

SB0097S01 compared with SB0097

~~deleted text~~ shows text that was in SB0097 but was deleted in SB0097S01.

inserted text shows text that was not in SB0097 but was inserted into SB0097S01.

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Senator Evan J. Vickers proposes the following substitute bill:

CHARITABLE PRESCRIPTION DRUG RECYCLING PROGRAM AMENDMENTS

2021 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Evan J. Vickers

House Sponsor: _____

LONG TITLE

General Description:

This bill modifies the Charitable Prescription Drug Recycling Act.

Highlighted Provisions:

This bill:

- ▶ allows an individual to transfer prescription drugs to an eligible pharmacy or an eligible physician's office;
- ▶ removes the requirement that only state residents receive donated drugs; and
- ▶ requires that a medically indigent individual be located in the state when the drug is dispensed.

Money Appropriated in this Bill:

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None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

58-17b-902, as last amended by Laws of Utah 2020, Chapter 384

58-17b-903, as last amended by Laws of Utah 2020, Chapter 384

58-17b-905, as enacted by Laws of Utah 2016, Chapter 405

58-17b-907, as last amended by Laws of Utah 2020, Chapter 384

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

Section 1. Section **58-17b-902** is amended to read:

58-17b-902. Definitions.

As used in this part:

- (1) "Assisted living facility" means the same as that term is defined in Section 26-21-2.
- (2) "Cancer drug" means a drug that controls or kills neoplastic cells and includes a drug used in chemotherapy to destroy cancer cells.
- (3) "Charitable clinic" means a charitable nonprofit corporation that:
 - (a) holds a valid exemption from federal income taxation issued under Section 501(a), Internal Revenue Code;
 - (b) is exempt from federal income taxation under Section 501(c)(3), Internal Revenue Code;
 - (c) provides, on an outpatient basis, for a period of less than 24 consecutive hours, to an individual not residing or confined at a facility owned or operated by the charitable nonprofit corporation:
 - (i) advice;
 - (ii) counseling;
 - (iii) diagnosis;
 - (iv) treatment;
 - (v) surgery; or
 - (vi) care or services relating to the preservation or maintenance of health; and

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(d) has a licensed outpatient pharmacy.

(4) "Charitable pharmacy" means an eligible pharmacy that is operated by a charitable clinic.

(5) "County health department" means the same as that term is defined in Section 26A-1-102.

(6) "Donated prescription drug" means a prescription drug that an eligible donor or individual donates to an eligible pharmacy under the program.

(7) "Eligible donor" means a donor that donates a prescription drug from within the state and is:

- (a) a nursing care facility;
- (b) an assisted living facility;
- (c) a licensed intermediate care facility for people with an intellectual disability;
- (d) a manufacturer;
- (e) a pharmaceutical wholesale distributor;
- (f) an eligible pharmacy; or
- (g) a physician's office.

(8) "Eligible pharmacy" means a pharmacy that:

- (a) is registered by the division as eligible to participate in the program; and
- (b) (i) is licensed in the state as a Class A retail pharmacy; or
- (ii) is operated by:
 - (A) a county;
 - (B) a county health department;
 - (C) a pharmacy under contract with a county health department;
 - (D) the Department of Health, created in Section 26-1-4;
 - (E) the Division of Substance Abuse and Mental Health, created in Section

62A-15-103; or

(F) a charitable clinic.

(9) "Eligible prescription drug" means a prescription drug, described in Section 58-17b-904, that is not:

- (a) a controlled substance; or
- (b) a drug that can only be dispensed to a patient registered with the drug's

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manufacturer in accordance with federal Food and Drug Administration requirements.

(10) "Licensed intermediate care facility for people with an intellectual disability" means the same as that term is defined in Section 58-17b-503.

(11) "Medically indigent individual" means an individual who:

(a) (i) does not have health insurance; and

(ii) lacks reasonable means to purchase prescribed medications; or

(b) (i) has health insurance; and

(ii) lacks reasonable means to pay the insured's portion of the cost of the prescribed medications.

(12) "Nursing care facility" means the same as that term is defined in Section 26-18-501.

(13) "Physician's office" means a fixed medical facility that:

(a) is staffed by a physician, physician's assistant, nurse practitioner, or registered nurse, licensed under Title 58, Occupations and Professions; and

(b) treats an individual who presents at, or is transported to, the facility.

(14) "Program" means the Charitable Prescription Drug Recycling Program created in Section 58-17b-903.

(15) "Unit pack" means the same as that term is defined in Section 58-17b-503.

(16) "Unlawful conduct" means the same as that term is defined in Sections 58-1-501 and 58-17b-501.

(17) "Unprofessional conduct" means the same as that term is defined in Sections 58-1-501 and 58-17b-502.

Section 2. Section **58-17b-903** is amended to read:

58-17b-903. Charitable Prescription Drug Recycling Program -- Creation -- Requirements.

(1) There is created the Charitable Prescription Drug Recycling Program.

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

(a) implement the program, on a statewide basis, to permit:

(i) an individual or an eligible donor to transfer an eligible prescription drug to an eligible pharmacy for dispensing to a medically indigent individual; and

(ii) an individual to transfer an eligible prescription drug to a physician's office:

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(A) that is an eligible donor; and

(B) for transfer to an eligible pharmacy for dispensing to a medically indigent individual;

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

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

Section 3. Section **58-17b-905** is amended to read:

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

(1) An eligible donor, an individual, or an eligible pharmacy may participate in the program.

(2) An eligible pharmacy:

(a) shall comply with all applicable federal and state laws related to the storage and distribution of a prescription drug;

(b) shall comply with all applicable federal and state laws related to the acceptance and transfer of a prescription drug, including 21 U.S.C. Chapter 9, Subchapter V, Part H, Pharmaceutical Distribution Supply Chain;

(c) shall, before accepting or dispensing a prescription drug under the program, inspect each prescription drug to determine whether the prescription drug is an eligible prescription drug;

(d) may dispense an eligible prescription drug to a medically indigent individual who:

(i) ~~[is a resident of the state]~~ is located in the state when the drug is dispensed; and

(ii) has a prescription issued by a practitioner;

(e) may charge a handling fee, adopted by the division under Section 63J-1-504; and

(f) may not accept, transfer, or dispense a prescription drug in violation of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. Sec. 301 et seq.

Section 4. Section **58-17b-907** is amended to read:

58-17b-907. Rules made by the division.

The rules made by the division under Subsection 58-17b-903(2)(b) shall include:

(1) registration requirements to establish the eligibility of a pharmacy to participate in the program;

(2) a formulary that includes all eligible prescription drugs approved by the federal

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Food and Drug Administration;

(3) standards and procedures for:

(a) verifying whether a pharmacy or pharmacist participating in the program is licensed and in good standing with the board;

(b) handling of an eligible prescription drug transferred in accordance with Subsection 58-17b-903(2) to an eligible pharmacy or a physician's office, including:

(i) acceptance;

(ii) identification, including redundant criteria for verification;

(iii) documentation, under 21 U.S.C. Sec. 360eee-1, of transaction information, history, and statements;

(iv) safe storage;

(v) security;

(vi) inspection;

(vii) transfer; and

(viii) dispensing;

(c) a pharmacist, pharmacy intern, or licensed pharmacy technician;

(i) working in or consulting with a participating eligible donor; or

(ii) assisting an individual donating the eligible prescription drug;

(d) disposition of a donated prescription drug that is a controlled substance;

(e) record keeping regarding:

~~[(i) the eligible donor that donated each prescription drug;]~~

~~[(ii) an individual who transferred an eligible prescription drug to a physician's office under Subsection 58-17b-903(2)(a)(ii);]~~

(i) the individual or eligible donor that transferred an eligible prescription drug under Subsection 58-17b-903(2)(a);

~~[(iii)]~~ (ii) the identification and evaluation of a donated prescription drug by a pharmacist or licensed pharmacy technician; and

~~[(iv)]~~ (iii) the dispensing or disposition of a prescription drug;

(f) determining the status of a medically indigent individual;

(g) labeling requirements to:

(i) ensure compliance with patient privacy laws relating to:

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- (A) an individual who receives an eligible prescription drug; and
- (B) patient information that may appear on a donated prescription drug;
 - (ii) clearly identify an eligible prescription drug dispensed under the program; and
 - (iii) communicate necessary information regarding the manufacturer's recommended expiration date or the beyond use date; and
- (h) ensuring compliance with the requirements of this part;
- (4) a process for seeking input from:
 - (a) the Department of Health, created in Section 26-1-4, to establish program standards and procedures for assisted living facilities and nursing care facilities; and
 - (b) the Division of Substance Abuse and Mental Health, created in Section 62A-15-103, to establish program standards and procedures for mental health and substance abuse clients; and
- (5) the creation of a special training program that a pharmacist and a licensed pharmacy technician at an eligible pharmacy must complete before participating in the program.