

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: **39923** Date filed: **11-9-2016**
 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:**
The purpose of this filing is to (1) address changes made by H.B. 395 and S.B. 119 passed during the 2015 Legislative General Session; (2) incorporate changes recommended by the Controlled Substance Database (CSD) Administrator and the Pharmacy Licensing Board; and (3) to make technical changes.
- 5. This change is a response to comments from the Administrative Rules Review Committee.**
No XXX; Yes ___
- 6. Summary of the rule or change:**

Subsection R156-37f-203(1): This change allows for any version of the American Society for Automation in Pharmacy (ASAP) Telecommunications Format for Controlled Substances published by the American Society for Automation in Pharmacy to be used for submission, collection, and maintenance of CSD data. The current rule only allows for and incorporates by reference the ASAP Format, revised May 1995. The change also adds customer identification number and five digit zip code as CSD mandatory data fields. Subsection R156-37f-203(3): This change modifies and proscribes the method of submission of data to the CSD to be (1) electronic data sent via a secured internet transfer method, including sFTP site transfer; 2) a web base service; or (3) any other method approved by the Database manager prior to submission. Subsection R156-37f-203(5)(a): This change changes the time standard for submission to the CSD to either real time or daily batch file reporting, as required by statute, and specifies that submitted data shall be from the point of sale date. Subsection R156-37f-203(5)(b): This change deletes language that is unnecessary as it is adequately addressed by the modified language that follows in this Subsection by allowing for a waiver. Subsection R156-37f-203(5)(c): The current Subsection (c) renumbered as Subsection (5)(b). The change allows a Class A, B, or D pharmacy that has a controlled substance license but does not dispense and does not anticipate dispensing controlled substances, to request a waiver or submit a certification of such for null reporting. The Subsection currently only allows only a certification. The change replaces the method by which null reporting will be carried out. Section R156-37f-203(6): This subsection has become largely obsolete and is deleted from the section. Subsection 156-37f-301(4): This change implements the new statutory search warrant requirement for law enforcement access to the CSD. The rule change deletes the former case number of the investigation or prosecution standard for law enforcement accessed to the CSD. It also details how a search warrant may be submitted. Subsection R156-37f-301(5): This change implements the new statutory requirement to provide an accounting of persons or entities that have requested or received CSD information about an individual. Previously the rule prohibited such an accounting. The change specifies how an individual may submit such a request and the required content of a request. It also addresses how the accounting may be disseminated. Section R156-37f-801a: This section is now obsolete and is deleted from the rule. Section R156-37f-801b: This section is now obsolete and is deleted from the rule.

7. Aggregate anticipated cost or savings to:

A) State budget:

Affected: No ; Yes

The change to real time reporting or daily batch reporting was required by statute and the cost was addressed by fiscal note during the 2015 Legislative General Session. Such reporting will allow users of the CSD to have more current data, which will assist users of the CSD to better prevent, control, and address controlled substance abuse. These costs and cost savings to all who are impacted cannot be estimated. Implementation of various rule changes will result in a cost savings to the Division of Occupational and Professional Licensing with regard to the cost of paper and toner. These savings will be minimal and cannot be estimated. The rules will have to be reprinted and distributed at an approximate cost of \$50. Any printing and distribution costs incurred will be absorbed in the Division's current budget.

B) Local government:

Affected: No ; Yes

The Division anticipates the proposed amendments would not apply to local governments and therefore the Division now anticipates there are no costs or savings to local governments beyond what may have been included in fiscal notes during the 2015 Legislative General Session with respect to HB 395 and SB 119.

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

Affected: No ; Yes

The change to real time reporting or daily batch reporting was required by statute and the cost was addressed by fiscal note. Such reporting will allow users of the CSD to have more current data, which will assist users of the CSD to better prevent, control, and address controlled substance abuse. These costs and cost savings to all who are impacted cannot be estimated. Implementation of various rule changes will save resources at the pharmacies that qualify as small businesses with regard to the cost of paper and toner. The savings will be minimal and cannot be estimated.

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

The change to real time reporting or daily batch reporting was required by statute and the cost was addressed by fiscal note. Such reporting will allow users of the CSD to have more current data, which will assist users of the CSD to better prevent, control, and address controlled substance abuse. These costs and cost savings to all who are impacted cannot be estimated.

8. Compliance costs for affected persons:

The change to real time reporting or daily batch reporting was required by statute and the cost was addressed by fiscal note. Such reporting will allow users of the CSD to have more current data, which will assist users of the CSD to better prevent, control, and address controlled substance abuse. These costs and cost savings to all who are impacted cannot be estimated. Implementation of various rule changes will save resources at the pharmacy and state levels in the cost of paper and toner. The savings will be minimal and cannot be estimated.

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

As stated in the rule analysis, this filing updates this rule section to address changes made by House Bill 395 and Senate Bill 119, passed in the 2015 Legislative Session; makes changes recommended by the Controlled Substance Database Administrator and the Pharmacy Licensing Board, and makes technical changes. This rule change will impact some pharmacies or pharmacy groups because of the requirement for real-time reporting or daily batch reporting, replacing the previous weekly-reporting requirement.

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)	ASAP Telecommunications Format for Controlled Substances	
Publisher	American Society for Automation in Pharmacy (ASAP)	
Date Issued		
Issue, or version	May 1995	
ISBN Number (optional)		
ISSN Number (optional)		
Cost of Incorporated Reference		
Action: Adds, updates, or removes	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):

12/31/2015

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

On (mm/dd/yyyy):

At (hh:mm AM/PM):

At (place):

12/15/2015

10:30 AM

160 East 300 South, Conference Room 474
(4th floor), Salt Lake City, Utah

13 This rule change may become effective on (mm/dd/yyyy): 01/07/2016

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.

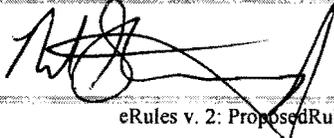
14 Indexing information -- keywords (maximum of four, in lower case, except for acronyms (e.g., "GRAMA") or proper nouns (e.g., "Medicaid")); may not include the name of the agency:
controlled substance database licensing

15 Attach an RTF document containing the text of this rule change (filename): R156-37f.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): 11/9/2015

R156. Commerce, Occupational and Professional Licensing.

R156-37f. Controlled Substance Database Act Rule.

R156-37f-203. Submission, Collection, and Maintenance of Data.

(1) The format used as a guide for submission to the Database shall be in accordance with any version of the ASAP Telecommunications Format for Controlled Substances published by the American Society for Automation in Pharmacy [~~revised May 1995 (ASAP Format), which is hereby incorporated by reference~~]. The Division may approve alternative formats substantially similar to this standard. This standard is further classified by the Database as follows:

(a) Mandatory Data. The following Database data fields are mandatory:

- (i) pharmacy NABP or NCPDP number;
- (ii) customer identification number;
- (~~iii~~) iii) patient birth date;
- (~~iii~~) iv) patient gender code;
- (~~iv~~) v) date filled;
- (v) Rx number;
- (vii) new-refill code;
- (viii) metric quantity;
- (~~viii~~) ix) days supply;
- (~~ix~~) x) NDC number;
- (xi) prescriber identification number;
- (xii) date Rx written;
- (xiii) number refills authorized;
- (~~xiii~~) xiv) patient last name;
- (~~xiv~~) xv) patient first name; and
- (xvi) patient street address [~~, including zip code (extended)~~];
- (xvii) five digit zip code.

(b) Preferred Data. The following Database data fields are strongly suggested:

- (i) [~~customer identification number;~~
- ~~(ii)~~] compound code;
- (ii~~+~~) DEA suffix;
- (~~iv~~) iii) Rx origin code;
- (iv) customer location;
- (v~~+~~) alternate prescriber number; and
- (vi~~+~~) state in which the prescription is filled.

(c) Optional Data. All other data fields in the ASAP Format not included in Subsections (a) and (b) are optional.

(2) Upon request, the Division will consider approving alternative formats, or adjustments to the ASAP Format, as might be necessary due to the capability or functionality of Database collection instruments. A proposed alternative format shall contain all mandatory data elements.

(3) In accordance with Subsection 58-37f-203(1)(~~c~~)a), the data required in Subsection (1) shall be submitted to the Database through one of the following methods:

(a) electronic data sent via a secured internet transfer method, including sFTP site transfer; [telephone modem];

~~(b) secure web base service; or [electronic data submitted on floppy disk or compact disc (CD);]~~

~~(c) any other electronic method approved by the Database manager prior to submission. [if approved by the Database staff prior to submission, electronic data sent via encrypted electronic mail (e-mail);~~

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

~~(e) any other electronic method approved by the Database manager prior to submission.~~

~~(4) The required information may be submitted on paper if:~~

~~(a) the pharmacy or pharmacy group submits a written request to the Division and receives prior approval for a paper submission, and~~

~~(b) (i) the pharmacy or pharmacy group has no computerized record keeping system upon which the data can be electronically recorded; or~~

~~(ii) The pharmacy or pharmacy group is unable to conform its submission(s) to an electronic format without incurring undue financial hardship.]~~

(4) In accordance with Subsection 58-37f-203(1) (a):

~~[(+5)] (a) Effective January 1, 2016, each [Each] pharmacy or pharmacy group shall submit [all-] data collected on a daily basis either in real time or daily batch file reporting [at least once every seven days on a weekly reporting cycle established by the pharmacy]. The submitted data shall be from the point of sale (POS) date.~~

~~(i) If the data is submitted by a single pharmacy entity, the data shall be submitted in chronological order according to the date each prescription was filled.~~

~~(ii) If the data is submitted by a pharmacy group, the data is required to be sorted by individual pharmacy within the group, and the data of each individual pharmacy within the group is required to be submitted in chronological order according to the date each prescription was filled.~~

~~[~~(b) (i) A Class A, B, or D pharmacy or pharmacy group that has a controlled substance license but has not dispensed a controlled substance during the preceding seven days shall:~~~~

~~(A) submit a null report stating that no controlled substance was dispensed during the preceding seven days; or~~

~~(B) comply with this Subsection (5) (c).~~

~~(ii) A null report may be submitted on paper without prior approval of the Division. The Division shall facilitate electronic null reporting as resources permit.]~~

~~[(c) (b) (i) A Class A, B, or D pharmacy or pharmacy group that has a controlled substance license but is not dispensing controlled substances and does not anticipate doing so in the immediate future may request a waiver or submit a certification of such, in a form preapproved by the Division, in lieu of [weekly] daily null reporting.~~

~~(ii) The waiver or certification must be resubmitted at the end of~~

each calendar year.

(iii) If a pharmacy or pharmacy group that has submitted a waiver or certification under this Subsection (5)([c]b) dispenses a controlled substance:

(A) the waiver or certification shall immediately and automatically terminate;

(B) the pharmacy or pharmacy group shall provide written notice of the waiver or certification termination to the Division within seven days of dispensing the controlled substance; and

(C) the Database reporting requirements shall be applicable to the pharmacy or pharmacy group immediately upon the dispensing of the controlled substance. [

~~(6) The pharmacist-in-charge, or his or her designee, for each reporting pharmacy shall submit its report, regardless of the reporting method, on a data transmission form (DTF) substantially equivalent to the DTF approved by the Division. The DTF may be mailed, faxed, emailed, or electronically uploaded to the Database. A copy of the DTF is required to be kept at the pharmacy unless an alternate location has been designated by the reporting pharmacy and approved by the Division. The DTF shall include the following information:~~

~~(a) pharmacy name;~~

~~(b) pharmacy facsimile (fax) and voice phone numbers;~~

~~(c) pharmacy e-mail address;~~

~~(d) pharmacy NABP/NCPDP number;~~

~~(e) period of time covered by each submission of data;~~

~~(f) number of prescriptions in the submission;~~

~~(g) submitting pharmacist's signature attesting to the accuracy of the report; and~~

~~(h) date of the report submission.]~~

R156-37f-301. Access to Database Information.

In accordance with Subsections 58-37f-301(1)(a) and (b):

(1) The Division Director [~~shall~~may] designate [~~in writing~~] those individuals employed by the Division who [~~shall~~may] have access to the information in the Database (Database staff).

(2) (a) A request for information from the Database may be made:

(i) directly to the Database by electronic submission, if the requester is registered to use the Database; or

(ii) by oral or written submission to the Database staff, if the requester is not registered to use the Database.

(b) An oral request may be submitted by telephone or in person.

(c) A written request may be submitted by facsimile, email, regular mail, or in person except as otherwise provided herein.

(d) The Division may in its discretion require a requestor to verify the requestor's identity.

(3) The following Database information may be disseminated to a verified requestor who is permitted to obtain the information:

- (a) dispensing/reporting pharmacy ID number/name;
- (b) subject's birth date;
- (c) date prescription was filled;
- (d) prescription (Rx) number;
- (e) metric quantity;
- (f) days supply;
- (g) NDC code/drug name;
- (h) prescriber ID/name;
- (i) date prescription was written;
- (j) subject's last name;
- (k) subject's first name; and
- (l) subject's street address;

(4) (a) Federal, state and local law enforcement authorities and state and local prosecutors requesting information from the Database under Subsection 58-37f-301(2) ([d]k) must provide a valid [case number of the investigation or prosecution.] search warrant authorized by the courts and may be provided using one of the following methods:

- (i) in person;
- (ii) be email to csdb@utah.gov;
- (iii) facsimile; or
- (iv) U.S. Mail.

(b) Information in the search warrant should be limited to subject's name and birth date.

(c) Information provided as a result of the search warrant shall be in accordance with Subsection (3).

(5) (a) An individual [whose records are contained within the Database] may [not] receive an accounting of persons or entities that have requested or received Database information about the individual.

(b) An individual may request the information in person or in writing by the following means:

- (i) email;
- (ii) facsimile; or
- (iii) U.S. Mail.

(c) The request for information shall include the following:

- (i) individuals' full name, including all aliases;
- (ii) birth date;
- (iii) home address;
- (iv) government issued identification; and
- (v) date-range.

(d) The results may be disseminated in accordance with Subsection (14).

(6) An individual whose records are contained within the Database may obtain his or her own information and records by:

(a) personally appearing before the Database staff with government-issued picture identification confirming the requester's identity; or

(b) submitting a signed and notarized request that includes the requester's:

- (i) full name;
- (ii) complete home address;
- (iii) date of birth; and
- (iv) driver license or state identification card number.

(7) A requester holding power of attorney for an individual whose records are contained within the Database may obtain the individual's information and records by:

- (a) personally appearing before the Database staff with government-issued picture identification confirming the requester's identity; and
- (b) providing:
 - (i) an original, properly executed power of attorney designation; and
 - (ii) a signed and notarized request, executed by the individual whose information is contained within the Database, and including the individual's:

- (A) full name;
- (B) complete home address;
- (C) date of birth; and
- (D) driver license or state identification card number verifying the individual's identity.

(8) A requestor who is the legal guardian of a minor or incapacitated individual whose records are contained within the Database may obtain the individual information and records by:

- (a) personally appearing before the Database staff with government-issued picture identification confirming the requester's identity;

(b) submitting the minor or incapacitated individual's:

- (i) full name;
- (ii) complete home address;
- (iii) date of birth; and
- (iv) if applicable, state identification card number verifying the individual's identity; and

(c) submitting legal proof that the requestor is the guardian of the individual who is the subject of the request for information from the Database.

(9) A requestor who has a release-of-records from an individual whose records are contained within the Database may obtain the individual's information and records by:

(a) submitting a request in writing;

(b) submitting an original, signed and notarized release-of-records in a format acceptable to the Database staff, identifying the purpose of the release; and

(c) submitting the individual's:

- (i) full name;
- (ii) complete home address;
- (iii) telephone number;
- (iv) date of birth; and

(v) driver license or state identification card number verifying the identity of the person who is the subject of the request.

(10) An employee of a licensed practitioner who is authorized to prescribe controlled substances may obtain Database information to the extent permissible under Subsection 58-37f-301(2)(d) if, prior to making the request:

(a) the licensed practitioner has provided to the Division a written designation that includes the designating practitioner's DEA number and the designated employee's:

- (i) full name;
- (ii) complete home address;
- (iii) e-mail address;
- (iv) date of birth; and
- (v) driver license number or state identification card number;

(b) the designated employee has registered for an account for access to the Database and provided a unique user identification [~~and password~~];

(c) the designated employee has passed a Database background check of available criminal court and Database records; and

(d) the Database has issued the designated employee a user personal identification number (PIN) and activated the employee's Database account.

(11) An employee of a business that employs a licensed practitioner who is authorized to prescribe controlled substances may obtain Database information to the extent permissible under Subsection 58-37f-301(2)(d) if, prior to making the request:

(a) the licensed practitioner and employing business have provided to the Division a written designation that includes:

- (i) the designating practitioner's DEA number;
- (ii) the name of the employing business; and
- (iii) the designated employee's:

- (A) full name;
- (B) complete home address;
- (C) e-mail address;
- (D) date of birth; and
- (E) driver license number or state identification card number;

(b) the designated employee has registered for an account for access to the Database and provided a unique user identification and password;

(c) the designated employee has passed a Database background check of available criminal court and Database records; and

(d) the Database has issued the designated employee a user personal identification number (PIN) and activated the employee's Database account.

(12) An individual who is employed in the emergency room of a hospital that employs a licensed practitioner who is authorized to prescribe controlled substances may obtain Database information to the extent permissible under Subsection 58-37f-301(2)(d) if, prior to making the request:

(a) the practitioner and the hospital operating the emergency room have provided to the Division a written designation that includes:

- (i) the designating practitioner's DEA number;
- (ii) the name of the hospital;

- (iii) the names of all emergency room practitioners employed at the hospital; and
 - (iv) the designated employee's:
 - (A) full name;
 - (B) complete home address;
 - (C) e-mail address;
 - (C) date of birth; and
 - (D) driver license number or state identification card number;
 - (b) the designated employee has registered for an account for access to the Database and provided a unique user identification and password;
 - (c) the designated employee has passed a Database background check of available criminal court and Database records; and
 - (d) the Database has issued the designated employee a user personal identification number (PIN) and activated the employee's Database account.
- (13) The Utah Department of Health may access Database information for purposes of scientific study regarding public health. To access information, the scientific investigator shall:
- (a) demonstrate to the satisfaction of the Division that the research is part of an approved project of the Utah Department of Health;
 - (b) provide a description of the research to be conducted, including:
 - (i) a research protocol for the project; and
 - (ii) a description of the data needed from the Database to conduct that research;
 - (c) provide assurances and a plan that demonstrates all Database information will be maintained securely, with access being strictly restricted to the requesting scientific investigator;
 - (d) provide for electronic data to be stored on a secure database computer system with access being strictly restricted to the requesting scientific investigator; and
 - (e) pay all relevant expenses for data transfer and manipulation.
- (14) Database information that may be disseminated under Section 58-37f-301 may be disseminated by the Database staff either:
- (a) verbally;
 - (b) by facsimile;
 - (c) by email;
 - (d) by U.S. mail; or
 - (e) where adequate technology is in place to ensure that a record will not be compromised, intercepted, or misdirected, by electronic access.

~~[R156-37f-801a. Reporting of Information by Pharmacies Participating in the Pilot Program for Real-time Reporting.~~

~~(1) In accordance with Subsection 58-37f-801(1)(a), the pilot area is designated as the entire state of Utah. Any pharmacy or pharmacy group that submits information to the Database is eligible and may participate in the Real-time Pilot Program.~~

~~(2) In accordance with Subsection 58-37f-801(8), each licensed pharmacy participating in the pilot program for real-time reporting shall,~~

~~in conjunction with controlled substance point of sale, submit from the pharmacy's database to the Controlled Substance Database, the information required by Section 58-37f-203 as implemented by Section R156-37f-203, through real-time interface and reporting software developed by the Division's contract provider.~~

~~**R156-37f-801b. Access to Information in the Database Submitted by Pharmacies Participating in the Pilot Program for Real-time Reporting.**~~

~~— In accordance with Subsection 58-37f-801(8), access to information in the Database submitted by pharmacies participating in the pilot program for real-time reporting shall be the same as set forth in Section 58-37f-301 as implemented by Section R156-37f-301.]~~

KEY: controlled substance database, licensing

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

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