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LEGISLATIVE RESEARCH COMMISSION

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MEMORANDUM

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

FROM: Emily Caudill, Regulations Compiler

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

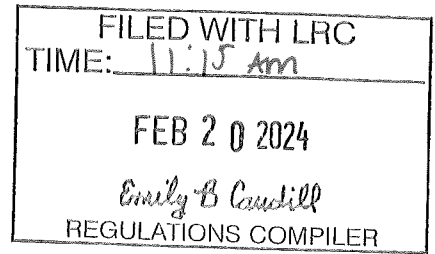
DATE: February 20, 2024

A copy of the administrative regulation listed above is enclosed for your files. This regulation is **tentatively** scheduled for review by the Administrative Regulation Review Subcommittee at its **JUNE 2024** meeting. We will notify you of the date and time of this meeting once it has been scheduled.

Pursuant to KRS 13A.280, **if** comments are received during the public comment period, a Statement of Consideration or a one-month extension request for this regulation is due **by noon on JUNE 14, 2024**. Please reference KRS 13A.270 and 13A.280 for other requirements relating to the public hearing and public comment period and Statements of Consideration.

If you have questions, please contact us at RegsCompiler@LRC.ky.gov or (502) 564-8100.

Enclosures



1 BOARDS AND COMMISSIONS

2 BOARD OF PHARMACY

3 (AMENDMENT)

4 201 KAR 2:220. Collaborative care agreements.

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

6 STATUTORY AUTHORITY: KRS 315.191(1)(a)

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

13 Section 1. A collaborative care agreement shall:

14 (1) Be in writing;

15 (2) Be signed and dated by:

16 (a) Each practitioner; and

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

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

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

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

3 (1) Name;

4 (2) Address and phone number;

5 (3) Emergency notification contact;

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

7 (5) Medical history, including:

8 (a) Known diseases;

9 (b) Known allergies;

10 (c) Reactions and conditions relating to:

11 1. Prescription medications; and

12 2. Nonprescription medications;

13 (d) Current prescription regimen; and

14 (e) Current nonprescription regimen;

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

16 (7) Assessment of patient outcomes;

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

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

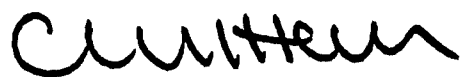
19 Section 3. Documentation relating to the care and course of therapy of the patient pursuant to
20 the agreement shall be documented in the patient's record maintained by the pharmacist,
21 provided to the collaborating practitioner, and be readily available to other healthcare
22 professionals providing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

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

- 1 (1) Protocol, criteria, standing orders, or other method by which services are authorized;
- 2 (2) The method established for the assessment of patient outcomes, if appropriate; and
- 3 (3) Lab tests that may be ordered.

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

- 6 (1) At the pharmacist's practice site; and
- 7 (2) For at least five (5) years after the termination of the agreement.



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

February 19, 2024

Date

PUBLIC HEARING AND PUBLIC COMMENT PERIOD:

A public hearing on this administrative regulation shall be held on May 22, 2024, at 10:00 a.m. Eastern Time at 125 Holmes Street, Frankfort, KY 40601 and via teleconference. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through May 31, 2024. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

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

REGULATORY IMPACT ANALYSIS
AND TIERING STATEMENT

201 KAR 2:220. Collaborative Care Agreements.

Contact person: Christopher Harlow

Contact Phone No.: 502-564-7910

Contact email: Christopher.harlow@ky.gov

(1) Provide a brief summary of:

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

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

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

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

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This amendment is only to make technical changes for language efficacy and to cite the correct sections of statutory law that had been modified since this regulation was originally promulgated in 1997 and last revised in 2015.

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

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

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

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

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

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

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

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

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

(a) Initially: No costs will be incurred.

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

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

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding will be required because of this amendment.

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

(9) TIERING: Is tiering applied? (Explain why tiering was or was not used) Tiering is not applied because the regulation is applicable to all pharmacists that desire to utilize collaborative care agreements.

FISCAL NOTE

Regulation No. 201 KAR 2:220. Collaborative Care Agreements.

Contact Person: Christopher Harlow

Contact Phone No.: 502-564-7910

Contact email: Christopher.harlow@ky.gov

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

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

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

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

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

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

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

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

Revenues (+/-): 0

Expenditures (+/-): 0

Other Explanation: This regulation does not impact costs.

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

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

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

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

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

Cost Savings (+/-): 0

Expenditures (+/-): 0

Other Explanation: There are no costs incorporated into this regulation or implied with compliance.

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