

## BOARDS AND COMMISSIONS

### Board of Pharmacy

#### (Amended After Comments)

#### **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)

CERTIFICATION STATEMENT: This is to certify that the administrative regulation complies with the requirements of 2025 RS HB 6, Section 8. The Board of Pharmacy is not one of the agencies that is directed by House Bill 6, Section 8(3) to include a certification by the Governor.

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate administrative 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 may be performed outside of the permitted space of the pharmacy by a pharmacist licensed in Kentucky, or a pharmacy technician registered in Kentucky or a pharmacy intern certified in Kentucky. This administrative regulation establishes the minimum requirements for pharmacies located in Kentucky engaged in remote prescription processing ~~conducted via telework~~ and the requirements for electronic supervision.

#### Section 1. Definitions.

(1) "Electronic Supervision" means the oversight provided by a pharmacist licensed in Kentucky and supervising, by means of a real-time electronic communication system, a ~~pharmacy 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 pharmacist licensed in Kentucky or a pharmacy technician registered in Kentucky or a pharmacy intern certified in Kentucky ~~contractor or an employee of the pharmacy~~ from a remote location outside of the permitted pharmacy.

(3) "Telework Functions" means:

(a) For a pharmacist includes:

1. Receiving, interpreting, or clarifying medical orders or prescription drug orders;
2. Order entry and order entry verification;
3. Transfer of prescription information;
4. Prospective drug utilization reviews;
5. Interpretation of clinical data;
6. Refill authorizations;
7. Performing therapeutic intervention; and
8. Patient counseling; and

(b) For a pharmacy technician are limited to tasks authorized under KRS 315.020(5).

(4) "Telework Site" means a location within the United States where a Kentucky-registered pharmacy technician assists in the practice of pharmacy, or a Kentucky-licensed pharmacist or Kentucky-certified pharmacy pharmacist intern engages in the practice of pharmacy ~~as a contractor or an employee~~ outside of the pharmacy that is located and permitted in Kentucky.

Section 2. ~~[Registration. The pharmacy and the pharmacist in charge of the pharmacy shall ensure 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 law.]}~~

~~{(3)}~~ Prescription drugs and related devices shall not be at a telework site.

(2) ~~{(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.

(3) ~~{(5)}~~ The pharmacist-in-charge or the designee appointed by the pharmacist-**in-charge**~~{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, and 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, **pharmacy** intern, and pharmacy technician responsible for telework functions; and

(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 **pharmacy**~~{pharmacist}~~ intern is engaged in the practice of pharmacy by a pharmacist at least once every twelve (12) months or more frequently as determined necessary by the pharmacist. The inspection shall be documented and records retained. Board staff may request and participate in virtual inspections.

Section 3. ~~{Section 4.}~~ Electronic Supervision Requirements. The pharmacy, pharmacist-in-charge, or the designee appointed by the pharmacist-**in-charge**~~{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 **pharmacy** 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 **pharmacy** intern or pharmacy technician knows the identity of the pharmacist who is providing supervision and direction.

Section 4. ~~{Section 5.}~~ Confidentiality. The ~~{Kentucky permitted}~~ pharmacy, pharmacist-in-charge of the pharmacy, or the designee appointed by the pharmacist-**in-charge**~~{in-charge}~~, and the pharmacist, **pharmacy** 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; and
- (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 5. ~~[Section 6.]~~ Technology. The pharmacist-in-charge or the designee appointed by the pharmacist-~~in-charge~~~~[in-charge]~~ shall:

- (1) Test the electronic communication system with the telework site and document that it operates properly before the **pharmacy**\_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 **pharmacy**\_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; and
- (4) Train the pharmacists, **pharmacy**\_interns, and pharmacy technicians in the operation of the electronic communication system.

Section 6. ~~[Section 7.]~~ Security.

- (1) The pharmacist-in-charge or the designee appointed by the pharmacist-~~in-charge~~~~[in-charge]~~ and each pharmacist supervising a telework site shall ensure 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 so that patient information cannot be viewed or overheard by anyone other than the pharmacist, **pharmacy**\_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 if:
    1. There is not a pharmacist actively supervising the **pharmacy**\_intern or pharmacy technician at a telework site;
    2. There is not ~~a~~ **pharmacy**~~[an]~~ 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 if 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 7. ~~[Section 8.]~~ Policies and Procedures.

- (1) The pharmacy and the pharmacist-in-charge, or the designee appointed by the pharmacist-~~in-charge~~~~[in-charge]~~ shall be 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 **pharmacy** 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 8. ~~[Section 9.]~~ Records.

(1) The recordkeeping requirements of this administrative regulation shall be 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, **pharmacy**~~[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 if accessed via telework.

(5) Records shall be stored in a manner that prevents unauthorized access.

(6) Records shall include items such as:

- (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;
- (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 **pharmacy** intern or pharmacy technician;
    - b. Approved licensee to telework; and
    - c. Approved each telework site; and

(h) Electronic communication system testing and training.

Section 9. [~~Section 10.~~] Prohibited Practices. Final product verification and dispensing from a location outside of or other than a permitted pharmacy shall not occur in telework.

*CHRISTOPHER HARLOW, PHARM.D., Executive Director*

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## REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

**Contact Person:** Christopher Harlow

**Subject Headings:** Pharmacy; Drugs and Medicines; Health and Medical Services

**(1) Provide a brief summary of:**

**(a) What this administrative regulation does:**

The purpose 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.

**(b) The necessity of this administrative regulation:**

To codify the process referenced in KRS 315.020(5) regarding remote order entry and electronic supervision.

**(c) How this administrative regulation conforms to the content of the authorizing statutes:**

This regulation establishes rules regarding telework and electronic supervision for remote prescription processing as KRS 315.020(5) authorizes.

**(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:**

315.191(1) authorizes the board to promulgate administrative regulations to regulate pharmacists, pharmacies, wholesalers and manufacturers. KRS 315.020(5) authorized remote prescription processing under electronic supervision. This regulation outlines what electronic supervision is and how it is to be utilized.

**(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:**

**(a) How the amendment will change this existing administrative regulation:**

This amendment ensures that the amendment the regulation is not interpreted to exceed what is required by KRS 315.020(5).

**(b) The necessity of the amendment to this administrative regulation:**

To ensure that the Board's statutory grant of authority is not exceeded.

**(c) How the amendment conforms to the content of the authorizing statutes:**

This amendment mirrors the language found in KRS 315.020(5) to ensure conformance to the authorizing statute.

**(d) How the amendment will assist in the effective administration of the statutes:**

This amendment makes it clear that the Board is not attempting to require something beyond what is statutorily authorized.

**(3) Does this administrative regulation or amendment implement legislation from the previous five years? The regulation amendment strengthens the consistency and clarity of KRS 315.020 which was enacted in 2022.**

**(4) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:**

Pharmacies, pharmacists, technicians, and interns are affected by this regulation.

**(5) Provide an analysis of how the entities identified in question (4) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:**

**(a) List the actions that each of the regulated entities identified in question (4) will have to take to comply with this administrative regulation or amendment:**

The regulated entities will need to familiarize themselves with this regulation and ensure compliance with the regulation.

**(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (4):**

nothing unless they have to modify internal processes to ensure compliance.

**(c) As a result of compliance, what benefits will accrue to the entities identified in question (4):**

The entities will have greater clarity about the rules concerning telework and remote prescription processing, including electronic supervision.

**(6) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:**

**(a) Initially:**

There is no cost.

**(b) On a continuing basis:**

There is no cost.

**(7) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation or this amendment:**

Board revenues from pre-existing fees provide the funding to enforce the regulation.

**(8) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment:**

No fee increase will be needed.

**(9) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:**

No fees are established directly or indirectly by this regulation.

**(10) TIERING: Is tiering applied?**

Tiering is not applied because the regulation is applicable to all pharmacists and pharmacies equally.

## FISCAL IMPACT STATEMENT

**(1) Identify each state statute, federal statute, or federal regulation that requires or authorizes the action taken by the administrative regulation:**

KRS 315.191(1)(a) and KRS 315.020(5).

**(2) State whether this administrative regulation is expressly authorized by an act of the General Assembly, and if so, identify the act:**

KRS 315.191(1)(a) and KRS 315.020(5).

**(3)(a) Identify the promulgating agency and any other affected state units, parts, or divisions:**

The Kentucky Board of Pharmacy

**(b) Estimate the following for each affected state unit, part, or division identified in (3)(a):**

**1. Expenditures:**

**For the first year: none.**

**For subsequent years: none.**

**2. Revenues:**

**For the first year: none.**

**For subsequent years: none.**

**3. Cost Savings:**

**For the first year: none.**

**For subsequent years: none.**

**(4)(a) Identify affected local entities (for example: cities, counties, fire departments, school districts):**

None.

**(b) Estimate the following for each affected local entity identified in (4)(a):**

**1. Expenditures:**

**For the first year: n/a**

**For subsequent years: n/a**

**2. Revenues:**

**For the first year: n/a**

**For subsequent years: n/a**

**3. Cost Savings:**

**For the first year: n/a**

**For subsequent years: n/a**

**(5)(a) Identify any affected regulated entities not listed in (3)(a) or (4)(a):**

pharmacies, pharmacists and technicians participating in telework as authorized in KRS 315.020(5).

**(b) Estimate the following for each regulated entity identified in (5)(a):**

**1. Expenditures:**

**For the first year:none.**

**For subsequent years:none.**

**2. Revenues:**

**For the first year:none.**

**For subsequent years:none.**

**3. Cost Savings:**

**For the first year:This could be substantial because a pharmacy can have a smaller footprint since some staff can work remotely.**

**For subsequent years:This could be substantial because a pharmacy can have a smaller footprint since some staff can work remotely.**

**(6) Provide a narrative to explain the following for each entity identified in (3)(a), (4)(a), and (5)(a)**

**(a) Fiscal impact of this administrative regulation:**

There is no fiscal impact from this regulation but there is potential cost-savings for pharmacies.

**(b) Methodology and resources used to reach this conclusion:**

Consultation with regulated entities.

**(7) Explain, as it relates to the entities identified in (3)(a), (4)(a), and (5)(a):**

**(a) Whether this administrative regulation will have a "major economic impact", as defined by KRS 13A.010(14):**

This administrative regulation will not have an overall negative or adverse major economic impact to the entities identified.

**(b) The methodology and resources used to reach this conclusion:**

Consultation with regulated entities and reviewing the Board's own budget and expenditures to enforce the regulation