

1 The proposed rule amendments to *Div 044 Charitable Pharmacies* incorporate new statutory
2 language put forth by Senate Bill 1514 (2016), available at this link:

3 <https://olis.leg.state.or.us/liz/2016R1/Downloads/MeasureDocument/SB1514/Enrolled>

4 The rule (1) clarifies that this is an Oregon specific program that allows donations and
5 distribution of donated drugs within Oregon; and (2) prohibits a Charitable Pharmacy from
6 accepting an FDA REMS drug.

8 **DIVISION 44**

9 **CHARITABLE PHARMACIES**

10 **855-044-0001**

11 **Purpose**

12 The purpose of the program is to provide a process to make donated prescription drugs available
13 to needy or uninsured individuals and those with limited access to pharmaceuticals. Under the
14 rules in this Division, a Charitable Pharmacy that is registered with the Oregon Board of
15 Pharmacy (Board) may accept ~~donated~~ drugs for **donation and** distribution **within this state**
16 when the pharmacist can reasonably be assured of the purity and integrity of the drug. The
17 program may not include categories of drugs specified by the Board as excluded from the
18 program.

19 Stat. Auth.: ORS 689.205

20 Stats. Implemented: ORS 689.772 & 689.774

23 **855-044-0030**

24 **Drug Donation**

25 (1) A charitable pharmacy may not accept:

26 (a) Any controlled substance or any kit, package or blister pack that contains any controlled
27 substance;

28 (b) A non-prescription drug;

29 (c) A drug in a container or package that does not contain a product identification label (PIL),
30 except that a drug in a manufacturer's original container or a manufacturer's blister pack does
31 not need to bear a PIL;

32 **(d) An FDA REMS (Risk Evaluation and Mitigation Strategy) drug;**

33 **(e) A drug donated from another state.**

34 (2) A charitable pharmacy may accept:

35 (a) A prescription drug received in original, sealed, tamper-evident packaging that displays the
36 lot number and expiration date of the drug; and

37 (b) Sealed single unit dose packages received in opened packages containing multiple single unit
38 doses.

39 (3) The following are examples of acceptable packaging:

40 (a) Manufacturer's original container;

41 (b) Single-dose blister packs in sealed outer package;

42 (c) Single-dose blister packs in opened outer package;

43 (d) Tamper-evident hospice kit containing manufacturer's original containers.

44 (4) Donated drugs that do not meet the above criteria or are judged by the pharmacist to be
45 unsafe for re-dispensing must be stored separately from the drug supply until they can be
46 destroyed.

47 (5) A charitable pharmacy may accept a drug from:

48 (a) An individual;

49 (b) A long-term care facility;

50 (c) A pharmacy;

51 (d) A practitioner who has been given dispensing privileges by their licensing board and is acting
52 within their scope of practice;

53 (e) Another registered charitable pharmacy;

54 (f) A medical clinic;

55 (g) A drug manufacturer or wholesaler;

56 (h) A Medication Assistance Program (MAP) such as those supported by drug manufacturers.

57 (6) The donor must certify on a Donor Form provided by the Board that the donated drug has
58 been properly stored, in accordance with manufacturer's recommendations, and has never been
59 opened, used, adulterated or misbranded.

60 (7) Upon written request, the Board may waive any of the requirements of this rule if a waiver
61 will further public health and safety. A waiver granted under this section shall only be effective
62 when it is issued in writing.

63 Stat. Auth.: ORS 689.205

64 Stats. Implemented: ORS 689.772 & 689.774

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PROPOSED RULES