LEGISLATIVE GENERAL COUNSEL
₵ Approved for Filing: G. Gunn ₵
₵ 02-07-24 8:03 AM ₵

PHARMACY PRACTICE ACT AMENDMENTS

2024 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Evan J. Vickers

House Sponsor: Steve Eliason

LONG TITLE

General Description:

This bill amends provisions related to the licensure of pharmacies.

Highlighted Provisions:

This bill:

- requires the pharmacist in charge of a pharmacy that is not a class D pharmacy, and not each manager at the pharmacy, to submit fingerprint cards and consent to a fingerprint background check;
- subject to statutory limitations, grants rulemaking authority to the Division of Professional Licensing to prescribe a method by which a pharmacy may update the address registered to a pharmacy's license;
- allows a hospital pharmacy to dispense a limited supply of a prescription drug to an individual who is no longer a patient in the hospital, if the drug is necessary for the patient's immediate needs;
- allows a pharmacy to update the address registered to a pharmacy's license, if there has been no change in the underlying ownership or control of the pharmacy;
- applies the provisions of Title 58, Chapter 88, Part 2, Dispensing Practice, to a physician who dispenses a prescription drug or device to a patient for the patient's immediate needs, in an emergency department, and in accordance with other code provisions; and
- makes corresponding technical changes.

S.B. 207

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

58-17b-306, as last amended by Laws of Utah 2023, Chapter 223

58-17b-603, as enacted by Laws of Utah 2004, Chapter 280

58-17b-610.6, as last amended by Laws of Utah 2022, Chapter 465

58-17b-613, as last amended by Laws of Utah 2015, Chapter 336

58-17b-614, as last amended by Laws of Utah 2020, Chapter 339

58-17b-622, as last amended by Laws of Utah 2023, Chapter 329

58-88-202, as enacted by Laws of Utah 2022, Chapter 353

REPEALS:

58-17b-610.5, as last amended by Laws of Utah 2020, Chapter 81

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

Section 1. Section **58-17b-306** is amended to read:

58-17b-306. Qualifications for licensure as a pharmacy.

(1) Each applicant for licensure under this section, except for those applying for a class D license, shall:

(a) submit a written application in the form prescribed by the division;

(b) pay a fee as determined by the department under Section 63J-1-504;

(c) satisfy the division that the applicant, and each owner, officer, or manager of the applicant have not engaged in any act, practice, or omission, which when considered with the duties and responsibilities of a licensee under this section indicates there is cause to believe that issuing a license to the applicant is inconsistent with the interest of the public's health, safety, or welfare;

(d) demonstrate the licensee's operations will be in accordance with all federal, state, and local laws relating to the type of activity engaged in by the licensee, including regulations of the Federal Drug Enforcement Administration and Food and Drug Administration;

(e) maintain operating standards established by division rule made in collaboration with the board and in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act;

(f) for each pharmacy [~~manager, submit~~] license, ensure that the pharmacist in charge, as defined by the division, submits fingerprint cards and [~~consent~~] consents to a fingerprint background check in accordance with Section 58-17b-307; and

(g) acknowledge the division's authority to inspect the licensee's business premises pursuant to Section 58-17b-103.

(2) Each applicant applying for a class D license shall:

(a) submit a written application in the form prescribed by the division;

(b) pay a fee as determined by the department under Section 63J-1-504;

(c) present to the division verification of licensure in the state where physically located and verification that such license is in good standing;

(d) satisfy the division that the applicant and each of the applicant's pharmacy managers has not engaged in any act, practice, or omission, which when considered with the duties and responsibilities of a licensee under this section, indicates there is cause to believe that issuing a license to the applicant is inconsistent with the interest of the public's health, safety, or welfare;

(e) for each pharmacy manager, submit fingerprint cards and consent to a fingerprint background check in accordance with Section 58-17b-307;

(f) provide a statement of the scope of pharmacy services that will be provided and a detailed description of the protocol as described by rule by which pharmacy care will be provided, including any collaborative practice arrangements with other health care practitioners;

(g) sign an affidavit attesting that any healthcare practitioners employed by the applicant and physically located in Utah have the appropriate license issued by the division and in good standing;

(h) sign an affidavit attesting that the applicant will abide by the pharmacy laws and regulations of the jurisdiction in which the pharmacy is located; and

(i) if an applicant engages in compounding, submit the most recent inspection report:

(i) conducted within two years before the application for licensure; and

(ii) (A) conducted as part of the National Association of Boards of Pharmacy Verified Pharmacy Program; or

(B) performed by the state licensing agency of the state in which the applicant is a resident and in accordance with the National Association of Boards of Pharmacy multistate inspection blueprint program.

(3) (a) Each license issued under this section shall be [~~issued for~~] associated with a single, specific address[~~, and is not transferable or assignable~~].

(b) By rule made in collaboration with the board and in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, the division shall allow a licensee to update, by request to the division, the address associated with the licensee under Subsection (3)(a), to a new address if the licensee requests the change of address at least 90 days before the day on which the licensee begins operating at the new address.

Section 2. Section **58-17b-603** is amended to read:

58-17b-603. Identification of pharmacy personnel.

[~~(1)~~] All individuals employed in a pharmacy facility having any contact with the public or patients receiving services from that pharmacy facility shall wear on their person a clearly visible and readable identification showing the individual's name and position.

[~~(2) When communicating by any means, written, verbal, or electronic, pharmacy personnel must identify themselves as to licensure classification.~~]

Section 3. Section **58-17b-610.6** is amended to read:

58-17b-610.6. Hospital pharmacy dispensing prescription drugs.

(1) As used in this section, "controlled substance" means a substance classified as a controlled substance under the Controlled Substances Act, Title II, Pub. L. No. 91-513 et seq., or Section 58-37-4.

[~~(1)~~] (2) The division shall make rules, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, in consultation with hospital pharmacies, to establish guidelines under which a hospital pharmacy may dispense a limited supply of a prescription drug to an individual who is no longer a patient in the hospital setting if:

(a) the individual is discharged from the hospital on the same day that the hospital pharmacy dispenses the prescription drug to the individual;

(b) in the professional judgment of the practitioner, dispensing the drug is necessary for

the patient's immediate needs;

[~~(b)~~] (c) the class A pharmacy with which the patient has an established pharmacy-patient relationship:

(i) is not open at the time of the patient's discharge; or

(ii) unable to dispense the medication for any reason;

[~~(c)~~] (d) the hospital pharmacy dispenses a quantity of the prescription drug that is not more than a 72-hour supply; and

[~~(d)~~] (e) dispensing the prescription drug complies with protocols established by the hospital pharmacy.

(3) A hospital pharmacy may dispense an opioid antagonist to a patient regardless of whether a class A pharmacy with which the patient has an established relationship is closed at the time of the patient's discharge.

(4) A practitioner or pharmacist in the hospital may dispense a prescription drug in accordance with Subsection (2).

(5) Under Subsection (2), a practitioner may not dispense more than a two-day supply of a controlled substance.

[~~(2)~~] (6) A hospital pharmacy may dispense a prescription drug in accordance with rules made under Subsection [~~(1)~~] (2).

Section 4. Section **58-17b-613** is amended to read:

58-17b-613. Patient counseling.

(1) A pharmacy shall verbally offer to counsel a patient or a patient's agent in a personal face-to-face discussion regarding each prescription drug dispensed, if the patient or patient's agent:

(a) delivers the prescription in person to the pharmacist or pharmacy intern; or

(b) receives the drug in person at the time it is dispensed at the pharmacy facility.

(2) A pharmacist or pharmacy intern at a pharmacy that receives a prescription from a patient by means other than personal delivery, and that dispenses [~~prescription drugs~~] a prescribed drug to the patient by means other than personal delivery, shall provide the patient with:

[~~(a) provide patient counseling to a patient regarding each prescription drug the pharmacy dispenses; and~~]

(a) a toll-free telephone number at which the patient may contact a pharmacist or pharmacy intern at the mail-order pharmacy for patient counseling regarding the prescribed drug; or

(b) [~~provide each patient with a toll-free telephone number by which the patient can~~] a telephone number by which the patient may contact a pharmacist or pharmacy intern at the pharmacy for [~~counseling~~] patient counseling regarding the prescribed drug.

(3) Notwithstanding the provisions of Subsections (1) and (2), a pharmacist or a pharmacy intern may provide patient counseling to an individual under the jurisdiction of the Utah Department of Corrections or a county detention facility via a written, telephone, or electronic communication.

Section 5. Section **58-17b-614** is amended to read:

58-17b-614. Notification.

(1) A pharmacy shall report in writing to the division not later than 10 business days:

(a) before the date of:

(i) a permanent closure of the pharmacy facility;

(ii) a change of business name or ownership of the pharmacy facility;

(iii) a change of location of the pharmacy facility;

(iv) a sale or transfer of any controlled substance as a result of the permanent closing or change of ownership of the pharmacy facility; or

(v) any matter or occurrence that the division requires by rule to be reported; or

(b) after the day on which:

(i) a final administrative disciplinary order is issued against the pharmacy license holder by the regulatory or licensing agency of the state in which the pharmacy is located if the pharmacy is a class D pharmacy;

(ii) a final order against a pharmacist is issued who is designated as the pharmacist-in-charge of the pharmacy by the regulatory or licensing agency of the state in which the pharmacy is located if the pharmacy is a class D pharmacy; or

(iii) any matter or occurrence that the division requires by rule to be reported.

(2) The division may grant a licensee's request to change the business name registered to a licensed pharmacy facility, if there has been no change in the underlying ownership or control of the pharmacy since the last time the business name of the pharmacy was registered

or changed.

[~~(2)~~] (3) A pharmacy shall report in writing to the division a disaster, accident, or emergency that may affect the purity or labeling of a drug, medication, device, or other material used in the diagnosis or treatment of injury, illness, or disease immediately upon the occurrence of the disaster, accident, or emergency as defined by rule.

[~~(3)~~] (4) A reporting pharmacy shall maintain a copy of any notification required by this section for two years and make a copy available for inspection.

Section 6. Section **58-17b-622** is amended to read:

58-17b-622. Pharmacy benefit management services -- Auditing of pharmacy records -- Appeals.

(1) For purposes of this section:

(a) "Audit" means a review of the records of a pharmacy by or on behalf of an entity that finances or reimburses the cost of health care services or pharmaceutical products.

(b) "Audit completion date" means:

(i) for an audit that does not require an on-site visit at the pharmacy, the date on which the pharmacy, in response to the initial audit request, submits records or other documents to the entity conducting the audit, as determined by:

(A) postmark or other evidence of the date of mailing; or

(B) the date of transmission if the records or other documents are transmitted electronically; and

(ii) for an audit that requires an on-site visit at a pharmacy, the date on which the auditing entity completes the on-site visit, including any follow-up visits or analysis which shall be completed within 60 days after the day on which the on-site visit begins.

(c) "Entity" includes:

(i) a pharmacy benefits manager or coordinator;

(ii) a health benefit plan;

(iii) a third party administrator as defined in Section 31A-1-301;

(iv) a state agency; or

(v) a company, group, or agent that represents, or is engaged by, one of the entities described in Subsections (1)(c)(i) through (iv).

(d) "Fraud" means an intentional act of deception, misrepresentation, or concealment in

order to gain something of value.

(e) "Health benefit plan" means:

(i) a health benefit plan as defined in Section 31A-1-301; or

(ii) a health, dental, medical, Medicare supplement, or conversion program offered under Title 49, Chapter 20, Public Employees' Benefit and Insurance Program Act.

(2) (a) Except as provided in Subsection (2)(b), this section applies to:

(i) a contract for the audit of a pharmacy entered into, amended, or renewed on or after July 1, 2012; and

(ii) an entity that conducts an audit of the pharmacy records of a pharmacy licensed under this chapter.

(b) This section does not apply to an audit of pharmacy records:

(i) for a federally funded prescription drug program, including:

(A) the state Medicaid program;

(B) the Medicare Part D program;

(C) a Department of Defense prescription drug program; and

(D) a Veterans Affairs prescription drug program; or

(ii) when fraud or other intentional and willful misrepresentation is alleged and the pharmacy audit entity has evidence that the pharmacy's actions reasonably indicate fraud or intentional and willful misrepresentation.

(3) (a) An audit that involves clinical or professional judgment shall be conducted by or in consultation with a pharmacist who is employed by or working with the auditing entity and who is licensed in the state or another state.

(b) If an audit is conducted on site at a pharmacy, the entity conducting the audit:

(i) shall give the pharmacy 10 days advanced written notice of:

(A) the audit; and

(B) the range of prescription numbers or a date range included in the audit; and

(ii) may not audit a pharmacy during the first five business days of the month, unless the pharmacy agrees to the timing of the audit.

(c) An entity may not audit claims:

(i) submitted more than 18 months prior to the audit, unless:

(A) required by federal law; or

(B) the originating prescription is dated in the preceding six months; or

(ii) that exceed 200 selected prescription claims.

(4) (a) An entity may not:

(i) include dispensing fees in the calculations of overpayments unless the prescription is considered a misfill;

(ii) recoup funds for prescription clerical or recordkeeping errors, including typographical errors, scrivener's errors, and computer errors on a required document or record unless the audit entity is alleging fraud or other intentional or willful misrepresentation and the audit entity has evidence that the pharmacy's actions reasonably indicate fraud or intentional and willful misrepresentation;

(iii) recoup funds for refills dispensed in accordance with Section 58-17b-608.1, unless the health benefit plan does not cover the prescription drug dispensed by the pharmacy;

(iv) collect any funds, charge-backs, or penalties until the audit and all appeals are final, unless the audit entity is alleging fraud or other intentional or willful misrepresentation and the audit entity has evidence that the pharmacy's actions reasonably indicate fraud or intentional and willful misrepresentation; or

(v) recoup funds or collect any funds, charge-backs, or penalties from a pharmacy in response to a request for audit unless the pharmacy confirms to the entity the date on which the pharmacy received the request for audit.

(b) Auditors shall only have access to previous audit reports on a particular pharmacy if the previous audit was conducted by the same entity except as required for compliance with state or federal law.

(5) A pharmacy subject to an audit:

(a) may use one or more of the following to validate a claim for a prescription, refill, or change in a prescription:

(i) electronic or physical copies of records of a health care facility, or a health care provider with prescribing authority;

(ii) any prescription that complies with state law;

(iii) the pharmacy's own physical or electronic records; or

(iv) the physical or electronic records, or valid copies of the physical or electronic records, of a practitioner or health care facility as defined in Section 26B-2-201; and

(b) may not be required to provide the following records to validate a claim for a prescription, refill, or change in a prescription:

(i) if the prescription was handwritten, the physical handwritten version of the prescription; or

(ii) a note from the practitioner regarding the patient or the prescription that is not otherwise required for a prescription under state or federal law.

(6) (a) (i) An entity that audits a pharmacy shall establish:

(A) a maximum time for the pharmacy to submit records or other documents to the entity following receipt of an audit request for records or documents; and

(B) a maximum time for the entity to provide the pharmacy with a preliminary audit report following submission of records under Subsection (6)(a)(i)(A).

(ii) The time limits established under Subsections (6)(a)(i)(A) and (B):

(A) shall be identical; and

(B) may not be less than seven days or more than 60 days.

(iii) An entity that audits a pharmacy may not, after the audit completion date, request additional records or other documents from the pharmacy to complete the preliminary audit report described in Subsection (6)(b).

(b) An entity that audits a pharmacy shall provide the pharmacy with a preliminary audit report, delivered to the pharmacy or its corporate office of record, within the time limit established under Subsection (6)(a)(i)(B).

(c) (i) Except as provided in Subsection (6)(c)(ii), a pharmacy has 30 days following receipt of the preliminary audit report to respond to questions, provide additional documentation, and comment on and clarify findings of the audit.

(ii) An entity may grant a reasonable extension under Subsection (6)(c)(i) upon request by the pharmacy.

(iii) Receipt of the report under Subsection (6)(c)(i) shall be determined by:

(A) postmark or other evidence of the date of mailing; or

(B) the date of transmission if the report is transmitted electronically.

(iv) If a dispute exists between the records of the auditing entity and the pharmacy, the records maintained by the pharmacy shall be presumed valid for the purpose of the audit.

(7) If an audit results in the dispute or denial of a claim, the entity conducting the audit

shall allow:

(a) the pharmacy to resubmit a claim using any commercially reasonable method, including fax, mail, or electronic claims submission provided that the period of time when a claim may be resubmitted has not expired under the rules of the plan sponsor; and

(b) the health benefit plan or other entity that finances or reimburses the cost of health care services or pharmaceutical products to rerun the claim if the health benefit plan or other entity chooses to rerun the claim at no cost to the pharmacy.

(8) (a) Within 60 days after the completion of the appeals process under Subsection (9), a final audit report shall be delivered to the pharmacy or its corporate office of record.

(b) The final audit report shall include a disclosure of any money recovered by the entity that conducted the audit.

(9) (a) An entity that audits a pharmacy shall establish a written appeals process for appealing a preliminary audit report and a final audit report, and shall provide the pharmacy with notice of the written appeals process.

(b) If the pharmacy benefit manager's contract or provider manual contains the information required by this Subsection (9), the requirement for notice is met.

(10) In accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, the department may make rules prescribing the administration of this section.

Section 7. Section **58-88-202** is amended to read:

58-88-202. Dispensing practice -- Drugs that may be dispensed -- Limitations and exceptions.

(1) Notwithstanding Section 58-17b-302, a dispensing practitioner may dispense a drug at a licensed dispensing practice if the drug is:

(a) packaged in a fixed quantity per package by:

(i) the drug manufacturer;

(ii) a pharmaceutical wholesaler or distributor; or

(iii) a pharmacy licensed under Chapter 17b, Pharmacy Practice Act;

(b) dispensed:

(i) at a licensed dispensing practice at which the dispensing practitioner regularly practices; and

(ii) under a prescription issued by the dispensing practitioner to the dispensing

practitioner's patient;

(c) for a condition that is not expected to last longer than 30 days; and

(d) for a condition for which the patient has been evaluated by the dispensing practitioner on the same day on which the dispensing practitioner dispenses the drug.

(2) A dispensing practitioner may not dispense:

(a) a controlled substance as defined in Section 58-37-2;

(b) a drug or class of drugs that is designated by the division under Subsection 58-88-205(2);

(c) gabapentin; or

(d) a supply of a drug under this part that exceeds a 30-day supply.

(3) A dispensing practitioner may not make a claim against workers' compensation or automobile insurance for a drug dispensed under this part for outpatient use unless the dispensing practitioner is contracted with a pharmacy network established by the claim payor.

(4) When a dispensing practitioner dispenses a drug to the patient under this part, a dispensing practitioner shall:

(a) disclose to the patient verbally and in writing that the patient is not required to fill the prescription through the licensed dispensing practice and that the patient has a right to fill the prescription through a pharmacy; and

(b) if the patient will be responsible to pay cash for the drug, disclose:

(i) that the patient will be responsible to pay cash for the drug; and

(ii) the amount that the patient will be charged by the licensed dispensing practice for the drug.

(5) This part does not:

(a) require a dispensing practitioner to dispense a drug under this part;

(b) limit a health care prescriber from dispensing under Chapter 17b, Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy; or

(c) apply to a physician who dispenses:

(i) a drug sample, as defined in Section 58-17b-102, to a patient in accordance with Section 58-1-501.3 or Section 58-17b-610; or

[~~(ii) a prescription drug or device to a patient for a patient's immediate need in an emergency department in accordance with Section 58-17b-610.5; or~~]

[~~(iii)~~] (ii) a drug in an emergency situation as defined by the division in rule under Chapter 17b, Pharmacy Practice Act.

Section 8. **Repealer.**

This bill repeals:

Section **58-17b-610.5, Dispensing in emergency department -- Patient's immediate need.**

Section 9. **Effective date.**

This bill takes effect on May 1, 2024.