

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. Giani, 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):	At (hh:mm AM/PM):	At (place):
11/17/2016	11:00 AM	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)