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REGULATORY IMPACT STATEMENT and COST-BENEFT ANALYSIS (RIS)

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Rule Set Information:
ARD assigned rule set number:
2021-93 LR
Title of proposed rule set:
Central Fill Pharmacies

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.

Each state establishes its own requirements with respect to centralized prescription processing. The purpose of the Centralized Prescription Processing Pharmacies rules is to regulate the processing by a pharmacy, of a request from another pharmacy, to fill or refill a prescription drug order, perform processing functions such as dispensing, perform drug utilization review, complete claims adjudication, obtain refill authorization, initiate therapeutic intervention, and perform other functions related to the practice of pharmacy.

The subject matter of these rules is contained in section 17753 of the Public Health Code (Code), MCL 333.17753, and the Code of Federal Regulations, Part 1306, entitled Prescriptions, 21 CFR 1306.15 and 21 CFR 1306.27. The proposed rules are similar to the federal regulations except for the following:

The Code of Federal Regulations, Part 1306, entitled Prescriptions, 21 CFR 1306.15(a)(3) and 1306.27(4) requires the originating pharmacy that transmits a controlled substance prescription to a central fill pharmacy, to maintain the original prescription for a period of 2 years from the date the prescription was filled. The proposed rule requires an originating pharmacy to maintain an original controlled substance prescription for a period of 5 years from the date the prescription was filled. Further, after 2 years, the proposed rule allows the originating pharmacy to make an electronic duplicate of the original printed prescription, which becomes the original prescription. The proposed rule is more restrictive than the federal regulation as section 17752 of the Code, MCL 333.17752(1), requires that a prescription or equivalent record be maintained for not less than 5 years.

There are no standards set by a state or national licensing agency or accreditation association regarding centralized processing that the proposed rules can be compared to.

A. Are these rules required by state law or federal mandate?

No, these rules are not required by state law or federal mandate. MCL 333.16145 authorizes the Board of Pharmacy (Board), to promulgate rules necessary or appropriate to fulfill its functions as prescribed in Article 15 of the Code. The following provisions also authorize rulemaking: MCL 333.16145; MCL 333.17753; MCL 333.17767; MCL 338.3501; MCL 445.2001; MCL 445.2011; and MCL 445.2030.

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 Code of Federal Regulations, Part 1306, entitled Prescriptions, 21 CFR 1306.15(a)(3) and 1306.27(4) requires the originating pharmacy that transmits a controlled substance prescription to a central fill pharmacy, to maintain the original prescription for a period of 2 years from the date the prescription was filled. The proposed rule requires an originating pharmacy to maintain an original controlled substance prescription for a period of 5 years from the date the prescription was filled. Further, after 2 years, the proposed rule allows the originating pharmacy to make an electronic duplicate of the original printed prescription, which becomes the original prescription. The proposed rule is more restrictive than the federal regulation as section 17752 of the Code, MCL 333.17752(1), requires that a prescription or equivalent record be maintained for not less than 5 years.

If there is a cost to maintaining a document for 5 years instead of 2 years, it is a minimal cost. The benefit arising out of the deviation is that the prescription is available for a longer period of time if a review of prescription is needed to protect the public, as required by state law.

2. Compare the proposed rules to standards in similarly situated states, based on geographic location, topography, natural resources, commonalities, or economic similarities.

Each state establishes its own requirements with respect to centralized prescription processing. The proposed rules are largely consistent with the other states in the Great Lakes region which address pharmacy responsibilities, information on prescriptions, maintenance of records, and policy and procedures. All states in the Great Lakes region, Illinois, Indiana, Minnesota, Ohio, Pennsylvania, and Wisconsin allow centralized prescription processing.

A. If the rules exceed standards in those states, please explain why and specify the costs and benefits arising out of the deviation.

There are differences between states, however, the requirements are similar. Although all states in the Great Lakes region do not address pharmacy responsibilities, information on prescriptions, maintenance of records, and policy and procedures, the proposed rules do not exceed standards in the other states in the Great Lakes region.

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

21 CFR 1306.15 regulates schedule II-controlled substance prescriptions transferred to a central fill pharmacy. 21 CFR 1306.27 regulates schedule III, IV, or V controlled substance prescriptions transferred to a central fill pharmacy.

MCL 333.17753 authorizes centralized prescription processing in Michigan.

The proposed rules regulate centralized prescription processing for both controlled and non-controlled substances. The proposed rules overlap MCL 333.17753 and duplicate the federal regulations. Except for the requirement to maintain a prescription for 5 years, the proposed rules do not exceed the federal regulations.

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.

21 CFR 1306.15 regulates schedule II-controlled substance prescriptions transferred to a central fill pharmacy. 21 CFR 1306.27 regulates schedule III, IV, or V controlled substance prescriptions transferred to a central fill pharmacy.

MCL 333.17753 authorizes centralized prescription processing in Michigan.

The proposed rules regulate centralized prescription processing for both controlled and non-controlled substances. The proposed rules overlap MCL 333.17753 and duplicate the federal regulations. Except for the requirement to maintain a prescription for 5 years, the proposed rules do not exceed the federal regulations.

In writing the proposed rules, the Board has recommended that the federal regulations be included in the proposed rules to provide clarity to pharmacies.

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.

21 CFR 1306.15(a)(3) and 1306.27(4) require the originating pharmacy that transmits a controlled substance prescription to a central fill pharmacy, to maintain the original prescription for a period of 2 years from the date the controlled substance prescription was filled. The proposed rule requires an originating pharmacy to maintain an original prescription for a for a period of 5 years from the date the prescription was filled. Two years after the prescription is filled, the originating pharmacy may make an electronic duplicate of the original printed prescription, which becomes the original prescription. The proposed rule is more restrictive than the federal regulation as MCL 333.17752(1) requires that a prescription or equivalent record be maintained for not less than 5 years.

Purpose and Objectives of the Rule(s)

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

The behavior and frequency in behavior the proposed rules are designed to alter include: a pharmacy only following the central fill rules instead of following the central fill rules and other pharmacy rules; a pharmacy not maintaining prescription records for 5 years from the date of dispensing; an originating pharmacy not maintaining the prescription for both controlled and non-controlled substances for 5 years from the date the prescription was filled and not making an electronic copy of the original paper prescription 2 years after the prescription was filled; and a pharmacy that receives a transmitted prescription not maintaining a record that includes the date the prescription was dispensed and the method of dispensing.

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

It is expected that: a pharmacy participating in centralized prescription processing will always follow all Board rules that do not conflict with the central fill pharmacy rules; a pharmacy that participates in centralized prescription processing services will maintain the prescription records for 5 years from the date of dispensing; the originating pharmacy will maintain the prescription for both controlled and non-controlled substances for 5 years from the date the prescription was filled and will make an electronic duplicate of the original paper prescription 2 years after the prescription was filled; and a pharmacy that receives a transmitted prescription will maintain a record that includes the date the prescription was dispensed and the method of dispensing.

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

The difference between the current behavior/practice and desired behavior/practice is: a pharmacy participating in centralized prescription processing will follow all Board rules that do not conflict with the central fill pharmacy rules instead of assuming that the only rules that apply to centralized prescription processing are the Centralized Prescription Processing rules; a pharmacy that participates in centralized prescription processing services will know that they must maintain prescription records from the time the prescription is dispensed; the originating pharmacy will maintain a prescription for 5 years from the date the prescription was filled and will make an electronic duplicate of the original paper prescription 2 years after the prescription was filled instead of keeping the original prescription in hard copy for 5 years; and a pharmacy that receives a transmitted prescription will now maintain a record that includes the date the prescription was dispensed and the method of dispensing.

C. What is the desired outcome?

The desired outcome is that: a pharmacy participating in centralized prescription processing will follow all applicable rules that do not conflict with the central fill pharmacy rules; a pharmacy that participates in centralized prescription processing services will maintain the prescription records for 5 years from the date of dispensing; the originating pharmacy will maintain the prescription for both controlled and non-controlled substances for 5 years from the date the prescription was filled and will make an electronic duplicate of the original paper prescription 2 years after the prescription was filled; and a pharmacy that receives a transmitted prescription will maintain a record that includes the date the prescription was dispensed and the method of dispensing.

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 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 is: a pharmacy participating in centralized prescription processing will not follow all of the applicable rules; a pharmacy that participates in centralized prescription processing services will not maintain prescription records for the full 5 years from the date the prescription is dispensed; an originating pharmacy will not maintain an original prescription for 5 years from the date the prescription was filled or may make an electronic duplicate of the original paper prescription before 2 years has passed from the time the prescription was filled; and a pharmacy that receives a transmitted prescription would not maintain a record that includes the date the prescription was dispensed and the method of dispensing.

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

The rationale for changing the rules is: a pharmacy participating in centralized prescription processing must know what rules are applicable; and a pharmacy participating in centralized prescription processing must maintain the appropriate records to ensure public safety.

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 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, as the proposed rules will require the following: pharmacies participating in centralized prescription processing will know what rules are applicable; and pharmacies participating in centralized prescription processing will maintain the appropriate records to ensure that the public is receiving the correct prescriptions as well as allow the Department of Licensing and Regulatory Affairs (Department) and Board to investigate claims regarding prescriptions.

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

No rules are rescinded.

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).

The proposed rules are not expected to have a fiscal impact on the agency.

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

No agency appropriation has been made nor has a funding source been provided 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.

There are no additional burdens placed on individuals as a result of the proposed rules.

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

There are no additional burdens placed on individuals as a result of the proposed rules.

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.

There are no anticipated increases in revenues, or cost increases or reductions, to other state or local government units as a result of the proposed rules.

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

There are no anticipated or intended programs, services, duties, or responsibilities imposed on any city, county, town, village, or school district as a result of these proposed rules.

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.

There are no actions that governmental units must take to comply with these 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.

No appropriations have been made to any governmental units as a result of these rules. No additional expenditures are anticipated or intended with the proposed rules.

Rural Impact

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

The proposed rules are not expected to impact rural areas. The proposed rules apply to pharmacies, regardless of their location.

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

The proposed rules are not expected to impact rural areas. The proposed rules apply to licensees in the state regardless of their location.

Environmental Impact

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

No, the rules do not have an impact on the environment.

Small Business Impact Statement

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

The proposed rules impose requirements on pharmacies that participate in centralized prescription processing. Some pharmacies may qualify as small businesses. The agency did not consider exempting small businesses, as the proposed rules regulate the handling of controlled substances and non-controlled substances, and it is essential for the public's best interest that prescriptions that are the subject of centralized prescription processing are consistently regulated no matter the size of the pharmacy.

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 will impose requirements on pharmacies which may qualify as a small business. The Department did not consider exempting small businesses from the proposed rules as the proposed rules are necessary for the safety of the public no matter the size of the business. Therefore, reducing any disproportionate impact upon small businesses is not feasible.

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

As of September 21, 2022, the most recent professional licensing active counts, there were approximately 3,525 pharmacies licensed in Michigan that may be considered small businesses depending on their size and annual sales.

The Department does not collect or have access to information that would allow it to identify and estimate the number of pharmacies that qualify as a small business.

The effect on a small business, if a pharmacy is considered a small business is: a pharmacy participating in centralized prescription processing will always follow all Board rules that do not conflict with the central fill pharmacy rules; a pharmacy that participates in centralized prescription processing services will maintain the prescription records for 5 years from the date of dispensing; the originating pharmacy will maintain the prescription for both controlled and non-controlled substances for 5 years from the date the prescription was filled and will make an electronic duplicate of the original paper prescription 2 years after the prescription was filled; and a pharmacy that receives a transmitted prescription will maintain a record that includes the date the prescription was dispensed and the method of dispensing.

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.

The agency did not establish separate compliance or reporting requirements for small businesses. The rules were drafted to be the least burdensome on all affected licensees.

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.

The agency did not consolidate or simplify the compliance and reporting requirements with the proposed rules.

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

The agency did not establish performance standards to replace design or operation standards required by these rules.

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

The proposed rules impact pharmacies. There may be an impact on a small business in that all pharmacies, that participate in centralized prescription processing, no matter the size, are affected by the proposed rules. Therefore, there is no disproportionate effect on small businesses because of 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.

There is no separate cost for report preparation specific to small businesses.

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.

There are no expected increased costs for small businesses concerning the costs of equipment, supplies, labor, or administrative costs.

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.

There are no expected increased costs for small businesses concerning legal, consulting, or accounting services.

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

There are no expected costs to small businesses that will cause economic harm to a small business or the marketplace as a result of the proposed rules. All pharmacies that choose to participate in centralized prescription processing in Michigan are subject to the same requirements and costs as a result of the proposed rules so there are no expected costs that should 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.

Exempting or setting lesser standards of compliance for pharmacies that are small businesses is not in the best interest of the public and could increase the cost of protecting the public.

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 businesses is not in the best interest of the public.

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

The Department worked with multiple stakeholders at the Michigan Board of Pharmacy Rules Committee Work Group meetings, which included members from the Board of Pharmacy, educational institutions, businesses, and other members of the public in the development of the proposed rules. The Board is composed of members of the profession and members of the public who may work in businesses in Michigan.

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

Representatives from businesses were involved in the development of the rules. However, the Department is not aware if they meet the definition of a "small business."

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 Department does not expect any statewide compliance costs of the proposed rules on businesses or groups.

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

The Department does not expect any businesses or groups to be directly affected by, bear the cost of, or directly benefit from the proposed rules other than pharmacies.

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.

There are approximately 3,525 pharmacies in this state as of September 21, 2022. The proposed rules will impact pharmacies as follows: a pharmacy participating in centralized prescription processing will always follow all Board rules that do not conflict with the central fill pharmacy rules; a pharmacy that participates in centralized prescription processing services will maintain the prescription records for 5 years from the date of dispensing; the originating pharmacy will maintain the prescription for both controlled and non-controlled substances for 5 years from the date the prescription was filled and will make an electronic duplicate of the original paper prescription 2 years after the prescription was filled; and a pharmacy that receives a transmitted prescription will maintain a record that includes the date the prescription was dispensed and the method of dispensing.

The proposed rules clarify the requirements that were already in place so no additional burdens should be placed on pharmacies.

The Department does not expect the proposed rules to result in any additional costs such as new equipment, supplies, labor, accounting, or recordkeeping on businesses or other groups.

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.

The Department does not expect the proposed rule to result in any additional educational costs, training, application fees, examination fees, license fees, new equipment, supplies, labor, accounting, or record keeping on regulated individuals or the public.

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

As of September 21, 2022, the most recent professional licensing active counts, there were approximately 17,384 pharmacists and 24,978 pharmacy technicians licensed in Michigan. Pharmacists and pharmacy technicians will be affected by the rules, as they work in the pharmacies regulated by the proposed rules.

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

Pharmacists and pharmacy technicians participating in centralized prescription processing in a pharmacy will be impacted as follows: they will always follow all Board rules that do not conflict with the central fill pharmacy rules; they will maintain the prescription records for 5 years from the date of dispensing; they will maintain the prescription for both controlled and non-controlled substances for 5 years from the date the prescription was filled and will make an electronic duplicate of the original paper prescription 2 years after the prescription was filled; and if they are employed in a pharmacy that receives a transmitted prescription they will maintain a record that includes the date the prescription was dispensed and the method of dispensing.

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

Although they cannot be quantified at this time, there may be reductions in costs for pharmacies who maintain duplicate electronic copies of prescriptions instead of hard copies.

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.

A direct benefit of the proposed rules to pharmacies is that they are able to electronically duplicate an original prescription 2 years after the prescription was filled instead of maintaining the document in hard copy for 5 years.

The proposed rules use clear, concise language which provides a direct benefit to pharmacies. This clear, concise language allows pharmacies using centralized prescription processing services to better understand the requirements, which also provides an indirect benefit to the public.

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

The rules are not expected to have an impact on business growth, job creation, or job elimination.

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.

There is not expected to be a disproportionate effect due to industrial sector, segment of the public, business size, or geographic location.

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.

Survey of Pharmacy Law, National Association of Boards of Pharmacy

NABP | National Association of Boards of Pharmacy

Illinois
https://www.ilga.gov/commission/jcar/admincode/068/068013300G07700R.html

Indiana
Indiana General Assembly - Indiana Register

A00010 (1).pdf

Minnesota
Guidance_for_Central_Service_Policies_tcm21-450447.pdf (mn.gov)

6800.4075 - MN Rules Part

Ohio
Rule 4729:5-5-19 - Ohio Administrative Code | Ohio Laws

Pennsylvania
49 Pa. Code § 27.203. Centralized prescription processing. (pacodeandbulletin.gov)

Wisconsin
(000001.ildoc) (wisconsin.gov)

Central Fill Federal
2001 - Allowing Central Fill Pharmacies To Fill Prescriptions for Controlled Substances on Behalf of Retail Pharmacies (usdoj.gov)

eCFR :: 21 CFR 1306.15 -- Provision of prescription information between retail pharmacies and central fill pharmacies for prescriptions of Schedule II controlled substances.

CFR - Code of Federal Regulations Title 21 (fda.gov)

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.

No estimates or assumptions were made.

Alternative to Regulation

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

There is no other reasonable alternative to the proposed rules that would achieve the same or similar goal.

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

There is no other reasonable alternative to the proposed rules that would achieve the same or similar goal.

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.

Since the rules are authorized by statute, private market-based systems cannot serve as an alternative. Each state is responsible for implementing its own laws and rules pertaining to centralized prescription processing. Private market -based systems are not used for regulating pharmacies. The licensing and regulation of pharmacies are state functions, so a regulatory program independent of state intervention cannot be established.

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.

No alternatives were considered during rule development.

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 methods of complying with the rules.