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S.B. 100

PHARMACIST LICENSING AMENDMENTS

2002 GENERAL SESSION

STATE OF UTAH

Sponsor: Peter C. Knudson

This act modifies the Pharmacy Practices Act. The act amends the definition of practice of pharmacy to include nutritional assessment, therapy, and counseling. The act includes violating a patient's right to privacy as unprofessional conduct. The act makes technical amendments.

This act affects sections of Utah Code Annotated 1953 as follows:

AMENDS:

58-17a-102, as last amended by Chapter 162, Laws of Utah 1999

58-17a-502, as last amended by Chapter 162, Laws of Utah 1999

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

Section 1. Section **58-17a-102** is amended to read:

58-17a-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 directions of the veterinarian.

(2) "Analytical laboratory":

(a) means a facility in possession of prescription drugs for the purpose of analysis; and

(b) 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.

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

(4) "Board" means the State Board of Pharmacy created in Section 58-17a-201.

(5) "Branch pharmacy" means a drug outlet 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.

(6) "Compounding":

(a) means the preparation, mixing, assembling, packaging, or labeling of reasonable quantities of a prescription drug or device by a licensed pharmacist or pharmacy intern upon receipt of a valid prescription or medication order from a practitioner for an individually identified patient;

(b) includes preparation, mixing, assembling, packaging, or labeling of reasonable quantities of a prescription drug for the purpose of, or incidental to research, teaching, or chemical analysis on the condition the prescription drug is not offered for sale or dispensing;

(c) includes the preparation of a reasonable quantity of a prescription drug by a licensed pharmacist or pharmacy intern in anticipation of a valid prescription or medication order to be dispensed or administered to a patient based on routine, regularly observed prescribing patterns of a practitioner; and

(d) does not include the preparation of prescription drugs by a pharmacist or pharmacy intern for sale to another pharmacist, drug outlet, or 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.

(7) "Controlled substance" has the same definition as in Section 58-37-2.

(8) "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.

(9) "Dispense" means to prepare and deliver a prescription drug 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, an animal, or other individual entitled to receive the prescription drug or device.

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

(11) "Drug" or "drugs" means a prescription drug as defined in this chapter.

(12) "Drug outlet" means any person, other than an individual licensed as a pharmacist, pharmacy technician, or pharmacy intern, who engages in dispensing, delivering, distributing, manufacturing, or wholesaling prescription drugs or devices within or into this state.

(13) "Drug product equivalent" means a drug product that is designated 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.

(14) "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.

(15) "Extern" means a college of pharmacy student enrolled in a college coordinated practical experience program in a licensed pharmacy under the supervision of a preceptor, as defined in Subsection (45), and approved by the college of pharmacy.

(16) "Filling" or "refilling" have same meaning as dispense.

(17) "General supervision" means the supervising pharmacist is in the pharmacy or the facility in which the pharmacy is located and is available for immediate oral contact with the supervised pharmacy technician or pharmacy intern.

(18) "Hospital pharmacy" means a drug outlet providing pharmaceutical service 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.

(19) "Institutional pharmacy":

(a) means a drug outlet providing pharmaceutical service 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 health maintenance organizations and infusion companies; and

(b) does not include hospital pharmacies, drug outlets engaged in retail sales of prescription drugs and devices to the general public, or the offices of practitioners.

(20) "Labeling" means the process of preparing and affixing a label to the container of any drug or device, exclusive of the labeling by a manufacturer, packer, or distributor of a nonprescription drug or commercially packaged legend drug or device. Any label shall include all information required by federal and state law or rule.

(21) "Licensee" means any person to whom a license has been granted under this chapter.

(22) "Manufacture":

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

(b) does not include the preparation or compounding of a noncontrolled substance drug by an individual for that individual's own use or the preparation, compounding, packaging, or labeling of a drug:

(i) by a pharmacist, pharmacy intern, or practitioner incident to administering or dispensing of a drug in the course of professional practice; or

(ii) by a practitioner or by that practitioner's authorization under supervision for the purpose of or incident to research, teaching, or chemical analysis and not for sale.

(23) "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 for potential harmful or dangerous interactions, or other factors, or other drugs or devices prescribed for the patient.

(24) "Nonprescription drugs" means medicines or drugs which may be sold without a prescription and which are prepackaged for use by the consumer and labeled in accordance with the requirements of the statutes and rules of this state and of the federal government.

(25) "Nuclear pharmacy" means a drug outlet providing radiopharmaceutical service.

(26) "Out-of-state mail service pharmacy" means a drug outlet located outside the state that:

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

(b) provides information to a resident of 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.

(27) "Person" means an individual, corporation, partnership, association, or any other legal entity.

(28) "Pharmaceutical administration facility" means a health care facility or agency, including birthing centers, ambulatory surgical facilities, abortion clinics, home health agencies, hospices, nursing care facilities, end stage renal disease facilities, and penal institutions in which:

(a) a licensed drug outlet is not located;

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

(c) 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

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

(29) (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.

(30) "Pharmaceutical dog trainer" means a person who is employed by or under contract to a law enforcement agency who uses prescription drugs for the purpose of training dogs in the detection of prescription drugs.

(31) "Pharmaceutical manufacturer" means a person engaged in the manufacture of prescription drugs or devices.

(32) "Pharmaceutical researcher" means a person who is 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.

(33) "Pharmaceutical teaching organization" means an accredited school of pharmacy within the state, or a school or program meeting the requirements established in accordance with Subsection 58-17a-302(4) providing education for pharmacy technicians within the state.

(34) "Pharmaceutical wholesaler/distributor":

(a) means a drug outlet 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 drug outlet has not produced, manufactured, compounded, or dispensed; and

(b) does not include a drug outlet 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 drug outlet to alleviate a temporary shortage; or

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

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

(36) "Pharmacy" means a facility or location where the practice of pharmacy is carried out.

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

(38) "Pharmacy patient" or "patient" means an individual for whom a practitioner has prescribed a drug or device which is to be administered to or taken or used by that individual or an animal.

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

(40) "Physician" means an individual licensed by this state to engage in the practice of medicine.

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

(42) "Practice as a pharmacy technician":

(a) 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; and

(b) does not include performing a 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 or nonprescription drug.

(43) "Practice of pharmacy" includes any of the following:

(a) interpreting prescription orders;

(b) compounding, packaging, labeling, dispensing, administering, and the coincident distribution of prescription drugs and 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 Physician's 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;

(c) participating in drug utilization review;

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

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

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

(g) providing drug product equivalents;

(h) supervising pharmacist's supportive personnel, pharmacy interns, and pharmacy technicians;

(i) providing patient counseling, including adverse and therapeutic effects of drugs; [~~and~~]

(j) providing nutritional assessment, therapy, and counseling; however, this Subsection (43)(j) does not limit the scope of practice of a naturopathic physician licensed under Chapter 71, Naturopathic Physician Practice Act, or a dietitian certified under Chapter 49, Dietitian Certification Act; and

[~~(j)~~] (k) providing pharmaceutical care.

(44) "Practitioner" means any person licensed by the state to prescribe drugs, medications, or devices dispensed by prescription only.

(45) "Preceptor" means a licensed pharmacist approved by the division in collaboration with the board to serve as a teacher, example of professional conduct, and supervisor of interns and externs in the professional practice of pharmacy.

(46) "Prescription" means an order issued by a licensed practitioner, in the course of that practitioner's professional practice, for a controlled substance, other prescription drug or device with the intent the prescription drug or device will be used by a patient or an animal. The order may be issued by word of mouth, written document, telephone, facsimile transmission, computer, or other electronic means of communication as defined by division rule.

(47) "Prescription drug or device" or "legend drug or device" means:

(a) a drug or device which, under federal law, is required to be labeled with either of the following statements or their equivalent:

(i) "CAUTION: Federal law prohibits dispensing without prescription"; or

(ii) "CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian"; or

(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.

(48) "Prescription drug or device order" means a lawful written or oral order of a practitioner for a prescription drug or device for use in humans or animals.

(49) "Retail pharmacy" means a drug outlet dispensing prescription drugs and devices to the general public.

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

(a) may assist a pharmacist, pharmacy intern, or pharmacy technician in nonjudgmental duties not included in the definition of the practice of pharmacy, and as those duties may be further defined by division rule made in collaboration with the board; and

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

(51) "Unlawful conduct" is as defined in Sections 58-1-501 and 58-17a-501.

(52) "Unprofessional conduct" is as defined in Sections 58-1-501 and 58-17a-502, and as may be further defined by rule.

(53) "Veterinary pharmaceutical outlet" means a drug outlet dispensing veterinary prescription drugs.

Section 2. Section **58-17a-502** is amended to read:

58-17a-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) paying rebates to practitioners or any other health care providers, or 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 of 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 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) 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 or manufacturer's sealed container;

(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 aspects of the practice of pharmacy in violation of this chapter;

(7) violation of 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 of them;

(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; [~~and~~]

(9) administering without:

(a) appropriate training as defined by rule;

(b) written guidelines or protocols of a practitioner or in conflict with such guidelines or protocols; or

(c) a lawful order, when one is required by law[~~.~~]; and

(10) violating a patient's right to privacy regarding the patient's person, condition, diagnosis, or other confidential information to any person who does not have:

(a) a legal right to the information concerning the patient; or

(b) a professional need to know the information concerning the patient based on generally recognized professional or ethical standards that authorize or require disclosure.

Legislative Review Note
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A limited legal review of this legislation raises no obvious constitutional or statutory concerns.

Office of Legislative Research and General Counsel