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REGULATORY IMPACT STATEMENT and COST-BENEFIT ANALYSIS (RIS)

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Rule Set Information:
ARD assigned rule set number:
2022-62 LR
Title of proposed rule set:
Pharmacy – Program for Utilization of Unused Prescription Drugs

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 the utilization and destruction of unused prescription drugs.

The subject matter of these rules is contained in sections 17775 and 17776 of the Public Health Code (Code), MCL 333.17775 and 333.17776.

The purpose of the Pharmacy – Program for Utilization of Unused Prescription Drugs rules is to establish, implement, and administer a voluntary statewide unused prescription drug repository and distribution program consistent with the public health and safety, where unused or donated prescription drugs, other than controlled substances, may be transferred from a medical institution or manufacturer to a pharmacy or a charitable clinic that elects to participate in the program. In addition, the rules allow for controlled substances, as permitted by federal law, or prescriptions that are ineligible for distribution, to be accepted by participants in the program to be destroyed.

There are no federal standards related to the donation of non-controlled substance prescription drugs. However, there are federal standards for the collection and disposal of controlled substances. Specifically, the Secure and Responsible Drug Disposal Act of 2010 (Public Law 111-273, 124 Stat. 2858), grants the United States Attorney General authority to promulgate regulations that allow patients to deliver unused controlled substance prescriptions to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion. The Drug Enforcement Administration's (DEA) rules, 21 CFR Part 1317, effective in 2014, expanded the options available to collect unused controlled substances for destruction, in addition to just discarding the drugs into the general waste stream or flushing the substances. The regulations allow for take-back events, mail-back programs, and collection receptacles. The proposed rules are consistent with the DEA regulations.

Additionally, the Drug Supply Chain Security Act, (DSCSA), 21 USC 360eee-360eee-4, became effective on November 27, 2023. This law enhances the security and traceability of pharmaceutical products within the United States supply chain. Its primary objective is to safeguard patients form exposure to counterfeit, stolen or, otherwise harmful drugs.

Under the Controlled Substances Act, (CSA), 21 USC 801 et seq., the federal government regulates the practice of pharmacy with respect to controlled substances and chemicals used in the manufacture of controlled substances and requires pharmacies to register or self-certify with the DEA. Registration with the DEA is required to prevent diversion and abuse of controlled substances and chemicals used in the manufacture of controlled substances, and to ensure an adequate and uninterrupted supply of controlled substances for the United States. A pharmacy must maintain a state license to get a DEA license.

Taking into consideration the federal laws and regulations referenced above, each state establishes its own requirements with respect to the utilization and destruction of unused prescription drugs.

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

The proposed rules are required by section 17775(12) and 17776 of the Code, MCL 333.17775, 333.17776. The rules are not federally mandated.

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.

Each state establishes its own requirements with respect to the utilization and destruction of unused prescription drugs.

Many states have enacted laws for drug donation and reuse or destruction. All states in the Great Lakes region have enacted drug donation and reuse or destruction programs. However, Indiana and New York do not have operational programs. Pennsylvania's program is limited to cancer drugs. Illinois, Minnesota, Ohio, and Wisconsin permit drugs to be donated and dispensed to patients who meet eligibility requirements.

Ohio permits controlled substances in long acting or extended-release form used for the treatment of opioid dependence to be donated and dispensed. No other Great Lakes state permits the donation of a controlled substance. Ohio requires a facility participating in its drug donation program to be licensed as a terminal distributor of dangerous drugs.

Illinois, Minnesota, and Wisconsin permit participating facilities to reject ineligible donations. Minnesota, Pennsylvania, and Wisconsin require someone on the facility's premises to be designated to receive donations. Minnesota and Wisconsin prohibit the use of drop boxes.

The proposed rules are comparable to programs in other Great Lakes states. The proposed change to require donated drugs to be inspected for misbranding would bring Michigan in line with Illinois, Minnesota, and Wisconsin.

However, Michigan's program differs from those of other Great Lakes states because MCL 333.17775 and 17776 require a pharmacy, health professional, or charitable clinic that participates in the program to accept an ineligible medication for destruction and disposal. Therefore, pharmacies and charitable clinics participating in Michigan's program must be prepared to accept any drug, including a controlled substance, for destruction and must comply with the federal regulations concerning the destruction of controlled substances.

The proposed rules are less stringent than Minnesota's and Wisconsin's programs in that they would permit the use of drop boxes to accept donations. The proposal to change the limit on the handling fee a pharmacy or charitable clinic may charge an eligible participant to receive a donated medication would make Michigan's restrictions less stringent than those of Ohio, Minnesota, and Wisconsin. Ohio limits the handling fee to $20, while Minnesota limits the handling fee to 250% of the dispensing fee for its medical assistance program and Wisconsin limit the handling fee to 300% of the dispensing fee for Medicaid.

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

The proposed rules do not exceed standards in other states in the Great Lakes region. The proposed rules are required by section 17775 and 17776 of the Code, MCL 333.17775, 333.17776, and participation is voluntary.

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

As discussed in Question #1, sections 17775 and 17776 of the Code, MCL 333.17775, 333.17776, require rules to create an unused prescription repository, distribution, and destruction program.

Section 17775 of the Code, MCL 333.17775, expressly addresses any conflict which may arise with Michigan's cancer drug repository program established under section 17780 of the Code, MCL 333.17780, by stating that in the event of conflict, section 17780 of the Code, MCL 333.17780, controls.

The proposed rules are consistent with the DEA's regulations in 21 CFR Part 1317, effective in 2014, which expanded the options available to collect unused controlled substances, in addition to discarding or flushing the substances, by allowing for take-back events, mail-back programs, and collection receptacles.

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.

As a result of the Michigan board of pharmacy (board) rules committee work group process with the public, and research regarding federal laws and regulations, the resulting proposed rules are not in conflict with, and are consistent with, the Secure and Responsible Drug Disposal Act of 2010, the Drug Supply Chain Security Act of 2013, and the DEA's regulations in 21 CFR Part 1317.

Purpose and Objectives of the Rule(s)

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

The rules allow for re-distribution of prescription drug medication, whose integrity has been maintained in a closed system, to patients who may not otherwise be able to afford the medication. Secondly, the rules set standards for the destruction of prescription medication received from individuals that is not eligible for re-distribution. The rules allow for safe and environmentally conscious destruction of medications. They prevent diversion, and the use of expired medications. The proposed changes to the rules are designed to provide updates; increase the use of the program by pharmacies, charitable clinics, manufacturers, medical institutions, and individuals; and reduce the complexity and type of forms necessary to participate in the program.

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

The proposed rules are expected to alter the frequency of the targeted behavior by increasing the use of the program and reducing the complexity and type of forms necessary to participate in the program.

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

The difference between current behavior and desired behavior is that more pharmacies, charitable clinics, medical institutions, manufacturers, and individuals will use the program, and those using the program will have an easier time filling out and maintaining forms.

C. What is the desired outcome?

The rules serve a two-fold purpose. The rules allow for re-distribution of prescription drug medication, whose integrity has been maintained in a closed system, to patients who may not otherwise be able to afford the medication. Secondly, the rules set standards for the destruction of prescription medication received from individuals that is not eligible for re-distribution. The rules provide for the safe and environmentally conscious destruction of medications and prevent diversion, overdoses, and the use of expired medications. The desired outcome is that more pharmacies, charitable clinics, medical institutions, manufacturers, and individuals participate in the program.

5. 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 proposed rules modify the prescription drug repository, distribution, and destruction program under the requirements of the Code. The rules are designed to allow for re-distribution of prescription drug medication to avoid medication waste, diversion, overdoses, and the use of expired drugs. The rules also attempt to avoid discarding prescription drugs by throwing them away with other household waste or allowing them to enter the water system by flushing them when they could be maintained in a closed system and used for patients who may not otherwise be able to afford the medication or discarded in an environmentally conscious process.

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

The harm that will result from the behavior that the proposed rules are designed to alter will continue in the absence of the proposed rules. The proposed rules clarify concerns with the rules that have been raised by licensees, the department, or the public, which have resulted in previous harm to the public.

6. 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 establish, implement, and administer the requirements of the program for the utilization of unused prescription drugs required by the Code. The rules permit the re-distribution of unused medication from a closed system to an eligible patient who may not otherwise be able to afford the medications. Since participation in the program is voluntary, the rules provide for the minimum amount of regulation necessary to ensure the integrity and safe dispensing of the donated medications and to ensure the patient has given informed consent for the acceptance of donated medications.

The Code also requires participating pharmacies and charitable clinics to collect and destroy ineligible prescriptions, as permitted by federal law. The rules provide for the safe and environmentally conscious destruction of medications and prevent diversion, overdoses, and the use of expired medications. Since participation in the program is voluntary, the rules are designed to provide the minimum amount of regulation necessary to ensure for safe collection and disposal of medication while comporting with federal standards.

Promulgation of rules related to the donation, utilization, or destruction of unused prescription drugs.
is required by statute. The proposed rules will protect the welfare of Michigan citizens by providing greater clarity to the process of donation, utilization, or destruction of unused prescription drugs while reducing waste, lessening environmental concerns, and reducing diversion of drugs.

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

R 338.3613 is being rescinded as the guardian or medical institution may donate unused drugs without a form.
R 338.3619 is being rescinded as the record keeping requirements are being moved to the form requirements in R 338.3621.
R 338.3623 is being rescinded as the requirements for each form are being modified and placed into a separate rule, numbered R 338.3621 through R 338.3621d.

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.

8. 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 department does not expect the implementation of the proposed rules to result in additional costs or savings for the department.

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

The implementation and administration of the program for the utilization of unused prescription drugs including the promulgation and implementation of the rules, is funded by the collection of licensing fees. As a result, there was no reason to make an agency appropriation or provide a funding source. Also, the department does not expect the proposed rules to increase expenditures.

10. 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.

The rules are required by statute to provide the program for the utilization of unused prescription drugs. The rules are not any more restrictive than is allowed by statute. There is no expectation of additional burdens, fiscal, administrative, or duplicative acts, on individuals. The proposed rules reduce the burdens on participants by reducing the number of forms and the amount of record keeping.

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

No additional burdens have been identified. The rules are required by statute to provide the program for the utilization of unused prescription drugs. The rules are not any more restrictive than is allowed by statute.

Impact on Other State or Local Governmental Units

11. 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.

The authorizing statute provides that an eligible participant is an individual eligible to receive Medicare, Medicaid, does not have health insurance, or does not have the reasonable means to purchase prescription drugs. R 338.3627 provides that a participating pharmacy or charitable clinic shall not be reimbursed for prescription drugs dispensed through the program but may charge a handling fee. Therefore, the state Medicaid agency may experience savings in prescription drug reimbursement costs. However, participation in the program is voluntary for participants as well as a pharmacies and charitable clinics. Any savings would be dependent upon the level of participation and the quantity and type of drugs donated and dispensed through the program.

If a county medical care facility chose to participate in the program, the facility would incur administrative costs and transportation costs for transferring the donated drugs to the participating pharmacy or charitable clinic.

There are no other anticipated increases or decreases in revenues or costs to other state or local government units because of the proposed rules.

12. 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 because 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 the proposed rules.

13. 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 because of these rules. No additional expenditures are anticipated or intended with the proposed rules.

Rural Impact

14. 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 program participants regardless of their location, however, with the changes to the rules more pharmacies, charitable clinics, medical institutions, manufacturers, and individuals who live in rural areas may choose to participate in the program. Eligible and low-income citizens in both rural and urban areas may be able to obtain prescription drugs that they may not otherwise be able to afford.

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 pharmacies, charitable clinics, medical institutions, manufacturers, and individuals who participate in the program regardless of their location.

Environmental Impact

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

R 338.3633 requires participating pharmacies or charitable clinic to accept ineligible prescriptions for destruction. The destruction of the ineligible medication shall be in accordance with state and federal standards. As a result, dependent on the number of participating pharmacies and charitable clinics, there will be a greater opportunity for the public to safely dispose of unused medications. The safe disposal of unused medications protects the environment, including the water supply.

Small Business Impact Statement

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

Participation in the program for the utilization of unused prescription drugs is voluntary. The proposed rules are to ensure for the public health, safety, and welfare in the redistribution and collection of unused prescription medication; the rules are not to regulate business. Therefore, small businesses that choose to participate are not exempt from complying with the rules.

17. 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.

Participation in the program for the utilization of unused prescription drugs is voluntary. If a drug manufacturer, medical institution, or participating pharmacy that meets the definition of "small business" chooses to participate, the small business would be subject to the same rules as participants that are not small businesses. The rules are not meant to regulate business but to ensure the protection of the public health, safety, and welfare in the re-distribution and collection of unused prescription medication.

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

The entities that could potentially participate in this voluntary program include medical institutions, manufacturers, pharmacies, and charitable clinics.

For medical institutions, census data from 2021 shows there were 34 establishments in the hospital category that were not organized as nonprofits or government entities and had fewer than 250 employees. The same census information shows 1,843 establishments in the nursing and residential care facility category that are not organized as nonprofits and have fewer than 250 employees. Therefore, it is estimated there are approximately 1,877 medical institutions that are small businesses that could choose to participate in the program.

For manufacturers, census data shows there were approximately 9 employer firms in Michigan in the pharmaceutical and medicine manufacturing industry with fewer than 250 employees.

According to the Pharmaceutical Care Management Association, there were 1,097 independent pharmacies in Michigan in 2023. Independent pharmacies are used to estimate the number of pharmacies that are small businesses because they are not affiliated with large chains or hospitals.

To participate in the program, a charitable clinic is required to be a charitable nonprofit or not-for-profit corporation. It is estimated that zero charitable clinics would be defined as small businesses, as small businesses are understood to be organized for profit.

In practice, only one pharmacy has notified the department that it is participating in the program. It is unknown whether this participating pharmacy is a small business.

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.

Participation in the program is voluntary. Therefore, compliance requirements are as minimal as possible to encourage participation while still protecting for the public health, safety, and welfare.

The agency did not consolidate or simplify compliance and reporting requirements with the proposed rules for small businesses. However, the proposed rules have simplified the compliance requirements regarding forms and record keeping for all participants.

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

Participation in the program is voluntary. Therefore, the department has not established and performance standards to replace design or operation standards required by these rules. The only design standard is R 338.3635, which sets forth the requirements for collection devices. The design standard sets forth the minimum requirements to ensure for tamper resistance and the confidential collection of unused prescription medication.

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

Participation in the program is voluntary. The proposed rules will not have a disproportionate impact on small businesses because of their size or geographic location.

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

Participation in the program for the utilization of unused prescription medication is voluntary. However, a drug manufacturer, medical institution, or participating pharmacy satisfying the definition of "small business" that chose to participate would be required to comply with minimal record keeping requirements.

Medical institutions or manufacturers that donate unused prescription medications would be required to complete donation and transfer forms. The records must be kept for a minimum of five years.

Participating pharmacies are required to document information about each donated prescription; maintain a destruction record for abandoned controlled substances and other donations ineligible for re-distribution; create and maintain a destruction record for ineligible prescriptions from collection devices; complete and maintain participating patient forms, and any other pharmacy record required by state or federal law, rules, or regulations. The records must be kept for a minimum period of five years. However, two years after the record is made, the holder of the record may make an electronic duplicate of the original record that becomes the original record.

The estimated cost of the reports will vary depending upon the level of participation. However, the costs are expected to be negligible since the required records closely relate to records required by the practice of pharmacy.

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

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

Because participation in the program is voluntary, no small business is required to incur compliance costs.

However, for those small businesses that choose to participate in the program, the estimated costs of compliance with the rule amendments are zero. There are no proposed form fees, changes to transport requirements, or anticipated additional staff time.

The proposed rules add a requirement that pharmacists inspect the donated drugs for misbranding. However, because the current rules already require the drugs to be inspected for tampering and adulteration, adding misbranding is not expected to increase the time it takes a pharmacist to complete the inspection.

To maintain consistency with federal law and regulations, the proposed rules contain requirements that federal law must be followed when controlled substances are destroyed, which may result in additional costs. However, the federal laws and regulations apply to all pharmacies disposing of controlled substances regardless of the rule amendments. Therefore, the rule amendments do not impose additional costs for the destruction of controlled substances.

21. 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.

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

Participation in the program is voluntary, and the costs of the rule changes are estimated to be zero.

Further, a pharmacy is a small business that chooses to participate in the program may offset the costs of participating in the program by charging a handling fee. The proposed amendment to the handling fee limit will permit pharmacies and charitable clinics to charge up to the reasonable costs of participating in the program, using reasonable efforts to ensure the handling fee does not exceed the cost of obtaining the drug outside of the program.

The effect on competition is likely to be small, as currently only one pharmacy is participating in the program.

23. 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.

If a rule exempts or sets lesser standards for compliance by a small business, there would be no cost to the agency for administering that rule.

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

The rules are intended to protect the public and comply with federal requirements in the least restrictive way. Exempting or setting lesser standards for small businesses would compromise the safety of donated medications intended to help individuals without the means to purchase them. For example, if the donated drugs are not inspected by a pharmacist, patients could receive expired or mislabeled medications that would be ineffective or harmful.

25. 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 board rules committee work group meetings, which included members from the board, businesses, and other members of the public in the development of the proposed rules. The board is composed of members of the profession and public members who 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)

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

Because participation in the program is voluntary, no business or group is required to incur compliance costs.

However, for those businesses or groups that choose to participate in the program, the estimated costs of compliance with the rule amendments are zero. There are no proposed form fees, changes to transport requirements, or anticipated additional staff time.

The proposed rules add a requirement that pharmacists inspect the donated drugs for misbranding. However, because the current rules already require the drugs to be inspected for tampering and adulteration, adding misbranding is not expected to increase the time it takes a pharmacist to complete the inspection.

To maintain consistency with federal law and regulations, the proposed rules contain requirements that federal law must be followed when controlled substances are destroyed, which may result in additional costs. However, the federal laws and regulations apply to all pharmacies disposing of controlled substances regardless of the rule amendments. Therefore, the rule amendments do not impose additional costs for the destruction of controlled substances.

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

The businesses or groups who will be directly affected by the proposed rules include the pharmacy currently participating in the program, other pharmacies and charitable clinics interested in participating, and medical institutions and manufacturers that donate unused drugs.

Businesses and groups are not expected to bear the cost of the proposed rule amendments. Pharmacies and charitable clinics may directly benefit from the proposed easing of the limit on the handling fee they may charge to offset the costs of participating in the program.

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.

The proposed changes to the rules are not expected to impose any additional costs to businesses or other groups. Participation in the program will remain voluntary, so no business or group need incur any costs.

The proposed rules will change the current limit on the handling fee that a participating pharmacy or charitable clinic may charge the eligible participant to offset the costs of the program from 300% of the Medicaid standard pharmacy dispensing fee to an amount not to exceed the reasonable costs of participating in the program, using reasonable efforts to endure the handling fee does not exceed the cost of obtaining the same drug outside the program. The proposed change to the handling fee gives participating businesses and charitable clinics more flexibility to offset the cost so participation in the program than the current rules.

The businesses and groups affected by the proposed rules include the pharmacy currently participating in the program as well as those medical institutions, manufacturers, pharmacies, and charitable clinics interested in participating. According to census data from 2021, there are 190 hospitals and 3,464 nursing and residential care facilities that could donate drugs as medical institutions. There are 559 licensed manufacturers that could donate drugs. There are 3,517 licensed pharmacies that could participate in the program. Charitable clinics must have a licensed pharmacy to participate, so any eligible charitable clinics are included in the licensed pharmacy count.

27. 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 compliance costs for regulated individuals are estimated to be zero, as the requirements for handling prescription drugs within the donation program are similar to the requirements to handle prescription drugs outside of the donation program. Individual licensees working at organizations participating in the program would not have additional costs compared to individual licensees employed by nonparticipating organizations.

The are no associated costs for eligible participants to comply with the proposed rules.

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

There are 17,204 pharmacists, 26,716 pharmacy technicians, and 1,682 pharmacy interns in Michigan. Eligible participants to receive donated medications are Michigan residents eligible to receive Medicaid or Medicare or those who have no health insurance and otherwise lack reasonable means to purchase prescription drugs. Approximately 2.7 million Michigan residents are enrolled in Medicaid, and approximately 2.2 million are enrolled in Medicare. In 2021, Michigan's uninsured population was approximately 526,900. Of these numbers, it is impossible to determine how many in this group need the medication that can be donated to the program as the bureau does not have access to the medical records of these individuals.

Pharmacists, pharmacy staff, and the public will be affected by the rules, but the department does not expect any additional costs to these individuals.

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

Qualitative Impact

Eligible and low-income citizens may be able to obtain prescription drugs from a closed system that they may not otherwise be able to afford.

The rules provide for the safe and environmentally conscious destruction of medications. The rules also prevent diversion, overdoses, and the use of expired medications.

Quantitative Impact

The proposed changes in the rules are not expected to quantitatively impact individual licensees.

The proposed changes in the rules will alter the limit on the handling fee from no more than 300% of the Medicaid pharmacy dispensing fee to a fee not exceeding the reasonable costs of participating in the program, using reasonable efforts not to exceed the cost of obtaining the drug outside of the program.

Under the current rule, the Medicaid professional dispensing fee in Michigan ranges from $9.00 to $20.02, depending on the drug, so the handling fee is capped at $18.00 to $60.06. The proposed change to the handling fee would permit a pharmacy or charitable clinic to charge more than $60.06, provided the reasonable cost of participating in the program exceeds $60.06 and the pharmacy or charitable clinic uses reasonable efforts to ensure the fee does not exceed the cost of obtaining the drug outside of the program.

It is assumed that eligible participants will engage in comparison shopping to obtain the lowest price. Therefore, it is not expected that participants would pay more to obtain a drug through the program than it would cost to obtain the same drug outside of the program.

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

The proposed rules are not expected to reduce costs for businesses. However, because the program is voluntary, no business need incur any cost to comply with the rules.

The proposed rules are not expected to reduce costs for individuals, groups of individuals or governmental units.

29. 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.

Primary benefits

The proposed rules implement and administer a program which utilizes safe, unused prescription medications and distributes these prescription medications to low-income patients who may not otherwise be able to afford the medications. The proposed rules also provide for the collection of ineligible prescription medication for disposal and destruction, preventing diversion, overdose, and consumption of expired drugs as well as environmental protection.

Although negligible, the proposed changes to forms and record retention are also beneficial to participants.

The public benefits from every substantive change in the proposed rules as all changes have been proposed to protect the public.

30. 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.

31. 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.

32. 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.

Michigan Public Health Code, MCL 333.1101 et seq.

State Prescription Drug Repository Programs (ncsl.org)

https://www.fda.gov/drugs/disposal-unused-medicines-what-you-should-know/drug-disposal-drug-take-back-locations

https://www.getsmartaboutdrugs.gov/gsad/national-take-back-day

Can Unused Prescription Drugs Be Donated? | What You Need to Know (therecoveryvillage.com)

https://www.dea.gov/press-releases/2014/09/08/dea-releases-new-rules-create-convenient-safe-and-secure-prescription

https://sirum.org/

BPL-Active-License-Counts.pdf (michigan.gov)

https://www.congress.gov/112/plaws/publ273/PLAW-112publ273.pdf

https://www.getsmartaboutdrugs.gov/gsad/national-take-back-day

https://www.deadiversion.usdoj.gov/faq/disp_destr_faq.htm

https://www.congress.gov/111/plaws/publ273/PLAW-111publ273.pdf

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U.S. Census Bureau. "Annual Business Survey: Statistics for Employer Firms by Industry, Sex, Ethnicity, Race, and Veteran Status for the U.S., States, and Metro Areas: 2021." Economic Surveys, ECNSVY Annual Business Survey Company Summary, Table AB2100CSA01, 2021, https://data.census.gov/table/ABSCS2021.AB2100CSA01?t=BusinessandEconomy&g=040XX00US26&n=3254. Accessed on March 15, 2024.

The Independent Pharmacy Marketplace is Stable | PCMA (pcmanet.org)

https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html

https://data.cms.gov/tools/medicare-enrollment-dashboard

State and Local Estimates of the Uninsured Population in the U.S. Using the Census Bureau's 2021 American Community Survey | ASPE (hhs.gov)

Drug Dispensing Fees (michigan.gov)

https://michigandrugprices.com/Compare

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 were made using the following sources:

U.S. Census Bureau. "All Sectors: County Business Patterns, including ZIP Code Business Patterns, by Legal Form of Organization and Employment Size Class for the U.S., States, and Selected Geographies: 2021." Economic Surveys, ECNSVY Business Patterns County Business Patterns, Table CB2100CBP, 2021, https://data.census.gov/table/CBP2021.CB2100CBP?g=010XX00US_040XX00US26&n=622. Accessed on March 1, 2024.

U.S. Census Bureau. "Annual Business Survey: Statistics for Employer Firms by Industry, Sex, Ethnicity, Race, and Veteran Status for the U.S., States, and Metro Areas: 2021." Economic Surveys, ECNSVY Annual Business Survey Company Summary, Table AB2100CSA01, 2021, https://data.census.gov/table/ABSCS2021.AB2100CSA01?t=BusinessandEconomy&g=040XX00US26&n=3254. Accessed on March 15, 2024.

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https://michigandrugprices.com/Compare

For the estimated number Michigan residents enrolled in Medicaid and Medicare, it is unknown how many may be enrolled in both programs.

Assumptions

The following assumptions were made:

-Independent pharmacies are a good proxy for pharmacies that are small businesses. It is possible that some independent pharmacies are not small businesses.

-Businesses will not participate in the program if the costs outweigh the benefits.

-Eligible participants will engage in comparison shopping to obtain the lowest price for their medications.

Alternative to Regulation

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

There are no other reasonable alternatives to the proposed rules that would achieve the same or similar goals except to modify the Code. The Code requires the department in consultation with the board to establish and implement by rule and administer a statewide unused prescription drug repository and distribution program. The program shall allow unused or donated prescription drugs, other than controlled substances, to be transferred from a medical institution or manufacturer to a pharmacy or charitable clinic that elects to participate in the program. In addition, the Code requires that subject to rules, the program accept medications that are ineligible for distribution, which shall be destroyed and disposed of.

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

Eliminate the Code provisions that require rules to establish, implement, and administer a statewide program.

34. 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.

Under the Code, the department and the board are responsible for establishing, implementing, and administering the program for the utilization of unused prescription drugs. Therefore, it is not feasible to establish a regulatory program that would operate through private market-based mechanisms.

35. 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

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

The rules will explicitly inform applicants of the eligibility requirements, how to apply as a participant in the program, the necessary forms, and the record retention requirements.