

1                   **CHARITABLE PRESCRIPTION DRUG RECYCLING**  
2   **PROGRAM**

3   2016 GENERAL SESSION

4   STATE OF UTAH

5   **Chief Sponsor: Gage Froerer**

6   Senate Sponsor: Evan J. Vickers

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8 **LONG TITLE**

9 **General Description:**

10               This bill creates a program that allows certain pharmacies to accept and dispense  
11 donated unused prescription medications to certain individuals.

12 **Highlighted Provisions:**

13               This bill:

- 14               ▶ amends the Pharmacy Practice Act;
- 15               ▶ defines terms;
- 16               ▶ directs the Division of Occupational and Professional Licensing (DOPL) to make  
17 rules, in consultation with the Utah State Board of Pharmacy, to create a charitable  
18 prescription drug recycling program;
- 19               ▶ establishes criteria for prescription drugs eligible for the program;
- 20               ▶ establishes requirements for donors and pharmacies;
- 21               ▶ limits the liability of program participants and drug manufacturers;
- 22               ▶ directs DOPL to make rules establishing certain requirements, standards,  
23 procedures, and processes; and
- 24               ▶ makes technical changes.

25 **Money Appropriated in this Bill:**

26               None

27 **Other Special Clauses:**

28               None

29 **Utah Code Sections Affected:**

30 AMENDS:

31 **58-17b-502**, as last amended by Laws of Utah 2015, Chapter 336

32 **58-17b-503**, as last amended by Laws of Utah 2011, Chapter 366

33 ENACTS:

34 **58-17b-901**, Utah Code Annotated 1953

35 **58-17b-902**, Utah Code Annotated 1953

36 **58-17b-903**, Utah Code Annotated 1953

37 **58-17b-904**, Utah Code Annotated 1953

38 **58-17b-905**, Utah Code Annotated 1953

39 **58-17b-906**, Utah Code Annotated 1953

40 **58-17b-907**, Utah Code Annotated 1953

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42 *Be it enacted by the Legislature of the state of Utah:*

43 Section 1. Section **58-17b-502** is amended to read:

44 **58-17b-502. Unprofessional conduct.**

45 "Unprofessional conduct" includes:

46 (1) willfully deceiving or attempting to deceive the division, the board, or their agents  
47 as to any relevant matter regarding compliance under this chapter;

48 (2) (a) except as provided in Subsection (2)(b):

49 (i) paying or offering rebates to practitioners or any other health care providers, or  
50 receiving or soliciting rebates from practitioners or any other health care provider; or

51 (ii) paying, offering, receiving, or soliciting compensation in the form of a commission,  
52 bonus, rebate, kickback, or split fee arrangement with practitioners or any other health care  
53 provider, for the purpose of obtaining referrals.

54 (b) Subsection (2)(a) does not apply to:

55 (i) giving or receiving price discounts based on purchase volume;

56 (ii) passing along pharmaceutical manufacturer's rebates; or

57 (iii) providing compensation for services to a veterinarian.

58 (3) misbranding or adulteration of any drug or device or the sale, distribution, or  
59 dispensing of any outdated, misbranded, or adulterated drug or device;

60 (4) engaging in the sale or purchase of drugs or devices that are samples or packages  
61 bearing the inscription "sample" or "not for resale" or similar words or phrases;

62 (5) except as provided in Section [58-17b-503](#) or Part 9, Charitable Prescription Drug  
63 Recycling Act, accepting back and redistributing [of] any unused drug, or a part of it, after it  
64 has left the premises of any pharmacy, unless the drug is in a unit pack, as defined in Section  
65 [58-17b-503](#), or the manufacturer's sealed container, as defined in rule;

66 (6) an act in violation of this chapter committed by a person for any form of  
67 compensation if the act is incidental to the person's professional activities, including the  
68 activities of a pharmacist, pharmacy intern, or pharmacy technician;

69 (7) violating Federal Title II, P.L. 91, Controlled Substances Act, Title 58, Chapter 37,  
70 Utah Controlled Substances Act, or rules or regulations adopted under either act;

71 (8) requiring or permitting pharmacy interns or technicians to engage in activities  
72 outside the scope of practice for their respective license classifications, as defined in this  
73 chapter and division rules made in collaboration with the board, or beyond their scope of  
74 training and ability;

75 (9) administering:

76 (a) without appropriate training, as defined by rule;

77 (b) without a physician's order, when one is required by law; and

78 (c) in conflict with a practitioner's written guidelines or written protocol for  
79 administering;

80 (10) disclosing confidential patient information in violation of the provisions of the  
81 Health Insurance Portability and Accountability Act of 1996 or other applicable law;

82 (11) engaging in the practice of pharmacy without a licensed pharmacist designated as  
83 the pharmacist-in-charge;

84 (12) failing to report to the division any adverse action taken by another licensing  
85 jurisdiction, government agency, law enforcement agency, or court for conduct that in

86 substance would be considered unprofessional conduct under this section; and

87 (13) as a pharmacist or pharmacy intern, compounding a prescription drug in a dosage  
88 form which is regularly and commonly available from a manufacturer in quantities and  
89 strengths prescribed by a practitioner.

90 Section 2. Section **58-17b-503** is amended to read:

91 **58-17b-503. Exception to unprofessional conduct.**

92 (1) For purposes of this section:

93 (a) "Licensed intermediate care facility for people with an intellectual disability" means  
94 an intermediate care facility for people with an intellectual disability that is licensed as a  
95 nursing care facility or a small health care facility under Title 26, Chapter 21, Health Care  
96 Facility Licensing and Inspection Act.

97 (b) "Nursing care facility" ~~[has the same definition as]~~ means the same as that term is  
98 defined in Section 26-21-2.

99 (c) "Unit pack" means a tamper-resistant nonreusable single-dose single-drug package  
100 with identification that indicates the lot number and expiration date for the drug.

101 (2) ~~[Notwithstanding the provisions of Subsection 58-17b-502(5), a]~~ A pharmacist  
102 may:

103 (a) accept and redistribute an unused drug under Part 9, Charitable Prescription Drug  
104 Recycling Act; or

105 (b) accept back and redistribute any unused drug, or a part of it, after it has left the  
106 premises of the pharmacy if:

107 ~~[(a)]~~ (i) the drug was prescribed to a patient in a nursing care facility, ~~[a]~~ licensed  
108 intermediate care facility for people with an intellectual disability, or state prison facility,  
109 county jail, or state hospital;

110 ~~[(b)]~~ (ii) the drug was stored under the supervision of a licensed health care provider  
111 according to manufacturer recommendations;

112 ~~[(c)]~~ (iii) the drug is in a unit pack or in the manufacturer's sealed container;

113 ~~[(d)]~~ (iv) the drug was returned to the original dispensing pharmacy;



- 142           (d) has a licensed outpatient pharmacy.
- 143           (4) "Charitable pharmacy" means an eligible pharmacy that is operated by a charitable  
144 clinic.
- 145           (5) "County health department" means the same as that term is defined in Section  
146 26A-1-102.
- 147           (6) "Donated prescription drug" means a prescription drug that an eligible donor  
148 donates to an eligible pharmacy under the program.
- 149           (7) "Eligible donor" means a donor that donates a prescription drug from within the  
150 state and is:
- 151           (a) a nursing care facility;
- 152           (b) an assisted living facility;
- 153           (c) a licensed intermediate care facility for people with an intellectual disability;
- 154           (d) a manufacturer;
- 155           (e) a pharmaceutical wholesale distributor;
- 156           (f) an eligible pharmacy; or
- 157           (g) a physician's office.
- 158           (8) "Eligible pharmacy" means a pharmacy that:
- 159           (a) is registered by the division as eligible to participate in the program; and
- 160           (b) is operated by:
- 161           (i) a county;
- 162           (ii) a county health department;
- 163           (iii) a pharmacy under contract with a county health department;
- 164           (iv) the Department of Health, created in Section 26-1-4;
- 165           (v) the Division of Substance Abuse and Mental Health, created in Section  
166 62A-15-103; or
- 167           (vi) a charitable clinic.
- 168           (9) "Eligible prescription drug" means a prescription drug, described in Section  
169 58-17b-904, that is not:

- 170           (a) a controlled substance; or
- 171           (b) a drug that can only be dispensed to a patient registered with the drug's
- 172 manufacturer in accordance with federal Food and Drug Administration requirements.
- 173           (10) "Licensed intermediate care facility for people with an intellectual disability"
- 174 means the same as that term is defined in Section [58-17b-503](#).
- 175           (11) "Medically indigent individual" means an individual who:
- 176           (a) (i) does not have health insurance; and
- 177           (ii) lacks reasonable means to purchase prescribed medications; or
- 178           (b) (i) is covered under Medicaid or Medicare; and
- 179           (ii) lacks reasonable means to pay the insured's portion of the cost of the prescribed
- 180 medications.
- 181           (12) "Nursing care facility" means the same as that term is defined in Section
- 182 [26-18-501](#).
- 183           (13) "Physician's office" means a fixed medical facility that:
- 184           (a) is staffed by a physician, physician's assistant, nurse practitioner, or registered
- 185 nurse, licensed under Title 58, Occupations and Professions; and
- 186           (b) treats an individual who presents at, or is transported to, the facility.
- 187           (14) "Program" means the Charitable Prescription Drug Recycling Program created in
- 188 Section [58-17b-903](#).
- 189           (15) "Unit pack" means the same as that term is defined in Section [58-17b-503](#).
- 190           (16) "Unlawful conduct" means the same as that term is defined in Sections [58-1-501](#)
- 191 and [58-17b-501](#).
- 192           (17) "Unprofessional conduct" means the same as that term is defined in Sections
- 193 [58-1-501](#) and [58-17b-502](#).
- 194           Section 5. Section **58-17b-903** is enacted to read:
- 195           **58-17b-903. Charitable Prescription Drug Recycling Program -- Creation --**
- 196 **Requirements.**
- 197           (1) There is created the Charitable Prescription Drug Recycling Program.

198           (2) The division, in consultation with the board, shall:

199           (a) implement the program, on a statewide basis, to permit an eligible donor to transfer  
200 an eligible prescription drug to an eligible pharmacy for dispensing to a medically indigent  
201 individual;

202           (b) in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act,  
203 make rules necessary to implement the program; and

204           (c) provide technical assistance to entities that desire to participate in the program.

205           Section 6. Section **58-17b-904** is enacted to read:

206           **58-17b-904. Criteria for eligible prescription drugs.**

207           An eligible pharmacy may not accept or dispense an unused prescription drug under the  
208 program unless the unused prescription drug:

209           (1) (a) is in a unit pack or the manufacturer's sealed container; or

210           (b) is an injectable medication;

211           (2) (a) is unopened; or

212           (b) is a cancer drug packaged in an unopened single-unit dose that has been removed  
213 from a multi-dose package;

214           (3) is accepted and dispensed by the eligible pharmacy before:

215           (a) a beyond use date that appears on the label;

216           (b) the expiration date recommended by the manufacturer; or

217           (c) a date, established by division rule for a specific prescription drug, in accordance  
218 with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, that is later than the date in  
219 Subsection (3)(a) or (3)(b);

220           (4) (a) is not adulterated or mislabeled; and

221           (b) the pharmacist or licensed pharmacist technician accepting or dispensing the  
222 prescription drug does not have reason to believe that the prescription drug is adulterated or  
223 mislabeled.

224           Section 7. Section **58-17b-905** is enacted to read:

225           **58-17b-905. Participation in program -- Requirements -- Fees.**

226           (1) An eligible donor or an eligible pharmacy may participate in the program.  
227           (2) An eligible pharmacy:  
228           (a) shall comply with all applicable federal and state laws related to the storage and  
229 distribution of a prescription drug;  
230           (b) shall comply with all applicable federal and state laws related to the acceptance and  
231 transfer of a prescription drug, including 21 U.S.C. Chapter 9, Subchapter V, Part H,  
232 Pharmaceutical Distribution Supply Chain;  
233           (c) shall, before accepting or dispensing a prescription drug under the program, inspect  
234 each prescription drug to determine whether the prescription drug is an eligible prescription  
235 drug;  
236           (d) may dispense an eligible prescription drug to a medically indigent individual who:  
237           (i) is a resident of the state; and  
238           (ii) has a prescription issued by a practitioner;  
239           (e) may charge a handling fee, adopted by the division under Section [63J-1-504](#); and  
240           (f) may not accept, transfer, or dispense a prescription drug in violation of the federal  
241 Food, Drug, and Cosmetic Act, 21 U.S.C. Sec. 301 et seq.  
242           Section 8. Section **58-17b-906** is enacted to read:  
243           **58-17b-906. Liability of participating organizations and manufacturers.**  
244           In the absence of bad faith or gross negligence, a person is not criminally or civilly  
245 liable for injury, death, or loss of property based solely on the fact that the person  
246 manufactured, provided, donated, accepted, or dispensed an eligible prescription drug under  
247 this part.  
248           Section 9. Section **58-17b-907** is enacted to read:  
249           **58-17b-907. Rules made by the division.**  
250           The rules made by the division under Subsection [58-17b-903](#)(2)(b) shall include:  
251           (1) registration requirements to establish the eligibility of a pharmacy to participate in  
252 the program;  
253           (2) a formulary that includes all eligible prescription drugs approved by the federal

254 Food and Drug Administration;  
255 (3) standards and procedures for:  
256 (a) verifying whether a pharmacy or pharmacist participating in the program is licensed  
257 and in good standing with the board;  
258 (b) handling of a donated eligible prescription drug, including:  
259 (i) acceptance;  
260 (ii) identification, including redundant criteria for verification;  
261 (iii) documentation, under 21 U.S.C. Sec. 360eee-1, of transaction information, history,  
262 and statements;  
263 (iv) safe storage;  
264 (v) security;  
265 (vi) inspection;  
266 (vii) transfer; and  
267 (viii) dispensing;  
268 (c) a pharmacist or licensed pharmacy technician working in or consulting with a  
269 participating eligible donor;  
270 (d) disposition of a donated prescription drug that is a controlled substance;  
271 (e) record keeping regarding:  
272 (i) the eligible donor that donated each prescription drug;  
273 (ii) the identification and evaluation of a donated prescription drug by a pharmacist or  
274 licensed pharmacy technician; and  
275 (iii) the dispensing or disposition of a prescription drug;  
276 (f) determining the status of a medically indigent individual;  
277 (g) labeling requirements to:  
278 (i) ensure compliance with patient privacy laws relating to:  
279 (A) an individual who receives an eligible prescription drug; and  
280 (B) patient information that may appear on a donated prescription drug;  
281 (ii) clearly identify an eligible prescription drug dispensed under the program; and

282           (iii) communicate necessary information regarding the manufacturer's recommended  
283 expiration date or the beyond use date; and  
284           (h) ensuring compliance with the requirements of this part;  
285           (4) a process for seeking input from:  
286           (a) the Department of Health, created in Section [26-1-4](#), to establish program standards  
287 and procedures for assisted living facilities and nursing care facilities; and  
288           (b) the Division of Substance Abuse and Mental Health, created in Section  
289 [62A-15-103](#), to establish program standards and procedures for mental health and substance  
290 abuse clients; and  
291           (5) the creation of a special training program that a pharmacist and a licensed pharmacy  
292 technician at an eligible pharmacy must complete before participating in the program.