

Article 23. Telepharmacy

68-23-1. Definitions. Each of the following terms, as used in this article of the board's regulations, shall have the meaning specified in this regulation:

(a) "Community mental health center" has the meaning specified in K.S.A. 39-2002, and amendments thereto.

(b) "Dispensing threshold" means a dispensation average of 65 prescriptions per day per quarter. The average shall be calculated by dividing the total number of prescriptions dispensed by the number of days the telepharmacy outlet was open during the quarter. Each quarter shall consist of January 1 through March 31, April 1 through June 30, July 1 through September 30, and October 1 through December 31 of each year.

(c) "Federally qualified health center" means a center that meets the requirements for federal funding under the federal public health service act, 42 U.S.C. § 1396d, as in effect on March 15, 2022, and that has been designated as a "federally qualified health center" by the federal government.

(d) "Indigent health care clinic" has the meaning specified in K.S.A. 75-6102, and amendments thereto.

(e) "Pharmacy prescription application" has the meaning specified in K.S.A. 65-1626, and amendments thereto.

(f) "Telepharmacy" has the meaning specified in K.S.A. 2022 Supp. 65-16,130, and amendments thereto.

(g) "Telepharmacy outlet" has the meaning specified in K.S.A. 2022 Supp. 65-16,130, and

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amendments thereto.

(h) "Telepharmacy system" means an electronic system that links a managing pharmacy to a telepharmacy outlet. (Authorized by K.S.A. 65-16,130; implementing K.S.A. 65-1626 and 65-16,130; effective P-_____.)

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68-23-2. Telepharmacy outlet application; facility; managing pharmacy. Each owner and each pharmacist-in-charge shall ensure that the telepharmacy outlet meets the requirements of this article of the board's regulations to be registered and to remain registered with the board.

(a) Application.

(1) The owner of the telepharmacy outlet or the owner's authorized representative shall apply for registration and renewal on forms approved by the board. The owner of the telepharmacy outlet shall pay an annual pharmacy registration fee as specified in K.A.R. 68-11-2.

(2) Each owner that receives, maintains, or dispenses controlled substances shall obtain a registration from the DEA and provide a copy of the valid registration to the board.

(3) Upon receipt of a completed application, both the owner or the owner's authorized representative and the pharmacist-in-charge may be required to meet with the board or the board's representative.

(b) Location and delivery.

(1)(A) Except as specified in paragraph (b)(1)(B), each telepharmacy outlet shall meet the following requirements at the time of application:

(i) Be at least 20 miles from any registered pharmacy; and

(ii) not be in a county that contains a city or municipality with a population greater than 50,000 individuals.

(B) Any telepharmacy outlet may be located in any of the following:

(i) A community mental health center;

(ii) an indigent health care clinic; or

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(iii) a federally qualified health center.

(2) Each telepharmacy outlet shall be fewer than 50 miles from the managing pharmacy.

(3) Any telepharmacy outlet may dispense prescriptions by delivery or mail carrier within 20 miles of the telepharmacy outlet.

(4) For purposes of this regulation, miles shall be calculated by the most direct driving route.

(c) Dispensing threshold.

(1) The telepharmacy outlet owner shall notify the board in writing no more than five days after exceeding the dispensing threshold.

(2) No more than 30 days after exceeding the dispensing threshold, a pharmacist shall be physically present at the telepharmacy outlet when it is open.

(3) After demonstrating two consecutive quarters of operating under the dispensing threshold, the telepharmacy outlet owner may submit to the board a written request for the telepharmacy outlet to be open while a pharmacist is not physically present at the telepharmacy outlet.

(d) Managing pharmacy.

(1) Any managing pharmacy may supervise no more than two telepharmacy outlets.

(2) No telepharmacy outlet may serve as a managing pharmacy for another telepharmacy outlet.

(e) Exemption or waiver. Any telepharmacy outlet owner may submit a written request to the board for an exemption from or waiver of the requirements of this article of the board's regulations, except for the requirements of subsection (b). The following factors shall be

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considered by the board or the board's designee in determining whether to grant an exemption or waiver:

(1) The number of prescriptions dispensed or reasonably expected to be dispensed by the telepharmacy outlet;

(2) the number of patients served or reasonably expected to be served by the telepharmacy outlet;

(3) the education, experience, and training of any pharmacy personnel physically present at the telepharmacy outlet or supervising from the managing pharmacy;

(4) the prescription drugs or devices received, stored, and dispensed at the telepharmacy outlet;

(5) medical necessity;

(6) the effect on the health and welfare of persons in Kansas;

(7) any circumstance that makes a requirement unreasonable or unnecessarily burdensome;

and

(8) any event that directly resulted from the occurrence of natural causes outside the control of the telepharmacy outlet or managing pharmacy.

(f) Compliance. Except as specified in this article of the board's regulations, each telepharmacy outlet owner and each pharmacist-in-charge shall ensure that the telepharmacy outlet meets the requirements of a pharmacy specified in the pharmacy act of the state of Kansas and amendments thereto, the uniform controlled substances act and amendments thereto, and the implementing regulations. (Authorized by and implementing K.S.A. 65-16,130; effective P-_____.)

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68-23-3. Personnel, staffing, training, and supervision. (a) Each telepharmacy outlet owner shall designate a pharmacist-in-charge, as defined by K.S.A. 65-1626 and amendments thereto, who shall also be the pharmacist-in-charge of the managing pharmacy.

(b) Except for the provisions of K.A.R. 68-7-13, the pharmacist-in-charge shall comply with all requirements of a pharmacist-in-charge specified in the pharmacy act of the state of Kansas, and amendments thereto, and the implementing regulations.

(c) The pharmacist-in-charge shall ensure that the telepharmacy outlet is open only when the supervising pharmacist is physically present at the managing pharmacy or is physically present at the telepharmacy outlet.

(d) The pharmacist-in-charge shall ensure that documentation of training and qualifications is maintained at the telepharmacy outlet and the managing pharmacy for all personnel working in the prescription area of the telepharmacy outlet, including proof that all personnel meet the requirements of subsection (g).

(e) The pharmacist-in-charge shall establish policies and procedures for the telepharmacy outlet and managing pharmacy. The policies and procedures shall include the following:

- (1) Self-inspection criteria for the telepharmacy outlet; and
- (2) a plan for continuation of pharmaceutical services for patients at the telepharmacy outlet in case of emergency, telepharmacy system outage, unavailability of video surveillance, temporary closure, or interruption of services, including a plan for the arrival of necessary pharmacy personnel at the telepharmacy outlet or the delivery of necessary supplies or equipment to the telepharmacy outlet within a reasonable period of time.

(f) The pharmacist-in-charge shall ensure that a pharmacist conducts an on-site, monthly

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self-inspection of the telepharmacy outlet no more than 31 days after the previous self-inspection. The pharmacist conducting the self-inspection shall compile a report at the time of self-inspection, which shall include the name and license number of the pharmacist, the date and time the self-inspection was conducted, the items reviewed, the findings, and, as needed, a corrective action plan. Each report shall be maintained at the telepharmacy outlet in a readily retrievable manner for five years. Each self-inspection shall include the pharmacist's review and evaluation of the following:

- (1) Audit and reconciliation of all inventories of controlled substances and drugs of concern;
- (2) audit of the electronic keypad or other electronic entry system and all related records;
- (3) verification that the continuous video surveillance system is functioning and recordings are maintained and available for at least 60 days following the date of the recording;
- (4) the number of prescriptions filled during the preceding 30 days;
- (5) the number of hours when a pharmacist was physically present at the telepharmacy outlet during the preceding 30 days;
- (6) compliance with policies and procedures for the telepharmacy outlet;
- (7) compliance with an ongoing continuous quality improvement program pursuant to K.S.A. 65-1695 and amendments thereto, review of incident reports, and necessary training or education of pharmacy personnel in response to any incident;
- (8) records of the receipt and disbursement of prescription drugs to monitor for diversion, theft, or loss;
- (9) inspection of drug supplies and storage areas to ensure the removal and quarantine of

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outdated drugs and devices;

(10) inspection of stock drug supplies and storage areas to ensure that the drugs are maintained in a manner to prevent diversion, theft, or loss and to maintain the integrity of the drugs; and

(11) verification that the temperature and humidity of storage areas for the stored drugs, devices, and equipment are maintained in accordance with the manufacturer's or distributor's recommendations.

(g) Whenever a pharmacist is not physically present at the telepharmacy outlet, one of the following individuals shall be authorized to be in the prescription area of the telepharmacy outlet while the telepharmacy outlet is open:

(1) A pharmacy technician who has the following education, experience, and training:

(A) At least one year of experience as a pharmacy technician in a retail pharmacy located in Kansas in the two years preceding the date the pharmacy technician begins working at the telepharmacy outlet;

(B) at least 160 hours of training either with the current pharmacist-in-charge or the pharmacist-in-charge's designee;

(C) documentation of passing a certification examination approved by the board in accordance with K.A.R. 68-5-17;

(D) a score of at least 85 percent on the telepharmacy outlet examination administered by the board;

(E) understanding of the telepharmacy outlet policies and procedures; and

(F) demonstrated proficiency in operating the telepharmacy system and pharmacy

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prescription application used by the telepharmacy outlet; or

(2) a pharmacist intern who has completed at least two years of pharmacy school and has demonstrated proficiency in operating the telepharmacy system and pharmacy prescription application used by the telepharmacy outlet. Any pharmacist intern may perform only the duties of a pharmacy technician. Hours worked in a telepharmacy outlet shall not be counted as the qualifying pharmaceutical experience required by K.A.R. 68-1-3a.

(h) When calculating the ratio of pharmacy technicians to pharmacists in accordance with K.A.R. 68-5-16, the following requirements shall apply:

(1) If a pharmacist is not present at the telepharmacy outlet, each pharmacy technician or pharmacist intern at the telepharmacy outlet shall be included in the ratio calculated for the supervising pharmacist at the managing pharmacy.

(2) If a pharmacist is present at the telepharmacy outlet, each pharmacy technician or pharmacist intern at the telepharmacy outlet shall be included in the ratio calculated for the pharmacist present at the telepharmacy outlet.

(i) The pharmacist-in-charge shall maintain a list of all pharmacy technicians and pharmacist interns authorized to work at the telepharmacy outlet. The list shall be maintained at the telepharmacy outlet and the managing pharmacy.

(j) Any clerk, cashier, or delivery driver may be present at the telepharmacy outlet. However, none of these individuals shall have access to the prescription area of the telepharmacy outlet.

(k) Unless a pharmacist is physically present at the telepharmacy outlet, each pharmacy technician or pharmacist intern at the telepharmacy outlet shall be under continuous electronic

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supervision by a supervising pharmacist physically present at the managing pharmacy. Except to turn on the relevant technology, no pharmacy technician or pharmacist intern shall be allowed in the prescription area of the telepharmacy outlet unless the pharmacy technician or pharmacist intern is under continuous electronic supervision.

(l) Electronic supervision conducted in accordance with this article of the board's regulations shall constitute direct supervision. (Authorized by and implementing K.S.A. 65-16,130; effective P-_____.)

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68-23-4. Practice of pharmacy. (a) Each prescription to be dispensed by a telepharmacy outlet shall be reviewed by a pharmacist after being filled but before being dispensed. The pharmacist shall perform prescription utilization review, prescription verification, and final verification. If the pharmacist is not physically present at the telepharmacy outlet, the final verification shall require using the telepharmacy system to verify the source container, prescription medication, and prescription label against the prescription order.

(b) A pharmacy technician or pharmacist intern shall not compound a sterile preparation or nonsterile preparation unless a pharmacist is physically present at the telepharmacy outlet.

(c) Any pharmacy technician or pharmacist intern may reconstitute commercially available oral or topical medications according to manufacturer directions, for dispensing at a telepharmacy outlet. Each reconstituted drug shall be visually verified by the pharmacist before dispensing.

(d) An immunization shall not be administered to any individual at a telepharmacy outlet unless a pharmacist is physically present.

(e) Except as specified in this article of the board's regulations, pharmacy personnel at the telepharmacy outlet shall not participate in shared services as defined by K.A.R. 68-7-20.

(f) Each pharmacist, pharmacy technician, or pharmacist intern filling a prescription at a telepharmacy outlet shall ensure that a label meeting the requirements of K.A.R. 68-7-14 is affixed to the package and includes the names, addresses, and phone numbers of the following:

(1) The telepharmacy outlet; and

(2) the managing pharmacy.

(g) A pharmacist shall counsel each patient or the patient's agent in accordance with

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K.A.R. 68-2-20. Each refusal of counseling by the patient shall be made directly to the pharmacist. (Authorized by and implementing K.S.A. 65-16,130; effective P-_____.) _____.)

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68-23-5. Operation of telepharmacy outlet. Each telepharmacy outlet shall be operated in accordance with the following requirements:

(a) The telepharmacy outlet shall not open any earlier than 15 minutes after the managing pharmacy has opened and shall close at least 15 minutes before the managing pharmacy closes.

(b) The telepharmacy outlet shall use a pharmacy prescription application under common control with the managing pharmacy or shall provide the managing pharmacy with total and remote access to the pharmacy prescription application. When using a pharmacy prescription application under common control, the prescriptions filled at the telepharmacy outlet shall be distinguishable from those prescriptions filled at any other location.

(c) The telepharmacy outlet shall receive all prescription drugs and devices directly from the managing pharmacy or a wholesale distributor registered with the board. All prescription drugs and devices shall be received from the managing pharmacy or the wholesale distributor in the prescription area of the telepharmacy outlet. The telepharmacy outlet shall not distribute drugs or devices except to the managing pharmacy.

(d) The telepharmacy outlet shall prominently display the following, in a location visible to the public:

- (1) A copy of the current pharmacy registration from the board;
- (2) a copy of the current license renewal certificate of the pharmacist-in-charge;
- (3) a copy of the current registration of each pharmacy technician or pharmacist intern working at the telepharmacy outlet;

(4) a copy of the current license of each pharmacist providing patient counseling or other pharmacy services for the telepharmacy outlet; and

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(5) a sign posted in the prescription drop-off area informing the public that the pharmacy is a telepharmacy outlet supervised by a pharmacist at the managing pharmacy and including the name, location, and phone number of the managing pharmacy.

(e) A pharmacist shall be physically present at the telepharmacy outlet at least eight hours each month.

(f) Except as authorized by the board in writing, the owner and the pharmacist-in-charge shall transfer all remaining inventory and records to the managing pharmacy upon ceasing the operations of the telepharmacy outlet.

(g) If the managing pharmacy ceases to meet the requirements in the pharmacy act of the state of Kansas and amendments thereto and the implementing regulations, the telepharmacy outlet shall cease operations in accordance with K.A.R. 68-2-10.

(h) All prescription drugs or devices, including prescriptions that have been filled but not dispensed to a patient, shall be stored in the prescription area of the telepharmacy outlet.

(i) If the operation of the telepharmacy system is interrupted or the telepharmacy system malfunctions, the telepharmacy outlet shall immediately close. No prescription shall be dispensed during the interruption or while the telepharmacy system is malfunctioning, and pharmacy personnel shall post a sign at the entrance to the telepharmacy outlet stating that the telepharmacy outlet is closed and estimating a date and time for resumption of services.

(j) The telepharmacy outlet shall maintain a perpetual inventory or continuous count of any controlled substances and drugs of concern, as defined by K.S.A. 65-1682 and amendments thereto, at the telepharmacy and shall electronically submit dispensing reports to the board in accordance with the Kansas prescription monitoring program act, and amendments thereto, and

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the implementing regulations. (Authorized by and implementing K.S.A. 65-16,130; effective P-_____.)

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68-23-6. Structural, security, technology, and equipment requirements; restrictions.

(a) The owner and the pharmacist-in-charge of each telepharmacy outlet shall ensure that the prescription area of the telepharmacy outlet meets the following requirements:

(1) Is restricted to authorized pharmacy personnel and is inaccessible to the public. If an authorized pharmacy technician, pharmacist intern, or pharmacist is not present, the prescription area shall be completely enclosed and secured with suitable locks and a monitored alarm system capable of detecting unauthorized entry;

(2) includes an electronic keypad or other electronic entry system into the prescription area that requires and records the unique identification code of each individual accessing the telepharmacy outlet, including the date and time of access. Complete access records shall be maintained for at least five years beyond the date of access;

(3) contains sufficient fixtures, equipment, and supplies consistent with the nature and scope of practice for the telepharmacy outlet;

(4) includes a sink with plumbing for hot and cold running water and sewer connections;

(5) is free from infestation by insects, rodents, birds, or vermin of any kind; and

(6) in all areas where drugs and devices are stored, is dry, well-lighted, well-ventilated, and maintained at temperatures and humidity levels to preserve the stability of the drugs and devices before dispensing as specified in the "United States pharmacopeia," USP-NF 2022, issue 1, as in effect on May 1, 2022, and the manufacturer's or distributor's recommendations.

(b) All pharmacy personnel shall maintain prescription and other patient information in a manner that protects the integrity and confidentiality of the information.

(c) Each telepharmacy outlet shall be connected to the managing pharmacy using a

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telepharmacy system that meets the following minimum requirements:

(1) Each telepharmacy system shall provide built-in safeguards relating to verification of the accuracy of the dispensing processes, drug utilization review, and electronic patient counseling services, including the use of the following types of technology:

(A) Audio and video;

(B) barcode technology at the telepharmacy outlet to verify the accuracy of each drug and each device before dispensing;

(C) electronic recording and storage of the digital image of the dispensed drug or device that is used by the pharmacist during final verification; and

(D) storage and forwarding of all data, images, and video for future review.

(2) Each telepharmacy system shall be configured and equipped to maintain optimal operation and be secure from unauthorized access.

(d) Each telepharmacy outlet owner shall maintain the continuous video surveillance and recordings required in this article of the board's regulations for at least 60 days following the date of the recording.

(e) Each telepharmacy outlet owner shall have technology in place to prevent a drug or device from being sold, dispensed, or delivered to a patient before a pharmacist has performed the final verification of the accuracy of the prescription and released the drug or device for sale, dispensing, or delivery from the telepharmacy outlet.

(f) Each pharmacy prescription application shall record the name of each pharmacist responsible for verification of the prescription and the name of each pharmacy technician and pharmacist intern assisting with the dispensing or sale of the prescription.

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(g) The loading of each automated dispensing system shall be completed using barcode technology.

(h) A telepharmacy outlet shall not manage an automated dispensing system in a long-term care facility. (Authorized by and implementing K.S.A. 65-16,130; effective

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