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 and enacts provisions related to pharmacists and pharmacies.

Highlighted Provisions:

This bill:

- makes technical corrections;
- defines "written communication";
- for a pharmacy other than a class D pharmacy, requires the pharmacist-in-charge, and not each manager, to submit fingerprint cards and consent to a fingerprint background check;
- grants limited 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;
- under certain conditions, 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;
- modifies provisions governing patient counseling;
- allows for the delivery of medication guides and medication package inserts via written communication, as defined;
- permits 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;
- modifies requirements related to pharmacy audits; and
- 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, subject to conditions.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

58-17b-102, as last amended by Laws of Utah 2023, Chapters 223, 328

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-102** is amended to read:

58-17b-102 . Definitions.

In addition to the definitions in Section 58-1-102, as used in this chapter:

(1) "Administering" means:

(a) the direct application of a prescription drug or device, whether by injection, inhalation, ingestion, or by any other means, to the body of a human patient or research subject by another person; or

(b) the placement by a veterinarian with the owner or caretaker of an animal or group of animals of a prescription drug for the purpose of injection, inhalation, ingestion, or any other means directed to the body of the animal by the owner or caretaker in accordance with written or verbal directions of the veterinarian.

(2) "Adulterated drug or device" means a drug or device considered adulterated under 21 U.S.C. Sec. 351 (2003).

(3) (a) "Analytical laboratory" means a facility in possession of prescription drugs for the purpose of analysis.

(b) "Analytical laboratory" does not include a laboratory possessing prescription drugs used as standards and controls in performing drug monitoring or drug screening analysis if the prescription drugs are prediluted in a human or animal body fluid,

human or animal body fluid components, organic solvents, or inorganic buffers at a concentration not exceeding one milligram per milliliter when labeled or otherwise designated as being for in vitro diagnostic use.

(4) "Animal euthanasia agency" means an agency performing euthanasia on animals by the use of prescription drugs.

(5) "Automated pharmacy systems" includes mechanical systems which perform operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing, or distribution of medications, and which collect, control, and maintain all transaction information.

(6) "Beyond use date" means the date determined by a pharmacist and placed on a prescription label at the time of dispensing that indicates to the patient or caregiver a time beyond which the contents of the prescription are not recommended to be used.

(7) "Board of pharmacy" or "board" means the Utah State Board of Pharmacy created in Section 58-17b-201.

(8) "Branch pharmacy" means a pharmacy or other facility in a rural or medically underserved area, used for the storage and dispensing of prescription drugs, which is dependent upon, stocked by, and supervised by a pharmacist in another licensed pharmacy designated and approved by the division as the parent pharmacy.

(9) "Centralized prescription processing" means the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order or to perform processing functions such as dispensing, drug utilization review, claims adjudication, refill authorizations, and therapeutic interventions.

(10) "Class A pharmacy" means a pharmacy located in Utah that is authorized as a retail pharmacy to compound or dispense a drug or dispense a device to the public under a prescription order.

(11) "Class B pharmacy":

(a) means a pharmacy located in Utah:

(i) that is authorized to provide pharmaceutical care for patients in an institutional setting; and

(ii) whose primary purpose is to provide a physical environment for patients to obtain health care services; and

(b) (i) includes closed-door, hospital, clinic, nuclear, and branch pharmacies; and

(ii) pharmaceutical administration and sterile product preparation facilities.

(12) "Class C pharmacy" means a pharmacy that engages in the manufacture, production,

wholesale, or distribution of drugs or devices in Utah.

(13) "Class D pharmacy" means a nonresident pharmacy.

(14) "Class E pharmacy" means all other pharmacies.

(15) (a) "Closed-door pharmacy" means a pharmacy that:

(i) provides pharmaceutical care to a defined and exclusive group of patients who have access to the services of the pharmacy because they are treated by or have an affiliation with a specific entity, including a health maintenance organization or an infusion company; or

(ii) engages exclusively in the practice of telepharmacy and does not serve walk-in retail customers.

(b) "Closed-door pharmacy" does not include a hospital pharmacy, a retailer of goods to the general public, or the office of a practitioner.

(16) "Collaborative pharmacy practice" means a practice of pharmacy whereby one or more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more practitioners under protocol whereby the pharmacist may perform certain pharmaceutical care functions authorized by the practitioner or practitioners under certain specified conditions or limitations.

(17) "Collaborative pharmacy practice agreement" means a written and signed agreement between one or more pharmacists and one or more practitioners that provides for collaborative pharmacy practice for the purpose of drug therapy management of patients and prevention of disease of human subjects.

(18) (a) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a limited quantity drug, sterile product, or device:

(i) as the result of a practitioner's prescription order or initiative based on the practitioner, patient, or pharmacist relationship in the course of professional practice;

(ii) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; or

(iii) in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(b) "Compounding" does not include:

(i) the preparation of prescription drugs by a pharmacist or pharmacy intern for sale to another pharmacist or pharmaceutical facility;

(ii) the preparation by a pharmacist or pharmacy intern of any prescription drug in a

dosage form which is regularly and commonly available from a manufacturer in quantities and strengths prescribed by a practitioner; or

(iii) the preparation of a prescription drug, sterile product, or device which has been withdrawn from the market for safety reasons.

(19) "Confidential information" has the same meaning as "protected health information" under the Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. Parts 160 and 164.

(20) "Controlled substance" means the same as that term is defined in Section 58-37-2.

(21) "Dietary supplement" has the same meaning as Public Law Title 103, Chapter 417, Sec. 3a(ff) which is incorporated by reference.

(22) "Dispense" means the interpretation, evaluation, and implementation of a prescription drug order or device or nonprescription drug or device under a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient, research subject, or an animal.

(23) "Dispensing medical practitioner" means an individual who is:

(a) currently licensed as:

(i) a physician and surgeon under Chapter 67, Utah Medical Practice Act;

(ii) an osteopathic physician and surgeon under Chapter 68, Utah Osteopathic Medical Practice Act;

(iii) a physician assistant under Chapter 70a, Utah Physician Assistant Act;

(iv) a nurse practitioner under Chapter 31b, Nurse Practice Act; or

(v) an optometrist under Chapter 16a, Utah Optometry Practice Act, if the optometrist is acting within the scope of practice for an optometrist; and

(b) licensed by the division under the Pharmacy Practice Act to engage in the practice of a dispensing medical practitioner.

(24) "Dispensing medical practitioner clinic pharmacy" means a closed-door pharmacy located within a licensed dispensing medical practitioner's place of practice.

(25) "Distribute" means to deliver a drug or device other than by administering or dispensing.

(26) (a) "Drug" means:

(i) a substance recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(ii) a substance that is required by any applicable federal or state law or rule to be dispensed by prescription only or is restricted to administration by practitioners only;

(iii) a substance other than food intended to affect the structure or any function of the body of humans or other animals; and

(iv) substances intended for use as a component of any substance specified in Subsections [~~(26)(a)(i), (ii), (iii), and (iv)~~] (26)(a)(i) through (iv).

(b) "Drug" does not include dietary supplements.

(27) "Drug regimen review" includes the following activities:

(a) evaluation of the prescription drug order and patient record for:

(i) known allergies;

(ii) rational therapy-contraindications;

(iii) reasonable dose and route of administration; and

(iv) reasonable directions for use;

(b) evaluation of the prescription drug order and patient record for duplication of therapy;

(c) evaluation of the prescription drug order and patient record for the following interactions:

(i) drug-drug;

(ii) drug-food;

(iii) drug-disease; and

(iv) adverse drug reactions; and

(d) evaluation of the prescription drug order and patient record for proper utilization, including over- or under-utilization, and optimum therapeutic outcomes.

(28) "Drug sample" means a prescription drug packaged in small quantities consistent with limited dosage therapy of the particular drug, which is marked "sample", is not intended to be sold, and is intended to be provided to practitioners for the immediate needs of patients for trial purposes or to provide the drug to the patient until a prescription can be filled by the patient.

(29) "Electronic signature" means a trusted, verifiable, and secure electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.

(30) "Electronic transmission" means transmission of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment.

(31) "Hospital pharmacy" means a pharmacy providing pharmaceutical care to inpatients of

a general acute hospital or specialty hospital licensed by the Department of Health and Human Services under Title 26B, Chapter 2, Part 2, Health Care Facility Licensing and Inspection.

(32) "Legend drug" has the same meaning as prescription drug.

(33) "Licensed pharmacy technician" means an individual licensed with the division, that may, under the supervision of a pharmacist, perform the activities involved in the technician practice of pharmacy.

(34) "Manufacturer" means a person or business physically located in Utah licensed to be engaged in the manufacturing of drugs or devices.

(35) (a) "Manufacturing" means:

(i) the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container; and

(ii) the promotion and marketing of such drugs or devices.

(b) "Manufacturing" includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners, or other persons.

(c) "Manufacturing" does not include the preparation or compounding of a drug by a pharmacist, pharmacy intern, or practitioner for that individual's own use or the preparation, compounding, packaging, labeling of a drug, or incident to research, teaching, or chemical analysis.

(36) "Medical order" means a lawful order of a practitioner which may include a prescription drug order.

(37) "Medication profile" or "profile" means a record system maintained as to drugs or devices prescribed for a pharmacy patient to enable a pharmacist or pharmacy intern to analyze the profile to provide pharmaceutical care.

(38) "Misbranded drug or device" means a drug or device considered misbranded under 21 U.S.C. Sec. 352 (2003).

(39) (a) "Nonprescription drug" means a drug which:

(i) may be sold without a prescription; and

(ii) is labeled for use by the consumer in accordance with federal law.

(b) "Nonprescription drug" includes homeopathic remedies.

(40) "Nonresident pharmacy" means a pharmacy located outside of Utah that sells to a person in Utah.

(41) "Nuclear pharmacy" means a pharmacy providing radio-pharmaceutical service.

(42) "Out-of-state mail service pharmacy" means a pharmaceutical facility located outside the state that is licensed and in good standing in another state, that:

(a) ships, mails, or delivers by any lawful means a dispensed legend drug to a patient in this state pursuant to a lawfully issued prescription;

(b) provides information to a patient in this state on drugs or devices which may include, but is not limited to, advice relating to therapeutic values, potential hazards, and uses; or

(c) counsels pharmacy patients residing in this state concerning adverse and therapeutic effects of drugs.

(43) "Patient counseling" means the written and oral communication by the pharmacist or pharmacy intern of information, to the patient or caregiver, in order to ensure proper use of drugs, devices, and dietary supplements.

(44) "Pharmaceutical administration facility" means a facility, agency, or institution in which:

(a) prescription drugs or devices are held, stored, or are otherwise under the control of the facility or agency for administration to patients of that facility or agency;

(b) prescription drugs are dispensed to the facility or agency by a licensed pharmacist or pharmacy intern with whom the facility has established a prescription drug supervising relationship under which the pharmacist or pharmacy intern provides counseling to the facility or agency staff as required, and oversees drug control, accounting, and destruction; and

(c) prescription drugs are professionally administered in accordance with the order of a practitioner by an employee or agent of the facility or agency.

(45) (a) "Pharmaceutical care" means carrying out the following in collaboration with a prescribing practitioner, and in accordance with division rule:

(i) designing, implementing, and monitoring a therapeutic drug plan intended to achieve favorable outcomes related to a specific patient for the purpose of curing or preventing the patient's disease;

(ii) eliminating or reducing a patient's symptoms; or

(iii) arresting or slowing a disease process.

(b) "Pharmaceutical care" does not include prescribing of drugs without consent of a

prescribing practitioner.

(46) "Pharmaceutical facility" means a business engaged in the dispensing, delivering, distributing, manufacturing, or wholesaling of prescription drugs or devices within or into this state.

(47) (a) "Pharmaceutical wholesaler or distributor" means a pharmaceutical facility engaged in the business of wholesale vending or selling of a prescription drug or device to other than a consumer or user of the prescription drug or device that the pharmaceutical facility has not produced, manufactured, compounded, or dispensed.

(b) "Pharmaceutical wholesaler or distributor" does not include a pharmaceutical facility carrying out the following business activities:

(i) intracompany sales;

(ii) the sale, purchase, or trade of a prescription drug or device, or an offer to sell, purchase, or trade a prescription drug or device, if the activity is carried out between one or more of the following entities under common ownership or common administrative control, as defined by division rule:

(A) hospitals;

(B) pharmacies;

(C) chain pharmacy warehouses, as defined by division rule; or

(D) other health care entities, as defined by division rule;

(iii) the sale, purchase, or trade of a prescription drug or device, or an offer to sell, purchase, or trade a prescription drug or device, for emergency medical reasons, including supplying another pharmaceutical facility with a limited quantity of a drug, if:

(A) the facility is unable to obtain the drug through a normal distribution channel in sufficient time to eliminate the risk of harm to a patient that would result from a delay in obtaining the drug; and

(B) the quantity of the drug does not exceed an amount reasonably required for immediate dispensing to eliminate the risk of harm;

(iv) the distribution of a prescription drug or device as a sample by representatives of a manufacturer; and

(v) the distribution of prescription drugs, if:

(A) the facility's total distribution-related sales of prescription drugs does not exceed 5% of the facility's total prescription drug sales; and

(B) the distribution otherwise complies with 21 C.F.R. Sec. 1307.11.

(48) "Pharmacist" means an individual licensed by this state to engage in the practice of pharmacy.

(49) "Pharmacist-in-charge" means a pharmacist currently licensed in good standing who accepts responsibility for the operation of a pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy and the distribution of drugs, and who is personally in full and actual charge of the pharmacy and all personnel.

(50) "Pharmacist preceptor" means a licensed pharmacist in good standing with one or more years of licensed experience. The preceptor serves as a teacher, example of professional conduct, and supervisor of interns in the professional practice of pharmacy.

(51) "Pharmacy" means any place where:

(a) drugs are dispensed;

(b) pharmaceutical care is provided;

(c) drugs are processed or handled for eventual use by a patient; or

(d) drugs are used for the purpose of analysis or research.

(52) "Pharmacy benefits manager or coordinator" means a person or entity that provides a pharmacy benefits management service as defined in Section 31A-46-102 on behalf of a self-insured employer, insurance company, health maintenance organization, or other plan sponsor, as defined by rule.

(53) "Pharmacy intern" means an individual licensed by this state to engage in practice as a pharmacy intern.

(54) "Pharmacy manager" means:

(a) a pharmacist-in-charge;

(b) a licensed pharmacist designated by a licensed pharmacy to consult on the pharmacy's administration;

(c) an individual who manages the facility in which a licensed pharmacy is located;

(d) an individual who oversees the operations of a licensed pharmacy;

(e) an immediate supervisor of an individual described in Subsections (54)(a) through (d); or

(f) another operations or site manager of a licensed pharmacy.

(55) "Pharmacy technician training program" means an approved technician training program providing education for pharmacy technicians.

(56) (a) "Practice as a dispensing medical practitioner" means the practice of pharmacy, specifically relating to the dispensing of a prescription drug in accordance with Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic

Pharmacy, and division rule adopted after consultation with the Board of pharmacy and the governing boards of the practitioners described in Subsection (23)(a).

(b) "Practice as a dispensing medical practitioner" does not include:

(i) using a vending type of dispenser as defined by the division by administrative rule; or

(ii) except as permitted by Section 58-17b-805, dispensing of a controlled substance as defined in Section 58-37-2.

(57) "Practice as a licensed pharmacy technician" means engaging in practice as a pharmacy technician under the general supervision of a licensed pharmacist and in accordance with a scope of practice defined by division rule made in collaboration with the board.

(58) "Practice of pharmacy" includes the following:

(a) providing pharmaceutical care;

(b) collaborative pharmacy practice in accordance with a collaborative pharmacy practice agreement;

(c) compounding, packaging, labeling, dispensing, administering, and the coincident distribution of prescription drugs or devices, provided that the administration of a prescription drug or device is:

(i) pursuant to a lawful order of a practitioner when one is required by law; and

(ii) in accordance with written guidelines or protocols:

(A) established by the licensed facility in which the prescription drug or device is to be administered on an inpatient basis; or

(B) approved by the division, in collaboration with the board and, when appropriate, the Physicians Licensing Board, created in Section 58-67-201, if the prescription drug or device is to be administered on an outpatient basis solely by a licensed pharmacist;

(d) participating in drug utilization review;

(e) ensuring proper and safe storage of drugs and devices;

(f) maintaining records of drugs and devices in accordance with state and federal law and the standards and ethics of the profession;

(g) providing information on drugs or devices, which may include advice relating to therapeutic values, potential hazards, and uses;

(h) providing drug product equivalents;

(i) supervising pharmacist's supportive personnel, pharmacy interns, and pharmacy

technicians;

(j) providing patient counseling, including adverse and therapeutic effects of drugs;

(k) providing emergency refills as defined by rule;

(l) telepharmacy;

(m) formulary management intervention;

(n) prescribing and dispensing a self-administered hormonal contraceptive in accordance with Title 26B, Chapter 4, Part 5, Treatment Access; and

(o) issuing a prescription in accordance with Section 58-17b-627.

(59) "Practice of telepharmacy" means the practice of pharmacy through the use of telecommunications and information technologies.

(60) "Practice of telepharmacy across state lines" means the practice of pharmacy through the use of telecommunications and information technologies that occurs when the patient is physically located within one jurisdiction and the pharmacist is located in another jurisdiction.

(61) "Practitioner" means an individual currently licensed, registered, or otherwise authorized by the appropriate jurisdiction to prescribe and administer drugs in the course of professional practice.

(62) "Prescribe" means to issue a prescription:

(a) orally or in writing; or

(b) by telephone, facsimile transmission, computer, or other electronic means of communication as defined by division rule.

(63) "Prescription" means an order issued:

(a) by a licensed practitioner in the course of that practitioner's professional practice or by collaborative pharmacy practice agreement; and

(b) for a controlled substance or other prescription drug or device for use by a patient or an animal.

(64) "Prescription device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, and any component part or accessory, which is required under federal or state law to be prescribed by a practitioner and dispensed by or through a person or entity licensed under this chapter or exempt from licensure under this chapter.

(65) "Prescription drug" means a drug that is required by federal or state law or rule to be dispensed only by prescription or is restricted to administration only by practitioners.

(66) "Repackage":

(a) means changing the container, wrapper, or labeling to further the distribution of a prescription drug; and

(b) does not include:

(i) Subsection (66)(a) when completed by the pharmacist responsible for dispensing the product to a patient; or

(ii) changing or altering a label as necessary for a dispensing practitioner under Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, for dispensing a product to a patient.

(67) "Research using pharmaceuticals" means research:

(a) conducted in a research facility, as defined by division rule, that is associated with a university or college in the state accredited by the Northwest Commission on Colleges and Universities;

(b) requiring the use of a controlled substance, prescription drug, or prescription device;

(c) that uses the controlled substance, prescription drug, or prescription device in accordance with standard research protocols and techniques, including, if required, those approved by an institutional review committee; and

(d) that includes any documentation required for the conduct of the research and the handling of the controlled substance, prescription drug, or prescription device.

(68) "Retail pharmacy" means a pharmaceutical facility dispensing prescription drugs and devices to the general public.

(69) (a) "Self-administered hormonal contraceptive" means a self-administered hormonal contraceptive that is approved by the United States Food and Drug Administration to prevent pregnancy.

(b) "Self-administered hormonal contraceptive" includes an oral hormonal contraceptive, a hormonal vaginal ring, and a hormonal contraceptive patch.

(c) "Self-administered hormonal contraceptive" does not include any drug intended to induce an abortion, as that term is defined in Section 76-7-301.

(70) "Self-audit" means an internal evaluation of a pharmacy to determine compliance with this chapter.

(71) "Supervising pharmacist" means a pharmacist who is overseeing the operation of the pharmacy during a given day or shift.

(72) "Supportive personnel" means unlicensed individuals who:

(a) may assist a pharmacist, pharmacist preceptor, pharmacy intern, or licensed pharmacy technician in nonjudgmental duties not included in the definition of the

practice of pharmacy, practice of a pharmacy intern, or practice of a licensed pharmacy technician, and as those duties may be further defined by division rule adopted in collaboration with the board; and

(b) are supervised by a pharmacist in accordance with rules adopted by the division in collaboration with the board.

(73) "Unlawful conduct" means the same as that term is defined in Sections 58-1-501 and 58-17b-501.

(74) "Unprofessional conduct" means the same as that term is defined in Sections 58-1-501 and 58-17b-502 and may be further defined by rule.

(75) "Veterinary pharmaceutical facility" means a pharmaceutical facility that dispenses drugs intended for use by animals or for sale to veterinarians for the administration for animals.

(76) "Written communication" means a physical document, or an electronic communication, by or from which the recipient may read or access the information intended to be communicated, including:

(a) email;

(b) text message; and

(c) quick response (QR) code.

Section 2. 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 3. 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 4. 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) (a) [~~The~~] Subject to Subsection (2)(b), 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)~~] (i) the individual is discharged from the hospital on the same day that the hospital pharmacy dispenses the prescription drug to the individual;

(ii) in the professional judgment of the practitioner, dispensing the drug is necessary for the patient's immediate needs;

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

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

[~~(ii)~~] (B) unable to dispense the medication for any reason;

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

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

(b) (i) A hospital pharmacy may dispense an opioid antagonist to a patient without satisfying Subsection (2)(a)(iii).

(ii) A hospital pharmacy that dispenses an opioid antagonist to a patient under Subsection (2)(b)(i) shall accept as payment the wholesale acquisition cost at the time of dispensing.

[~~(2)~~] (3) A hospital pharmacy, or a practitioner or pharmacist in the hospital, may dispense a prescription drug in accordance with rules made under Subsection [~~(1)~~] (2).

Section 5. 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) for a class D pharmacy, a toll-free telephone number at which the patient may contact a pharmacist or pharmacy intern at the pharmacy for patient counseling regarding the prescribed drug; or

(b) [~~provide each patient with a toll-free telephone number by which the patient can~~] for a class A pharmacy, 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:

(a) 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[.] ; and

(b) provide medication guides or package inserts via written communication.

Section 6. 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 7. 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) "Extrapolation" means a method of using a mathematical formula that uses the audit results from a small sample of insurance claims and projects the results over a larger group of insurance claims.

[~~(d)~~] (e) "Fraud" means an intentional act of deception, misrepresentation, or concealment in order to gain something of value.

[~~(e)~~] (f) "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 annually.

(d) Subsection (3)(c)(ii) does not apply to any investigative audit that involves fraud, waste, abuse, or willful misrepresentation.

(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[~~,~~] :

(i) delivered to the pharmacy or its corporate office of record, within the time limit established under Subsection (6)(a)(i)(B)[~~.~~] ; and

(ii) that includes a notation and detailed explanation for each suspected error.

(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 any of the following:

(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~~] within 30 days from the day on which the audit report is received by the pharmacy; or

(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:

(i) a disclosure of any money recovered by the entity that conducted the audit[.] ; and

(ii) legal or contractual information supporting any money recovered, recoupments, or penalties included in the report.

(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) An auditing entity conducting a pharmacy audit may not:

(a) use extrapolation when conducting an audit, including calculating recoupments or penalties for audits, unless otherwise required by federal law or a self-funded insurance plan; or

(b) compensate an employee or contractor participating in the audit in a manner that is based on the amount claimed or the actual amount recouped from the pharmacy being audited.

Section 8. 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 9. **Repealer.**

This bill repeals:

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

Section 10. **Effective date.**

This bill takes effect on May 1, 2024.