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S.B. 158

PHARMACY AMENDMENTS

2015 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Evan J. Vickers

House Sponsor: Jon E. Stanard

LONG TITLE

General Description:

This bill amends the Pharmacy Practice Act and the Controlled Substance Database Act.

Highlighted Provisions:

This bill:

- amends definitions;
- amends the requirement of the affidavit a pharmacy submits with its application for license;
- amends provisions related to a pharmacist-in-charge;
- makes a technical amendment to patient counseling;
- amends unprofessional conduct provisions;
- authorizes administrative rulemaking regarding dispensing an emergency supply of certain drugs from an emergency room in limited circumstances; and
- amends access to the controlled substance database to allow a pharmacist in charge to give a pharmacy intern access to the controlled substance database.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

S.B. 158

AMENDS:

58-17b-102, as last amended by Laws of Utah 2014, Chapters 72, 308, and 308

58-17b-306, as last amended by Laws of Utah 2009, Chapter 183

58-17b-502, as last amended by Laws of Utah 2014, Chapter 72

58-17b-612, as last amended by Laws of Utah 2014, Chapter 72

58-17b-613, as last amended by Laws of Utah 2014, Chapter 72

58-37f-301, as last amended by Laws of Utah 2014, Chapters 68 and 401

ENACTS:

58-17b-610.5, Utah Code Annotated 1953

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.[~~S.~~] 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) "Closed-door pharmacy" means a pharmacy that 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, but not including 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" [~~has the same definition as~~] 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, 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).

(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 under Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act.

(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.[~~S.~~] 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 pharmacy benefit management services as defined in Section 49-20-502 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 technician training program" means an approved technician training program providing education for pharmacy technicians.

(55) (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.

(56) (a) "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.

(b) "Practice as a licensed pharmacy technician" does not include:

(i) performing a drug utilization review, prescription drug order clarification from a prescriber, final review of the prescription, dispensing of the drug, or counseling a patient with respect to a prescription drug;

(ii) except as permitted by rules made by the division in consultation with the board, final review of a prescribed drug prepared for dispensing;

(iii) counseling regarding nonprescription drugs and dietary supplements unless delegated by the supervising pharmacist; or

(iv) receiving new prescription drug orders when communicating telephonically or electronically unless the original information is recorded so the pharmacist may review the prescription drug order as transmitted.

(57) "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 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; and

(m) formulary management intervention.

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

(59) "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.

(60) "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.

(61) "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.

(62) "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.

(63) "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.

(64) "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.

(65) "Repackage":

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

(b) does not include:

(i) Subsection (65)(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.

[~~(65)~~] (66) "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.

[~~(66)~~] (67) "Retail pharmacy" means a pharmaceutical facility dispensing prescription drugs and devices to the general public.

[~~(67)~~] (68) "Self-audit" means an internal evaluation of a pharmacy to determine compliance with this chapter.

[~~(68)~~] (69) "Supervising pharmacist" means a pharmacist who is overseeing the operation of the pharmacy during a given day or shift.

[~~(69)~~] (70) "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.

[~~(70)~~] (71) "Unlawful conduct" [~~is as~~] means the same as that term is defined in Sections 58-1-501 and 58-17b-501.

[~~(71)~~] (72) "Unprofessional conduct" [~~is as~~] means the same as that term is defined in Sections 58-1-501 and 58-17b-502 and may be further defined by rule.

[~~(72)~~] (73) "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.

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

(f) 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) 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;

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

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

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

Section 3. Section **58-17b-502** is amended to read:

58-17b-502. Unprofessional conduct.

"Unprofessional conduct" includes:

(1) willfully deceiving or attempting to deceive the division, the board, or their agents as to any relevant matter regarding compliance under this chapter;

(2) (a) except as provided in Subsection (2)(b):

(i) paying or offering rebates to practitioners or any other health care providers, or receiving or soliciting rebates from practitioners or any other health care provider; or

(ii) paying, offering, receiving, or soliciting compensation in the form of a commission, bonus, rebate, kickback, or split fee arrangement with practitioners or any other health care provider, for the purpose of obtaining referrals.

(b) Subsection (2)(a) does not apply to:

(i) giving or receiving price discounts based on purchase volume;

(ii) passing along pharmaceutical manufacturer's rebates; or

(iii) providing compensation for services to a veterinarian.

(3) misbranding or adulteration of any drug or device or the sale, distribution, or dispensing of any outdated, misbranded, or adulterated drug or device;

(4) engaging in the sale or purchase of drugs or devices that are samples or packages bearing the inscription "sample" or "not for resale" or similar words or phrases;

(5) except as provided in Section 58-17b-503, accepting back and redistributing of any unused drug, or a part of it, after it has left the premises of any pharmacy, unless the drug is in a unit pack, as defined in Section 58-17b-503, or the manufacturer's sealed container, as defined in rule;

(6) an act in violation of this chapter committed by a person for any form of compensation if the act is incidental to the person's professional activities, including the activities of a pharmacist, pharmacy intern, or pharmacy technician;

(7) violating Federal Title II, P.L. 91, Controlled Substances Act, Title 58, Chapter 37, Utah Controlled Substances Act, or rules or regulations adopted under either act;

(8) requiring or permitting pharmacy interns or technicians to engage in activities outside the scope of practice for their respective license classifications, as defined in this chapter and division rules made in collaboration with the board, or beyond their scope of training and ability;

(9) administering:

(a) without appropriate training, as defined by rule;

(b) without a physician's order, when one is required by law; and

(c) in conflict with a practitioner's written guidelines or written protocol for administering;

(10) disclosing confidential patient information in violation of the provisions of the Health Insurance Portability and Accountability Act of 1996 or other applicable law;

(11) engaging in the practice of pharmacy without a licensed pharmacist designated as the pharmacist-in-charge;

(12) failing to report to the division any adverse action taken by another licensing jurisdiction, government agency, law enforcement agency, or court for conduct that in substance would be considered unprofessional conduct under this section; and

(13) as a pharmacist or pharmacy intern, [~~preparing~~] compounding a prescription drug in a dosage form which is regularly and commonly available from a manufacturer in quantities and strengths prescribed by a practitioner.

Section 4. Section **58-17b-610.5** is enacted to read:

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

(1) The division shall adopt administrative rules in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, in consultation with hospital pharmacies and the boards of dispensing medical practitioners to establish guidelines under which a dispensing medical practitioner may dispense prescription drugs to a patient in a hospital emergency department if:

(a) the hospital pharmacy is closed;

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

(c) the prescription drug is not a controlled substance subject to reporting under Chapter 37f, Controlled Substance Database Act; and

(d) dispensing the prescription drug meets protocols established by the hospital pharmacy.

(2) A prescribing medical practitioner in an emergency department may dispense a prescription drug in accordance with Subsection (1).

Section 5. Section **58-17b-612** is amended to read:

58-17b-612. Supervision -- Pharmacist-in-charge.

(1) (a) Any pharmacy, except a wholesaler, distributor, out-of-state mail service pharmacy, or class E pharmacy, shall be under the general supervision of at least one pharmacist licensed to practice in Utah. One pharmacist licensed in Utah shall be designated as the pharmacist-in-charge, whose responsibility it is to oversee the operation of the pharmacy.

(b) Notwithstanding Subsection 58-17b-102[~~(68)~~](69), a supervising pharmacist does not have to be in the pharmacy or care facility but shall be available via a telepharmacy system for immediate contact with the supervised pharmacy technician or pharmacy intern if:

(i) the pharmacy is located in:

(A) a remote rural hospital, as defined in Section 26-21-13.6; or

(B) a clinic located in a remote rural county with less than 20 people per square mile;

(ii) the supervising pharmacist described in Subsection (1)(a) is not available; and

(iii) the telepharmacy system maintains records and files quarterly reports as required by division rule to assure that patient safety is not compromised.

(2) Each out-of-state mail service pharmacy shall designate and identify to the division a pharmacist holding a current license in good standing [~~issued by the state in which the pharmacy is located~~] in Utah and who serves as the pharmacist-in-charge for all purposes under this chapter.

Section 6. Section **58-17b-613** is amended to read:

58-17b-613. Patient counseling.

(1) A [~~retail~~] 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 to the patient by means other than personal delivery, shall:

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

(b) provide each patient with a toll-free telephone number by which the patient can

contact a pharmacist or pharmacy intern at the pharmacy for counseling.

(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 7. Section **58-37f-301** is amended to read:

58-37f-301. Access to database.

(1) The division shall make rules, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, to:

(a) effectively enforce the limitations on access to the database as described in this part; and

(b) establish standards and procedures to ensure accurate identification of individuals requesting information or receiving information without request from the database.

(2) The division shall make information in the database and information obtained from other state or federal prescription monitoring programs by means of the database available only to the following individuals, in accordance with the requirements of this chapter and division rules:

(a) personnel of the division specifically assigned to conduct investigations related to controlled substance laws under the jurisdiction of the division;

(b) authorized division personnel engaged in analysis of controlled substance prescription information as a part of the assigned duties and responsibilities of their employment;

(c) in accordance with a written agreement entered into with the department, employees of the Department of Health:

(i) whom the director of the Department of Health assigns to conduct scientific studies regarding the use or abuse of controlled substances, if the identity of the individuals and pharmacies in the database are confidential and are not disclosed in any manner to any individual who is not directly involved in the scientific studies; or

(ii) when the information is requested by the Department of Health in relation to a person or provider whom the Department of Health suspects may be improperly obtaining or providing a controlled substance;

(d) in accordance with a written agreement entered into with the department, a designee of the director of the Department of Health, who is not an employee of the Department of Health, whom the director of the Department of Health assigns to conduct scientific studies regarding the use or abuse of controlled substances pursuant to an application process established in rule by the Department of Health, if:

(i) the designee provides explicit information to the Department of Health regarding the purpose of the scientific studies;

(ii) the scientific studies to be conducted by the designee:

(A) fit within the responsibilities of the Department of Health for health and welfare;

(B) are reviewed and approved by an Institutional Review Board that is approved for human subject research by the United States Department of Health and Human Services; and

(C) are not conducted for profit or commercial gain; and

(D) are 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;

(iii) the designee protects the information as a business associate of the Department of Health; and

(iv) the identity of the prescribers, patients, and pharmacies in the database are de-identified, confidential, not disclosed in any manner to the designee or to any individual who is not directly involved in the scientific studies;

(e) in accordance with the written agreement entered into with the department and the Department of Health, authorized employees of a managed care organization, as defined in 42 C.F.R. Sec. 438, if:

(i) the managed care organization contracts with the Department of Health under the provisions of Section 26-18-405 and the contract includes provisions that:

(A) require a managed care organization employee who will have access to information from the database to submit to a criminal background check; and

(B) limit the authorized employee of the managed care organization to requesting either the division or the Department of Health to conduct a search of the database regarding a specific Medicaid enrollee and to report the results of the search to the authorized employee; and

(ii) the information is requested by an authorized employee of the managed care organization in relation to a person who is enrolled in the Medicaid program with the managed care organization, and the managed care organization suspects the person may be improperly obtaining or providing a controlled substance;

(f) a licensed practitioner having authority to prescribe controlled substances, to the extent the information:

(i) (A) relates specifically to a current or prospective patient of the practitioner; and

(B) is provided to or sought by the practitioner for the purpose of:

(I) prescribing or considering prescribing any controlled substance to the current or prospective patient;

(II) diagnosing the current or prospective patient;

(III) providing medical treatment or medical advice to the current or prospective patient; or

(IV) determining whether the current or prospective patient:

(Aa) is attempting to fraudulently obtain a controlled substance from the practitioner; or

(Bb) has fraudulently obtained, or attempted to fraudulently obtain, a controlled substance from the practitioner;

(ii) (A) relates specifically to a former patient of the practitioner; and

(B) is provided to or sought by the practitioner for the purpose of determining whether the former patient has fraudulently obtained, or has attempted to fraudulently obtain, a controlled substance from the practitioner;

(iii) relates specifically to an individual who has access to the practitioner's Drug Enforcement Administration identification number, and the practitioner suspects that the individual may have used the practitioner's Drug Enforcement Administration identification number to fraudulently acquire or prescribe a controlled substance;

(iv) relates to the practitioner's own prescribing practices, except when specifically prohibited by the division by administrative rule;

(v) relates to the use of the controlled substance database by an employee of the practitioner, described in Subsection (2)(g); or

(vi) relates to any use of the practitioner's Drug Enforcement Administration

identification number to obtain, attempt to obtain, prescribe, or attempt to prescribe, a controlled substance;

(g) in accordance with Subsection (3)(a), an employee of a practitioner described in Subsection (2)(f), for a purpose described in Subsection (2)(f)(i) or (ii), if:

(i) the employee is designated by the practitioner as an individual authorized to access the information on behalf of the practitioner;

(ii) the practitioner provides written notice to the division of the identity of the employee; and

(iii) the division:

(A) grants the employee access to the database; and

(B) provides the employee with a password that is unique to that employee to access the database in order to permit the division to comply with the requirements of Subsection 58-37f-203(3)(b) with respect to the employee;

(h) an employee of the same business that employs a licensed practitioner under Subsection (2)(f) if:

(i) the employee is designated by the practitioner as an individual authorized to access the information on behalf of the practitioner;

(ii) the practitioner and the employing business provide written notice to the division of the identity of the designated employee; and

(iii) the division:

(A) grants the employee access to the database; and

(B) provides the employee with a password that is unique to that employee to access the database in order to permit the division to comply with the requirements of Subsection 58-37f-203(3)(b) with respect to the employee;

(i) a licensed pharmacist having authority to dispense a controlled substance to the extent the information is provided or sought for the purpose of:

(i) dispensing or considering dispensing any controlled substance; or

(ii) determining whether a person:

(A) is attempting to fraudulently obtain a controlled substance from the pharmacist; or

(B) has fraudulently obtained, or attempted to fraudulently obtain, a controlled substance from the pharmacist;

(j) in accordance with Subsection (3)(a), a licensed pharmacy technician and pharmacy intern who is an employee of a pharmacy as defined in Section 58-17b-102, for the purposes described in Subsection (2)(h)(i) or (ii), if:

(i) the employee is designated by the pharmacist-in-charge as an individual authorized to access the information on behalf of a licensed pharmacist employed by the pharmacy;

(ii) the pharmacist-in-charge provides written notice to the division of the identity of the employee; and

(iii) the division:

(A) grants the employee access to the database; and

(B) provides the employee with a password that is unique to that employee to access the database in order to permit the division to comply with the requirements of Subsection 58-37f-203(3)(b) with respect to the employee;

(k) federal, state, and local law enforcement authorities, and state and local prosecutors, engaged as a specified duty of their employment in enforcing laws:

(i) regulating controlled substances;

(ii) investigating insurance fraud, Medicaid fraud, or Medicare fraud; or

(iii) providing information about a criminal defendant to defense counsel, upon request during the discovery process, for the purpose of establishing a defense in a criminal case;

(l) employees of the Office of Internal Audit and Program Integrity within the Department of Health who are engaged in their specified duty of ensuring Medicaid program integrity under Section 26-18-2.3;

(m) a mental health therapist, if:

(i) the information relates to a patient who is:

(A) enrolled in a licensed substance abuse treatment program; and

(B) receiving treatment from, or under the direction of, the mental health therapist as part of the patient's participation in the licensed substance abuse treatment program described in Subsection (2)(m)(i)(A);

(ii) the information is sought for the purpose of determining whether the patient is using a controlled substance while the patient is enrolled in the licensed substance abuse treatment program described in Subsection (2)(m)(i)(A); and

(iii) the licensed substance abuse treatment program described in Subsection

(2)(m)(i)(A) is associated with a practitioner who:

(A) is a physician, a physician assistant, an advance practice registered nurse, or a pharmacist; and

(B) is available to consult with the mental health therapist regarding the information obtained by the mental health therapist, under this Subsection (2)(m), from the database;

(n) an individual who is the recipient of a controlled substance prescription entered into the database, upon providing evidence satisfactory to the division that the individual requesting the information is in fact the individual about whom the data entry was made;

(o) the inspector general, or a designee of the inspector general, of the Office of Inspector General of Medicaid Services, for the purpose of fulfilling the duties described in Title 63A, Chapter 13, Part 2, Office and Powers; and

(p) the following licensed physicians for the purpose of reviewing and offering an opinion on an individual's request for workers' compensation benefits under Title 34A, Chapter 2, Workers' Compensation Act, or Title 34A, Chapter 3, Utah Occupational Disease Act:

(i) a member of the medical panel described in Section 34A-2-601; or

(ii) a physician offering a second opinion regarding treatment.

(3) (a) (i) A practitioner described in Subsection (2)(f) may designate up to three employees to access information from the database under Subsection (2)(g), (2)(h), or (4)(c).

(ii) A pharmacist described in Subsection (2)(i) who is a pharmacist-in-charge may designate up to [~~three~~] five employees to access information from the database under Subsection (2)(j).

(b) The division shall make rules, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, to:

(i) establish background check procedures to determine whether an employee designated under Subsection (2)(g), (2)(h), or (4)(c) should be granted access to the database; and

(ii) establish the information to be provided by an emergency room employee under Subsection (4).

(c) The division shall grant an employee designated under Subsection (2)(g), (2)(h), or (4)(c) access to the database, unless the division determines, based on a background check, that the employee poses a security risk to the information contained in the database.

(4) (a) An individual who is employed in the emergency room of a hospital may exercise access to the database under this Subsection (4) on behalf of a licensed practitioner if the individual is designated under Subsection (4)(c) and the licensed practitioner:

(i) is employed in the emergency room;

(ii) is treating an emergency room patient for an emergency medical condition; and

(iii) requests that an individual employed in the emergency room and designated under Subsection (4)(c) obtain information regarding the patient from the database as needed in the course of treatment.

(b) The emergency room employee obtaining information from the database shall, when gaining access to the database, provide to the database the name and any additional identifiers regarding the requesting practitioner as required by division administrative rule established under Subsection (3)(b).

(c) An individual employed in the emergency room under this Subsection (4) may obtain information from the database as provided in Subsection (4)(a) if:

(i) the employee is designated by the practitioner as an individual authorized to access the information on behalf of the practitioner;

(ii) the practitioner and the hospital operating the emergency room provide written notice to the division of the identity of the designated employee; and

(iii) the division:

(A) grants the employee access to the database; and

(B) provides the employee with a password that is unique to that employee to access the database in order to permit the division to comply with the requirements of Subsection 58-37f-203(3)(b) with respect to the employee.

(d) The division may impose a fee, in accordance with Section 63J-1-504, on a practitioner who designates an employee under Subsection (2)(g), (2)(h), or (4)(c) to pay for the costs incurred by the division to conduct the background check and make the determination described in Subsection (3)(b).

(5) (a) An individual who is granted access to the database based on the fact that the individual is a licensed practitioner or a mental health therapist shall be denied access to the database when the individual is no longer licensed.

(b) An individual who is granted access to the database based on the fact that the

individual is a designated employee of a licensed practitioner shall be denied access to the database when the practitioner is no longer licensed.

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