



Common Sense Initiative

Mike DeWine, Governor

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Business Impact Analysis

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Regulation/Package Title (<i>a general description of the rules' substantive content</i>):	
<u>Pharmacy Benefit Managers</u>	
Rule Number(s): <u>3901-12-01, 3901-12-02</u>	
Date of Submission for CSI Review: <u>September 23, 2026</u>	
Public Comment Period End Date: <u>October 7, 2026, 11:59PM</u>	
Rule Type/Number of Rules:	
☒ New/ 2 rules	☐ No Change/ rules (FYR?)
☐ Amended/ rules (FYR?)	☐ Rescinded/ rules (FYR?)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.

Which adverse impact(s) to businesses has the Agency determined the rule(s) create?

The rule(s):

- ☒ a. Requires a license, permit, or any other prior authorization to engage in or operate a line of business.
- ☐ b. Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.
- ☒ c. Requires specific expenditures or the report of information as a condition of compliance.
- ☐ d. Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.

Regulatory Intent

2. Please briefly describe the draft regulation in plain language.

Please include the key provisions of the regulation as well as any proposed amendments.

Pharmacy benefit managers (PBM's) are companies that may contract with insurance plans in order to manage prescription drug benefits. PBM's can negotiate prices with drug manufacturers, create and manage formularies, process prescription claims when a pharmacy bills an insurance plan, negotiate contracts with pharmacies, manage networks and administer programs, and receive payments and or rebates.

The proposed rules establish standards for how PBMs must be licensed and overseen in Ohio. It requires PBMs to meet strict qualifications, provide complete and accurate application information, and maintain insurance coverage to protect consumers. The regulation also ensures transparency by requiring PBMs to report changes in ownership or business operations, renew their licenses annually, and follow rules designed to prevent fraud or misconduct. Together, these licensing requirements help the state verify that PBMs operating in Ohio are trustworthy, properly managed, and accountable, strengthening consumer protection and maintaining the integrity of the prescription drug system.

3. Please list the Ohio statute(s) that authorizes the Agency to adopt the rule(s) and the statute(s) that amplify that authority.

Ohio Revised Code 3901.041 and 3957.02 grant authority to the Department to adopt both rules. Specifically, rule 3901-12-01 amplifies Ohio Revised Code 3957.01, and rule 3901-12-02 amplifies Ohio Revised Code 3957.03 through 3957.08.

4. Does the regulation implement a federal requirement? ☐ Yes ☒ No

Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?

☐ Yes ☒ No

If yes, please briefly explain the source and substance of the federal requirement.

Not applicable.

5. If the regulation implements a federal requirement, but includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

Not applicable.

6. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

PBMs play a significant role in shaping prescription drug costs, so regulations are designed to promote transparency, competition, and affordability in the marketplace. These oversight measures help ensure that PBMs act in the best interests of patients and health plan members while preventing unnecessary expenses and conflicts of interest.

7. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

The Department will be able to measure the success of PBM regulations by ensuring that PBMs follow licensing requirements and provide transparent pricing information, reviewing quarterly reports on drug prices, rebates, and savings, and relying on annual independent quality reviews to verify accurate reporting. Together, these measures help protect patients, pharmacies, and health plans by promoting accountability, transparency, and affordability.

8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931? ☐ Yes ☒ No

If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

Not applicable.

Development of the Regulation

9. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation. *If applicable, please include the date and medium by which the stakeholders were initially contacted.*

On Friday, July 17th, 2026, the Department distributed an email to stakeholders requesting comments, including the Ohio Pharmacists Association, the Pharmaceutical Care Management Association, the Ohio Chamber of Commerce, the Ohio Association of Health Plans, the Ohio State Medical Association, the National Association of Benefits and Insurance Professionals, as well as the Department's standard rule-vetting list.

10. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

The Department received comments from a total of four interested parties including; the Ohio Pharmacists Association, the National Association of Chain Drug Stores, the Pharmaceutical Care Management Association, and Navitus Health Solutions, LLC (Navitus). All comments were supportive of the rule.

Navitus requested specifically that the Department protect confidential, proprietary or trade secret information disclosed during the licensing or renewal process. ORC 3957.14(A) addresses this matter and therefore the Department does not believe further amendments to the rule are necessary.

11. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

The Department is required by law to establish licensing standards for PBMs, the regulation focuses on implementing those legal mandates through clear eligibility criteria, documentation requirements, and oversight procedures. As a result, its development centered on fulfilling these statutory obligations rather than scientific or technical research.

12. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives? *Alternative regulations may include performance based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.*

Regulatory alternatives were not considered because a comprehensive licensing framework was needed to establish clear, consistent oversight for PBMs in Ohio. Since no comparable structure previously existed, a full licensing rule was the only approach that met statutory requirements and ensured effective regulation.

13. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

The Department ensured that this regulation does not duplicate any existing Ohio requirements by establishing a standalone licensing framework specifically for PBMs, which did not previously exist in state rule. Creating a dedicated PBM rule allowed the department to address PBM-specific licensing needs without repeating or overlapping existing standards. The rule was drafted to clearly define new obligations unique to PBMs, ensuring that its requirements complement—rather than duplicate—other insurance regulations already in place.

14. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

The Ohio Department of Insurance plans to implement this regulation by using a structured, uniform licensing process that applies the same standards and documentation requirements to every PBM applicant. The rule outlines specific steps PBMs must follow—such as submitting complete applications, providing required documentation, maintaining insurance and bonds, and reporting organizational changes—which ensures the licensing process is predictable and consistent. The department further supports consistent application by prescribing standardized forms, requiring timely notifications of changes, and reserving the ability to request additional information when needed. By using these uniform procedures and clear requirements, the agency ensures that all PBMs are evaluated according to the same criteria and that compliance is monitored in a reliable, transparent, and fair manner across the regulated community.

Adverse Impact to Business

15. Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:

- a. Identify the scope of the impacted business community; and
- b. Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a representative business. Please include the source for your information/estimated impact.

a. This regulation applies to all entities seeking to operate as Pharmacy Benefit Managers (PBMs) in Ohio, including both individuals and business entities, whether located in-state or out-of-state. Any organization—large or small—that administers pharmacy benefits or contracts with pharmacies on behalf of insurers, employers, public plans, or other payers would be required to obtain and maintain an Ohio PBM license. There are no exemptions or alternative compliance pathways for small businesses in the draft rule, so the entire PBM industry is equally affected.

b. The regulation imposes several direct costs on PBMs, including required licensing and renewal fees, mandatory insurance and bonding, and the administrative effort needed to complete detailed applications, background checks, and ongoing reporting. PBMs must also maintain compliance by updating the superintendent on changes in ownership or business operations and responding to additional information requests, all of which create ongoing time and resource burdens. These impacts apply uniformly to all PBMs operating in the state.

16. Are there any proposed changes to the rule(s) that will reduce a regulatory burden imposed on the business community? Please identify. (*Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors.*)

Both proposed rules introduce new regulatory requirements, as they are entirely new provisions. However, the rules are intentionally drafted in a clear and streamlined format to improve readability and support straightforward compliance.

17. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The regulatory intent behind the PBM licensing rule is to protect Ohioans by ensuring that any organization managing prescription drug benefits meets strict standards for honesty, financial responsibility, and accountability. While the rule introduces new responsibilities for PBMs—such as completing detailed applications, undergoing background checks, maintaining insurance and bonds, reporting ownership changes, and renewing licenses annually—these requirements are designed to prevent fraud, ensure transparency, and verify that PBMs operating in Ohio are trustworthy and compliant with

state law. Although these obligations may create administrative and financial burdens for PBMs, they serve a broader public interest by strengthening oversight of a sector that significantly influences prescription drug access and costs. In short, the adverse impact on PBMs is justified because these safeguards help protect consumers, promote fair business practices, and support a more transparent and reliable healthcare system across the state.

Regulatory Flexibility

18. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

The regulation does not offer alternative compliance options for small businesses; instead, all pharmacy benefit managers must meet the same licensing, reporting, and insurance requirements to ensure consistent oversight and consumer protection across the industry.

19. How will the Agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

The Department will apply section 119.14 of the Revised Code into the implementation of this regulation by working with businesses on first-time violations of this rule.

20. What resources are available to assist small businesses with compliance of the regulation?

Department staff is available to answer questions, regardless of the size of business. Furthermore, the Department provides filing information and instructions on its website. The Department intends to continue dialogue with stakeholders through the implementation process to ensure compliance and facilitate questions.