

R156. Commerce, Occupational and Professional Licensing.

R156-37f. Controlled Substance Database Act Rule.

R156-37f-102. Definitions.

In addition to the definitions in Sections 58-17b-102, 58-37-2 and 58-37f-102, as used in this chapter:

(1) "ASAP" means the American Society for Automation in Pharmacy system.

(2) "DEA" means Drug Enforcement Administration.

(3) "NABP" means the National Association of Boards of Pharmacy.

(4) "NCPDP" means National Council for Prescription Drug Programs.

(5) "NDC" means National Drug Code.

(6) "ORI" means Originating Agency Identifier Number.

[6] 7) "Positive identification" means:

(a) one of the following photo identifications issued by a foreign or domestic government:

(i) driver's license;

(ii) non-driver identification card;

(iii) passport;

(iv) military identification; or

(v) concealed weapons permit; or

(b) if the individual does not have government-issued identification, alternative evidence of the individual's identity as deemed appropriate by the pharmacist, as long as the pharmacist documents in a prescription record a description of how the individual was positively identified.

[7] 8) "Research facility" means a facility in which research takes place that has policies and procedures describing such research.

[8] 9) "Rx" means a prescription.

R156-37f-203. Submission, Collection, and Maintenance of Data.

(1) The format used as a guide for submission to the Database shall be in accordance with [any] version 4.2 of the ASAP Telecommunications Format for Controlled Substances published by the American Society for Automation in Pharmacy. The Division may approve alternative formats substantially similar to this standard. This standard is further classified by the Database as follows:

(a) Mandatory Data. The following Database data fields are mandatory:

(i) pharmacy NABP or NCPDP number;

(ii) customer identification number;

(iii) patient birth date;

(iv) patient gender code;

(v) date filled;

(vi) Rx number;

(vii) new-refill code;

(viii) metric quantity;

(ix) days supply;

(x) NDC number;

(xi) prescriber identification number;

(xii) date Rx written;

(xiii) number refills authorized;

(xiv) patient last name;

(xv) patient first name;

(xvi) patient street address; [and]

(xvii) five-digit zip code[-];

- (xviii) date sold (point of sale);
- (xix) identification number of person dropping off or picking up prescription;
- (xx) dispensing pharmacist state license number; and
- (xxi) method of payment.

(b) Preferred Data. The following Database data fields are strongly suggested:

- (i) compound code;
- (ii) DEA suffix;
- (iii) Rx origin code;
- (iv) customer location;
- (v) alternate prescriber number; and
- (vi) state in which the prescription is filled.

(c) Optional Data. All other data fields in the ASAP 4.2 Format not included in Subsections (a) and (b) are optional.

(2) Upon request, the Division will consider approving alternative formats, or adjustments to the ASAP Format, as might be necessary due to the capability or functionality of Database collection instruments. A proposed alternative format shall contain all mandatory data elements.

(3) In accordance with Subsection 58-37f-203(1)(a), the data required in Subsection (1) shall be submitted to the Database through one of the following methods:

- (a) electronic data sent via a secured internet transfer method, including sFTP site transfer;;
- (b) secure web base service; or
- (c) any other electronic method approved by the Database manager prior to submission.

(4) In accordance with Subsection 58-37f-203(1)(a):

(a) Effective January 1, 2016, each pharmacy or pharmacy group shall submit data collected on a daily basis either in real time or daily batch file reporting. The submitted data shall be from the point of sale (POS) date.

(i) If the data is submitted by a single pharmacy entity, the data shall be submitted in chronological order according to the date each prescription was filled.

(ii) If the data is submitted by a pharmacy group, the data is required to be sorted by individual pharmacy within the group, and the data of each individual pharmacy within the group is required to be submitted in chronological order according to the date each prescription was filled.

(b)(i) A Class A, B, or D pharmacy or pharmacy group that has a controlled substance license but is not dispensing controlled substances and does not anticipate doing so in the immediate future may request a waiver or submit a certification of such, in a form preapproved by the Division, in lieu of daily null reporting.

(ii) The waiver or certification must be resubmitted at the end of each calendar year.

(iii) If a pharmacy or pharmacy group that has submitted a waiver or certification under this Subsection (5)(b) dispenses a controlled substance:

(A) the waiver or certification shall immediately and automatically terminate;

(B) the pharmacy or pharmacy group shall provide written notice of the waiver or certification termination to the Division within seven days of dispensing the controlled substance; and

(C) the Database reporting requirements shall be applicable to the pharmacy or pharmacy group immediately upon the dispensing of the controlled substance.

R156-37f-301. Access to Database Information.

In accordance with Subsections 58-37f-301(1)(a) and (b):

(1) The Division Director may designate those individuals employed by the Division who may have access to the information in the Database (Database staff).

(2) (a) A request for information from the Database may be made:

(i) directly to the Database by electronic submission, if the requester is registered to use the Database;

or

(ii) by oral or written submission to the Database staff, if the requester is not registered to use the Database.

(b) An oral request may be submitted by telephone or in person.

(c) A written request may be submitted by facsimile, email, regular mail, or in person except as otherwise provided herein.

(d) The Division may in its discretion require a requestor to verify the requestor's identity.

(3) The following Database information may be disseminated to a verified requestor who is permitted to obtain the information:

(a) dispensing/reporting pharmacy ID number/name;

(b) subject's birth date;

(c) date prescription was filled;

(d) prescription (Rx) number;

(e) metric quantity;

(f) days supply;

(g) NDC code/drug name;

(h) prescriber ID/name;

(i) date prescription was written;

(j) subject's last name;

(k) subject's first name; and

(l) subject's street address;

(4)(a) Federal, state, and local law enforcement authorities and state and local prosecutors requesting information from the Database under Subsection 58-37f-301(2)(k) must provide a valid search warrant authorized by the courts, which [and] may be provided using one of the following methods:

(i) in person;

(ii) [be] email to csdb@utah.gov;

(iii) facsimile; or

(iv) U.S. Mail.

(b) Information in the search warrant should be limited to subject's name and birth date.

(c) Information provided as a result of the search warrant shall be in accordance with Subsection (3).

(5) In accordance with Subsection 58-37f-301(2)(n), a probation or parole officer employed by the Department of Corrections or a political subdivision, may have access to the database without a search warrant for supervision of a specific probationer or parolee under the officer's direct supervision, if:

(a) a security agreement signed by the officer is submitted to the division for access, which contains:

(i) the agency's name;

(ii) the agency's complete address, including city and zip code;

(iii) the agency's ORI number;

(iv) a copy of the officer's driver's license;

(v) the officer's full name;

(vi) the officer's contact phone number;

(vii) the officer's email address; and

(b) the online database account includes the officer's:

(i) full name;

(ii) email address;

(iii) complete home address, including city and zip code;

(iv) work title;

(v) contact phone number;

(vi) complete work address, including city and zip code;

(vii) work phone number; and

(viii) driver's license number.

([5]6) (a) Pursuant to Utah Code Ann. 58-37f-301(2)(q), [A] an individual may receive an accounting of persons or entities that have requested or received Database information about the individual.

(b) An individual may request the information in person or in writing by the following means:

- (i) email;
- (ii) facsimile; or
- (iii) U.S. Mail.

(c) The request for information shall include the following:

- (i) individual's['] full name, including all aliases;
- (ii) birth date;
- (iii) home address;
- (iv) government-issued identification; and
- (v) date[-]range.

(d) The results may be disseminated in accordance with Subsection ([14] 17).

(e) The information provided in the report may include the following:

- (i) the role of the person that accessed the information;
- (ii) the date and a description of the information that was accessed;
- (iii) the name of the person or entity that requested the information; and
- (iv) the name of the practitioner on behalf of whom the request for information was made, if applicable.

([6]7) An individual whose records are contained within the Database may obtain his or her own information and records by:

(a) personally appearing before the Database staff with government-issued picture identification confirming the requester's identity; or

(b) submitting a signed and notarized request that includes the requester's:

- (i) full name;
- (ii) complete home address;
- (iii) date of birth; and
- (iv) driver license or state identification card number.

([7]8) A request[e]or holding power of attorney for an individual whose records are contained within the Database may obtain the individual's information and records by:

(a) personally appearing before the Database staff with government-issued picture identification confirming the requester's identity; and

(b) providing:

- (i) an original, properly executed power of attorney designation; and
- (ii) a signed and notarized request, executed by the individual whose information is contained within the Database, and including the individual's:

- (A) full name;
- (B) complete home address;
- (C) date of birth; and
- (D) driver license or state identification card number verifying the individual's identity.

([8]9) A requestor who is the legal guardian of a minor or incapacitated individual whose records are contained within the Database may obtain the individual information and records by:

(a) personally appearing before the Database staff with government-issued picture identification confirming the requester's identity;

(b) submitting the minor or incapacitated individual's:

- (i) full name;
- (ii) complete home address;
- (iii) date of birth; and
- (iv) if applicable, state identification card number verifying the individual's identity; and

(c) submitting legal proof that the requestor is the guardian of the individual who is the subject of the request for information from the Database.

([9]10) A requestor who has a release-of-records from an individual whose records are contained within the Database may obtain the individual's information and records by:

(a) submitting a request in writing;
(b) submitting an original, signed and notarized release-of-records in a format acceptable to the Database staff, identifying the purpose of the release; and

(c) submitting the individual's:

(i) full name;

(ii) complete home address;

(iii) telephone number;

(iv) date of birth; and

(v) driver license or state identification card number verifying the identity of the person who is the subject of the request.

([10]11) An employee of a licensed practitioner who is authorized to prescribe controlled substances may obtain Database information to the extent permissible under Subsection 58-37f-301(2)(d) (i) if, prior to making the request:

(a) the licensed practitioner has provided to the Division a written designation that includes the designating practitioner's DEA number and the designated employee's:

(i) full name;

(ii) complete home address;

(iii) e-mail address;

(iv) date of birth; and

(v) driver license number or state identification card number; and

(vi) the written designation is manually signed by the licensed practitioner and employee.

(b) the designated employee has registered for an account for access to the Database and provided a unique user identification;

(c) the designated employee has passed a Database background check of available criminal court and Database records; and

(d) the Database has issued the designated employee a user personal identification number (PIN) and activated the employee's Database account.

([11]12) An employee of a business that employs a licensed practitioner who is authorized to prescribe controlled substances may obtain Database information to the extent permissible under Subsection 58-37f-301(2)(d) (i) if, prior to making the request:

(a) the licensed practitioner and employing business have provided to the Division a written designation that includes:

(i) the designating practitioner's DEA number;

(ii) the name of the employing business; and

(iii) the designated employee's:

(A) full name;

(B) complete home address;

(C) e-mail address;

(D) date of birth; and

(E) driver license number or state identification card number;

(b) the designated employee has registered for an account for access to the Database and provided a unique user identification and password;

(c) the designated employee has passed a Database background check of available criminal court and Database records; and

(d) the Database has issued the designated employee a user personal identification number (PIN) and activated the employee's Database account.

([12]13) An individual who is employed in the emergency room of a hospital that employs a licensed practitioner who is authorized to prescribe controlled substances may obtain Database information to the extent permissible under Subsection 58-37f-301(2)(d) if, prior to making the request:

(a) the practitioner and the hospital operating the emergency room have provided to the Division a written designation that includes:

- (i) the designating practitioner's DEA number;
- (ii) the name of the hospital;
- (iii) the names of all emergency room practitioners employed at the hospital; and
- (iv) the designated employee's:
 - (A) full name;
 - (B) complete home address;
 - (C) e-mail address;
 - (C) date of birth; and
 - (D) driver license number or state identification card number;

(b) the designated employee has registered for an account for access to the Database and provided a unique user identification and password;

(c) the designated employee has passed a Database background check of available criminal court and Database records; and

(d) the Database has issued the designated employee a user personal identification number (PIN) and activated the employee's Database account.

(14) Pursuant to Utah Code Ann, 58-37f-301(5), an individual's requests to the division regarding third-party notice when a controlled substance prescription is dispensed to that individual, shall be made as follows:

(a) A request to provide notice to a third party shall be made by a writing dated and signed by the individual, and shall include the following information:

- (i) the requesting individual's full name;
- (ii) the requesting individual's birth date;
- (iii) the requesting individual's complete home address, including city and zip code;
- (iv) the requesting individual's email address;
- (v) the requesting individual's contact phone number;
- (vi) the designated third party's full name;
- (vii) the designated third party's complete home address, including city and zip code;
- (viii) the designated third party's email address; and
- (ix) the designated third party's contact phone number.

(b) A request to discontinue providing notice to a third party shall be made by a writing dated and signed by the individual, after which the division shall:

- (i) provide notice to the individual that the discontinuation notice was received; and
- (ii) provide notice to the designated third party that the notification has been rescinded.
- (c) An individual may only have one active designated third party.

(15) A licensed pharmacy technician or pharmacy intern employed by a pharmacy may obtain Database information to the extent permissible under Subsection 58-37f-301(2)(1) if, prior to making the request:

(a) the pharmacist-in-charge (PIC) has provided to the Division a written designation authorizing access to the pharmacy technician or pharmacy intern on behalf of a licensed pharmacist employed by the pharmacy;

(b) the written designation includes the pharmacy technician or pharmacy intern's:

- (i) full name;
- (ii) professional license number assigned by the Division;
- (iii) email address;
- (iv) contact phone number;

- (v) pharmacy name and location;
- (vi) pharmacy DEA number;
- (vii) pharmacy phone number; and
- (c) the written designation includes the pharmacist-in-charge's (PIC's):
 - (i) full name;
 - (ii) professional license number assigned by the Division;
 - (iii) email address;
 - (iv) contact phone number;
- (d) the written designation includes the assigned pharmacist's:
 - (i) full name;
 - (ii) professional license number assigned by the Division;
 - (iii) email address;
 - (iv) contact phone number; and
- (e) the written designation includes the following signatures:
 - (i) pharmacy technician or pharmacy intern;
 - (ii) pharmacist-in-charge (PIC); and
 - (iii) assigned pharmacist if different than the PIC.

([13] 16) The Utah Department of Health may access Database information for purposes of scientific study regarding public health. To access information, the scientific investigator shall:

- (a) demonstrate to the satisfaction of the Division that the research is part of an approved project of the Utah Department of Health;
- (b) provide a description of the research to be conducted, including:
 - (i) a research protocol for the project; and
 - (ii) a description of the data needed from the Database to conduct that research;
- (c) provide assurances and a plan that demonstrates all Database information will be maintained securely, with access being strictly restricted to the requesting scientific investigator;
- (d) provide for electronic data to be stored on a secure database computer system with access being strictly restricted to the requesting scientific investigator; and
- (e) pay all relevant expenses for data transfer and manipulation.

([14] 17) Database information that may be disseminated under Section 58-37f-301 may be disseminated by the Database staff either:

- (a) verbally;
- (b) by facsimile;
- (c) by email;
- (d) by U.S. mail; or
- (e) by electronic access, where adequate technology is in place to ensure that a record will not be compromised, intercepted, or misdirected~~[, by electronic access]~~.

R156-17b-905. Fees

As authorized by Subsection 58-17b-905(2)(e), an eligible pharmacy may charge the following handling fees:

- (1) Before accepting a prescription drug under the program: \$0 - \$10; and
- (2) Before dispensing a prescription drug under the program: \$0 - \$5.

R156-17b-907a. Registration Requirements - Eligible Pharmacy.

- (1) A pharmacy seeking registration with the division as an eligible pharmacy shall submit an application on a form provided by the division.
- (2) The division's form shall at minimum require the applicant pharmacy to establish that:
 - (a) the applicant is currently licensed and in good standing with the division;
 - (b) the applicant agrees to maintain, subject to inspection by the division, written standards and procedures addressing the requirements of Subsection 58-17b-907;
 - (c) the applicant agrees to create and maintain, subject to inspection by the division, a special training program in accordance with R156-17b-907e that its pharmacists and licensed pharmacy technicians shall complete before participating in the program; and
 - (d) as required by Subsection 58-17b-902(8)(b), the applicant is operated by a county, county health department, a pharmacy under contract with a county health department, the Department of Health, the Division of Substance Abuse and Mental Health, or a charitable clinic.

R156-17b-907b. Formulary.

The formulary established under Subsection 58-17b-907(2) shall include all prescription drugs approved by the federal Food and Drug Administration that meet Section 58-17b-904 criteria, except for:

- (1) controlled substances;
- (2) compounded drugs; and
- (3) drugs that can only be dispensed to a patient registered with the drug's manufacturer per federal Food and Drug Administration requirements.

R156-17b-907c. Standards and Procedures.

A pharmacy registered with the division as an eligible pharmacy shall maintain, subject to inspection by the division, written standards and procedures addressing all of the requirements of Section 58-17b-907. The eligible pharmacy may, but need not, use any forms developed for the administration of this program that are available on the division's website, _____, or on the Department of Health's website, _____, such as an intake form for determining the status of a medically indigent individual.

R156-17b-907d. Required Input Process.

??A process for seeking input from

the Department of Health, to establish program standards and procedures for assisted living facilities and nursing care facilities;

the Division of Substance Abuse and Mental Health, to establish program standards and procedures for mental health and substance abuse clients.

R156-17b-907e. Special Training Program.

Eligible pharmacies shall:

(1) create and maintain a special training program that its pharmacists and licensed pharmacy technicians shall complete before participating in the program; and

(2) maintain a record for at least two years of all pharmacists and licensed pharmacy technicians that have completed the special training program.

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

7

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



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^o 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;

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

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

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

119 **Part 9. Charitable Prescription Drug Recycling Act**

120 **58-17b-901. Title.**

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

122 Section 4. Section **58-17b-902** is enacted to read:

123 **58-17b-902. Definitions.**

124 As used in this part:

125 (1) "Assisted living facility" means the same as that term is defined in Section 26-21-2.

126 (2) "Cancer drug" means a drug that controls or kills neoplastic cells and includes a
127 drug used in chemotherapy to destroy cancer cells.

128 (3) "Charitable clinic" means a charitable nonprofit corporation that:

129 (a) holds a valid exemption from federal income taxation issued under Section 501(a),
130 Internal Revenue Code;

131 (b) is exempt from federal income taxation under Section 501(c)(3), Internal Revenue
132 Code;

133 (c) provides, on an outpatient basis, for a period of less than 24 consecutive hours, to
134 an individual not residing or confined at a facility owned or operated by the charitable
135 nonprofit corporation:

136 (i) advice;

137 (ii) counseling;

138 (iii) diagnosis;

139 (iv) treatment;

140 (v) surgery; or

141 (vi) care or services relating to the preservation or maintenance of health; and

- 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.

o

R156-17b-904. Criteria for eligible prescription drug – beyond use date or expiration date

The division in collaboration with the board has not established a date later than the beyond use date or the expiration date recommended by the manufacturer for a specific prescription drug.

R156-17b-905. Fees

(1) In accordance with Subsection 58-17b-905 (2) (e) an eligible pharmacy may charge a handling fee:

- (a) before accepting a prescription drug under the program: \$0 - \$10
- (b) before dispensing a prescription drug under the program: \$0 - \$5

R156-17b-907a. Applicants seeking registration to become eligible pharmacies under Subsection 58-17b-902 (8) - Supporting Documents and Information.

An applicant seeking registration under Subsection 58-17b-902 (8) shall submit an application on a form provided by the division that at minimum establishes:

- (1) the entity in which the eligible pharmacy will operate under is either a:
 - (a) county
 - (b) county health department
 - (c) pharmacy under contract with a county health department
 - (d) the Department of Health, created under Section 26-1-4
 - (e) the Division of Substance Abuse and Mental Health, created om Section 62A-15-103; or
 - (f) charitable clinic;
- (2) the applicant is currently licensed and in good standing with the Division;

R156-17b-907b. Formulary

(1) The formulary under Section 58-17b-907 (2) includes all prescription drugs approved by the federal Food and Drug Administration that meet the criteria for eligible prescription drugs in Section 58-17b-904.

- (2) The formulary does not include:
 - (a) controlled substances; and
 - (b) drugs that can only be dispensed to a patient registered with the drug's manufacturer in accordance with the deferral Food and drug Administration requirements.
 - (c) compounded drugs

R156-17b-907c. Standards and Procedures

In accordance with Subsection 58-17b-907 (3) an eligible pharmacy shall maintain standards and procedures, that are available for inspection, regarding.

- (1) Handling of a donated eligible prescription drug, including:
 - (a) program eligibility of the donor;
 - (b) acceptance;
 - (c) identification of and evaluation of a donated prescription drug by a licensed pharmacist or pharmacy technician;
 - (d) tracking of the complete inventory cycle;
 - (e) safe storage;
 - (f) security;

- (g) transfer;
- (h) dispensing.
- (2) Determining the status of a medically indigent individual.
- (3) Labeling requirements, including:
 - (a) satisfying the requirements of the labeling requirements of Subsections;
 - (b) patient information that may appear on a donated prescription drug;
 - (c) compliance with privacy laws;
 - (d) clearly identify the eligible drug dispensed under the program;
 - (e) information regarding the beyond use date or manufacturer's recommended expiration date.

R156-17b-907d. Special Training Program

- (1) Eligible pharmacies shall create and maintain a training program that pharmacists and licensed pharmacy technicians shall complete before participating in the program.
- (2) Eligible pharmacies shall maintain record, for at least two years, of the pharmacists and licensed pharmacy technicians that have completed the training program required by Subsection R156-17b-907d (1).

R156-17b-907d. Program Standards and Procedures

- (1) In accordance with Subsections 58-17b-907 (4) (a) and (b) the division will coordinate an annual meeting with the Department of Health, created in Section 26-1-4, the Division of Substance Abuse and Mental Health, create in Section 62A-15-103, and eligible pharmacies.

State of Utah
Administrative Rule Analysis

NOTICE OF PROPOSED RULE

- * The agency identified below in box 1 provides notice of proposed rule change pursuant to Utah Code Section 63G-3-301.
- * Please address questions regarding information on this notice to the agency.
- * The full text of all rule filings is published in the Utah State Bulletin unless excluded because of space constraints.
- * The full text of all rule filings may also be inspected at the Division of Administrative Rules.

DAR file no:

40863

Date filed:

10-11-2016

State Admin Rule Filing Id:

Time filed:

	Agency No.	Rule No.	Section No.
Utah Admin. Code Ref (R no.):	R 156	- 17b	-
Changed to Admin. Code Ref. (R no.):	R	-	-

1. Agency: Commerce/Division of Occupational and Professional Licensing

Room no.:

Building: Heber M. Wells Building

Street address 1: 160 East 300 South

Street address 2:

City, state, zip: Salt Lake City UT 84111-2316

Mailing address 1: PO Box 146741

Mailing address 2:

City, state, zip: Salt Lake City UT 84114-6741

Contact person(s):

Name:	Phone:	Fax:	E-mail:
Dane Ishihara	801-530-7632	801-530-6511	dishihara@utah.gov

(Interested persons may inspect this filing at the above address or at the Division of Administrative Rules during business hours)

2. Title of rule or section (catchline):

Pharmacy Practice Act Rule

3. Type of notice:

New ; Amendment XXX; Repeal ; Repeal and Reenact

4. Purpose of the rule or reason for the change:

The Utah State Board of Pharmacy and Physicians Licensing Board reviewed the proposed rule amendments in their September 2016 meetings. The Boards agreed to the same language with one exception. The only difference was that the Utah State Board of Pharmacy preferred no requirement for pharmacists to report to the Division at the same time they make their annual report to the physicians. After considering comments from both Boards, the Division determined to require the same report that is sent to the physician to be sent to the Division and increased the reporting time from 10 to 15 days to ease the impact of compliance. Since the report to the Division is no different than the report to the physician, which both Boards agreed is satisfactory, and since the proposed amendments now provides 15 days for reporting, the Division considered the impact of reporting to the Division to be minimal. H.B. 240, passed by the Legislature during the 2016 General Session made changes to the newly defined Opiate Overdose Response Act, Title 26, Chapter 55, and to the Pharmacy Practice Act, Title 58, Chapter 17b. These changes permit physicians to issue a standing order for the dispensing of an opiate antagonist by pharmacists, and require the Division to promulgate rules to address the standing order and the requirements for dispensing. The Division is filing this rule to accomplish that mandate.

5. This change is a response to comments from the Administrative Rules Review Committee.

No XXX; Yes

6. Summary of the rule or change:

Section 502: This section establishes that failing to report as required in Section R156-17b-625 is unprofessional conduct. Section 625: This new section defines the requirements for dispensing an opiate antagonist, including information that must be maintained and reported to the Division and physicians.

7. Aggregate anticipated cost or savings to:

A) State budget:

Affected: No ; Yes XXX

This filing should have no impact to the state budget beyond a minimal cost of \$75.00 to reprint and distribute the rule once proposed amendments may become effective. The Division also anticipates no additional costs should be incurred by the Division to receive the required reports.

B) Local government:

Affected: No XXXX; Yes

Local governments are unlikely to be impacted by this rule unless a local health department chooses to participate in issuing a standing order for an opiate antagonist through their medical director. Even then the decision is optional by the local government.

C) Small businesses ("small business" means a business employing fewer than 50 persons):

Affected: No XXXX; Yes

Physicians and pharmacists are not required to participate in the issuing of a standing order or the dispensing of an opiate antagonist. This rule creates no fiscal impact beyond those identified in the passage of H.B. 240. Those who benefit from the lifesaving, overdose-reversing efforts of someone who previously could not obtain an opiate antagonist will receive the benefits of prolonged life. These costs or benefits are impossible to quantify. Pharmacies are not required to collect any information that they do not already collect.

D) Persons other than small businesses, businesses, or local government entities ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an agency):

Affected: No XXXX; Yes

Physicians and pharmacists are not required to participate in the issuing of a standing order or the dispensing of an opiate antagonist. This rule creates no fiscal impact beyond those identified in the passage of H.B. 240. Those who benefit from the lifesaving, overdose-reversing efforts of someone who previously could not obtain an opiate antagonist will receive the benefits of prolonged life. These costs or benefits are impossible to quantify.

8. Compliance costs for affected persons:

Physicians and pharmacists are not required to participate in the issuing of a standing order or the dispensing of an opiate antagonist. This rule creates no fiscal impact beyond those identified in the passage of H.B. 240. Those who benefit from the lifesaving, overdose-reversing efforts of someone who previously could not obtain an opiate antagonist will receive the benefits of prolonged life. These costs or benefits are impossible to quantify. Pharmacies are not required to collect any information that they do not already collect.

9. A) Comments by the department head on the fiscal impact the rule may have on businesses:

Pharmacies are required by the newly adopted HB 240 to provide a report to any physician who issues a standing prescription drug order of an opiate antagonist and to the Division of Occupational and Professional Licensing. This rule implements the statutory provision. Pharmacies are not required to collect any information that they do not already collect. They merely need to format information regarding dispensed opiate antagonists into the required report. The report to the Division and to the physician contain the same information. The rule creates no fiscal impact beyond those identified in HB 240 as being the consequence of the statute itself.

B) Name and title of department head commenting on the fiscal impacts:

Francine A. Gian, Executive Director

10 This rule change is authorized or mandated by state law, and implements or interprets the following state and federal laws.

State code or constitution citations (required) (e.g., Section 63G-3-402; Subsection 63G-3-601(3); Article IV) :

Section 58-17b-101

Subsection 58-17b-601(1)

Section 58-37-1

Subsection 58-1-106(1)(a)

Subsection 58-1-202(1)(a)

11 This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Division of Administrative Rules; if none, leave blank):

	First Incorporation	Second Incorporation
Official Title of Materials Incorporated (from title page)		
Publisher		
Date Issued		
Issue, or version		
ISBN Number (optional)		
ISSN Number (optional)		
Cost of Incorporated Reference		
Action: Adds, updates, or removes		

(If this rule incorporates more than two items by reference, please attach additional pages)

12 The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the Utah State Bulletin. See Section 63G-3-302 and Rule R15-1 for more information.)

A) Comments will be accepted until 5:00 p.m. on (mm/dd/yyyy):

12/01/2016

B) A public hearing (optional) will be held:

On (mm/dd/yyyy):

11/17/2016

At (hh:mm AM/PM):

11:00 AM

At (place):

160 East 300 South, Hearing Room 403 (4th floor), Salt Lake City, Utah

R156. Commerce, Occupational and Professional Licensing.

R156-17b. Pharmacy Practice Act Rule.

R156-17b-502. Unprofessional Conduct.

"Unprofessional conduct" includes:

- (1) violating any provision of the American Pharmaceutical Association (APhA) Code of Ethics for Pharmacists, October 27, 1994, which is hereby incorporated by reference;
- (2) failing to comply with the USP-NF Chapters 795 and 797 if such chapters are applicable to activities performed in the pharmacy;
- (3) failing to comply with the continuing education requirements set forth in these rules;
- (4) failing to provide the Division with a current mailing address within a 10 business day period of time following any change of address;
- (5) defaulting on a student loan;
- (6) failing to abide by all applicable federal and state law regarding the practice of pharmacy;
- (7) failing to comply with administrative inspections;
- (8) failing to return according to the deadline established by the Division, or providing false information on a self-inspection report;
- (9) violating the laws and rules regulating operating standards in a pharmacy discovered upon inspection by the Division;
- (10) abandoning a pharmacy or leaving prescription drugs accessible to the public;
- (11) failing to identify licensure classification when communicating by any means;
- (12) practicing pharmacy with an inappropriate pharmacist to pharmacy intern ratio established by Subsection R156-17b-606(1)(d) or pharmacist to pharmacy technician ratio as established by Subsection R156-17b-601(3);
- (13) allowing any unauthorized persons in the pharmacy;
- (14) failing to offer to counsel any person receiving a prescription medication;
- (15) failing to pay an administrative fine that has been assessed in the time designated by the Division;
- (16) failing to comply with the PIC or DMPIC standards as established in Section R156-17b-603;
- (17) failing to adhere to institutional policies and procedures related to technician checking of medications when technician checking is utilized;
- (18) failing to take appropriate steps to avoid or resolve identified drug therapy management problems as referenced in Subsection R156-17b-611(3);
- (19) dispensing medication that has been discontinued by the FDA;
- (20) failing to keep or report accurate records of training hours;

(21) failing to provide PIC or DMPIC information to the Division within 30 days of a change in PIC or DMPIC;

(22) requiring a pharmacy, pharmacist, or DMP to operate the pharmacy or allow operation of the pharmacy with a ratio of supervising pharmacist or DMP to other pharmacy personnel in circumstances that result in, or reasonably would be expected to result in, an unreasonable risk of harm to public health, safety, and welfare;

(23) failing to update the Division within seven calendar days of any change in the email address designated for use in self-audits or pharmacy alerts; [~~and~~]

(24) failing to ensure, as a DMP or DMP clinic pharmacy, that a DMP designee has completed a formal or on-the-job dispensing training program that meets standards established in Section R156-17b-622; and

(25) failing to make a timely report regarding dispensing of an opiate antagonist to the division and to the physician who issued the standing order as required in Section R156-17b-625.

R156-17b-625. Standards - Reporting and Maintaining Records on the Dispensing of an Opiate Antagonist.

(1) In accordance with Subsections 26-55-105(2)(c) and (d), the pharmacist-in-charge or a responsible corporate officer of each pharmacy licensee that dispenses an opiate antagonist pursuant to a valid standing prescription drug order issued by a physician, shall affirm that the pharmacy licensee has complied with the protocol for dispensing an opiate antagonist as set forth in Section 26-55-105, and shall report, on an annual basis, to the division and to the physician who issued the opiate antagonist standing drug order, the following information:

(a) the total number of single doses of opiate antagonists dispensed during the reporting period; and

(b) the name of each opiate antagonist dispensed, along with the total number of single doses of that particular named opiate antagonist.

(2) Corporations or organizations with multiple component pharmacy licenses may submit one cumulative report for all its component pharmacy licensees. However, that report must contain the information described above for each of the component pharmacy licensees.

(3) Null reporting is not required. If a pharmacy licensee does not dispense an opiate antagonist during any year, that pharmacy licensee is not required to make an affirmation or report to the division.

(4) The annual affirmation and report described above is due to the division and to the physician who issued the standing drug order no later than 15 days following December 31 of each calendar year.

(5) In accordance with Subsection 26-55-105(2)(d), a pharmacy licensee who dispenses an opiate antagonist pursuant to

a valid standing prescription order issued by a physician, shall maintain, subject to audit, the following information:

- (a) the name of the individual to whom the opiate antagonist is dispensed;
- (b) the name of the opiate antagonist dispensed;
- (c) the quantity of the opiate antagonist dispensed;
- (d) the strength of the opiate antagonist dispensed;
- (e) the dosage quantity of the opiate antagonist dispensed;
- (f) the full name of the drug outlet which dispensed the opiate antagonist;
- (g) the date the opiate antagonist was dispensed; and
- (h) the name of physician issuing the standing order to dispense the opiate antagonist.

(6) The division approves the protocol for the issuance of a standing prescription drug order for opiate antagonists, which is set forth in Subsection 26-55-105(2)(a) through (d) along with the requirements set forth in the foregoing provisions, and the reporting requirements set forth in Sections R156-67-604 and R156-68-604.

KEY: pharmacists, licensing, pharmacies

**Date of Enactment or Last Substantive Amendment: [~~April 21,~~
]2016**

Notice of Continuation: January 5, 2015

Authorizing, and Implemented or Interpreted Law: 58-17b-101; 58-17b-601(1); 58-37-1; 58-1-106(1)(a); 58-1-202(1)(a)