LEGISLATIVE RESEARCH COMMISSION
State Capitol 700 Capital Avenue Frankfort Kentucky 40601
502-564-8100
Capitol Fax 502-564-2922
Annex Fax 502-564-6543
legislature.ky.gov

Jay D. Hartz
Director

MEMORANDUM

TO: Eden Davis, General Counsel, Board of Pharmacy

FROM: Emily Caudill, Regulations Compiler

RE: Amended After Comments – 201 KAR 002:416.

DATE: April 14, 2025

A copy of the Amended After Comments regulation listed above along with the required Statement of Consideration are enclosed for your files.

This administrative regulation is scheduled to be reviewed by the Administrative Regulation Review Subcommittee at its **MAY 2025** meeting. Please notify the proper person(s) of this meeting.

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

Enclosure

BOARD AND COMMISSIONS

Kentucky 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: 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 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 **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.

d. 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.

e. 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.

f. 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.

g. Depreciation and amortization costs, including:

(1) Depreciation of building, equipment and fixtures; and

(2) Amortization of software and intangible assets.

h. Total number of prescriptions dispensed each month of the prior year; and

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

j. 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 renumeration 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 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.

(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

April 13, 2025

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

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 statues: 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) 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.
2. Revenues:
For the first year: This amendment does not create revenue.
For subsequent years: This amendment does not create revenue.
Revenues: This amendment does not create any additional 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 additional 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): 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 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.

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.

STATEMENT OF CONSIDERATION
Relating to 201 KAR 2:416

Board of Pharmacy
(Amended After Comments)

I. The public hearing on 201 KAR 2:416E, scheduled for March 26, 2025 at 10:00 a.m. at 125 Holmes Street, 1st floor conference room, Frankfort, KY 40601 occurred with two participants providing oral comments. Written comments were also received during the public comment period.

II. The following people submitted comments:

Name and Title	Agency/Organization/Entity/Other
John Long, RPh., MBA, Regulatory Affairs Director	CVS Health
Nichole Cover, RPh, Director, Pharmacy Affairs	Walgreens
Ben Mudd, PharmD Executive Director	Kentucky Pharmacists Association
Rachel Swope, PharmD, President	Kentucky Health-System Pharmacists
Shannon Stiglitz, Senior VP of Gov. Affairs	Kentucky Retail Federation

III. The following people from the Board of Pharmacy responded to the written comments:

Name and Title
Anthony Tagavi, Board Vice-President
Jonathan Van Lahr, Board President
Meredith Figg, Board Member
Jason Belcher, Board Member
Kimberly Croley, Board Member
Ron Poole, Board Member
Eden Davis, General Counsel
Christopher Harlow, Executive Director

IV. Summary of Comments and Responses

(1) Subject Matter: Concern about Disclosure of Proprietary Information
(a) Comment: Ben Mudd - The Kentucky Pharmacists' Association expressed concerns regarding who within the Board would have access to confidential data submitted, as required, by the regulation. The Association is asking for board members to not have access to data since they are market actors in their private lives.

(b) Response: The Board agrees to amend the regulation to only allow for Board staff to have access to data submitted by pharmacies.

(2) Subject Matter: Pharmacies not billing third parties should be exempted from the regulation.
(a) Comment: Ben Mudd - SB188 from the 2024 legislative session does not authorize waivers or exemptions from the reporting requirement; however, the Board will exercise enforcement discretion should a pharmacy that does not bill third parties fails to submit data. The Board will add a question to the pharmacy renewal application to assess if third parties are billed.

(3) Subject Matter: Data should be allowed to be submitted in the aggregate.
(a) Comment: Nichole Cover –When pharmacies provide data, pharmacies that are commonly owned should be allowed to submit their data at one time rather than for each individual permit.
(b) Response: The Board has made this change in the amended after comments draft.

(4) Subject Matter: The Board of Pharmacy's Regulation must follow rulemaking by the Department of Insurance.
(a) Comment: John Long—The Department of Insurance did not promulgate a rule with the data points required to be submitted by pharmacies. The Board of Pharmacy did promulgate this rule; however SB188 required the Department of Insurance to first promulgate a rule with the data points so that the data points would be subject to notice and comment procedures as required by KRS 13A.
(b) Response: The Board of Pharmacy acknowledges that the Department of Insurance should have promulgated a rule with the data points; however, the Board of Pharmacy had their own statutory mandate to file the regulation before January 1, 2025. Therefore, the Board of Pharmacy promulgated the data points that the Department of Insurance provided them, and these data points are now subject to comment.

(5) Subject Matter: The regulation is overly broad and ambiguous.
(a) Comment: John Long—If the board cannot clearly identify what data is required, there are due process concerns because pharmacies do not clearly know what is required of them.
(b) Response: The Board of Pharmacy believes the data points are clear. If there are questions about specific data points, the Board of Pharmacy can address those, but those specific concerns were not provided by Mr. Long in his comment.

(6) Subject Matter: The regulation presents concerns regarding confidentiality.
(a) Comment: John Long—Seeing that confidential and proprietary data is having to be submitted to the Board, CVS asks that the Board amend the regulation to provide a provision ensuring confidentiality of sensitive information.
(b) Response: The Board agreed to only allow staff of the Board of Pharmacy to have access to the data submitted. Board members who are also private market actors will not have access to the data submitted to the Board of Pharmacy.

(7) Subject Matter: The regulation reporting requirements create a burden on health systems.
(a) Comment: Rachel Swope-- All ambulatory pharmacies must submit detailed costs of several items that may not be easily accessible or directly tracked within individual pharmacy departments. The burden of this reporting will require additional staff, software, and legal

oversight, thereby increasing operational costs for pharmacies and reducing their ability to serve their patients. A more generalized approach could significantly reduce the administrative cost of this regulation while still achieving the same intended result. Additionally, we have serious concerns about contractual limitations and privacy.
(b) Response: The Board will allow aggregate submissions of data to streamline the reporting burdens. If there are further solutions that need to be implemented, please make the Board aware.

(8) Subject Matter: The voluntary submission of data is highly specific and may prove challenging to provide.
(a) Comment: Rachel Swope--Section 2 outlines the optional submission of detailed data for each prescription dispensed. Although this submission is voluntary, the depth of information requested—such as the date the claim was submitted, the prescription insurance member identification number, specific payment amounts, and any retroactive fees assessed by pharmacy benefit managers—is highly claim-specific and may prove challenging to compile on an annual basis. A more generalized reporting approach could be more practical and less resource-intensive for pharmacies.
(b) Response: The data in section 2 is optional for submission. If it proves challenging to provide, there is no requirement to provide it.

(9) Subject Matter: The regulation should be amended to reference the statute regarding confidentiality of data submitted.
(a) Comment: Shannon Stiglitz-- Senate Bill 188 (2024) created KRS 315.038, the reason for this regulation requires all information and data requested for the cost of dispensing study to be deemed protected and confidential, and this information is not subject to open records. We would request the regulation be amended to include reference to this statute.
(b) Response: The Board has included the proposed language citing the statutory requirement for confidentiality.

(10) Subject Matter: Pharmacies should be authorized to submit data in the aggregate.
(a) Comment: Shannon Stiglitz-- For pharmacies with multiple locations, a requested change is a reporting process that allows stores with multiple locations to submit one report per corporate organization in a batched report. The state of Washington allows for batching report, and a copy of the Washington cost of dispensing study for review by the board of pharmacy and consideration of the requested change.
(b) Response: The Board has included the proposed change in their amended after comments version.

(11) Subject Matter: Expand Section 1 subsection (1)(d) to consider square footage for pharmacy operations as a proportion of total space.
(a) Comment: Shannon Stiglitz-- Many retailers operate with more than one business purpose that could include a portion of their physical space as a pharmacy. Therefore, we would recommend expanding Section 1 Subsection 1(d) to consider the square footage that is used for pharmacy operations as a proportion of the facility's total rent and /or mortgage payment.
(b) Response: The Board has included the proposed change in their amended after comments version.

(12) Subject Matter: Section 2 should include information on the cost of acquiring prescription drugs.
(a) Comment: Shannon Stiglitz-- Regarding Section 2 subsection 21—would recommend including information on the cost of acquiring prescriptions drugs be included in the voluntary section as well, if the goal is to get a true picture prescription drug costs and prescription drug reimbursements. This would assist in capturing a clear picture to determine if pharmacy reimbursements are below costs.
(b) Response: The Department of Insurance did not include this in their data elements. However, the Board will consult with them about this inclusion.

(13) Subject Matter: Specialty Drugs should be defined as adopted in SB188 (2024).
(a) Comment: Shannon Stiglitz-- In Section 2, KRF requests clarification that specialty medications would be defined as it is adopted in SB 188 (2024).
(b) Response: There is no definition in SB188 (2024) for specialty drug.

Summary of Statement of Consideration and
Action Taken by Kentucky Board of Pharmacy

The public hearing on this administrative regulation was held on March 26, 2025, and Ben Mudd and Nichole Cover attended and offered comments. Written comments were also received from John Long, Rachel Swope and Shannon Stiglitz. The Board of Pharmacy responded to the comments and amends the administrative regulation as follows:

Page 2
Section 1
Line 3
After "previous year" insert the following:
which shall remain confidential and only be shared with the Department of Insurance as required by KRS 315.038:

Page 2
Section 1
Line 21
After "pharmacy space." insert the following:
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

Page 4
Section 1
Line 13
After "12/2024." insert the following:
Data may be submitted in the aggregate for pharmacies with multiple locations.

Page 6
Section 3
Line 10

After "61.884." insert the following:
Only board staff will have access to the data submitted. Board of Pharmacy members will not have access to the data submitted.

Page 6
Section 4
Line 12
After "Section 4." Insert the following:
Enforcement discretion will be exercised if a pharmacy fails to submit mandatory data under Section 1 if they do not bill third parties.
Section 5.