

State of Utah  
Administrative Rule Analysis  
Revised October 2019

OUR FILE NO. 52325

Filed on 11-14-2019

**NOTICE OF PROPOSED RULE**

TYPE OF RULE: New \_\_\_; Amendment XXX; Repeal \_\_\_; Repeal and Reenact \_\_\_

Title No. - Rule No. - Section No.

Utah Admin. Code Ref (R no.): R156-17b-309.7

Filing No. (Office Use Only)

Changed to Admin. Code Ref. (R no.): R

**Agency Information**

1. Agency: Commerce/Division of Occupational and Professional Licensing  
Room no.:  
Building: Heber M. Wells Building  
Street address: 160 East 300 South  
City, state: Salt Lake City UT 84111-2316  
Mailing address: PO Box 146741  
City, state, zip: Salt Lake City UT 84114-6741  
Contact person(s):  
Name: Phone: Email:  
Larry Marx 801-530-6254 lmarx@utah.gov

Please address questions regarding information on this notice to the agency.

**General Information**

**2. Rule or section catchline:**

Exemptions from Licensure - Opioid Treatment Program

**3. Purpose of the new rule or reason for the change** (If this is a new rule, what is the purpose of the rule? If this is an amendment, repeal, or repeal and reenact, what is the reason for the filing?):

In accordance with Section 58-17b-309.7, enacted by 2019 HB 398, after consultation with pharmacies, physicians, and practitioners who work in opioid treatment programs (OTPs) the Division proposes this new Section R156-17b-309.7 to further define, clarify, and establish standards for practitioners dispensing methadone to patients in an OTP.

**4. Summary of the new rule or change:**

New Section R156-17b-309.7 defines "under the direction" of a pharmacist as used in Subsection 58-17b-309.7 to mean that the pharmacist has delegated to the practitioner the authority to perform one or more selected dispensing tasks on behalf of the pharmacist under the general supervision of the pharmacist, and specifically references that delegated tasks may include preparing, packaging, or labeling take-home dosages. This section also prohibits further delegation, or any expansion of the scope of a delegated task without the express permission of the pharmacist.

**Fiscal Information**

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

**A) State budget:**

New Section R156-17b-309.7 defines "under the direction" of a pharmacist as used in Subsection 58-17b-309.7 to mean that the pharmacist has delegated to the practitioner the authority to perform one or more selected dispensing tasks on behalf of the pharmacist under the general supervision of the pharmacist, and specifically references that delegated tasks may include preparing, packaging, or labeling take-home dosages. This section also prohibits further delegation, or any expansion of the scope of a delegated task without the express permission of the pharmacist.

**B) Local governments:**

No cost or saving impact is expected for local government because this new rule will not affect any local government practices or procedures.

**C) Small businesses** ("small business" means a business employing 1-49 persons):

This proposed new rule is expected to create a fiscal benefit for the approximately 100 small-business OTP facilities that employ pharmacists for dispensing (NAICS code 621420). However, the exact fiscal impact cannot be determined because the various employment and staffing characteristics and ratios for all of these OTPs, or what savings may result to an OTP from a pharmacist delegating one or more dispensing tasks to practitioners, is unknown and the relevant data is not available. The full fiscal impact on small business is inestimable as it will depend on the unique individual characteristics of the delegating pharmacists and the delegatee practitioners, on the characteristics of the patients involved, the nature of each OTP, and on the number and type of individual dispensing tasks that are delegated and the manner in which these tasks are completed.

**D) Non-small businesses** ("non-small business" means a business employing 50 or more persons):

This proposed new rule is expected to create a fiscal benefit for the approximately seven non-small business OTP facilities that employ pharmacists for dispensing (NAICS code 621420). However, the exact fiscal impact cannot be determined because the various employment and staffing characteristics and ratios for these OTPs, as well as what savings may result to an OTP from a pharmacist delegating one or more dispensing tasks to practitioners, is unknown and the relevant data is not available. The full fiscal impact on these non-small businesses is inestimable as it will depend on the unique individual characteristics of the delegating pharmacists and the delegatee practitioners, on the characteristics of the patients involved, the nature of each OTP, and on the number and type of individual dispensing tasks that are delegated and the manner in which these tasks are completed.

**E) Persons other than small businesses, non-small businesses, state, 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**):

This proposed new rule is expected to create a fiscal benefit for the approximately seven non-small business OTP facilities that employ pharmacists for dispensing (NAICS code 621420). However, the exact fiscal impact cannot be determined because the various employment and staffing characteristics and ratios for these OTPs, as well as what savings may result to an OTP from a pharmacist delegating one or more dispensing tasks to practitioners, is unknown and the relevant data is not available. The full fiscal impact on these non-small businesses is inestimable as it will depend on the unique individual characteristics of the delegating pharmacists and the delegatee practitioners, on the characteristics of the patients involved, the nature of each OTP, and on the number and type of individual dispensing tasks that are delegated and the manner in which these tasks are completed.

**F) Compliance costs for affected persons:**

No cost or saving impact is expected for affected persons above the impact described in the Fiscal Note for 2019 HB 398, available online at: <https://le.utah.gov/~2019/bills/static/HB0398.html>, as it merely clarifies the methadone dispensing procedures in accordance with the mandates of new Section 58-17b-309.7.

**G) Regulatory Impact Summary Table** (This table only includes fiscal impacts that could be measured. If there are inestimable fiscal impacts, they will not be included in this table. Inestimable impacts will be included in narratives above.)

**Regulatory Impact Summary Table**

<b>Fiscal Costs</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
State Government	\$75	\$0	\$0
Local Government	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Person	\$0	\$0	\$0
<b>Total Fiscal Costs:</b>	<b>\$75</b>	<b>\$0</b>	<b>\$0</b>
<b>Fiscal Benefits</b>			
State Government	\$0	\$0	\$0
Local Government	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
<b>Total Fiscal Benefits:</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>
<b>Net Fiscal Benefits:</b>	<b>\$(75)</b>	<b>\$0</b>	<b>\$0</b>

**H) Department head sign-off on regulatory impact:**

The head of the Department of Commerce, Francine Giani, has reviewed and approved this fiscal analysis.

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

After consultation with pharmacies, physicians, and practitioners who work in opioid treatment programs (OTPs) that dispense methadone, the Division proposes the new Section R156-17b-309.7 pursuant to Section 58-17b-309.7 enacted by 2019 HB 398. The new Section R156-17b-309.7 defines the OTPs processes for being "under the direction" of a pharmacist relating to delegations to the practitioner of the authority to perform dispensing tasks on behalf of the pharmacist under the general supervision of the pharmacist. This section also prohibits further delegation, or any expansion of the scope of a delegated task without the express permission of the pharmacist. This section is narrowly tailored so that there will be a limited fiscal impact to licensed pharmacists, APRNs, RNs and physician assistants. **Small Businesses:** This proposed rule has the potential to impact the approximately 100 small-business OTP facilities that employ pharmacists for dispensing (NAICS code 621420). However, the exact fiscal impact cannot be determined because the characteristics for these OTPs is unknown and the relevant data is not available. The full fiscal impact on small business is inestimable as it will depend on the individual characteristics of the delegating pharmacists and the delegatee practitioners, on the characteristics of the patients involved, the nature of each OTP, and on the number and type of individual dispensing tasks that are delegated and the manner in which these tasks are completed. **Non-Small Businesses:** This proposed new rule has the potential to affect approximately seven non-small business OTP facilities that employ pharmacists for dispensing (NAICS code 621420). However, the proposed amendments are not expected to result in any measurable fiscal impact for non-small business for the same reasons as described above for small business. These costs are either inestimable, for the reasons stated, or there is no fiscal impact.

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

Francine A. Giani, Executive Director

**Citation Information**

**7. 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):**

Section 58-17b-101  
Subsection 58-1-106(1)(a)

Subsection 58-17b-601(1)  
Subsection 58-1-202(1)(a)

Section 58-37-1

**Incorporations by Reference Information**

(If this rule incorporates more than two items by reference, please include additional tables)

**8. A) 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 Office of Administrative Rules; *if none, leave blank*):

**First Incorporation**

**Official Title of Materials  
Incorporated (from title page)**  
**Publisher**  
**Date Issued**  
**Issue, or version**

**B) 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 Office of Administrative Rules; *if none, leave blank*):

**Second Incorporation**

**Official Title of Materials  
Incorporated (from title page)**  
**Publisher**  
**Date Issued**  
**Issue, or version**

**Public Notice Information**

**9. 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** (mm/dd/yyyy): 12/31/2019

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

**On** (mm/dd/yyyy):  
12/3/2019

**At** (hh:mm AM/PM):  
11:00 AM

**At** (place):  
160 East 300 South, Conference Room  
474, Salt Lake City, Utah

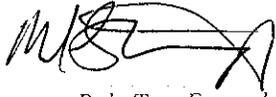
**10. This rule change MAY\* become effective on** (mm/dd/yyyy): 01/07/2020

\*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 10, the agency must submit a Notice of Effective Date to the Office 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.

**Agency Authorization Information**

**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 head or  
designee, and  
title:



Date  
(mm/dd/yyyy):  
11/14/2019

*Rule Text Example (Delete this line after entering your rule text)*

R156. Commerce, Occupational and Professional Licensing.

R156-17b. Pharmacy Practice Act Rule.

R156-17b-309.7. Exemptions from Licensure - Opioid Treatment Program.

(1) In accordance with Section 58-17-b-309.7 "under the direction of a pharmacist" means that the pharmacist has delegated to a licensed practitioner the authority to perform one or more selected dispensing tasks on behalf of the pharmacist:

(a) in accordance with all state and federal laws and rules; and

(b) under the general supervision of the pharmacist as defined in Subsection R156-1-102a(4)(c).

(2) Dispensing tasks that may be delegated include preparing, packaging, or labeling take-home dosages and medications for subsequent use.

(3) A delegating pharmacist retains accountability for the appropriate delegation of tasks and for the pharmaceutical care of the patient.

(4) A practitioner may not:

(a) further delegate to another person any task delegated to the practitioner by the pharmacist; or

(b) expand the scope of a delegated task without the express permission of the pharmacist.

KEY: pharmacists, licensing, pharmacies

Date of Enactment or Last Substantive Amendment: [~~December 27,~~  
2018]2020

Notice of Continuation: September 5, 2019

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)