

PUBLIC HEALTH CODE (EXCERPT)
Act 368 of 1978

333.17775 "Program for utilization of unused prescription drugs"; definitions; unused prescription drug repository and distribution program; rules; standards and procedures.

Sec. 17775. (1) This section and section 17776 shall be known and may be referred to as the "program for utilization of unused prescription drugs".

(2) As used in this section and section 17776:

(a) "Board" means the Michigan board of pharmacy created under section 17721.

(b) "Cancer drug" means that term as defined in section 17780.

(c) "Charitable clinic" means a charitable nonprofit corporation or facility that meets all of the following requirements:

(i) Is organized as a not-for-profit corporation pursuant to the nonprofit corporation act, 1982 PA 162, MCL 450.2101 to 450.3192.

(ii) Holds a valid exemption from federal income taxation issued under section 501(a) of the internal revenue code of 1986, 26 USC 501.

(iii) Is listed as an exempt organization under section 501(c) of the internal revenue code of 1986, 26 USC 501.

(iv) Is organized under or operated as a part of a health facility or agency licensed under article 17.

(v) Provides on an outpatient basis for a period of less than 24 consecutive hours to persons not residing or confined at the facility advice, counseling, diagnosis, treatment, surgery, care, or services relating to the preservation or maintenance of health.

(vi) Has a licensed pharmacy.

(d) "Eligible facility" means a medical institution as that term is defined in R 338.486 of the Michigan administrative code.

(e) "Eligible participant" means an individual who meets all of the following requirements:

(i) Is a resident of this state.

(ii) 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 this section.

(f) "Health professional" means any of the following individuals licensed and authorized to prescribe and dispense drugs or to provide medical, dental, or other health-related diagnoses, care, or treatment within the scope of his or her professional license:

(i) A physician licensed to practice medicine or osteopathic medicine and surgery under part 170 or 175.

(ii) A physician's assistant licensed under part 170, 175, or 180.

(iii) A dentist licensed under part 166.

(iv) An optometrist licensed under part 174.

(v) A pharmacist licensed under this part.

(vi) A podiatrist licensed under part 180.

(g) "Program" means the statewide unused prescription drug repository and distribution program known as the program for utilization of unused prescription drugs that is established under this section.

(3) The board shall 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, may be transferred from an eligible facility or manufacturer to a pharmacy or a charitable clinic that elects to participate in the program. The program is created to dispense unused or donated prescription drugs, other than controlled substances, to eligible participants and to provide for the destruction and disposal of prescription drugs or other medications that are ineligible for dispensing under the program.

(4) Participation in the program by an eligible facility, manufacturer, pharmacy, or charitable clinic is voluntary. Nothing in this section or section 17776 requires any eligible facility, manufacturer, pharmacy, or charitable clinic to participate in the program.

(5) Pharmacies, health professionals, and charitable clinics that participate in the program shall use the following criteria in accepting unused or donated prescription drugs from eligible facilities or manufacturers for use in the program:

(a) Only prescription drugs in their original sealed, tamper-evident, and unopened unit dose packaging may be accepted for dispensing. However, prescription drugs packaged in single-unit dose packaging may be accepted for dispensing even if the outside packaging is open as long as the single-unit dose packaging is unopened.

(b) The following shall not be accepted for dispensing:

- (i) Expired prescription drugs.
- (ii) Controlled substances as defined in article 7 or article 8 or by federal law.
- (iii) Drugs that have been held outside of a health professional's control where sanitation and security cannot be assured.
- (iv) Drugs that can only be dispensed to a patient registered with the drug's manufacturer under federal food and drug administration requirements.
- (c) A prescription drug shall not be accepted for dispensing if the person accepting the drug has reason to believe that the drug is adulterated.
- (d) Subject to the limitations prescribed in this subsection, unused or donated prescription drugs dispensed for purposes of a medical assistance program or drug product donation program may be accepted for dispensing under the program.
- (e) Any additional criteria established in rules promulgated under this section.
- (6) A pharmacy or charitable clinic that meets the eligibility requirements for participation in the program and any rules promulgated under this section may do any of the following:
 - (a) Dispense prescription drugs accepted under the program to eligible participants.
 - (b) If established by rule under this section, charge eligible participants who receive prescription drugs under the program a handling fee for the service.
- (7) A pharmacy or charitable clinic that participates in the program and accepts prescription drugs for the program shall do all of the following:
 - (a) Comply with all applicable federal laws and regulations and state laws and rules related to the storage and distribution of harmful drugs.
 - (b) Inspect all accepted prescription drugs before dispensing the prescription drugs to determine that the drugs are not adulterated.
 - (c) Dispense prescription drugs only pursuant to a prescription issued by a health professional.
- (8) A pharmacy, health professional, or charitable clinic that accepts prescription drugs under the program shall not resell the prescription drugs. Receipt of a fee from an eligible participant, if established in rules promulgated under this section, or reimbursement from a governmental agency to a charitable clinic does not constitute resale of prescription drugs under this subsection.
- (9) For purposes of the lawful donation, acceptance, or dispensing of prescription drugs under the program, the following persons that are in compliance with the program, this section and section 17776, and any rules promulgated under this section and in the absence of bad faith or gross negligence are not subject to criminal or civil liability for injury other than death, or loss to person or property, or professional disciplinary action:
 - (a) The board.
 - (b) The department.
 - (c) An eligible facility or manufacturer that donates prescription drugs to the program.
 - (d) A manufacturer or its representative that directly donates prescription drugs in professional samples to a charitable clinic under the program.
 - (e) A pharmacy, charitable clinic, or health professional that accepts or dispenses prescription drugs for the program.
 - (f) 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.
- (10) A manufacturer is not, in the absence of bad faith, 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 manufactured by the manufacturer that is donated by any person under the program, including, but not limited to, liability for failure to transfer or communicate product or consumer information or the expiration date of the donated prescription drug.
- (11) Subject to subsection (12), the department, in consultation with the board, shall promulgate rules under the administrative procedures act of 1969 and establish procedures necessary to establish, implement, and administer the program. The board shall provide technical assistance to eligible facilities, manufacturers, pharmacies, and charitable clinics that participate in the program.
- (12) The department, in consultation with the board, shall promulgate emergency rules under the administrative procedures act of 1969 on or before September 28, 2013 to establish, implement, and administer the program. The department, in consultation with the board, shall promulgate permanent rules under the administrative procedures act of 1969 as soon as practical after emergency rules have been promulgated under this subsection. The department and the board shall include all of the following in rules promulgated under this section:
 - (a) Eligibility criteria for pharmacies and charitable clinics authorized to accept and dispense prescription drugs for the program.

- (b) Eligibility criteria for eligible participants.
 - (c) A list of prescription drugs that are not eligible for acceptance and dispensing under the program.
 - (d) Standards and procedures for transfer, transportation, acceptance, safe storage, security, and dispensing of prescription drugs.
 - (e) A process for seeking input from the department of human services and the department of community health in establishing provisions that affect eligible facilities.
 - (f) A process for seeking input from the department of human services and the department of community health in establishing provisions that affect mental health and substance abuse clients.
 - (g) Standards and procedures for inspecting accepted prescription drugs to ensure that the prescription drugs meet the requirements of the program and to ensure that, in the professional judgment of the pharmacist, the prescription drugs meet all federal and state standards for product integrity.
 - (h) Procedures for the destruction and environmentally sound disposal of prescription drugs or other medications that are accepted and that are ineligible for dispensing under the program.
 - (i) 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.
 - (j) Standards for acceptance of unused or donated prescription drugs from eligible facilities.
 - (k) Standards for the acceptance by a pharmacy, health professional, or charitable clinic that participates in the program from any person of a prescription drug or any other medication that is ineligible for dispensing under the program for destruction and disposal.
 - (l) Any other standards and procedures the department, in consultation with the board, considers appropriate or necessary to establish, implement, and administer the program.
- (13) Pursuant to the rules promulgated and standards and procedures established for the program under this section, a resident of an eligible facility or the representative or guardian of a resident of an eligible facility may donate unused prescription drugs for dispensing to eligible participants under the program.
- (14) Pursuant to rules promulgated and standards and procedures established for the program under this section, a person may deliver to a pharmacy, health professional, or charitable clinic that participates in the program a prescription drug or any other medication that is ineligible for dispensing under the program for destruction and disposal.
- (15) This section and section 17776 do not impair or supersede the provisions regarding the cancer drug repository program established in section 17780. If any provision of this section or section 17776 conflicts with a provision of section 17780 with regard to a cancer drug, section 17780 controls.

History: Add. 2012, Act 383, Eff. Mar. 28, 2013;—Am. 2013, Act 268, Imd. Eff. Dec. 30, 2013.