PHARMACY PRACTICE ACT AMENDMENTS

1998 GENERAL SESSION STATE OF UTAH

Sponsor: Patrice Arent

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AN ACT RELATING TO OCCUPATIONS AND PROFESSIONS; AUTHORIZING THE DIVISION OF OCCUPATIONS AND PROFESSIONAL LICENSING TO CONDUCT ADMINISTRATIVE INSPECTIONS AND TO SEIZE ADULTERATED OR MISBRANDED DRUGS AND DEVISES; CLARIFYING THAT THE FAILURE TO PERMIT AN INSPECTION CONSTITUTES UNLAWFUL CONDUCT; AND AMENDING LICENSING PROVISIONS RELATED TO PHARMACY INTERNS.

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

AMENDS:

58-17a-302, as enacted by Chapter 247, Laws of Utah 1996

58-17a-303, as enacted by Chapter 247, Laws of Utah 1996

58-17a-501, as enacted by Chapter 247, Laws of Utah 1996

ENACTS:

58-17a-103, Utah Code Annotated 1953

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

Section 1. Section 58-17a-103 is enacted to read:

58-17a-103. Administrative inspections.

- (1) The division may, for the purpose of ascertaining compliance with the provisions of this chapter, enter and inspect on a routine basis the business premises of a person:
 - (a) licensed under Section 58-17a-303; or
- (b) who holds himself out to the general public as providing a good or service for which a license is required under Section 58-17a-303.
- (2) Before conducting an inspection under Subsection (1), the division shall, after identifying the person in charge:
 - (a) give proper identification;

- (b) request to see the applicable license;
- (c) describe the nature and purpose of the inspection; and
- (d) if necessary, explain the authority of the division to conduct the inspection and the penalty for refusing to permit the inspection as provided in Section 58-17a-501.
- (3) In conducting an inspection under Subsection (1), the division may, after meeting the requirements of Subsection (2):
- (a) examine any record, prescription, order, drug, device, equipment, machine, or area related to a good or service for which a license has been issued under or is required by Section 58-17a-303 for the purpose of ascertaining compliance with the applicable provisions of this chapter;
 - (b) take a drug or device for further analysis if considered necessary; and
- (c) temporarily seize a drug or device which is found to be adulterated, misbranded, or otherwise in violation of this chapter, pending an adjudicative proceeding on the matter.
 - (4) An inspection conducted under Subsection (1) shall be during regular business hours.
 - (5) The division's authority to conduct an inspection is not affected by a person's failure to:
 - (a) acknowledge the division's authority as is required by Section 58-17a-303; or
 - (b) receive notice under Subsection (6).
- (6) Before July 1, 1998, the division shall mail a notice to the last-known address of each person licensed under Section 58-17a-303, explaining the division's authority to conduct inspections.

Section 2. Section **58-17a-302** is amended to read:

58-17a-302. Qualifications for licensure of pharmacist, pharmacy technician, and pharmacy intern.

- (1) Each applicant for licensure as a pharmacist and to practice pharmacy 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) 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;
- (d) have completed an internship meeting standards established by division rule made in collaboration with the board;

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

- (f) produce satisfactory evidence of good moral character as it relates to the applicant's ability to practice pharmacy; and
- (g) 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.
- (2) Each applicant for a license as a pharmacist by endorsement under Section 58-1-302 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 currently licensed in good standing as a pharmacist in another state, territory, or possession of the United States;
- (d) produce satisfactory evidence of completing the professional education and internship required under Subsection (1);
- (e) be of good moral character as required of applicants for licensure as pharmacists under Subsection (1);
- (f) produce satisfactory evidence of having met the examination requirements which existed in this state at the time the applicant became licensed in the other state;
- (g) pass the jurisprudence examination prescribed by division rule made in collaboration with the board;
- (h) have lawfully practiced as a licensed pharmacist a minimum of 2,000 hours in the four years immediately preceding the date of application; <u>and</u>
- [(i) pass the Federal Drug Law Examination (FDLE) of the National Boards of Pharmacy if the applicant has not practiced pharmacy a minimum of 2,000 hours in the four years immediately preceding the date of application; and]
- [(j)] (i) 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.
 - (3) Each applicant for licensure as a pharmacist whose pharmacy education was completed

at a foreign pharmacy school, shall, in addition to the requirements under Subsection (1), demonstrate educational equivalency of the foreign pharmacy school education with a domestically accredited school of pharmacy by obtaining certification of equivalency from the Foreign Pharmacy Graduate Examination Committee of the National Association of Boards of Pharmacy Foundation.

- (4) Each applicant for licensure as a pharmacy technician shall:
- (a) submit an application in a form prescribed by the division;
- (b) pay a fee determined by the department under Section 63-38-3.2;
- (c) be of good moral character;
- (d) have no physical or mental condition of a nature which prevents the applicant from engaging in practice as a pharmacy technician with reasonable skill, competency, and safety to the public; and
- (e) (i) prior to July 1, 1998, have completed a program of education and training, meeting standards established by division rule made in collaboration with the board, in either a formal educational setting or on-the-job training in a licensed Utah pharmacy; or
 - (ii) after July 1, 1998:
- (A) have completed a program of education and training, meeting standards established by division rule made in collaboration with the board, in either a formal educational setting or on-the-job training in a licensed Utah pharmacy; and
- (B) successfully passed examinations required by division rule made in collaboration with the board.
 - (5) Each applicant for a license to become a pharmacy intern shall:
- (a) (i) be a current pharmacy student, or a resident or fellow in a program approved by the division in collaboration with the board; [or]
- [(ii) a pharmacist who is currently licensed in another U.S. state or territory, and has not passed the examination required under this chapter for licensure as a pharmacist in Utah, but a license issued under this Subsection (5)(a)(ii) may be for not longer than one year, and may be issued only once;]
 - (ii) 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; or

(iii) have graduated from a foreign pharmacy school and received a certificate of equivalency from the Foreign Pharmacy Graduate Examination Committee of the National Association of Boards of Pharmacy foundation;

- (b) meet the preliminary educational qualifications required by division rule made in collaboration with the board, which rules shall require not less than completion of preprofessional college training and [one quarter or] the equivalent of 15 semester hours or more of training in professional pharmacy courses, or its equivalent, completed in a college or school of pharmacy recognized by the division in collaboration with the board;
 - (c) submit an application in a form prescribed by the division; and
 - (d) pay a fee determined by the department under Section 63-38-3.2.
 - (6) (a) The duration of a pharmacy intern license may be no longer than:
 - (i) one year for a license issued under Subsection (5)(a)(ii) or (iii); and
 - (ii) four years for a license issued under Subsection (5)(a)(i).
- (b) A pharmacy intern license issued under this chapter may not be renewed, but may be extended by the division in collaboration with the board.

Section 3. Section **58-17a-303** is amended to read:

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

- (1) A license is required as a condition precedent to engaging in activities regulated under the license classifications set forth in Subsections (2) and (3), except as a person or activity is specifically exempted from licensure under Section 58-1-307.
- (2) The division shall issue to a person who qualifies under this chapter a license in the drug outlet classifications:
 - (a) retail pharmacy;
 - (b) hospital pharmacy;
 - (c) institutional pharmacy;
 - (d) nuclear pharmacy;

- (e) out-of-state mail order pharmacy;
- (f) veterinary pharmaceutical outlet;
- (g) branch pharmacy;
- (h) pharmaceutical manufacturer; or
- (i) pharmaceutical wholesaler/distributor.
- (3) The division shall issue to a person who qualifies under this chapter a license in the classifications:
 - (a) pharmaceutical researcher;
 - (b) pharmaceutical teaching organization;
 - (c) pharmaceutical dog trainer;
 - (d) animal euthanasia agency;
 - (e) analytical laboratory;
 - (f) pharmaceutical administration facility; and
 - (g) lethal injection use.
 - (4) Each applicant for licensure under this section shall:
 - (a) submit an application in a form prescribed by the division;
 - (b) pay a fee determined by the department under Section 63-38-3.2;
- (c) satisfy the division that the applicant, and each owner, officer, or manager of the applicant has not engaged in any act, practice, or omission, which when considered with the duties and responsibilities of a licensee under this section indicates there is cause to believe that issuing a license to the applicant is inconsistent with the interests of the public's health, safety, or welfare; [and]
- (d) demonstrate the licensee's operations will be in accordance with all federal, state, and local laws relating to the type of activity engaged in by the licensee, including regulations of the Federal Drug Enforcement Administration and Food and Drug Administration, and operating standards established in this chapter and by division rule made in collaboration with the board[-]; and
 - (e) acknowledge the division's authority to inspect the licensee's business premises pursuant

to Section 58-17a-103.

- (5) Each license issued under this section:
- (a) shall be issued for a single, specific location; and
- (b) is not transferable or assignable.

Section 4. Section **58-17a-501** is amended to read:

58-17a-501. Unlawful conduct.

"Unlawful conduct" includes:

- (1) knowingly preventing or refusing to permit any authorized agent of the division to [enter a pharmacy or any other place where prescription drugs or devices are kept, manufactured, stored, dispensed, or distributed to a consumer, for the purpose of lawful] conduct an inspection [or other purpose in accordance with this chapter and rules made under it] pursuant to Section 58-17a-103;
- (2) failing to deliver the license, permit, or certificate to the division upon demand, if it has been revoked, suspended, or refused;
- (3) (a) using the title "pharmacist," "druggist," "pharmacy intern," "pharmacy technician," "apothecary," or any term having similar meaning, except by a person licensed as a pharmacist, pharmacy intern, or pharmacy technician; or
- (b) conducting or transacting business under a name which contains, as part of that name, the words "drugstore," "pharmacy," "drugs," "medicine store," "medicines," "drug shop," "apothecary," "prescriptions," or any term having a similar meaning, or in any manner advertising, otherwise describing, or referring to the place of the conducted business or profession, unless the place is a pharmacy issued a license by the division, except any establishment selling nonprescription drugs and supplies may display signs bearing the words "packaged drugs", "drug sundries", or "nonprescription drugs", and is not considered to be a pharmacy or drugstore by reason of the display;
- (4) buying, selling, or causing to be sold, or offering for sale, any drug or device which bears, or the package bears or originally did bear, the inscription "sample," "not for resale," "for investigational or experimental use only," or other similar words, except when a cost is incurred in the bona fide acquisition of an investigational or experimental drug;

(5) using to his own advantage or revealing to anyone other than the division, board, and its authorized representatives, or to the courts, when relevant to any judicial or administrative proceeding under this chapter, any information acquired under authority of this chapter or concerning any method or process which is a trade secret;

- (6) procuring or attempting to procure any drug for himself or to have someone else procure or attempt to procure any drug:
 - (a) by fraud, deceit, misrepresentation, or subterfuge;
 - (b) by forgery or alteration of a prescription or any written order;
 - (c) by concealment of a material fact;
 - (d) by use of a false statement in any prescription, chart, order, or report; or
 - (e) by theft;
- (7) filling, refilling, or advertising the filling or refilling of prescriptions for any consumer or patient residing in this state if that person is not licensed under this chapter;
- (8) requiring any employed pharmacist, pharmacy intern, pharmacy technician, or authorized supportive personnel to engage in any conduct in violation of this chapter;
 - (9) being in possession of a prescription drug for any unlawful purpose;
- (10) dispensing a prescription drug to anyone who does not have a prescription from a practitioner or to anyone who he knows or should know is attempting to obtain drugs by fraud or misrepresentation;
- (11) selling, dispensing, or otherwise trafficking in prescription drugs when not licensed to do so or when not exempted from licensure; and
- (12) engaging in the practice of pharmacy without a licensed pharmacist designated as the pharmacist-in-charge.