

1 201 KAR 2:480

2 BOARDS AND COMMISSIONS

3 Kentucky Board of Pharmacy

4 (New Administrative Regulation)

5 Telework and Electronic Supervision for Remote Prescription Processing.

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

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

8 NECESSITY, FUNCTION, AND CONFORMITY: The purpose is to provide minimum
9 requirements for pharmacies located in Kentucky engaged in remote prescription
10 processing conducted via telework and to establish rules for electronic supervision.

11 Section 1. Definitions.

12 (1) "Telework" means the practice or assistance in the practice of pharmacy located
13 outside of a pharmacy when working as a contractor or an employee of a pharmacy
14 located in Kentucky in a telework site.

15 (2) "Telework Functions" of a pharmacist include:

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

17 (b) Order entry and order entry verification;

18 (c) Transfer of prescription information;

19 (d) Prospective drug utilization reviews;

20 (e) Interpretation of clinical data;

21 (f) Refill authorizations;

22 (g) Performing therapeutic intervention;

23 (h) Patient counseling;

1 (3) "Telework Functions" of a pharmacy technician are limited to tasks authorized under
2 Kentucky law under electronic supervision.

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

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

10 Section 3. Requirements.

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

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

18 (3) Prescription drugs and related devices may not be at a telework site.

19 (4) The pharmacy utilizing telework functions shall:

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

- 1 (b) Maintain a continuously updated, readily retrievable, list of all licensees and
2 registrants engaged in telework and the:
- 3 1. Address and phone number for each telework site;
 - 4 2. Functions being performed by licensees or registrants engaged in telework; and
 - 5 3. The name of the pharmacist providing supervision for each non-pharmacist
6 registrant.

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

- 9 (a) Develop, implement and enforce a continuous quality improvement program
10 designed to objectively and systematically:
- 11 1. Monitor, evaluate, document the quality and appropriateness of patient care;
 - 12 2. Improve patient care;
 - 13 3. Identify, resolve and establish the root cause of dispensing and drug utilization review
14 errors; and
 - 15 4. Implement measures to prevent reoccurrence;

16 (b) Develop, implement and enforce a procedure for identifying the pharmacist, intern,
17 and pharmacy technician responsible for telework functions;

18 (c) Develop, implement and enforce a process for a virtual inspection of each telework
19 site by a pharmacist at least once every six (6) months or more frequently as deemed
20 necessary by the pharmacist. The inspection shall be documented and records
21 retained. Board staff are authorized to request and participate in virtual inspections;

22 Section 4. Electronic Supervision Requirements.

1 (1) The pharmacy, pharmacist-in-charge or the designee appointed by the pharmacist in
2 charge and the supervising pharmacist from the pharmacy shall:

3 (a) Utilize an electronic communication system and have appropriate technology or
4 interface to allow access to information required to complete assigned duties;

5 (b) Ensure a pharmacist is supervising and directing each intern and pharmacy
6 technician and that the electronic communication system is operational;

7 (c) Ensure that a pharmacist, using professional judgment, determines the frequency of
8 check-ins with registrants to ensure patient safety, competent practice and compliance
9 with federal and state laws.

10 (d) Ensure that a pharmacist is be readily available to answer questions and be fully
11 responsible for the practice and accuracy of the registrant; and

12 (e) Ensure the intern or pharmacy technician knows the identity of the pharmacist who
13 is providing supervision and direction.

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

17 (1) Ensure patient and prescription information is managed in compliance with current
18 state and federal law;

19 (2) Ensure the security and confidentiality of patient information and pharmacy records;

20 (3) Document in writing and report to the board within ten (10) days of discovery any
21 confirmed breach in the security of the system or breach of confidentiality.

22 (4) Report any violation of law to the Kentucky permitted pharmacy within twenty-four
23 (24) hours of discovery and to the board within ten (10) days.

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

3 (1) Test the electronic communication system with the telework site and document that
4 it operates properly before the intern or pharmacy technician engages in telework at the
5 telework site.

6 (2) Develop, implement, and enforce a plan for responding to and recovering from an
7 interruption of service which prevents a pharmacist from supervising-and_directing the
8 intern and pharmacy technician at the telework site.

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

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

15 Section 7. Security.

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

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

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

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

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

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

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

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

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

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

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

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

16 Section 8. Policies and Procedures.

17 (1) The pharmacy and the pharmacist-in-charge or the designee appointed by the
18 pharmacist in charge are accountable for establishing, maintaining, and enforcing
19 written policies and procedures for the licensees working via telework. The written
20 policies and procedures shall be maintained at the pharmacy and shall be available to
21 the board upon request.

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

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

17 Section 10. Records.

- 18 (1) The recordkeeping requirements of this rule are in addition to 201 KAR 2:171.
- 19 (2) A pharmacy utilizing registrants or licensees via telework shall be able to produce a
- 20 record of each pharmacist, pharmacist intern, or pharmacy technician involved in each
- 21 order entry function. The record shall include the date and time when each step function
- 22 was completed.
- 23 (3) Physical records may not be stored at the telework site.

- 1 (4) Records may not be duplicated, downloaded, or removed when accessed via
- 2 telework.
- 3 (5) Records shall be stored in a manner that prevents unauthorized access.
- 4 (6) Records shall include, but are not limited to:
- 5 (a) Patient profiles and records;
- 6 (b) Patient contact and services provided;
- 7 (c) Date, time and identification of the licensee or registrant accessing patient or
- 8 pharmacy records;
- 9 (d) If processing prescriptions, date, time and identification of the licensee or registrant
- 10 and the specific activity or function of the person performing each step in the process;
- 11 (e) Training records;
- 12 (f) Virtual inspections; and
- 13 (g) List of employees performing telework that includes:
- 14 1. Name;
- 15 2. License or registration number and expiration date;
- 16 3. Address of Telework Site; and
- 17 4. Name of the Kentucky licensed Pharmacist who:
- 18 a. Supervised the intern or pharmacy technician;
- 19 b. Approved licensee to telework; and
- 20 c. Approved each telework site.
- 21 (f) Electronic communication system testing and training;
- 22 Section 11. Prohibited Practices.

- 1 (1) Final product verification and dispensing from a location outside of or other than a
- 2 pharmacy are prohibited in telework.

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