

Enrolled
House Bill 2535

Sponsored by Representatives GELSER, BARTON; Representatives BUCKLEY, GREENLICK,
MAURER, STIEGLER, THOMPSON, WITT (at the request of Deanna Kingston)

CHAPTER

AN ACT

Relating to donated medical items; and declaring an emergency.

Be It Enacted by the People of the State of Oregon:

SECTION 1. Sections 2 to 7 of this 2009 Act are added to and made a part of ORS chapter 689.

SECTION 2. As used in sections 2 to 7 of this 2009 Act, “the Charitable Prescription Drug Program” means a drug outlet that has:

- (1) A valid certificate of registration issued by the State Board of Pharmacy;
- (2) Volunteered to participate in the Charitable Prescription Drug Program; and
- (3) Been approved by the board to accept and distribute to needy individuals donated prescription drugs through the program.

SECTION 3. (1) There is created in the State Board of Pharmacy the Charitable Prescription Drug Program. The purpose of the program is to distribute donated prescription drugs to needy or uninsured individuals. Participation in the program is voluntary.

- (2) The program may accept and distribute:
 - (a) Prescription drugs received in original, sealed, tamper-evident packaging that displays the lot number and expiration date of the drug; and
 - (b) Sealed single unit dose packages received in opened packages containing multiple single unit doses.
- (3) The program may not distribute donated prescription drugs that:
 - (a) Fail to meet the requirements of this section;
 - (b) Bear an expiration date that is less than nine months from the date the drug is donated;
 - (c) Are adulterated or misbranded; or
 - (d) Belong to a category of controlled substances that may not be distributed under the program as adopted by the board by rule pursuant to section 4 of this 2009 Act.
- (4) The program shall:
 - (a) Require a donor of prescription drugs to complete and sign a donor form, adopted by rule by the board, releasing the prescription drug to the program for distribution under the program and certifying that the donated drug has been properly stored and has never been opened, used, adulterated or misbranded;
 - (b) Require that the pharmacist will use professional judgment, based on a visual inspection, to verify compliance with this section and rules adopted by the board under section 4 of this 2009 Act;

(c) Properly dispose of all prescription drugs that do not meet the requirements of this section and rules adopted by the board under section 4 of this 2009 Act;

(d) Maintain separate confidential files for individuals receiving donated prescription drugs through the program;

(e) Eliminate personal information from the labels of donated prescription drugs;

(f) Maintain an inventory of donated prescription drugs separate from any other inventory;

(g) Store donated prescription drugs in a secure location to be used exclusively for the program;

(h) Report to the board on the activities of the program in the form and manner required by the board; and

(i) Require a recipient of a donated prescription drug to sign a form, as adopted by the board by rule, attesting that the recipient has been notified by the program that:

(A) The prescription drug distributed to the recipient was donated to the program;

(B) A visual inspection was conducted by a pharmacist to ensure that the drug has not expired, been adulterated or misbranded and is in its original, sealed packaging;

(C) A pharmacist has determined that the drug is safe to distribute based on the accuracy of the donor's form and the visual inspection by the pharmacist; and

(D) Participants in the program are immune from liability as provided in section 7 of this 2009 Act.

(5) The program may not charge a fee for accepting a donation but may charge a fee established by the board by rule for distributing a prescription drug.

(6) The program may not sell any prescription drugs received as a donation through the program.

(7) The program may refuse to accept a prescription drug that, upon visual inspection, appears not to qualify for distribution under this section or rules adopted by the board under section 4 of this 2009 Act.

(8) The program may distribute donated prescription drugs to:

(a) Another charitable prescription drug program; or

(b) An individual with a new prescription for prescription drugs who meets the requirements of section 6 of this 2009 Act.

SECTION 4. The State Board of Pharmacy shall adopt rules to carry out sections 2 to 7 of this 2009 Act, including but not limited to:

(1) Specifying categories of prescription drugs that the program may not distribute under the program;

(2) Prescribing the forms described in section 3 of this 2009 Act;

(3) Establishing the criteria for licensure and regulation under the program;

(4) Establishing standards and procedures for accepting, storing, distributing, shipping and disposing of donated prescription drugs under the program;

(5) Establishing standards and procedures for inspecting donated prescription drugs to ensure that the drugs comply with the requirements of this section and section 3 of this 2009 Act; and

(6) Establishing record keeping and reporting requirements for the program.

SECTION 5. The State Board of Pharmacy shall ensure compliance with sections 2 to 7 of this 2009 Act by:

(1) Inspecting the Charitable Prescription Drug Program on a regular basis; and

(2) Auditing records required to be maintained by a pharmacy in connection with the program.

SECTION 6. An individual is eligible to obtain donated prescription drugs through the Charitable Prescription Drug Program created in section 3 of this 2009 Act if the individual:

(1) Is a resident of this state; and

(2)(a) Does not have health insurance coverage for the prescription drug requested;

- (b) Is enrolled in a program of public assistance, as defined in ORS 411.010; or
- (c) Meets other requirements adopted by rule by the State Board of Pharmacy that identify needy individuals with barriers to accessing prescription drugs.

SECTION 7. (1) As used in this section, "participant" means:

- (a) A person who donates a prescription drug to the Charitable Prescription Drug Program;
- (b) The Charitable Prescription Drug Program;
- (c) The State Board of Pharmacy;
- (d) A pharmacist;
- (e) A drug manufacturer; or
- (f) A health practitioner.

(2) A participant who accepts or distributes donated prescription drugs through the Charitable Prescription Drug Program is not subject to criminal prosecution or civil liability for any injury, death or loss of or damage to person or property that results from the acceptance or distribution of the donated prescription drugs if the participant accepts or distributes the donated prescription drugs in good faith.

SECTION 8. The State Board of Pharmacy may take any action before the operative date of sections 2 to 7 of this 2009 Act that is necessary to enable the board to carry out the provisions of sections 2 to 7 of this 2009 Act on and after the operative date of sections 2 to 7 of this 2009 Act.

SECTION 9. Sections 2 to 7 of this 2009 Act become operative on January 1, 2010.

SECTION 10. This 2009 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2009 Act takes effect on its passage.

Passed by House April 29, 2009

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 Chief Clerk of House

 Speaker of House

Passed by Senate May 22, 2009

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 President of Senate

Received by Governor:

.....M.,....., 2009

Approved:

.....M.,....., 2009

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 Governor

Filed in Office of Secretary of State:

.....M.,....., 2009

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 Secretary of State