

BOARDS AND COMMISSIONS

Board of Pharmacy

(Amended After Comments)

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

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

STATUTORY AUTHORITY: KRS 315.038, 315.191(1)

CERTIFICATION STATEMENT: **This is to certify that the administrative regulation complies with the requirements of 2025 RS HB 6, Section 8. The Board of Pharmacy is not one of the agencies that is directed by House Bill 6, Section 8(3) to include a certification by the Governor.**

NECESSITY, FUNCTION, AND CONFORMITY: **KRS 315.191(1)** authorizes the board to promulgate administrative regulations to regulate pharmacists, pharmacies, wholesalers and manufacturers. Senate Bill 188 from the 2024 legislative session requires the Board of Pharmacy to promulgate regulations to require all ambulatory pharmacies permitted by the Board of Pharmacy to report annually beginning March 1, 2026 cost of dispensing data to the Board of Pharmacy. The Board of Pharmacy shall then submit that data to the Department of Insurance within thirty **(30)** days.

Section 1. Mandatory Submission of Data.

(1) On an annual basis, beginning March 1, 2026, and by March 1 every year thereafter, every ambulatory pharmacy permitted by the Board of Pharmacy shall submit to the Board, the following data relating to the dispensing costs for the previous year year **which shall remain confidential and only be shared with the Department of Insurance as required by KRS 315.038:**

- (a) NCPDP number;
- (b) Labor costs, including:
 - 1. Pharmacist salaries, including benefits and taxes;
 - 2. Pharmacy technician salaries, including benefits and taxes;
 - 3. Salaries of other support staff involved in the dispensing of prescriptions; and
 - 4. Other employee benefits.
- (c) Cost to acquire the medications dispensed;
- (d) Cost of materials, including:
 - 1. Cost of prescription labels and paper;
 - 2. Cost of bottles, vials and packaging;
 - 3. Prescription delivery costs;
 - 4. Inventory services costs;
 - 5. Lost inventory costs; and
 - 6. Warehouse expenses.
- (e) Facility costs, including:
 - 1. Rent or mortgage payments for the pharmacy space. **If the pharmacy shares a building with retail space, the proportion of the square footage that is permitted for pharmacy operations shall be applied to the total rent for the building;**
 - 2. Mortgage interest;
 - 3. Utilities, including electricity, water, heating and communications costs;
 - 4. Facility taxes, including personal property, real estate and payroll as well as insurance
 - 5. Maintenance, cleaning and repair costs; and
 - 6. Security and alarm fees.

- (f) Operational costs, including:
 1. Insurance, including liability and property;
 2. Software and IT systems;
 3. Switch or e-prescribing fees;
 4. Office supplies and equipment;
 5. Professional liability insurance for pharmacists;
 6. Credit card processing fees;
 7. Prescription department licenses, permits, accreditation and fees;
 8. Cost of continuing education and certification for pharmacists and technicians;
 9. Dues and subscriptions for pharmacy department;
 10. Delivery and mailing expenses for the prescription department;
 11. Transaction fees;
 12. Charitable contributions;
 13. Employee training;
 14. Bad debts for prescriptions, including uncollected copays; and
 15. Third party prescriptions audit adjustments.
 - (g) Store costs, including:
 1. Marketing and advertising;
 2. Professional accounting and legal services;
 3. Franchise fees, if applicable; and
 4. Other costs not included elsewhere.
 - (h) Depreciation and amortization costs, including:
 1. Depreciation of building, equipment and fixtures; and
 2. Amortization of software and intangible assets.
 - (i) Total number of prescriptions dispensed each month of the prior year; and
 - (j) Total number of prescriptions prepared via a central fill pharmacy each month of the prior year; and
 - (k) Percent of revenue coming directly from the pharmacy department.
- (2) All data shall be reported to the Board electronically through the Board's licensing gateway on Reporting Form A, Pharmacy Cost of Dispensing Data, 12/2024. **Data may be submitted in the aggregate for pharmacies with multiple locations.**

Section 2. Optional Submission of Data.

- (1) On an annual basis, beginning March 1, 2026 and by March 1 every year thereafter, any ambulatory pharmacy permitted by the Board of Pharmacy may submit to the Board, the following data for each prescription dispensed:
- (a) The date the claim was submitted to the pharmacy benefit manager;
 - (b) The date the prescription was written;
 - (c) The NCPDP transaction type;
 - (d) The prescription insurance member identification number;
 - (e) The prescription number assigned by the pharmacy;
 - (f) The number of the refill;
 - (g) The NDC number of the product dispensed;
 - (h) The name of the product dispensed;
 - (i) The strength of the medication dispensed;
 - (j) The quantity of the medication dispensed;
 - (k) The days supply of medication dispensed;
 - (l) Whether the medication dispensed was generic;
 - (m) Whether the medication dispensed was a specialty drug;
 - (n) The NABP identification number of the pharmacy where the medication was dispensed;

- (o) The NPI identification number of the pharmacy where the medication was dispensed;
- (p) The name of the pharmacy where the medication was dispensed;
- (q) The amount, in dollars, paid to the pharmacy by the prescription benefit plan;
- (r) The amount, in dollars, paid to the pharmacy by the health plan member;
- (s) The total amount, in dollars, paid to the pharmacy for the prescription dispensed, including what the patient paid and what the health plan paid;
- (t) The amount, in dollars, paid to the pharmacy for dispensing the medication; and
- (u) The amount (in dollars) of retroactive fees that were assessed to the pharmacy by the pharmacy benefit manager for the medication dispensed at any time after the medication was dispensed, including, but not limited to:
 - 1. Direct remuneration fees;
 - 2. Indirect remuneration fees;
 - 3. Generic effective rates;
 - 4. In-network fees;
 - 5. Performance fees;
 - 6. Point-of-sale fees; and
 - 7. Pre and post adjudication fees.

(2) If the pharmacy chooses to submit this data, the data shall be reported to the Board electronically through the Board's licensing gateway on Reporting Form B, Pharmacy Claims Data, 12/2024.

Section 3. All information and data submitted to the Board shall be deemed confidential and proprietary and shall not be subject to disclosure pursuant to KRS 61.870 to 61.884. **Only board staff will have access to the data submitted. Board of Pharmacy members will not have access to the data submitted.**

Section 4. **Enforcement discretion will be exercised if a pharmacy fails to submit mandatory data under Section 1 of this administrative regulation if they do not bill third parties.**

Section 5. Incorporation by Reference.

- (1) The following material is incorporated by reference:
 - (a) Reporting Form A, Pharmacy Cost of Dispensing Data, 12/2024; and
 - (b) Reporting Form B, Pharmacy Claims Data, 12/2024.
- (2) This material may be inspected, copied, or obtained, subject to applicable copyright law at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m. or on the Web site at <https://pharmacy.ky.gov/Businesses/Pages/Pharmacy.aspx>.

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REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Christopher Harlow

(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:

(5) Provide an estimate of how much it will cost the administrative body 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?

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

(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) State whether this administrative regulation is expressly authorized by an act of the General Assembly, and if so, identify the act:

SB188 during the 2024 legislative session of the General Assembly.

(3)(a) 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.

(b) Estimate the following for each affected state unit, part, or division identified in (3)(a):

1. Expenditures:

For the first year:This amendment does not create further expenditures outside of what is already allocated for licensing.

For subsequent years:

2. Revenues:

For the first year:This amendment does not create revenue.

For subsequent years:This amendment does not create revenue.

3. Cost Savings:

For the first year:This regulation does not generate any cost savings over the first year of implementation.

For subsequent years:This regulation will not generate cost savings over subsequent years. **(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.**

(4)(a) Identify affected local entities (for example: cities, counties, fire departments, school districts):

None.

(b) Estimate the following for each affected local entity identified in (4)(a):

1. Expenditures:

For the first year:none.

For subsequent years:none.

2. Revenues:

For the first year:none

For subsequent years:none.

3. Cost Savings:

For the first year:none.

For subsequent years:none.

(5)(a) Identify any affected regulated entities not listed in (3)(a) or (4)(a):

All ambulatory pharmacies permitted by the Board.

(b) Estimate the following for each regulated entity identified in (5)(a):

1. Expenditures:

For the first year:If the data isn't readily retrievable, there could be a cost for time compiling the data. It is anticipated that the bulk of the data required to be submitted is found in the tax return filing for each regulated entity.

For subsequent years:If the data isn't readily retrievable, there could be a cost for time compiling the data. It is anticipated that the bulk of the data required to be submitted is found in the tax return filing for each regulated entity.

2. Revenues:

For the first year:none

For subsequent years:none.

3. Cost Savings:

For the first year:none.

For subsequent years:none.

(6) Provide a narrative to explain the following for each entity identified in (3)(a), (4)(a), and (5)(a)

(a) Fiscal impact of this administrative regulation:

The Board will not generate any expenditures not already expended in our licensing software. The Board will not generate any revenue or cost-savings from this rulemaking either. No local entities are impacted. However, all ambulatory pharmacies are required to submit the data per SB188 from the 2024 session of the General Assembly. If this data is not readily available, it could take considerable time to compile which could equate to a cost. That cost however would only be speculative. Most likely, the tax return of the pharmacy will contain the data that is required to be submitted per this regulation.

(b) Methodology and resources used to reach this conclusion:

Reviewing our contract with our licensing software and speaking to regulated pharmacists.

(7) Explain, as it relates to the entities identified in (3)(a), (4)(a), and (5)(a):

(a) Whether this administrative regulation will have a "major economic impact", as defined by KRS 13A.010(13):

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.