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MEMORANDUM

TO: Christopher Harlow, Pharm.D., Executive Director, Board of Pharmacy

FROM: Emily Caudill, Regulations Compiler

RE: Proposed Amendment or New Regulation – 201 KAR 002:210 and 201 KAR 002:480.

DATE: June 10, 2024

A copy of each administrative regulation listed above is enclosed for your files. These regulations are tentatively scheduled for review by the Administrative Regulation Review Subcommittee at its **SEPTEMBER 2024** meeting. We will notify you of the date and time of this meeting once it has been scheduled.

Pursuant to KRS 13A.280, **if** comments are received during the public comment period, a Statement of Consideration or a one-month extension request for these regulations is due **by noon on SEPTEMBER 13, 2024**. Please reference KRS 13A.270 and 13A.280 for other requirements relating to the public hearing and public comment period and Statements of Consideration.

If you have questions, please contact us at RegsCompiler@LRC.ky.gov or (502) 564-8100.

Enclosures

1 BOARDS AND COMMISSIONS

2 Kentucky Board of Pharmacy

3 (New Administrative Regulation)

4 201 KAR 2:480. Telework and Electronic Supervision for Remote Prescription

5 Processing.

6 RELATES TO: KRS 315.020(5), KRS 315.310

7 STATUTORY AUTHORITY: KRS 315.191(1)(a)

8 NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the

9 board to promulgate regulations to regulate and control all matters prescribed in KRS

10 Chapter 315. KRS 315.020(5) authorizes order entry, order entry verification and drug

11 regimen review as tasks that can be performed outside of the permitted space of the

12 pharmacy. The purpose of this administrative regulation is to provide minimum

13 requirements for pharmacies located in Kentucky engaged in remote prescription

14 processing conducted via telework and to establish rules for electronic supervision.

15 Section 1. Definitions.

16 (1) "Electronic Supervision" shall mean the oversight provided by a pharmacist licensed

17 in Kentucky and supervising, by means of real-time electronic communication system, a

18 pharmacist intern or registered pharmacy technician who is working for a permitted

19 pharmacy.

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

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

5 (a) Receiving, interpreting, or clarifying medical orders or prescription drug orders;

6 (b) Order entry and order entry verification;

7 (c) Transfer of prescription information;

8 (d) Prospective drug utilization reviews;

9 (e) Interpretation of clinical data;

10 (f) Refill authorizations;

11 (g) Performing therapeutic intervention;

12 (h) Patient counseling;

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

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

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

22 Section 3. Requirements.

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

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

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

9 (4) The pharmacy utilizing telework functions shall:

10 (a) Possess a written agreement with the licensee or registrant that includes all
11 conditions, duties and policies governing the licensee or registrant engaged in telework
12 activities;

13 (b) Maintain a continuously updated, readily retrievable, list of all licensees and
14 registrants engaged in telework and the:

- 15 1. Address and phone number for each telework site;
- 16 2. Functions being performed by licensees or registrants engaged in telework; and
- 17 3. The name of the pharmacist providing supervision for each non-pharmacist
18 registrant.

19 (5) The pharmacist-in-charge or the designee appointed by the pharmacist in charge of
20 a pharmacy utilizing telework functions shall:

21 (a) Develop, implement and enforce a continuous quality improvement program
22 designed to objectively and systematically:

- 23 1. Monitor, evaluate, document the quality and appropriateness of patient care;

- 1 2. Improve patient care;
- 2 3. Identify, resolve and establish the root cause of dispensing and drug utilization review
- 3 errors; and
- 4 4. Implement measures to prevent recurrence;
- 5 (b) Develop, implement and enforce a procedure for identifying the pharmacist, intern,
- 6 and pharmacy technician responsible for telework functions;
- 7 (c) Develop, implement and enforce a process for a virtual inspection of each telework
- 8 site where a pharmacist technician is assisting in the practice of pharmacy or a
- 9 pharmacist intern is engaged in the practice of pharmacy by a pharmacist at least once
- 10 every twelve (12) months or more frequently as deemed necessary by the pharmacist.
- 11 The inspection shall be documented and records retained. Board staff are authorized to
- 12 request and participate in virtual inspections;

13 Section 4. Electronic Supervision Requirements.

- 14 (1) The pharmacy, pharmacist-in-charge or the designee appointed by the pharmacist in
- 15 charge and the supervising pharmacist from the pharmacy shall:
- 16 (a) Utilize an electronic communication system and have appropriate technology or
- 17 interface to allow access to information required to complete assigned duties;
- 18 (b) Ensure a pharmacist is supervising and directing each intern and pharmacy
- 19 technician and that the electronic communication system is operational;
- 20 (c) Ensure that a pharmacist, using professional judgment, determines the frequency of
- 21 check-ins with registrants to ensure patient safety, competent practice and compliance
- 22 with federal and state laws.

- 1 (d) Ensure that a pharmacist is be readily available to answer questions and be fully
2 responsible for the practice and accuracy of the registrant; and
3 (e) Ensure the intern or pharmacy technician knows the identity of the pharmacist who
4 is providing supervision and direction.

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

- 8 (1) Ensure patient and prescription information is managed in compliance with current
9 state and federal law;
10 (2) Ensure the security and confidentiality of patient information and pharmacy records;
11 (3) Document in writing and report to the board within ten (10) days of discovery any
12 confirmed breach in the security of the system or breach of confidentiality.
13 (4) Report any breach of security or confidentiality to the Kentucky permitted pharmacy
14 within twenty-four (24) hours of discovery and to the board within ten (10) days.

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

- 17 (1) Test the electronic communication system with the telework site and document that
18 it operates properly before the intern or pharmacy technician engages in telework at the
19 telework site.
20 (2) Develop, implement, and enforce a plan for responding to and recovering from an
21 interruption of service which prevents a pharmacist from supervising-and_directing the
22 intern and pharmacy technician at the telework site.

1 (3) Ensure access to appropriate and current pharmaceutical references based on the
2 services offered and shall include Kentucky Revised Statutes, Kentucky Administrative
3 Regulations, United States Code, Code of Federal Regulations, standards adopted by
4 reference and the Board of Pharmacy quarterly newsletters.

5 (4) Train the pharmacists, interns, and pharmacy technicians in the operation of the
6 electronic communication system.

7 Section 7. Security.

8 (1) The pharmacist-in-charge or the designee appointed by the pharmacist in charge
9 and each pharmacist supervising a telework site is responsible for ensuring the telework
10 site has a designated work area that is secure and has been approved by a pharmacist
11 prior to utilization.

12 (2) Confidentiality shall be maintained such that patient information cannot be viewed or
13 overheard by anyone other than the pharmacist, intern, or pharmacy technician.

14 (3) All computer equipment used for telework shall:

15 (a) Establish and maintain a secure connection to the pharmacy and patient information;

16 (b) Utilize a program that prevents unauthorized access to the pharmacy and patient
17 information; and

18 (c) Ensure the pharmacy and patient information is not accessed when:

19 1. There is no pharmacist actively supervising the intern or pharmacy technician at a
20 telework site;

21 2. There is no intern or pharmacy technician present at the electronically supervised
22 telework site; or

23 3. Any component of the electronic communication system is not functioning; or

1 (d) Be configured so information from any patient or pharmacy records are not
2 duplicated, downloaded, or removed from the electronic database when an electronic
3 database is accessed remotely.

4 (4) A record shall be maintained with the date, time and identification of the licensee or
5 registrant accessing patient or pharmacy records at a telework site.

6 (5) All records shall be stored in a secure manner that prevents access by unauthorized
7 persons.

8 Section 8. Policies and Procedures.

9 (1) The pharmacy and the pharmacist-in-charge or the designee appointed by the
10 pharmacist in charge are accountable for establishing, maintaining, and enforcing
11 written policies and procedures for the licensees working via telework. The written
12 policies and procedures shall be maintained at the pharmacy and shall be available to
13 the board upon request.

14 (2) The written policies and procedures shall include the services and responsibilities of
15 the licensee or registrant engaging in telework including:

16 (a) Security;

17 (b) Operation, testing, training and maintenance of the electronic communication
18 system;

19 (c) Detailed description of work performed;

20 (d) Pharmacist supervision and direction of interns and pharmacy technicians;

21 (e) Recordkeeping;

22 (f) Patient confidentiality;

23 (g) Continuous quality improvement;

- 1 (h) Plan for discontinuing and recovering services if the electronic communication
- 2 system is disrupted;
- 3 (i) Confirmation of secure telework sites;
- 4 (j) Documenting the identity, function, location, date and time of the licensees engaging
- 5 in telework at a telework site;
- 6 (k) Written agreement with contracted licensees engaging in telework outlining the
- 7 specific functions performed and requirement to comply with telework policies and
- 8 procedures; and
- 9 (l) Equipment.

10 Section 9. Records.

11 (1) The recordkeeping requirements of this administrative regulation are in addition to

12 201 KAR 2:171.

13 (2) A pharmacy utilizing registrants or licensees via telework shall be able to produce a

14 record of each pharmacist, pharmacist intern, or pharmacy technician involved in each

15 order entry function. The record shall include the date and time when each step function

16 was completed.

17 (3) Physical records shall not be stored at the telework site.

18 (4) Records shall not be duplicated, downloaded, or removed when accessed via

19 telework.

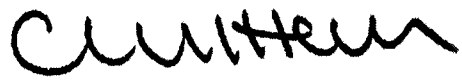
20 (5) Records shall be stored in a manner that prevents unauthorized access.

21 (6) Records shall include, but are not limited to:

22 (a) Patient profiles and records;

23 (b) Patient contact and services provided;

- 1 (c) Date, time, and identification of the licensee or registrant accessing patient or
- 2 pharmacy records;
- 3 (d) If processing prescriptions, date, time and identification of the licensee or registrant
- 4 and the specific activity or function of the person performing each step in the process;
- 5 (e) Training records;
- 6 (f) Virtual inspections; and
- 7 (g) List of employees performing telework that includes:
 - 8 1. Name;
 - 9 2. License or registration number and expiration date;
 - 10 3. Address of Telework Site; and
 - 11 4. Name of the Kentucky licensed Pharmacist who:
 - 12 a. Supervised the intern or pharmacy technician;
 - 13 b. Approved licensee to telework; and
 - 14 c. Approved each telework site.
- 15 (f) Electronic communication system testing and training;
- 16 Section 10. Prohibited Practices.
 - 17 (1) Final product verification and dispensing from a location outside of or other than a
 - 18 permitted pharmacy are prohibited in telework.



Christopher Harlow, Pharm.D.
Executive Director
Board of Pharmacy

June 13, 2024

PUBLIC HEARING AND PUBLIC 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.

Contact person: Christopher Harlow, Executive Director, Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, Frankfort, Kentucky 40601, phone (502) 564-7910, fax (502) 696-3806, email Christopher.harlow@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

201 KAR 2:480 Telework and Electronic Supervision for Remote Prescription Processing.

Contact person: Christopher Harlow, Phone 502-564-7910, email christopher.harlow@ky.gov

(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: n/a
- (b) The necessity of the amendment to this administrative regulation: n/a
- (c) How the amendment conforms to the content of the authorizing statutes: n/a
- (d) How the amendment will assist in the effective administration of the statutes: n/a

(3) 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 effected by this regulation.

(4) Provide an analysis of how the entities identified in question (3) 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 (3) 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 (3): 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 (3): The entities will have greater clarity about the rules concerning telework and remote prescription processing, including electronic supervision.

(5) Provide an estimate of how much it will cost to implement this administrative Regulation:

(a) Initially: There is no cost.

(b) On a continuing basis: There is no cost.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Board revenues from pre-existing fees provide the funding to enforce the regulation.

(7) 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.

(8) 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.

(9) TIERING: Is tiering applied? (Explain why tiering was or was not used) Tiering is not applied because the regulation is applicable to all pharmacists and pharmacies equally.

FISCAL IMPACT STATEMENT

201 KAR 2:480 Telework and Electronic Supervision for Remote Prescription Processing.

Contact person: Christopher Harlow, Phone 502-564-7910, email christopher.harlow@ky.gov

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).

(2) Identify the promulgating agency and any other affected state units, parts, or divisions:
The Kentucky Board of Pharmacy

(a) Estimate the following for the first year:

Expenditures: none.

Revenues: none.

Cost Savings: none.

(b) How will expenditures, revenues, or cost savings differ in subsequent years? There will be no expenditures or cost savings.

(3) Identify affected local entities (for example: cities, counties, fire departments, school districts): None, only the Kentucky Board of Pharmacy is impacted.

(a) Estimate the following for the first year:

Expenditures: none.

Revenues: none.

Cost Savings: none.

(b) How will expenditures, revenues, or cost savings differ in subsequent years? This regulation does not create any expenditures, revenues or cost savings.

(4) Identify additional regulated entities not listed in questions (2) or (3): none.

(a) Estimate the following for the first year:

Expenditures: none.

Revenues: none.

Cost Savings: none.

(b) How will expenditures, revenues, or cost savings differ in subsequent years? This regulation does not create any expenditures, revenues or cost savings.

(5) Provide a narrative to explain the:

(a) Fiscal impact of this administrative regulation: There is no fiscal impact from this regulation.

(b) Methodology and resources used to determine the fiscal impact: There are no fees or costs associated with this regulation.

(6) Explain:

(a) Whether this administrative regulation will have an overall negative or adverse major economic impact to the entities identified in questions (2) - (4). (\$500,000 or more, in aggregate). 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: There are no costs, expenditures or revenues from this regulation.

