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H.B. 236
2nd Sub. (Gray)

Representative Gage Froerer proposes the following substitute bill:

CHARITABLE PRESCRIPTION DRUG RECYCLING PROGRAM

2016 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Gage Froerer

Senate Sponsor: Evan J. Vickers

LONG TITLE

General Description:

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

Highlighted Provisions:

This bill:

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

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

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

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

ENACTS:

58-17b-901, Utah Code Annotated 1953

58-17b-902, Utah Code Annotated 1953

58-17b-903, Utah Code Annotated 1953

58-17b-904, Utah Code Annotated 1953

58-17b-905, Utah Code Annotated 1953

58-17b-906, Utah Code Annotated 1953

58-17b-907, Utah Code Annotated 1953

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

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

58-17b-502. Unprofessional conduct.

"Unprofessional conduct" includes:

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

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

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

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

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

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

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

(iii) providing compensation for services to a veterinarian.

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

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

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

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

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

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

(9) administering:

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

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

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

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

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

(12) failing to report to the division any adverse action taken by another licensing jurisdiction, government agency, law enforcement agency, or court for conduct that in substance would be considered unprofessional conduct under this section; and

(13) as a pharmacist or pharmacy intern, compounding a prescription drug in a dosage

form which is regularly and commonly available from a manufacturer in quantities and strengths prescribed by a practitioner.

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

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

(1) For purposes of this section:

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

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

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

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

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

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

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

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

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

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

[~~(e)~~] (v) the drug was initially dispensed by a licensed pharmacist or licensed pharmacy intern; and

[~~(f)~~] (vi) accepting back and [~~redistribution~~] redistributing of the drug complies with federal Food and Drug Administration and Drug Enforcement Administration regulations.

Section 3. Section **58-17b-901** is enacted to read:

Part 9. Charitable Prescription Drug Recycling Act

58-17b-901. Title.

This part is known as the "Charitable Prescription Drug Recycling Act."

Section 4. Section **58-17b-902** is enacted 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

(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 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) is operated by:

(i) a county;

(ii) a county health department;

(iii) a pharmacy under contract with a county health department;

(iv) the Department of Health, created in Section 26-1-4;

(v) the Division of Substance Abuse and Mental Health, created in Section 62A-15-103; or

(vi) 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 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 does not have health insurance and lacks reasonable means to purchase 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 5. Section **58-17b-903** is enacted 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 an eligible donor to transfer an eligible prescription drug 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 6. Section **58-17b-904** is enacted to read:

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

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

(1) (a) is in the original sealed unit pack; or

(b) is an injectable medication;

(2) (a) is unopened; or

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

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

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

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

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

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

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

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

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

(1) An eligible donor 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; 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 8. Section **58-17b-906** is enacted to read:

58-17b-906. Liability of participating organizations and manufacturers.

In the absence of bad faith or gross negligence, a person is not criminally or civilly liable for injury, death, or loss of property based solely on the fact that the person manufactured, provided, donated, accepted, or dispensed an eligible prescription drug under

this part.

Section 9. Section **58-17b-907** is enacted 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 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 a donated eligible prescription drug, 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 or licensed pharmacy technician working in or consulting with a participating eligible donor;

(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) the identification and evaluation of a donated prescription drug by a pharmacist or licensed pharmacy technician; and

(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:

(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.