



Senate Fiscal Agency
P. O. Box 30036
Lansing, Michigan 48909-7536

BILL



ANALYSIS

Telephone: (517) 373-5383
Fax: (517) 373-1986

House Bill 5089 (Substitute H-2 as passed by the House)
House Bill 5090 (Substitute H-1 as passed by the House)
Sponsor: Representative Joel Johnson (H.B. 5089)
Representative Jim Ananich (H.B. 5090)
House Committee: Health Policy
Senate Committee: Health Policy

Date Completed: 9-12-12

CONTENT

House Bill 5089 (H-2) would add Section 17775 to the Public Health Code to do the following:

- **Require the Michigan Board of Pharmacy to establish, implement, and administer a voluntary statewide unused prescription drug repository and distribution program for prescription drugs other than controlled substances.**
- **Require the program to dispense unused or donated drugs to eligible participants, and to provide for the destruction and disposal of prescription drugs or other medications that were ineligible for dispensing.**
- **Prescribe the criteria that participating pharmacies, health professionals, and charitable clinics would have to use in accepting drugs for use in the program.**
- **Prohibit the resale of prescription drugs accepted under the program.**
- **Provide immunity from criminal or civil liability for injury other than death, or loss to person or property, and from professional disciplinary action, for participating individuals and entities.**
- **Provide criminal and civil immunity for manufacturers of prescription drugs donated to the program.**
- **Require the Department of Licensing and Regulatory Affairs (LARA) to promulgate emergency rules within**

six months after the bill took effect to establish, implement, and administer the program, and then promulgate permanent rules as soon as practical.

House Bill 5090 (H-1) would add Section 17776 to the Code to require a pharmacy, health professional, or charitable clinic that participated in the unused prescription drug program to accept for destruction and disposal a prescription drug or other medication that was ineligible for distribution.

The bills are tie-barred. House Bill 5089 (H-2) provides that Sections 17775 and 17776 would be known and could be referred to as the "Program for Utilization of Unused Prescription Drugs".

House Bill 5089 (H-2)

Program Creation; Participation

The bill would require the Michigan Board of Pharmacy to establish, implement, and administer a statewide unused prescription drug repository and distribution program consistent with public health and safety through which unused or donated prescription drugs, other than controlled substances, could be transferred from an eligible facility or manufacturer to a pharmacy or a charitable clinic that elected to participate in the program.

The bill states that the program would be created to dispense unused or donated prescription drugs to eligible participants and to provide for the destruction and disposal of prescription drugs or other medications that were ineligible for dispensing under the program.

Participation in the program by an eligible facility, manufacturer, pharmacy, or charitable clinic would be voluntary. The bill provides that nothing in Section 17775 or 17776 would require participation. "Eligible facility" would mean a medical institution as that term is defined in R 338.486 of the Michigan Administrative Code (i.e., a hospital, skilled nursing facility, county medical care facility, nursing home, or other health facility that is licensed or approved by the State and that directly or indirectly provides or includes pharmacy services).

"Charitable clinic" would mean a charitable nonprofit corporation or facility that meets all of the following requirements:

- Is organized as a not-for-profit corporation pursuant to the Nonprofit Corporation Act.
- Holds a valid exemption from Federal income taxation and is listed as an exempt organization under Section 501 of the Internal Revenue Code (which exempts certain categories of nonprofit entities from taxation).
- Is organized under or operated as a part of a licensed health facility or agency.
- Provides on an outpatient basis for a period of less than 24 consecutive hours to people not residing or confined at the facility advice, counseling, diagnosis, treatment, surgery, care, or services relating to the preservation or maintenance of health.
- Has a licensed pharmacy.

"Eligible participant" would mean an individual who is a Michigan resident; and who is eligible to receive Medicaid or Medicare or has no health insurance and otherwise lacks reasonable means to purchase prescription drugs, as prescribed in rules promulgated under Section 17775.

Drug Acceptance

Pharmacies, health professionals, and charitable clinics that participated in the program would have to use criteria

promulgated in rules as well as the criteria described below in accepting unused or donated prescription drugs from eligible facilities or manufacturers for use in the program.

Only prescription drugs in their original sealed, tamper-evident, and unopened unit dose packaging could be accepted for dispensing. Drugs packaged in single-unit dose packaging could be accepted, however, even if the outside packaging was open as long as the single-unit dose packaging was unopened.

The following could not be accepted for dispensing:

- Expired prescription drugs.
- Controlled substances.
- Drugs that had been held outside of a health professional's control where sanitation and security could not be assured.
- Drugs that could be dispensed only to a patient registered with the drug's manufacturer under U.S. Food and Drug Administration requirements.

A person could not accept a prescription drug for dispensing if he or she had reason to believe that it was adulterated.

Subject to limitations prescribed in the bill, unused or donated drugs dispensed for purposes of a medical assistance program or drug product donation program could be accepted for dispensing under the proposed program.

Drug Dispensing

A pharmacy or charitable clinic that met the eligibility requirements for participation in the program and any applicable rules could dispense prescription drugs accepted under the program to eligible participants, and, if established by rule, charge the participants a handling fee for the service.

A participating pharmacy or charitable clinic would have to do all of the following:

- Comply with all applicable Federal laws and regulations and State laws and rules related to the storage and distribution of harmful drugs.

- Inspect all accepted prescription drugs before dispensing them to determine that they were not adulterated.
- Dispense prescription drugs only pursuant to a prescription issued by a health professional.

A pharmacy, health professional, or charitable clinic that accepted prescription drugs under the program could not resell them. Receiving a fee from an eligible participant, if established in administrative rules, or reimbursement from a governmental agency to a charitable clinic would not constitute resale.

Immunity

For purposes of the lawful donation, acceptance, or dispensing of prescription drugs under the program, the following people who were in compliance with the program and proposed Sections 17775 and 17776, as well as any applicable rules, in the absence of bad faith or gross negligence would not be subject to criminal or civil liability for injury other than death, or loss to person or property, or professional disciplinary action:

- The Board of Pharmacy.
- The Department of Licensing and Regulatory Affairs.
- An eligible facility or manufacturer that donated drugs to the program.
- A manufacturer or its representative that directly donated prescription drugs in professional samples to a charitable clinic under the program.
- A pharmacy, charitable clinic, or health professional that accepted or dispensed drugs for the program.
- A pharmacy or charitable clinic that employed a health professional who accepted drugs for the program and who could legally dispense them under Part 177 (Pharmacy Practice and Drug Control).

In the absence of bad faith, a manufacturer would not be subject to criminal prosecution or liability in tort or other civil action for injury, death, or loss to person or property for matters related to the donation, acceptance, or dispensing of a prescription drug made by that manufacturer that was donated by any person under the program, including liability for failure to transfer or communicate product or consumer

information or the expiration date of the donated drug.

Rules

In consultation with the Board of Pharmacy, LARA would have to promulgate rules under the Administrative Procedures Act and establish procedures necessary to establish, implement, and administer the program. The Board would have to provide technical assistance to participating eligible facilities, manufacturers, pharmacies, and charitable clinics.

In consultation with the Board, LARA also would have to promulgate emergency rules within six months after the bill took effect to establish, implement, and administer the program. In consultation with the Board, LARA would have to promulgate permanent rules as soon as practical after the emergency rules were promulgated. The Department and the Board would have to include all of the following in the rules:

- Eligibility criteria for pharmacies and charitable clinics authorized to accept and dispense prescription drugs for the program.
- Eligibility criteria for eligible participants.
- Establishment of a list of prescription drugs that were not eligible for acceptance and dispensing under the program.
- Standards and procedures for transfer, transportation, acceptance, safe storage, security, and dispensing of prescription drugs.
- A process for seeking input from the Department of Human Services and the Department of Community Health in establishing provisions that affected eligible facilities and mental health and substance abuse clients.
- Standards and procedures for inspecting accepted drugs to ensure that they met the program's requirements and to ensure that, in the pharmacist's professional judgment, they met all Federal and State standards for product integrity.
- Procedures for verifying whether the participating charitable clinic, pharmacy, pharmacist, or other health professional was licensed and in good standing with the applicable licensing board.

- Establishment of standards for acceptance of unused or donated prescription drugs from eligible facilities.
- Establishment of standards for the acceptance by a participating pharmacy, health professional, or charitable clinic from any person of a prescription drug or any other medication that was ineligible for dispensing under the program, for destruction and disposal.
- Any other standards and procedures that LARA, in consultation with the Board, considered appropriate or necessary to establish, implement, and administer the program.

Drug Donation & Delivery

Pursuant to the promulgated rules and the standards and procedures established under Section 17775, the following would apply:

- A resident of an eligible facility or his or her representative or guardian could donate unused prescription drugs for dispensing to eligible participants under the program.
- A person could deliver to a participating pharmacy, health professional, or charitable clinic a prescription drug or any other medication that was ineligible for dispensing, for destruction and disposal.

The bill provides that proposed Sections 17775 and 17776 would not impair or supersede the provisions regarding the cancer drug repository program established in Section 17780. If any provision of either of those sections conflicted with a provision of Section 17780 with regard to a cancer drug, the latter would control. (Section 17780 requires the Board to establish and maintain a cancer drug repository program that allows a person to donate a cancer drug or supply for use by an individual who meets prescribed eligibility criteria.)

House Bill 5090 (H-1)

Subject to all applicable Federal laws and regulations and State laws and rules, a pharmacy, health professional, or charitable clinic that participated in the Program for Utilization of Unused Prescription Drugs would have to accept from any person for destruction and disposal a prescription drug or other medication that was ineligible for distribution under the program. The

pharmacy, health professional, or charitable clinic would have to destroy and dispose of the drugs and medications subject to the rules promulgated under Section 17775.

Proposed MCL 333.17775 (H.B. 5089)
Proposed MCL 333.17776 (H.B. 5090)

Legislative Analyst: Julie Cassidy

FISCAL IMPACT

The bills would have an indeterminate fiscal impact on the State, and no impact on local government. The bills would introduce some new administrative costs for the Department of Licensing and Regulatory Affairs Bureau of Health Professions. The costs would primarily be borne by existing revenue of the Board of Pharmacy, which receives revenue from fees paid by pharmacists and pharmacies.

The bills would result in relatively minor one-time and ongoing costs. The bills would require LARA, with consultation from the Board of Pharmacy, to promulgate rules to establish and administer the unused prescription drug repository and distribution program. Rule promulgation is generally a one-time expense and costs a few thousand dollars, depending on the complexity of the rules.

The bills also would result in some ongoing, but likely relatively minor costs related to the establishment, implementation, and administration of the proposed program. It is unknown how much the program would cost, as this would depend largely on the scope of involvement that the Board of Pharmacy and LARA would have in the program.

To the extent that Medicaid recipients would participate in the program, the State could save an indeterminate amount. However, there is no requirement that Medicaid recipients participate in an unused prescription program, so participation by Medicaid recipients would be totally voluntary.

Fiscal Analyst: Josh Sefton

S1112\S5089sa

This analysis was prepared by nonpartisan Senate staff for use by the Senate in its deliberations and does not constitute an official statement of legislative intent.