

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: **40928** Date filed: **11-1-2017**
State Admin Rule Filing Id: _____ Time filed: _____

	Agency No.	Rule No.	Section No.
Utah Admin. Code Ref (R no.):	R 156	- 37f	-
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:
Marvin Sims	801-530-6232	801-530-6511	msims@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):**
Controlled Substance Database Act Rule
3. **Type of notice:**
New ___; Amendment XXX; Repeal ___; Repeal and Reenact ___
4. **Purpose of the rule or reason for the change:**
H.B. 239, Access to Opioid Prescription Information via Practitioner Data Management Systems, passed during the 2016 General Session, required the division to make rules to limit access to and use of opioid prescription information in the Controlled Substance Database ("database") by an electronic data system, and by any prescriber, pharmacist, or other individual granted access to the database via an electronic data system ("EDS user"). These new rules accomplish that 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:

New Section R156-37f-302 clarifies that deposition testimony is included in the restrictions of Subsection 58-37f-302(2), prohibiting any individual or organization with lawful access to data from being compelled to testify regarding that data. New Section R156-37f-303 limits and protects access and use of opioid prescription information in the database by: (1) requiring an electronic data system accessing opioid prescription information to interface with the database through the Appriss Prescription Monitoring Program (PMP) Gateway system, and to comply with all other database access and use restrictions of the Controlled Substance Database Act and Controlled Substance Database Act Rule; (2) requiring an EDS user who is accessing opioid prescription information via an electronic data system to register with the database, to use the same personal identification number (PIN) number for all access, and to comply with all of the other access and use restrictions of the Controlled Substances Database Act and Controlled Substance Database Act Rule; and (3) establishing a proactive administrative action for the division, where the division may immediately suspend an electronic data system's or EDS user's access to the database without notice or opportunity to be heard, if the division determines such access may lead to an unlawful release or use of database information under Section 58-37f-601, or would otherwise compromise the integrity, privacy, or security of the database's opioid prescription information.

7. Aggregate anticipated cost or savings to:

A) State budget:

Affected: No ___; Yes XXXX

The Division will incur minimal costs of approximately \$75 to print and distribute the rules once the proposed rules are made effective. The cost to the state to implement the standards imposed by the proposed new rules are addressed in the fiscal note attached to H.B. 239. Any additional costs to the Department of Commerce and to the Division should be absorbed in their current budgets, because implementation will be handled within regular working hours and through existing vendors providing ongoing maintenance and support.

B) Local government:

Affected: No ___; Yes XXX

The proposed new rules may impact local governments if they need to upgrade their software to meet the new standards. Such costs, if any, should be minimal since any required changes should be absorbed through the support costs paid to the local government's computer software vendor for ongoing maintenance and support. The amount of any cost cannot be estimated as it will vary depending on circumstances.

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

Affected: No ___; Yes XXX

The proposed new rules will impact small-business pharmacies and prescribers who will be accessing the opioid prescription information in the database via electronic data systems. As addressed in the fiscal note attached to H.B. 239, the vendors for small business electronic data systems will need to work with Appriss on establishing connectivity to the PMP Gateway, and Appriss estimated that there will be a startup fee of \$7,500 and then a \$50 per year cost per prescriber. There may also be costs incurred by small business users to access this data via the Appriss PMP Gateway, once the system is up and running. However, access to the system by this method is voluntary. Additional costs will be incurred by small businesses that will need to further upgrade their software to meet the new standards, though such costs may be minimal since most of those changes should be absorbed through the support costs these pharmacies and prescribers already pay to their computer software vendors for ongoing maintenance and support. The proposed amendments may provide some cost savings for small-business pharmacies and prescribers if the new systems upgrade and streamline their work process. The exact amount of the costs, or of any savings, cannot be estimated as it will vary depending on circumstances. H.B. 239 required the division to prepare the improved system, but does not require health systems to use the improved system.

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 XXX

The anticipated costs and savings that apply to small businesses will also impact larger businesses accessing the database; they also will need to work with Appriss on establishing connectivity to the PMP Gateway, pay the startup fee and per-prescriber fee, and any Gateway data access fees. These larger businesses also may need to upgrade their software to meet the new standards, although such costs may be minimal since most changes should be absorbed through support costs they already pay to their computer software vendors for ongoing maintenance and support. The proposed amendments may provide some cost savings for larger pharmacies and prescribers if the new systems they implement upgrade and streamline their work process. The exact amount of the costs or of any savings to larger businesses cannot be estimated as it will vary from business to business depending on circumstances. Again, H.B. 239 required the division to prepare the improved system, but does not require health systems to use the improved system. There are no anticipated costs or savings to persons other than businesses, small businesses, and local government entities, as the new rules only implement procedures regarding database access for businesses and government entities.

8. Compliance costs for affected persons:

There are no anticipated compliance costs for affected persons, as the new rules only implement procedures regarding database access for businesses and government entities.

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

These new rules implement the mandate of the Legislature related to limiting access to and use of opioid prescription information in the Controlled Substance Database ("CSD") when accessed by electronic data system users (EDS users). The rules are required by H.B. 239, adopted in the 2016 legislative session. The use of an EDS to access the database is wholly voluntary, but requires the user to interface with the database through the Appriss Prescription Monitoring Program Gateway system. The current Appriss startup fee is \$7,500 with a \$50 per year cost per prescriber. This startup cost may be burdensome to certain small businesses and they may choose to access the database other than through an EDS.

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 58-37f-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): 12/15/2016

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

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:

controlled substance database

licensing

15 Attach an RTF document containing the text of this rule change (filename): R156-37f.PRO2

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: Mark B. Steinagel, Director

Date (mm/dd/yyyy) 11/01/2016

R156. Commerce, Occupational and Professional Licensing.

R156-37f. Controlled Substance Database Act Rule.

R156-37f-302. Other Restrictions on Access to Database.

Subsection 58-37f-302(2), which prohibits any individual or organization with lawful access to the data from being compelled to testify with regard to the data, includes deposition testimony.

R156-37f-303. Access to Opioid Prescription Information Via an Electronic Data System.

In accordance with Subsection 58-37f-301(1) and Section 58-37f-303:

(1) Pursuant to Subsection 58-37f-303(4)(a)(i), to access opioid prescription information in the database, an electronic data system just:

(a) interface with the database through the Appriss Prescription Monitoring Program (PMP) Gateway system; and

(b) comply with all restrictions on database access and use of database information, as established by the Utah Controlled Substances Database Act and the Controlled Substance Database Act Rule.

(2) Pursuant to Subsection 58-37f-303(4)(a)(ii), to access opioid prescription information in the database via an electronic data system, an EDS user must:

(a) register to use the database;

(b) use a unique personal identification number (PIN) that is identical to the PIN the EDS user was issued to access database information through the original internet access system;

(c) comply with all restrictions on database access established by the Utah Controlled Substance Database Act and the Controlled Substance Database Act Rule; and

(d) use opioid prescription information in the database only for the purposes and uses designated in Section 58-37f-201, and as more particularly described in the Utah Controlled Substances Database Act and the Controlled Substances Database Act Rule.

(3) The division may immediately suspend, without notice or opportunity to be heard, an electronic data system's or an EDS user's access to the database, if the division determines by audit or other means that such access may lead to a violation of Section 58-37f-601 or may otherwise compromise the integrity, privacy, or security of the database's opioid prescription information. This remedy shall be in addition to the criminal and civil penalties imposed by Section 58-37f-601 for unlawful release or use of database information, and the division's obligation under Subsections 58-37f-303(5) and (6) to immediately suspend or revoke database access and pursue appropriate corrective or disciplinary action against a non-compliant electronic data system or EDS user.

KEY: controlled substance database, licensing

Date of Enactment or Last Substantive Amendment: [~~January 7,~~]2016

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

301 (1)