PHARMACY SOFTWARE AMENDMENTS

2021 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Rosemary T. Lesser

Senate Sponsor: Evan J. Vickers

Cosponsors: Cheryl K. Acton, Stewart E. Barlow, Stephen G. Handy, Suzanne Harrison, Candice B. Pierucci, Elizabeth Weight

LONG TITLE

General Description:

This bill amends provisions relating to an electronic prescription for a controlled substance.

Highlighted Provisions:

This bill:

- requires a pharmacy software system that receives electronic prescriptions for a controlled substance to allow an unfilled prescription to be transferred to a different pharmacy; and
- makes technical changes.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

58-37-6, as last amended by Laws of Utah 2020, Chapter 81

ENACTS:

58-37-22, Utah Code Annotated 1953

Be it enacted by the Legislature of the state of Utah:

Section 1. Section **58-37-6** is amended to read:

58-37-6. License to manufacture, produce, distribute, dispense, administer, or conduct research -- Issuance by division -- Denial, suspension, or revocation -- Records required -- Prescriptions.

(1) (a) The division may adopt rules relating to the licensing and control of the manufacture, distribution, production, prescription, administration, dispensing, conducting of research with, and performing of laboratory analysis upon controlled substances within this state.

(b) The division may assess reasonable fees to defray the cost of issuing original and renewal licenses under this chapter pursuant to Section 63J-1-504.

(2) (a) (i) Every person who manufactures, produces, distributes, prescribes, dispenses, administers, conducts research with, or performs laboratory analysis upon any controlled substance in Schedules I through V within this state, or who proposes to engage in manufacturing, producing, distributing, prescribing, dispensing, administering, conducting research with, or performing laboratory analysis upon controlled substances included in Schedules I through V within this state shall obtain a license issued by the division.

(ii) The division shall issue each license under this chapter in accordance with a two-year renewal cycle established by rule. The division may by rule extend or shorten a renewal period by as much as one year to stagger the renewal cycles it administers.

(b) Persons licensed to manufacture, produce, distribute, prescribe, dispense, administer, conduct research with, or perform laboratory analysis upon controlled substances in Schedules I through V within this state may possess, manufacture, produce, distribute, prescribe, dispense, administer, conduct research with, or perform laboratory analysis upon those substances to the extent authorized by their license and in conformity with this chapter.

(c) The following persons are not required to obtain a license and may lawfully possess controlled substances included in Schedules II through V under this section:

(i) an agent or employee, except a sales representative, of any registered manufacturer, distributor, or dispenser of any controlled substance, if the agent or employee is acting in the usual course of the agent or employee's business or employment; however, nothing in this subsection shall be interpreted to permit an agent, employee, sales representative, or detail man to maintain an inventory of controlled substances separate from the location of the person's employer's registered and licensed place of business;

(ii) a motor carrier or warehouseman, or an employee of a motor carrier or warehouseman, who possesses a controlled substance in the usual course of the person's business or employment; and

(iii) an ultimate user, or a person who possesses any controlled substance pursuant to a lawful order of a practitioner.

(d) The division may enact rules waiving the license requirement for certain manufacturers, producers, distributors, prescribers, dispensers, administrators, research practitioners, or laboratories performing analysis if waiving the license requirement is consistent with public health and safety.

(e) A separate license is required at each principal place of business or professional practice where the applicant manufactures, produces, distributes, dispenses, conducts research with, or performs laboratory analysis upon controlled substances.

(f) The division may enact rules providing for the inspection of a licensee or applicant's establishment, and may inspect the establishment according to those rules.

(3) (a) (i) Upon proper application, the division shall license a qualified applicant to manufacture, produce, distribute, conduct research with, or perform laboratory analysis upon controlled substances included in Schedules I through V, unless it determines that issuance of a license is inconsistent with the public interest.

(ii) The division may not issue a license to any person to prescribe, dispense, or administer a Schedule I controlled substance except under Subsection (3)(a)(i).

(iii) In determining public interest under this Subsection (3)(a), the division shall consider whether the applicant has:

(A) maintained effective controls against diversion of controlled substances and any Schedule I or II substance compounded from any controlled substance into channels other than legitimate medical, scientific, or industrial channels;

(B) complied with applicable state and local law;

(C) been convicted under federal or state laws relating to the manufacture, distribution, or dispensing of substances;

(D) past experience in the manufacture of controlled dangerous substances;

(E) established effective controls against diversion; and

(F) complied with any other factors that the division establishes that promote the public health and safety.

(b) Licenses granted under Subsection (3)(a) do not entitle a licensee to manufacture, produce, distribute, conduct research with, or perform laboratory analysis upon controlled substances in Schedule I other than those specified in the license.

(c) (i) Practitioners shall be licensed to administer, dispense, or conduct research with substances in Schedules II through V if they are authorized to administer, dispense, or conduct research under the laws of this state.

(ii) The division need not require a separate license for practitioners engaging in research with nonnarcotic controlled substances in Schedules II through V where the licensee is already licensed under this chapter in another capacity.

(iii) With respect to research involving narcotic substances in Schedules II through V, or where the division by rule requires a separate license for research of nonnarcotic substances in Schedules II through V, a practitioner shall apply to the division prior to conducting research.

(iv) Licensing for purposes of bona fide research with controlled substances by a practitioner considered qualified may be denied only on a ground specified in Subsection (4), or upon evidence that the applicant will abuse or unlawfully transfer or fail to safeguard adequately the practitioner's supply of substances against diversion from medical or scientific use.

(v) Practitioners registered under federal law to conduct research in Schedule I substances may conduct research in Schedule I substances within this state upon providing the division with evidence of federal registration.

(d) Compliance by manufacturers, producers, and distributors with the provisions of federal law respecting registration, excluding fees, entitles them to be licensed under this chapter.

(e) The division shall initially license those persons who own or operate an establishment engaged in the manufacture, production, distribution, dispensation, or administration of controlled substances prior to April 3, 1980, and who are licensed by the state.

(4) (a) Any license issued pursuant to Subsection (2) or (3) may be denied, suspended, placed on probation, or revoked by the division upon finding that the applicant or licensee has:

(i) materially falsified any application filed or required pursuant to this chapter;

(ii) been convicted of an offense under this chapter or any law of the United States, or any state, relating to any substance defined as a controlled substance;

(iii) been convicted of a felony under any other law of the United States or any state within five years of the date of the issuance of the license;

(iv) had a federal registration or license denied, suspended, or revoked by competent federal authority and is no longer authorized to manufacture, distribute, prescribe, or dispense controlled substances;

(v) had the licensee's license suspended or revoked by competent authority of another state for violation of laws or regulations comparable to those of this state relating to the manufacture, distribution, or dispensing of controlled substances;

(vi) violated any division rule that reflects adversely on the licensee's reliability and integrity with respect to controlled substances;

(vii) refused inspection of records required to be maintained under this chapter by a person authorized to inspect them; or

(viii) prescribed, dispensed, administered, or injected an anabolic steroid for the

purpose of manipulating human hormonal structure so as to:

(A) increase muscle mass, strength, or weight without medical necessity and without a written prescription by any practitioner in the course of the practitioner's professional practice; or

(B) improve performance in any form of human exercise, sport, or game.

(b) The division may limit revocation or suspension of a license to a particular controlled substance with respect to which grounds for revocation or suspension exist.

(c) (i) Proceedings to deny, revoke, or suspend a license shall be conducted pursuant to this section and in accordance with the procedures set forth in Title 58, Chapter 1, Division of Occupational and Professional Licensing Act, and conducted in conjunction with the appropriate representative committee designated by the director of the department.

(ii) Nothing in this Subsection (4)(c) gives the Division of Occupational and Professional Licensing exclusive authority in proceedings to deny, revoke, or suspend licenses, except where the division is designated by law to perform those functions, or, when not designated by law, is designated by the executive director of the Department of Commerce to conduct the proceedings.

(d) (i) The division may suspend any license simultaneously with the institution of proceedings under this section if it finds there is an imminent danger to the public health or safety.

(ii) Suspension shall continue in effect until the conclusion of proceedings, including judicial review, unless withdrawn by the division or dissolved by a court of competent jurisdiction.

(e) (i) If a license is suspended or revoked under this Subsection (4), all controlled substances owned or possessed by the licensee may be placed under seal in the discretion of the division.

(ii) Disposition may not be made of substances under seal until the time for taking an appeal has lapsed, or until all appeals have been concluded, unless a court, upon application, orders the sale of perishable substances and the proceeds deposited with the court.

(iii) If a revocation order becomes final, all controlled substances shall be forfeited.

(f) The division shall notify promptly the Drug Enforcement Administration of all orders suspending or revoking a license and all forfeitures of controlled substances.

(g) If an individual's Drug Enforcement Administration registration is denied, revoked, surrendered, or suspended, the division shall immediately suspend the individual's controlled substance license, which shall only be reinstated by the division upon reinstatement of the federal registration, unless the division has taken further administrative action under Subsection (4)(a)(iv), which would be grounds for the continued denial of the controlled substance license.

(5) (a) A person licensed under Subsection (2) or (3) shall maintain records and inventories in conformance with the record keeping and inventory requirements of federal and state law and any additional rules issued by the division.

(b) (i) A physician, dentist, naturopathic physician, veterinarian, practitioner, or other individual who is authorized to administer or professionally use a controlled substance shall keep a record of the drugs received by the individual and a record of all drugs administered, dispensed, or professionally used by the individual otherwise than by a prescription.

(ii) An individual using small quantities or solutions or other preparations of those drugs for local application has complied with this Subsection (5)(b) if the individual keeps a record of the quantity, character, and potency of those solutions or preparations purchased or prepared by the individual, and of the dates when purchased or prepared.

(6) Controlled substances in Schedules I through V may be distributed only by a licensee and pursuant to an order form prepared in compliance with division rules or a lawful order under the rules and regulations of the United States.

(7) (a) An individual may not write or authorize a prescription for a controlled substance unless the individual is:

(i) a practitioner authorized to prescribe drugs and medicine under the laws of this state or under the laws of another state having similar standards; and

(ii) licensed under this chapter or under the laws of another state having similar

standards.

(b) An individual other than a pharmacist licensed under the laws of this state, or the pharmacist's licensed intern, as required by Sections 58-17b-303 and 58-17b-304, may not dispense a controlled substance.

(c) (i) A controlled substance may not be dispensed without the written prescription of a practitioner, if the written prescription is required by the federal Controlled Substances Act.

(ii) That written prescription shall be made in accordance with Subsection (7)(a) and in conformity with Subsection (7)(d).

(iii) In emergency situations, as defined by division rule, controlled substances may be dispensed upon oral prescription of a practitioner, if reduced promptly to writing on forms designated by the division and filed by the pharmacy.

(iv) Prescriptions reduced to writing by a pharmacist shall be in conformity with Subsection (7)(d).

(d) Except for emergency situations designated by the division, an individual may not issue, fill, compound, or dispense a prescription for a controlled substance unless the prescription is signed by the prescriber in ink or indelible pencil or is signed with an electronic signature of the prescriber as authorized by division rule, and contains the following information:

(i) the name, address, and registry number of the prescriber;

(ii) the name, address, and age of the person to whom or for whom the prescription is issued;

(iii) the date of issuance of the prescription; and

(iv) the name, quantity, and specific directions for use by the ultimate user of the controlled substance.

(e) A prescription may not be written, issued, filled, or dispensed for a Schedule I controlled substance unless:

(i) the individual who writes the prescription is licensed under Subsection (2); and

(ii) the prescribed controlled substance is to be used in research.

(f) Except when administered directly to an ultimate user by a licensed practitioner, controlled substances are subject to the restrictions of this Subsection (7)(f).

(i) A prescription for a Schedule II substance may not be refilled.

(ii) A Schedule II controlled substance may not be filled in a quantity to exceed a one-month's supply, as directed on the daily dosage rate of the prescriptions.

(iii) (A) Except as provided in Subsection (7)(f)(iii)(B), a prescription for a Schedule II or Schedule III controlled substance that is an opiate and that is issued for an acute condition shall be completely or partially filled in a quantity not to exceed a seven-day supply as directed on the daily dosage rate of the prescription.

(B) Subsection (7)(f)(iii)(A) does not apply to a prescription issued for a surgery when the practitioner determined that a quantity exceeding seven days is needed, in which case the practitioner may prescribe up to a 30-day supply, with a partial fill at the discretion of the practitioner.

(C) Subsection (7)(f)(iii)(A) does not apply to prescriptions issued for complex or chronic conditions which are documented as being complex or chronic in the medical record.

(D) A pharmacist is not required to verify that a prescription is in compliance with Subsection (7)(f)(iii).

(iv) A Schedule III or IV controlled substance may be filled only within six months of issuance, and may not be refilled more than six months after the date of its original issuance or be refilled more than five times after the date of the prescription unless renewed by the practitioner.

(v) All other controlled substances in Schedule V may be refilled as the prescriber's prescription directs, but they may not be refilled one year after the date the prescription was issued unless renewed by the practitioner.

(vi) Any prescription for a Schedule II substance may not be dispensed if it is not presented to a pharmacist for dispensing by a pharmacist or a pharmacy intern within 30 days after the date the prescription was issued, or 30 days after the dispensing date, if that date is specified separately from the date of issue.

(vii) A practitioner may issue more than one prescription at the same time for the same Schedule II controlled substance, but only under the following conditions:

(A) no more than three prescriptions for the same Schedule II controlled substance may be issued at the same time;

(B) no one prescription may exceed a 30-day supply; and

(C) a second or third prescription shall include the date of issuance and the date for dispensing.

[~~(g) (i) Beginning January 1, 2022, each prescription issued for a controlled substance shall be transmitted electronically as an electronic prescription unless the prescription is:~~]

[~~(A) for a patient residing in an assisted living facility as that term is defined in Section 26-21-2, a long-term care facility as that term is defined in Section 58-31b-102, or a correctional facility as that term is defined in Section 64-13-1;~~]

[~~(B) issued by a veterinarian licensed under Title 58, Chapter 28, Veterinary Practice Act;~~]

[~~(C) dispensed by a Department of Veterans Affairs pharmacy;~~]

[~~(D) issued during a temporary technical or electronic failure at the practitioner's or pharmacy's location; or~~]

[~~(E) issued in an emergency situation.~~]

[~~(ii) The division, in collaboration with the appropriate boards that govern the licensure of the licensees who are authorized by the division to prescribe or to dispense controlled substances, shall make rules in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act to:~~]

[~~(A) require that controlled substances prescribed or dispensed under Subsection (7)(g)(i)(D) indicate on the prescription that the prescribing practitioner or the pharamacy is experiencing a technical difficulty or an electronic failure;~~]

[~~(B) define an emergency situation for purposes of Subsection (7)(g)(i)(E);~~]

[~~(C) establish additional exemptions to the electronic prescription requirements established in this Subsection (7)(g);~~]

[~~(D) establish guidelines under which a prescribing practitioner or a pharmacy may obtain an extension of up to two additional years to comply with Subsection (7)(g)(i);~~]

[~~(E) establish a protocol to follow if the pharmacy that receives the electronic prescription is not able to fill the prescription; and~~]

[~~(F) establish requirements that comply with federal laws and regulations for software used to issue and dispense electronic prescriptions.~~]

[~~(h)~~] (g) An order for a controlled substance in Schedules II through V for use by an inpatient or an outpatient of a licensed hospital is exempt from all requirements of this Subsection (7) if the order is:

(i) issued or made by a prescribing practitioner who holds an unrestricted registration with the federal Drug Enforcement Administration, and an active Utah controlled substance license in good standing issued by the division under this section, or a medical resident who is exempted from licensure under Subsection 58-1-307(1)(c);

(ii) authorized by the prescribing practitioner treating the patient and the prescribing practitioner designates the quantity ordered;

(iii) entered upon the record of the patient, the record is signed by the prescriber affirming the prescriber's authorization of the order within 48 hours after filling or administering the order, and the patient's record reflects the quantity actually administered; and

(iv) filled and dispensed by a pharmacist practicing the pharmacist's profession within the physical structure of the hospital, or the order is taken from a supply lawfully maintained by the hospital and the amount taken from the supply is administered directly to the patient authorized to receive it.

[~~(i)~~] (h) A practitioner licensed under this chapter may not prescribe, administer, or dispense a controlled substance to a child, without first obtaining the consent required in Section 78B-3-406 of a parent, guardian, or person standing in loco parentis of the child except in cases of an emergency. For purposes of Subsection (7)[~~(i)~~](h), "child" has the same meaning as defined in Section 78A-6-105, and "emergency" means any physical condition requiring the administration of a controlled substance for immediate relief of pain or suffering.

[~~(j)~~] (i) A practitioner licensed under this chapter may not prescribe or administer dosages of a controlled substance in excess of medically recognized quantities necessary to treat the ailment, malady, or condition of the ultimate user.

[~~(k)~~] (j) A practitioner licensed under this chapter may not prescribe, administer, or dispense any controlled substance to another person knowing that the other person is using a false name, address, or other personal information for the purpose of securing the controlled substance.

[~~(l)~~] (k) A person who is licensed under this chapter to manufacture, distribute, or dispense a controlled substance may not manufacture, distribute, or dispense a controlled substance to another licensee or any other authorized person not authorized by this license.

[~~(m)~~] (l) A person licensed under this chapter may not omit, remove, alter, or obliterate a symbol required by this chapter or by a rule issued under this chapter.

[~~(n)~~] (m) A person licensed under this chapter may not refuse or fail to make, keep, or furnish any record notification, order form, statement, invoice, or information required under this chapter.

[~~(o)~~] (n) A person licensed under this chapter may not refuse entry into any premises for inspection as authorized by this chapter.

[~~(p)~~] (o) A person licensed under this chapter may not furnish false or fraudulent material information in any application, report, or other document required to be kept by this chapter or willfully make any false statement in any prescription, order, report, or record required by this chapter.

(8) (a) (i) Any person licensed under this chapter who is found by the division to have violated any of the provisions of Subsections (7)(k) through (o) or Subsection (10) is subject to a penalty not to exceed $5,000. The division shall determine the procedure for adjudication of any violations in accordance with Sections 58-1-106 and 58-1-108.

(ii) The division shall deposit all penalties collected under Subsection (8)(a)(i) [~~in~~] into the General Fund as a dedicated credit to be used by the division under Subsection 58-37f-502(1).

(iii) The director may collect a penalty that is not paid by:

(A) referring the matter to a collection agency; or

(B) bringing an action in the district court of the county where the person against whom the penalty is imposed resides or in the county where the office of the director is located.

(iv) A county attorney or the attorney general of the state shall provide legal assistance and advice to the director in an action to collect a penalty.

(v) A court shall award reasonable attorney fees and costs to the prevailing party in an action brought by the division to collect a penalty.

(b) Any person who knowingly and intentionally violates Subsections (7)(h) through (j) or Subsection (10) is:

(i) upon first conviction, guilty of a class B misdemeanor;

(ii) upon second conviction, guilty of a class A misdemeanor; and

(iii) on third or subsequent conviction, guilty of a third degree felony.

(c) Any person who knowingly and intentionally violates Subsections (7)(k) through (o) shall upon conviction be guilty of a third degree felony.

(9) Any information communicated to any licensed practitioner in an attempt to unlawfully procure, or to procure the administration of, a controlled substance is not considered to be a privileged communication.

(10) A person holding a valid license under this chapter who is engaged in medical research may produce, possess, administer, prescribe, or dispense a controlled substance for research purposes as licensed under Subsection (2) but may not otherwise prescribe or dispense a controlled substance listed in Section 58-37-4.2.

Section 2. Section **58-37-22** is enacted to read:

58-37-22. Electronic prescriptions for controlled substances.

(1) Beginning January 1, 2022, each prescription issued for a controlled substance shall be transmitted electronically as an electronic prescription unless the prescription is:

(a) for a patient residing in an assisted living facility as that term is defined in Section 26-21-2, a long-term care facility as that term is defined in Section 58-31b-102, or a

correctional facility as that term is defined in Section 64-13-1;

(b) issued by a veterinarian licensed under Title 58, Chapter 28, Veterinary Practice Act;

(c) dispensed by a Department of Veterans Affairs pharmacy;

(d) issued during a temporary technical or electronic failure at the practitioner's or pharmacy's location; or

(e) issued in an emergency situation.

(2) The division, in collaboration with the appropriate boards that govern the licensure of the licensees who are authorized by the division to prescribe or to dispense controlled substances, shall make rules in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, to:

(a) require that controlled substances prescribed or dispensed under Subsection (1)(d) indicate on the prescription that the prescribing practitioner or the pharmacy is experiencing a technical difficulty or an electronic failure;

(b) define an emergency situation for purposes of Subsection (1)(e);

(c) establish additional exemptions to the electronic prescription requirements established in this section;

(d) establish guidelines under which a prescribing practitioner or a pharmacy may obtain an extension of up to two additional years to comply with Subsection (1);

(e) establish a protocol to follow if the pharmacy that receives the electronic prescription is not able to fill the prescription; and

(f) establish requirements that comply with federal laws and regulations for software used to issue and dispense electronic prescriptions.

(3) Beginning July 1, 2024, a pharmacy software program for receiving an electronic prescription for a controlled substance shall be capable of electronically transferring a prescription to a different pharmacy:

(a) upon the request of the patient or the practitioner;

(b) with the approval of a pharmacist at the originating pharmacy; and

(c) if the prescription is unfilled.