

Pharmacy Board Report  
September 2015

	2013	2014	2015	Sep-15
Administrative Filings	37	52	29	2
Criminal Filing/Felony	3	0	1	1
Letter of Concern	60	146	69	4
Referred to Diversion	1	2	0	0
PR/Outreach	3	4	0	1
Cases Received	710	567	445	46
Case Assigned	676	555	440	46
Closed Cases	731	595	417	45
Citations Issued	103	60	55	2
Pharmacy Inspections	225	335	189	25
Pharmacy Alerts	191	261	165	14
Dr. Shopper Letters	209	571	1032	32

**NOTES: Pharmacy Group**

NASCSA Conference 2015

Chief David Furlong attended the National Association of State Controlled Substances Authority Conference in Scottsdale, AZ, from October 19, 2015 to October 23, 2015.

PR/Outreach

The Pharmacy Group had a booth at the Utah Pharmacy Association Conference. They answered questions, and educated attendees on the Laws and Rules. There were over 200 attendees.

Administrative Action / Criminal Felony Filing

Pharmacist was entering the pharmacy vault and taking Oxycodone, Temazepam, and Alprazolam. The Pharmacist admitted to taking the controlled substances for chronic pain and addiction. He also admitted to forging initials of other employees on the drug entry/inventory sheet. The Pharmacist was arrested by Orem Police Department charged with 1 Count 3rd Degree Felony Theft, 5 Counts 3rd Degree Felony Forgery, 2 Counts 3rd Degree Felony Possession of a Controlled Substance, and 2 Counts Class B Misdemeanor Possession of a Controlled Substance. The Pharmacist signed a Surrender Stipulation and Order with the Division.

Administrative Action

Pharmacist diverted, for her own use, quantities of Controlled Substances, Hydrocodone, and Tramadol, without authorization from her place of employment. The Pharmacist signed a Surrender Stipulation and Order with the Division.

Pharmacy Board Report  
September 2015

Citation

Pharmacy was issued a Citation with a \$1,050 fine for Pharmacy Violations found during a Random Inspection. The violations state that all controlled substance inventories included a combined controlled substance count, and schedule II inventories were not listed separate from Schedule III, IV, and V inventories. On November 15, 2014, and June 5, 2015, the time of the inventory was taken, was not noted.

Citation

Pharmacy was issued a Citation with a \$1,050 fine for Pharmacy Violations found during a Random Inspection. The following violations were found: 131 medications, compounded preparations and APIs were found that were either expired, or had indeterminate expiration dates, or were improperly labeled; 88 items were compounding stock; 43 items were from regular stock; Not all CII invoices were stored separately from other records; CIII-V invoices were not all stored separately from other records; discrepancy was found with Vynase 50mg capsules but was quickly corrected; a list was provided of the contents of e-kits and facilities serviced; education was provided that patient address is required on all prescriptions; Pharmacy was compounding Domperidone until email received on 5/8/2015; Pharmacy needs SOPs on the facility and personnel; Facility needs to write the date of receipt of products that do not have an expiration date; the transfer date of product to other container needs to be listed on the container that product is transferred into; need to review 795 as part of training; clean equipment, especially the dust in hoods from API; Master worksheet needs: Container used; Packaging/storage info; Preparation sheet needs: Documentation of quality control/adverse reactions; Make sure that the lot# is being written down consistently; Container specifications; Comparison of the anticipated yield to the anticipated yield.

#2

## Compound Labeling

### R156-17b-614a. Operating Standards - General Operating Standards, Class A and B Pharmacy.

(1) In accordance with Subsection 58-17b-601(1), the following operating standards apply to all Class A and Class B pharmacies, which may be supplemented by additional standards defined in this rule applicable to specific types of Class A and B pharmacies. The general operating standards include:

- (a) shall be well lighted, well ventilated, clean and sanitary;
- (b) if transferring a drug from a manufacturer's or distributor's original container to another container, the dispensing area, if any, shall have a sink with hot and cold culinary water separate and apart from any restroom facilities. This does not apply to clean rooms where sterile products are prepared. Clean rooms should not have sinks or floor drains that expose the area to an open sewer. All required equipment shall be clean and in good operating condition;
- (c) be equipped to permit the orderly storage of prescription drugs and durable medical equipment in a manner to permit clear identification, separation and easy retrieval of products and an environment necessary to maintain the integrity of the product inventory;
- (d) be equipped to permit practice within the standards and ethics of the profession as dictated by the usual and ordinary scope of practice to be conducted within that facility;
- (e) be stocked with the quality and quantity of product necessary for the facility to meet its scope of practice in a manner consistent with the public health, safety and welfare; and
- (f) if dispensing controlled substances, be equipped with a security system to:
  - (i) permit detection of entry at all times when the facility is closed; and
  - (ii) provide notice of unauthorized entry to an individual; and
- (g) be equipped with a lock on any entrances to the facility where drugs are stored.

(2) The temperature of the pharmacy shall be maintained within a range compatible with the proper storage of drugs. If a refrigerator or freezer is necessary to properly store drugs at the pharmacy, the pharmacy shall keep a daily written or electronic log of the temperature of the refrigerator or freezer on days of operation. The pharmacy shall retain each log entry for at least three years.

(3) Facilities engaged in simple, moderate or complex non-sterile or any level of sterile compounding activities shall be required to maintain proper records and procedure manuals and establish quality control measures to ensure stability, equivalency where applicable and sterility. The following requirements shall be met:

- (a) shall follow USP-NF Chapter 795, compounding of non-sterile preparations, and USP-NF Chapter 797 if compounding sterile preparations;
- (b) may compound in anticipation of receiving prescriptions in limited amounts;
- (c) bulk active ingredients shall:
  - (i) be procured from a facility registered with the federal Food and Drug Administration; and
  - (ii) not be listed on the federal Food and Drug Administration list of drug products withdrawn or removed from the market for reasons of safety or effectiveness;

(d) All facilities that dispense prescriptions must comply with the record keeping requirements of their State Boards of Pharmacy. When a facility compounds a preparation according to the manufacturer's labeling instructions, then further documentation is not required. All other compounded preparations require further documentation as described in this section.

([d]e) a [master worksheet sheet] master formulation record shall be approved by a pharmacist or DMP for each batch of sterile or non-sterile pharmaceuticals to be prepared. Once

approved, a duplicate of the ~~[master worksheet sheet]~~ master formulation record shall be used as the ~~[preparation worksheet sheet]~~ compounding record from which each batch is prepared and on which all documentation for that batch occurs. The ~~[master worksheet sheet]~~ master formulation record may be stored electronically and shall contain at a minimum:

(i) ~~[the formula]~~ official or assigned name;  
(ii) ~~[the components]~~ strength;  
(iii) ~~[the compounding directions]~~ dosage form of the preparation;  
(iv) ~~[a sample label information]~~ calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients;

(v) ~~[evaluation and testing requirements]~~ description of all ingredients and their quantities;

(vi) ~~[sterilization methods, if applicable]~~ compatibility and stability information, including references when available;

(vii) ~~[specific equipment used during preparation such as specific compounding device]~~ equipment needed to prepare the preparation;

(viii) ~~[storage requirements;]~~ mixing instructions shall include:

a. order of mixing;

b. mixing temperatures or other environmental controls;

c. duration of mixing; and

d. other factors pertinent to the replication of the preparation as compounded.

(ix) sample labeling information, which shall contain, in addition to legally required information:

a. generic name and quantity or concentration of each active ingredient

b. assigned beyond use date

c. storage conditions

d. prescription or control number, whichever is applicable;

(x) container used in dispensing;

(xi) packaging and storage requirements;

(xii) description of final preparation; and

(xiii) quality control procedures and expected results.

(~~e~~) f) a ~~[preparation worksheet sheet]~~ compounding record for each batch of sterile or non-sterile pharmaceuticals shall document the following:

(i) ~~[identity of all solutions and ingredients and their corresponding amounts, concentrations, or volumes]~~ official or assigned name;

(ii) ~~[manufacturer lot number for each component]~~ strength and dosage of the preparation;

(iii) ~~[component manufacturer or suitable identifying number]~~ Master Formulation Record reference for the preparation;

(iv) ~~[container specifications (e.g. syringe, pump cassette)]~~ names and quantities of all components;

(v) ~~[unique lot or control number assigned to batch]~~ sources, lot numbers, and expiration dates of components;

(vi) ~~[beyond use date of batch prepared products]~~ total quantity compounded;

(vii) ~~[date of preparation]~~ name of the person who prepared the preparation;

(viii) ~~[name, initials or electronic signature of the person or persons involved in the preparation]~~ name of the compounder who approved the preparation;

(ix) [~~names, initials or electronic signature of the responsible pharmacist or DMP~~] name of the person who performed the quality control procedures;

(x) [~~end product evaluation and testing specifications, if applicable; and~~] date of preparation;

(xi) [~~comparison of actual yield to anticipated yield, when appropriate~~] assigned control, if for anticipation of use or prescription number, if patient specific, whichever is applicable;

(xii) assigned beyond use date;

(xiii) duplicate label as described in the Master Formulation Record;

(xiv) description of final preparation;

(xv) results of quality control procedures (e.g., weight range of filled capsules, pH of aqueous liquids); and

(xvi) documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver.

(fg) the label of each batch prepared of sterile or non-sterile pharmaceuticals shall bear at a minimum:

(i) the unique lot number assigned to the batch;

(ii) all active solution and ingredient names, amounts, strengths and concentrations, when applicable;

(iii) quantity;

(iv) beyond use date and time, when applicable;

(v) appropriate ancillary instructions, such as storage instructions or cautionary statements, including cytotoxic warning labels where appropriate; and

(vi) device-specific instructions, where appropriate;

(h) all prescription labels for compounded sterile and non-sterile medications when dispensed to the ultimate user or agent shall bear at a minimum in addition to what is required in UCA 58-17b-602L the following.

(i) generic name and quantity or concentration of each active ingredient. In the instance of a sterile preparation for parenteral use, labeling shall include the name and base solution for infusion preparation.

(ii) assigned compounding record or lot number.

(iii) "this is a compounded preparation" or similar language shall be indicated.

(gi) the beyond use date assigned shall be based on currently available drug stability information and sterility considerations or appropriate in-house or contract service stability testing;

(i) sources of drug stability information shall include the following:

(A) references can be found in Trissel's "Handbook on Injectable Drugs", 17th Edition, October 31, 2012;

(B) manufacturer recommendations; and

(C) reliable, published research;

(ii) when interpreting published drug stability information, the pharmacist or DMP shall consider all aspects of the final sterile product being prepared such as drug reservoir, drug concentration and storage conditions; and

(iii) methods for establishing beyond use dates shall be documented; and

([h]j) there shall be a documented, ongoing quality control program that monitors and evaluates personnel performance, equipment and facilities that follows the USP-NF Chapters 795 and 797 standards.

(4) The facility shall have current and retrievable editions of the following reference publications in print or electronic format and readily available and retrievable to facility personnel:

- (a) Title 58, Chapter 1, Division of Occupational and Professional Licensing Act
- (b) R156-1, General Rule of the Division of Occupational and Professional Licensing;
- (c) Title 58, Chapter 17b, Pharmacy Practice Act;
- (d) R156-17b, Utah Pharmacy Practice Act Rule;
- (e) Title 58, Chapter 37, Utah Controlled Substances Act;
- (f) R156-37, Utah Controlled Substances Act Rule;
- (g) Title 58, Chapter 37f, Controlled Substance Database Act;
- (h) R156-37f, Controlled Substance Database Act Rule;
- (i) Code of Federal Regulations (CFR) 21, Food and Drugs, Part 1300 to end or equivalent such as the USP DI Drug Reference Guides;
- (j) current FDA Approved Drug Products (orange book); and
- (k) any other general drug references necessary to permit practice dictated by the usual and ordinary scope of practice to be conducted within that facility.

(5) The facility shall maintain a current list of licensed employees involved in the practice of pharmacy at the facility. The list shall include individual licensee names, license classifications, license numbers, and license expiration dates. The list shall be readily retrievable for inspection by the Division and may be maintained in paper or electronic form.

(6) Facilities shall have a counseling area to allow for confidential patient counseling, where applicable.

(7) A pharmacy shall not dispense a prescription drug or device to a patient unless a pharmacist or DMP is physically present and immediately available in the facility.

(8) Only a licensed Utah pharmacist, DMP or authorized pharmacy personnel shall have access to the pharmacy when the pharmacy is closed.

(9) The facility or parent company shall maintain a record for not less than 5 years of the initials or identification codes that identify each dispensing pharmacist or DMP by name. The initials or identification code shall be unique to ensure that each pharmacist or DMP can be identified; therefore identical initials or identification codes shall not be used.

(10) The pharmacy facility shall maintain copy 3 of DEA order form (Form 222) that has been properly dated, initialed and filed and all copies of each unaccepted or defective order form and any attached statements or other documents.

(11) If applicable, a hard copy of the power of attorney authorizing a pharmacist, DMP, or DMP designee to sign DEA order forms (Form 222) shall be available to the Division whenever necessary.

(12) A pharmacist, DMP or other responsible individual shall verify that controlled substances are listed on the suppliers' invoices and were actually received by clearly recording their initials and the actual date of receipt of the controlled substances.

(13) The pharmacy facility shall maintain a record of suppliers' credit memos for controlled substances.

(14) A copy of inventories required under Section R156-17b-605 shall be made available to the Division when requested.

(15) The pharmacy facility shall maintain hard copy reports of surrender or destruction of controlled substances and legend drugs submitted to appropriate state or federal agencies.

(16) If the pharmacy does not store drugs in a locked cabinet and has a drop/false ceiling,

the pharmacy's perimeter walls shall extend to the hard deck, or other measures shall be taken to prevent unauthorized entry into the pharmacy.

# DRAFT

## 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;

~~(ii)~~ (iii) patient birth date;

~~(iii)~~ (iv) patient gender code;

~~(iv)~~ (v) date filled;

~~(v)~~ (vi) Rx number;

~~(vi)~~ (vii) new-refill code;

(vii) (viii) metric quantity;

~~(viii)~~ (ix) days supply;

~~(ix)~~ (x) NDC number;

~~(x)~~ (xi) prescriber identification number;

~~(xi)~~ (xii) date Rx written;

~~(xii)~~ (xiii) number refills authorized;

~~(xiii)~~ (xiv) patient last name;

~~(xiv)~~ (xv) patient first name; and

~~(xv)~~ (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)~~ (i) compound code;

~~(iii)~~ (ii) DEA suffix;

~~(iv)~~ (iii) Rx origin code;

~~(v)~~ (iv) customer location;

~~(vi)~~ (v) alternate prescriber number; and

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

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

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

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

~~(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.

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

# DRAFT

(a) ~~Beginning July 1, 2015, each pharmacy or pharmacy group may 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. Effective January 1, 2016, each pharmacy or pharmacy group shall submit data 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 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.~~

~~(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)(e) (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;

# DRAFT

- (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 provide using one of the following methods:

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

(b) information in the search warrant should be limited to subject's name(s) 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) facsimilie; or
- (iii) U.S. Mail.

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

- (i) individual's 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;

# DRAFT

(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;

# DRAFT

- (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.~~

**PROPOSED AMENDMENT TO  
PHARMACY PRACTICE ACT RULE R156-17B-615  
TREAT DEVICE MANUFACTURERS THE SAME AS DRUG MANUFACTURERS**

**William J. Stilling  
October 27, 2015**

**I. BACKGROUND**

A. *R156-17b-615: Operating Standards - Class C Pharmacy - Pharmaceutical Wholesaler/Distributor and Pharmaceutical Manufacturer.*

1. Requires licensing for pharmaceutical manufacturers and wholesalers to be licensed as Class C Pharmacies
2. Exempts a pharmaceutical wholesaler or manufacturer that distributes its own FDA-approved products or co-licensed products from licensure as a Class C pharmacy.

(1) Each pharmaceutical wholesaler or manufacturer that distributes or manufactures drugs or medical devices in Utah shall be licensed by the Division. A separate license shall be obtained for each separate location engaged in the distribution or manufacturing of prescription drugs. Business names cannot be identical to the name used by another unrelated wholesaler licensed to purchase drugs and devices in Utah.

(2) Manufacturers distributing only their own FDA-approved prescription drugs or co-licensed product shall satisfy this requirement by registering their establishment with the Federal Food and Drug Administration pursuant to 21 CFR Part 207 and submitting the information required by 21 CFR Part 205, including any amendments thereto, to the Division.

B. Proposed Change would include device manufacturers in the exemption.

(2) Manufacturers distributing only their own FDA-approved prescription drugs, devices (including products packaged with devices that are exempt from the definition of transaction in the 21 U.S.C. § 360ccc.), or co-licensed product(s) shall satisfy ~~this~~the requirement in subsection (1) by registering their establishment with the Federal Food and Drug Administration pursuant to 21 CFR Part 207 or 21 CFR 807, as applicable, and submitting the information required by 21 CFR Part 205 as applicable, including any amendments thereto, to the Division.

## **II. FEDERAL LAW REFERENCES IN CURRENT VERSION OF RULE**

- A. 21 CFR Part 207—*Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution*
- B. 21 CFR Part 807—*Guidelines for State Licensing of Wholesale Prescription Drug Distributors*

## **III. FEDERAL LAW REFERENCES IN NEW VERSION OF RULE**

- A. 21 CFR 807--Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices
- B. 21 USC Subchapter H § 360eee—Pharmaceutical Distribution Chain (Definitions)
  - 1. Provides an exemption from the track and trace requirements, including exemption for devices that are combination of devices and drugs such as kits (see next page for text of exemption)

## 21 U.S. Code Part H - Pharmaceutical Distribution Supply Chain

### 21 U.S. Code § 360eee - Definitions

#### (24) Transaction

##### (A) In general

The term "transaction" means the transfer of product between persons in which a change of ownership occurs.

##### (B) Exemptions

~~The term "transaction" does not include—~~

- (i) intracompany distribution of any product between members of an affiliate or within a manufacturer;
- (ii) the distribution of a product among hospitals or other health care entities that are under common control;
- (iii) the distribution of a product for emergency medical reasons including a public health emergency declaration pursuant to section 247d of title 42, except that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;
- (iv) the dispensing of a product pursuant to a prescription executed in accordance with section 353 (b)(1) of this title;
- (v) the distribution of product samples by a manufacturer or a licensed wholesale distributor in accordance with section 353 (d) of this title;
- (vi) the distribution of blood or blood components intended for transfusion;
- (vii) the distribution of minimal quantities of product by a licensed retail pharmacy to a licensed practitioner for office use;
- (viii) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501 (c)(3) of title 26 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
- (ix) the distribution of a product pursuant to the sale or merger of a pharmacy or pharmacies or a wholesale distributor or wholesale distributors, except that any records required to be maintained for the product shall be transferred to the new owner of the pharmacy or pharmacies or wholesale distributor or wholesale distributors;
- (x) the dispensing of a product approved under section 360b (c) of this title;
- (xi) products transferred to or from any facility that is licensed by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 2021 of title 42;
- (xii) ~~a combination product that is not subject to approval under section 355 of this title or licensure under section 262 of title 42, and that is—~~

(I) a product comprised of a device and 1 or more other regulated components (such as a drug/device, biologic/device, or drug/device/biologic) that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

(II) 2 or more separate products packaged together in a single package or as a unit and comprised of a drug and device or device and biological product; or

(III) 2 or more finished medical devices plus one or more drug or biological products that are packaged together in what is referred to as a "medical convenience kit" as described in clause (xiii);

(xiii) the distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in this clause as a "medical convenience kit") if—

(I) the medical convenience kit is assembled in an establishment that is registered with the Food and Drug Administration as a device manufacturer in accordance with section 360 (b)(2) of this title;

(II) the medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970 [21 U.S.C. 801 et seq.];

(III) in the case of a medical convenience kit that includes a product, the person that manufactures the kit—

(aa) purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

(bb) does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

(IV) in the case of a medical convenience kit that includes a product, the product is—

(aa) an intravenous solution intended for the replenishment of fluids and electrolytes;

(bb) a product intended to maintain the equilibrium of water and minerals in the body;

(cc) a product intended for irrigation or reconstitution;

(dd) an anesthetic;

(ee) an anticoagulant;

(ff) a vasopressor; or

(gg) a sympathomimetic;

- (xiv) the distribution of an intravenous product that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);
- (xv) the distribution of an intravenous product used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;
- (xvi) the distribution of a product that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;
- (xvii) the distribution of a medical gas (as defined in section 360ddd of this title); or
- (xviii) the distribution or sale of any licensed product under section 262 of title 42 that meets the definition of a device under section 321 (h) of this title.

## CURRENT VERSION

### **R156-17b-615. Operating Standards - Class C Pharmacy - Pharmaceutical Wholesaler/Distributor and Pharmaceutical Manufacturer.**

In accordance with Subsections 58-17b-102(47) and 58-17b-601(1), the operating standards for Class C pharmacies designated as pharmaceutical wholesaler/distributor and pharmaceutical manufacturer licensees includes the following:

- (1) Each pharmaceutical wholesaler or manufacturer that distributes or manufactures drugs or medical devices in Utah shall be licensed by the Division. A separate license shall be obtained for each separate location engaged in the distribution or manufacturing of prescription drugs. Business names cannot be identical to the name used by another unrelated wholesaler licensed to purchase drugs and devices in Utah.
- (2) Manufacturers distributing only their own FDA-approved prescription drugs or co-licensed product shall satisfy this requirement by registering their establishment with the Federal Food and Drug Administration pursuant to 21 CFR Part 207 and submitting the information required by 21 CFR Part 205, including any amendments thereto, to the Division.
- (3) An applicant for licensure as a pharmaceutical wholesale distributor shall provide the following minimum information: [list of requirements]
- (4) [supervision requirements—pharmacist-like individual]
- (5) [requirement for supervisor’s name to be submitted]
- (6) [License display requirement]
- (7) All Class C pharmacies shall:  
[list of operating standards]
- (8) [security requirements]
- (9) [storage requirements]
- (10) [pedigree requirements]
- (11) [additional record keeping, receipt, and return requirements]
- (12) [can only provide drugs to another licensed person or entity]
- (13) [delivery only to business address]
- (14) [record of transactions]
- (15) [requirement for written policies and procedures]
- (16) [have list of officers, etc. available for inspection]
- (17) [must comply with all laws]
- (18) [comply with laws regarding salvaging drugs]
- (19) [cannot be located in same building unless in different suites]

**PROPOSED VERSION R156-17b-615**

(2) Manufacturers distributing only their own FDA-approved prescription drugs, devices (including products packaged with devices that are exempt from the definition of transaction in the 21 U.S.C. § Subchapter H § 360eee), or co-licensed product(s) shall satisfy ~~this~~ the requirement in subsection (1) by registering their establishment with the Federal Food and Drug Administration pursuant to 21 CFR Part 207 or 21 CFR 807 as applicable and submitting the information required by 21 CFR Part 205 as applicable, including any amendments thereto, to the Division.

Define: Co licensed Products