A-Engrossed Senate Bill 1514

Ordered by the Senate February 5 Including Senate Amendments dated February 5

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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

Permits drug outlet participating in Charitable Prescription Drug Program to repackage certain donated prescription drugs for distribution by other program participants. [Specifies that distribution of donated prescription drugs is not distribution by wholesaler or wholesale drug outlet.] Requires drug outlet to maintain separate inventory of donated prescription drugs received by drug outlet and transferred to another drug outlet. Limits distribution of donated prescription drugs received by drug outlet from another drug outlet only to individuals with prescription for prescription drugs.

Declares emergency, effective on passage.

A BILL FOR AN ACT

Relating to prescription drugs; amending ORS 689.772 and 689.774; and declaring an emergency. 2

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

- **SECTION 1.** ORS 689.772 is amended to read:
- 689.772. (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.
- 7 (2) The program may accept and distribute within this state:
 - (a) Prescription drugs received as donations 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[.]; and
 - (c) Prescription drugs received as donations and repackaged by another charitable prescription drug program.
 - (3)(a) Except as provided in paragraph (b) of this subsection, the Charitable Prescription Drug Program may not distribute donated prescription drugs that:
 - (A) Fail to meet the requirements of this section;
- 18 (B) Bear an expiration date that is less than nine months from the date the [drug is] drugs are 19 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 ORS 689.774.
 - (b) The board may waive a requirement of this subsection if the board determines that the

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- waiver is in the interest of public health and safety. A waiver under this subsection must be issued in writing in accordance with rules adopted by the board.
 - (4) The program shall:

- (a) Require a donor of **a** prescription [drugs] **drug** 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 **prescription** 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 ORS 689.774;
- (c) Properly dispose of all prescription drugs **received as donations** that do not meet the requirements of this section and rules adopted by the board under ORS 689.774;
- (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] a separate inventory of donated prescription drugs [separate from any other inventory] received by the program and transferred to another charitable prescription drug program;
 - (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 **donated prescription** drug has not expired, been adulterated or misbranded, and is in its original, sealed packaging or has been repackaged by another charitable prescription drug program;
- (C) A pharmacist has determined that the **donated prescription** 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 ORS 689.780.
- (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 **donated** prescription drug.
- (6) The program may not sell any prescription drugs received as a donation through the program.
- (7) The program may distribute donated prescription drugs that it received from another charitable prescription drug program only to an individual with a new prescription for prescription drugs who meets the requirements of ORS 689.778.
- [(7)] (8) The program may refuse to accept **from a donor** a prescription drug that, upon visual inspection, appears not to qualify for distribution under this section or rules adopted by the board under ORS 689.774.
 - [(8)] (9) The program may distribute donated prescription drugs to:
- 41 (a) Another charitable prescription drug program, subject to subsection (7) of this section; 42 or
- 43 (b) An individual with a new prescription for prescription drugs who meets the requirements of 44 ORS 689.778.
 - **SECTION 2.** ORS 689.774 is amended to read:

- 1 689.774. The State Board of Pharmacy shall adopt rules to carry out ORS 689.770 to 689.780, 2 including but not limited to: 3 (1) Specifying categories of prescription drugs that the **Charitable Prescription Drug** Program
 - (1) Specifying categories of prescription drugs that the **Charitable Prescription Drug** Program may not distribute under the program;
 - (2) Prescribing the forms described in ORS 689.772;

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- (3) Establishing the criteria for licensure and regulation under the program;
- (4) Establishing standards and procedures for accepting, storing, **repackaging**, 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 ORS 689.772; and
 - (6) Establishing record keeping and reporting requirements for the program.

SECTION 3. This 2016 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2016 Act takes effect on its passage.
