OAR File No. 55007
Date Filed 10/25/2022

State of Utah
Administrative Rule Analysis
Revised June 2022

NOTICE OF PROPOSED RULE

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

Title No. - Rule No. - Section No.		
Rule or Section Number:	**R156-37**	**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	801-530-6254	lmarx@utah.gov

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

General Information

2. Rule or section catchline:

Utah Controlled Substances Act Rule

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

This filing updates the rule to implement H.B. 265 passed during the 2021 Legislative General Session, which amended the rule governing pharmacy software for receiving and transferring electronic controlled substance prescriptions. These amendments also incorporate statutory changes made by H.B. 177 passed during the 2020 Legislative General Session, which amended the Controlled Substances Act regarding electronic transmission of controlled substance prescriptions. Additionally, changes are made in accordance with Executive Order 2021-12 to update and clarify the rule to facilitate compliance and enforcement, in particular with respect to recommendations by the Board of Pharmacy and the Division regarding certain definitions and to make changes consistent with OAR's current Rule Writing Manual.

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 If this is a repeal and reenact, explain the substantive differences between the repealed rule and the reenacted rule):

The amendments to Section R156-37-102 add definitions for "electronic controlled substance prescribing extension," "emergency situation," "forward," and "technical difficulty or electronic failure."

The amendments to Section R156-37-502 add to the definition of unprofessional conduct for a prescribing practitioner or pharmacy, failing to seek to correct a technical difficulty or electronic failure under Subsection 58-37-22(1)(d) that is reasonably within their control.

The substantive amendments to Section R156-37-603 are at the request of the Pharmacy Board, with concurrence by the Physicians Licensing Board and the Osteopathic Physicians and Surgeons Licensing Board. These amendments eliminate the prohibitive language regarding the prescribing of schedule II stimulants, and allow the prescribing provider to ensure they are prescribing stimulants in the best interest of the patient and within the standard of care.

In compliance with Section 58-37-22, new Sections R156-37-609 and R156-37-610 provide guidance for electronic prescriptions for controlled substances by establishing: (1) that a prescribing practitioner or pharmacy experiencing a technical difficulty or electronic failure shall document it on the prescription's hard copy; (2) a protocol to follow if a pharmacy that receives an electronic prescription is not able to fill the prescription; (3) additional exemptions to electronic prescription requirements; (4) guidelines under which a prescribing practitioner or pharmacy may obtain an extension of time to comply with the electronic prescribing requirements in Subsection 58-37-22(1); and (5) a requirement to issue and dispense an electronic prescription in accordance with 21 CFR 1311.

In accordance with Executive Order 2021-12, the remaining amendments make formatting changes throughout to update and clarify the rule to facilitate compliance and enforcement and make changes consistent with OAR's current Rule Writing Manual, including amendments to Section R156-37-305 that clarify that a practitioner shall maintain appropriate licensure when prescribing controlled substances, and amendments to Section R156-37-606 that update the reference to 21 CFR 1317.

Fiscal Information

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

A) State budget:

None of these proposed changes are expected to impact state government revenues or expenditures because the changes merely update the rules to establish operating standards that encompass current statutory requirements and practices in the profession, and make nonsubstantive changes for clarity to facilitate compliance and enforcement in accordance with Executive Order 2021-12, and will not affect existing state government procedures. The Division estimates that these proposed amendments will have no measurable impact on state government revenues or expenditure as none of these amendments are expected to impact state government practices or procedures beyond the fiscal analysis for 2020 HB 0177 https://le.utah.gov/~2020/bills/static/HB0177.html and for 2021 HB 0265 https://le.utah.gov/~2021/bills/static/HB0265.html.

B) Local governments:

These proposed amendments will impact businesses in the healthcare and pharmacy industry that employ prescribers, pharmacists, pharmacy interns, and pharmacy technicians (NAICS 446110, 621399, 621112, 621111, 621330, 622110, 622310, 621493, 623220, 621420, 621420, 623110) and this may potentially include certain local government entities acting as businesses. However, the Division estimates that these proposed amendments will have no impact on local government because the changes merely update the rules to establish operating standards that encompass current statutory requirements and practices in the profession, and make nonsubstantive changes for clarity to facilitate compliance and enforcement in accordance with Executive Order 2021-12.

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

These amendments will affect small businesses in the healthcare industry that employ controlled substance prescribers or dispense controlled substances; these involve businesses in NAICS 446110, 621399, 621112, 621111, 621330, 622110, 622310, 621493, 623220, 621420, 621420, and 623110. However, none of the amendments are expected to impact small business revenues or expenditures, as they are based on extensive collaboration with the Board of Pharmacy, as well as the Physicians Licensing Board and the Osteopathic Physicians and Surgeons Licensing Board, to update the rules to establish operating standards that encompass current statutory requirements and practices in the profession, and make nonsubstantive changes for clarity to facilitate compliance and enforcement in accordance with Executive Order 2021-12. Additionally, funding for software that allows electronic health records and pharmaceutical dispensing software has been available through Centers for Medicare and Medicaid Services since 2006.

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

These amendments will affect non-small businesses in the healthcare industry that employ controlled substance prescribers and/or dispense controlled substances, these involve businesses in NAICS 446110, 621399, 621112, 621111, 621330, 622110, 622310, 621493, 623220, 621420, 621420, and 623110. However, as described in Subparagraph 5.C for small businesses, none of the amendments are expected to impact non-small business revenues or expenditures.

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***):

These amendments will affect Utah licensed controlled substance prescribers and controlled substance dispensers. However, as described in Subparagraph 5.C for small businesses, none of the amendments are expected to impact the revenues or expenditures for these persons.

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 Subparagraph 5.E for other persons, no compliance costs are expected 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 Utah Board of Pharmacy, Utah Physicians Licensing Board, and the Utah Osteopathic Physicians and Surgeons Licensing Board, propose amendments to R156-37, the Utah Controlled Substances Act Rule. Changes to the rule are proposed to comply with H.B. 265 passed during the 2021 Legislative General Session, which amended the rule governing pharmacy software for receiving and transferring electronic controlled substance prescriptions. These amendments also incorporate statutory changes made by H.B. 177 passed during the 2020 Legislative General Session, which amended the Controlled Substances Act regarding electronic transmission of controlled substance prescriptions. Also, the Division has made formatting changes throughout the rule to conform the rule to 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 to small businesses in the Utah healthcare industry with the proposed amendments (relevant NAICS codes were identified as 446110, 621399, 621112, 621111, 621330, 622110, 622310, 621493, 623220, 621420, 621420, and 623110). The changes are to update the rule to establish operating standards that encompass current statutory requirements and practices in the profession. Further, the Division does not foresee any negative impact on small businesses since the grammatical amendments are made to make the rule 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 healthcare industry in the NAICS codes aforementioned, will not suffer a negative fiscal impact from the proposed rule amendments. However, these amendments 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)	Subsection 58-37-6(1)(a)	Subsection 58-37f-301(1)

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)	21 CFR Part 1311
Publisher	Code of Federal Regulations/US Food and Drug Administration
Issue Date	July 26, 2022
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)	21 CFR Part 1317
Publisher	Code of Federal Regulations/US Food and Drug Administration

Issue Date	July 26, 2022
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:		**12/15/2022**
B) A public hearing (optional) will be held:		
On (mm/dd/yyyy):	**At** (hh:mm AM/PM):	**At** (place):
11/22/2022	10:00 AM	160 East 300 South - Conference Room 402 and electronically via Google Meet **Meeting link** meet.google.com/har-yfec-vbm **Join by phone** (US) +1 443-574-7046 PIN: 108791761

9. This rule change MAY become effective on:	**12/22/2022**

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:**	**10/25/2022**

R156. Commerce, [~~Occupational and~~]Professional Licensing.
R156-37. Utah Controlled Substances Act Rule.
R156-37-101. Title - Authority.

(1) This rule is known as the "Utah Controlled Substances Act Rule."

(2) This rule is adopted by the Division under the authority of Subsections 58-1-106(1)(a) and 58-37-6(1)(a) to enable the Division to administer Title 58, Chapter 37, Utah Controlled Substances Act.

R156-37-102. Definitions.

[~~In addition to the~~]The following definitions supplement the definitions in Title 58, Chapter[~~s~~] 1, Division of Professional Licensing Act, and Title 58, Chapter 37, Utah Controlled Substances Act[~~as used in Title 58, Chapters 1 and 37, or this rule~~]:

(1) "DEA" means the Drug Enforcement Administration of the United States Department of Justice.

(2) "Electronic Controlled Substance Prescribing Extension" means the prescribing practitioner or pharmacy has a controlled substance designation class indicated on the license, approved by the Division under Section R156-37-610, and does not participate in electronic prescriptions for controlled substances.

(3) "Emergency situation," for purposes of Subsection 58-37-6(7)(c)(iii) and Section R156-37-605 for emergency verbal prescriptions, Subsection 58-37-6(7)(d) for prescription signature and information requirements, and Subsection 58-37-22(10(e) for electronic prescription requirements:

(a) means a situation in which the prescribing practitioner who intends to prescribe a controlled substance, or the pharmacy that intends to dispense a controlled substance, has determined that:

(i) the controlled substance prescription cannot be issued, filled, compounded, dispensed, or transmitted electronically as an electronic prescription in compliance with the statutory requirement without causing a delay;

(ii) the delay would adversely impact the patient's medical condition; and

(iii) the prompt prescribing or dispensing of the controlled substance is necessary for the proper treatment of the patient; and

(b) includes a situation when a prescription is written for an emergent or urgent condition:

(i) at a time when the prescribing practitioner is not reasonably able to transmit an electronic prescription to the patient's desired pharmacy for dispensing; or

(ii) after normal pharmacy business hours including weekends, holidays, late evening or overnight, and the patient cannot fill the prescription secondary to limited access to 24-hour pharmacy locations and no access to their regular pharmacy.

(4) "Forward" in Subsection R156-37-609(5)(a) means an original unfilled electronic controlled substance prescription.

([~~2~~]5) "NABP" means the National Association of Boards of Pharmacy.

([~~3~~]6) "Principal place of business or professional practice"[~~, as used~~] in Subsection 58-37-6(2)(e), means any location where controlled substances are received or stored.

([~~4~~]7) "Schedule II controlled stimulant" means any material, compound, mixture, or preparation listed in Subsection 58-37-4(2)(b)(iii).

([~~5~~]8) "SBIRT training" means training in the Screening, Brief Intervention, and Referral to Treatment approach used by the federal Substance Abuse and Mental Health Services Administration, as defined in Subsections 58-37-6.5(1)(e) and 58-37-6.5(3).

(9) "Technical difficulty or electronic failure" in Subsection 58-37-22(1)(d) means a loss of electrical power or internet service, a failure of a computer system, application, or device, or other service interruption to a computer system that reasonably prevents:

(a) a practitioner from transmitting an electronic controlled substance prescription to a pharmacy;

(b) a pharmacy from receiving an electronic controlled substance prescription or transmitting an electronic controlled substance prescription to a different pharmacy in accordance with Subsection 58-37-22(3); or

(c) compliance by a practitioner or a pharmacy with the requirements of state or federal law, including 21 CFR Part 1311 (July 26, 2022), which is incorporated by reference.

([~~6~~]10) "Unprofessional conduct"[~~,~~] as defined in Title 58, Occupations and Professions, is further defined in accordance with Subsections 58-1-203(1)(e) and 58-37-6(1)(a), in Section R156-37-502.[

~~**R156-37-103. Purpose - Authority.**~~

~~This rule is adopted by the Division under the authority of Subsections 58-1-106(1)(a) and 58-37-6(1)(a) to enable the Division to administer Title 58, Chapter 37.~~]

R156-37-301. License Classifications - Restrictions.

(1) [~~Consistent with the provisions of law,~~]Under Subsection 58-37-6(2), the Division may issue a controlled substance license to[~~manufacture, produce, distribute, dispense, prescribe, obtain, administer, analyze, or conduct research with controlled substances in Schedules I, II, III, IV, or V to qualified persons. Licenses shall be issued to qualified persons in the following categories~~]:

(a) a qualified person licensed in good standing in the classification of:

([~~a~~]i) pharmacist;

([~~b~~]ii) optometrist;

([~~c~~]iii) podiatric physician;

([~~d~~]iv) dentist;

([e]v) osteopathic physician and surgeon;

([~~f~~]vi) physician and surgeon;

([~~g~~vii]) physician assistant;

([~~h~~]viii) veterinarian;

(ix) advanced practice registered nurse or advanced practice registered nurse-certified registered nurse anesthetist;

([~~j~~]x) certified nurse midwife;

([~~k~~]xi) naturopathic physician;

(xii) anesthesiologist assistant;

([~~l~~]xiii) Class A pharmacy[~~retail operations located in Utah~~] under Subsection R156-17b-302(1);

([~~m~~]xiv) Class B pharmacy under Subsection R156-17b-302(2);[~~located in Utah providing services to a target population unique to the needs of the healthcare services required by the patient, including:~~

~~(i) closed door pharmacy;~~

~~(ii) hospital clinic pharmacy;~~

~~(iii) methadone clinic pharmacy;~~

~~(iv) nuclear pharmacy;~~

~~(v) branch pharmacy;~~

~~(vi) hospice facility pharmacy;~~

~~(vii) veterinarian pharmaceutical facility pharmacy;~~

~~(viii) pharmaceutical administration facility pharmacy;~~

~~(ix) sterile product preparation facility pharmacy; and~~

~~(x) dispensing medical practitioner clinic pharmacy.~~]

([~~n~~]xv) Class C pharmacy under Subsection R156-17b-302(3);[~~engaged in:~~

~~(i) manufacturing;~~

~~(ii) producing;~~

~~(iii) wholesaling;~~

~~(iv) distributing; and~~

~~(v) reverse distributing.~~]

([~~o~~]xvi) Class D [~~Out-of-state mail order pharmacies.~~]pharmacy under Subsection R156-17b-302(4); or

([~~p~~]xvii) Class E pharmacy under Subsection R156-17b-302(5); or[~~including:~~

~~(i) medical gases provider;~~

~~(ii) analytical laboratory pharmacy;~~

~~(iii) animal control pharmacy;~~

~~(iv) human clinical investigational drug research facility pharmacy; and~~

~~(v) animal narcotic detection training facility pharmacy.~~]

([~~q~~]xviii) the Utah Department of Corrections, for the conduct of execution by the administration of lethal injection [~~under its statutory authority and~~]in accordance with Section 77-18-113[~~its policies and procedures~~].

(2) [~~A~~]The Division may restrict a controlled substance license [~~may be restricted~~]to the extent [~~determined by~~]the Division, in collaboration with the appropriate licensing boards, determines [~~that a restriction is~~]necessary to protect the [~~public~~]health, safety, or welfare of:

(a) the public; or

(b) [~~, or the welfare of~~]the licensee.

(3) A person [~~receiving~~]holding a restricted controlled substance license [~~shall manufacture, produce, obtain, distribute, dispense, prescribe, administer, analyze, or conduct research with controlled substances only to the extent of the terms and conditions under which the restricted license is issued by the Division~~]may use the license only to the extent of the restricted terms and conditions.

R156-37-302. Qualifications for Licensure - Application Requirements.

(1) An applicant for a controlled substance license shall:

(a) submit an application in a form [~~as~~]prescribed by the Division;[~~and~~]

(b) [~~shall~~]pay the [~~required~~]fee [~~as~~]established by the Division under [~~the provisions of~~]Section 63J-1-504[~~.~~]; and

(c) [~~(2) Any person seeking a controlled substance license shall~~]be currently licensed in good standing by the state in [~~the appropriate professional license~~]a classification [~~as listed~~]in Section R156-37-301[~~ and shall maintain that license classification as current at all times while holding a controlled substance license~~].

(3) The Division and the reviewing board may request from the applicant information that is reasonable and necessary to permit an evaluation of[~~the applicant's~~]:

(a) the applicant's qualifications to engage in practice with controlled substances; and

(b) the public interest in the issuance of a controlled substance license to the applicant.

(4) To determine if an applicant is qualified for licensure, the Division may:

(a) assign the application to a qualified and appropriate licensing board for review and recommendation to the Division[~~with respect to issuance of a license.~~

~~**R156-37-303. Qualifications for Licensure -- Site Inspections -- Investigations.**~~

~~The Division shall have the right to~~]; and

(b) conduct site inspections, review research protocol, conduct interviews with persons knowledgeable about the applicant, and conduct any other investigation [~~which~~]that is reasonable and necessary to determine the applicant is [~~of good moral character and~~]qualified to receive a controlled substance license.

R156-37-305. Qualifications for Licensure - Drug Enforcement Administration (DEA) Registration - Active License.

(1)(a) Except as specified in Subsection (1)(b), an [~~An~~] individual who obtains a controlled substance license [~~except those individuals described in Subsection (2) below,~~]shall obtain a DEA registration within 120 days of the date the controlled substance license is issued.

([~~2~~]b) [~~Any~~]A controlled substance licensee who [~~obtains prior~~]has written consent [~~of~~]from the licensee's employer to use the employer's hospital or institution DEA registration to administer [~~and/~~]or prescribe controlled substances, or both, is not required to obtain an individual practitioner DEA registration.

(2) A person who holds a controlled substance license shall maintain their license under Subsection R156-37-301(1) active and in good standing.

(3) If a person's license under Subsection R156-37-301(1) expires or is revoked, surrendered, or suspended, the Division shall:

(a) immediately suspend the person's controlled substance license; and

(b) reinstate the person's controlled substance license only upon reinstatement of the underlying license, without further administrative action that would be grounds for the continued denial of the controlled substance license.

R156-37-306. Exemption from Licensure - Law Enforcement Personnel, University Research, Narcotic Detection Training of Animals, and Animal Control.

[~~In accordance with~~]Under Subsection 58-37-6(2)(d), the following persons are exempt from licensure under Title 58, Chapter 37, Utah Controlled Substances Act:

(1)(a) except as specified in Subsection (1)(b), law[~~—Law~~] enforcement agencies and their sworn personnel, [~~are exempt from the licensing requirements of the Controlled Substance Act~~]to the extent their official duties require them to possess controlled substances[~~,~~], if they:

(i) [~~they~~]act within the scope of their enforcement responsibilities;

(ii) [~~they~~]maintain accurate records of controlled substances that come into their possession; and

(iii) [~~they~~]maintain an effective audit trail[~~.~~];

(b) [~~Nothing herein shall authorize~~]law enforcement personnel [~~to~~]may not purchase or possess controlled substances for administration to animals unless the purchase or possession is in accordance with a [~~duly issued~~]controlled substance license[~~.~~];

(2) [~~I~~]individuals and entities engaged in research using pharmaceuticals as defined in Subsection 58-17b-102([~~65~~]66) within a research facility as defined in Subsection R156-17b-102([~~49~~]48)[~~.~~]; and

(3) [~~I~~]individuals employed by a facility engaged in the following activities, if the facility employing that individual has a controlled substance license in Utah[~~,~~] and a DEA registration number, and uses the controlled substances according to a written protocol:

(a) narcotic detection training of animals for law enforcement use; or

(b) animal control, including:

(i) animal euthanasia; or

(ii) animal immobilization.

R156-37-402. Continuing Professional Education for Controlled Substance Prescribers.

[~~In accordance with~~]Under Section 58-37-6.5, qualified continuing professional education requirements for controlled substance prescribers are further established as follows:

(1) Continuing education under this section shall:

(a) be prepared and presented by individuals who are qualified by education, training, and experience to provide the controlled substance prescriber continuing education; and

(b) have a method of verification of attendance and a post-course knowledge assessment or examination.

(2) In accordance with Subsections 58-37-6.5(2)(b), 58-37-6.5(5), 58-37-6.5(7), and 58-37-6.5(8), the controlled substance prescribing classes and SBIRT training that satisfy the [~~d~~]Division's continuing education requirements for license renewal, and that are delivered by an accredited or approved continuing education provider recognized by the [~~d~~]Division as offering appropriate continuing education, shall be posted on the [~~d~~]Division's website at [~~http://~~]dopl.utah.gov[~~/~~].

(3) Credit for continuing education shall be recognized as follows:

(a) Unlimited hours shall be recognized for continuing education completed in blocks of time of not less than 50 minutes;

(b) Continuing education hours for licensees who have not been licensed for the entire two-year period shall be prorated from the date of licensure;

(c) In accordance with Subsection 58-37f-304(3), the required 1/2 hour of continuing education for the online tutorial and test relating to the controlled substance database shall be waived by the [~~d~~]Division for a controlled substance prescriber renewing a license, if the prescriber attests on the license renewal form that:

(i) in the past license period, the prescriber accessed the controlled substance database; and

(ii) upon the prescriber's information and belief, the prescriber's use of the database reduced the prescribing, dispensing, and use of opioids in an unprofessional or unlawful manner, or in quantities or frequencies inconsistent with generally recognized standards of dosage for an opioid.

(4)(a) A licensee shall maintain competent records of completed qualified continuing professional education for a period of [~~four~~]two years after close of the two-year period to which the records pertain.

(b) The [~~d~~]Division may review controlled substance database usage by the prescriber or proxy to audit an attestation [~~provided~~]under Subsection [~~R156-37-402~~](3)(c).

R156-37-502. Unprofessional Conduct.

"Unprofessional conduct" includes:

(1) as a licensee with authority to prescribe or administer controlled substances:

(a) prescribing or administering to oneself any Schedule II or III controlled substance that is not lawfully prescribed by another licensed practitioner having authority to prescribe the drug;

(b) prescribing or administering a controlled substance for a condition that the [~~preseriber~~]licensee is not licensed or competent to treat;

(2) violating a[~~ny~~] federal or state law relating to controlled substances;

(3) failing to deliver to the Division [~~all~~]each controlled substance license certificate[~~s~~] issued by the Division [~~to the Division~~]upon an action that revokes, suspends, or limits the license;

(4) failing to maintain controls over controlled substances that a prudent licensee would [~~be considered by a prudent practitioner to be~~]maintain as effective against diversion, theft, or shortage of controlled substances;

(5) [~~being unable~~]failing to account for shortages of [~~any~~]controlled substance inventory for which the licensee has responsibility;

(6) knowingly prescribing, selling, giving away, or administering, directly or indirectly, or offering to prescribe, sell, furnish, give away, or administer any controlled substance to a drug dependent person, as defined in Subsection 58-37-2(1)(s), except for legitimate medical purposes as permitted by law;

(7) refusing to make available for inspection controlled substance stock, inventory, [~~and~~]or records as required under [~~this rule~~]Rule R156-37 or other law regulating controlled substances and controlled substance records;

(8) failing to submit controlled substance prescription information to the [~~d~~]Database [~~m~~]Manager after being notified in writing by the Division to do so;[~~ or~~]

(9) failing to [~~obtain~~]get a DEA registration within the time frame [~~established~~] in Section R156-37-305[~~.~~];

(10) as a prescribing practitioner, failing to seek to correct a technical difficulty or electronic failure under Subsection 58-37-22(1)(d) that is reasonably within the prescribing practitioner's control; or

(11) as a pharmacy, failing to seek to correct a technical difficulty or electronic failure under Subsection 58-37-22(1)(d) that is reasonably within the pharmacy's control.

R156-37-601. Access to Records, Facilities and Inventory.

[~~Applicants~~]During regular business hours, and at other reasonable times, each applicant for licensure and [~~all~~]licensee[~~s~~] shall make available for inspection to a[~~ny~~] person authorized to conduct an administrative inspection[~~ pursuant to this rule;~~] under federal law, Title 58, Chapter 37, [~~the~~]Utah Controlled Substances Act[~~; or federal law during regular business hours and at other reasonable times in the event of an emergency~~], or Rule R156-37, their:

(1) controlled substance stock or inventory;

(2) records required in accordance with state and federal laws and rules[~~under the Utah Controlled Substances Act, this rule, or Federal controlled substance laws~~]; and

(3) facilities related to activities involving controlled substances.

R156-37-602. Records.

(1)(a) Records of controlled substances shall be kept in accordance with state and federal laws and rules for their:

(i) purchase[~~.~~];

(ii) distribution[~~.~~];

(iii) dispensing[~~.~~];

(iv) prescribing[~~.~~] and

(v) administration[~~ of controlled substances shall be kept according to state and federal law~~].

(b) Prescribing practitioners shall keep accurate records for each patient reflecting[~~ the~~]:

(i) examination[~~.~~];

(ii) evaluation; and

(iii) treatment[~~ of all patients~~].

(c) Patient medical records shall:

(i) accurately reflect the prescription or administration of controlled substances in the treatment of the patient[~~.~~];

(ii) the purpose for which the controlled substance is utilized[~~.~~]; and

(iii) information upon which the diagnosis is based.

(d) Practitioners shall keep records apart from patient records of each controlled substance purchased, and with respect to each controlled substance, its disposition, whether by administration or any other means, date of disposition, to whom given, and the quantity given.

(2) A[~~ny~~] licensee who experiences any theft, including diversion, or significant loss of controlled substances shall immediately:

(a) file the appropriate forms with the [~~Drug Enforcement Administration~~]DEA, with a copy to the Division directed to the attention of the Investigation Bureau; and

(b) report the incident to the local law enforcement agency.

(3) [~~All~~]Each record[~~s~~] required by federal and state laws or rules [~~must~~]shall be maintained by the licensee for [~~a period of~~]five years. If a licensee [~~should~~]sells or transfers ownership of records in anyway, those records shall be maintained separately from other records of the new owner.

(4) Prescription records may be maintained electronically [~~so long as~~]if:

(a) the original of each prescription, including telephone prescriptions, is maintained in a physical file and contains [~~all of~~]the information required by federal and state law; and

(b) an automated data processing system is used for the storage and immediate retrieval of refill information for prescription orders for controlled substances in Schedule III and IV, in accordance with federal guidelines.

(5) [~~All~~]Each record[~~s~~] relating to Schedule II controlled substances received, purchased, administered, or dispensed by the practitioner shall be maintained separately from [~~all~~]other records of the pharmacy or practice.

(6) [~~All~~]Each record[~~s~~] relating to Schedules III, IV, and V controlled substances received, purchased, administered, or dispensed by the practitioner shall be maintained separately from [~~all~~]other records of the pharmacy or practice.

R156-37-603. Restrictions Upon the Prescription, Dispensing, and Administration of Controlled Substances.

(1) A practitioner may prescribe or administer the Schedule II controlled substance cocaine hydrochloride only as:

(a) a topical anesthetic for mucous membranes in surgical situations in which it is [~~properly~~]indicated; and

(b) as local anesthetic for the repair of facial and pediatric lacerations, if [~~when~~]the controlled substance is mixed and dispensed by a [~~registered~~]licensed pharmacist in the proper formulation and dosage.

(2) A practitioner [~~shall~~]may not prescribe or administer a controlled substance without taking into account the drug's potential for abuse, and the possibility:

(a) that the drug may lead to dependence[~~,~~];

(b) that [~~the possibility the~~]patient [~~will~~]may get [~~obtain~~]the drug for a nontherapeutic use or to distribute to others[~~,~~]; and

(c) [~~the possibility of~~]that an illicit market exists for the drug.

(3) [~~In accordance with~~]Under Subsection 58-37-6(7)(f)(vii)[~~(D)~~], unless the [~~prescriber~~]prescribing practitioner determines there is a valid medical reason to allow an earlier dispensing date, the dispensing

date of a second or third prescription shall be [~~no less than~~]at least 30 days from the dispensing date of the previous prescription, to allow for receipt of the subsequent prescription before the previous prescription runs out.

(4)(a) If a practitioner fails to document [~~his~~]the practitioner's intentions relative to refills of controlled substances in Schedules III through V on a prescription form, it shall mean no refills are authorized.

(b) [~~No~~]A refill is not permitted on a prescription for a Schedule II controlled substance.

(5) Refills of controlled substance prescriptions shall be permitted for the following periods from the original date of the prescription[~~as follows~~]:

(a) Schedules III and IV, for six months from the original date of the prescription; and

(b) Schedule V, for one year from the original date of the prescription.

(6) [~~No~~]A refill may not be dispensed until [~~such~~]sufficient time has passed since the date of the last dispensing that 80% of the medication in the previous dispensing should have been consumed if taken according to the [~~prescriber's~~]prescribing practitioner's instruction.

(7) [~~No~~]A controlled substance prescription [~~for a controlled substance shall~~]may not be issued or dispensed without specific instructions from the [~~prescriber~~]prescribing practitioner on how and when the drug is to be used.

(8) Refills after expiration of the original prescription term shall require[~~s the~~] issuance of a new prescription by the prescribing practitioner.

(9) Each prescription for a controlled substance and the number of refills authorized shall be documented in the patient records by the prescribing practitioner.

(10) [~~A practitioner shall not prescribe or administer a Schedule II controlled stimulant for any purpose except:~~

~~(a) the treatment of narcolepsy as confirmed by neurological evaluation;~~

~~(b) the treatment of abnormal behavioral syndrome, attention deficit disorder, hyperkinetic syndrome, or related disorders;~~

~~(c) the treatment of drug-induced brain dysfunction;~~

~~(d) the differential diagnostic psychiatric evaluation of depression;~~

~~(e) the treatment of depression shown to be refractory to other therapeutic modalities, including pharmacologic approaches, such as tricyclic antidepressants or MAO inhibitors;~~

~~(f) in the terminal stages of disease, as adjunctive therapy in the treatment of chronic severe pain or chronic severe pain accompanied by depression;~~

~~(g) the clinical investigation of the effects of the drugs, in which case the practitioner shall submit to the Division a written investigative protocol for its review and approval before the investigation has begun. The investigation shall be conducted in strict compliance with the investigative protocol, and the practitioner shall, within 60 days following the conclusion of the investigation, submit to the Division a~~

~~written report detailing the findings and conclusions of the investigation; or~~

~~(h) in treatment of depression associated with medical illness after due consideration of other therapeutic modalities.~~

~~(11)~~] A practitioner may prescribe, dispense, or administer a Schedule II controlled stimulant when [~~properly~~]indicated[~~for any purpose listed in Subsection (10), provided that all of the following conditions are met:~~

~~(a)~~] if, before initiating treatment [~~utilizing a~~]using the Schedule II controlled stimulant, the practitioner:

(a) obtains an appropriate history and physical examination;[~~, and~~]

(b) rules out the existence of [~~any~~]recognized contraindications; and[~~to the use of the controlled substance to be utilized;~~

~~(b) the practitioner shall not prescribe, dispense or administer any Schedule II controlled stimulant when he knows or has reason to believe that a recognized contraindication to its use exists;~~

~~(c) the practitioner shall not prescribe, dispense or administer any Schedule II controlled stimulant in the treatment of a patient who he knows or should know is pregnant; and~~

~~(d) the practitioner shall not initiate or shall discontinue prescribing, dispensing or administering all Schedule II controlled stimulants immediately upon ascertaining or having~~]

(c) has no reason to believe that the patient has consumed or disposed of any controlled stimulant other than in compliance with the treating practitioner's directions.

R156-37-604. Prescribing of Controlled Substances for Weight Reduction or Control.

(1) A practitioner [~~shall~~]may not prescribe, dispense, or administer a Schedule II or Schedule III controlled substance for [~~purposes of~~]weight reduction or control.

(2) A prescribing practitioner may prescribe or administer a Schedule IV controlled substance in treating excessive weight leading to increased health risks only [~~when all~~]if the prescribing practitioner complies with each of the following conditions[~~are met~~]:

(a) medication is used only as an adjunct to a comprehensive weight loss program based on supplemental weight loss activities including[~~, but not limited to,~~] changing lifestyle counseling, nutritional education, and a regular, individualized exercise regimen;

(b) [~~prior to~~]before initiating treatment the prescribing practitioner[~~shall~~]:

(i) determines through thorough review of past medical records that the patient has made a substantial good-faith effort to lose weight in a comprehensive weight loss program without the use of controlled substances, and the previous regimen has not been effective;

(ii) obtains a complete history, performs a complete physical examination of the patient, and rules out the existence of [~~any~~]recognized contraindications to the use of the medication[~~(s)~~];

(iii) determines and documents [~~this~~]the assessment in the patient's medical record, that the health benefit to the patient greatly outweighs the possible risks of the medications prescribed; and

(iv) discusses with the patient the possible risks associated with the medication, and [~~have~~]has on record an informed consent [~~which~~]that clearly documents that the long term effects of using controlled substances for weight loss or weight control are not known;

(c) throughout the prescribing period, the prescribing practitioner[~~shall~~]:

(i) supervises, oversees, and regularly monitors the patient, including [~~his~~]the patient's participation in supplemental weight loss activities, efficacy of the medication, and advisability of continuing to prescribe the weight loss or weight control medication; and

(ii) maintains a central medical record[~~, containing at least,~~] that contains at least the following information:

(A) the goal of treatment or target weight[~~,~~];

(B) the ongoing progress toward that goal or maintenance of the weight loss[~~,~~];

(C) the patient's supplemental weight loss activities with documentation of compliance with the comprehensive weight loss program; and

(d) the prescribing practitioner shall immediately discontinue the weight loss medication [~~in any of the following situations~~]if:

(i) the practitioner knows or should know that the patient is pregnant;

(ii) the patient has consumed or disposed of any controlled substance other than in compliance with the prescribing practitioner's directions;

(iii) the patient is abusing the controlled substance being prescribed for weight loss;

(iv) the patient develops a contraindication [~~during the course~~]of therapy;[~~or~~]

(v) the medication is not effective; or

(vi) [~~that~~]the patient is not [~~abiding with and following through~~]complying with the agreed upon comprehensive weight loss program.

R156-37-605. Emergency Verbal Prescription of Schedule II Controlled Substances.

(1) Under Subsection 58-37-6(7), in an emergency situation a prescribing[~~Prescribing~~] practitioner[~~s~~] may give an oral [~~verbal~~]prescription for a Schedule II controlled substance if:

(a) the quantity dispensed is only sufficient to cover the patient for the emergency period, not to exceed 72 hours;

(b)(i) the prescribing practitioner has examined the patient within the past 30 days[~~,~~];

(ii) the patient is under the continuing care of the prescribing practitioner for a chronic disease or ailment[~~,~~]; or

(iii) the prescribing practitioner is covering for another practitioner and has knowledge of the patient's condition; and

(c) a written prescription is delivered to the pharmacist within seven [~~working~~]business days of the [~~verbal~~]oral order.

(2) Under Subsection 58-37-6(7), in an emergency situation a[~~A~~] pharmacist may fill [~~an emergency verbal or telephonic~~]an oral prescription from a prescribing practitioner for a Schedule II controlled substance if:

(a) the amount does not exceed a 72 hour supply; and

(b) the [~~filling~~]pharmacist reasonably believes, or makes a reasonable effort to determine, that the prescribing practitioner is licensed to prescribe the controlled substance[~~s or makes a reasonable effort to determine that he is licensed~~].

R156-37-606. Disposal of Controlled Substances.

(1) [~~Any disposal of controlled substances by licensees shall be consistent with the provisions of~~]A licensee shall dispose of controlled substances in accordance with 21 CFR Part 1317 (July 26, 2022) which is incorporated by reference[~~1307.21 of the Code of Federal Regulations~~].

(2) [~~Records of disposal of controlled substances shall be maintained and made~~]A licensee who disposes of controlled substances shall:

(a) maintain records of the disposal for five years from the date of disposal; and

(b) make the records available for inspection upon request to the Division or its agents[~~for inspection for a period of five years~~].

R156-37-607. Surrender of Suspended or Revoked License.

(1) [~~Licenses which have been~~]A licensee whose license has been restricted, suspended, or revoked shall [~~be surrendered~~]surrender the license to the Division within 30 days of the effective date of the order[~~of restriction, suspension or revocation~~].

(2) The Division shall consider compliance [~~Compliance~~] with this section [~~will be a consideration~~]in evaluating an application[~~s~~] for relicensing.

R156-37-608. Restricted Applicability - Herbs, Herbal Products, or Food Supplements.

[~~The~~]Under Section 58-37-2.5, the Division [~~shall~~]may not apply [~~the provisions of~~]Title 58, Chapter 37, Utah [~~the~~]Controlled Substance Act or [~~this rule~~]Rule R156-37 [~~in restricting~~]to restrict citizens or practitioners, regardless of their license status, from the sale or use of [~~food or~~]herbs, herbal products, or food supplements that are not scheduled as controlled substances by [~~S~~]state or [~~F~~]federal law.

R156-37-609. Electronic Prescriptions for Controlled Substances.

(1) Under Subsection 58-37-22(2)(a), a prescribing practitioner or pharmacy experiencing a temporary technical difficulty or electronic failure under Subsection 58-37-22(1)(d) shall document the nature of the technical difficulty or electronic failure on the prescription's hard copy.

(2) A pharmacist who receives a written, oral, or faxed controlled substance prescription is not required to verify that the prescription qualifies for an exemption under this section, and may dispense and deliver medication from an otherwise valid written, oral, or faxed controlled substance prescription.

(3) Under Subsection 58-37--22(2)(c), a prescribing practitioner or pharmacy is exempt from the electronic prescription requirements of Section 58-37-22 if:

(a)(i)(A) the prescribing practitioner is licensed in a jurisdiction other than Utah; and

(B) the receiving pharmacy orally confirms the prescription with the prescribing practitioner;

(ii) the prescribing practitioner and dispensing pharmacy are the same entity;

(iii) the prescription is a Schedule II oral prescription issued in an emergency situation under Section R156-37-605;

(iv) the federal Food and Drug Administration requires the prescription to contain elements that cannot be included in an electronic prescription;

(v) the prescription drug is under a research protocol; or

(vi) the prescription is for a medication that requires compounding two or more ingredients; and

(b) the prescribing practitioner or pharmacy documents the exemption on the prescription's hard copy.

(4) Under Subsection 58-37-22(2)(d), a prescribing practitioner or pharmacy may apply for an extension of time to comply with Subsection 58-37-22(1) by submitting a form to the Division under Section R156-37-610.

(5) Under Subsection 58-37-22(2)(e), if an originating pharmacy that receives an electronic controlled substance prescription cannot fill the prescription, the following protocol shall apply:

(a) if the pharmacy can electronically transmit the prescription, the pharmacy shall:

(i) contact the ultimate user to determine the pharmacy that is to receive the forward prescription; and

(ii) document in the automated pharmacy system the identity of the pharmacy receiving the forward prescription;

(b) if the pharmacy cannot electronically transmit the prescription:

(i) the pharmacy shall:

(A) contact the prescribing practitioner and state the pharmacy cannot fill or transmit the prescription;

(B) document in the automated pharmacy system the individual contacted at the prescribing office; and

(C) void the prescription; and

(ii) the prescribing practitioner may electronically transmit a new prescription to a different pharmacy.

(6) Under Subsection 58-37-22(2)(f), an electronic prescription shall be issued and dispensed in accordance with 21 CFR Part 1311 (July 26, 2022), which is incorporated by reference.

R156-37-610. Electronic Prescribing for Controlled Substance Extension Designation.

(1) Under Subsection 58-37-22(2)(d), a prescribing practitioner or pharmacy that cannot comply with Subsection 58-37-22(1) may apply for an electronic prescribing controlled substance extension on a form provided by the Division, that includes:

(a) the prescribing practitioner's or pharmacy's:

(i) name, address, and license number; and

(ii) current electronic prescribing capabilities;

(b) the reason for the extension, including:

(i) economic hardship;

(ii) technological barrier; or

(iii) exceptional circumstance; and

(c) an attestation that the prescribing practitioner or pharmacy understands that the prescribing practitioner or pharmacy shall comply with Subsection 58-37-22(1) beginning January 1, 2024, and that no further extensions are permitted.

(2) The Division may request supporting documentation to justify the reason for the extension, and the applicant's anticipated date of compliance with Section 58-37-22.

KEY: controlled substances, licensing
Date of Enactment or Last Substantive Amendment: [~~December 27, 2018~~]2022
Notice of Continuation: December 14, 2021
Authorizing, and Implemented or Interpreted Law: 58-1-106(1)(a); 58-37-6(1)(a); 58-37f-301(1)