4) a fax machine;
- (5) real-time communication equipment that meets the operating requirements listed

in K.A.R. 68-17-6; and

- (6) a pharmacy counting and verification system.

(b) When the telepharmacy branch pharmacy is open for business, all required equipment shall be fully operational.

(c) Any pharmacy technician, pharmacy student, or pharmacy intern may enter the telepharmacy branch pharmacy to activate the data, video, or audio links, but drugs shall not be received, counted, packaged, or dispensed by a pharmacy technician, pharmacy student, or pharmacy intern unless that person's activities are being supervised by a pharmacist either in person or at the parent pharmacy utilizing the data, video, and audio links. (Authorized by K.S.A. 65-1630; implementing K.S.A. 2009 Supp. 65-1642; effective P-_____.)



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68-17-6. Minimum operating requirements. (a) A telepharmacy branch pharmacy shall not remain open for business if an interruption occurs in any of the data, video, or audio links. Whenever an interruption in any of the data, video, or audio links occurs, no prescription shall be dispensed and a sign shall be posted noting the closure and an estimated time until resumption of services can be expected.

(b) Under no circumstance shall the telepharmacy branch pharmacy remain open for business without a pharmacy technician, pharmacy student, pharmacy intern, or pharmacist on duty.

(c) Each pharmacy technician, pharmacy student, and intern shall be supervised by a pharmacist at the parent pharmacy utilizing the data, video, and audio links.

(d) Any pharmacy technician, pharmacy student, or pharmacy intern may receive drugs at the telepharmacy branch pharmacy only if the activities of the pharmacy technician, pharmacy student, or pharmacy intern are being supervised by a pharmacist either in person or at the parent pharmacy utilizing the data, video, and audio links.

(e) Data entry may be performed at the parent pharmacy or at the telepharmacy branch pharmacy. Each entry performed at the telepharmacy branch pharmacy shall be verified by a pharmacist at the parent pharmacy before the label is printed at the telepharmacy branch pharmacy.

(f) All prescriptions processed at the telepharmacy branch pharmacy shall be scanned and sequentially numbered.



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(g) All prescriptions processed at the telepharmacy branch pharmacy and prescription information shall be capable of being displayed on a computer terminal at both the telepharmacy branch pharmacy and the parent pharmacy. Scanned prescriptions shall be available for review for each new prescription and each refill prescription processed at the telepharmacy branch pharmacy in real time.

(h) All patient demographic information shall be viewable at both the telepharmacy branch pharmacy and parent pharmacy in real time.

(i) Each orally administered solid drug dispensed at the telepharmacy branch pharmacy shall be counted by a pharmacy counting and verification system.

(j) Each drug, including orally administered solid drugs, dispensed at the telepharmacy branch pharmacy shall be electronically verified.

(k) Each prescription dispensed at the telepharmacy branch pharmacy shall meet the following requirements:

- (1) Be distinguishable from the prescriptions dispensed at the parent pharmacy; and
- (2) include a unique label with a unique identifier in the prescription database and the initials of the pharmacist who released the prescription from the parent pharmacy on the prescription label.

(l) Each prescription dispensed from a telepharmacy branch pharmacy shall have a label that meets the requirements of K.A.R. 68-7-14 and is attached to the drug container.

(m) Verification of the prescriptions entered and dispensed at the telepharmacy branch pharmacy shall include the following requirements:

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
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(1) If the drug is being dispensed to the patient for the first time, the pharmacist at the parent pharmacy shall utilize the data, audio, and video links and review the patient profile and the original scanned prescription. Before printing the label, the pharmacist at the parent pharmacy shall review the directions as entered by the pharmacy technician, pharmacy student, or intern. After the review is complete and the pharmacist is satisfied that the drug can be dispensed, the pharmacist shall release the label to be printed and affixed manually to the unit-of-issue package by the pharmacy technician, pharmacy student, or intern or to be printed and affixed automatically to a prescription vial by an automated dispensing device. The pharmacist shall view the label affixed to the unit-of-issue package or filled vial to ensure accuracy using the video link. Electronic images of the label, showing its attachment to the unit-of-issue package or filled vial, shall be captured, viewed by the pharmacist using the video link, associated with the electronic image of the written prescription, and retained for the same time period as that required for the written prescription. The offer to counsel shall be made by the pharmacist.

(2) For each refilled prescription, the pharmacist at the parent pharmacy shall utilize the data, audio, and video links and review the patient profile and the electronic image of the prescription. Before the label is printed, the pharmacist at the parent pharmacy shall review the directions as entered by the pharmacy technician, pharmacy student, or intern. After the review is complete and the pharmacist is satisfied that the drug can be dispensed, the pharmacist shall release the label to be printed and affixed manually to the unit-of-issue package by the pharmacy technician, pharmacy student, or intern or to be printed and affixed automatically to a prescription vial by an automated dispensing device. The pharmacist shall view the label affixed

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to the unit-of-issue package or filled vial to ensure accuracy using the video link. Electronic images of the label, showing its attachment to the unit-of-issue package or filled vial, shall be captured, viewed by the pharmacist using the video link, associated with the electronic image of the written prescription, and retained for the same time period as that required for the written prescription.

(n) The verification of prescriptions entered at the parent pharmacy and dispensed at the telepharmacy shall include the following:

(1) The pharmacist shall perform a prospective drug utilization.

(2) The pharmacist, utilizing the audio-video link, shall review the label affixed to the package or filled vial selected for dispensing and ensure that the label is affixed to the correct package or filled vial at the telepharmacy branch pharmacy. Electronic images of the label, showing its attachment to the package or filled vial, shall be captured, viewed by the pharmacist using the video link, associated with the electronic image of the written prescription, and retained for at least five years.

(o) Prescription drug samples shall not be stored or dispensed at the telepharmacy branch pharmacy.

(p) Each written prescription presented by a patient or patient representative to the telepharmacy branch pharmacy shall be scanned into the electronic data processing equipment so that on initial dispensing and each refill, the original prescription can be viewed on the monitor at both the telepharmacy branch pharmacy and the parent pharmacy. Each scanned prescription shall be retained electronically for at least five years from the date scanned. All written



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prescriptions presented by a patient or patient representative to the telepharmacy branch pharmacy shall be delivered within seven business days to the parent pharmacy for filing. For each prescription dispensed, electronic images of the drug product dispensed and the prescription label, showing its attachment to the package or filled vial, shall be captured, viewed by the pharmacist using the video link, associated with the electronic image of the written prescription, and retained for the same time period as that required for the written prescription. Records shall be maintained at the parent pharmacy in files separate from the parent pharmacy files.

(q) All schedule II controlled substances at the telepharmacy branch pharmacy shall be inventoried at least monthly. All controlled substances other than schedule II controlled substances at the telepharmacy branch pharmacy shall be inventoried at least quarterly.

(Authorized by K.S.A. 65-1630; implementing K.S.A. 2009 Supp. 65-1642 and K.S.A. 2009 Supp. 65-1643; effective P- _____.)



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68-17-7. Minimum security requirements. Each telepharmacy branch pharmacy shall meet the following security requirements:

(a) For each door to the telepharmacy branch pharmacy, meet the following requirements:

(1) Be solid core or metal; and

(2) have a deadbolt and a locking doorknob;

(b) have in place dedicated intrusion detectors that provide coverage throughout the pharmacy;


(c) have pharmacy walls that extend to the roof or, if in a multistory building, an adjoining floor or that otherwise provide security acceptable to the board; and

(d) meet all applicable federal and state regulations concerning security access.

(Authorized by K.S.A. 65-1630; implementing K.S.A. 2009 Supp. 65-1637 and K.S.A. 2009 Supp. 65-1643; effective P- _____.)

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68-17-8. Renewal of registration. (a) The registration of each telepharmacy branch pharmacy shall be renewed when the registration of the parent pharmacy is renewed.

(b) The administrator of the parent pharmacy shall submit an application for renewal of the registration of a telepharmacy branch pharmacy on a form provided by the board, which shall be submitted to the board with the renewal application of the parent pharmacy. (Authorized by K.S.A. 65-1630; implementing K.S.A. 2009 Supp. 65-1645; effective P-_____.)

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68-17-9. Fees. The fees for the registration and renewal of a registration for a telepharmacy branch pharmacy shall be the same as the fees for the registration and renewal of a registration for a pharmacy specified in K.A.R. 68-11-2. (Authorized by and implementing K.S.A. 2009 Supp. 65-1645; effective P- _____.)

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ECONOMIC IMPACT STATEMENT

Pursuant to K.S.A. 77-420(b), the Kansas Pharmacy Board submits the following description of the economic impact of the proposed regulations K.A.R. 68-17-1 through 68-17-9.

1. These regulations establish requirements for the registration, equipping and operation of a telepharmacy branch pharmacy.
2. The proposed regulation is not mandated by federal laws.
3. No new costs will be borne by pharmacists, pharmacy technicians, or others because telepharmacy branch pharmacies are not now in operation. In addition, use of a telepharmacy branch pharmacy is an option being made available to pharmacies and not a requirement. It is anticipated that the cost to establish and equip a telepharmacy branch pharmacy from scratch at the current time would be \$150,000 to \$200,000.
4. The Board is not aware of any less costly or less intrusive methods to achieve the stated purpose and thus none were considered.
5. This is not a proposed environmental regulation.

