

	2014	2015	2016	Aug-16
Administrative Filings	52	33	14	1
Criminal Filing/Felony	0	3	0	0
Letter of Concern	146	98	78	9
Referred to Diversion	2	0	1	0
PR/Outreach	4	1	2	0
Cases Received	567	666	347	31
Case Assigned	555	659	345	31
Closed Cases	595	624	409	46
Citations Issued	60	64	24	2
Pharmacy Inspections	335	316	212	21
Pharmacy Alerts	261	220	175	41
Dr. Shopper Letters	571	1251	2345	

NOTES: Pharmacy Group

Administrative

Pharmacy Technician's employment had a sales incentive program where its employees could receive greater commissions for recruiting new customers with health insurance benefits that accepted a metabolic supplement. The Pharmacy Technician recruited patients, but failed to disclose to them that in order for their insurance to cover the supplement, a doctor's prescription would be required, and submitted the claims without the patient having seen the doctor listed on the claim for their metabolic supplement. The Pharmacy Technician signed a Surrender Stipulation and Order, surrendering his license with a \$1,000 fine.

Citation

During a Random Inspection violations were found, 29 items needed to be removed from the inventory, The items consisted of APIs that did not have a transfer date on the container (10), and also items that had expired BUD dating (19). The Pharmacy was issued a Citation with a \$1,050 fine.

Citation

During a Random Inspection violations were found, 41 items needed to be removed from the inventory. The items consisted mainly of items that were in the non-sterile compounding area. The Pharmacy was issued a Citation with a \$1,050 fine.

R156-17b-904. Criteria for eligible prescription drug – beyond use date or expiration date

The division in collaboration with the board has not established a date later than the beyond use date or the expiration date recommended by the manufacturer for a specific prescription drug.

R156-17b-905. Fees

(1) In accordance with Subsection 58-17b-905 (2) (e) an eligible pharmacy may charge a handling fee:

- (a) before accepting a prescription drug under the program: \$0 - \$10
- (b) before dispensing a prescription drug under the program: \$0 - \$5

R156-17b-907a. Applicants seeking registration to become eligible pharmacies under Subsection 58-17b-902 (8) - Supporting Documents and Information.

An applicant seeking registration under Subsection 58-17b-902 (8) shall submit an application on a form provided by the division that at minimum establishes:

- (1) the entity in which the eligible pharmacy will operate under is either a:
 - (a) county
 - (b) county health department
 - (c) pharmacy under contract with a county health department
 - (d) the Department of Health, created under Section 26-1-4
 - (e) the Division of Substance Abuse and Mental Health, created on Section 62A-15-103; or
 - (f) charitable clinic;
- (2) the applicant is currently licensed and in good standing with the Division;

R156-17b-907b. Formulary

(1) The formulary under Section 58-17b-907 (2) includes all prescription drugs approved by the federal Food and Drug Administration that meet the criteria for eligible prescription drugs in Section 58-17b-904.

- (2) The formulary does not include:
 - (a) controlled substances; and
 - (b) drugs that can only be dispensed to a patient registered with the drug's manufacturer in accordance with the deferral Food and drug Administration requirements.
 - (c) compounded drugs

R156-17b-907c. Standards and Procedures

In accordance with Subsection 58-17b-907 (3) an eligible pharmacy shall maintain standards and procedures, that are available for inspection, regarding.

- (1) Handling of a donated eligible prescription drug, including:
 - (a) program eligibility of the donor;
 - (b) acceptance;
 - (c) identification of and evaluation of a donated prescription drug by a licensed pharmacist or pharmacy technician;
 - (d) tracking of the complete inventory cycle;
 - (e) safe storage;
 - (f) security;

- (g) transfer;
- (h) dispensing.
- (2) Determining the status of a medically indigent individual.
- (3) Labeling requirements, including:
 - (a) satisfying the requirements of the labeling requirements of Subsections;
 - (b) patient information that may appear on a donated prescription drug;
 - (c) compliance with privacy laws;
 - (d) clearly identify the eligible drug dispensed under the program;
 - (e) information regarding the beyond use date or manufacturer's recommended expiration date.

R156-17b-907d. Special Training Program

- (1) Eligible pharmacies shall create and maintain a training program that pharmacists and licensed pharmacy technicians shall complete before participating in the program.
- (2) Eligible pharmacies shall maintain record, for at least two years, of the pharmacists and licensed pharmacy technicians that have completed the training program required by Subsection R156-17b-907d (1).

R156-17b-618. Change in Ownership or Location.

(1) In accordance with Section 58-17b-614, except for changes in ownership caused by a change in the stockholders in corporations that are publicly listed and whose stock is publicly traded, a licensed pharmaceutical facility shall make application for a new license and receive approval from the Division no later than ten business days prior to any of the following proposed changes:

(a) location or address, except for a reassignment of a new address by the United States Postal Service that does not involve any change of location;

(b) name, except for a doing-business-as (DBA) name change that is properly registered with the Division of Corporations and filed with the Division of Occupational and Professional Licensing; or

(c) ownership when one of the following occurs:

(i) a change in entity type; or

(ii) the sale or transfer of 51% or more of an entity's ownership or membership interest to another individual or entity.

(2) Upon approval of the change in location, name, or ownership, and the issuance of a new license, the original license shall be surrendered to the Division.

(3) Upon approval of the name change, the original licenses shall be surrendered to the Division.

R156-17b-614. Modification of Licensure

(1) The following licensure modifications shall be handled in the same manner as applications for licensure:

(a) the sale or transfer of 51% or more of an entity's direct ownership except for changes in ownership caused by a change in the stockholders in corporations that are publicly listed and whose stock is publicly traded;

(b) change in entity type;

(d) location or address change; and

(2) The following licensure modifications require division approval and required notification submitted to the division:

(c) name change;

(d) a remodel

(3) In accordance with Section 58-17b-614 a licensed pharmaceutical facility shall make application or notify the division no later than ten business days before the date of the proposed modifications listed in this Section.

R156-17b-601

(5) No more than one pharmacy technician trainee per shift per pharmacist shall practice in a pharmacy. A pharmacy technician trainee shall practice only under the direct supervision of a pharmacist.

A pharmacy technician trainee shall practice only under the direct supervision of a pharmacist and in a ratio not to exceed one pharmacy technician trainee to one pharmacists.

R156-17b-625 - Standards- Reporting and Maintaining Records on the Dispensing of an Opiate Antagonist.

(1) In accordance with Utah Code Ann. § 26-55-105(2)(c) and (d), the pharmacist-in-charge or a responsible corporate officer of each pharmacy licensee that dispenses an opiate antagonist pursuant to a valid standing prescription drug order issued by a physician, shall affirm that the pharmacy licensee has complied with the protocol for dispensing an opiate antagonist as set forth in Utah Code Ann. § 26-55-105, and shall report, on an annual basis, to the physician who issued the opiate antagonist standing drug order, the following information:

(a) the total number of single doses of opiate antagonists dispensed during the reporting period; and

(b) the name of each opiate antagonist dispensed along with the total number of single doses of that particular named opiate antagonist.

(2) Corporations or organizations with multiple component pharmacy licensees may submit one cumulative report for all its component pharmacy licensees. However, that report must contain the information described above for each of the component pharmacy licensees.

(3) Null reporting is not required. If a pharmacy licensee does not dispense an opiate antagonist during any year, that pharmacy licensee is not required to make an affirmation or report to the division.

(4) The annual affirmation and report described above is due to the physician who issued the standing drug order no later than 10 days following December 31 of each calendar year.

(5) In accordance with Utah Code Ann. § 26-55-105(2)(d), a pharmacy licensee who dispenses an opiate antagonist pursuant to a valid standing prescription drug order issued by a physician, shall maintain, subject to audit, the following information:

(a) the name of the individual to whom the opiate antagonist is dispensed;

(b) the name of the opiate antagonist dispensed;

(c) the quantity of the opiate antagonist dispensed;

(d) the strength of the opiate antagonist dispensed;

(e) the dosage quantity of the opiate antagonist dispensed;

(f) the full name of the drug outlet which dispensed the opiate antagonist;

(g) the date the opiate antagonist was dispensed; and

(h) the name of physician issuing the standing order to dispense the opiate antagonist.

(6) The division approves the protocol for the issuance of a standing prescription drug order for opiate antagonists, which is set forth in Utah Code Ann. § 26-55-105(2)(a) through (d)

along with the requirements set forth in the foregoing provisions, and the reporting requirements set forth in Utah Admin. Code R156-67-604 and R156-68-604.

R156-17b-502. Unprofessional Conduct.

"Unprofessional conduct" includes:

(25) failing to make a timely report regarding dispensing of an opiate antagonist to the physician who issued the standing order as required in Utah Admin. Code R156-17b-625.

R156-67-604 - Required Reporting of Annual Review by Physicians of Dispensing Practices of those Authorized to Dispense an Opiate Antagonist.

(1) In accordance with Utah Code Ann. § 26-55-105(2)(c), a physician who issues a standing prescription drug order authorizing the dispensing of an opiate antagonist shall annually submit a written report to the division indicating that he or she has reviewed at least annually the dispensing practices of those authorized by the physician to dispense the opiate antagonist.

(2) The report described above shall be submitted no later than January 31 of each calendar year and shall continue as long as the standing order remains in effect. Null reporting is not required.

(3) A physician shall be considered to have satisfactorily reviewed the dispensing practices of those authorized by the physician to dispense the opiate antagonist by reviewing the report of the licensee dispensing the opiate antagonist specified in Utah Admin. Code R156-17b-625(1).

R156-67-502. Unprofessional Conduct.

"Unprofessional conduct" includes:

(16) failing to timely submit an annual written report to the division indicating that the physician has reviewed at least annually the dispensing practices of those authorized by the physician to dispense an opiate antagonist, pursuant to Utah Admin Code R156-67-604.

R156-68-604 - Required Reporting of Annual Review by Osteopathic Physicians of Dispensing Practices of those Authorized to Dispense an Opiate Antagonist.

(1) In accordance with Utah Code Ann. § 26-55-105(2)(c), an osteopathic physician who issues a standing prescription drug order authorizing the dispensing of an opiate antagonist shall annually submit a written report to the division indicating that he or she has reviewed at least

annually the dispensing practices of those authorized by the osteopathic physician to dispense the opiate antagonist.

(2) The report described above shall be submitted no later than January 31 of each calendar year and shall continue as long as the standing order remains in effect. Null reporting is not required.

(3) An osteopathic physician shall be considered to have satisfactorily reviewed the dispensing practices of those authorized by the osteopathic physician to dispense the opiate antagonist by reviewing the report of the licensee dispensing the opiate antagonist specified in Utah Admin. Code R156-17b-625(1).

R156-68-502. Unprofessional Conduct.

"Unprofessional conduct" includes:

(15) failing to timely submit an annual written report to the division indicating that the osteopathic physician has reviewed at least annually the dispensing practices of those authorized by the osteopathic physician to dispense an opiate antagonist, pursuant to Utah Admin Code R156-67-604.