

R156. Commerce, Occupational and Professional Licensing.

R156-37f. Controlled Substance Database Act Rule.

R156-37f-101. Title.

This rule shall be known as the "Controlled Substance Database Act Rule".

R156-37f-102. Definitions.

In addition to the definitions in Sections 58-17b-102, 58-37-2 and 58-37f-102, as used in this chapter:

- (1) "ASAP" means the American Society for Automation in Pharmacy system.
- (2) "DEA" means Drug Enforcement Administration.
- (3) "NABP" means the National Association of Boards of Pharmacy.
- (4) "NCPDP" means National Council for Prescription Drug Programs.
- (5) "NDC" means National Drug Code.
- (6) "Positive identification" means:
 - (a) one of the following photo identifications issued by a foreign or domestic government:
 - (i) driver's license;
 - (ii) non-driver identification card;
 - (iii) passport;
 - (iv) military identification; or
 - (v) concealed weapons permit; or
 - (b) if the individual does not have government-issued identification, alternative evidence of the individual's identity as deemed appropriate by the pharmacist, as long as the pharmacist documents in a prescription record a description of how the individual was positively identified.
- (7) "Research facility" means a facility in which research takes place that has policies and procedures describing such research.
- (8) "Rx" means a prescription.

R156-37f-103. Authority - Purpose.

This rule is adopted by the Division under the authority of Subsection 58-1-106(1)(a) to enable the Division to administer Title 58, Chapter 37f.

R156-37f-104. Organization - Relationship to Rule R156-1.

The organization of this rule and its relationship to Rule R156-1 is as described in Section R156-1-107.

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. 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) patient birth date;
 - (iv) patient gender code;
 - (v) date filled;
 - (vi) Rx number;
 - (vii) new-refill code;
 - (viii) metric quantity;
 - (ix) days supply;
 - (x) NDC number;
 - (xi) prescriber identification number;
 - (xii) date Rx written;
 - (xiii) number refills authorized;
 - (xiv) patient last name;
 - (xv) patient first name; and
 - (xvi) patient street address;
 - (xvii) five digit zip code.
- (b) Preferred Data. The following Database data fields are strongly suggested:
 - (i) compound code;
 - (ii) DEA suffix;

- (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)(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;;
- (b) secure web base service; or
- (c) any other electronic method approved by the Database manager prior to submission.

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

(a) Effective January 1, 2016, each pharmacy or pharmacy group shall submit data collected on a daily basis either in real time or daily batch file reporting. 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 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 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)(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.

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

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

(1) The Division Director may designate those individuals employed by the Division who 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)(k) must provide a valid 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 may 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;
- (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.

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CONTROLLED SUBSTANCE DATABASE ACT RULE

R156-37f
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