

PRESCRIPTION DRUG REUSE PROGRAM

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House Bill 5089

Sponsor: Rep. Joel Johnson

House Bill 5090

Sponsor: Rep. Jim Ananich

Committee: Health Policy

Complete to 1-18-12

A SUMMARY OF HOUSE BILLS 5089 AND 5090 AS INTRODUCED 10-18-11

Together, the bills would create **the Program for Utilization of Unused Prescription Drugs**. The program would:

- (1) Allow an eligible facility (e.g., hospital, nursing home) or resident of an eligible facility to transfer unused prescription drugs—except for controlled substances—to a participating pharmacy or charitable clinic for distribution to seniors, Medicaid beneficiaries, and the uninsured who cannot afford prescription drugs; and
- (2) Require participating pharmacies, health professionals, or charitable clinics to accept from any source a prescription drug or other medication that was ineligible for distribution under the program for the purpose of destruction and disposal.

House Bill 5089 would create the statewide **Unused Prescription Drug Repository and Distribution Program**. House Bill 5090 would add a new section to the Public Health Code (MCL 333.17776) to require the destruction and disposal of drugs and medications that could not be redistributed. The bills are tie-barred to each other. A more detailed description of each bill follows.

House Bill 5089

The bill would add a new section to the Public Health Code (MCL 333.17775) to create the Unused Prescription Drug Repository and Distribution Program. In brief, the bill would do the following:

- Create a voluntary program by which eligible facilities (and residents of those facilities) could transfer unused prescription drugs to participating charitable clinics for distribution to eligible participants.
- Exclude the donation, acceptance, reuse, and redistribution of controlled substances.
- Define terms.
- Accept only unadulterated or unexpired drugs in their original sealed, tamper-evident, and unopened unit dose packaging.
- Accept only drugs that had been under the control of health professionals.

- Require the receiving pharmacy or charitable clinic to inspect the drugs for signs of adulteration or expiration.
- Dispense the drugs only under a prescription.
- Provide limited immunity for acts in compliance with the Program.
- Require emergency rules to be in place within six months of the bill's effective date to implement, administer, and enforce the Program, with permanent rules to be in place as soon as practical thereafter.
- Require certain provisions to be included in the rules.
- Require the departmental rules to allow any person to drop off drugs and other medications ineligible for reuse under the Program to participating pharmacies, charitable clinics, and health professionals for destruction and disposal.
- Protect the provisions of the Cancer Drug Repository Program.

A more detailed description of the bill follows.

Definitions

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

- Is organized as such under the Michigan Nonprofit Corporation Act.
- Holds a valid exemption from federal income taxation under Section 501(a) of the Internal Revenue Code (IRC).
- Is listed as an exempt organization under Section 501(c)(3) of the IRC.
- Is organized or operated as part of a state-licensed health facility or agency.
- Provides counseling, diagnoses, treatment, surgery, care, or services relating to the preservation or maintenance of health on an outpatient basis for a period of less than 24 consecutive hours.
- Has a licensed pharmacy.

"Eligible facility" would include a licensed adult foster care facility, assisted living facility, or health facility or agency (most notably a hospital or nursing home but also includes an ambulance operation, aircraft transport operation, nontransport prehospital life support operation, or medical first response service; clinical laboratory; county medical care facility; freestanding surgical outpatient facility; health maintenance organization; home for the aged; hospice; hospice residence; and any of these located in a university, college, or other educational institution).

For the purposes of the Program, "assisted living facility" would mean any home or establishment offering, coordinating, or providing services to two or more individuals, where those individuals meet the following requirements:

- They are domiciled (live) in the home or establishment.
- They are not related to the home's operator.
- By choice or functional impairments, they need assistance with personal care or nursing supervision.
- They may need intermittent or unscheduled nursing care, medication assistance, and/or assistance with transfer or ambulation.

"Eligible participant" would be a state resident who is eligible to receive Medicaid or Medicare or who had no health insurance and lacks reasonable means to purchase prescription drugs under rules to be promulgated under the bill.

Statewide Prescription Drug Repository and Distribution Program

The Program, which must be consistent with the public health and safety, would be established, implemented, and administered by the Michigan Board of Pharmacy. Participation in the Program would be voluntary. The Program would authorize an eligible facility or a drug manufacturer to transfer unused or donated drugs (with the exception of controlled substances) to a participating pharmacy or charitable clinic for redistribution to eligible participants. The Program would also provide for the destruction and disposal of prescription drugs and other medications that are ineligible for distribution under the Program.

Donation of drugs. Controlled substances listed on Schedules 2-5 would not be allowed to be transferred by the eligible facilities or accepted, reused, or redistributed by charitable clinics. Participating pharmacies, charitable clinics, and health professionals (defined to include a licensed physician, RN, physician's assistant, dentist, optometrist, pharmacist, and podiatrist) that participate in the Program would have to use the following criteria when accepting unused or donated prescription drugs from the eligible facilities or manufacturers for use in the Program:

- Accept and dispense only prescription drugs in their original sealed, tamper-evident, and unopened unit dose packaging. Prescription drugs packaged in single-unit dose packaging would be accepted and dispensed even if the outside packaging was open as long as the single-unit dose packaging was unopened.
- Refuse to accept or dispense expired prescription drugs, controlled substances, and drugs that have been held outside of a health professional's control where sanitation and security cannot be assured.
- Refuse to accept or dispense a drug when there is reason to believe the drug was adulterated.
- Subject to the bill's limitations, allow acceptance and dispensing under the Program of unused or donated prescription drugs that had been dispensed for a medical assistance program or drug product donation program.
- Any additional criteria established in rules promulgated under the bill.

Participating Pharmacies and Charitable Clinics

Pharmacies and charitable clinics eligible to participate in the Program could dispense prescription drugs accepted under the Program to eligible participants and could charge an eligible participant a handling fee for receiving a prescription drug (if established under departmental rules). Reselling the transferred drugs would be prohibited. Receiving a handling fee (if established in departmental rules) or a reimbursement from a governmental agency to a charitable clinic would not constitute resale of prescription drugs.

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 to determine that the drugs are not adulterated.
- Dispense the transferred or donated drugs only under a prescription issued by a health professional.

Immunity

For purposes of the lawful donation, acceptance, or dispensing of prescription drugs under the Program the following would not be subject to civil or criminal liability for injury other than death, or loss to person or property, or professional disciplinary action, **if** they complied with the Program, with the provisions of House Bills 5089 and 5090, and with any rules promulgated under House Bill 5089— and absent bad faith or gross negligence:

- Board of Pharmacy.
- The Department of Licensing and Regulatory Affairs (LARA).
- 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 pharmacy or charitable clinic.
- A pharmacy, charitable clinic, or health professional that accepts or dispenses prescription drugs for the Program.
- A pharmacy or charitable clinic that employs a health professional who accepts prescription drugs for the Program and who may legally dispense prescription drugs under this part.

Similarly, the bill would specify that for purposes of the lawful donation, acceptance, or dispensing of a prescription drug manufactured by a manufacturer that is donated by any entity under the Program, the manufacturer would not—in the absence of bad faith or gross negligence—be subject to criminal or civil liability for injury other than death, or for loss to person or property. Immunity would include, but not be limited to, liability for failure to transfer or communicate the expiration date of the donated prescription drug.

Duties of Department and Board of Pharmacy

The Department of Licensing and Regulatory Affairs (LARA), in consultation with the Board of Pharmacy, would have to promulgate rules 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.

LARA would have to promulgate emergency rules within six months of the bill's effective date to establish, implement, and administer the program.

Permanent Rules

Permanent rules that include all of the following would have to be promulgated by LARA and the Board as soon as practical after the emergency rules have been promulgated:

- 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 formulary that includes all FDA-approved prescription drugs.
- Standards and procedures for transfer, transportation, acceptance, safe storage, security, and dispensing of prescription drugs.
- A process for seeking input from the Departments of Human Services (DHS) and LARA in establishing provisions that affect eligible facilities. (Note: The reference to LARA in this provision should be the Department of Community Health.)
- A process for seeking input from DHS in establishing provisions that affect mental health and substance abuse clients.
- Standards and procedures for inspecting accepted prescription drugs to ensure that the drugs meet program requirements and to ensure that, in the professional judgment of the pharmacist, the prescription drugs meet all federal and state standards for product integrity.
- Procedures for the destruction and environmentally sound disposal of prescription drugs or other medications that are accepted and that are controlled substances or otherwise ineligible for distribution under the Program.
- Establishment of standards for the acceptance by a participating pharmacy, health professional or charitable clinic of prescription drugs or any other medication ineligible for distribution from any person.
- Procedures for verifying whether the charitable clinic, pharmacy, pharmacist, or other health professionals participating in the Program are licensed and in good standing with the applicable licensing board.
- Establishment of standards for acceptance of unused or donated prescription drugs from eligible facilities.
- Any other standards and procedures LARA, in consultation with the Board, considers appropriate or necessary to establish, implement, and administer the program.

Donations by Residents of Eligible Facilities

Under the rules promulgated and standards and procedures established for the Program, a resident of an eligible facility, or a resident's representative or guardian, could donate unused prescription drugs for dispensing to eligible participants.

Delivery of drugs for Destruction and Disposal

Under rules promulgated and standards established for the Program, a person could deliver to a participating pharmacy, health professional, or charitable clinic for destruction and disposal a prescription drug or any other medication that is ineligible for distribution.

Cancer Drug Repository Program

The provisions of House Bills 5089 and 5090 would not impair or supersede provisions of the Cancer Drug Repository Program established in Section 17780 of the code. In case of conflict with regard to a cancer drug, Section 17780 would control.

House Bill 5090

The bill would add a new section to the Public Health Code (MCL 333.17776) to require a participating pharmacy, health professional, or charitable clinic to accept from any person for destruction and disposal a prescription drug or any other medication that is ineligible for distribution under the Program. The drugs and other medications accepted would have to be destroyed and disposed of as provided in the rules promulgated under House Bill 5089.

FISCAL IMPACT:

House Bills 5089 and 5090 would have a fiscal impact on the Department of Licensing and Regulatory Affairs (LARA) in the promulgation of rules and administration of the Program for the Utilization of Unused Prescription Drugs (Program). Administrative services for the Board of Pharmacy (Board) are performed by the Bureau of Health Professions within LARA; House Bills 5089 and 5090 would require LARA, in consultation with the Board, to develop and promulgate administrative rules delineating the guidelines and procedures of the Program¹. The costs for LARA to advertise the public hearing and hire a court reporter to transcribe the hearing would be approximately \$2,000. Following the Board's approval of the proposed rules, they would proceed through the rule promulgation process. The rule promulgation process requires indeterminate staff resources of LARA, the Office of Regulatory Reinvention, the Legislative Service Bureau, and the Legislature.

Concerning the administrative costs of implementing the Program, LARA estimates that if participation in the Program is restricted to already licensed health facilities and agencies, then the administrative costs would likely be nominal. However, if agencies such as unlicensed "assisted living facilities" are eligible to participate in the Program, LARA would have to develop and administer additional regulatory and evaluative procedures, which would increase the costs of administering the Program.

Potential savings to the state's Medicaid program are at this point indeterminate and perhaps small in comparison to the \$12.0 billion annual expenditures. Savings are a factor of those Medicaid eligibles who would choose to utilize the new distribution program, and the type and volume of drugs available. There is no prohibition or requirement that Medicaid eligibles participate in the unused prescription drug program.

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■ This analysis was prepared by nonpartisan House staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.

¹ The provisions of HB 5089 are explicitly exempted from affecting the Cancer Drug Repository Program created by 2006 PA 416. The Board of Pharmacy established the policies and procedures for the Cancer Drug Repository Program and the required forms and guidelines to participate in this program are available on the LARA website. However, since the program's establishment in 2008 no pharmacies or health facilities have submitted an application to participate and so the program has yet to be implemented.