DAR File NO 55074
Date Filed 11-14-2022

State of Utah
Administrative Rule Analysis
Revised June 2022

NOTICE OF PROPOSED RULE

TYPE OF RULE: New XXX; Amendment ___; Repeal ___; Repeal and Reenact ___

	Title No. - Rule No. - Section No.	
Rule or Section Number:	**R156-88a**	**Filing ID: Office Use Only**

Agency Information

1. Department:	Department of Commerce
Agency:	Division of Professional Licensing
Room number:	
Building:	Heber M. Wells Building
Street address:	160 East 300 South
City, state and zip:	Salt Lake City UT 84111-2316
Mailing address:	PO Box 146741
City, state and zip:	Salt Lake City UT 84114-6741
Contact persons:	

Name:	**Phone:**	**Email:**
Larry Marx	801-530-6628	lmarx@utah.gov

Please address questions regarding information on this notice to the agency.

General Information

2. Rule or section catchline:

Dispensing Practice Rule

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

The Division in collaboration with the Physicians Licensing Board and the Board of Pharmacy is submitting this filing to create new Rule R156-88a in accordance with Title 58, Chapter 88, Part 2, Dispensing Practice, enacted by H.B. 301 during the 2022 General Session.

4. Summary of the new rule or change (What does this filing do? If this is a repeal and reenact, explain the substantive differences between the repealed rule and the reenacted rule):

New Title 58, Chapter 88, Part 2, Dispensing Practice creates a new license type, "Licensed Dispensing Practice." This Rule R156-88a will enable the Division to administer this license as mandated by the statute. The filing establishes definitions, renewal and restatement procedures, and various operating standards including "responsible dispensing practitioner" requirements, required notifications, administrative inspections and audit standards, and standards for the storage and dispensing of prescription drugs and devices.

Fiscal Information

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

A) State budget:

This new Rule R156-88a is not expected to impact state government revenues or expenditures beyond the fiscal impact of new Title 58, Chapter 88, Part 2, Dispensing Practice as described in the fiscal note for H.B. 301 at https://le.utah.gov/~2022/bills/static/HB0301.html, because the rule is established in accordance with the mandates of Title 58, Chapter 88, Part 2, Dispensing Practice to administer the new license and establish operating standards that encompass the statutory requirements and practices in the profession, and will not affect existing state government procedures beyond those identified in the fiscal note for H.B. 301.

B) Local governments:

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

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

This proposed Rule R156-88a does not create new obligations for small businesses, nor does it increase the costs associated with any existing obligation for small businesses. Participation in this new license type by a small business is voluntary and optional. Accordingly, the Division does not anticipate any fiscal impact to small businesses in the NAICS categories of 62111, 621112, and 621399 beyond those identified in the fiscal note for H.B. 301, at https://le.utah.gov/~2022/bills/static/HB0301.html.

D) Non-small businesses ("non-small business" means a business employing 50 or more persons):

This proposed Rule R156-88a does not create new obligations for non-small businesses, nor does it increase the costs associated with any existing obligation for non-small businesses. Participation in this new license type by a non-small business is voluntary and optional. Accordingly, the Division does not anticipate any fiscal impact to non-small businesses in the NAICS categories of 62111, 621112, and 621399 beyond those identified in the fiscal note for H.B. 301, at https://le.utah.gov/~2022/bills/static/HB0301.html.

E) Persons other than small businesses, non-small businesses, state, or local government entities ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an ***agency***):

This proposed new Rule R156-88a may impact approximately 14,341 licensed physicians in Utah. However, because participation in dispensing under this new rule is voluntary and optional for these licensees, and because this new rule does not create new obligations for these licensees or increase the costs associated with any existing obligation for these licensees, the Division does not anticipate any fiscal impact to these persons beyond those identified in the fiscal note for H.B. 301 at https://le.utah.gov/~2022/bills/static/HB0301.html.

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

As described in Box 5.E for other persons, the Division does not anticipate compliance costs for any affected persons.

G) Regulatory Impact Summary Table (This table only includes fiscal impacts that could be measured. If there are inestimable fiscal impacts, they will not be included in this table. Inestimable impacts will be included in narratives above.)

Regulatory Impact Table

Fiscal Cost	**FY2023**	**FY2024**	**FY2025**
State Government	$0	$0	$0
Local Governments	$0	$0	$0
Small Businesses	$0	$0	$0
Non-Small Businesses	$0	$0	$0
Other Persons	$0	$0	$0
Total Fiscal Cost	**$0**	**$0**	**$0**
Fiscal Benefits	**FY2023**	**FY2024**	**FY2025**
State Government	$0	$0	$0
Local Governments	$0	$0	$0
Small Businesses	$0	$0	$0
Non-Small Businesses	$0	$0	$0
Other Persons	$0	$0	$0
Total Fiscal Benefits	**$0**	**$0**	**$0**
Net Fiscal Benefits	**$0**	**$0**	**$0**

H) Department head comments on fiscal impact and approval of regulatory impact analysis:

The Executive Director of the Department of Commerce, Margaret W. Busse, has reviewed and approved this fiscal analysis.

The Division of Professional Licensing ("Division"), in concert with the Physicians Licensing Board and the Board of Pharmacy, propose to create new Rule R156-88a in accordance with Title 58, Chapter 88, Part 2, Dispensing Practice, enacted by H.B. 301 during the 2022 General Session. The rule will allow the Division to administer this licenses, establishes definitions, renewal and restatement procedures, and standards for a "responsible dispensing practitioner." The rule also has requirements, processes for notifications, administrative inspections and audit standards, and standards for the storage and dispensing of prescription drugs and devices. Also, the Division has made formatting conformities throughout the rule to align with the Office of Administrative Rules' Formatting Manual in accordance with Executive Orders 2021-1 and 2021-12.

Small Businesses (less than 50 employees):
The Division finds that will not be a fiscal impact for small businesses. This proposed Rule R156-88a does not create new obligations for non-small businesses and it will not increase the costs associated with any existing obligation for non-small businesses. Participation in this new license type by a small business is voluntary and optional. Accordingly, the Division does not anticipate any fiscal impact to small businesses in the beyond those identified in the fiscal note for H.B. 301 (NAICS categories 62111, 621112, and 621399). Further, the Division does not foresee any negative impact on small businesses from the grammar since the new rule was drafted to comport to the Office of Administrative Rules *Rule Writing Manual.*

Regulatory Impact to Non-Small Businesses (50 or more employees)
The Division finds that the non-small businesses in the Utah will not suffer a negative fiscal impact from the proposed rule (NAICS categories of 62111, 621112, and 621399). However, the rule will have no expected fiscal impact for non-small businesses in Utah for the same rationale as described above for small businesses. Further, any of these costs are either inestimable, for the reasons stated above, or there is no fiscal impact.

Citation Information

6. Provide citations to the statutory authority for the rule. If there is also a federal requirement for the rule, provide a citation to that requirement:

Subsection 58-1-106(1)(a)	Section 58-88a-205	

Incorporations by Reference Information

7. Incorporations by Reference (if this rule incorporates more than two items by reference, please include additional tables):

A) 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 Office of Administrative Rules; *if none, leave blank*):

Official Title of Materials Incorporated (from title page)	
Publisher	
Issue Date	
Issue or Version	

B) 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 Office of Administrative Rules; *if none, leave blank*):

Official Title of Materials Incorporated (from title page)	
Publisher	
Issue Date	
Issue or Version	

Public Notice Information

8. 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. See Section 63G-3-302 and Rule R15-1 for more information.)

A) Comments will be accepted until: **01/03/2023**

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

On (mm/dd/yyyy):	**At** (hh:mm AM/PM):	**At** (place):
12/14/2022	9:00 AM	160 East 300 South - Conference Room 210 (2nd floor) and also electronically via Google Meet Google Meet information: Meeting link meet.google.com/zne-vudb-xsh Join by phone (US) +1 219-316-1005 PIN: 228330145

9. This rule change MAY become effective on:	**01/10/2023**

NOTE: The date above is the date the agency anticipates making the rule or its changes effective. It is NOT the effective date.

Agency Authorization Information

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 head or designee and title:	Mark B. Steinagel, Division Director	**Date:**	**11/10/2022**

R156. Commerce, Professional Licensing.

R156-88a. Dispensing Practice Rule.

R156-88a-101. Title - Authority - Organization and Relationship to Rule R156-1.

(1) This rule is known as the "Dispensing Practice Rule."

(2) This rule is adopted by the Division under the authority of Subsection 58-1-106(1)(a) to enable the Division to administer Title 58, Chapter 88, Part 2, Dispensing Practice.

(3) The organization of this rule and its relationship to Rule R156-1 is as described in Section R156-1-107.

R156-88a-102. Definitions.

The following definitions supplement the definitions in Title 58, Chapter 1, Division of Professional Licensing Act, and Title 58, Chapter 88, Part 2, Dispensing Practice:

(1) "LDP" means licensed dispensing practice.

(2) "RDP" means responsible dispensing practitioner under Subsection 58-88-203(2).

R156-88a-203a. Requirements - Responsible Dispensing Practitioner (RDP).

(1) Under Subsections 58-88-201(2) and 58-88-203(2), an RDP:

(a) shall be currently licensed in good standing;

(b) may practice at an LDP on a full-time or part-time basis; and

(c) may serve as the RDP for more than one LDP.

(2) Under Subsection 58-88-203(2), the responsibilities of each RDP shall include the following:

(a) ensuring that a reasonable effort is made by the LDP to obtain, record, and maintain patient medication records;

(b) ensuring that each person working at the LDP, including each dispensing practitioner, complies with Title 58, Chapter 88, Part 2, Dispensing Practice;

(c) establishing policies for procurement, storage, distribution, and disposal of the drugs and devices dispensed from the LDP;

(d) maintaining records of transactions necessary to maintain accurate control over and accountability for the dispensing of drugs and devices by the LDP as required by federal and state laws, rules, and regulations applicable to licensing dispensing practice;

(e) establishing and maintaining effective controls against theft or diversion of dispensed drugs, devices, and records;

(f) if records are kept on a data processing system, maintaining the records in that system in compliance with LDP requirements;

(g) legal operation of the LDP, including compliance with operating standards, inspection requirements, and other requirements of federal and state laws, rules, and regulations applicable to licensed dispensing practice; and

(h) implementation of an ongoing quality assurance program that monitors performance of the LDP, as evidenced by written policies and procedures.

R156-88a-203b. Requirements - License Term, Expiration, Renewal, and Reinstatement.

(1) Under Subsection 58-88-203(3), the renewal date for the two-year renewal cycle for licensees under Title 58, Chapter 88, Part 2, Dispensing Practice is established in Section R156-1-308a.

(2) Renewal and reinstatement procedures shall be in accordance with Sections R156-1-308a through R156-1-308l.

R156-88a-203c. Requirements - Notification.

(1) Under Subsection 58-88-204(1), an LDP shall:

(a) establish a unique email address for the LDP, to be used for self-audits and Division notices and pharmacy alerts; and

(b) if an LDP's unique email address changes, immediately update the email address with the Division.

(2) Under Subsection 58-88-203(4)(b), an LDP shall immediately notify the Division of the theft of a drug, or of a disaster, accident, or emergency that may affect purity or labeling, by emailing to the Division the form provided by the Division.

(3) Under Subsection 58-88-203(2), an LDP shall notify the Division of each designated RDP or termination of designation of an RDP, by completing and submitting to the Division the RDP form provided by the Division, within 45 days of designation or termination of designation.

(4) Under Subsection 58-88-203(4), except for changes in ownership caused by a change in stockholders in publicly listed corporations whose stock is publicly traded, an LDP shall apply for a new license and receive approval from the Division no later than ten business days before a change in:

(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 Professional Licensing; or

(c) ownership, resulting from:

(i) a change in entity type; or

(ii) the sale or transfer of 51% or more of the entity's ownership or membership interest to another individual or entity, except if the sale or transfer results from the retirement from professional practice of an LDP physician who is licensed in good standing.

(5) Upon Division approval of a change and its issuance of a new license to the LDP, the LDP shall surrender its original license to the Division.

R156-88a-204. Administrative Inspections and Audits.

(1) Under Section 58-88-204, for ascertaining compliance with Title 58, Chapter 88, Part 2, Dispensing Practice, the Division may require a self-audit or enter and inspect the business premises of a person:

(a) licensed under Subsection 58-88-201(2)(a);

(b) licensed as an LDP under Section 58-88-203; or

(c) who is engaged in activities that require a license under Title 58, Chapter 88, Part 2, Dispensing Practice.

(2) Before conducting an inspection under Subsection (1), the Division shall, after identifying the person in charge:

(a) give proper identification;

(b) request to see the applicable license or licenses;
(c) describe the nature and purpose of the inspection; and
(d) provide upon request, the authority of the Division to conduct the inspection and the penalty for refusing to permit the inspection as provided in Section 58-88-204.
(3) In conducting an inspection under Subsection (1), the Division may, after meeting the requirements of Subsection (2):
(a) examine any record, prescription, order, drug, device, equipment, machine, electronic device, or area related to activities for which a license has been issued or is required by Title 58, for ascertaining compliance with Title 58, Chapter 88, Part 2, Dispensing Practice; and
(b) reproduce any record at the Division's own cost.
(4) An investigator may, upon determination that a violation observed poses an imminent peril to the public health, safety, or welfare, recommend to the Division Director to issue an emergency licensure action, such as cease and desist.
(5) The Division shall conduct an inspection under Subsection (1) during regular business hours.
(6) An LDP shall conduct a self-audit on a form provided by the Division, in the following time periods:
(a) within ten business days of Division request;
(b) within 45 days of a change of RDP;
(c) within 45 days of the opening of a new LDP; and
(d) at least 90 days before the end of each renewal cycle.
(7) An LDP shall maintain each self-audit form for two years from the date of the self-audit, and provide an electronic or hard copy of the self-audit form to the Division upon Division request.

R156-88a-205. Operating Standards.
(1) Under Subsection 58-88-205(1), the operating standards for a licensed dispensing practice shall include the standards in this section. This section does not apply to dispensing that is limited or excepted from Title 58, Chapter 88, Part 2, Dispensing Practice, including dispensing under Subsection 58-88-202(5).
(2) An LDP shall store and maintain drugs and devices to be dispensed as follows:
(a) by expiration date, with appropriate labeling and inventory documentation;
(b) in a sanitary and controlled environment in accordance with federal and state laws, rules, and regulations applicable to licensing dispensing practice; and
(c) in a secure, locked area under the control of the RDP, with access limited to the LDP's RDPs and dispensing practitioners and the individuals under their supervision.
(3) An LDP shall label dispensed drugs in accordance with federal and state laws, rules, and regulations applicable to licensed dispensing practice, and include the following:
(a) facility name, address, and phone number;
(b) patient's name;
(c) prescriber's name;
(d) medication name and strength;

(e) date dispensed;
(f) directions for use and cautionary statements; and
(g) beyond use date.
(4) LDP inventory control standards for dispensed drugs shall be in accordance with federal and state laws, rules, and regulations applicable to licensed dispensing practice, and include the following:
(a) authorized personnel shall remove out-of-date legend drugs from the inventory at regular intervals and in correlation to the beyond use date imprinted on the label;
(b) general requirements for inventory of an LDP shall include the following:
(i) the RDP shall be responsible for taking required inventories, but may delegate performance of an inventory to one or more persons;
(ii) inventory records shall be maintained for five years and be available for inspection upon request, either in hard copy or electronic format;
(iii) inventory records shall be filed separately from all other records;
(iv) inventory records shall be in a written, typewritten, printed, or electronic form;
(v) an inventory taken by use of a verbal recording device shall be promptly transcribed;
(vi) an inventory may be taken either as the opening of the business or the close of business on the inventory date;
(vii) the individual taking the inventory and the RDP shall indicate the time the inventory was taken, and shall sign and date the inventory with the date the inventory was taken;
(viii) the signature of the RDP and the date of the inventory shall be documented within 72 hours or three business days of the completed initial, annual, change of ownership, or closing inventory; and
(ix) the initial inventory shall serve as the LDP inventory until the next completed inventory.
(5) A dispensing practitioner shall provide counseling to each patient receiving a dispensed drug or device as follows:
(a) counseling shall be offered orally in person, unless the patient or patient's agent is not at the LDP or a specific communication barrier prohibits oral communication;
(b) counseling may be provided electronically;
(c) if a prescription drug or device is delivered to the patient or patient's agent, the information in Subsection (d) may be delivered with the dispensed prescription in writing; and
(d) based upon the professional judgment of the dispensing practitioner, patient counseling may include the following elements:
(i) name and description of the prescription drug;
(ii) dosage form, dose, route of administration and duration of drug therapy;
(iii) intended use of the drug and expected action;
(iv) special directions and precautions for preparation, administration and use;
(v) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action recommended if they occur;

(vi) techniques for self-monitoring drug therapy;
(vii) proper storage;
(viii) prescription refill information;
(ix) action to be taken in the event of a missed dose;
(x) comments relevant to the individual's drug therapy, including any other information specific to the patient or drug; or
(xi) date after which the prescription should not be taken or used, or the beyond use date.
(6) Only a dispensing practitioner may orally provide counseling to a patient or patient's agent and answer questions concerning a dispensed drug or device.
(7) Operating standards for closing an LDP shall be as follows:
(a) by the date of closing, the RDP shall remove the LDP prescription drugs and devices from the LDP by one or a combination of the following methods:
(i) returning to manufacturer or supplier for credit or disposal; or
(ii) selling or giving to one or more persons legally entitled to possess the drug or device, such as an LDP, underserved population clinic, hospital, or pharmacy;
(b) within ten business days of closing, the LDP shall submit a surrender notice to the Division on a form provided by the Division, which includes the following:
(i) the actual date of closing;
(ii) a surrender of the LDP license; and
(iii) a statement attesting:
(A) that the LDP has conducted a closing inventory under Section R156-88a-205; and
(B) the manner in which the LDP drugs and devices were transferred or disposed; and
(c) if the LDP is closed suddenly due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, or other emergency circumstances, the LDP shall comply with this subsection in the detail and as promptly as allowed by the circumstances.
(8) Unlicensed LDP personnel who are supervised by a dispensing practitioner may assist in dispensing tasks not requiring professional licensure, such as:
(a) stock ordering and restocking;
(b) cashiering;
(c) billing;
(d) filing;
(e) housekeeping; and
(f) delivering a pre-filled prescription to a patient.
(9) An LDP that employs the United States Postal Service, other common carrier, or LDP personnel to deliver a filled prescription to a patient shall:
(a) use adequate storage or shipping containers and shipping processes to ensure drug stability and potency and appropriate storage temperatures throughout delivery, with packaging material and devices recommended by the manufacturer or the United States Pharmacopeia Chapter 1079;
(b) use shipping containers sealed in a manner to detect evidence of opening or tampering;

(c) have policies and procedures to ensure accountability, safe delivery, and compliance with temperature requirements, including the following:

(i) when drugs do not arrive on time or there is evidence that the integrity of a drug was compromised during shipment; and

(ii) providing for the replacement of drugs; and

(d) provide information to the patient indicating what the patient should do if the integrity of the packaging or drug was compromised during shipment.

(10) An LDP shall maintain a medication profile for each patient receiving a dispensed drug or device, as follows:

(a) a patient profile, once established, shall be maintained by the LDP on a recurring basis for a minimum of one year from the date of the most recent prescription filled; and

(b) information to be included in the profile shall be determined by the dispensing practitioner, but shall include at minimum:

(i) full name of the patient, address, telephone number, and date of birth or age and gender; and

(ii) patient history where significant, including known allergies and drug reactions, and a list of prescription drugs and devices obtained by the patient at the LDP, including:

(A) name of prescription;

(B) strength of prescription drug;

(C) quantity dispensed;

(D) date of filling;

(E) charge for the prescription drug or device as dispensed to the patient; and

(F) any additional comments relevant to the patient's drug or device use.

KEY: licensing, dispensing practice
Date of Enactment or Last Substantive Amendment: 2023
Authorizing, and Implemented or Interpreted Law: 58-1-106(1)(a); 58-88a-205