

State of Utah
Administrative Rule Analysis

NOTICE OF PROPOSED RULE

- * The agency identified below in box 1 provides notice of proposed rule change pursuant to Utah Code Section 63G-3-301.
- * Please address questions regarding information on this notice to the agency.
- * The full text of all rule filings is published in the Utah State Bulletin unless excluded because of space constraints.
- * The full text of all rule filings may also be inspected at the Division of Administrative Rules.

DAR file no:

40218

Date filed:

2/22/2016

State Admin Rule Filing Id:

Time filed:

	Agency No.	Rule No.	Section No.
Utah Admin. Code Ref (R no.):	R 156	- 17b	- 614a
Changed to Admin. Code Ref. (R no.):	R	-	-

1. **Agency:** Commerce/Division of Occupational and Professional Licensing

Room no.:

Building: Heber M. Wells Building

Street address 1: 160 East 300 South

Street address 2:

City, state, zip: Salt Lake City UT 84111-2316

Mailing address 1: PO Box 146741

Mailing address 2:

City, state, zip: Salt Lake City UT 84114-6741

Contact person(s):

Name:	Phone:	Fax:	E-mail:
Dane Ishihara	801-530-7632	801-530-6511	dishihara@utah.gov

(Interested persons may inspect this filing at the above address or at the Division of Administrative Rules during business hours)

2. **Title of rule or section (catchline):**

Operating Standards - General Operating Standards, Class A and B Pharmacy

3. **Type of notice:**

New ___; Amendment XXXX; Repeal ___; Repeal and Reenact ___

4. **Purpose of the rule or reason for the change:**

The Division and Utah State Board of Pharmacy are proposing these amendments to clarify the documentation requirements for compounded preparations in Class A and Class B pharmacies. NOTE: Concurrent to this proposed rule filing, there is an additional rule filing that will modify R156-17b, the Pharmacy Practice Act Rule. The two proposed rule amendment filings are being filed separately due to the entities affected by the proposed changes are different.

5. **This change is a response to comments from the Administrative Rules Review Committee.**

No XXX; Yes ___

6. Summary of the rule or change:

Subsections are added, renumbered and modified to add clarification to the documentation standards that compounding pharmacies must adhere to and to become more consistent with the federal compounded preparation documentation standards. The proposed rule changes do not add new requirements. The intent of the proposed changes are to list the documentation standards in a single location to provide licensees easier access to the information.

7. Aggregate anticipated cost or savings to:

A) State budget:

Affected: No ; Yes XXXX

The Division will incur minimal costs of approximately \$75.00 to print and distribute the rule once the proposed amendments are made effective. Any costs incurred will be absorbed in the Division's current budget.

B) Local government:

Affected: No XXXX; Yes

The proposed amendments apply only to licensed Class A and Class B pharmacies that are involved in compounding. As a result, the proposed amendments do not apply to local governments.

C) Small businesses ("small business" means a business employing fewer than 50 persons):

Affected: No XXXX; Yes

The proposed amendments apply only to licensed Class A and Class B pharmacies that are involved in compounding. No fiscal impact to small business is anticipated. The proposed amendments add clarification to existing practices in the industry.

D) Persons other than small businesses, businesses, 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):

Affected: No XXX; Yes

(The proposed amendments apply only to licensed Class A and Class B pharmacies that are involved in compounding. No fiscal impact to other persons is anticipated. The proposed amendments add clarification to existing practices in the industry.

8. Compliance costs for affected persons:

The proposed amendments should have no increased compliance cost or impact for licensed Class A and Class B pharmacies that are involved in compounding. The proposed amendments add clarification to existing practices in the industry.

9. A) Comments by the department head on the fiscal impact the rule may have on businesses:

This rule change clarifies documentation standards for compounding pharmacies, and makes the documentation standards more consistent with federal standards. No new requirements are added. No fiscal impact to businesses is anticipated.

B) Name and title of department head commenting on the fiscal impacts:

Francine A. Giani, Executive Director

10. This rule change is authorized or mandated by state law, and implements or interprets the following state and federal laws.

State code or constitution citations (required) (e.g., Section 63G-3-402; Subsection 63G-3-601(3); Article IV) :

Section 58-17b-101

Subsection 58-17b-601(1)

Section 58-37-1

Subsection 58-1-106(1)(a)

Subsection 58-1-202(1)(a)

11. This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Division of Administrative Rules; if none, leave blank):

First Incorporation

Second Incorporation

Official Title of Materials
Incorporated (from title page)

Publisher

Date Issued

Issue, or version

ISBN Number (optional)

ISSN Number (optional)

Cost of Incorporated Reference

Action: Adds, updates, or removes

(If this rule incorporates more than two items by reference, please attach additional pages)

- 12 The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the Utah State Bulletin. See Section 63G-3-302 and Rule R15-1 for more information.)

A) Comments will be accepted until 5:00 p.m. on (mm/dd/yyyy): 04/14/2016

B) A public hearing (optional) will be held:

On (mm/dd/yyyy):

03/22/2016

At (hh:mm AM/PM):

8:30 AM

At (place):

160 East 300 South, Conference Room
474, Salt Lake City, Utah

- 13 This rule change may become effective on (mm/dd/yyyy): 04/21/2016

NOTE: The date above is the date on which this rule MAY become effective. It is NOT the effective date. After the date designated in Box 12(A) above, the agency must submit a Notice of Effective Date to the Division of Administrative Rules to make this rule effective. Failure to submit a Notice of Effective Date will result in this rule lapsing and will require the agency to start the rulemaking process over.

- 14 Indexing information -- keywords (maximum of four, in lower case, except for acronyms (e.g., "GRAMA") or proper nouns (e.g., "Medicaid")); may not include the name of the agency:

pharmacists

licensing

pharmacies

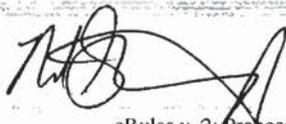
- 15 Attach an RTF document containing the text of this rule change R\56-17b.pro2

(filename):

To the agency: Information requested on this form is required by Sections 63G-3-301, 302, 303, and 402. Incomplete forms will be returned to the agency for completion, possibly delaying publication in the *Utah State Bulletin*, and delaying the first possible effective date.

AGENCY AUTHORIZATION

Agency head or
designee, and title:



Date

(mm/dd/yyyy)

Feb 22 2016

R156. Commerce, Occupational and Professional Licensing.

R156-17b. Pharmacy Practice Act Rule.

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) Facilities shall follow USP-NF Chapter 795, compounding of non-sterile preparations, and USP-NF Chapter 797 if compounding sterile preparations[7].

(b) Facilities may compound in anticipation of receiving prescriptions in limited amounts[7].

(c) ~~[b]~~ 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[7].

(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.

(e) A master formulation record [a master worksheet sheet] 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 formulation record [worksheet sheet] 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] 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; [-and]

(viii) ~~[storage requirements;]~~ mixing instructions, which 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; and

(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] A 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];

(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) duplicate label as described in the Master Formulation Record means the sample labeling information that is dispensed on the final product given to the patient and shall at minimum contain:

(A) active ingredients;

(B) beyond-use-date;

(C) storage conditions; and

(D) lot number;

(xiv) proof of the duplicate labeling information, which proof shall:

(A) be kept at the pharmacy;

(B) be immediately retrievable;
(C) include an audit trail for any altered form; and
(D) be reproduced in:
(I) the original format that was dispensed;
(II) an electronic format; or
(III) a scanned electronic version;
(xvii) description of final preparation;
(xviii) results of quality control procedures (e.g. weight range of filled capsules, pH of aqueous liquids); and
(xix) documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver.

([f]g) [the]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[7].

(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 Section 58-17b-602 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; and

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

([g]i) [the]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~~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.

KEY: pharmacists, licensing, pharmacies

Date of Enactment or Last Substantive Amendment: [~~December 1, 2015~~2016

Notice of Continuation: January 5, 2015

Authorizing, and Implemented or Interpreted Law: 58-17b-101; 58-17b-601(1); 58-37-1; 58-1-106(1) (a); 58-1-202(1) (a)