

A-Engrossed
House Bill 2535

Ordered by the House April 24
Including House Amendments dated April 24

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

SUMMARY

The following summary is not prepared by the sponsors of the measure and is not a part of the body thereof subject to consideration by the Legislative Assembly. It is an editor's brief statement of the essential features of the measure.

[Creates voluntary Prescription Drug Repository Program in State Board of Pharmacy. Authorizes designated repositories to accept donated prescription drugs and medical supplies and transfer to other repositories or dispense to individuals who are uninsured, receiving public assistance or have other barriers to health care as adopted by board by rule.]

[Specifies conditions for receipt and dispensing of prescription drugs and medical supplies through program. Makes repositories and drug manufacturers immune from civil or criminal liability for participating in program unless conduct is willful and wanton.]

Creates Charitable Prescription Drug Program in State Board of Pharmacy for purpose of distributing donated prescription drugs to needy or uninsured individuals. Specifies types of drugs that program may accept and distribute. Specifies requirements for program participants. Directs board to adopt rules to carry out program.

Provides immunity from criminal prosecution and civil liability for program participants that accept and distribute donated drugs in good faith.

Becomes operative January 1, 2010.

Declares emergency, effective on passage.

A BILL FOR 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:

NOTE: Matter in **boldfaced** type in an amended section is new; matter *[italic and bracketed]* is existing law to be omitted. New sections are in **boldfaced** type.

- 1 (a) Fail to meet the requirements of this section;
- 2 (b) Bear an expiration date that is less than nine months from the date the drug is do-
3 nated;
- 4 (c) Are adulterated or misbranded; or
- 5 (d) Belong to a category of controlled substances that may not be distributed under the
6 program as adopted by the board by rule pursuant to section 4 of this 2009 Act.
- 7 (4) The program shall:
 - 8 (a) Require a donor of prescription drugs to complete and sign a donor form, adopted by
9 rule by the board, releasing the prescription drug to the program for distribution under the
10 program and certifying that the donated drug has been properly stored and has never been
11 opened, used, adulterated or misbranded;
 - 12 (b) Require that the pharmacist will use professional judgment, based on a visual in-
13 spection, to verify compliance with this section and rules adopted by the board under section
14 4 of this 2009 Act;
 - 15 (c) Properly dispose of all prescription drugs that do not meet the requirements of this
16 section and rules adopted by the board under section 4 of this 2009 Act;
 - 17 (d) Maintain separate confidential files for individuals receiving donated prescription
18 drugs through the program;
 - 19 (e) Eliminate personal information from the labels of donated prescription drugs;
 - 20 (f) Maintain an inventory of donated prescription drugs separate from any other inven-
21 tory;
 - 22 (g) Store donated prescription drugs in a secure location to be used exclusively for the
23 program;
 - 24 (h) Report to the board on the activities of the program in the form and manner required
25 by the board; and
 - 26 (i) Require a recipient of a donated prescription drug to sign a form, as adopted by the
27 board by rule, attesting that the recipient has been notified by the program that:
 - 28 (A) The prescription drug distributed to the recipient was donated to the program;
 - 29 (B) A visual inspection was conducted by a pharmacist to ensure that the drug has not
30 expired, been adulterated or misbranded and is in its original, sealed packaging;
 - 31 (C) A pharmacist has determined that the drug is safe to distribute based on the accu-
32 racy of the donor's form and the visual inspection by the pharmacist; and
 - 33 (D) Participants in the program are immune from liability as provided in section 7 of this
34 2009 Act.
- 35 (5) The program may not charge a fee for accepting a donation but may charge a fee
36 established by the board by rule for distributing a prescription drug.
- 37 (6) The program may not sell any prescription drugs received as a donation through the
38 program.
- 39 (7) The program may refuse to accept a prescription drug that, upon visual inspection,
40 appears not to qualify for distribution under this section or rules adopted by the board under
41 section 4 of this 2009 Act.
- 42 (8) The program may distribute donated prescription drugs to:
 - 43 (a) Another charitable prescription drug program; or
 - 44 (b) An individual with a new prescription for prescription drugs who meets the require-
45 ments of section 6 of this 2009 Act.

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

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

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

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

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

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

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

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

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

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

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

20 (1) Is a resident of this state; and

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

22 (b) Is enrolled in a program of public assistance, as defined in ORS 411.010; or

23 (c) Meets other requirements adopted by rule by the State Board of Pharmacy that
24 identify needy individuals with barriers to accessing prescription drugs.

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

26 (a) A person who donates a prescription drug to the Charitable Prescription Drug Pro-
27 gram;

28 (b) The Charitable Prescription Drug Program;

29 (c) The State Board of Pharmacy;

30 (d) A pharmacist;

31 (e) A drug manufacturer; or

32 (f) A health practitioner.

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

38 **SECTION 8.** The State Board of Pharmacy may take any action before the operative date
39 of sections 2 to 7 of this 2009 Act that is necessary to enable the board to carry out the
40 provisions of sections 2 to 7 of this 2009 Act on and after the operative date of sections 2 to
41 7 of this 2009 Act.

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

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

