

1 BOARDS AND COMMISSIONS

2 Kentucky Board of Pharmacy

3 (Amendment)

4 201 KAR 2:165. Transfer of prescription information.

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

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

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

14 Section 1.

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

17 (a) It is orally communicated directly between two (2) pharmacists or pharmacist interns in the
18 Commonwealth or between a pharmacist and an individual located in a state or U.S. Territory or
19 District outside the Commonwealth and similarly credentialed as a pharmacist by that state or
20 U.S. Territory or District;

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

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

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

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

- 14 (a) That the prescription is void;
- 15 (b) The name and address of the pharmacy or the establishment located in a state or U.S.
16 Territory or District outside the Commonwealth that is similarly credentialed as a pharmacy by
17 that state or U.S. Territory or District to which it was transferred and the name of the pharmacist
18 or the individual located in a state or U.S. Territory or District outside the Commonwealth that is
19 similarly credentialed as a pharmacist by that state or U.S. Territory or District receiving the
20 prescription information; and
- 21 (c) The date of the transfer and the name of the pharmacist transferring the information.

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

- 24 (a) That the prescription is a transfer;

- 1 (b) The date of issuance of the original prescription;
- 2 (c) The refill authorization on the original prescription;
- 3 (d) The date of original dispensing, if applicable;
- 4 (e) The refill authorization remaining and the date of the last refill if applicable;
- 5 (f) The name and address of the pharmacy or the establishment located in a state or U.S.
- 6 Territory or District outside the Commonwealth that is similarly credentialed as a pharmacy by
- 7 that state or U.S. Territory or District and the original prescription number from which the
- 8 prescription was transferred; and
- 9 (g) The name of the transferor pharmacist or the individual located in a state or U.S. Territory or
- 10 District outside the Commonwealth that is similarly credentialed as a pharmacist by that state or
- 11 U.S. Territory or District.

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

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

16 Section 2.

17 a. The transfer for an initial or new dispensing of an electronic e-prescription for schedules II-V
18 [information for a controlled substance prescription, except a Schedule II controlled substance,
19 for the purpose of refill dispensing] may occur if the transfer complies with the requirements of
20 21 C.F.R. 1306.08 [21 C.F.R. 1306.25].

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

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

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

CHITHEM

October 10, 2023

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

Date

PUBLIC HEARING AND PUBLIC COMMENT PERIOD:

A public hearing on this administrative regulation shall be held on December 21, 2023, 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 December 31, 2023. 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.

(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, in accordance with new federal regulation, when controlled substances may be transferred and the rules around those transfers.

(b) The necessity of the amendment to this administrative regulation: This amendment is necessary to ensure clarity on what is authorized amidst a change in federal law.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations pertaining to pharmacists and pharmacies.

(d) How the amendment will assist in the effective administration of the statutes: The amendment will further promote, preserve, and protect public health through effective regulation of pharmacists and pharmacies by ensuring state law clearly demonstrates what is authorized under the application of the federal rule.

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

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

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Pharmacies and pharmacists will have to familiarize themselves with amended language. The board will help to educate pharmacists and pharmacies in these changes.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There is no fee.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Clarity about what is permitted for transfer of controlled substances.

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

(a) Initially: No costs will be incurred.

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

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Board revenues from pre-existing fees provide the funding to enforce the regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: This regulation does not increase fees.

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

(9) TIERING: Is tiering applied? (Explain why tiering was or was not used)
Tiering is not applied because the regulation is applicable to all special limited medical gas permit holders.

FISCAL NOTE

Regulation No. 201 KAR 2:165. Transfer of Prescription Information
Contact Person: Christopher Harlow, Phone 502-564-7910, Email:
Christopher.harlow@ky.gov

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

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

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

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

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

(c) How much will it cost to administer this program for the first year? This program does not contain a cost.

(d) How much will it cost to administer this program for subsequent years? It is built into operation of board operations and will not increase cost.

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

Revenues (+/-): n/a

Expenditures (+/-): n/a

Other Explanation:

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

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

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

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

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

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

Cost Savings (+/-): 0

Expenditures (+/-): 0

Other Explanation:

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