RESEARCH USING PHARMACEUTICALS

2013 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Patricia W. Jones

House Sponsor: Ronda Rudd Menlove

LONG TITLE

General Description:

This bill amends the Pharmacy Practice Act.

Highlighted Provisions:

This bill:

- defines "research using pharmaceuticals";
- exempts research using pharmaceuticals from licensure to engage in the practice of pharmacy, telepharmacy, or the practice of a pharmacy technician;
- exempts research using pharmaceuticals from licensure to act as a pharmacy; and
- makes technical corrections.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

58-17b-102, as last amended by Laws of Utah 2012, Chapters 265 and 320

58-17b-301, as enacted by Laws of Utah 2004, Chapter 280

58-17b-302, as last amended by Laws of Utah 2007, Chapter 279

58-17b-612, as last amended by Laws of Utah 2010, Chapter 101

ENACTS:

58-17b-309.6, 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 located in Utah that is authorized to engage in the manufacture, production, wholesale, or distribution of drugs or devices.

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

(24) (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 (24)(a)(i), (ii), (iii), and (iv).

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

(25) "Drug product equivalent" means a drug product that is designated as the therapeutic equivalent of another drug product in the Approved Drug Products with

Therapeutic Equivalence Evaluations prepared by the Center for Drug Evaluation and Research of the Federal Food and Drug Administration.

(26) "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.

(27) "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.

(28) "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.

(29) "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.

(30) "Extern" means a college of pharmacy student enrolled in a college coordinated practical experience program in a health care setting under the supervision of a preceptor, as defined in this act, and approved by a college of pharmacy.

(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 any prescription drug or device to other than the consumer or user of the prescription drug or device, which 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 offer to sell, purchase or trade a prescription drug or device between hospitals or other health care facilities that are under common ownership or control of the management and operation of the facilities;

(iii) the sale, purchase, or trade of a prescription drug or device, or offer to sell,

purchase, or trade a prescription drug or device for emergency medical reasons, or to supply another pharmaceutical facility to alleviate a temporary shortage; or

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

(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 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 and prescribed drug prepared for dispensing, dispensing of the drug, or counseling a patient with respect to a prescription drug;

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

(iii) 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.

(56) "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.

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

(58) "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.

(59) "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.

(60) "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.

(61) "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.

(62) "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.

(63) "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.

(64) "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.

[~~(64)~~] (65) "Retail pharmacy" means a pharmaceutical facility dispensing prescription drugs and devices to the general public.

[~~(65)~~] (66) "Self-audit" means an internal evaluation of a pharmacy to determine compliance with this chapter.

[~~(66)~~] (67) "Supervising pharmacist" means a pharmacist who is overseeing the operation of the pharmacy during a given day or shift.

[~~(67)~~] (68) "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.

[~~(68)~~] (69) "Unlawful conduct" is as defined in Sections 58-1-501 and 58-17b-501.

[~~(69)~~] (70) "Unprofessional conduct" is as defined in Sections 58-1-501 and 58-17b-502 and may be further defined by rule.

[~~(70)~~] (71) "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-301** is amended to read:

58-17b-301. License required -- License classifications for individuals.

(1) A license is required to engage in the practice of pharmacy, telepharmacy, or the practice of a pharmacy technician, except as specifically provided in Section 58-1-307 [~~or~~], 58-17b-309, or 58-17-309.6.

(2) The division shall issue to an individual who qualifies under this chapter a license in the classification of:

(a) pharmacist;

(b) pharmacy intern; or

(c) pharmacy technician.

Section 3. Section **58-17b-302** is amended to read:

58-17b-302. License required -- License classifications for pharmacy facilities.

(1) A license is required to act as a pharmacy, except as specifically exempted from licensure under Section 58-1-307 or 58-17-309.6.

(2) The division shall issue a pharmacy license to a facility that qualifies under this chapter in the classification of a:

(a) class A pharmacy;

(b) class B pharmacy;

(c) class C pharmacy;

(d) class D pharmacy; or

(e) class E pharmacy.

(3) Each place of business shall require a separate license. If multiple pharmacies exist at the same address, a separate license shall be required for each pharmacy.

(4) The division may further define or supplement the classifications of pharmacies. The division may impose restrictions upon classifications to protect the public health, safety, and welfare.

(5) Each pharmacy shall have a pharmacist-in-charge, except as otherwise provided by rule.

(6) Whenever an applicable statute or rule requires or prohibits action by a pharmacy, the pharmacist-in-charge and the owner of the pharmacy shall be responsible for all activities of the pharmacy, regardless of the form of the business organization.

Section 4. Section **58-17b-309.6** is enacted to read:

58-17b-309.6. Exemptions from licensure for research using pharmaceuticals.

Research using pharmaceuticals, as defined in Subsection 58-17b-102(64), is exempt from licensure under Sections 58-17b-301 and 58-17b-302.

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[~~(66)~~](67), 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 and who serves as the pharmacist-in-charge for all purposes under this chapter.