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S.B. 142

PHARMACY PRACTICE ACT AMENDMENTS

2005 GENERAL SESSION

STATE OF UTAH

Sponsor: Peter C. Knudson

LONG TITLE

General Description:

This bill makes technical and clarifying changes to the Pharmacy Practice Act.

Highlighted Provisions:

This bill:

- clarifies and modifies definitions;
- updates an organization name;
- amends the definition of "unprofessional conduct"; and
- makes technical and clarifying changes.

Monies Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

58-17b-102, as enacted by Chapter 280, Laws of Utah 2004

58-17b-303, as enacted by Chapter 280, Laws of Utah 2004

58-17b-304, as enacted by Chapter 280, Laws of Utah 2004

58-17b-502, as enacted by Chapter 280, Laws of Utah 2004

58-17b-503, as enacted by Chapter 280, Laws of Utah 2004

58-17b-612, as enacted by Chapter 280, Laws of Utah 2004

REPEALS:

58-17a-303, as last amended by Chapter 28, Laws of Utah 1998

58-17a-605.1, as last amended by Chapter 18, Laws of Utah 2002, Fifth Special Session

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 [~~a~~] the date determined by a pharmacist and [~~should be~~] placed on a prescription label at the time of dispensing that [~~is intended to indicate~~] indicates to the patient or caregiver a time beyond which the contents of the prescription are not recommended to be used.

(7) "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.

(8) "Board of pharmacy" or "board" means the Utah State Board of Pharmacy [~~as~~] created in Section 58-17b-201.

(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, [~~clinics~~] clinic, nuclear, and branch[~~; pharmaceutical research facilities,~~] pharmacies; and

(ii) pharmaceutical administration [~~facilities,~~] 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[~~, to include any pharmacy outside of Utah, that is authorized to deliver drugs or devices to residents of Utah~~].

(14) "Class E pharmacy" means all other [~~pharmacy facilities~~] 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 [~~organizations and~~] organization or an infusion [~~companies, and does not include~~] company, but not including a hospital [~~pharmacies, retail sales~~] pharmacy, a retailer of goods to the general public, or the [~~offices of practitioners~~] 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 [~~administration~~] 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) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part or accessory, which is required under federal or state law to be prescribed by a practitioner and dispensed by a pharmacist or pharmacy intern.

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

(23) "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.

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

(25) "Drug" means:

(a) a substance recognized as a drug in any official compendium, or supplement thereto, designated from time to time by the division in collaboration with the board for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals, excluding nonprescription drugs or dietary supplements;

(b) a drug or device that is required by any applicable federal or state law or rule to be dispensed on prescription only or is restricted to use by practitioners only;

(c) substances other than food intended to affect the structure or any function of the body of humans or other animals, excluding nonprescription dietary supplements; and

(d) substances intended for use as a component of any substance specified in Subsection (25)(a), (b), or (c).

(26) "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.

(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) "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.

(32) "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.

(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) "Nonprescription drug" means a drug which may be sold without a prescription and which is labeled for use by the consumer in accordance with federal law and includes homeopathic remedies.

(40) "Nonresident pharmacy" means [~~any~~] a pharmacy [~~that sells to anyone in Utah, but is not physically~~] located [~~in~~] outside of Utah that sells to a patient 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 [~~resident~~] patient in this state pursuant to a [~~legally~~] lawfully issued prescription;

(b) provides information to a [~~resident of~~] 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[~~, pharmacy preceptor,~~] 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 [~~health care~~] facility [~~or~~], 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 research facility" means a facility engaged in conducting scientific research regarding drugs and their use in accordance with standard research protocols and techniques, who maintains competent documentation with respect to the research, and who uses prescription drugs in the conduct of the research.~~]

[~~(b) "Pharmaceutical research facility" does not include any licensed facility or clinic whose primary researchers are licensed practitioners.~~]

[~~(48)~~] (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.

[~~(49)~~] (48) "Pharmacist" means an individual licensed by this state to engage in the practice of pharmacy.

[~~(50)~~] (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.

[~~(51)~~] (50) "Pharmacist preceptor" means a licensed pharmacist in good standing with two or more years of licensed experience [~~whose name appears on a division list of approved preceptors~~]. The preceptor serves as a teacher, example of professional conduct, and supervisor of interns in the professional practice of pharmacy.

[~~(52)~~] (51) "Pharmacy" means any place [~~within Utah~~] where:

(a) drugs are dispensed [~~and~~];

(b) pharmaceutical care is provided [~~and any place outside of Utah where drugs are dispensed and pharmaceutical care is provided to residents of Utah.~~];

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

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

[~~(53)~~] (52) "Pharmacy benefits manager or coordinator" means a person or entity that administers the prescription drug or device portion of a health insurance [~~plans~~] plan on behalf of [~~plan sponsors, such as~~] a self-insured [~~employers~~] employer, insurance [~~companies~~] company, [~~and~~] health maintenance [~~organizations, and may be further~~] organization, or other plan sponsor, as defined by rule.

[~~(54)~~] (53) "Pharmacy intern" means an individual licensed by this state to engage in practice as a pharmacy intern.

[~~(55)~~] (54) "Pharmacy technician training program" means an approved technician training program providing education for pharmacy technicians.

[~~(56)~~] (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 [~~as~~] 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.

[~~(57)~~] (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.

[~~(58)~~] (57) "Practice of telepharmacy" means the practice of pharmacy through the use of telecommunications and information technologies.

[~~(59)~~] (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.

[~~(60)~~] (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.

[~~(61)~~] (60) "Prescription" means an order:

(a) issued by a licensed practitioner:

(i) orally, in writing, by telephone, facsimile transmission, computer, or other electronic means of communication as defined by division rule;

(ii) in the course of the practitioner's professional practice; or

(iii) by collaborative pharmacy practice agreement; and

(b) for a controlled substance, other prescription drug, or device with the intent that the controlled substance, prescription drug, or device will be used by a patient or an animal.

[~~(62)~~] (61) "Prescription drug or device" means:

(a) a legend drug or device; or

(b) a drug or device that is required by an applicable federal or state law or rule to be dispensed on prescription only or is restricted to use by practitioners only.

[~~(63)~~] (62) "Retail pharmacy" means a pharmaceutical facility dispensing prescription drugs and devices to the general public.

[~~(64)~~] (63) "Self-audit" means an internal evaluation of a pharmacy to determine compliance with this chapter.

[~~(65)~~] (64) "Supervising pharmacist" means a pharmacist who is overseeing the operation of the pharmacy during a given day or shift.

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

[~~(67)~~] (66) "Unlawful conduct" is as defined in Sections 58-1-501 and 58-17b-501.

[~~(68)~~] (67) "Unprofessional conduct" is as defined in Sections 58-1-501 and 58-17b-502 and may be further defined by rule.

[~~(69)~~] (68) "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-303** is amended to read:

58-17b-303. Qualifications for licensure as a pharmacist.

(1) Each applicant for licensure as a pharmacist shall:

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

(b) pay a fee as determined by the department under Section 63-38-3.2;

(c) produce satisfactory evidence of good moral character as it relates to the applicant's ability to practice pharmacy;

(d) complete a criminal background check and be free from criminal convictions as required by Section 58-17b-307, or as described in Section 58-1-501;

(e) have no physical or mental condition of a nature which prevents the applicant from engaging in the practice of pharmacy with reasonable skill, competency, and safety to the public;

(f) have graduated and received a professional entry degree from a school or college of pharmacy which is accredited by the [~~American Council on Pharmaceutical Education~~] Accreditation Council on Pharmacy Education;

(g) have completed an internship meeting standards established by division rule made in collaboration with the board; and

(h) have successfully passed examinations required by division rule made in collaboration with the board.

(2) Each applicant for licensure as a pharmacist whose pharmacy education was completed at a foreign pharmacy school shall, in addition to the requirements under Subsections (1)(a) through (e), (g), and (h), obtain a certification of equivalency from a credentialing agency required by division rule made in collaboration with the board.

(3) Each applicant for a license by endorsement as a pharmacist under this section

shall:

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

(b) pay the fee determined by the department under Section 63-38-3.2;

(c) be of good moral character as required of applicants for licensure as pharmacists under Subsection (1);

(d) complete a criminal background check and be free from criminal convictions as required by Section 58-17b-307, or as otherwise described in Section 58-1-501;

(e) have no physical or mental condition of a nature which prevents the applicant from engaging in the practice of pharmacy with reasonable skill, competency, and safety to the public;

(f) have lawfully practiced as a licensed pharmacist a minimum of 2,000 hours in the four years immediately preceding the date of application;

(g) produce satisfactory evidence of completing the professional education required under Subsection (1);

(h) be currently licensed in good standing as a pharmacist in another state, territory, or possession of the United States;

(i) produce satisfactory evidence that the examination requirements are or were at the time the license was issued, equal to those of this state; and

(j) pass the jurisprudence examination prescribed by division rule made in collaboration with the board.

Section 3. Section **58-17b-304** is amended to read:

58-17b-304. Qualifications for licensure of pharmacy intern.

Each applicant for licensure as a pharmacy intern shall:

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

(2) pay a fee determined by the department under Section 63-38-3.2;

(3) produce satisfactory evidence of good moral character as it relates to the applicant's ability to practice pharmacy;

(4) complete a criminal background check and be free from criminal convictions as required by Section 58-17b-307, or as otherwise described in Section 58-1-501;

(5) have no physical or mental condition of a nature which prevents the applicant from engaging in the practice of pharmacy with reasonable skill, competency, and safety to the

public;

(6) meet the preliminary educational qualifications required by division rule made in collaboration with the board; and

(7) meet one of the following educational criteria:

(a) be a current pharmacy student, a resident, or fellow in a program approved by division rule in collaboration with the board;

(b) have graduated and received a pharmacy degree from a school or college of pharmacy which is accredited by the [~~American Council on Pharmaceutical Education~~] Accreditation Council on Pharmacy Education; or

(c) have graduated from a foreign pharmacy school and received certification of equivalency from a credentialing agency approved by the division rule in collaboration with the board.

Section 4. 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 for price discounts conditional upon volume purchases:

(a) paying rebates to practitioners or any other health care providers[~~, or~~]; and

(b) entering into any agreement with a medical practitioner or any other person for the payment or acceptance of compensation or its economic equivalent for recommending the professional services of either party[~~, except as allowed under Subsection (2)(b); and~~];

[~~(b) price discounts conditional upon volume purchases are not prohibited under Subsection (2)(a);~~]

(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 [~~the original sealed unit dose package~~] a unit pack, as defined in Section 58-17b-503, or the

manufacturer's sealed container, as defined in rule[~~, except as provided in Section 58-17b-503~~];

(6) being employed as a pharmacist, pharmacy intern, or pharmacy technician, or sharing or receiving compensation in any form arising out of an act incidental to professional activities in the course of which any person requires him to engage in any aspect of the practice of pharmacy in violation of this chapter;

(7) violating Federal Title II, P.L. 91, Controlled Substances Act, or Title 58, Chapter 37, Utah Controlled Substances Act, or rules and 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 an individual's scope of training and ability;

(9) administering:

(a) without appropriate training, as defined by rule[~~:~~];

[~~(a) written guidelines or protocols of a practitioner or in conflict with such guidelines or protocols; or~~]

(b) without a [~~lawful~~] 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 would constitute grounds for action, as defined in this section;

(13) preparing as a pharmacist or pharmacy intern, a prescription drug for sale to another pharmacist or pharmaceutical facility; and

(14) preparing as a pharmacist or pharmacy intern, 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 5. Section **58-17b-503** is amended to read:

58-17b-503. Exception to unprofessional conduct.

(1) For purposes of this section:

(a) "ICFMR" means an intermediate care facility for the mentally retarded licensed as a nursing care facility or a small health care facility under Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act.

(b) "Nursing care facility" has the same definition as in Section 26-21-2.

(c) "Unit pack" means a tamper-resistant nonreusable single-dose single-drug package [~~which~~] with identification that indicates the lot number and expiration date for the drug.

(2) Notwithstanding the provisions of Subsection 58-17b-502(5), a pharmacist may accept back and redistribute any unused drug, or a part of it, after it has left the premises of the pharmacy if:

(a) the drug was prescribed to a patient in a nursing care facility, an ICFMR, or state prison facility, county jail, or state hospital;

(b) the drug was stored under the supervision of a licensed health care provider according to manufacturer recommendations;

(c) the drug is in a unit pack or in the manufacturer's sealed container;

(d) the drug was returned to the original dispensing pharmacy;

(e) the drug was initially dispensed by a licensed pharmacist or licensed pharmacy intern; and

(f) accepting back and redistribution of the drug complies with Federal Food and Drug Administration and Drug Enforcement Administration regulations.

Section 6. Section **58-17b-612** is amended to read:

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

(1) (a) Any pharmacy, except a wholesaler, distributor, or out-of-state mail service 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 the provisions of Subsection 58-17b-102[~~(63)~~](64), 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.

Section 7. **Repealer.**

This bill repeals:

Section **58-17a-303, License classifications of drug outlets and other facilities -- Qualifications for licensure.**

Section **58-17a-605.1, Restrictive drug formulary prohibited.**

Legislative Review Note
as of 1-24-05 5:33 PM

Based on a limited legal review, this legislation has not been determined to have a high probability of being held unconstitutional.

Office of Legislative Research and General Counsel

State Impact

No fiscal impact.

Individual and Business Impact

No fiscal impact.

Office of the Legislative Fiscal Analyst