NOTICE OF EMERGENCY (120-DAY) RULE		
Utah Admin. Code Ref (R no.):	**R156-37f-203**	**Filing ID: 54209**

Agency Information

1. Department:	Commerce	
Agency:	Occupational and Professional Licensing	
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Please address questions regarding information on this notice to the agency.		

General Information

2. Rule or section catchline:

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

3. Effective Date (mm/dd/yyyy)**:**

01/01/2022

4. Purpose of the new rule or reason for the change (Why is the agency submitting this filing?)**:**

This filing adds a new subsection into the data reportable under Subsection R156-37f-203(4) to change the ASAP 4.2 field known as DSP12 (Transmission Form of Rx Origin Code) from a situation field that is reported voluntarily to a required field that cannot be null.

5. Summary of the new rule or change (What does this filing do?)**:**

New Subsection R156-37f-203(4)(z) is added to provide that the pharmacist shall provide the data field "origin code of how the pharmacy received the prescription (DSP12)."

6. A) The agency finds that regular rulemaking would:

X	cause an imminent peril to the public health, safety, or welfare;
	cause an imminent budget reduction because of budget restraints or federal requirements; or
	place the agency in violation of federal or state law.

B) Specific reasons and justifications for this finding:

The Utah Controlled Substance Database (CSD) tracks and collects data on the dispensing of known addictive drugs by most hospitals and pharmacies as a state-level intervention to improve opioid prescribing, inform clinical practice, and protect patients from harm. A review of the CSD's required ASAP 4.2 fields by DOPL's new CSD manager and newly hired Public Health Policy Manager indicates that when Utah's new e-prescribing statute will go into effect on 01/01/2022, it will be necessary to require the DSP12 field beginning on that date to accurately track e-prescribing data in relation to cases of drug over-utilization, misuse, and over-prescribing.

Fiscal Information

7. Provide an estimate and written explanation of the aggregate anticipated cost or savings to:

A) State budget:

There is no aggregate anticipated cost or savings to the state budget, as this amendment will simply allow the CSD to gather the DSP12 field data on a mandatory rather than a situational basis for better tracking of addictive substance prescriptions.

B) Local governments:

There is no aggregate anticipated cost or savings to local governments because local governments are not required to comply with or enforce this rule.

C) Small businesses ("small business" means a business employing 1-49 persons)**:**

The proposed amendment will affect controlled substance prescribers and pharmacies who dispense controlled substances, (North American Industry Classification System (NAICS) 446110, 621399, 621112, 621111, 621330, 622110, 622310, 621493,

623220, 621420, 621420, and 623110), but the amendment is expected to have no measurable impact on these small businesses' revenues or expenditures as they are already subject to reporting the ASAP 4.2 DSP12 origin code on a situational basis, and any increase in time for a required report would be limited to dispensers who are not already reporting this data, and funding for electronic health records and pharmaceutical dispensing software has been available through Centers for Medicare and Medicaid Services since 2006. Additionally, any increase in cost for those not reporting at this time is inestimable as it would be based on the time spent to look at the prescription and add the applicable code and would only affect those who have such information to report, so it will vary based on the dispensing and the individual reporting and this data is unavailable.

D) Persons other than small businesses, non-small businesses, state, 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***)**:**

The proposed amendment will affect controlled substance prescribers and pharmacies who dispense controlled substances, but the amendment is expected to have no measurable impact on these affected persons' revenues or expenditures as they are already subject to reporting the ASAP 4.2 DSP12 origin code on a situational basis, and any increase in time for a required report would be limited to dispensers who are not already reporting this data, and funding for electronic health records and pharmaceutical dispensing software has been available through Centers for Medicare and Medicaid Services since 2006. Additionally, any increase in cost for those not reporting at this time is inestimable as it would be based on the time spent to look at the prescription and add the applicable code and would only affect only those who have such information to report, so it will vary based on the dispensing and the person reporting and this data is unavailable.

E) Compliance costs for affected persons (How much will it cost an impacted entity to adhere to this rule or its changes?)**:**

As described for other persons in Box 7(D) above, no compliance costs are expected for affected persons.

F) Comments by the department head on the fiscal impact this rule may have on businesses (Include the name and title of the department head):

The Division of Occupational and Professional Licensing (Division) proposes an emergency amendment to the Controlled Substance Database Act Rule. The Utah CSD tracks and collects data on the dispensing of known addictive drugs by hospitals and pharmacies as a state-level intervention to improve opioid prescribing, inform clinical practice, and protect patients from harm. The CSD Manager and Public Health Policy Manager indicate that when Utah's new e-prescribing statute will go into effect on 01/01/2022, it will be necessary to require the "DSP12" field in the database beginning on that date to accurately track e-prescribing data in relation to cases of drug over-utilization, misuse, and over-prescribing.

Small Businesses: The Division does not foresee any foreseeable impact on small businesses since this amendment is made to make the rule comport to necessary requirements. Thus, the fiscal impacts cannot be estimated due to the lack of data necessary for such a calculation.

Regulatory Impact to Non-Small Businesses: This change will have no expected fiscal impact for non-small businesses in Utah for the same rationale as described above for small businesses. These costs are either inestimable, for the reasons stated above, or there is no fiscal impact.

Margaret W. Busse, Executive Director

Citation Information

8. Provide citations to the statutory authority for the rule. If there is also a federal requirement for the rule, provide a citation to that requirement:		
Subsection 58-1-106(1)(a)	Subsection 58-37f-301(1)	

Agency Authorization Information

Agency head or designee, and title:	Mark B. Steinagel, Division Director	**Date** (mm/dd/yyyy)**:**	12/13/2021

R156. Commerce, Occupational and Professional Licensing.
R156-37f. Controlled Substance Database Act Rule.
R156-37f-203. Submission, Collection, and Maintenance of Data.

(1) Under Subsection 58-37f-203(1), each pharmacy or pharmacy group shall submit the data required in this section on a daily basis, either in real time or daily batch file reporting. The submitted data shall be from the point of sale date.

(a) 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 sold.

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

(2) Under Subsections 58-37f-203(2), (3), and (6), the data required by this section 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) another electronic method approved by the Database administrator prior to submission.

(3) Under Subsections 58-37f-203(2), (3), and (6), the format for submission to the Database shall be Version 4.2 of the ASAP Format for Controlled Substances. The Division may approve alternative formats substantially similar to this standard.

(4) Under Subsection 58-37f-203(6), the pharmacist-in-charge and the pharmacist identified in Subsections 58-37f-203(2) and (3) shall provide the following data fields to the Division:

(a) version of ASAP used to send transaction (ASAP 4.2 code TH01);
(b) transaction control number (TH02);
(c) date transaction created (TH05);
(d) time transaction created (TH06);
(e) file type (production or test) (TH07);
(f) segment terminator character (TH09);
(g) information source identification number (IS01);
(h) information source entity name (IS02);
(i) reporting pharmacy's:
(i) National Provider Identifier (PHA01); and
(ii) identifier assigned by NCPDP or NABP (PHA02), or if none, then DEA registration number (PHA03);
(j) patient last name (PAT07);
(k) patient first name (PAT08);
(l) patient address (PAT12);
(m) patient city of residence (PAT14);
(n) patient zip code (PAT 16);
(o) patient date of birth (PAT18);
(p) dispensing status - new, revised, or void (DSP01);
(q) prescription number (DSP02);
(r) date prescription written by prescriber (DSP03);
(s) number of refills authorized by prescriber (DSP04);
(t) date prescription filled at dispensing pharmacy (DSP05);
(u) if current dispensed prescription is a refill, the number of the refill being dispensed (DSP06);
(v) product identification qualifier (DSP07);
(w) NDC 11-digit drug identification number (DSP08);
(x) quantity of drug dispensed in metric units (DSP09);
(y) days supply dispensed (DSP10);
(z) origin code of how the pharmacy received the prescription (DSP12);
([~~z~~]aa) date drug left the pharmacy, meaning date sold (DSP17);
([~~aa~~]bb) DEA registration number of prescribing practitioner (PRE02);
([~~bb~~]cc) state that issued identification of individual picking up dispensed drug (AIR03);
([~~cc~~]dd) type of identification used by individual picking up dispensed drug (AIR04);
([~~dd~~]ee) identification number of individual picking up dispensed drug (AIR05);
([~~ee~~]ff) last name of individual picking up dispensed drug (AIR07);
([~~ff~~]gg) first name of individual picking up dispensed drug (AIR08);
([~~gg~~]hh) dispensing pharmacist last name or initial (AIR09);
([~~hh~~]ii) dispensing pharmacist first name (AIR10);
([~~ii~~]jj) number of detail segments included for the pharmacy (TP01);
([~~jj~~]kk) transaction control number (TT01); and
([~~kk~~]ll) total number of segments included in the transaction (TT02).

(5) Under Subsection 58-37f-203(6), if no controlled substance required to be reported has been dispensed since the previous submission of data, then the pharmacist-in-charge and the pharmacist shall submit a zero report to the Division, which shall include the following data fields:

(a) version of ASAP used to send transaction (TH01);
(b) transaction control number (TH02);
(c) date transaction created (TH05);
(d) time transaction created (TH06);
(e) file type (production or test) (TH07);
(f) segment terminator (TH09);
(g) information source identification number (IS01);
(h) information source entity name (IS02);
(i) date range (IS03);
(j) reporting pharmacy's:
(i) National Provider Identifier (PHA01); and
(ii) identifier assigned by NCPDB or NABP (PHA02), or if none, then DEA registration number (PHA03);
(k) patient last name [=]- "Report" (PAT07);
(l) patient first name [=]- "Zero" (PAT08);
(m) date prescription dispensed at dispensing pharmacy (DSP05);
(n) number of detail segments included for the pharmacy (TP01);
(o) transaction control number (TT01); and
(p) total number of segments included in the transaction (TT02).

(6) Under Subsection 58-37f-203(2), a Class A, B, D, or E 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, in a form preapproved by the Division, in lieu of daily zero reports:

(a) The pharmacy or pharmacy group shall renew its waiver or certification at the end of each calendar year.
(b) If a pharmacy or pharmacy group with a current waiver or certification dispenses a controlled substance:

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

(ii) the Database reporting requirements of Subsections 58-37f-203(1) and R156-37f-203(1) shall apply to the pharmacy or pharmacy group immediately upon the dispensing of the controlled substance; and

(iii) the pharmacy or pharmacy group shall notify the Division in writing of the waiver or certification termination within 24 hours or the next business day of the dispensing of the controlled substance, whichever is later.

(7) The Database shall collect information regarding the prescription noncontrolled substance 1-(Aminomethyl)-cyclohexaneacetic acid (Gabapentin), in accordance with Subsection 58-37f-203(8).

(8) The Database shall collect information regarding "any substance which contains any quantity of a derivative of barbituric acid or any salt of any of them" (Butalbital), in accordance with Subsection 58-37-4(2)(c)(ii) which designates this as a Schedule III controlled substance.

KEY: controlled substance database, licensing
Date of Last Change: January 1, 2022
Notice of Continuation: December 21, 2017
Authorizing, and Implemented or Interpreted Law: 58-1-106(1)(a); 58-37f-301(1)

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