BOARDS AND COMMISSIONS

Board of Pharmacy

(Amendment)

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

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 administrative 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" is not an automated device 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 to[obtained by] 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. [Section 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 administrative regulation;

(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 (2) of this section 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 administrative regulation shall be maintained by the pharmacy's records electronically or in writing for a minimum of five (5) years. When the verification requirements of subsection (2) of this section 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 if~~[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 9. ~~[Section 6.]~~ The provisions of this administrative regulation shall not apply:

(1) To ~~[inpatients of]~~a hospital or institution~~[,]~~ if other licensed health-care professionals are authorized to administer the drugs; and~~[or]~~

(2) Compliance with 902 KAR 20:0116, 201 KAR 2:074 and 201 KAR 2:076 is maintained. ~~[If there is documentation that the patient or caregiver refused consultation.]~~

CHRISTOPHER HARLOW, Pharm.D., Executive Director

APPROVED BY AGENCY: June 13, 2024
FILED WITH LRC: June 10, 2024 at 11:45 a.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall be held on August 28, 2024, at 10:00 a.m. Eastern Time via zoom teleconference. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through August 31, 2024. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

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

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person:Christopher Harlow

(1) Provide a brief summary of:

(a) What this administrative regulation does:
This regulation provides rules around the dispensing process of prescription drugs.

(b) The necessity of this administrative regulation:
This regulation is essential to provide the framework for what is authorized and what is prohibited as part of the dispensing process to ensure safety to the patient.

(c) How this administrative regulation conforms to the content of the authorizing statutes:
This regulation establishes rules for the dispensing process. KRS 315.191(1)(a) authorizes the Board of Pharmacy to make rules to govern any matter related to pharmacies or pharmacists.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:
315.191(1) authorizes the board to promulgate administrative regulations to regulate pharmacists, pharmacies, wholesalers and manufacturers. This regulation ensures that pharmacies, pharmacists, technicians and interns are fully aware of what is authorized and what is not as part of the dispensing process.

(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 cleans up the language removing the gender terms from the regulation. Moreover, this amendment re-orders the existing sections and add sections on automated filling systems and final product verification.

(b) The necessity of the amendment to this administrative regulation:
This amendment is necessary to ensure safety to the patient. This amendment ensures that a pharmacist verifies the prepared product before the product is provided to the patient. This amendment also creates rules for automated filling systems to ensure safety to the patient.

(c) How the amendment conforms to the content of the authorizing statutes:
The authorizing statute, KRS 315.191(1)(a) authorizes the Board to regulate any matters pertaining to pharmacies, pharmacists, technicians and interns.

(d) How the amendment will assist in the effective administration of the statutes:
This amendment ensures that the regulated parties are aware of the Board's expectations regarding the dispensing process, and it ensures safety to patients.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:
Pharmacies, pharmacists, technicians and interns are affected by this regulation.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment:

The regulated parties will need to ensure that their internal systems are aligned with the amendment. This could mean modifying the procedures they utilize.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):

In most situations it will not cost the regulated entity anything. However, if the regulated entity has implemented a dispensing system that does not align with this regulation, the regulated entity will need to modify their procedures to ensure compliance. There could be a cost to this.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):

The entities will have greater clarity about what is required as part of the dispensing process and the patients the regulated entities serve will be protected. This could promote business. (5) Provide an estimate of how much it will cost to implement this administrative regulation:

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

(a) Initially:

There is no cost.

(b) On a continuing basis:

There is no cost.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation:

Board revenues from pre-existing fees provide the funding to enforce the regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment:

No fee increase will be needed.

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

No fees are established directly or indirectly by this regulation.

(9) TIERING: Is tiering applied?

Tiering is not applied because the regulation is applicable to all pharmacists and pharmacies equally.

FISCAL IMPACT STATEMENT

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

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

(a) Estimate the following for the first year:

Expenditures:none.

Revenues:none.

Cost Savings:none.

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

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

(a) Estimate the following for the first year:

Expenditures:none.

Revenues:none.

Cost Savings:none.

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

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

(a) Estimate the following for the first year:

Expenditures:none.

Revenues:none.

Cost Savings:none.

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

(5) Provide a narrative to explain the:

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

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

(6) Explain:

(a) Whether this administrative regulation will have an overall negative or adverse major economic impact to the entities identified in questions (2) - (4). ($500,000 or more, in aggregate)

This administrative regulation will not have an overall negative or adverse major economic impact to the entities identified.

(b) The methodology and resources used to reach this conclusion:

There are no costs, expenditures or revenues from this regulation.