PHARMACY PRACTICE REVISIONS

2021 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Evan J. Vickers

House Sponsor: Paul Ray

LONG TITLE

General Description:

This bill amends provisions related to pharmacy.

Highlighted Provisions:

This bill:

- amends definitions;
- amends requirements for licensure as a pharmacy technician trainee;
- amends provisions governing the dispensing of opiate medication assisted treatment at an opioid treatment program;
- amends provisions governing the audit of pharmacy records by or on behalf of an entity that finances or reimburses the cost of health care services or pharmaceutical products;
- amends provisions governing the administration of injectables by pharmacists;
- addresses corrections to data submitted to the controlled substance database; and
- makes technical changes.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

49-20-502, as enacted by Laws of Utah 2011, Chapter 83

58-17b-102, as last amended by Laws of Utah 2019, Chapter 343

58-17b-305.1, as last amended by Laws of Utah 2020, Chapter 339

58-17b-309.7, as enacted by Laws of Utah 2019, Chapter 311

58-17b-610, as last amended by Laws of Utah 2012, Chapter 320

58-17b-622, as last amended by Laws of Utah 2018, Chapter 39

58-17b-625, as last amended by Laws of Utah 2019, Chapter 343

58-37f-203, as last amended by Laws of Utah 2020, Chapters 147, 339, and 372

58-37f-303, as last amended by Laws of Utah 2020, Chapters 147 and 339

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

Section 1. Section **49-20-502** is amended to read:

49-20-502. Definitions.

As used in this part:

(1) "Health benefit plan" means:

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

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

(2) "Pharmacist" is as defined in Section 58-17b-102.

(3) "Pharmacy" is as defined in Section 58-17b-102.

(4) "Pharmacy benefits management service" means [~~any of the following services provided to a health benefit plan, or to a participant of the health benefit plan:~~] the same as that term is defined in Section 31A-46-102.

[~~(a) negotiating the amount to be paid by a health benefit plan for a prescription drug; or~~]

[~~(b) administering or managing prescription drug benefits provided by the health benefit plan for the benefit of a participant of the health benefit plan, including:~~]

[~~(i) mail service pharmacy;~~]

[~~(ii) specialty pharmacy;~~]

[~~(iii) claims processing;~~]

[~~(iv) payment of a claim;~~]

[~~(v) retail network management;~~]

[~~(vi) clinical formulary development;~~]

[~~(vii) clinical formulary management services;~~]

[~~(viii) rebate contracting;~~]

[~~(ix) rebate administration;~~]

[~~(x) a participant compliance program;~~]

[~~(xi) a therapeutic intervention program;~~]

[~~(xii) a disease management program; or~~]

[~~(xiii) a service that is similar to, or related to, a service described in Subsection (4)(a) or (4)(b)(i) through (xii).~~]

(5) "Pharmacy benefits manager" means a person that provides a pharmacy benefits management service to [~~a health benefit plan~~] the program.

(6) "Pharmacy service" means a product, good, or service provided by a pharmacy or pharmacist to an individual.

Section 2. 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).

(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. 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 [~~49-20-502~~] 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 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) "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.

(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, 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; and

(n) prescribing and dispensing a self-administered hormonal contraceptive in accordance with Title 26, Chapter 64, Family Planning Access Act.

(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.

(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.

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

(68) (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.

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

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

(71) "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.

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

(73) "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.

(74) "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 3. Section **58-17b-305.1** is amended to read:

58-17b-305.1. Qualifications for licensure of pharmacy technician trainee.

(1) An applicant for licensure as a pharmacy technician trainee shall:

(a) submit an application to the division on a form created by the division;

(b) pay a fee established by the division in accordance with Section 63J-1-504;

(c) unless exempted by the division, submit a completed criminal background check;

(d) demonstrate, as determined by the division, that the applicant does not have a physical or mental condition that would prevent the applicant from engaging in practice as a pharmacy technician with reasonable skill, competency, and safety to the public; [~~and~~]

(e) submit evidence that the applicant is enrolled in a training program approved by the division[~~.~~]; and

(f) satisfy any other criteria established by division rule made in collaboration with the board.

(2) A pharmacist whose license has been denied, revoked, suspended, or restricted for disciplinary purposes is not eligible to be licensed as a pharmacy technician trainee during division probation.

Section 4. Section **58-17b-309.7** is amended to read:

58-17b-309.7. Opioid treatment program.

(1) As used in this section:

[~~(a) "Dispense" means to prepare, package, or label for subsequent use.~~]

[~~(b) "Nurse practitioner" means an individual who is licensed to practice as an advanced practice registered nurse under Chapter 31b, Nurse Practice Act.~~]

(a) "Covered provider" means an individual who is licensed to engage in:

(i) the practice of advanced practice registered nursing as defined in Section 58-31b-102;

(ii) the practice of registered nursing as defined in Section 58-31b-102; or

(iii) practice as a physician assistant as defined in Section 58-70a-102.

[~~(c)~~] (b) "Opioid treatment program" means a program or practitioner that is:

(i) engaged in [~~opioid treatment of an individual using~~] dispensing an opiate [~~agonist~~] medication assisted treatment for opioid use disorder;

(ii) registered under 21 U.S.C. Sec. 823(g)(1);

(iii) licensed by the Office of Licensing[~~,~~] within the Department of Human Services[~~,~~] created in Section 62A-2-103; and

(iv) certified by the Substance Abuse and Mental Health Services Administration in accordance with 42 C.F.R. 8.11.

[~~(d) "Physician" means an individual licensed to practice as a physician or osteopath in this state under Chapter 67, Utah Medical Practice Act, or Chapter 68, Utah Osteopathic Medical Practice Act.~~]

[~~(e) "Physician assistant" means an individual who is licensed to practice as a physician assistant under Chapter 70a, Utah Physician Assistant Act.~~]

[~~(f) "Practitioner" means a nurse practitioner, physician's assistant, or a registered nurse.~~]

[~~(g) "Registered nurse" means the same as that term is defined in Section 78B-3-403.~~]

(2) A [~~practitioner~~] covered provider may dispense [~~methadone~~] opiate medication assisted treatment at an opioid treatment program [~~regardless of whether the practitioner is licensed to dispense methadone under this chapter if the practitioner~~] if the covered provider:

(a) is operating under the direction of a pharmacist;

(b) dispenses the [~~methadone~~] opiate medication assisted treatment under the direction of a pharmacist; and

(c) acts in accordance with division rule made under Subsection (3).

(3) The division shall, in consultation with [~~pharmacies, physicians, and~~] practitioners who work in an opioid treatment program, make rules in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, to establish guidelines under which a [~~practitioner~~] covered provider may dispense [~~methadone~~] opiate medication assisted treatment to a patient in an opioid treatment program under this section.

Section 5. Section **58-17b-610** is amended to read:

58-17b-610. Patients' immediate needs -- Dispensing drug samples.

(1) This chapter may not be construed to prevent the personal administration of drugs or medicines by practitioners licensed to prescribe in order to supply the immediate needs of the practitioner's patients.

(2) Immediate need for a patient includes giving out drug samples that:

(a) are not Schedule II drugs, [~~opiods, or Benzodiazepines~~] opioids, or benzodiazepines;

(b) are prepackaged by the original manufacturer;

(c) are provided to the prescribing practitioner free of charge and provided to the patient free of any direct or indirect charge;

(d) do not exceed a 30-day supply for:

(i) controlled substances; or

(ii) non-controlled substances, unless a prescribing practitioner documents that providing more than a 30-day supply is medically necessary; and

(e) (i) are marked on the immediate container to indicate that the drug is a sample; or

(ii) are recorded in the patient's chart with the name and number of samples provided.

(3) A prescribing practitioner who provides samples for a patient shall comply with Subsection (2).

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

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

(1) For purposes of this section:

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

(b) "Audit completion date" means:

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

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

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

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

[~~(b)~~] (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)[~~(b)~~](c)(i) through (iv).

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

[~~(d)~~] (e) "Health benefit plan" means:

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

(ii) a health, dental, medical, Medicare supplement, or conversion program offered

under Title 49, Chapter 20, Public Employees' Benefit and Insurance Program Act.

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

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

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

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

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

(A) the state Medicaid program;

(B) the Medicare Part D program;

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

(D) a Veterans Affairs prescription drug program; or

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

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

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

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

(A) the audit; and

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

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

(c) An entity may not audit claims:

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

(A) required by federal law; or

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

(ii) that exceed 200 selected prescription claims.

(4) (a) An entity may not:

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

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

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

(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 [~~records~~] to validate a claim for a prescription, refill, or change in a prescription:

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

[~~(b)~~] (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 26-21-2; 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).

[~~(6) (a)~~] (b) An entity that audits a pharmacy shall provide the pharmacy with a preliminary audit report, delivered to the pharmacy or its corporate office of record, within [~~60 days after completion of the audit~~] the time limit established under Subsection (6)(a)(i)(B).

[~~(b)~~] (c) (i) [~~A~~] 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 [~~based on the~~] determined

by:

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

(B) the date of [~~a computer~~] transmission if [~~transferred~~] the report is transmitted electronically.

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

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

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

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

(8) (a) Within [~~120~~] 60 days after the completion of the appeals process under Subsection (9), a final audit report shall be delivered to the pharmacy or its corporate office of record.

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

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

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

Section 7. Section **58-17b-625** is amended to read:

58-17b-625. Administration of a long-acting injectable and naloxone.

(1) A pharmacist may, in accordance with this section, administer a drug described in Subsection (2).

(2) Notwithstanding the provisions of Subsection 58-17b-102(57)(c)(ii)(B), the division shall make rules[~~;~~] in collaboration with the board and, when appropriate, the Physicians Licensing Board created in Section 58-67-201, and in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, [~~establishing~~] to establish training for a pharmacist to administer [~~the following~~] naloxone and long-acting injectables intramuscularly[~~:~~].

[~~(a) aripiprazole;~~]

[~~(b) aripiprazole lauroxil;~~]

[~~(c) paliperidone;~~]

[~~(d) risperidone;~~]

[~~(e) olanzapine;~~]

[~~(f) naltrexone;~~]

[~~(g) naloxone; and~~]

[~~(h) drugs approved and regulated by the United States Food and Drug Administration for the treatment of the Human Immunodeficiency Virus.~~]

(3) A pharmacist may not administer [~~a drug listed under Subsection (2)~~] naloxone or a long-acting injectable intramuscularly unless the pharmacist:

(a) completes the training described in Subsection (2);

(b) administers the drug at a clinic or community pharmacy, as those terms are defined by the division, by administrative rule made in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act; and

(c) is directed by the physician, as that term is defined in Section 58-67-102 or Section 58-68-102, who issues the prescription to administer the drug.

Section 8. Section **58-37f-203** is amended to read:

58-37f-203. Submission, collection, and maintenance of data.

(1) (a) The division shall implement on a statewide basis, including non-resident pharmacies as defined in Section 58-17b-102, the following two options for a pharmacist to submit information:

(i) real-time submission of the information required to be submitted under this part to the controlled substance database; and

(ii) 24-hour daily or next business day, whichever is later, batch submission of the information required to be submitted under this part to the controlled substance database.

(b) A pharmacist shall comply with either:

(i) the submission time requirements established by the division under Subsection (1)(a)(i); or

(ii) the submission time requirements established by the division under Subsection (1)(a)(ii).

(c) Notwithstanding the time requirements described in Subsection (1)(a), a pharmacist may submit corrections to data that the pharmacist has submitted to the controlled substance database within seven business days after the day on which the division notifies the pharmacist that data is incomplete or corrections to the data are otherwise necessary.

[~~(c)~~] (d) The division shall comply with Title 63G, Chapter 6a, Utah Procurement Code.

(2) (a) The pharmacist-in-charge and the pharmacist of the drug outlet where a controlled substance is dispensed shall submit the data described in this section to the division in accordance with:

(i) the requirements of this section;

(ii) the procedures established by the division;

(iii) additional types of information or data fields established by the division; and

(iv) the format established by the division.

(b) A dispensing medical practitioner licensed under Chapter 17b, Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, shall comply with the provisions of this section and the dispensing medical practitioner shall assume the duties of the pharmacist under this chapter.

(3) (a) Except as provided in Subsection (3)(b), the pharmacist-in-charge and the pharmacist described in Subsection (2)(a) shall, for each controlled substance dispensed by a

pharmacist under the pharmacist's supervision, submit to the division any type of information or data field established by the division by rule in accordance with Subsection (6) regarding:

(i) each controlled substance that is dispensed by the pharmacist or under the pharmacist's supervision; and

(ii) each noncontrolled substance that is:

(A) designated by the division under Subsection (8)(a); and

(B) dispensed by the pharmacist or under the pharmacist's supervision.

(b) Subsection (3)(a) does not apply to a drug that is dispensed for administration to, or use by, a patient at a health care facility, including a patient in an outpatient setting at the health care facility.

(4) An individual whose records are in the database may obtain those records upon submission of a written request to the division.

(5) (a) A patient whose record is in the database may contact the division in writing to request correction of any of the patient's database information that is incorrect.

(b) The division shall grant or deny the request within 30 days from receipt of the request and shall advise the requesting patient of its decision within 35 days of receipt of the request.

(c) If the division denies a request under this Subsection (5) or does not respond within 35 days, the patient may submit an appeal to the Department of Commerce, within 60 days after the patient's written request for a correction under this Subsection (5).

(6) The division shall make rules, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, to establish submission requirements under this part, including:

(a) electronic format;

(b) submission procedures; and

(c) required information and data fields.

(7) The division shall ensure that the database system records and maintains for reference:

(a) the identification of each individual who requests or receives information from the database;

(b) the information provided to each individual; and

(c) the date and time that the information is requested or provided.

(8) (a) The division, in collaboration with the Utah Controlled Substance Advisory Committee created in Section 58-38a-201, shall designate a list of noncontrolled substances described in Subsection (8)(b) by rule made in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act.

(b) To determine whether a prescription drug should be designated in the schedules of controlled substances under this chapter, the division may collect information about a prescription drug as defined in Section 58-17b-102 that is not designated in the schedules of controlled substances under this chapter.

Section 9. Section **58-37f-303** is amended to read:

58-37f-303. Access to opioid prescription information via an electronic data system.

(1) As used in this section:

(a) "Dispense" means the same as that term is defined in Section 58-17b-102.

(b) "EDS user":

(i) means:

(A) a prescriber;

(B) a pharmacist;

(C) a pharmacy intern;

(D) a pharmacy technician; or

(E) an individual granted access to the database under Subsection 58-37f-301(3)(c); and

(ii) does not mean an individual whose access to the database has been revoked by the division pursuant to Subsection 58-37f-301(5)(c).

(c) "Electronic data system" means a software product or an electronic service used by:

(i) a prescriber to manage electronic health records; or

(ii) a pharmacist, pharmacy intern, or pharmacy technician working under the general supervision of a licensed pharmacist [~~to manage~~], for the purpose of:

(A) managing the dispensing of prescription drugs[.]; or

(B) providing pharmaceutical care as defined in Section 58-17b-102 to a patient.

(d) "Opioid" means any substance listed in Subsection 58-37-4(2)(b)(i) or (2)(b)(ii).

(e) "Pharmacist" means the same as that term is defined in Section 58-17b-102.

(f) "Prescriber" means a practitioner, as that term is defined in Section 58-37-2, who is licensed under Section 58-37-6 to prescribe an opioid.

(g) "Prescription drug" means the same as that term is defined in Section 58-17b-102.

(2) Subject to Subsections (3) through (6), no later than January 1, 2017, the division shall make opioid prescription information in the database available to an EDS user via the user's electronic data system.

(3) An electronic data system may be used to make opioid prescription information in the database available to an EDS user only if the electronic data system complies with rules established by the division under Subsection (4).

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

(i) an electronic data system's:

(A) allowable access to and use of opioid prescription information in the database; and

(B) minimum actions that must be taken to ensure that opioid prescription information accessed from the database is protected from inappropriate disclosure or use; and

(ii) an EDS user's:

(A) allowable access to opioid prescription information in the database via an electronic data system; and

(B) allowable use of the information.

(b) The rules shall establish:

(i) minimum user identification requirements that in substance are the same as the

database identification requirements in Section 58-37f-301;

(ii) user access restrictions that in substance are the same as the database identification requirements in Section 58-37f-301; and

(iii) any other requirements necessary to ensure that in substance the provisions of Sections 58-37f-301 and 58-37f-302 apply to opioid prescription information in the database that has been made available to an EDS user via an electronic data system.

(5) The division may not make opioid prescription information in the database available to an EDS user via the user's electronic data system if:

(a) the electronic data system does not comply with the rules established by the division under Subsection (4); or

(b) the EDS user does not comply with the rules established by the division under Subsection (4).

(6) (a) The division shall periodically audit the use of opioid prescription information made available to an EDS user via the user's electronic data system.

(b) The audit shall review compliance by:

(i) the electronic data system with rules established by the division under Subsection (4); and

(ii) the EDS user with rules established by the division under Subsection (4).

(c) (i) If the division determines by audit or other means that an electronic data system is not in compliance with rules established by the division under Subsection (4), the division shall immediately suspend or revoke the electronic data system's access to opioid prescription information in the database.

(ii) If the division determines by audit or other means that an EDS user is not in compliance with rules established by the division under Subsection (4), the division shall immediately suspend or revoke the EDS user's access to opioid prescription information in the database via an electronic data system.

(iii) If the division suspends or revokes access to opioid prescription information in the database under Subsection (6)(c)(i) or (6)(c)(ii), the division shall also take any other

appropriate corrective or disciplinary action authorized by this chapter or title.