

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* Sections 63-46a-4. 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:		Date filed:	
Utah Admin. Code ref. (R no.):	R156-37-609a	Time filed:	
Changed to Admin. Code Ref. (R no.):			

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:
	Laura Poe	801-530-6789	801-530-6511	lpoe@utah.gov

(Interested persons may inspect this filing at the above address or at DAR between 8:00 a.m. and 5:00 p.m. on business days.)

2.	Title of rule or section (catchline):
	Controlled Substance Database - Reporting Procedure and Format for Submission to the Database for Pharmacies and Pharmacy Groups Selected by the Division for the Real Time Pilot Program
3.	Type of notice:
	New ___; Amendment XX; Repeal ___; Repeal and Reenact ___
4.	Purpose of the rule or reason for the change:
	The Division is filing amendments to implement the data reporting rules for the Controlled Substance Databank Real Time Reporting Pilot Program.
5.	This change is a response to comments from the Administrative Rules Review Committee.
	Yes ___; No XX
6.	Summary of the rule change:
	Section 609a is amended to provide additional modes of electronic data transfer including email, compact discs, secured Internet transfer or FTP (File Transfer Protocol) site transfer. New paragraph (5) allows any pharmacy or pharmacy group within the state of Utah to participate in the pilot program as long as the participant is able to submit the data based upon information available at the time of dispensing to the ultimate user. Information would be transferred at the time the prescription is picked up (dispensed to) the customer and not at the time it was poured and packaged.
7.	Aggregate anticipated cost or savings to:
	A) State budget:

	<p>The Division will incur minimal costs of approximately \$50 to reprint the rule once the proposed amendments are made effective. Any costs incurred will be absorbed in the Division's current budget. The Division has been told by ITstaff that any of the changes needed within the current databank configuration can occur under the current budget and does not require additional monies to the Division.</p>	
	<p>B) Local government:</p>	
	<p>The only effect on local government would be if the government ran a pharmacy or pharmacy group that chooses to enter into the pilot program.</p>	
	<p>C) Small businesses (fewer than 50 employees) AND persons other than businesses:</p>	
	<p>Most non-chain pharmacies fall under the category of small business. Those pharmacies wishing to participate in this voluntary pilot program would need to have software that would track and record the data at the time the patient picks up the medication rather than most current systems which are based on downloading data based on the time the prescription is filled. Implementation of these proposed amendments will help those interested and able to participate in a daily reporting to the Controlled Substance Database. This is a voluntary system so those who do not have a system that will report pick up time do not have to make any changes in their system and simply would not need to participate. If the program ever becomes mandatory, some pharmacies would incur the cost of changes to their computer system to save and transfer information at the time the patient picks up the medication. It is unknown what those costs would be.</p>	
8.	<p>Compliance costs for affected persons ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization or any character other than an agency):</p>	
	<p>Most non-chain pharmacies fall under the category of small business. Those pharmacies wishing to participate in this voluntary pilot program would need to have software that would track and record the data at the time the patient picks up the medication rather than most current systems which are based on downloading data based on the time the prescription is filled. Implementation of these proposed amendments will help those interested and able to participate in a daily reporting to the Controlled Substance Database. This is a voluntary system so those who do not have a system that will report pick up time do not have to make any changes in their system and simply would not need to participate. If the program ever becomes mandatory, some pharmacies would incur the cost of changes to their computer system to save and transfer information at the time the patient picks up the medication. It is unknown what those costs would be.</p>	
9.	<p>Comments by the department head on the fiscal impact the rule may have on businesses:</p>	
	<p>No fiscal impact to businesses is anticipated with this rule filing, which further clarifies provisions regarding methods of transferring data into the Controlled Substance Database, as well as the time frames and formats for such transfer of data. Francine A. Giani, Executive Director</p>	
10.	<p>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):</p>	
	<p>Subsections 58-1-106(1)(a), 58-37-6(1)(a), 58-37-7.5(7)</p>	
11.	<p>This rule adds, updates, or otherwise changes the following titles of materials incorporated by references (a copy of materials incorporated by reference must be submitted to DAR; if none, leave blank):</p>	
	<p></p>	
12.	<p>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 <i>Utah State Bulletin</i>. See Section 63-46a-5 and Rule R15-1 for more information.)</p>	
	<p>A) Comments will be accepted until 5:00 p.m. on (mm/dd/yyyy):</p>	<p>04/14/2009</p>
	<p>B) A public hearing (optional) will be held:</p>	
	<p>on (mm/dd/yyyy):</p>	<p>at (time):</p>
	<p>03/24/2009</p>	<p>9:00 am</p>
	<p>At (place):</p>	
	<p>160 East 300 South, Conference Room 402 (4th floor), Salt Lake City, Utah</p>	

13.	This rule change may become effective on (mm/dd/yyyy):	04/21/2009	
	NOTE: The date above is the date on which this rule MAY become effective. It is <i>NOT</i> the effective date. After the date designated in Box 12(A) above, the agency <i>must</i> 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., "NASA") or proper nouns (e.g., "Medicaid")):		
	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 63-46a-4, 5, 6, and 10. Incomplete forms will be returned to the agency for completion, possibly delaying publication in the <i>Utah State Bulletin</i> , and delaying the first possible effective date.			
AGENCY AUTHORIZATION			
Agency head or designee, and title:	F. David Stanley, Director	Date (mm/dd/yyyy):	02/26/2009

R156. Commerce, Occupational and Professional Licensing.

R156-37. Utah Controlled Substances Act Rules.

R156-37-609a. Controlled Substance Database - Reporting Procedure and Format for Submission to the Database for Pharmacies and Pharmacy Groups Selected by the Division for the Real Time Pilot Program.

(1) In accordance with Subsection 58-37-7.8(8), the information required under Section 58-37-7.5 shall be submitted to the Division's database manager by licensees designated by the Division to participate in the real time reporting pilot program in the following format:

(a) electronic data via telephone modem [~~using the software provided by the Division or software approved by the Division~~]; and

(b) electronic data stored on floppy disk or compact discs (CD); [~~using the real time data transmission system established by the Division.~~]

(c) electronic data sent via electronic mail (e-mail) if encrypted and approved by the database manager;

(d) electronic data sent via a secured internet transfer methods, including, but not limited to, FTP site transfer and HyperSend; or

(e) any other electronic method preapproved by the database manager.

(2) Each pharmacy or pharmacy group shall enter and submit data required under Section 58-37-7.5 [~~as soon as the data is available to the pharmacy or pharmacy group~~] on a daily basis each day that the pharmacy or pharmacy group is open for business or the data reporting entity of the pharmacy or pharmacy group is open for business.

(3) The format for submission to the database shall be in accordance with the uniform formatting developed by the American Society for Automation in Pharmacy System (ASAP). The Division may approve alternative formats.

(4) The pharmacist-in-charge of each reporting pharmacy or pharmacy group shall be responsible for compliance with this rule.

(5) In accordance with Subsection 58-37-7.8(1)(a)(i), the pilot area is designated as the entire state of Utah. Any pharmacy or pharmacy group that submits information to the database based upon information available at the time of dispensing to the ultimate user is eligible and may participate in the Real Time Pilot Program.

KEY: controlled substances, licensing

Date of Enactment or Last Substantive Amendment: [~~September 9, 2008~~] **2009**

Notice of Continuation: March 15, 2007

Authorizing, and Implemented or Interpreted Law: 58-1-106(1)(a); 58-37-6(1)(a); 58-37-7.5(7)