

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:	40216	Date filed:	2-22-2016
State Admin Rule Filing Id:		Time filed:	
	Agency No.	Rule No.	Section No.
Utah Admin. Code Ref (R no.):	R 156	- 37	-
Changed to Admin. Code Ref. (R no.):	R	-	-

<b>1.</b>	<b>Agency:</b>	Commerce/Division of Occupational and Professional Licensing		
	<b>Room no.:</b>			
	<b>Building:</b>	Heber M. Wells Building		
	<b>Street address 1:</b>	160 East 300 South		
	<b>Street address 2:</b>			
	<b>City, state, zip:</b>	Salt Lake City UT 84111-2316		
	<b>Mailing address 1:</b>	PO Box 146741		
	<b>Mailing address 2:</b>			
	<b>City, state, zip:</b>	Salt Lake City UT 84114-6741		
	<b>Contact person(s):</b>			
	<b>Name:</b>	<b>Phone:</b>	<b>Fax:</b>	<b>E-mail:</b>
	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)

<b>2.</b>	<b>Title of rule or section (catchline):</b>	Utah Controlled Substances Act Rule		
<b>3.</b>	<b>Type of notice:</b>	New ___; Amendment XXX; Repeal ___; Repeal and Reenact ___		
<b>4.</b>	<b>Purpose of the rule or reason for the change:</b>	The Division and Utah State Board of Pharmacy reviewed this rule and determined the following changes need to be made. The purpose of this filing is to: (1) establish a time frame within which an applicant for a controlled substance license must obtain a Drug Enforcement Administration (DEA) registration; (2) establish criteria that exclude particular applicants from having to obtain a DEA registration; and (3) add failing to obtain a DEA registration in the specified time period to unprofessional conduct.		
<b>5.</b>	<b>This change is a response to comments from the Administrative Rules Review Committee.</b>	No XXX; Yes ___		

**6. Summary of the rule or change:**

Section 305, Paragraph (1): This new section is added to establish that an applicant for a controlled substance license must obtain a DEA registration within 120 days of the date the controlled substance license is issued unless the applicant is described in paragraph (2) of this section. Paragraph (2) is added to establish that an applicant who obtains the prior written consent of their employer to use the employer's hospital or institution DEA registration to administer and/or prescribe controlled substances, is not required to obtain an individual practitioner DEA registration. Section 306: This section is renumbered from R156-37-305 due to the addition of new section 305. Section 502: Paragraph (9) is added to include failing to obtain a DEA registration within the time frame established in Section R156-37-305 to unprofessional conduct.

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

**A) State budget:**

**Affected:**  No \_\_\_; Yes XXX

The Division will incur minimal costs of approximately \$75.00 to print and distribute the rule once the proposed amendments are made effective. Any costs incurred will be absorbed in the Division's current budget.

**B) Local government:**

**Affected:**  No XXX; Yes \_\_\_

The proposed amendments apply only to licensees provided in Title 58, Chapter 37. As a result, the proposed amendments do not apply to local governments.

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

**Affected:**  No XXX; Yes \_\_\_

The proposed amendments apply only to licensees provided in Title 58, Chapter 37. Licensees may work in a small business; however, the proposed amendments would not directly affect the business.

**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 XXX; Yes \_\_\_

The proposed amendments apply only to licensees provided in Title 58, Chapter 37. It is anticipated the proposed amendments should have no increased compliance cost or impact for individuals that obtain a controlled substance license and the corresponding DEA registration. No fiscal impact to other persons is anticipated.

**8. Compliance costs for affected persons:**

The proposed amendments apply only to licensees provided in Title 58, Chapter 37. It is anticipated the proposed amendments should have no increased compliance cost or impact for individuals that obtain a controlled substance license.

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

This rule change: establishes a time frame within which a controlled substance license applicant must obtain a DEA registration, establishes criteria that exclude certain applicants from having to obtain a DEA registration, and adds "failing to obtain a DEA registration within the specified time period" to the definition of unprofessional conduct. No fiscal impact to businesses is anticipated.

**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) :

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

Subsection 58-37-6(1)(a)

Subsection 58-37f-301(1)

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): 04/14/2016

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

On (mm/dd/yyyy):	At (hh:mm AM/PM):	At (place):
03/22/2016	8:30 AM	160 East 300 South, Conference Room 474, Salt Lake City, Utah

13 This rule change may become effective on (mm/dd/yyyy): 04/21/2016

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:

controlled substances	licensing

15 Attach an RTF document containing the text of this rule change (filename): R156-37.pro

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):	Feb 22 2016
-------------------------------------	---	--------------------	-------------

R156. Commerce, Occupational and Professional Licensing.

R156-37. Utah Controlled Substances Act Rule.

R156-37-305. Qualification for Licensure - Drug Enforcement Administration (DEA) Registration.

(1) An individual who obtains a controlled substance license except those individuals described in Subsection (2) below, shall obtain a DEA registration within 120 days of the date the controlled substance license is issued.

(2) Any controlled substance licensee who obtains prior written consent of the licensee's employer to use the employer's hospital or institution DEA registration to administer and/or prescribe controlled substances, is not required to obtain an individual practitioner DEA registration.

R156-37-[305]306. Exemption from Licensure - Law Enforcement Personnel, University Research, Narcotic Detection Training of Animals, and Animal Control.

In accordance with Subsection 58-37-6(2)(d), the following persons are exempt from licensure under Title 58, Chapter 37:

(1) Law enforcement agencies and their sworn personnel are exempt from the licensing requirements of the Controlled Substance Act to the extent their official duties require them to possess controlled substances; they act within the scope of their enforcement responsibilities; they maintain accurate records of controlled substances that come into their possession; and they maintain an effective audit trail. Nothing herein shall authorize law enforcement personnel to purchase or possess controlled substances for administration to animals unless the purchase or possession is in accordance with a duly issued controlled substance license.

(2) Individuals and entities engaged in research using pharmaceuticals as defined in Subsection 58-17b-102(65) within a research facility as defined in Subsection R156-17b-102(49).

(3) Individuals employed by a facility engaged in the following activities if the facility employing that individual has a controlled substance license in Utah, a DEA registration number, and uses the controlled substances according to a written protocol:

- (a) narcotic detection training of animals for law enforcement use;
- or
- (b) animal control, including:
    - (i) animal euthanasia; or
    - (ii) animal immobilization.

R156-37-502. Unprofessional Conduct.

"Unprofessional conduct" includes:

(1) a licensee with authority to prescribe or administer controlled substances:

(a) prescribing or administering to himself any Schedule II or III controlled substance that is not lawfully prescribed by another licensed

practitioner having authority to prescribe the drug;

(b) prescribing or administering a controlled substance for a condition he is not licensed or competent to treat;

(2) violating any federal or state law relating to controlled substances;

(3) failing to deliver to the Division all controlled substance license certificates issued by the Division to the Division upon an action that revokes, suspends or limits the license;

(4) failing to maintain controls over controlled substances that would be considered by a prudent practitioner to be effective against diversion, theft, or shortage of controlled substances;

(5) being unable to account for shortages of any controlled substance inventory for which the licensee has responsibility;

(6) knowingly prescribing, selling, giving away, or administering, directly or indirectly, or offering to prescribe, sell, furnish, give away, or administer any controlled substance to a drug dependent person, as defined in Subsection 58-37-2(1)(s), except for legitimate medical purposes as permitted by law;

(7) refusing to make available for inspection controlled substance stock, inventory, and records as required under this rule or other law regulating controlled substances and controlled substance records;

(8) failing to submit controlled substance prescription information to the database manager after being notified in writing to do so;

(9) failing to obtain a DEA registration within the time frame established in Section R156-37-305.

**KEY: controlled substances, licensing**

**Date of Enactment or Last Substantive Amendment: [~~February 24, 2015~~2016**

**Notice of Continuation: February 21, 2012**

**Authorizing, and Implemented or Interpreted Law: 58-1-106(1)(a); 58-37-6(1)(a); 58-37f-301(1)**