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MEMORANDUM

TO: Christopher Harlow, Executive Director, Kentucky Board of Pharmacy

FROM: Emily Caudill, Regulations Compiler

RE: Acknowledgement of New Proposed & Emergency Regulations – 201 KAR 002:416 & E.

DATE: December 17, 2024

A copy of the ordinary and emergency administrative regulations listed above are enclosed for your files. Pursuant to KRS 13A.190, these emergency administrative regulations became effective upon filing with our office on **December 17, 2024** and, unless an extension on an accompanying ordinary is requested, will expire either in 270 days on **September 13, 2025**, or when replaced by its corresponding ordinary regulation, whichever occurs first. Please note - Expiration dates may be impacted by legislation or other statutes.

Emergency regulations

The emergency regulations are tentatively scheduled for review by the Administrative Regulation Review Subcommittee at its **March 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, a Statement of Consideration for these emergency regulations is due **by noon on March 14, 2025**.

Ordinary regulations

The ordinary regulations are tentatively scheduled for review by the Administrative Regulation Review Subcommittee at its **April 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, a Statement of Consideration for these ordinary regulations or a one-month extension request is due **by noon on April 15, 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

FILED WITH LRC
TIME: 4:18 pm
DEC 17 2024
Emily B Caudill
REGULATIONS COMPILER

1 BOARD AND COMMISSIONS

2 Kentucky Board of Pharmacy

3 (New Administrative Regulation)

4 201 KAR 2:416. Pharmacy annual reporting of cost of dispensing data.

5 RELATES TO: KRS 18A.2254, 304.9-053, 304.9-054, 304.9-055, 304.14-120, 304.14-
6 120, 304.17A-595, 304.17A-712, 304.17C-125, 304.38A-115, 367.828.

7 STATUTORY AUTHORITY: KRS 315.038, 315.191(1)

8 NECESSITY, FUNCTION, AND CONFORMITY: 315.191(1) authorizes the board to
9 promulgate administrative regulations to regulate pharmacists, pharmacies, wholesalers
10 and manufacturers. Senate Bill 188 from the 2024 legislative session requires the Board
11 of Pharmacy to promulgate regulations to require all ambulatory pharmacies permitted
12 by the Board of Pharmacy to report annually beginning March 1, 2026 cost of
13 dispensing data to the Board of Pharmacy. The Board of Pharmacy shall then submit
14 that data to the Department of Insurance within thirty days.

15 Section 1. Mandatory Submission of Data.

16 1. On an annual basis, beginning March 1, 2026 and by March 1 every year thereafter,
17 every ambulatory pharmacy permitted by the Board of Pharmacy shall submit to the
18 Board, the following data relating to the dispensing costs for the previous year:

19 a. NCPDP number;

- 1 b. Labor Costs, including:
- 2 (1) Pharmacist salaries, including benefits and taxes;
- 3 (2) Pharmacy technician salaries, including benefits and taxes;
- 4 (3) Salaries of other support staff involved in the dispensing of prescriptions; and
- 5 (4) Other employee benefits.
- 6 c. Cost to acquire the medications dispensed;
- 7 d. Cost of materials, including:
- 8 (1) Cost of prescription labels and paper;
- 9 (2) Cost of bottles, vials and packaging;
- 10 (3) Prescription delivery costs;
- 11 (4) Inventory services costs;
- 12 (5) Lost inventory costs; and
- 13 (6) Warehouse expenses.
- 14 d. Facility costs, including:
- 15 (1) Rent or mortgage payments for the pharmacy space;
- 16 (2) Mortgage interest;
- 17 (3) Utilities, including electricity, water, heating and communications costs;
- 18 (4) Facility taxes, including personal property, real estate and payroll as well as
- 19 insurance
- 20 (5) Maintenance, cleaning and repair costs; and
- 21 (6) Security and alarm fees.
- 22 e. Operational costs, including:
- 23 (1) Insurance, including liability and property;

- 1 (2) Software and IT systems;
- 2 (3) Switch or e-prescribing fees;
- 3 (4) Office supplies and equipment;
- 4 (5) Professional liability insurance for pharmacists;
- 5 (6) Credit card processing fees;
- 6 (7) Prescription department licenses, permits, accreditation and fees;
- 7 (8) Cost of continuing education and certification for pharmacists and technicians;
- 8 (9) Dues and subscriptions for pharmacy department;
- 9 (10) Delivery and mailing expenses for the prescription department;
- 10 (11) Transaction fees;
- 11 (12) Charitable contributions;
- 12 (13) Employee training;
- 13 (14) Bad debts for prescriptions, including uncollected copays; and
- 14 (15) Third party prescriptions audit adjustments.
- 15 f. Store costs, including:
 - 16 (1) Marketing and advertising;
 - 17 (2) Professional accounting and legal services;
 - 18 (3) Franchise fees, if applicable; and
 - 19 (4) Other costs not included elsewhere.
- 20 g. Depreciation and amortization costs, including:
 - 21 (1) Depreciation of building, equipment and fixtures; and
 - 22 (2) Amortization of software and intangible assets.
- 23 h. Total number of prescriptions dispensed each month of the prior year; and

1 i. Total number of prescriptions prepared via a central fill pharmacy each month of the
2 prior year; and

3 j. Percent of revenue coming directly from the pharmacy department.

4 2. All data shall be reported to the Board electronically through the Board's licens ing
5 gateway on Reporting Form A, Pharmacy Cost of Dispensing Data, 12/2024.

6 Section 2. Optional Submission of Data.

7 1. On an annual basis, beginning March 1, 2026 and by March 1 every year thereafter,
8 any ambulatory pharmacy permitted by the Board of Pharmacy may submit to the
9 Board, the following data for each prescription dispensed:

10 a. The date the claim was submitted to the pharmacy benefit manager;

11 b. The date the prescription was written;

12 c. The NCPDP transaction type;

13 d. The prescription insurance member identification number;

14 e. The prescription number assigned by the pharmacy;

15 f. The number of the refill;

16 g. The NDC number of the product dispensed;

17 h. The name of the product dispensed;

18 i. The strength of the medication dispensed;

19 j. The quantity of the medication dispensed;

20 k. The days supply of medication dispensed;

21 l. Whether the medication dispensed was generic;

22 m. Whether the medication dispensed was a specialty drug;

- 1 n. The NABP identification number of the pharmacy where the medication was
2 dispensed;
- 3 o. The NPI identification number of the pharmacy where the medication was dispensed;
- 4 p. The name of the pharmacy where the medication was dispensed;
- 5 q. The amount, in dollars, paid to the pharmacy by the prescription benefit plan;
- 6 r. The amount, in dollars, paid to the pharmacy by the health plan member;
- 7 s. The total amount, in dollars, paid to the pharmacy for the prescription dispensed,
8 including what the patient paid and what the health plan paid;
- 9 t. The amount, in dollars, paid to the pharmacy for dispensing the medication; and
- 10 u. The amount (in dollars) of retroactive fees that were assessed to the pharmacy by the
11 pharmacy benefit manager for the medication dispensed at any time after the
12 medication was dispensed, including, but not limited to:
- 13 (1) direct remuneration fees;
- 14 (2) indirect remuneration fees;
- 15 (3) generic effective rates;
- 16 (4) in-network fees;
- 17 (5) performance fees;
- 18 (6) point-of-sale fees; and
- 19 (7) pre and post adjudication fees.
- 20 2. If the pharmacy chooses to submit this data, the data shall be reported to the Board
21 electronically through the Board's licensing gateway on Reporting Form B, Pharmacy
22 Claims Data, 12/2024.

1 Section 3. All information and data submitted to the Board shall be deemed confidential
2 and proprietary and shall not be subject to disclosure pursuant to KRS 61.870 to
3 61.884.

4 Section 4. Incorporation by Reference (1) The following material is incorporated by
5 reference:

6 (a) Reporting Form A, Pharmacy Cost of Dispensing Data, 12/2024.

7 (b) Reporting Form B, Pharmacy Claims Data, 12/2024.

8 (2) This material may be inspected, copied, or obtained, subject to applicable copyright
9 law at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125
10 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.
11 or on the Web site at <https://pharmacy.ky.gov/Businesses/Pages/Pharmacy.aspx>

Clutter

December 17, 2024

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 March 26, 2025, at 10:00 a.m. Eastern Time via zoom teleconference and in-person at 125 Holmes Street in the 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 March 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 2:416. Pharmacy annual reporting of cost of dispensing data.

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 is required pursuant to KRS 315.038. This regulation establishes procedures for pharmacies to report data to the Department of Insurance per Senate Bill 188 during the 2024 legislative session. .

(b) The necessity of this administrative regulation: This administrative regulation is required by KRS 315.038.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation, authorized by KRS 315.191(1)(a), establishes data reporting procedures required by KRS 315.038.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation will ensure that pharmacies know how to report data that is required to be reported by KRS 315.038 and as established by the Commissioner of Insurance at the Public Protection Cabinet.

(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: n/a

(b) The necessity of the amendment to this administrative regulation: n/a

(c) How the amendment conforms to the content of the authorizing statutes: n/a

(d) How the amendment will assist in the effective administration of the statutes: n/a

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This regulation will impact all ambulatory pharmacies that are permitted by the Commonwealth of Kentucky.

(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: All ambulatory pharmacies permitted by the Board will have to review these data elements and collect data during the 2025 calendar year and then report the data by March 2026.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): It will not cost anything to comply with this administrative regulation.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): The Commissioner of Insurance will be able to review data submitted by pharmacies and compare it with data submitted by the pharmacy benefit managers.

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

(a) Initially: The implementation of this administrative regulation will not cost anything. We have a licensing software already developed that will allow for receipt of data and transmission of data to the Department of Insurance.

(b) On a continuing basis: There is no additional 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: There is no fee being amended here directly or indirectly.

(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 here beyond what the General Assembly has established as an ambulatory pharmacy and only applying the contents of this regulation to such.

FISCAL IMPACT STATEMENT

201 KAR 2:416. Pharmacy annual reporting of cost of dispensing data.
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 315.038 requires the Board promulgate this regulation by January 1, 2025.

(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 amendment does not create further expenditures outside of what is already allocated for licensing.

Revenues: This amendment does not create any additional revenue.

Cost Savings: none.

(b) How will expenditures, revenues, or cost savings differ in subsequent years? These things are not expected to change as there is no fee increase or change per this amendment.

(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: n/a

(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): All ambulatory pharmacies permitted by the Board.

(a) Estimate the following for the first year:

Expenditures: There are no expenditures.

Revenues: There are no expected revenues.

Cost Savings: n/a

(b) How will expenditures, revenues, or cost savings differ in subsequent years? It will not change unless there is a statutory change.

(5) Provide a narrative to explain the:

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

(b) Methodology and resources used to determine the fiscal impact: The estimated revenues generated for the budget are obtained from current and historical data.

(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.

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

SUMMARY OF MATERIAL INCORPORATED BY REFERENCE

“Reporting Form A, Pharmacy Cost of Dispensing Data, 12/2024” is the form provided by the Department of Insurance with the data elements that pharmacies will need to collect and submit to the Board by March 2026.

“Reporting Form B, Pharmacy Claims Data, 12/2024” is the form provided by the Department of Insurance with data elements that pharmacies may, but are not required to, submit to the Board by March 2026.