

KENTUCKY BOARD OF PHARMACY RETREAT

**Louisville Marriott Downtown – Bluegrass I and II
280 West Jefferson Street
Louisville KY 40202**

**July 26, 2022
9:00 a.m. – 5:00 p.m.**

AGENDA

TOPICS IN ORDER OF PRIORITY:

- 1) Workplace Conditions**
- 2) White, Clear, and Brown Bagging**
- 3) Remote Work/Common Database/Central Fill**
- 4) Pharmacy Technician Advancement**
- 5) Out of State Pharmacy Permit Regulation**
- 6) Compliance Packaging**

Proposed Rulemaking on Workplace Conditions
Modeled on Vermont

201 KAR 2:
BOARDS AND COMMISSIONS
Kentucky Board of Pharmacy
(Proposed New Ordinary Regulation)

Unprofessional conduct of a pharmacy permit holder
RELATES TO: KRS 315.121

STATUTORY AUTHORITY: KRS 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY:

- (1) It shall be unprofessional conduct for a pharmacy permit holder to:
- (a) Introduce or enforce policies and procedures related to the provision of pharmacy services in a manner that results in deviation from safe practices;
 - (b) Unreasonably prevent or restrict a patient's timely access to patient records or essential pharmacy services;
 - (c) Fail to identify and resolve conditions that interfere with a pharmacist's ability to practice with competency and safety or create an environment that jeopardizes patient care, including by failing to provide mandated rest periods; and
 - (d) Repeatedly, habitually, or knowingly fail to provide resources appropriate for a pharmacist of reasonable diligence to safely complete professional duties and responsibilities, including:
 1. drug utilization review;
 2. immunization;
 3. counseling;
 4. verification of the accuracy of a prescription; and
 5. all other duties and responsibilities of a pharmacist under state and federal laws and regulations.
- (2) Pharmacies under common ownership and control constitute a chain. Discipline against any one pharmacy permit holder in a chain may be imposed against all pharmacies in a chain, provided the state alleges in the Complaint and the Board subsequently finds:
- (a) unprofessional conduct has occurred at one or more pharmacies;
 - (b) the unprofessional conduct is attributable to pharmacy or pharmacy business-related policies, procedures, systems, or practices of the chain and whether or not those practices manifested in unprofessional conduct at each individual location; and
 - (c) imposition of disciplinary sanctions or conditions against all pharmacies in the chain is appropriate to protect the public.

1 201 KAR 2:
2 BOARDS AND COMMISSIONS
3 Kentucky Board of Pharmacy
4 (New Administrative Regulation)
5 Centralized and Remote Prescription Processing
6

7 RELATES TO: KRS 315.020(5)

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

9 NECESSITY, FUNCTION, AND CONFORMITY: The purpose is to provide minimum
10 requirements for pharmacies engaging in centralized prescription processing including
11 centralized prescription filling and remote prescription processing. Any facility engaging
12 in centralized prescription processing on behalf of a Kentucky pharmacy shall be
13 permitted as a pharmacy.

14
15 Section 1. Definitions.

16 (1) "Central Fill Pharmacy" means a Kentucky permitted pharmacy located in the
17 United States that provides centralized prescription filling for both initial or prescription
18 refills on behalf of a primary pharmacy and may dispense directly to the patient or
19 patient's agent.

20 (2) "Centralized Prescription Processing" means the processing by a pharmacy of a
21 request from another pharmacy to fill or refill a prescription drug order or to perform
22 processing functions such as dispensing, drug utilization review (DUR), claims
23 adjudication, refill authorizations, and therapeutic interventions. It includes centralized
24 prescription filling and remote prescription processing functions.

25 (3) "Centralized Prescription Filling" means the packaging, labeling and delivery of a
26 prepared prescription to the primary pharmacy or for the purpose of dispensing to the
27 patient or other individual entitled to receive the prescription drug.

28 (4) "Primary Pharmacy" means a pharmacy that maintains ownership of a prescription
29 located and permitted in Kentucky that receives a patient's or a prescribing practitioner's

1 request to fill a prescription, dispenses the prescription directly to the patient or patient's
2 agent, or the pharmacy delivers the drug to the patient's agent for administration.

3 (5) "Remote Processing Pharmacy" means a non-dispensing Kentucky permitted
4 pharmacy located in the United States that processes information related to the practice
5 of pharmacy and engages in remote prescription processing.

6 (6) "Remote Prescription Processing Functions " include only:

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

8 (b) Order entry and order entry verification;

9 (c) Transfer of prescription information;

10 (d) Prospective drug utilization reviews;

11 (e) Interpretation of clinical data;

12 (f) Refill authorizations;

13 (g) Performing therapeutic intervention;

14 (h) Patient counseling;

15 Section 2. Requirements.

16 1. A primary pharmacy may outsource prescription drug filling to a central fill pharmacy
17 or remote processing pharmacy provided that both pharmacies:

18 (1) Are under common ownership; or

19 (2) Have a written shared pharmacy services contract or agreement that specifies:

20 (a) The services and functions to be provided by each pharmacy; and

21 (b) The responsibilities of each pharmacy;

22 (3) Maintain a separate Kentucky pharmacy permit for each location involved in
23 providing prescription drugs or pharmacy services to Kentucky patients;

- 1 (4) Share a common electronic file or database or have appropriate technology or
2 interface to allow access to patient and prescription information required to process and
3 fill a prescription drug order;
- 4 (5) Establish, maintain and enforce a policy and procedures manual;
- 5 (6) Have adequate procedures to ensure that each medical order or prescription drug
6 order has been properly processed and filled and that an offer of counseling is provided;
- 7 (7) Ensure centralized and remote prescription processing functions for a Kentucky
8 patient are performed by a Kentucky licensed pharmacist;
- 9 (8) Ensure appropriately delegated prescription processing functions for a Kentucky
10 patient are performed by a Kentucky registered pharmacy technician supervised by a
11 Kentucky licensed pharmacist; and
- 12 (9) Comply with all applicable federal and state laws and rules.

13 Section 3. Policies and Procedures.

- 14 (1) Each pharmacy at each location is responsible for establishing, maintaining, and
15 enforcing a written policies and procedures manual that controls the centralized and
16 remote prescription processing between the two pharmacies. The policies and
17 procedures shall include, but need not be limited to the following topics:
 - 18 (a) The responsibilities of each pharmacy;
 - 19 (b) Prescription processing steps and functions;
 - 20 (c) Ensuring confidentiality and security of patient information;
 - 21 (d) Cancellation of prescription at any step in the process;

1 (e) Recordkeeping, including records of all pharmacists, pharmacist interns or pharmacy
2 technicians involved in the centralized prescription processing of a prescription and the
3 pharmacy where processing occurred;

4 (f) A continuous quality improvement program for pharmacy services designed to
5 objectively and systematically monitor and evaluate the quality and appropriateness of
6 patient care, to pursue opportunities to improve patient care, and to resolve identified
7 problems;

8 (g) Documentation of any errors or irregularities identified by the quality improvement
9 program; and

10 (h) Compliance with all applicable federal and state laws and rules.

11 (2) The policies and procedures shall be reviewed annually, and the review shall be
12 documented.

13 (3) The manual shall be made available to the Board upon request.

14 Section 4. Labeling. The prescription label shall clearly identify the name and address of
15 each pharmacy involved in the centralized prescription processing.

16 Section 5. Records.

17 (1) A pharmacy utilizing or providing centralized prescription processing shall be able to
18 produce a record of each pharmacist, pharmacist intern, or pharmacy technician
19 involved in the processing of a prescription. The record shall include the date and time
20 when each step in the process was completed and the location where it occurred.

21 (2) Records are to be maintained as required in accordance with other record keeping
22 requirements of the Board.

23 (3) Quality improvement program records are to be provided to the Board upon request.

- 1 (4) The primary pharmacy shall maintain records that:
- 2 (a) List the name, telephone number, address and permit number of each pharmacy
- 3 providing centralized prescription processing services;
- 4 (b) Document the receipt of filled prescriptions from Central Fill Pharmacy, including the
- 5 date and the identity of the person accepting delivery; and
- 6 (c) Document the request for the Central Fill Pharmacy to delivery prescriptions to the
- 7 patient or other individual entitled to receive the prescription drug.

8 (5) The central fill pharmacy shall maintain records that:

9 (a) List the name, address, telephone numbers, and all permit numbers of the

10 pharmacies for whom the central fill pharmacy provides centralized prescription filling

11 services;

12 (b) List the name, address, telephone numbers, and all permit numbers of the

13 pharmacies involved in centralized prescription processing;

14 (c) Document the name and address where the filled prescription was shipped; and

15 (d) Document the method of delivery (e.g., private, common, or contract carrier).

16 (6) The remote processing pharmacy shall maintain records that list the name, address,

17 telephone numbers, and all permit numbers of the pharmacies for whom the remote

18 processing pharmacy provides remote prescription processing services.

19 Section 6. Central Fill Pharmacy Responsibilities.

20 (1) The delivery of a prepared prescription shall be made:

21 (a) To the primary pharmacy or to the patient or other individual entitled to receive the

22 prescription drug; and

1 (b) Using a private, common or contract carrier, in compliance with all federal and state
2 transport requirements.

3 (2) A prescription for a controlled substance may be filled by a central fill pharmacy
4 when permitted by law, consistent with federal requirements set forth at 21 C.F.R. §
5 1300 et seq;

6 (3) The central fill pharmacy is responsible for reporting any in-transit loss of a
7 controlled substance in compliance with KRS 315.335.

8 (4) A central fill pharmacy shall maintain and use adequate storage or shipment
9 containers and shipping processes to ensure drug stability and potency. Such shipping
10 processes shall include the use of packaging material and devices to ensure that the
11 drug is maintained at the temperature range required to ensure the integrity of the
12 medication throughout the delivery process.

13 (5) Filled prescriptions shall be shipped in containers that are sealed in a manner that
14 shows evidence of opening or tampering.

15 (6) The central fill pharmacy shall be responsible for ensuring the order has been
16 properly prepared and verified by a pharmacist.

17 Section 7. Primary Pharmacy Responsibilities.

18 (1) A primary pharmacy shall notify patients the possible use of centralized prescription
19 processing. This notification shall be provided:

20 (a) In writing; or

21 (b) With posted signage.

1 (2) A primary pharmacy utilizing a central fill pharmacy to perform centralized
2 prescription filling shall provide the patient with written information that describes how a
3 patient may contact either:

4 (a) The central fill pharmacy if the patient has any questions about the preparation of
5 the prescription; or

6 (b) The primary pharmacy if the patient has any questions about the use of the
7 medication.

8 (3) The primary pharmacy shall be responsible for ensuring the prescription has been
9 properly processed, prepared, packaged, and labeled.

10 Section 8. Remote Pharmacy Responsibilities.

11 (1) A remote processing pharmacy is exempt from the following:

12 (a) Security and control of drugs and prescription requirements in 201 KAR 2:100
13 Section 1 (1)(a), Section 3 and Section 4; and

14 (b) Pharmacy sanitation requirements in 201 KAR 2:180.

15 (2) A medical order or prescription drug order for a controlled substance may be
16 processed by a remote processing pharmacy when permitted by law and consistent with
17 federal rules.

18 (3) The remote processing pharmacy shall be responsible for ensuring that remote
19 prescription processing functions have been properly performed by a Kentucky licensed
20 pharmacist or pharmacist intern or registered pharmacy technician under the
21 supervision of a Kentucky licensed pharmacist.

1 (4) A pharmacy other than a remote processing pharmacy may perform remote
2 prescription processing functions under common ownership or a shared services
3 contract or agreement.

4 Section 8. Prohibited Practices.

5 (1) A primary pharmacy shall not use the services of a central fill pharmacy or remote
6 processing pharmacy not permitted with the Board.

7 (2) A central fill pharmacy or remote processing pharmacy shall not fill a prescription on
8 behalf of a primary pharmacy that is not permitted with the Board if the laws and rules of
9 Kentucky require the primary pharmacy to be permitted with the Board.

1 201 KAR 2:

2 BOARDS AND COMMISSIONS

3 Kentucky Board of Pharmacy

4 (New Administrative Regulation)

5 Telework.

6 RELATES TO: KRS 315.020(5)

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

8 NECESSITY, FUNCTION, AND CONFORMITY: The purpose is to provide minimum
9 requirements for pharmacists and pharmacists interns engaged in the practice of
10 pharmacy and pharmacy technicians assisting in the practice of pharmacy using
11 telehealth.

12

13 Section 1. Definitions.

14 (1) "Telehealth" means the use of interactive audio, video, or other electronic media to
15 deliver healthcare. It includes the use of electronic media for diagnosis, consultation,
16 treatment, transfer of health or medical data, and continuing education.

17 (2) "Telework" means the practice or assistance in the practice of pharmacy located
18 outside of a permitted pharmacy when working as a contractor or an employee of a
19 Kentucky permitted pharmacy in a telework site providing telework functions.

20 (3) "Telework Site" means a location within the United States that is not a permitted
21 pharmacy where a pharmacy technician may assist in the practice of pharmacy or a
22 Kentucky licensed pharmacist or pharmacist intern engages in the practice of pharmacy
23 as contractors or employees of a Kentucky permitted pharmacy.

- 1 (4) "Telework Functions" include only:
- 2 (a) Receiving, interpreting, or clarifying medical orders or prescription drug orders;
- 3 (b) Ordering entry and order entry verification;
- 4 (c) Transferring of prescription information;
- 5 (d) Performing prospective drug utilization reviews;
- 6 (e) Interpreting clinical data;
- 7 (f) Refilling authorizations;
- 8 (g) Performing therapeutic intervention;
- 9 (h) Counseling patients;

10 Section 2. Registration. The Kentucky permitted pharmacy and the pharmacist-in-
11 charge of the pharmacy are responsible for all licensing and registrations of individuals
12 at telework sites.

13 Section 3. Requirements.

14 (1) Each Kentucky permitted pharmacy and pharmacist-in-charge shall ensure that
15 interns and pharmacy technicians working at a telework site work under the supervision
16 and direction of a Kentucky licensed Pharmacist.

17 (2) A Pharmacist or intern that engages in the practice of pharmacy and a pharmacy
18 technician that assists in the practice of pharmacy at a telework site for any person or
19 facility located in Kentucky shall:

- 20 (a) Be licensed or registered by the board; and
 - 21 (b) Comply with all applicable federal and state laws and rules.
- 22 (3) Prescription drugs and related devices may not be at a telework site.

- 1 (4) The Kentucky permitted pharmacy and the pharmacist-in-charge of the pharmacy
2 shall:
- 3 (a) Possess a written agreement with the licensee or registrant that includes all
4 conditions, duties and policies governing the licensee or registrant engaged in telework
5 activities;
- 6 (b) Maintain a continuously updated list of all licensees and registrants engaged in
7 telework and the:
- 8 1. Address and phone number for each telework site;
 - 9 2. Functions being performed by licensees or registrants engaged in telework; and
 - 10 3. The name of the pharmacist providing supervision for each non-pharmacist
11 registrants;
- 12 (5) The pharmacist-in-charge of the Kentucky permitted pharmacy shall:
- 13 (a) Develop, implement and enforce a continuous quality improvement program
14 designed to objectively and systematically:
- 15 1. Monitor, evaluate, document the quality and appropriateness of patient care;
 - 16 2. Improve patient care;
 - 17 3. Identify, resolve and establish the root cause of dispensing and DUR errors; and
 - 18 4. Implement measures to prevent reoccurrence.
- 19 (b) Develop, implement and enforce a procedure for identifying the pharmacist, intern,
20 and pharmacy technician responsible for each telework function.
- 21 (c) Develop, implement and enforce a process for a virtual inspection of each telework
22 site by a Kentucky licensed pharmacist at least once every six (6) months or more

1 frequently as deemed necessary by the pharmacist. The inspection shall be
2 documented and records retained; and
3 (d) Utilize a pharmacist and real-time audio communication to provide counseling from
4 the patient or the patient's agent and document the interaction.

5 Section 4. Electronic Supervision Requirements.

6 (1) The Kentucky permitted pharmacy, pharmacist-in-charge and the supervising
7 Kentucky licensed pharmacist from the pharmacy shall:

8 (a) Utilize an audiovisual communication system and have appropriate technology or
9 interface to allow access to information required to complete assigned duties;

10 (b) Ensure telephone audio is recorded and stored for all patient interactions completed
11 by interns and pharmacy technicians;

12 (c) Ensure a Kentucky licensed pharmacist is supervising and directing each intern and
13 pharmacy technician and that the audiovisual communication system is fully
14 operational;

15 (d) Ensure that a Kentucky licensed pharmacist, using professional judgment,
16 determines the frequency of "check-ins" with registrants to ensure patient safety and
17 compliance with federal and state laws with a minimum of at least once per work shift.

18 (e) Be readily available to answer questions and fully responsible for the practice and
19 accuracy of the registrant;

20 (f) Ensure the Intern or pharmacy technician knows the identity of the Kentucky licensed
21 pharmacist who is providing supervision, direction, and control at all times;

22 (g) Ensure the Kentucky licensed pharmacist who is supervising an intern or pharmacy
23 technician at a telework site:

- 1 1. Uses professional judgment to determine the percentage of patient interactions for
- 2 each registrant that shall be observed or reviewed to ensure public health and safety
- 3 with a minimum of five (5) percent of patient interactions observed or reviewed;
- 4 2. Reviews patient interactions within 48 hours of the patient interaction to ensure that
- 5 each registrant is acting within the authority permitted under their registration and
- 6 patients are connected with a pharmacist upon request;
- 7 3. Documents the following within 24 hours of the observation:
- 8 a. Number of each registrant's patient interactions;
- 9 b. Number of each registrant's patient interactions pharmacist has observed or
- 10 reviewed;
- 11 c. Date and time of registrant's patient interaction pharmacist has observed or reviewed;
- 12 d. Date and time of pharmacist observation or review of registrant's patient interaction;
- 13 e. Pharmacist notes of each interaction observed or reviewed; and
- 14 f. Reports any violation of law to the Kentucky permitted pharmacy within 24 hours of
- 15 discovery and to the board within 10 days.

16 (2) The Kentucky permitted pharmacy shall comply with the pharmacist's determination
17 and employ adequate staff to allow for:

- 18 (a) Observation or review within 48 hours;
- 19 (b) Creation of supervision records; and
- 20 (9) Retention of supervision records.

21 Section 5. Confidentiality. The Kentucky permitted pharmacy, pharmacist-in-charge of
22 the pharmacy, and the pharmacist, intern and pharmacy technician from the pharmacy
23 shall:

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

6 Section 6. Technology. The pharmacist-in-charge of the pharmacy shall:

- 7 (1) Test the audiovisual communication system with the telework site and document that
- 8 it operates properly before the intern or pharmacy technician engages in telework at the
- 9 telework site.
- 10 (2) Develop, implement, and enforce a plan for responding to and recovering from an
- 11 interruption of service which prevents a Kentucky licensed pharmacist from supervising,
- 12 directing and controlling the intern and pharmacy technician at the telework site.
- 13 (3) Ensure access to:
- 14 (a) Appropriate and current pharmaceutical references based on the services offered;
- 15 and
- 16 (b) Appropriate and current Kentucky Revised Statutes, Kentucky Administrative
- 17 Regulations, United States Code, Code of Federal Regulations, standards adopted by
- 18 reference (e.g. USP) based on services offered by the pharmacy, and the Board of
- 19 Pharmacy quarterly newsletters.
- 20 (4) Train the Kentucky licensed pharmacists, interns, and pharmacy technicians in the
- 21 operation of the audiovisual communication system.

22 Section 7. Personnel.

1 (1) The Kentucky licensed pharmacist-in-charge is responsible for all operations at the
2 pharmacy including responsibility for the audiovisual communication system and
3 enforcing policies and procedures.

4 (2) A pharmacy may not utilize unlicensed personnel to engage in telework.

5 (3) Prior to working at a telework site, the intern or pharmacy technician and the
6 Kentucky licensed pharmacist supervising the telework site shall have completed a
7 training program on the use of all equipment necessary for secure operation of the
8 telework site.

9 Section 8. Security.

10 (1) Telework Sites shall be located in a designated area where all equipment is stored,
11 and all work is performed.

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) The pharmacist-in-charge and each Kentucky licensed pharmacist supervising a
15 telework site is responsible for ensuring the telework site has a designated work area
16 that is secure and has been approved and documented by a Kentucky licensed
17 pharmacist prior to utilization.

18 (4) All computer equipment used for telework shall:

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

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

22 (c) Be configured so that the pharmacy and patient information is not accessible when:

- 1 1. There is no Kentucky licensed Pharmacist actively supervising the intern or pharmacy
2 technician who is assisting in the practice of pharmacy at a telework site;
- 3 2. There is no intern or pharmacy technician present at the telework site;
- 4 3. Any component of the audiovisual communication system with the telework site is not
5 functioning; or
- 6 (d) Be configured so information from any patient or pharmacy records are not
7 duplicated, downloaded, or removed from the electronic database when an electronic
8 database is accessed remotely.
- 9 (5) A record shall be maintained with the date, time and identification of the licensee or
10 registrant accessing patient or pharmacy records at a telework site.
- 11 (6) Interns and pharmacy technicians may only work at a telework site when authorized
12 in real-time by a Kentucky licensed pharmacist who is supervising the licensee.
- 13 (7) All records shall be stored in a secure manner that prevents access by unauthorized
14 persons.

15 Section 9. Policies and Procedures.

- 16 (1) If a Pharmacy utilizes licensees or registrants via telework, the pharmacy and the
17 Kentucky licensed pharmacist-in-charge are accountable for establishing, maintaining,
18 and enforcing written policies and procedures for the licensees working via telework.
19 The written policies and procedures shall be maintained at the Pharmacy and shall be
20 available to the board upon request.
- 21 (2) The written policies and procedures shall include the services and responsibilities of
22 the licensee or registrant engaging in telework including:
 - 23 (a) Security;

- 1 (b) Operation, testing and maintenance of the audiovisual communication;
- 2 (c) Detailed description of work performed;
- 3 (d) Kentucky licensed pharmacist supervision, direction and control of interns and
- 4 pharmacy technicians;
- 5 (e) Recordkeeping;
- 6 (f) Patient confidentiality;
- 7 (g) Continuous quality improvement;
- 8 (h) Plan for discontinuing and recovering services if the audiovisual communication
- 9 system is disrupted;
- 10 (i) Confirmation of dedicated, 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 licensees engaging in telework outlining the specific
- 14 functions performed and requirement to comply with telework policies and procedures;
- 15 and
- 16 (l) Equipment.

17 Section 10. Records.

18 (1) If a pharmacy utilizes registrants or licensees via telework, the recordkeeping
19 requirements of this rule are in addition to the requirements of other recordkeeping rules
20 of the board. Unless otherwise specified, all records and documentation required by
21 these rules shall be retained for five years and made available to the board for
22 inspection upon request. Records of telework site addresses shall be made available
23 within forty-eight (48) hours.

1 (2) A pharmacy utilizing registrants or licensees via telework shall be able to produce a
2 record of each pharmacist, pharmacist intern, or pharmacy technician involved in each
3 telework function. The record shall include the date and time when each step function
4 was completed.

5 (3) Physical records may not be stored at the telework site.

6 (4) Records may not be duplicated, downloaded, or removed when accessed via
7 telework.

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

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

10 (a) Patient profiles and records;

11 (b) Patient contact and services provided;

12 (c) Date, time and identification of the licensee or registrant accessing patient or
13 pharmacy records;

14 (d) If processing prescriptions, date, time and identification of the licensee or registrant
15 and the specific activity or function of the person performing each step in the process;
16 and

17 (e) List of employees performing telework that includes:

18 1. Name;

19 2. License or registration number and expiration date;

20 3. Address of Telework Site; and

21 4. Name of the Kentucky licensed Pharmacist who:

22 a. Supervised the intern or pharmacy technician;

23 b. Approved licensee to telework; and

- 1 c. Approved each telework site
- 2 (f) Audiovisual communication system testing and training;

Draft

1 BOARDS AND COMMISSIONS

2 Kentucky Board of Pharmacy

3 (New Ordinary Regulation)

4 **201 KAR 2:_____ Out of State Pharmacy Permits.**

5 Section 1. Inspection Requirements.

6 (1) Each pharmacy shall provide to the Board and also maintain, in readily retrievable
7 form, the record of a satisfactory inspection conducted within the previous twenty-four
8 (24) month period by the licensing entity of the state where the pharmacy is located.

9 (2) If no such inspection record is readily available, the record of the satisfactory
10 inspection conducted at the expense of the pharmacy within the previous twenty-four
11 (24) months by a third party recognized by the Board to inspect may be accepted.

12 (3) If no such inspection has been performed within the previous twenty-four (24)
13 months, the Board shall conduct or contract with a third party recognized by the Board
14 to inspect the pharmacy, for which all costs shall be borne by the applicant.

15 Section 2. Pharmacist-in-Charge.

16 (1) The pharmacist-in-charge shall directly and timely respond to any lawful request for
17 information from the Board or law enforcement authorities.

18 (2) The pharmacist-in-charge shall be responsible for receiving and maintaining
19 publications distributed by the Board.

20 (3) The pharmacist-in-charge shall be responsible for answering the toll-free telephone
21 service six days a week and a minimum of forty hours per week. The toll-free telephone
22 number shall be present on the label of each prescription dispensed by the pharmacy to
23 a Kentucky resident. If the pharmacist-in-charge is unavailable, a staff pharmacist with

1 access to patient records may answer the call but the staff pharmacist shall notify the
2 pharmacist-in-charge of the call and provide the pharmacist-in-charge with a callback
3 number for the patient. If the staff pharmacist is unable to resolve the patient's question,
4 the pharmacist-in-charge shall return the call of the patient within forty-eight hours.

5 Section 3. Exemptions.

6 (1) The Board may grant an exemption from the permitting requirements of this section
7 to any nonresident pharmacy which limits its dispensing activity to isolated transactions.

8 (2) An isolated transaction is defined as a transaction in which:

9 (a) dispensing is limited to an established patient of the dispensing pharmacy no more
10 than three times per calendar year; and

11 (b) on a regular basis.

12 Section 4. Applications.

13 (1) A prerequisite for receiving a permit as an out-of-state pharmacy is that the facility
14 must be in good standing in the state where it is located and submit evidence consisting
15 of the following:

16 (a) a copy of a valid license, permit or registration issued by the regulatory or licensing
17 agency of the state in which the pharmacy is located; and

18 (b) a letter from the regulatory or licensing agency of the state in which the pharmacy is
19 located that certifies the pharmacy is compliant with the pharmacy laws of that state.

20 (2) Each applicant must disclose the following:

21 (a) names and license numbers of all pharmacists and pharmacist-managers

22 dispensing prescription legend drugs to an ultimate user in Kentucky, the names and, if

1 available, the license or registration numbers of all supportive personnel employed by
2 the out-of-state pharmacy who assist pharmacists in such dispensing;

3 (b) names, locations, titles, social security number and date of birth of all principal
4 corporate officers or members, if incorporated; and

5 (c) if the pharmacy is owned by a partnership or sole proprietorship, the name, location,
6 title, social security number, and date of birth of any partner or owner of the pharmacy.

7 (d) A report containing this information shall be made on an annual basis and within
8 thirty (30) days of each change for any principal office, pharmacist manager, corporate
9 officer, partner, or owner of the pharmacy.

10 (3) Each non-resident pharmacy shall develop and provide the Board with a policy and
11 procedure manual that sets forth:

12 (a) normal delivery protocols and times;

13 (b) the procedure to be followed if the patient's medication is not available at the out-of-
14 state pharmacy, or if delivery will be delayed beyond normal delivery time;

15 (c) the procedure to be followed upon receipt of a prescription for an acute illness, which
16 shall include a procedure for delivery of the medication to the patient from the out-of-
17 state pharmacy at the earliest possible time, or an alternative that assures the patient
18 the opportunity to obtain medication at the earliest possible time;

19 (d) the procedure to be followed when the out-of-state pharmacy is advised that the
20 patient's medication has not been received within the normal delivery time and that the
21 patient is out of medication and requires interim dosage until mail prescription drugs
22 become available; and

1 (e) the procedure for shipping products pursuant to FDA approved and manufacturer
2 guidelines.

3 (4) An applicant for an out-of-state pharmacy permit must designate a resident agent in
4 Kentucky for service of process. Any such out-of-state pharmacy that does not so
5 designate a resident agent shall be deemed to have appointed the Secretary of State of
6 the State of Kentucky to be its true and lawful attorney upon whom process may be
7 served. All legal process in any action or proceeding against such pharmacy arising
8 from shipping, mailing or delivering prescription drugs in Kentucky shall be served on
9 the resident agent. In addition, a copy of such service of process shall be mailed to the
10 out-of-state pharmacy by certified mail, return receipt requested, at the address of the
11 out-of-state pharmacy as designated on the registration form filed with the Board. Any
12 out-of-state pharmacy which does not register in this State, shall be deemed to have
13 consented to service of process on the Secretary of State as sufficient service.

14 (5) Any person who ships, mails, or delivers prescription drugs to Kentucky residents
15 from more than one out-of-state pharmacy shall register each pharmacy separately.

16 (6) An out-of-state pharmacy shall report to the disciplinary action taken by another
17 state or jurisdiction against the pharmacy or pharmacy staff within thirty days of final
18 case resolution.

19 (7) An applicant shall submit photographs of the exterior of the pharmacy building and
20 working areas.

21 (8) An out-of-state pharmacy that has not completed the application process and is not
22 permitted by the Board may not advertise its services to residents of Kentucky.

- 1 (9) A person who engages in the practice of the profession of pharmacy for a Kentucky
- 2 resident shall hold an active Kentucky pharmacist license except under Section 3 of this
- 3 regulation.
- 4 (10) All pharmacy staff shall be provided a copy of this regulation.

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