KENTUCKY BOARD OF PHARMACY

Justice and Public Safety Building
125 Holmes Street, 1st Floor Conference Room
Frankfort, KY 40601

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May 22, 2024
10:00 a.m.

Board Meeting Agenda

I. CALL TO ORDER

II. INSTALLATION OF NEW BOARD MEMBER
- A. Kimberly S. Croley

III. PUBLIC HEARING
- A. 201 KAR 2:220

IV. MINUTES

V. APPEARANCES
- A. Wholesaler Application Request
  - i. Biopeptek
- B. Pharmacist Applications
  - i. Orr, Roger
  - ii. Vidrine, Kylee Brooke- MPJE Request
- C. Pharmacist Intern Applications
  - i. Parekh, Ashish (I09606)- Reinstatement Request
- D. Pharmacy Technician Applications
  - i. Keen (Noffsinger), Marita (PT00011451) - Reinstatement Request
  - ii. Latham-Cox, Haley
  - iii. Shively, Craig
  - iv. Mascorro, Caden

VI. INTERAGENCY/PROFESSIONAL ASSOCIATIONS

VII. BOARD REPORTS

A. Executive Director
    a. eMARs
    b. Board Retreat Update
    c. Staff Update
    d. SCRA Guidance for Pharmacist Licensure
B. General Counsel
    a. Expungement Request, 98-0126

VIII. COMMITTEE REPORTS

A. KYPRN
B. Regulation Committee
C. Advisory Council
D. Diversity & Inclusion Task Force
E. Protocol Review Committee
    i. Acute Influenza Infection Chemoprophylaxis Protocol
    ii. Self-Care Conditions: Over-the-Counter Dietary Supplement Protocol
    iii. Self-Care Conditions: Over-the-Counter Probiotics

IX. CORRESPONDENCE

A. Closure of Permit (non-use) Extension Request – Owensboro Health Community Pharmacy (P08277)
B. Shared Sink Request – St. Matthews Community Pharmacy (P07821) & St. Matthews Specialty Pharmacy (P07869)
C. Dual PIC request – Jordan Smith (018455); P02542 and CP00154 (upon approval)
D. Dual PIC request – Richard Slone (008306); P07140 and P06091

X. OLD BUSINESS

A. 201 KAR 2:370 Amendment: Pharmacy Services in long-term care facility.
B. 201 KAR 2:480 New Regulation: Telework.
C. 201 KAR 2:210 Amendment: Patient records, drug regimen review, patient counseling, and final product verification.
D. 201 KAR 2:470 New Regulation: Change of Ownership.

XI. NEW BUSINESS

A. Declaratory Opinion – Guidance for Kentucky Pharmacies Acquiring Human Compounded Products from 503B Outsourcing Facilities
B. Board of Physicians and Advisors Appointment (One Appointment)
    i. Baum, Regan A (015978)
    ii. Booker, Antonio (019273)
    iii. Cann, Amber (012015)

iv. Carrico, Matt (015231)
v. Kebodeaux, Clark (015036)
vi. Kramer, Andrea (015973)
vii. Moore, Daniel (015588)

XII. CLOSED SESSION

A. 2023 CRP Settlement Review
   i. 22-0029
   ii. 22-0106
B. 2024 CRP Evidentiary Review
   i. 24-0049A

ATTENTION: A portion of the meeting may be held in closed/executive session for the purpose of discussing and deliberating upon open investigations or the review of information required to be conducted in private according to federal and state law. The specific statutory sections authorizing closed session are KRS 61.810(1)(c) KRS 61.878(1)(a) KRS 61.810(1)(j) KRS 61.878(1)(h) KRS 61.810(1)(k). Following discussion and deliberation, any and all action will be taken in open/public session.

LEGISLATIVE RESEARCH COMMISSION
State Capitol 700 Capital Avenue Frankfort KY 40601
502-564-8100
Capitol Fax 502-564-2922
Annex Fax 502-564-6543
legislature.ky.gov

Jay D. Hartz
Director

MEMORANDUM

TO: Eden Davis, General Counsel, Kentucky Board of Pharmacy

FROM: Emily Caudill, Regulations Compiler

RE: Proposed Amendment or New Regulation – 201 KAR 002:220

DATE: February 20, 2024

A copy of the administrative regulation listed above is enclosed for your files. This regulation is **tentatively** scheduled for review by the Administrative Regulation Review Subcommittee at its **JUNE 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 this regulation is due **by noon on JUNE 14, 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

BOARDS AND COMMISSIONS

BOARD OF PHARMACY

(AMENDMENT)

201 KAR 2:220. Collaborative care agreements.

RELATES TO: KRS 315.010(5)[(4)], 315.121, 315.040(3)[(4)], 315.191(1)(a)

STATUTORY AUTHORITY: KRS 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the Board of Pharmacy to promulgate administrative regulations to regulate and control matters relating to pharmacists, pharmacist interns, pharmacy technicians, pharmacies, wholesale distributors, and manufacturers. This administrative regulation establishes minimum requirements for the development and maintenance of collaborative care agreements between pharmacist and practitioner.

Section 1. A collaborative care agreement shall:

(1) Be in writing;

(2) Be signed and dated by:

(a) Each practitioner; and

(b) Each pharmacist who is a party to the agreement;

(3) Provide the method for referral of patients to be managed under the agreement; and

(4) State the method for termination of the agreement.

Section 2. The following information relating to a patient managed under the collaborative care agreement shall be maintained by the pharmacist:

(1) Name;

(2) Address and phone number;

(3) Emergency notification contact;

(4) Date of birth, weight, height, and sex ~~gender~~;

(5) Medical history, including:

(a) Known diseases;

(b) Known allergies;

(c) Reactions and conditions relating to:

1. Prescription medications; and

2. Nonprescription medications;

(d) Current prescription regimen; and

(e) Current nonprescription regimen;

(6) Lab tests ordered, including results of lab tests;

(7) Assessment of patient outcomes;

(8) Notes relating to the care and course of therapy of the patient; and

(9) Documentation of patient consent to receive care under the collaborative care agreement.

Section 3. Documentation relating to the care and course of therapy of the patient pursuant to the agreement shall be documented in the patient's record maintained by the pharmacist, provided to the collaborating practitioner, and be readily available to other healthcare professionals providing care to the patient.

Section 4. A collaborative care agreement shall comply with KRS 315.010(5)[~~(4)~~] and contain the following information:

(1) Protocol, criteria, standing orders, or other method by which services are authorized;

(2) The method established for the assessment of patient outcomes, if appropriate; and

(3) Lab tests that may be ordered.

Section 5. A collaborative care agreement and information and records required by the provisions of this administrative regulation shall be maintained:

(1) At the pharmacist's practice site; and

(2) For at least five (5) years after the termination of the agreement.

February 19, 2024

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

Date

PUBLIC HEARING AND PUBLIC COMMENT PERIOD:

A public hearing on this administrative regulation shall be held on May 22, 2024, at 10:00 a.m. Eastern Time at 125 Holmes Street, Frankfort, KY 40601 and via 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 May 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 2:220. Collaborative Care Agreements.
Contact person: Christopher Harlow
Contact Phone No.: 502-564-7910
Contact email: Christopher.harlow@ky.gov

(1) Provide a brief summary of:

(a) What this administrative regulation does: This regulation creates rules for pharmacists engaged in collaborative practice with a practitioner.

(b) The necessity of this administrative regulation: KRS 315.191(1)(a) authorizes the Board of Pharmacy to promulgate administrative regulations to regulate and control all matters set forth in KRS Chapter 315. KRS 315.010(5) defines collaborative care agreements.

(c) How this administrative regulation conforms to the content of the authorizing statues: This administrative regulation establishes consistent with the requirements of KRS 315.191(1)(a) minimum requirements for those pharmacists utilizing collaborative care agreements.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This regulation allows for clear rules for those utilizing a collaborative care agreement. Without this regulation, it would be unclear what information relating to a patient managed under a collaborative care agreement needed to be maintained by the pharmacist.

(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 is only to make technical changes for language efficacy and to cite the correct sections of statutory law that had been modified since this regulation was originally promulgated in 1997 and last revised in 2015.

(b) The necessity of the amendment to this administrative regulation: To ensure that the correct statutory sections of law were cited.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 315.002 and 315.005 authorize the board to regulate the practice of pharmacy. KRS 315.191 authorizes the board to promulgate administrative regulations pertaining to pharmacists and pharmacies. KRS 315.191(1)(a) directs the Board of Pharmacy to promulgate administrative regulations to regulate and control all matters set forth in KRS 315.

(d) How the amendment will assist in the effective administration of the statutes: The amendment will further promote, preserve, and protect public health through effective regulation of pharmacists by ensuring that the appropriate statutory citations are correct.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The board anticipates pharmacies and pharmacists will be affected minimally by this regulation amendment.

(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: Pharmacies and pharmacists will have to familiarize themselves with amended language. The board will help to educate pharmacists and pharmacies in these changes.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There are no expected costs for the identities to comply with the amendment.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): The ability to participate in collaborative practice with practitioners as already authorized under KRS 315.010(5).

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

Regulation:

(a) Initially: No costs will be incurred.

(b) On a continuing basis: No costs will be incurred.

(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 increase in fees or funding will be required because of this amendment.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation does not establish fees or directly or indirectly increase any fees.

(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 that desire to utilize collaborative care agreements.

FISCAL NOTE

Regulation No. 201 KAR 2:220. Collaborative Care Agreements.
Contact Person: Christopher Harlow
Contact Phone No.: 502-564-7910
Contact email: Christopher.harlow@ky.gov

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Board of Pharmacy will be impacted by this administrative regulation.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 315.191(1)(a).

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation will not generate revenue for the board in the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation will not generate revenue for the board in subsequent years.

(c) How much will it cost to administer this program for the first year? No costs are required to administer this program for the first year.

(d) How much will it cost to administer this program for subsequent years? No costs are required to administer this program for subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation. N/A

Revenues (+/-): 0

Expenditures (+/-): 0

Other Explanation: This regulation does not impact costs.

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year? None

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years? None.

(c) How much will it cost the regulated entities for the first year? Nothing.

(d) How much will it cost the regulated entities for subsequent years? Nothing.

Cost Savings (+/-): 0
Expenditures (+/-): 0
Other Explanation: There are no costs incorporated into this regulation or implied with compliance.

(5) Explain whether this administrative regulation will have a major economic impact, as defined below. "Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars ($500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)] This regulation does not have major economic impact.

201 KAR 2:370. Pharmacy services in long-term care facility (LTCF).

RELATES TO: KRS 315.010, 315.020, 315.030, 315.121

STATUTORY AUTHORITY: KRS 315.002, 315.005, 315.191

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1) authorizes the Kentucky Board of Pharmacy to establish requirements to regulate and control pharmacies. KRS 315.002 and 315.005 require standards of practice in all settings where drugs are handled and require the board to ensure safety of all drug products provided to the citizens of Kentucky. This administrative regulation establishes requirements for pharmacy services in long-term care facilities.

Section 1. Definitions.

(1) "Automated Dispensing System" or "ADS" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications, and which collects, controls, and maintains all transaction information.

(2) "Emergency Drug" means drugs required to meet the immediate therapeutic needs of patients that are not available from any other authorized source in sufficient time to prevent risk of harm to patients because of delay.

(3) "Emergency Medication Kit" or "EMK" means an onsite manual or automated mechanism for delivering emergency medications.

(4) "Immediate supervision" is defined by KRS 315.010(12).

(5) "Individual dose" means smallest unit that is commercially available.

(6) "Long-term care facility" or "LTCF" is defined by KRS 216.510(1), excluding family-care homes **and assisted living communities.**

(7) "Long Term Care Facility Drug Stock" or "LTCF drug stock" means a dose or doses generated from a prescription order sufficient until the next pharmacy business day or IV fluids that are used for replenishment, which contain no additive drugs, or irrigation solutions.

(8) "Pharmacist-in-charge" or "PIC" means a pharmacist mandated as in charge under KRS 315.020 and who meets the requirements of 201 KAR 2:205.

(9) "Supervision" is defined by KRS 315.010(27).

(10) "Tamper-resistant secure container" means an enclosed container used in a tamper-resistant ADS and designed to prevent the opening of the container and manipulation of medications prior to loading the ADS and after the contents of the container have been enclosed and verified by a pharmacist.

Section 2. General Requirements.

(1) The pharmacist-in-charge of the dispensing pharmacy shall:

(a) Be responsible for policies and procedures governing the procurement, distribution, storage, security, access, administration, and control of all drugs that are provided to a LTCF;

(b) Review all policies and procedures at least once every twelve (12) months;

(c) Provide LTCF drug stock or an EMK only to facilities that authorize entry by a board agent for the purposes of inspection or investigation of the LTCF drug stock or EMK at the facility;

(d)

1. Maintain written authorization for entry; and

2. Immediately provide written authorization for entry to the board upon request of a board agent; and

(e) Maintain a current list of all locations where LTCF drug stock or an EMK are stored, which shall be made immediately available upon request by a board agent.

(2) Dispensing.

(a) Controlled substance medications shall be dispensed only by prescription drug order of a licensed practitioner.

(b) Non-controlled substance medications shall be dispensed only on a medical order or prescription drug order of a licensed practitioner.

(c) A medical order entered on the medical record of a patient at a LTCF shall contain:

1. Name of patient;

2. Date of issuance;

3. Name, strength, and dosage form of drug prescribed;

4. Directions for use; and

5. Practitioner's name.

(d) Each licensee shall comply with United States Pharmacopeia (USP) Chapter 7 Labeling regarding labeling and packaging.

(3) The services of a pharmacist shall be readily available at all times.

(4) Emergency drugs.

(a) Emergency drugs for controlled substances in a LTCF EMK shall be stocked pursuant to 902 KAR 55:070.

(b) Emergency drugs for non-controlled substances in an EMK shall not exceed six (6) individual doses of thirty (30) different non-controlled substances, per LTCF.

(c) The pharmacist-in-charge may request a waiver from the board to increase the number of doses or numbers of non-controlled substances in the EMK based on evidence of use.

(d) An EMK shall be assessed for outdated, damaged or adulterated drugs, and stock adequacy by:

1. A pharmacist or any lawful person as stated in 902 KAR 55:070 on a monthly basis for controlled substances; or

2. A pharmacist, a PIC authorized pharmacist intern, or certified pharmacy technician on a monthly basis for non-controlled substances.

(e) EMK drugs shall be supplied in unit dose packaging unless precluded by manufacturer packaging.

(f) An EMK shall be conspicuously labeled.

(g) An EMK drug shall be accessed only upon a lawful prescription order.

(h) All prescription orders shall be reviewed by a pharmacist within one (1) pharmacy business day.

(i) An EMK shall not be stocked in a personal care home without personnel lawfully licensed to administer medications.

(5) Initial dose of LTCF drug stock in a LTCF.

(a) Excluding personal care homes, LTCF drug stock of drugs shall not exceed fifteen (15) individual doses each of 150 non-controlled substances.

(b) LTCF drug stock in a personal care home shall not exceed five (5) individual doses each of thirty (30) non-controlled substances.

(c) The pharmacist-in-charge may request from the board a waiver to increase the number of non-controlled substance items to be placed in LTCF drug stock based upon evidence of use.

(d) The pharmacist-in-charge shall be responsible for authenticating the need for LTCF drug stock.

(e) A pharmacist shall review the prescription drug or medical order before the release of medication.

(f) LTCF drug stock shall be inspected by pharmacy personnel at least monthly and documentation shall be maintained to determine if:

1. Medications are outdated; and

2. Stocks are maintained at adequate levels.

(g) Except for LTCF drug stock of intravenous fluids with no additive drugs or irrigation solutions, the LTCF drug stock shall be replenished by:

1. A tamper-resistant secure container delivered from the pharmacy;

2. A tamper-resistant secure container for the stocking of an ADS;

3. A pharmacist, pharmacist intern, or a certified pharmacy technician who shall be under the immediate supervision of a pharmacist on-site, if there is no pharmacy on-site; or

4. A pharmacist, pharmacist intern, or a certified pharmacy technician who shall be under the supervision of a pharmacist, if there is a pharmacy on-site.

Section 3. The pharmacist-in-charge of an ADS in a LTCF shall be responsible for the following:

(1) Initial validation of the ADS accuracy prior to use for distribution to patients assuring that the ADS:

(a) Is in good order and accurately dispenses the correct strength, dosage form, and quantity of drug prescribed; and

(b) Complies with the recordkeeping and security safeguards pursuant to Section 4 of this administrative regulation.

(2) Assuring that non-controlled substance prescription drug orders and medical orders are reviewed and approved by a pharmacist prior to access, except for emergency drugs;

(3) Assuring that controlled substance prescription drug orders are reviewed and approved by a pharmacist prior to accessing the controlled substance emergency drugs;

(4) Implementing an ongoing quality assurance program that monitors performance of the ADS, pursuant to the written policies and procedures;

(5) Assigning, discontinuing, or changing personnel access to the system; and

(6) Assuring appropriate access to medications.

Section 4. Standards. A permit holder utilizing an ADS shall comply with the following provisions:

(1) A pharmacy shall maintain the following documentation:

(a) Name and address of the LTCF where the system is being used;

(b) The ADS manufacturer's name, model, and serial number;

(c) An operations manual;

(d) Description of how the system is used;

(e) Written quality assurance procedures to determine continued appropriate use of the system; and

(f) Written policies and procedures for system operation, safety, security, accuracy, access, and malfunction.

(2) All written policies and procedures shall be maintained in the pharmacy responsible for the ADS.

(3) An ADS shall maintain adequate security systems and procedures, pursuant to written policies and procedures that prevent unauthorized access to patient records and maintain patient confidentiality.

(4) ADS records and data shall meet the following requirements:

(a) All events involving the contents of the ADS shall be recorded electronically; and

(b) Records shall be maintained by the pharmacy for five (5) years, be available to the board, and shall include the following:

1. The time and location of each system access;

2. Identification of the individual accessing the system;

3. Name of the patient for whom the drug was ordered;

4. Name, strength, dosage form, and quantity of drug accessed;

5. Type of transaction;

6. The prescription or transaction number if assigned; and

7. The name of the prescriber.

(c) All events involving user database modifications shall be recorded electronically and maintained.

(d) A twenty-four (24) hour emergency call center shall be available for any ADS malfunction.

(5) The stocking of all medications in an ADS shall be performed by a:

(a) Pharmacist;

(b) Pharmacist intern; or

(c) Certified pharmacy technician who shall be under the supervision of a pharmacist on-site.

(6) If the pharmacy utilizes a tamper resistant barcoding technology, microchip, or other equivalent tamper-resistant ADS, a pharmacist-verified drug may then be loaded by a pharmacist-in-charge trained pharmacist, pharmacist intern, or certified pharmacy technician.

(7) A record of medications stocked in an ADS shall be maintained for five (5) years and shall include identification of the person stocking the ADS and the pharmacist checking for accuracy.

(8) The pharmacist-in-charge shall provide a policy for accounting for medications removed from an ADS and subsequently wasted.

(9) The pharmacist-in-charge shall provide a policy for accounting for medications returned to an ADS.

Section 5. Incorporation by Reference.

(1) "USP Chapter 7 Labeling", (December 1, 2017), is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. through 4:30 p.m.

BOARDS AND COMMISSIONS

Kentucky Board of Pharmacy

(New Administrative Regulation)

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

RELATES TO: KRS 315.020(5), KRS 315.310

STATUTORY AUTHORITY: KRS 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: 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.

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;

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

(4) “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 may 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.

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

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

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

(c) 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.

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

(e) 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 rule 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 may not be stored at the telework site.

(4) Records may 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.

(f) Electronic communication system testing and training;

Section 10. Prohibited Practices.

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

BOARDS AND COMMISSIONS

BOARD OF PHARMACY

(AMENDMENT)

201 KAR 2:210. Patient records, [~~and~~] ~~patient counseling~~ drug regimen review, patient counseling, and final product verification.

RELATES TO: KRS 217.015(9), 218A.010(11), 315.010(7),(9), (24), 315.020(5)(e), 315.191(1), [~~(5), (6),~~] 42 C.F.R. ~~Part~~ 456

STATUTORY AUTHORITY: KRS 217.215(2), 315.191(1), [~~(5)~~], 42 C.F.R. ~~Part~~ 456

NECESSITY, FUNCTION, AND CONFORMITY: [~~KRS 315.191(1),(56)~~]], 42 C.F.R. ~~CFR Part~~ 456 mandates that pharmacists implement drug regimen [~~utilization~~] reviews and provide patient counseling to those recipients of health-care benefits for which federal funds are allocated. [~~This administrative regulation provides for this mechanism and broadens its magnitude by rendering this valuable service available to all Kentucky's citizenry, equitably.~~] This regulation establishes rules for the dispensing of a prescription drug or medical order by a pharmacist and ensures comprehensive patient records are maintained and remain confidential.

Section 1. Definitions.

(1) “Automated filling system” means an automated system used by a pharmacy to assist in filling a prescription drug order or medical order by selecting, labeling, filling, or sealing medication for dispensing. An “automated filling system” shall not include automated devices

used solely to count medication, vacuum tube drug delivery systems, automated pharmacy systems as defined in KRS 218A.185, or automated dispensing systems as defined in 201 KAR 2:370.

(2) "Confidential information" is defined by KRS 315.010(7).

(3) "Dispense" or "Dispensing" is defined by KRS 315.010(9), KRS 217.015(9) and KRS 218A.010(11).

(4) "Electronic verification" means the non-physical visual verification a pharmacist utilizes to verify the accuracy of the final contents of the prepared prescription product and affixed label prior to dispensing.

(5) "Electronic verification system" means an electronic verification, bar code verification, weight verification, radio frequency identification, or similar electronic process or system that accurately verifies medication has been properly prepared and labeled by, or loaded into, an automated filling system.

(6) "Final Product Verification" means the process a pharmacist utilizes to verify the accuracy of the final contents of any prepared prescription product and affixed label prior to dispensing.

(7) "Manufacturer unit of use package" means a drug dispensed in the manufacturer's original and sealed packaging, or in the original and sealed packaging of a re-packager, without additional manipulation or preparation by the pharmacy, except for application of the pharmacy label;

(8) "Medical Order" is defined by KRS 315.010(14).

(9) "Prepared prescription product" is a prescription drug or medical order prepared for dispensing by a pharmacist.

(10) "Prescription drug order" is defined by KRS 315.010(25).

(11) “Re-packager” means a re-packager registered with the United States Food and Drug Administration.

(12) “Repacked” means any drug that has been removed from the original packaging of the manufacturer or a re-packager’s packaging and is placed in a container for use in an automated filling system.

Section 2. Patient Records.

(1) ~~(a)~~ A patient record system shall, with the exercise of professional judgment, be maintained by a pharmacy for patients for whom prescription drug or medical orders ~~prescriptive drug orders~~ are dispensed at that pharmacy location.

(2) [~~(b)~~] A pharmacist, with the exercise of professional judgment, shall establish a procedure for obtaining, recording, and maintaining information required for a patient record.

(3) [~~(c)~~] A pharmacist, or a pharmacy technician or a pharmacist intern ~~his designee~~, shall obtain, record, and maintain the information for a patient record.

(4) [~~(d)~~] A patient record shall:

(a) [~~1.~~] Be readily retrievable by manual or electronic means;

(b) [~~2.~~] Enable the pharmacist to identify previously dispensed drugs and known disease conditions;

(c) [~~3.~~] Enable the pharmacist to determine the impact of previously dispensed drugs and known disease conditions upon the newly submitted prescription drug or medical order [~~prescriptive drug order~~]; and

(d) [~~4.~~] Be maintained for not less than 180 days from the date of the last entry.

(5) [~~(2)~~] A patient record shall include:

(a) Full name of patient or animal for whom the drug is intended;

(b) Address and telephone number of the patient;

(c) Patient's age or date of birth;

(d) Patient's gender;

(e) A list of all prescriptions received by the pharmacy or dispensed ~~obtained by~~ to the patient at that pharmacy location for the past twelve (12) months by:

1. Prescription number;

2. Name and strength of medication;

3. Quantity;

4. Date received;

5. Identity of prescriber; and

6. Comments or other information as may be relevant to the specific patient or drug; and

(f) Individual medical history if significant, including known disease states, known allergies, idiosyncrasies, reactions or conditions relating to prospective drug use and drug regimen reviews.

Section 3. [~~2.~~] Prospective Drug Regimen Review.

(1) A prospective drug regimen review shall be conducted by a pharmacist prior to dispensing.

(2) It shall include an assessment of a patient's drug therapy and the prescription order.

(3) A prospective drug regimen review shall include a review by the pharmacist of the following:

(a) Known allergies;

(b) Rationale for use;

(c) Proper dose, route of administration, and directions;

(d) Synergism with currently employed modalities;

(e) Interaction or adverse reaction with applicable:

1. Drugs;

2. Foods; or

3. Known disease states;

(f) Proper utilization for optimum therapeutic outcomes; and

(g) Clinical misuse or abuse.

Section 4. Automated Filling Systems.

(1) Automated filling systems shall be stocked or loaded by a pharmacist or by a pharmacist intern or certified pharmacy technician under the supervision of a pharmacist. A registered pharmacy technician may stock or load an automated filling system under the immediate supervision of a pharmacist.

(2) A licensed pharmacist shall inspect and verify the accuracy of the final contents of any prepared prescription product filled or packaged by an automated filling system and the label affixed thereto prior to dispensing. A pharmacist shall be deemed to have verified the prepared prescription product and the label affixed thereto if:

(a) The filling process is fully automated from the time the filling process is initiated until a completed, labeled, and sealed prepared prescription product is produced by the automated filling system that is ready for dispensing to the patient. No manual intervention with the medication or prepared prescription product may occur after the medication is loaded into the automated filling system. Manual intervention shall not include preparing a finished prepared prescription product for mailing, delivery, or storage;

(b) A pharmacist verifies the accuracy of the prescription information used by or entered into the automated filling system for a specific patient prior to initiation of the automatic fill process. The name, initials, or identification code of the verifying pharmacist shall be recorded in the pharmacy's records and maintained for five (5) years after dispensing;

(c) The pharmacy establishes and follows a policy and procedure manual that complies with this rule;

(d) A pharmacist verifies the correct medication, repackaged container, or manufacturer unit of use package was properly stocked, filled, and loaded in the automated filling system prior to initiating the fill process. Alternatively, an electronic verification system may be used for verification of manufacturer unit of use packages or repacked medication previously verified by a pharmacist. The name, initials, or identification code of the verifying pharmacist shall be recorded in the pharmacy's records and maintained for five (5) years after dispensing;

(e) The medication to be dispensed is filled, labeled, and sealed in the prescription container by the automated filling system or dispensed by the system in a manufacturer's unit of use package or a repacked pharmacy container;

(f) An electronic verification system is used to verify the proper prescription label has been affixed to the correct medication, repackaged container, or manufacturer unit of use package for the correct patient; and

(g) Daily random quality testing is conducted by a pharmacist on a sample size of prescriptions filled by an automated filling system. The required sample size shall not be less than two (2) percent of the prescriptions filled by the automated system on the date tested or two (2) percent of the prescriptions filled by the automated system on the last day of system operation, as designated in writing by the pharmacist in charge. Proof of compliance, including date and results, of daily random quality testing shall be maintained and documented in the pharmacy's records.

(3) Pharmacies verifying prescriptions utilizing the method in subsection two (2) shall establish and follow written policies and procedures to ensure the proper, safe, and secure functioning of the system. Policies and procedures shall be reviewed annually by the pharmacist in charge and

shall be maintained in the pharmacy's records for a minimum of five (5) years. The required annual review shall be documented in the pharmacy's records and made available upon request.

(4) At a minimum, the pharmacy shall establish and follow policies and procedures for:

(a) Maintaining the automated filling system and any accompanying electronic verification system in good working order;

(b) Ensuring accurate filling, loading, and stocking of the system

(c) Ensuring sanitary operations of the system and preventing cross-contamination of cells, cartridges, containers, cassettes, or packages;

(d) Reporting, investigating, and addressing filling errors and system malfunctions;

(e) Testing the accuracy of the automated filling system and any accompanying electronic verification system. At a minimum, the automated filling system and electronic verification system shall be tested before the first use of the system or restarting the system and upon any modification to the automated filling system or electronic verification system that changes or alters the filling or electronic verification process;

(f) Training persons authorized to access, stock, restock, or load the automated filling system in equipment use and operations;

(g) Tracking and documenting prescription errors related to the automated filling system that are not corrected prior to dispensing to the patient. Such documentation shall be maintained for five (5) years and produced to the board upon request;

(h) Conducting routine and preventative maintenance, and, if applicable, calibration;

(i) Removing expired, adulterated, misbranded, or recalled drugs;

(j) Preventing unauthorized access to the system, including assigning, discontinuing, or changing security access;

(k) Identifying and recording persons responsible for stocking, loading, and filling the system;

(l) Ensuring compliance with state and federal law, including, all applicable labeling, storage and security requirements; and

(m) Maintaining an ongoing quality assurance program that monitors performance of the automatic fill system and any electronic verification system to ensure proper and accurate functioning.

(5) Records required by this rule shall be maintained by the pharmacy's records electronically or in writing for a minimum of five (5) years. When the verification requirements of section 4, subsection 2 of this rule are completed by a pharmacist, the name, initials or identification code of the verifying pharmacist shall be recorded in the pharmacy's records and maintained for five (5) years after dispensing. Records shall be made available for inspection and produced to the board upon request.

Section 5. Final Product Verification.

(1) Final product verification of a prepared prescription product shall be conducted by a pharmacist prior to delivery of the prepared prescription product to the patient.

(2) No further manipulation of a prepared prescription product shall occur after the pharmacist's verification is complete other than applying the required container lid or seal and preparing the prepared prescription product for mailing, delivery or storage.

(3) The identity of the pharmacist responsible for verifying the prepared prescription product shall be documented in the pharmacy's records.

(4) A mechanism shall be in place to record and communicate the pharmacist's verification.

(5) A licensed pharmacist may use an electronic verification system to verify the accuracy of a final prepared prescription product if:

(a) The electronic verification system allows the pharmacist to see an exact, clear, and unobstructed visual image or images of the prepared prescription product contents and the label

affixed to the container. If multiple units are being dispensed, the pharmacist shall be able to see and verify an image or images of each unit and each individual affixed label;

(b) Pharmacy technicians and pharmacist interns preparing a prescription to be verified with electronic verification shall be trained and competent to perform the duties assigned and have a documented initial and annual assessment of competency using the pharmacy's approved electronic verification system;

(c) The pharmacy maintains an ongoing quality assurance program that monitors performance of the electronic verification system to ensure proper and accurate functioning and must include procedures for system outages; and

(d) The pharmacy maintains records required by this rule electronically or in writing for a minimum of five (5) years. Records shall be made available for inspection and produced to the board upon request.

(6) Compounded preparations shall not be verified electronically. Compounded preparations shall be physically verified by a pharmacist.

(7) Final product verification of a prescription shall only occur on the premises of the originating pharmacy notwithstanding any final product verification occurring under 201 KAR 2:230.

(8) The board may, upon a petition by a permit holder and upon a showing of good cause and in the balancing the best interest of the public health, safety, and welfare, waive a specific portion of this section.

Section 6. Patient Counseling.

(1) The pharmacist shall offer to counsel a patient on matters which the pharmacist [~~he~~] believes will optimize drug therapy with each patient or caregiver:

(a) Upon the presentation of an original prescription order; and

(b) On refill prescriptions, as professional discretion dictates.

(2) [~~(a)~~] The offer shall be made by the pharmacist in a face-to-face communication with the patient or caregiver, unless, in the professional judgment of the pharmacist, it is deemed impractical or inappropriate.

(3) [~~(b)~~] If deemed impractical or inappropriate, the offer to counsel may be made:

(a) [~~1.~~] By the pharmacy technician or pharmacist intern [~~pharmacist designee~~];

(b) [~~2.~~] In written communication;

(c) [~~3.~~] By telephone [~~through access to a telephone service that is toll-free for long distance calls, unless the primary patient population is accessible through a local, measured, or toll-free exchange~~]; or

(d) [~~4.~~] In another manner determined by the pharmacist to be appropriate.

(4) [~~(3)~~] Patient counseling shall be:

(a) In person when practical; or

(b) With reasonable effort, by telephone or real-time video.

(5) [~~(4)~~] The pharmacist shall include the following elements of patient counseling that the pharmacist ~~he~~ has determined are appropriate:

(a) The name and description of the drug;

(b) The dosage form, dose, route of administration, and duration of therapy;

(c) Special directions and precautions;

(d) Common and clinically significant adverse effects, interactions, or contraindications that may be encountered, including their avoidance and the action required should they occur;

(e) Techniques for self-monitoring of drug therapy;

(f) Proper storage;

(g) Refill information;

(h) Action to be taken in event of a missed dose;

(i) The pharmacist's [~~His~~] comments relevant to the individual's therapy; and

(j) Any other information peculiar to the specific patient or drug.

(6) [~~(5)~~] If a pharmacist determines that it is appropriate, the pharmacist ~~he~~ may supplement patient counseling with additional forms of patient information, such as:

(a) Written, electronic, or printed information leaflets;

(b) Pictogram labels; and

(c) Video programs.

(7) [~~(6)~~] Mail-order pharmacies shall be subject to the same counseling requirements as any other pharmacy.

Section 7. Documentation of Counseling.

(1) A record that the patient refused the pharmacist's offer to counsel shall be maintained for one (1) year.

(2) If there is no record that the patient refused the pharmacist's offer to counsel, there shall be a presumption that:

(a) The offer to counsel, as required in Section 4 of this administrative regulation, was made and accepted; and

(b) The counseling was provided.

Section 8. ~~Section 3.~~ Confidentiality.

(1) A patient record shall be held in confidence.

(2) It shall be communicated or released:

(a) To the patient;

(b) As the patient directs; or

(c) As prudent, professional discretion dictates.

~~Section 4. Prospective Drug Use Review.~~

~~(1) A prospective drug use review shall be conducted by a pharmacist prior to dispensing.~~

~~(2) It shall include an assessment of a patient's drug therapy and the prescription order.~~

~~(3) A prospective drug use review shall include a review by the pharmacist of the following:~~

~~(a) Known allergies;~~

~~(b) Rationale for use;~~

~~(c) Proper dose, route of administration, and directions;~~

~~(d) Synergism with currently employed modalities;~~

~~(e) Interaction or adverse reaction with applicable:~~

~~1. Drugs;~~

~~2. Foods; or~~

~~3. Known disease states;~~

~~(f) Proper utilization for optimum therapeutic outcomes; and~~

~~(g) Clinical misuse or abuse.~~

~~Section 5. Documentation of Counseling.~~

~~(1) A record that the patient refused the pharmacist's offer to counsel shall be maintained for one (1) year.~~

~~(2) If there is no record that the patient refused the pharmacist's offer to counsel, there shall be a presumption that:~~

~~(a) The offer to counsel, as required in Section 2 of this administrative regulation, was made and accepted; and~~

~~(b) The counseling was provided.~~

Section 6. The provisions of this administrative regulation shall not apply:

(1) To a hospital or institution if other licensed health-care professionals are authorized to administer the drugs; and

(2) Compliance with 902 KAR 20:0116, 201 KAR 2:074 and 201 KAR 2:076 is maintained.

BOARD AND COMMISSIONS

Kentucky Board of Pharmacy

(New Administrative Regulation)

201 KAR 2:470. Change of Ownership

RELATES TO: KRS 315.035, 315.036(1), 315.340(6), 315.350(4), 315.405(5), 315.4104(1)

STATUTORY AUTHORITY: 315.191(1)

NECESSITY, FUNCTION, AND CONFORMITY: 315.191(1) authorizes the board to promulgate administrative regulations to regulate pharmacists, pharmacies, wholesalers and manufacturers. KRS 315.035 discusses changes of ownership of a pharmacy and requires notice to be provided no fewer than five days before the transaction occurs and authorizes a buyer to operate under a seller's permit pending the application. Due to the nature of business structures, it is not clear when a change of ownership of a regulated entity is considered to occur, and therefore this regulation provides clarity for making those determinations.

Section 1. Change of entity ownership requiring a new license or permit means:

(1) Partnership. In the case of a partnership, the removal, addition, or substitution of a partner.

(2) Unincorporated sole proprietorship. In the case of an unincorporated sole proprietorship, the transfer of title and property to another party.

(3) Corporation. In the case of a corporation, the merger of the licensed corporation into another corporation or the consolidation of two or more corporations, resulting in the creation of a new corporation.

(a) Transfer of corporate stock or the merger of another corporation into the licensed corporation does not constitute change of entity ownership; however, notification pursuant to section 2 of this regulation shall be provided within thirty days of the transaction occurring.

(4) Limited liability company (LLC). In the case of an LLC, the merger of the licensed LLC into another LLC or the consolidation of two or more LLCs, resulting in the creation of a new LLC.

(a) Transfer of company stock or the merger of another LLC into the licensed LLC does not constitute change of ownership; however, notification pursuant to section 2 of this regulation shall be provided within thirty days of the transaction occurring.

Section 2. Procedure.

1. Written notice of the following shall be provided to the Board no more than thirty calendar days after the transaction occurs:

(a) A transfer of stock of greater than 10% in a non-publicly traded corporation which is the direct owner of an entity;

(b) A transfer of membership interest in a limited liability company which is the direct owner of a entity; and

(c) A change of corporate officer.

Section 3. Responsibility.

1. A permit or license which has been served with a complaint and notice of hearing pursuant to KRS 13B for a pending disciplinary proceeding with the Board of Pharmacy may not change ownership until the issuance of a final order by the Board or upon the agreement of all parties to the terms of a settlement.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD:

A public hearing on this administrative regulation shall be held on [NEED DATE BETWEEN AUGUST 21-30] , at 10:00 a.m. Eastern Time at 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 2:470. Change of Ownership.
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:
(b) The necessity of this administrative regulation:
(c) How this administrative regulation conforms to the content of the authorizing statues:
(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:

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

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative 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:
(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):
(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):

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

(a) Initially:

(b) On a continuing basis:

(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:

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

(9) TIERING: Is tiering applied? (Explain why tiering was or was not used)

FISCAL NOTE

Regulation No. 201 KAR 2:470. Change of Ownership.
Contact Person: Christopher Harlow, Phone 502-564-7910; Email: Christopher.harlow@ky.gov
(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation?
The Kentucky Board of Pharmacy will be impacted by this administrative regulation.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 315.191(1)(a).

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.
(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation will not generate revenue for the board in the first year.
(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation will not generate revenue for the board in subsequent years.
(c) How much will it cost to administer this program for the first year?
(d) How much will it cost to administer this program for subsequent years?
Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.
Revenues (+/-):
Expenditures (+/-):
Other Explanation:

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.
(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year?
(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years?
(c) How much will it cost the regulated entities for the first year?
(d) How much will it cost the regulated entities for subsequent years?
Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Cost Savings (+/-): 0
Expenditures (+/-):
Other Explanation:

(5) Explain whether this administrative regulation will have a major economic impact, as defined below. "Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars ($500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)] This regulation does not have major economic impact.