

#1

Pharmacy Board Report
June 2014

	2013	2014	Jun-14
Administrative Filings	37	27	1
Criminal Filing/Felony	3	0	0
Letter of Concern	60	66	4
PR/Outreach	3	4	0
Cases Received	710	246	38
Case Assigned	676	240	32
Closed Cases	731	285	32
Citations Issued	103	9	1
Pharmacy Inspections	225	116	23
Pharmacy Alerts	191	102	28
Dr. Shopper/Law Enforcement Letters	209	211	79

NOTES: Pharmacy Group

Jun-14

New Positions	The Division hired Sharilee McIntyre as a Pharmacy Inspector, and Camille Farley as a Pharmacy Investigator. We will be hiring another Pharmacy Investigator in August 2014.
Administrative Action	Superior Care Pharmacy signed a Stipulation and Order. They were fined \$30,000.
Administrative Action	Pharmacist-In-Charge, Brent Call, signed a Stipulation and Order.
Citation	Citation was issued to Smith's Pharmacy #69 for Pharmacy Violations.

Senate Bill 77

58-17b-624. Prescription drugs -- Sale to a practitioner for office use.

(1) A pharmacy licensed under this chapter may, subject to rules established by the division, repackage or compound a prescription drug for sale to a practitioner if:

- (a) the prescription drug:
 - (i) does not include a compounded drug; or
 - (ii) (A) includes a compounded drug; and
(B) is not a controlled substance;
- (b) the pharmacy labels the prescription drug "for office use only";
- (c) the practitioner administers the drug to a patient in the practitioner's office or facility; and
- (d) the practitioner does not dispense the drug to the patient.

(2) The division shall establish, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, prescription drug labeling and control standards for a prescription drug that a pharmacy provides to a practitioner under this section.

R156-17b-624. Operating Standards. Repackaged or Compounded Prescription Drugs - Sale to a Practitioner for Office-Use Administration.

In accordance with Section 58-17b-624, a pharmacy may repackage or compound a prescription drug for sale to a practitioner for office use administration in compliance with the following standards:

(1) If repackaged or compounded, each drug sold by a pharmacy to a practitioner for office-use administration shall have a label securely affixed to the container indicating the following minimum information:

- (a) the name, address, and telephone number of the pharmacy;
- (b) the serial, batch, or lot number of the order as assigned by the pharmacy;
- (c) the filling date of the order;
- (e) the name of the clinic ordering the drug;
- (f) the directions for use or storage and cautionary statements, if any, which are contained in the order or are needed;
- (g) the trade, generic, or chemical name, amount and the strength of dosage form, but if multiple ingredient products with established proprietary or nonproprietary names are prescribed, those products' names may be used;
- (h) the beyond use date;
- (i) if repackaged and not compounded, the statement: "For office use only. Not for dispensing or resale."
- (j) if compounded, the statement: "Compounded medication for office use only. Not for dispensing or resale." and;
- (k) if compounded, the name and strength of the preparation list of active ingredients and strengths;

(2) An inventory record of a repackaged or compounded drug shall be kept in the pharmacy in compliance with R156-17b-605 and, if applicable, R156-17b-614a (3). The inventory record shall include the prescriber's order indicating, if applicable, the formula and quantity ordered.

(3) A pharmacy that compounds drugs for office use administration shall maintain a log of all compounded drugs for office use and shall monitor for recalled components. The log shall include the name of compounded products and ingredients, supplier's identification (lot numbers), expiration dates, product preparation date, and name of prescribing practitioner. If a component is recalled, the compounding pharmacy shall notify the practitioner and the practitioner is responsible to notify the patient for the reporting of any adverse reaction or compliant in order to facilitate a recall of batches of compounded medications.

(3) Only non-sterile compounded drugs shall be sold to a practitioner for office-use administration. Sterile compounded drugs shall not be sold by a pharmacy to a practitioner for office-use administration.

(4) Controlled substances shall not be compounded for office use administration.

(5) The repackaged or compounded drug shall be administered in the practitioner's office, health care facility, or treatment setting and not dispensed to the patient.

(6) The quantity of a drug compounded for office use administration:

- (a) shall not exceed the amount a practitioner anticipates may be used in the practitioner's office before the expiration date of the drug;
- (b) shall be reasonable considering the intended use of the compounded drug and the nature of the practitioner's practice.
- (c) shall not be greater than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality, and purity of the compounded drug that are consistent with United States Pharmacopoeia guidelines.

(7) The content of 21 U.S.C Section 353b or regulations or written guidance from the Federal Drug Administration regarding 21 U.S.C Section 353b shall supercede any provision of this rule that may be found to conflict with this rule.

R156-17b-102. Definitions.

"Office-use administration" means the provision and administration of a drug to a patient by a practitioner in the practitioner's office or by the practitioner in a health care facility or treatment setting, including a hospital or ambulatory clinic.

“For Office Use” Discussion

Definition of “for office use”:

“Office use “means the provision and administration of a medication or a compounded medication to a patient by a practitioner in the practitioner’s office or by the practitioner in a health care facility or treatment setting, including a hospital or ambulatory clinic.

Pharmacies may prepare compounded drug products for a duly authorized prescriber’s office use and the order must contain the following:

- 1.) A record of the compounded drug product must be kept as a prescription record in the pharmacy computer.
- 2.) A label must be generated and a number assigned by the pharmacy computer for the compounded drug product.
- 3.) An order by the duly authorized prescriber, indicating the formula and quantity ordered, will be filed in the pharmacy.
- 4.) The prescription label must follow all the label requirements set forth by UAC 58-17b-602 and must follow the guidelines set forth by USP <795> and USP <797>.
- 5.) The product shall be administered in the practitioner’s office, health care facility, or treatment setting and not dispensed to the patient.
- 6.) The product shall be labeled as follows:
 - a. The product shall be labeled “compounded medication for office use only-not for dispensing or resale.”
 - b. The label shall contain specific beyond-use-date information, special storage requirements, or a lot or batch number.
 - c. The label shall contain all prescribed components or active ingredient names, amounts, strengths, and concentrations.
 - d. The label shall indicate the name and address of the compounding pharmacy.
- 7.) Controlled substances shall not be compounded “for office use”
- 8.) A reasonable quantity shall only be dispensed to each prescriber’s office and this is to be deemed by the pharmacist. The quantity of a compounded drug is reasonable considering the intended use of the compounded drug and does not exceed the amount a practitioner anticipates may be used in the practitioner’s office before the beyond-use-date expiration.

- 9.) The compounding pharmacy shall maintain a log of all compounded products for office use and shall monitor for recalled components. Such log shall include name of compounded product and all ingredients, supplier's identification (lot numbers), expiration dates, product preparation date, and name of prescribing practitioner. In the event a component is recalled, the compounding pharmacy shall notify the practitioner and the practitioner will provide notification to the patient for the reporting of any adverse reaction or complaint in order to facilitate any recall of batches of compounded medications.

Pharmacies may dispense medications for a duly authorized prescriber's office and the order must contain the following:

1. The prescription label must follow all the label requirements set forth by UAC 58-17b-602.
2. The product shall be labeled "for office use only-not for dispensing or resale."

State Breakdown:

30 states permit

14 states undefined

2 only for nuclear pharmacies

2 states not permitted

2 states also require a written contract between the prescriber and the pharmacy for sterile products

Discuss in more detail:

Reasonable quantity? 5% rule

Report patient names back to pharmacy-time frame if so-only sterile products?



#6

Richard Oborn <roborn@utah.gov>

CSDB Issue

1 message

GregJones@harmonsgrocery.com <GregJones@harmonsgrocery.com>

Thu, Jul 10, 2014 at 12:29 PM

To: lhooper@utah.gov

Cc: roborn@utah.gov, "David L. Young" <dyoung@pharm.utah.edu>

Hi Lynn,

This issue is on the agenda for the next Rx Board meeting, and it seems that this conversation should be clarified at the board meeting.

These are my comments - not necessarily reflective of the board or the board chairman's opinion.

At least part of the issue is that the CSDB Act clearly states that the pharmacist must submit "**positive identification of the individual receiving the prescription, including the type of identification and any identifying numbers on the identification**" to the CSDB. The CSDB Rule; however, does not include this requirement in the data fields that are required to be submitted.

I do not see any place that states the pharmacies are required to store this information, just that it should be submitted to the division.

CSDB Act:

(2) The pharmacist described in Subsection (1) shall, for each controlled substance dispensed by a pharmacist under the pharmacist's supervision other than those dispensed for an inpatient at a health care facility, submit to the division the following information:

- (a) the name of the prescribing practitioner;
- (b) the date of the prescription;
- (c) the date the prescription was filled;
- (d) the name of the individual for whom the prescription was written;
- (e) **positive identification of the individual receiving the prescription, including the type of identification and any identifying numbers on the identification;**

CSDB Rule:

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

(1) The format for submission to the Database shall be in accordance with 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) patient birth date;
- (iii) patient gender code;

- (iv) date filled;
- (v) Rx number;
- (vi) new-refill code;
- (vii) metric quantity;
- (viii) days supply;
- (ix) NDC number;
- (x) prescriber identification number;
- (xi) date Rx written;
- (xii) number refills authorized;
- (xiii) patient last name;
- (xiv) patient first name; and
- (xv) patient street address, including zip code (extended).

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

- (i) customer identification number;
- (ii) compound code;
- (iii) DEA suffix;
- (iv) Rx origin code;
- (v) customer location;
- (vi) alternate prescriber number; and
- (vii) 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), the data required in Subsection (1) shall be submitted to the Database through one of the following methods:

Gregory J. Jones, R.Ph., MBA
Director of Pharmacy
Harmon City, Inc.
801-957-8454
3540 South 4000 West Suite 430
West Valley City, Utah 84120