Michigan Office of Administrative Hearings and Rules
Administrative Rules Division (ARD)
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REGULATORY IMPACT STATEMENT and COST-BENEFIT ANALYSIS (RIS)

Agency Information:

Department name:
Insurance and Financial Services

Bureau name:
Insurance

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Rule Set Information:

ARD assigned rule set number:
2023-10 IF

Title of proposed rule set:
Pharmacy Benefit Manager Licensure and Regulation Act

Comparison of Rule(s) to Federal/State/Association Standard

1. Compare the proposed rules to parallel federal rules or standards set by a state or national licensing agency or accreditation association, if any exist.
Parallel federal rules or standards set by a state or national licensing agency or accreditation do not exist.

A. Are these rules required by state law or federal mandate?
The proposed rules are required by state law under sections 11 and 13 of the pharmacy benefit manager licensure and regulation act, 2022 PA 11, MCL 550.821 and 550.823.

B. If these rules exceed a federal standard, please identify the federal standard or citation, describe why it is necessary that the proposed rules exceed the federal standard or law, and specify the costs and benefits arising out of the deviation.
The proposed rules do not exceed a federal standard.

2. Compare the proposed rules to standards in similarly situated states, based on geographic location, topography, natural resources, commonalities, or economic similarities.
The states that border Michigan—Minnesota, Wisconsin, Illinois, Indiana, and Ohio (which regulates pharmacy benefit managers as third-party administrators)— each impose licensing requirements on pharmacy benefit managers that include completing applications for initial licensure and renewal, paying fees, filing periodic reports, and being subject to state enforcement. The proposed rules implement specific provisions of Michigan's pharmacy benefit manager licensure and regulation act that contain distinct provisions regarding licensing and renewal applications, fees, network adequacy reports, and enforcement through fines, suspension, limitation of licensure, and revocation of licensure.

A. If the rules exceed standards in those states, please explain why and specify the costs and benefits arising out of the deviation.
Although the proposed rules implement distinct provisions in Michigan's statute, the proposed rules do not exceed the standards in those states.

3. Identify any laws, rules, and other legal requirements that may duplicate, overlap, or conflict with the proposed rules.

There are no laws, rules, or other legal requirements that may duplicate, overlap, or conflict with the proposed rules.

A. Explain how the rules have been coordinated, to the extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter. This section should include a discussion of the efforts undertaken by the agency to avoid or minimize duplication.

Because parallel federal rules or standards set by a state or national licensing agency or accreditation do not exist, there was no need to coordinate or undertake efforts to avoid or minimize duplication.

4. If MCL 24.232(8) applies and the proposed rules are more stringent than the applicable federally mandated standard, provide a statement of specific facts that establish the clear and convincing need to adopt the more stringent rules.

MCL 24.232(8) does not apply.

5. If MCL 24.232(9) applies and the proposed rules are more stringent than the applicable federal standard, provide either the Michigan statute that specifically authorizes the more stringent rules OR a statement of the specific facts that establish the clear and convincing need to adopt the more stringent rules.

MCL 24.232(9) does not apply.

Purpose and Objectives of the Rule(s)

6. Identify the behavior and frequency of behavior that the proposed rules are designed to alter.

The proposed rules would establish the application contents and fee, the license renewal schedule, and the license renewal fee under the act. The proposed rules also establish standards regarding fines, suspension of licensure, restriction of licensure, and revocation of licensure under the act. Accordingly, the proposed rules are designed to alter the behavior of pharmacy benefit managers by requiring them to comply with statutorily mandated requirements for obtaining and maintaining a pharmacy benefit manager's license, including by: (1) applying for an initial license; (2) filing biennial license renewal applications to maintain licensure; and (3) complying with licensee obligations under the pharmacy benefit manager licensure and regulation act, 2022 PA 11.

A. Estimate the change in the frequency of the targeted behavior expected from the proposed rules.

The proposed rules would implement statutory requirements that include completion of an application to obtain an initial pharmacy benefit manager's license as well as subsequent filings to renew licensure every two years. See Section 11(1) of the pharmacy benefit manager licensure and regulation act, MCL 550.821(1). The statutorily mandated enforcement rules are intended to ensure that licensees remain in continuous compliance with their obligations under the pharmacy benefit manager licensure and regulation act, 2022 PA 11.

B. Describe the difference between current behavior/practice and desired behavior/practice.

Pharmacy benefit managers did not need to apply for and maintain pharmacy benefit manager licenses prior to the enactment of the pharmacy benefit manager licensure and regulation act, 2022 PA 11, which takes effect on January 1, 2024. The proposed rules would implement the statutory requirements for the new type of license.

C. What is the desired outcome?

It is desired that pharmacy benefit managers will comply with statutorily mandated requirements for obtaining and maintaining a pharmacy benefit manager's license, including by: (1) applying for an initial license; (2) filing biennial license renewals; and (3) complying with licensee obligations under the pharmacy benefit manager licensure and regulation act, 2022 PA 11.

7. Identify the harm resulting from the behavior that the proposed rules are designed to alter and the likelihood that the harm will occur in the absence of the rule.

The legislation that provides the authority for the proposed rules was designed to minimize the harm resulting from pharmacy benefit managers operating outside of a licensing framework that specifically pertains to pharmacy benefit managers.

A. What is the rationale for changing the rules instead of leaving them as currently written?

The proposed rules do not amend an existing ruleset.

8. Describe how the proposed rules protect the health, safety, and welfare of Michigan citizens while promoting a regulatory environment in Michigan that is the least burdensome alternative for those required to comply.

The proposed rules would implement the pharmacy benefit manager licensure and regulation act, 2022 PA 11, which was designed to protect the health, safety, and welfare of Michigan citizens by requiring pharmacy benefit managers to maintain a license that requires them to comply with minimum standards of accountability.

9. Describe any rules in the affected rule set that are obsolete or unnecessary and can be rescinded.

The proposed rules would not amend an existing rule set.

Fiscal Impact on the Agency

Fiscal impact is an increase or decrease in expenditures from the current level of expenditures, i.e. hiring additional staff, higher contract costs, programming costs, changes in reimbursements rates, etc. over and above what is currently expended for that function. It does not include more intangible costs for benefits, such as opportunity costs, the value of time saved or lost, etc., unless those issues result in a measurable impact on expenditures.

10. Please provide the fiscal impact on the agency (an estimate of the cost of rule imposition or potential savings for the agency promulgating the rule).

DIFS has budgeted for 3 full-time equivalent positions for fiscal year 2023 to enforce the Pharmacy Benefit Manager Licensure and Regulation statute; the total annual cost is $439,778.36. However, the fiscal impact of the proposed rules on the agency would be minimal.

11. Describe whether or not an agency appropriation has been made or a funding source provided for any expenditures associated with the proposed rules.

An agency appropriation has been made to enforce the statute; no additional funding sources are necessary for expenditures associated with the proposed rules.

12. Describe how the proposed rules are necessary and suitable to accomplish their purpose, in relationship to the burden(s) the rules place on individuals. Burdens may include fiscal or administrative burdens, or duplicative acts.

Section 11 of the pharmacy benefit manager licensure and regulation act, MCL 550.821, mandates that DIFS promulgate rules regarding the application fee, renewal schedule and fee, and the renewal filing due date. Section 13 of the pharmacy benefit manager licensure and regulation act, MCL 550.823, requires that DIFS promulgate rules that are necessary or required to implement the act. Section 13 of the pharmacy benefit manager licensure and regulation act, MCL 550.823, also mandates that the rules include fines, suspension of licensure, restriction of licensure, and revocation of licensure in accordance with the act.

To meet those requirements, the proposed rules must impose certain burdens on pharmacy benefit managers, including application and license renewal fees, record disclosure requirements, costs associated with personnel who would comply with the program, and other associated costs.

A. Despite the identified burden(s), identify how the requirements in the rules are still needed and reasonable compared to the burdens.

Because the proposed rules are mandatory, the requirements would still be needed despite any burdens they may impose.

Impact on Other State or Local Governmental Units

13. Estimate any increase or decrease in revenues to other state or local governmental units (i.e. cities, counties, school districts) as a result of the rule. Estimate the cost increases or reductions for other state or local governmental units (i.e. cities, counties, school districts) as a result of the rule. Include the cost of equipment, supplies, labor, and increased administrative costs in both the initial imposition of the rule and any ongoing monitoring.

DIFS estimates that the proposed rules would not increase or decrease revenues or costs to other state or local governmental units.

14. Discuss any program, service, duty, or responsibility imposed upon any city, county, town, village, or school district by the rules.

The proposed rules would not impose any program, service, duty, or responsibility upon any city, county, town, village, or school district.

A. Describe any actions that governmental units must take to be in compliance with the rules. This section should include items such as record keeping and reporting requirements or changing operational practices.

No governmental units other than DIFS would be required to take action to be in compliance with the proposed rules.

15. Describe whether or not an appropriation to state or local governmental units has been made or a funding source provided for any additional expenditures associated with the proposed rules.

There would be no additional expenditures associated with the proposed rules.

Rural Impact

16. In general, what impact will the rules have on rural areas?

The proposed rules would not have an impact on an area due to it being rural.

A. Describe the types of public or private interests in rural areas that will be affected by the rules.

Public or private interests in rural areas would be affected by the proposed rules to the same extent as public or private interests in non-rural areas because the obligations of pharmacy benefit managers under the proposed rules would not vary according to the rural or non-rural status of a particular area.

Environmental Impact

17. Do the proposed rules have any impact on the environment? If yes, please explain.

The proposed rules would not have any impact on the environment.

Small Business Impact Statement

18. Describe whether and how the agency considered exempting small businesses from the proposed rules.

DIFS did not consider exempting small businesses.

19. If small businesses are not exempt, describe (a) the manner in which the agency reduced the economic impact of the proposed rules on small businesses, including a detailed recitation of the efforts of the agency to comply with the mandate to reduce the disproportionate impact of the rules upon small businesses as described below (in accordance with MCL 24.240(1)(a-d)), or (b) the reasons such a reduction was not lawful or feasible.

The proposed rules would not disproportionately impact small businesses because of the size of their businesses. Exempting small businesses furthermore would not be feasible because it is critical that licensing standards be consistent across all pharmacy benefit managers, regardless of their size.

A. Identify and estimate the number of small businesses affected by the proposed rules and the probable effect on small businesses.

DIFS does not collect data on which pharmacy benefit managers are “small businesses.”

B. Describe how the agency established differing compliance or reporting requirements or timetables for small businesses under the rules after projecting the required reporting, record-keeping, and other administrative costs.

DIFS would not establish differing compliance or reporting requirements or timetables for small businesses under the proposed rules.

C. Describe how the agency consolidated or simplified the compliance and reporting requirements for small businesses and identify the skills necessary to comply with the reporting requirements.

DIFS did not consolidate or simplify the compliance and reporting requirements for small businesses.

D. Describe how the agency established performance standards to replace design or operation standards required by the proposed rules.

The proposed rules would not include any design or operation standards.

20. Identify any disproportionate impact the proposed rules may have on small businesses because of their size or geographic location.

The proposed rules would not have a disproportionate impact on small businesses due to their size or geographic location.

21. Identify the nature of any report and the estimated cost of its preparation by small businesses required to comply with the proposed rules.

The proposed rules would not require any report except the retail pharmacy benefit manager network adequacy report that is already required as part of the renewal filing mandated in section 11(10)(c) of the pharmacy benefit manager licensure and regulation act, MCL 550.821. The additional cost of preparing the report would be minimal because the report is statutorily required under section 17 of the pharmacy benefit manager licensure and regulation act, MCL 550.827.

22. Analyze the costs of compliance for all small businesses affected by the proposed rules, including costs of equipment, supplies, labor, and increased administrative costs.

Application fees would be the same for all pharmacy benefit managers regardless of size. There would be minimal costs associated with preparing an application to obtain an initial pharmacy benefit manager's license and with preparing a license renewal filing; however, these costs would apply to all pharmacy benefit managers regardless of size.

23. Identify the nature and estimated cost of any legal, consulting, or accounting services that small businesses would incur in complying with the proposed rules.

All pharmacy benefit managers, regardless of size, would incur minimal compliance costs for legal, consulting, or accounting services that may be required to fulfill the application and renewal filing content requirements of the proposed rules.

24. Estimate the ability of small businesses to absorb the costs without suffering economic harm and without adversely affecting competition in the marketplace.

DIFS does not estimate that the proposed rules would cause small businesses to suffer economic harm or adversely affect competition in the marketplace.

25. Estimate the cost, if any, to the agency of administering or enforcing a rule that exempts or sets lesser standards for compliance by small businesses.

DIFS would have to collect and analyze data to determine whether any pharmacy benefit manager qualifies as a "small business." More importantly, establishing alternative standards would contravene the legislative purposes of the pharmacy benefit manager licensure and regulation act.

26. Identify the impact on the public interest of exempting or setting lesser standards of compliance for small businesses.

Exempting or setting lesser standards of compliance for small business would harm the public interest because it would contravene the intent of the Legislature, which is to subject all pharmacy benefit managers, regardless of size, to minimum standards of accountability.

27. Describe whether and how the agency has involved small businesses in the development of the proposed rules.

DIFS has not specifically involved small businesses in the development of the proposed rules.

A. If small businesses were involved in the development of the rules, please identify the business(es).

DIFS has not specifically involved small businesses in the development of the proposed rules.

Cost-Benefit Analysis of Rules (independent of statutory impact)

28. Estimate the actual statewide compliance costs of the rule amendments on businesses or groups.

The proposed rules would be new rules. Independent of statutory impact, DIFS estimates that the actual statewide compliance costs would primarily consist of fees and minimal additional costs related to paperwork for the initial application and subsequent renewals.

A. Identify the businesses or groups who will be directly affected by, bear the cost of, or directly benefit from the proposed rules.

Pharmacy benefit managers would be directly affected by, bear the cost of, and, to an extent, benefit from the proposed rules.

B. What additional costs will be imposed on businesses and other groups as a result of these proposed rules (i.e. new equipment, supplies, labor, accounting, or recordkeeping)? Please identify the types and number of businesses and groups. Be sure to quantify how each entity will be affected.

Independent of statutory impact, DIFS estimates that the additional costs that the proposed rules would impose on businesses and other groups would primarily consist of fees and the miscellaneous administrative costs associated with completing paperwork for the initial application and subsequent renewals. The proposed rules do not fix specific fee amounts. DIFS estimates that the miscellaneous administrative costs, independent of statutory impact, imposed on businesses and other groups by the proposed rules would be minimal.

29. Estimate the actual statewide compliance costs of the proposed rules on individuals (regulated individuals or the public). Include the costs of education, training, application fees, examination fees, license fees, new equipment, supplies, labor, accounting, or recordkeeping.

DIFS estimates that the actual statewide compliance costs of the proposed rules on individuals, independent of statutory impact, would be minimal. Pharmacy benefit managers, who would be regulated by the proposed rules, are generally sophisticated business entities. An individual who owns 10% or more of a pharmacy benefit manager possibly would bear minimal costs associated with providing the pharmacy benefit manager with information necessary to complete the paperwork that would be required to obtain a license or renew. DIFS does not estimate that individual members of the public would bear any actual compliance costs.

A. How many and what category of individuals will be affected by the rules?

DIFS is not aware of any individuals who would be licensed as pharmacy benefit managers. An individual who owns 10% or more of a pharmacy benefit manager possibly would be affected by the proposed rules.

B. What qualitative and quantitative impact do the proposed changes in rules have on these individuals?

An individual who owns 10% or more of a pharmacy benefit manager possibly would bear minimal costs associated with providing the pharmacy benefit manager with information necessary to complete the paperwork that would be required to obtain a license or renew. DIFS estimates that the costs would be minimal because the required paperwork would relate to basic biographical information: names, addresses, dates of birth, social security numbers, official positions, and professional qualifications.

30. Quantify any cost reductions to businesses, individuals, groups of individuals, or governmental units as a result of the proposed rules.

The proposed rules, independent of statutory impact, are not expected to result in cost reductions to businesses, individuals, groups of individuals, or governmental units.

31. Estimate the primary and direct benefits and any secondary or indirect benefits of the proposed rules. Please provide both quantitative and qualitative information, as well as your assumptions.

The primary and direct benefits of the proposed rules would be ensuring that pharmacy benefits managers meet licensing requirements to operate and that they are held to a minimum standard of accountability. Secondary or indirect benefits of the proposed rules would be fulfilling the pharmacy benefit manager licensure and regulation act's intent, which is to increase access to pharmacist services and lower the costs of prescription drugs for Michiganders.

32. Explain how the proposed rules will impact business growth and job creation (or elimination) in Michigan.

The proposed rules should not significantly impact business growth or job creation (or elimination) in Michigan.

33. Identify any individuals or businesses who will be disproportionately affected by the rules as a result of their industrial sector, segment of the public, business size, or geographic location.

Pharmacy benefit managers would be disproportionately affected by the rules as a result of their industrial sector inasmuch as, pursuant to the pharmacy benefit manager licensure and regulation act, pharmacy benefit managers are the entities that are subject to licensure and regulation under the proposed rules.

34. Identify the sources the agency relied upon in compiling the regulatory impact statement, including the methodology utilized in determining the existence and extent of the impact of the proposed rules and a cost-benefit analysis of the proposed rules.

DIFS relied on the following sources to compile the Regulatory Impact Statement:

Budget estimates prepared by DIFS Office of Financial and Administrative Services.

Pharmacy Benefit Managers. National Association of Insurance Commissioners (NAIC). (2022, March 11). Retrieved March 8, 2023, from https://content.naic.org/cipr-topics/pharmacy-benefit-managers

Gordon, R., Fox, A., Hawks, O., Brinks, W., VanderWall, C., Witwer, A., Vaupel, H., & Kuppa, P. (2020). Report of Governor Gretchen Whitmer's Prescription Drug Task Force. State of Michigan. https://www.michigan.gov/-/media/Project/Websites/mdhhs/Folder4/Folder3/Folder3/Folder103/Folder2/Folder203/Folder1/Folder303/Prescription_Drug_Task_Force_Report__12302020_FINALWeb_1.pdf?rev=ecfd371107f947399560c9bdd6f8ed40

McInerney, J., & Coffin, M. (2021). House Bill 4348 (H-1): Revised Summary as Reported from Committee. House Fiscal Agency. https://www.legislature.mi.gov/documents/2021-2022/billanalysis/House/pdf/2021-HLA-4348-0717C7E9.pdf

Jackson, S., & Raczkowski, E. (2021). H.B. 4348 (H-1): Summary of House-Passed Bill in Committee. Senate Fiscal Agency. http://www.legislature.mi.gov/documents/2021-2022/billanalysis/Senate/pdf/2021-SFA-4348-L.pdf

Statutes and regulations of the following states: Illinois, Indiana, Minnesota, Ohio, and Wisconsin.

A. How were estimates made, and what were your assumptions? Include internal and external sources, published reports, information provided by associations or organizations, etc., that demonstrate a need for the proposed rules.

Estimates regarding affected entities were based upon the number of affected entities, their sophistication, and what would be required of them under the proposed rules. Estimates regarding affected individuals were based upon the scope of information about them that would be required under the proposed rules.

Alternative to Regulation

35. Identify any reasonable alternatives to the proposed rules that would achieve the same or similar goals.

There are no reasonable alternatives to the proposed rules because the proposed rules are mandated under sections 11 and 13 of the pharmacy benefit manager licensure and regulation act, 2022 PA 11, MCL 550.821 and 550.823.

A. Please include any statutory amendments that may be necessary to achieve such alternatives.

Because the proposed rules are mandatory, there are no statutory amendments that could achieve the same or similar goals without removal of the statutory mandate in sections 11 and 13 of the pharmacy benefit manager licensure and regulation act, 2022 PA 11, MCL 550.821 and 550.823.

36. Discuss the feasibility of establishing a regulatory program similar to that proposed in the rules that would operate through private market-based mechanisms. Please include a discussion of private market-based systems utilized by other states.

Because the proposed rules are mandatory under sections 11 and 13 of the pharmacy benefit manager licensure and regulation act, 2022 PA 11, MCL 550.821 and 550.823, it would not be feasible to establish a regulatory program that would operate through private market-based mechanisms. DIFS is not aware of private market-based systems utilized by other states.

37. Discuss all significant alternatives the agency considered during rule development and why they were not incorporated into the rules. This section should include ideas considered both during internal discussions and discussions with stakeholders, affected parties, or advisory groups.

DIFS did not consider any significant alternatives during the development of the proposed rules because the proposed rules are mandatory under sections 11 and 13 of the pharmacy benefit manager licensure and regulation act, MCL 550.821 and 550.823.

Additional Information

38. As required by MCL 24.245b(1)(c), please describe any instructions regarding the method of complying with the rules, if applicable.

There are no instructions regarding the method of complying with the proposed rules.