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Jay D. Hartz
Director

MEMORANDUM

TO: Eden Davis, General Counsel, Board of Pharmacy

FROM: Emily Caudill, Regulations Compiler

RE: Proposed Amendment or New Regulation – 201 KAR 002:045 & 201 KAR 002:165

DATE: March 6, 2025

A copy of the administrative regulations listed above are enclosed for your files. These regulations are **tentatively** scheduled for review by the Administrative Regulation Review Subcommittee at its **JUNE 2025** 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, Statements of Consideration or one-month extension requests for these regulations are due **by noon on June 13, 2025**. 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

GENERAL GOVERNMENT CABINET

Kentucky Board of Pharmacy

(Amendment)

201 KAR 2:165. Transfer of prescription information.

RELATES TO: KRS 217.215(2), 315.191(1)(f), 21 C.F.R. 1306.08, 1306.25

STATUTORY AUTHORITY: KRS 217.215(2), 315.191(1)(a), (f)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(f) authorizes the Board of Pharmacy to promulgate administrative regulations to control the transfer of prescription drug orders between pharmacy personnel [~~pharmacists~~] and pharmacies. This administrative regulation establishes the procedures by which a prescription may be transferred between pharmacies in the Commonwealth or between a pharmacy and an establishment located in a state or United States Territory or District outside the Commonwealth and similarly credentialed as a pharmacy by that state or U.S. Territory or District for the purpose of dispensing.

Section 1.

(1) The transfer of prescription information for any noncontrolled substance prescription for the purpose of new or refill dispensing may occur if:

(a) It is orally communicated directly between two (2) pharmacists or pharmacist interns in the Commonwealth or between a pharmacist and an individual located in a state or

U.S. Territory or District outside the Commonwealth and similarly credentialed as a pharmacist by that state or U.S. Territory or District;

(b) It is made through an online real-time computer system that provides documentation of the presence of a pharmacist or an individual located in a state or U.S. Territory or District outside the Commonwealth and similarly credentialed as a pharmacist by that state or U.S. Territory or District when the information is transferred;

(c) It is made through the use of a facsimile machine and all the information required by this administrative regulation is provided to the sending and receiving pharmacist or an individual located in a state or U.S. Territory or District outside the Commonwealth and similarly credentialed as a pharmacist by that state or U.S. Territory or District; or

(d) It is made through the use of voice recording technology and all information required by this administrative regulation is provided to the sending and receiving pharmacist or an individual located in a state or U.S. Territory or District outside the Commonwealth and similarly credentialed as a pharmacist by that state or U.S. Territory or District.

(2) If in the Commonwealth the transferring pharmacist shall record the following information:

(a) That the prescription is void;

(b) The name and address of the pharmacy or the establishment located in a state or U.S. Territory or District outside the Commonwealth that is similarly credentialed as a pharmacy by that state or U.S. Territory or District to which it was transferred and the name of the pharmacist or the individual located in a state or U.S. Territory or District outside the Commonwealth that is similarly credentialed as a pharmacist by that state or U.S. Territory or District receiving the prescription information; and

(c) The date of the transfer and the name of the pharmacist transferring the information.

(3) If in the Commonwealth the pharmacist receiving the transferred prescription shall record the following information:

(a) That the prescription is a transfer;

(b) The date of issuance of the original prescription;

(c) The refill authorization on the original prescription;

(d) The date of original dispensing, if applicable;

(e) The refill authorization remaining and the date of the last refill if applicable;

(f) The name and address of the pharmacy or the establishment located in a state or U.S. Territory or District outside the Commonwealth that is similarly credentialed as a pharmacy by that state or U.S. Territory or District and the original prescription number from which the prescription was transferred; and

(g) The name of the transferor pharmacist or the individual located in a state or U.S. Territory or District outside the Commonwealth that is similarly credentialed as a pharmacist by that state or U.S. Territory or District.

(4) Both the original prescription and the transferred prescription shall be maintained for a period of five (5) years from the date of the last refill.

(5) Pharmacies electronically accessing the same prescription record shall satisfy all information of a manual mode for a prescription transfer.

(6) A pharmacist may delegate the transferring and the documentation of a transfer of a previously dispensed noncontrolled substance prescription to a certified pharmacy technician.

(7) For verbal prescriptions, the certified pharmacy technician shall document that they read back and verify the prescription information when transferring or receiving a prescription transfer.

Section 2.

(1) The transfer for an initial or new dispensing of an electronic prescription for schedules II-V may occur if the transfer complies with the requirements of 21 C.F.R. 1306.08.

(2) The transfer of prescription information for a controlled substance prescription for schedule III, IV, and V for the purposes of refill dispensing may occur if the transfer complies with the requirements of 21 C.F.R. 1306.25.

(3) Transfers the recordkeeping requirements in 201 KAR 2:171, Section 1.

Section 3. Pharmacies shall maintain documentation, as required in 201 KAR 2:171, of transferred prescriptions for a period of five (5) years.

Section 4. Violation of a provision of this administrative regulation may constitute unethical or unprofessional conduct in accordance with KRS 315.121(2)(d), (f), and (g).

March 6, 2025

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

PUBLIC HEARING AND PUBLIC COMMENT PERIOD:

A public hearing on this administrative regulation shall be held on May 28, 2025, at 10:00 a.m. Eastern Time via zoom teleconference or in-person at 125 Holmes Street, First Floor Conference Room, Frankfort, KY 40601. 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, 2025. 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 2:165. Transfer of Prescription Information
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: This administrative regulation establishes the requirements for transferring prescription records for both controlled and non-controlled substances.
(b) The necessity of this administrative regulation: KRS 315.191(1)(a) authorizes the Board of Pharmacy to promulgate administrative regulations with minimum requirements for pharmacies to operate. Part of pharmacy operation is the ability for a pharmacy to transfer a prescription drug order when a patient makes such request.
(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation establishes the requirements for transferring prescription information.
(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation establishes rules for the transfer of prescription information, as required when a patient wishes to have a different pharmacy from the originating pharmacy dispense their prescription drug order.

(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 only clarifies the process that a certified technician shall utilize in transferring a prescription. It ensures accuracy of the transfer of the prescription drug order.
(b) The necessity of the amendment to this administrative regulation: This amendment to an existing administrative regulation is necessary to assist pharmacists in the performance of their duties and give them more time to focus on clinical patient care and other aspects of pharmacy practice.
(c) How the amendment conforms to the content of the authorizing statutes: This amendment to an existing administrative regulation, authorized by KRS 315.191 (1)(a), establishes the process for a certified pharmacy technician to transfer a previously dispensed prescription drug order to ensure accuracy.
(d) How the amendment will assist in the effective administration of the statutes: This administrative regulation establishes rules for the transfer of prescription information, as required when a patient wishes to have a different pharmacy from the originating pharmacy dispense their prescription drug order. This amendment specifically authorizes certified pharmacy technicians to transfer previously dispensed prescription drug orders that are non-controlled substances.
(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The board anticipates that pharmacists, pharmacies and certified pharmacy technicians will be impacted 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: Pharmacists will need to know that they can delegate the transfer of a previously dispensed non-controlled substance prescription to a certified pharmacy technician. Certified pharmacy technicians will need to be made aware of a change to their authority authorizing them to perform this function. Pharmacies will need to be made aware of this change so that they can update operating procedures.
(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There is no cost associated with compliance of this administrative regulation.
(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Pharmacists will be able to delegate transfers of previously dispensed non-controlled substance prescription drug orders to certified pharmacy technicians. This will reduce their load of work and allow them to focus on other tasks.

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

(a) Initially: There is no cost to implement this administrative regulation.

(b) On a continuing basis: There is no cost to implement this administrative regulation.

(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 during routine pharmacy inspections.

(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, this amendment will not necessitate an increase in fees or funding.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This regulation does not establish 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 pharmacies, pharmacists and certified pharmacy technicians equally.

FISCAL IMPACT STATEMENT

201 KAR 2:165. Transfer of prescription information
Contact person: Christopher Harlow, Phone 502-564-7910, email: christopher.harlow@ky.gov

(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) authorizes the Board to regulate the practice of pharmacy. Part of the practice of pharmacy requires the transfer of prescription drug orders.

(2) Identify the promulgating agency and any other affected state units, parts, or divisions: The promulgating agency, the Board of Pharmacy, is the only affected state unit impacted.

(a) Estimate the following for the first year:
Expenditures: This regulation does not have any expenditures.
Revenues: This regulation does not produce revenue for the Board.
Cost Savings: none.
(b) How will expenditures, revenues, or cost savings differ in subsequent years? It will zero for expenditures and revenue.

(3) Identify affected local entities (for example: cities, counties, fire departments, school districts): There are no local affected entities with the exception of the Board.

(a) Estimate the following for the first year:
Expenditures: n/a
Revenues: n/a
Cost Savings: There could be cost savings due to certified pharmacy technicians being authorized to perform a function previously reserved for a pharmacist.
(b) How will expenditures, revenues, or cost savings differ in subsequent years? n/a

(4) Identify additional regulated entities not listed in questions (2) or (3): Resident and non-resident pharmacies, pharmacists and certified pharmacy technicians that are permitted or licensed with us will be regulated.

(a) Estimate the following for the first year:
Expenditures: n/a
Revenues: n/a
Cost Savings: There could be cost savings due to certified pharmacy technicians being authorized to perform a function previously reserved for a pharmacist.
(b) How will expenditures, revenues, or cost savings differ in subsequent years? n/a

(5) Provide a narrative to explain the:
(a) Fiscal impact of this administrative regulation: This regulation does not cost anything for regulated parties to implement nor does it have a cost on the Board to oversee.

(b) Methodology and resources used to determine the fiscal impact:

(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). No, this administrative regulation does not have an overall negative or adverse major economic impact to regulated entities or those entities identified in questions (2)-(4).

(b) The methodology and resources used to reach this conclusion: Analysis of the Board's expenditures as well as an assessment regarding cost of compliance for regulated entities.