

# D R A F T

## SUMMARY

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.

Declares emergency, effective on passage.

## A BILL FOR AN ACT

1  
2 Relating to prescription drugs, amending ORS 689.772 and 689.774; and de-  
3 claring an emergency.

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

5 **SECTION 1.** ORS 689.772 is amended to read:

6 689.772. (1) There is created in the State Board of Pharmacy the Chari-  
7 table Prescription Drug Program. The purpose of the program is to distribute  
8 donated prescription drugs to needy or uninsured individuals. Participation  
9 in the program is voluntary.

10 (2) The program may accept and distribute:

11 (a) Prescription drugs received **as donations** in original, sealed, tamper-  
12 evident packaging that displays the lot number and expiration date of the  
13 drug; *[and]*

14 (b) Sealed single unit dose packages received in opened packages con-  
15 taining multiple single unit doses[.]; **and**

16 (c) **Prescription drugs received as donations and repackaged by an-**  
17 **other charitable prescription drug program.**

18 (3)(a) Except as provided in paragraph (b) of this subsection, the **Chari-**  
19 **table Prescription Drug** Program may not distribute donated prescription

1 drugs that:

2 (A) Fail to meet the requirements of this section;

3 (B) Bear an expiration date that is less than nine months from the date  
4 the *[drug is]* **drugs are** donated;

5 (C) Are adulterated or misbranded; or

6 (D) Belong to a category of controlled substances that may not be dis-  
7 tributed under the program as adopted by the board by rule pursuant to ORS  
8 689.774.

9 (b) The board may waive a requirement of this subsection if the board  
10 determines that the waiver is in the interest of public health and safety. A  
11 waiver under this subsection must be issued in writing in accordance with  
12 rules adopted by the board.

13 (4) The program shall:

14 (a) Require a donor of **a** prescription *[drugs]* **drug** to complete and sign  
15 a donor form, adopted by rule by the board, releasing the prescription drug  
16 to the program for distribution under the program and certifying that the  
17 donated **prescription** drug has been properly stored and has never been  
18 opened, used, adulterated or misbranded;

19 (b) Require that the pharmacist will use professional judgment, based on  
20 a visual inspection, to verify compliance with this section and rules adopted  
21 by the board under ORS 689.774;

22 (c) Properly dispose of all prescription drugs **received as donations** that  
23 do not meet the requirements of this section and rules adopted by the board  
24 under ORS 689.774;

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

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

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

31 (g) Store donated prescription drugs in a secure location to be used ex-

1 clusively for the program;

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

4 (i) Require a recipient of a donated prescription drug to sign a form, as  
5 adopted by the board by rule, attesting that the recipient has been notified  
6 by the **Charitable** Program that:

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

9 (B) A visual inspection was conducted by a pharmacist to ensure that the  
10 **donated prescription** drug has not expired, been adulterated or  
11 misbranded, and is in its original, sealed packaging **or has been repack-**  
12 **aged by another charitable prescription drug program;**

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

16 (D) Participants in the program are immune from liability as provided in  
17 ORS 689.780.

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

21 (6) The program may not sell any prescription drugs received as a do-  
22 nation through the program.

23 (7) The program may refuse to accept **from a donor** a prescription drug  
24 that, upon visual inspection, appears not to qualify for distribution under  
25 this section or rules adopted by the board under ORS 689.774.

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

27 (a) Another charitable prescription drug program; or

28 (b) An individual with a new prescription for prescription drugs who  
29 meets the requirements of ORS 689.778.

30 **(9) Distribution of donated prescription drugs that meets the re-**  
31 **quirements of this section is not a distribution by a wholesaler or**

1 **wholesale drug outlet for purposes of this chapter.**

2 **SECTION 2.** ORS 689.774 is amended to read:

3 689.774. The State Board of Pharmacy shall adopt rules to carry out ORS  
4 689.770 to 689.780, including but not limited to:

5 (1) Specifying categories of prescription drugs that the **Charitable Pre-**  
6 **scription Drug** Program may not distribute under the program;

7 (2) Prescribing the forms described in ORS 689.772;

8 (3) Establishing the criteria for licensure and regulation under the pro-  
9 gram;

10 (4) Establishing standards and procedures for accepting, storing, **repack-**  
11 **aging**, distributing, shipping and disposing of donated prescription drugs  
12 under the program;

13 (5) Establishing standards and procedures for inspecting donated pre-  
14 scription drugs to ensure that the drugs comply with the requirements of this  
15 section and ORS 689.772; and

16 (6) Establishing record keeping and reporting requirements for the pro-  
17 gram.

18 **SECTION 3. This 2016 Act being necessary for the immediate pres-**  
19 **ervation of the public peace, health and safety, an emergency is de-**  
20 **clared to exist, and this 2016 Act takes effect on its passage.**

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