

BOARDS AND COMMISSIONS

Board of Pharmacy

(New Administrative Regulation)

201 KAR 2:480. Telework and electronic supervision for remote prescription processing.

RELATES TO: KRS 315.020(5), 315.310

STATUTORY AUTHORITY: KRS 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate regulations to regulate and control all matters prescribed in KRS Chapter 315. KRS 315.020(5) authorizes order entry, order entry verification and drug regimen review as tasks that can be performed outside of the permitted space of the pharmacy. The purpose of this administrative regulation is to provide minimum requirements for pharmacies located in Kentucky engaged in remote prescription processing conducted via telework and to establish rules for electronic supervision.

Section 1. Definitions.

(1) "Electronic Supervision" shall mean the oversight provided by a pharmacist licensed in Kentucky and supervising, by means of real-time electronic communication system, a pharmacist intern or registered pharmacy technician who is working for a permitted pharmacy.

(2) "Telework" means the practice or assistance in the practice of pharmacy by a contractor or an employee of the pharmacy from a remote location outside of the permitted pharmacy.

(3) "Telework Functions" of a pharmacist include:

- (a) Receiving, interpreting, or clarifying medical orders or prescription drug orders;
- (b) Order entry and order entry verification;
- (c) Transfer of prescription information;
- (d) Prospective drug utilization reviews;
- (e) Interpretation of clinical data;
- (f) Refill authorizations;
- (g) Performing therapeutic intervention;
- (h) Patient counseling;

(4) "Telework Functions" of a pharmacy technician are limited to tasks authorized under KRS 315.020.

(5) "Telework Site" means a location within the United States where a pharmacy technician may assist in the practice of pharmacy or a pharmacist or pharmacist intern engages in the practice of pharmacy as contractors or employees outside of the pharmacy located and permitted in Kentucky.

Section 2. Registration. The pharmacy and the pharmacist-in-charge of the pharmacy are responsible for ensuring individuals at telework sites are licensed or registered with the board.

Section 3. Requirements.

(1) The pharmacy and pharmacist-in-charge or the designee appointed by the pharmacist in charge shall ensure that interns and pharmacy technicians working under electronic supervision are supervised by a Kentucky licensed pharmacist.

(2) A pharmacist or intern that engages in the practice of pharmacy and a pharmacy technician that assists in the practice of pharmacy at a telework site shall be licensed or registered by the board and shall comply with all applicable federal and state laws and rules.

- (3) Prescription drugs and related devices shall not be at a telework site.
- (4) The pharmacy utilizing telework functions shall:
 - (a) Possess a written agreement with the licensee or registrant that includes all conditions, duties and policies governing the licensee or registrant engaged in telework activities;
 - (b) Maintain a continuously updated, readily retrievable, list of all licensees and registrants engaged in telework and the:
 - 1. Address and phone number for each telework site;
 - 2. Functions being performed by licensees or registrants engaged in telework; and
 - 3. The name of the pharmacist providing supervision for each non-pharmacist registrant.
- (5) The pharmacist-in-charge or the designee appointed by the pharmacist in charge of a pharmacy utilizing telework functions shall:
 - (a) Develop, implement and enforce a continuous quality improvement program designed to objectively and systematically:
 - 1. Monitor, evaluate, document the quality and appropriateness of patient care;
 - 2. Improve patient care;
 - 3. Identify, resolve and establish the root cause of dispensing and drug utilization review errors; and
 - 4. Implement measures to prevent recurrence;
 - (b) Develop, implement and enforce a procedure for identifying the pharmacist, intern, and pharmacy technician responsible for telework functions;
 - (c) Develop, implement and enforce a process for a virtual inspection of each telework site where a pharmacist technician is assisting in the practice of pharmacy or a pharmacist intern is engaged in the practice of pharmacy by a pharmacist at least once every twelve (12) months or more frequently as deemed necessary by the pharmacist. The inspection shall be documented and records retained. Board staff are authorized to request and participate in virtual inspections;

Section 4. Electronic Supervision Requirements. The pharmacy, pharmacist-in-charge or the designee appointed by the pharmacist in charge and the supervising pharmacist from the pharmacy shall:

- (1) Utilize an electronic communication system and have appropriate technology or interface to allow access to information required to complete assigned duties;
- (2) Ensure a pharmacist is supervising and directing each intern and pharmacy technician and that the electronic communication system is operational;
- (3) Ensure that a pharmacist, using professional judgment, determines the frequency of check-ins with registrants to ensure patient safety, competent practice and compliance with federal and state laws.
- (4) Ensure that a pharmacist is readily available to answer questions and be fully responsible for the practice and accuracy of the registrant; and
- (5) Ensure the intern or pharmacy technician knows the identity of the pharmacist who is providing supervision and direction.

Section 5. Confidentiality. The Kentucky permitted pharmacy, pharmacist-in-charge of the pharmacy or the designee appointed by the pharmacist in charge, and the pharmacist, intern and pharmacy technician shall:

- (1) Ensure patient and prescription information is managed in compliance with current state and federal law;
- (2) Ensure the security and confidentiality of patient information and pharmacy records;
- (3) Document in writing and report to the board within ten (10) days of discovery any confirmed breach in the security of the system or breach of confidentiality.

(4) Report any breach of security or confidentiality to the Kentucky permitted pharmacy within twenty-four (24) hours of discovery and to the board within ten (10) days.

Section 6. Technology. The pharmacist-in-charge or the designee appointed by the pharmacist in charge shall:

- (1) Test the electronic communication system with the telework site and document that it operates properly before the intern or pharmacy technician engages in telework at the telework site.
- (2) Develop, implement, and enforce a plan for responding to and recovering from an interruption of service which prevents a pharmacist from supervising and directing the intern and pharmacy technician at the telework site.
- (3) Ensure access to appropriate and current pharmaceutical references based on the services offered and shall include Kentucky Revised Statutes, Kentucky Administrative Regulations, United States Code, Code of Federal Regulations, standards adopted by reference and the Board of Pharmacy quarterly newsletters.
- (4) Train the pharmacists, interns, and pharmacy technicians in the operation of the electronic communication system.

Section 7. Security.

- (1) The pharmacist-in-charge or the designee appointed by the pharmacist in charge and each pharmacist supervising a telework site is responsible for ensuring the telework site has a designated work area that is secure and has been approved by a pharmacist prior to utilization.
- (2) Confidentiality shall be maintained such that patient information cannot be viewed or overheard by anyone other than the pharmacist, intern, or pharmacy technician.
- (3) All computer equipment used for telework shall:
 - (a) Establish and maintain a secure connection to the pharmacy and patient information;
 - (b) Utilize a program that prevents unauthorized access to the pharmacy and patient information; and
 - (c) Ensure the pharmacy and patient information is not accessed when:
 1. There is no pharmacist actively supervising the intern or pharmacy technician at a telework site;
 2. There is no intern or pharmacy technician present at the electronically supervised telework site; or
 3. Any component of the electronic communication system is not functioning; or
 - (d) Be configured so information from any patient or pharmacy records are not duplicated, downloaded, or removed from the electronic database when an electronic database is accessed remotely.
- (4) A record shall be maintained with the date, time and identification of the licensee or registrant accessing patient or pharmacy records at a telework site.
- (5) All records shall be stored in a secure manner that prevents access by unauthorized persons.

Section 8. Policies and Procedures.

- (1) The pharmacy and the pharmacist-in-charge or the designee appointed by the pharmacist in charge are accountable for establishing, maintaining, and enforcing written policies and procedures for the licensees working via telework. The written policies and procedures shall be maintained at the pharmacy and shall be available to the board upon request.
- (2) The written policies and procedures shall include the services and responsibilities of the licensee or registrant engaging in telework including:
 - (a) Security;

- (b) Operation, testing, training and maintenance of the electronic communication system;
- (c) Detailed description of work performed;
- (d) Pharmacist supervision and direction of interns and pharmacy technicians;
- (e) Recordkeeping;
- (f) Patient confidentiality;
- (g) Continuous quality improvement;
- (h) Plan for discontinuing and recovering services if the electronic communication system is disrupted;
- (i) Confirmation of secure telework sites;
- (j) Documenting the identity, function, location, date and time of the licensees engaging in telework at a telework site;
- (k) Written agreement with contracted licensees engaging in telework outlining the specific functions performed and requirement to comply with telework policies and procedures; and
- (l) Equipment.

Section 9. Records.

- (1) The recordkeeping requirements of this administrative regulation are in addition to 201 KAR 2:171.
- (2) A pharmacy utilizing registrants or licensees via telework shall be able to produce a record of each pharmacist, pharmacist intern, or pharmacy technician involved in each order entry function. The record shall include the date and time when each step function was completed.
- (3) Physical records shall not be stored at the telework site.
- (4) Records shall not be duplicated, downloaded, or removed when accessed via telework.
- (5) Records shall be stored in a manner that prevents unauthorized access.
- (6) Records shall include, but are not limited to:
 - (a) Patient profiles and records;
 - (b) Patient contact and services provided;
 - (c) Date, time, and identification of the licensee or registrant accessing patient or pharmacy records;
 - (d) If processing prescriptions, date, time and identification of the licensee or registrant and the specific activity or function of the person performing each step in the process;
 - (e) Training records;
 - (f) Virtual inspections; and
 - (g) List of employees performing telework that includes:
 - 1. Name;
 - 2. License or registration number and expiration date;
 - 3. Address of telework site; and
 - 4. Name of the Kentucky licensed pharmacist who:
 - a. Supervised the intern or pharmacy technician;
 - b. Approved licensee to telework; and
 - c. Approved each telework site.
 - (h) Electronic communication system testing and training;

Section 10. Prohibited Practices. Final product verification and dispensing from a location outside of or other than a permitted pharmacy are prohibited in telework.

CHRISTOPHER HARLOW, Pharm.D., Executive Director

APPROVED BY AGENCY: June 13, 2024

FILED WITH LRC: June 10, 2024 at 11:45 a.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall be held on August 28, 2024, at 10:00 a.m. Eastern Time via zoom teleconference. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through August 31, 2024. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

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