

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: 40902 Date filed: 10-24-2016  
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 XXXX; Repeal \_\_\_; Repeal and Reenact \_\_\_

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

H.B. 236, passed by the Legislature during the 2016 General Session, created a charitable prescription drug recycling program and required the Division to make rules to implement the program in consultation with the Utah State Board of Pharmacy. The Division is filing these proposed new rules to accomplish this mandate.

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

No XXXX; Yes \_\_\_

6. Summary of the rule or change:

Section R156-17b- 904: The authorizing statute prohibits a pharmacy from accepting or dispensing a drug under the program after either the drug label's beyond-use date, the expiration date recommended by the manufacturer, or any later date that has been established by division rule. This section makes clear that the division in collaboration with the Utah State Board of Pharmacy has not established any dates later than the beyond-use dates or the manufacturer's recommended expiration dates. Section R156-17b- 905: This section establishes the handling fees an eligible pharmacy may charge for accepting or dispensing a drug under the program. Section R156-17b- 907a: This section establishes the registration requirements to become an eligible pharmacy allowed to participate in the program. Section R156-17b- 907b: This section establishes the formulary of eligible prescription drugs for the program. Section R156-17b- 907c: This section establishes the program standards and procedures that eligible pharmacies must create and maintain. Section R156-17b- 907d: This section establishes that the division will coordinate annual meetings between (1) the Department of Health and eligible pharmacies, to obtain input to establish program standards and procedures for assisted living and nursing care facilities; and (2) between the Division of Substance Abuse and Mental Health and eligible pharmacies, to obtain input to establish program standards and procedures for mental health and substance abuse clients. Section R156-17b- 907e: This section requires an eligible pharmacy to create and maintain a training program for its pharmacists and pharmacy technicians to complete before they participate in the program, and requires the pharmacy to maintain a two-year record of such training.

**7. Aggregate anticipated cost or savings to:**

**A) State budget:**

**Affected:** No ; Yes

The Division will incur minimal costs of approximately \$75.00 to print and distribute the rule once the proposed amendments are made effective. Any printing and distribution costs incurred will be absorbed in the Division's current budget. Additional costs of registration and regulatory enforcement were included in the Legislature's consideration of H.B. 236.

**B) Local government:**

**Affected:** No ; Yes

Local governments that choose to participate in the program in coordination with an eligible pharmacy may be impacted by the costs of program management and recordkeeping. However, costs of participation would likely be offset by the savings resulting from enhanced health services to medically indigent persons within the local government's jurisdiction, which could result in a cost savings to the local government and to its community as a whole. One or more citizens may have their lives saved, or be able to work, or be able to better take care of their own needs and activities of daily living due to the availability of prescriptions issued pursuant to this program. This may translate into a cost savings for those persons as well as for their friends and families and the local government that provides them services. The Division is not able to determine any exact amount of costs or savings due to varying circumstances.

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

**Affected:** No ; Yes

Small-business pharmacies that choose to participate in the program may be impacted by the costs of program management and recordkeeping, as well as lost revenue if they substitute time they could be billing for professional services to provide these services under the program. These costs may be slightly offset by the allowed handling fees, and the small-business pharmacies may also receive "goodwill" benefits in their community from their volunteer services, and benefit from increased traffic to their location. The amount of the cost or savings cannot be estimated as it will vary from business to business depending on the services provided.

**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 ; Yes



(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):** 12/15/2016

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

**On (mm/dd/yyyy):**

11/15/2016

**At (hh:mm AM/PM):**

9:00 AM

**At (place):**

160 East 300 South, Conference Room 474  
(4th floor), Salt Lake City, Utah

- 13 **This rule change may become effective on (mm/dd/yyyy):** 12/22/2016

NOTE: The date above is the date on which this rule MAY become effective. It is NOT the effective date. After the date designated in Box 12(A) above, the agency must submit a Notice of Effective Date to the Division of Administrative Rules to make this rule effective. Failure to submit a Notice of Effective Date will result in this rule lapsing and will require the agency to start the rulemaking process over.

- 14 **Indexing information -- keywords** (maximum of four, in lower case, except for acronyms (e.g., "GRAMA") or proper nouns (e.g., "Medicaid")); may not include the name of the agency:

pharmacists

licensing

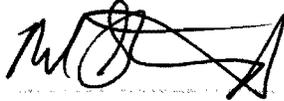
pharmacies

- 15 **Attach an RTF document containing the text of this rule change** R!56-17b.pro2  
(filename):

**To the agency:** Information requested on this form is required by Sections 63G-3-301, 302, 303, and 402. Incomplete forms will be returned to the agency for completion, possibly delaying publication in the *Utah State Bulletin*, and delaying the first possible effective date.

### AGENCY AUTHORIZATION

Agency head or  
designee, and title:



Date

(mm/dd/yyyy)

: 12/24/2016

**R156. Commerce, Occupational and Professional Licensing.**

**R156-17b. Pharmacy Practice Act Rule.**

**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.**

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 a 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 in compliance with Section R156-17b-907c;

(c) the applicant agrees to create and maintain, subject to inspection by the division, a special training program in accordance with Section R156-17b-907e; and

(d) as required by Subsection 58-17b-902(8), 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 - Eligible Pharmacies.**

An eligible pharmacy shall maintain written standards and procedures available for inspection by the division that:

- (1) satisfy the requirements of Section 58-17b-907; and
- (2) satisfy labeling requirements of Subsections 58-17b-602(5) through (8), and ensure that labels clearly identify the eligible drug was dispensed under the program.

**R156-17b-907d. Standards and Procedures - Facilities and Mental Health and Substance Abuse Clients.**

(1) In accordance with Subsection 58-17b-907(4)(a), the division shall schedule and facilitate an annual meeting between the Department of Health and eligible pharmacies to establish program standards and procedures for assisted living facilities and nursing care facilities; and

(2) In accordance with Subsection 58-17b-907(4)(b), the division shall schedule and facilitate an annual meeting between the Division of Substance Abuse and Mental Health and eligible pharmacies to establish program standards and procedures for mental health and substance abuse clients.

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

An eligible pharmacy 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.

**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)**