**KENTUCKY BOARD OF PHARMACY**

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

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**March 27, 2024**
**10:00 a.m.**

**Board Meeting Agenda**

**I.** CALL TO ORDER

**II.** MINUTES

**III.** APPEARANCES
- A. Child Fatality and Near Fatality External Review Panel
- B. Pharmacist Applications
  - i. Adams, James Pruett- License Transfer
  - ii. Henderson, Leann-License Reinstatement
  - iii. Kokoszka, Robert- License Transfer
- C. Pharmacy Technician Applications
  - i. Hinkle, Jaremeia
  - ii. Whitman, Danisha
- D. CVS Air Support

**IV.** INTERAGENCY/PROFESSIONAL ASSOCIATIONS

**V.** BOARD REPORTS
- A. Executive Director
  - a. eMARs
  - b. Board Retreat Update
  - c. Legislative Update
  - d. Staff Update
- B. General Counsel

a. "Walking" Quorums

C. Deputy Executive Director/Inspection Staff

**VI.** COMMITTEE REPORTS

A. KYPRN
B. Regulation Committee
C. Advisory Council
D. Protocol Review Committee
    i. Signature page

**VII.** FACILITY APPLICATIONS

A. Non-Resident Pharmacy Application
    i. Express Med Pharmaceuticals DBA SelectRx PA- REVISIT
    ii. Almac Clinical Services LLC - REVISIT

**VIII.** CORRESPONDENCE

A. Ohio County Healthcare Waiver Request: 201 KAR 2:074(7)(2)(a)(2)
B. Offsite Storage Requests
    i. P06279
    ii. P06700
C. Dual (multiple) PIC Request – P05146, P07677, and new application
D. Taylor, Mackynzie – NAPLEX and MPJE eligibility extension request

**IX.** OLD BUSINESS

A. 201 KAR 2:370 Clarification Request
B. 201 KAR 2:465 Non-Resident Pharmacy Applications and Waivers - New Regulation
C. 201 KAR 2:030 License Transfer and Non-Resident Pharmacist License-Amendment
D. 201 KAR 2:050 Licenses and permits; fees-Amendment.
E. 201 KAR 2:480 Telework-New Regulation
F. Central Fill/Shared Services Proposed Regulation
G. 201 KAR 2:210. Patient records, drug regimen review, patient counseling, and final product verification

**X.** NEW BUSINESS

A. 201 KAR 2:015 Proposed Amendment
B. CE Deferral Requests Pursuant to 201 KAR 2:015(5)(2)
    i. 007168
    ii. 010211
    iii. 013117
    iv. 017066
    v. 021938
C. Closure of W04422 Due to Nonuse

**XI.** CLOSED SESSION DISCUSSION REQUIRED

A. 2023 CRP

i. 22-0029

ii. 22-0106

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.

GENERAL GOVERNMENT CABINET

Kentucky Board of Pharmacy

(Amendment)

201 KAR 2:030. License transfer and Non-Resident Pharmacist License.

RELATES TO: KRS 315.191(1)(c), (d), 315.210. KRS 315.050

STATUTORY AUTHORITY: KRS 218A.205(8), 315.191(1)(a), (c), (d), 315.210

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.210 authorizes the board to establish conditions for licensure by reciprocity. KRS 218A.205(8) requires the board to establish requirements for background checks for licensees. This administrative regulation establishes conditions, forms, and examination requirements for licensure by reciprocity and for licensure of non-resident pharmacists.

Section 1. Definitions.

(1) “Board” is defined by KRS 315.010(4).

(2) “Good standing” means that a license is not suspended, revoked, surrendered, conditioned under terms of probation, or otherwise in a status that in any manner restricts the activity of the licensee.

(3) "License transfer" means a license to practice pharmacy in Kentucky issued by the board to a pharmacist licensed in another jurisdiction.

(4) [(3)] "NABP" means the National Association of Boards of Pharmacy.

(5) “Non-Resident Pharmacist License” means a license issued by the Board to a pharmacist licensed and located in another jurisdiction to practice pharmacy to citizens in Kentucky.

Section 2. An applicant licensed in another jurisdiction shall be eligible for license transfer, if the:

(1) Requirements for licensure of the jurisdiction that granted his or her license met or exceeded Kentucky requirements for licensure when the license in the other jurisdiction was granted;

(2) Applicant holds in good standing, an active license to practice pharmacy;

(3) Applicant has:

(a) Completed and certified the NABP Preliminary Application for Transfer of Pharmacist License form; and

(b) Received an NABP Official Application for Transfer of Pharmacist License;

(4) Applicant is currently in good standing in the jurisdiction from which he or she has applied;

(5) Applicant has successfully completed an examination in jurisprudence;

(6) Applicant has submitted to a nation-wide criminal background investigation by means of fingerprint check by the Department of Kentucky State Police and the Federal Bureau of Investigation; and

(7) Applicant has submitted to a query to the National Practitioner Data Bank of the United States Department of Health and Human Services.

Section 3.

Required Information. An applicant shall provide the information required by the NABP Preliminary Application for Transfer of Pharmacist License form, including:

(1) Name, maiden, and other names used currently or previously;

(2) Address, telephone number;

(3) Date of birth;

(4) Social Security number;

(5) Citizenship;

(6) Sex;

(7) State of original license by examination, including:

(a) License number;

(b) Original date of issue;

(c) Current status of original licensure; and

(d) State for which license transfer is requested;

(8) Pharmacy education, including:

(a) Name and location of pharmacy school;

(b) Name of pharmacy degree;

(c) Date degree was received; and

(d) Other professional degrees, including the information specified by paragraphs (a) to (c) of this subsection;

(9) Whether the applicant has earned certification by the Foreign Pharmacy Graduate Examination Committee, and, if so, the examination equivalency number assigned;

(10) Total hours of practical experience as an intern prior to licensure as a pharmacist;

(11) States, dates, and results of pharmacist licensure examinations;

(12) Pharmacist licenses currently held, including issue date, expiration date, status, and any board action taken against the licensee;

(13) Practice and employment, including nonpharmacist employment, from the past three (3) years;

(14) Record of charges or convictions of any felony or misdemeanor offense, other than traffic offenses, and whether or not a sentence was imposed or suspended;

(15) Record of any surrender of a pharmacist license or registration issued by the federal government or any state controlled substance authority;

(16) Record of any pharmacist license revocation, suspension, restriction, termination, or other disciplinary action by any board of pharmacy or other state authority;

(17) Record of whether the pharmacist is currently under investigation or subject to disciplinary action by the licensing jurisdiction, federal Food and Drug Administration, federal Drug Enforcement Administration or any state drug enforcement authority for the violation of any state or federal pharmacy, liquor, or drug laws;

(18) Record of any condition or impairment, such as substance or alcohol abuse or dependency that in any way affects the pharmacist's ability to practice pharmacy in a safe and competent manner; and

(19) Record of any application for initial licensure, renewal licensure, or licensure by transfer that was denied by any licensing authority, whether in pharmacy or any other profession.

Section 4.

The board shall accept license transfer applications from jurisdictions that:

(1) Are an active member of the NABP; and

(2) Grant license transfers to pharmacists pursuant to conditions and requirements that are the equivalent of conditions and requirements established by the board.

Section 5. An applicant for license transfer shall take and pass the Multistate Pharmacy Jurisprudence Examination administered by the NABP.

Section 6. An applicant licensed in another jurisdiction shall be eligible for non-resident pharmacist license if the applicant:

(1) Holds in good standing an active license to practice pharmacy in any state;

(2) The applicant is issued a NABP Verify credential; and

(3) The applicant submits to a fingerprint-supported criminal record check by the Department of Kentucky State Police and the Federal Bureau of Investigation pursuant to KRS 218A.205(8).

Section 7. An applicant for non-resident pharmacist license shall be exempt from:

(1) The requirements for license transfer;

(2) The Multistate Pharmacy Jurisprudence Examination administered by NABP;

(3) Continuing Education requirements of Kentucky.

Section 8. A non-resident pharmacist licensee shall:

(1) Maintain participation in the NABP Verify Program;

(2) Submit an initial application for non-resident pharmacist licensure;

(3) Submit an annual renewal of non-resident pharmacist license; and

(4) Pay the annual renewal of a pharmacist non-resident license fee specified by 201 KAR 2:050.

Section 9. The following acts are prohibited with the utilization of a non-resident pharmacist license:

(1) Engaging in the practice of pharmacy in Kentucky while:

(a) Residing in Kentucky; or

(b) Employed by a pharmacy located in Kentucky; and

(2) Serving as a pharmacist-in-charge of a Kentucky permitted facility.

~~[Section 6.]~~ Section 10.

~~[Section 7.]~~ Board Discretion.

(1) The Board maintains the discretion to deny an applicant a licensee if the applicant fails to demonstrate good mental health and moral character pursuant to KRS 315.050(1);

(2) The board may waive the provisions of section 9 during a declared state of emergency.

Section 12. Incorporation by Reference (1) The following material is incorporated by reference:

(a) "NABP Preliminary Application for Transfer of Pharmacist License", April 2018[~~, is incorporated by reference~~].

(b) "Application/Renewal for Non-Resident Pharmacist License," 04/2024.

(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. to 4:30 p.m. or on the Web site at https://pharmacy.ky.gov/professionals/Pages/Pharmacists.asp

GENERAL GOVERNMENT CABINET

Kentucky Board of Pharmacy

(Amendment)

201 KAR 2:050. Licenses and permits; fees.

RELATES TO: KRS 218A.205(3)(g), 315.035(1), (2), (4), 315.0351(1), 315.036(1), 315.050(5), 315.060, 315.110, 315.120, 315.191, 315.402

STATUTORY AUTHORITY: KRS 218A.205(3)(g), 315.035(1), (2), (4), 315.036(1), 315.050(5), 315.060, 315.110(1), 315.120(4), 315.191(1)(i), 315.402(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(i) authorizes the board to assess reasonable fees for services rendered to perform its duties and responsibilities. This administrative regulation establishes reasonable fees for the board to perform all the functions for which it is responsible.

Section 1. The following fees shall be paid in connection with pharmacist examinations and licenses, pharmacy permits, intern certificates, and the issuance and renewal of licenses and permits:

(1) Application for initial pharmacist license - $150;

(2) Application and initial license for a pharmacist license by license transfer - $250;

(3) Annual renewal of a pharmacist license - ninety-five (95) dollars;

(4) Delinquent renewal penalty for a pharmacist license - ninety-five (95) dollars;

(5) Annual renewal of an inactive pharmacist license - ten (10) dollars;

(6) Pharmacy intern certificate valid six (6) years - twenty-five (25) dollars;

(7) Duplicate of original pharmacist license wall certificate - seventy-five (75) dollars;

(8) Application for a permit to operate a pharmacy - $150;

(9) Renewal of a permit to operate a pharmacy - $150;

(10) Delinquent renewal penalty for a permit to operate a pharmacy - $150 dollars;

(11) Change of location or change of ownership of a pharmacy or manufacturer permit - $150;

(12) Application for a permit to operate as a manufacturer - $150;

(13) Renewal of a permit to operate as a manufacturer - $150;

(14) Delinquent renewal penalty for a permit to operate as a manufacturer - $150;

(15) Change of location or change of ownership of a wholesale distributor license - $150;

(16) Application for a license to operate as a wholesale distributor -$150;

(17) Renewal of a license to operate as a wholesale distributor -$150;

(18) Delinquent renewal penalty for a license to operate as a wholesale distributor -$150; ~~and~~

(19) Query to the National Practitioner Data Bank of the United States Department of Health and Human Services - twenty-five (25) dollars;

(20) Application for non-resident pharmacist license – fifty (50) dollars;

(21) Renewal for non-resident pharmacist license – fifty (50) dollars; and

(22) Delinquent renewal penalty for non-resident pharmacist license – fifty (50) dollars.

Section 2. A pharmacy permit applicant [~~An applicant~~] shall submit:

(1) An initial or renewal application for a pharmacy permit on either the:

(a)

1. Application for Permit to Operate a Pharmacy in Kentucky; or

2. Application for Resident Pharmacy Permit Renewal; or

(b)

1. Application for Non-Resident Pharmacy Permit; or

2. Application for Non-Resident Pharmacy Permit Renewal; and

(2) As appropriate, the:

(a) Initial application fee established by Section 1(8) of this administrative regulation; or

(b) Renewal fee established by Section 1(9) of this administrative regulation.

Section 3. All fees shall be non-refundable.

Section 4. Applications shall expire one (1) year after the date the application is received by the Board.

Section 5. Incorporation by Reference.

(1) The following material is incorporated by reference:

(a) "Application for Non-Resident Pharmacy Permit", Form 3, 9/2023;

(b) "Application for Non-Resident Pharmacy Permit Renewal", Form 4, 9/2023;

(c) "Application for Permit to Operate a Pharmacy in Kentucky", Form 1, 6/2023; and

(d) "Application for Resident Pharmacy Permit Renewal", Form 2, 6/2023.

(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. to 4:30 p.m. This material is also available on the board's Web site at https://pharmacy.ky.gov/Businesses/Pages/Pharmacy.aspx.

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 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 order ~~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 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;

(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; and

(b) Pharmacy technicians and pharmacist interns assisting the pharmacist 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.

(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 not occur from a location outside of or other than a pharmacy permitted by the board.

(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.

(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 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.

GENERAL GOVERNMENT CABINET

Kentucky Board of Pharmacy

(New Administrative Regulation)

201 KAR 2:465. Non-Resident Pharmacy Applications and Waivers.

RELATES TO: KRS 315.191(1)(a), (d), KRS 315.0351, 201 KAR 2:050

STATUTORY AUTHORITY: KRS 315.191(1)(a), (d)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a), (d) authorizes the board to promulgate administrative regulations and issue and renew permits for all pharmacies and require all persons who engage in the practice of the profession of pharmacy for a Kentucky resident to hold an active Kentucky pharmacist license. This administrative regulation establishes the requirements to obtain a non-resident pharmacy permit to engage in the practice of pharmacy in the Commonwealth.

Section 1. Inspection Requirements.

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

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

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

Section 2. Pharmacist-in-Charge.

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

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

(3) The pharmacist-in-charge shall be responsible for answering the toll-free telephone service six days a week and a minimum of forty hours per week. The toll-free telephone number shall be present on the label of each prescription dispensed by the pharmacy to a Kentucky resident. If the pharmacist-in-charge is unavailable, a staff pharmacist with access to patient records may answer the call but the staff pharmacist shall notify the pharmacist-in-charge of the call and provide the pharmacist-in-charge with a callback number for the patient. If the staff pharmacist is unable to resolve the patient's question, the pharmacist-in-charge shall return the call of the patient within forty-eight hours.

Section 3. Waiver.

(1) The Board may grant a waiver from the permitting requirements of this section to any nonresident pharmacy which limits dispensing activity to isolated transactions.

(2) An isolated transaction is defined as a transaction in which dispensing is limited to an established patient of the dispensing pharmacy no more than three times per calendar year.

Section 4. Applications.

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

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

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

(2) Each applicant must disclose the following:

(a) names and license numbers of all pharmacists and pharmacist-managers dispensing prescription legend drugs to an ultimate user in Kentucky, the names and, if available, the license or registration numbers of all supportive personnel employed by the out-of-state pharmacy who assist pharmacists in such dispensing;

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

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

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

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

(a) normal delivery protocols and times;

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

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

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

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

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

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

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

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

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

(9) A person who engages in the practice of the profession of pharmacy for a Kentucky resident shall hold an active Kentucky pharmacist license except under Section 3 of this regulation.

BOARDS AND COMMISSIONS

Kentucky Board of Pharmacy

(New Administrative Regulation)

201 KAR 2: ___. ~~**Centralized Prescription Processing**~~ **Central Fill and Shared Pharmacy Services (ensure changed throughout the draft)**

RELATES TO: 21 C.F.R. § 1300 et seq, KRS 315.020(5), KRS 315.0351, KRS 315.335

STATUTORY AUTHORITY: KRS 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: The purpose of this regulation is to set out the minimum requirements under which pharmacies may engage in **central fill and shared pharmacy services** ~~**"centralized prescription processing," which consist of centralized prescription filling services and**~~ **remote prescription processing,** as defined in this regulation~~**, with respect to any prescription to be dispensed by a primary pharmacy**~~.

Section 1. Definitions. (1) “Central Fill Pharmacy” means a Kentucky permitted pharmacy located in the United States that provides packaging, labeling, and delivery of a prescription product to the primary pharmacy for both initial or prescription refills on behalf of the primary pharmacy.

(2) “Primary Pharmacy” means a pharmacy permitted and located in Kentucky that receives a patient’s or a prescribing practitioner’s request to fill or refill a prescription, maintains ownership of that prescription, and provides the final dispensing to the patient.

(3) **“Shared Pharmacy Services” means a process by which two or more Kentucky permitted pharmacies process or dispense a prescription or medical order.** ~~“Remote Processing Pharmacy” means a non-dispensing Kentucky permitted pharmacy located in the United States that processes information related to the practice~~

~~of pharmacy and engages in remote prescription processing whether in the pharmacy or~~

via telework. **Removed "Remote Processing Pharmacy and replaced with "Shared Pharmacy Services."**

**~~(4) "Remote Prescription Processing Functions" are limited to:~~**

**~~(a) Receiving, interpreting, or clarifying medical orders or prescription drug orders from~~**

**~~a primary pharmacy;~~**

**~~(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; and~~**

**~~(h) Patient counseling;~~**

Section 2. Requirements. (1) A **~~primary~~** pharmacy may utilize a central fill pharmacy or

**shared pharmacy services** **~~remote processing pharmacy~~** provided that the **~~primary~~** **pharmacies** **~~pharmacy and the central fill~~**

**~~pharmacy or remote processing pharmacy~~** are:

(a) **~~Be either~~** under common ownership; or

(b) Have a written shared pharmacy services contract or agreement that specifies the

services and functions to be provided by each pharmacy and the responsibilities of each

pharmacy

(2) When **engaging in central fill or shared pharmacy services,** **~~centralized prescription processing is performed the primary pharmacy and~~**

the **pharmacies** ~~**central fill pharmacy or remote processing pharmacy**~~ shall:

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

(b) Share a common electronic file or database or have appropriate technology or interface to allow access to patient and prescription information required to process and fill a prescription drug order;

(c) Establish, maintain and enforce a policy and procedures manual;

(d) Have adequate procedures to ensure that each medical order or prescription drug order has been properly processed and filled;

(e) Ensure prescription processing functions for a Kentucky patient are performed by a Kentucky licensed pharmacist;

(f) Ensure that **pharmacy** technicians and **pharmacist** interns are limited to the performance of remote functions that are authorized under the laws of the state in which they are located and are authorized under Kentucky law;

(g) Comply with all applicable federal and state laws and rules; and

(h) Notify the board **in writing** before providing **central fill** ~~**centralized prescription processing**~~ **or shared pharmacy services**.

~~**(3) Remote prescription processing may be conducted via telework as permitted by rules set forth in 201 KAR 2:480.**~~

Section 3. Policies and Procedures. (1) Each pharmacy shall possess a written policies and procedures manual that controls **central fill and shared pharmacy services arrangement** ~~**centralized and remote prescription processing**~~.

(2) Each pharmacy is responsible for establishing, maintaining, and enforcing specific policies and procedures, including:

(a) Responsibilities of each pharmacy ~~**in remote prescription processing**~~;

(b) Prescription processing steps and functions **including the process for cancellation of a prescription**;

(c) Steps taken to ensure confidentiality and security of patient information;

~~**(d) The process for cancellation of a prescription;**~~

(e) Recordkeeping requirements, including maintenance of records for all pharmacists, pharmacist interns, pharmacy technicians and pharmacies involved in **central fill and shared pharmacy services** ~~**centralized prescription processing**~~;

(f) Details of a continuous quality improvement program ~~**for pharmacy services**~~ that objectively and systematically monitors and evaluates the quality and appropriateness of patient care to improve patient care ~~**and to resolve identified problems**~~;

(g) How errors or irregularities identified by the quality improvement program are documented; and

(h) Plans to ensure compliance with all applicable federal and state laws and rules.

(3) The policies and procedures shall be reviewed annually or as necessary, and the review shall be documented.

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

Section 4. Labeling. ~~The prescription label shall clearly identify the name and address of each pharmacy involved in the packaging, labeling, and delivery of the filled prescription.~~ The name and address of a pharmacy responsible for any part of the dispensing process to the patient shall be listed on the label except when there is common ownership of the pharmacies. When a contract between the dispensing pharmacy and the central fill pharmacy directs otherwise, the contract shall govern which pharmacy appears on the label. Contact information for all pharmacies utilized by the dispensing pharmacy for shared services shall be affixed to the package.

Section 5. Records. (1) A pharmacy utilizing or providing centralized prescription processing **or shared pharmacy services** shall be able to produce a record of each pharmacist, pharmacist intern, or

pharmacy technician involved in the processing of a prescription. The record shall include the date and time when each step in the process was completed and the location where it occurred.

(2) Records are to be maintained pursuant to 201 KAR 2:171.

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

(4) The primary pharmacy shall maintain records that:

(a) List the name, telephone number, address and permit number of each pharmacy providing ~~**centralized prescription processing services**~~ **central fill or shared pharmacy services**; and

(b) Document the receipt of filled prescription from the central fill pharmacy, including the date and the identity of the person accepting delivery.

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

(a) List the names, addresses, telephone numbers, and all permit numbers of the pharmacies for whom the central fill pharmacy provides ~~**centralized prescription filling services**~~ **central fill or shared pharmacy services**;

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

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

~~**(6) The remote processing pharmacy shall maintain records that list the names, addresses, telephone numbers, and all permit numbers of the pharmacies for whom the remote processing pharmacy provides remote prescription processing services.**~~

Section 6. Central Fill Pharmacy Responsibilities.

(1) The delivery of a prepared prescription shall be made to the primary pharmacy using a private, common or contract carrier in compliance with all federal and state transport requirements.

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

(3) Pursuant to KRS 315.335, the central fill pharmacy is responsible for reporting any in-transit loss of a controlled substance.

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

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

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

Section 7. Primary Pharmacy Responsibilities.

A primary pharmacy shall notify patients of the possible use of centralized prescription processing **and shared services** and shall provide offer to counsel as required by 201 KAR 2:210.

~~**Section 8. Remote Pharmacy Responsibilities.**~~

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

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

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

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

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

~~**(4) A pharmacy under common ownership or with a shared services contract or agreement with the remote processing pharmacy may perform remote prescription processing functions.**~~

~~**Section 8. Prohibited Practices.**~~

~~**(1) Final product verification and dispensing from a location outside of or other than a pharmacy are prohibited in centralized prescription filling.**~~

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) “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**.~~located outside of a pharmacy when working as a contractor or an employee of a pharmacy located in Kentucky in a telework site.~~

(2) “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.

**Comments: Edits made to definition of telework; committee addressed concerns ensuring telework site is secured to ensure patient privacy. Consider definition of electronic supervision:**

***“Electronic Supervision” shall mean the oversight provided by a pharmacist licensed in Kentucky and supervising, by means of real-time electronic communication system, a registered pharmacist intern or pharmacy technician who is working for a permitted pharmacy.***

**Consider limiting telework site definition to pharmacist interns and pharmacy technicians?**

**Recommendation made to exclude a decentralized pharmacy located in a health system, however 201 KAR 2:074 specifically states “(d) If a hospital pharmacy is decentralized, each decentralized section or separate organizational element shall be under the immediate supervision of a pharmacist responsible to the director of pharmacy services.”**

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 ~~reoccurrence~~ **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 ~~six (6)~~ **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;

**Comments: Discussion around telework virtual inspections- do not want to unintentionally prevent pharmacists from checking orders outside of the defined telework site; consider changing inspections from 6 months to 12 months**

**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 violation of law to the Kentucky permitted pharmacy within twenty-four (24) hours of discovery and to the board within ten (10) days.

**Comment: Clarification on subsection (4) on the specific violation of law this is referring to.**

**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.

**Comment: Is subsection 1 necessary if the work cannot be carried out? Is it the documentation that is necessary? Maybe consider removal of section 6 and cover under Policy and Procedure**

**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 ~~audiovisual~~ **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.

**Comments: Update audio-visual to electronic communication systems to align with rest of regulation**

Section **9** ~~10~~. 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** ~~11~~. Prohibited Practices.

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