+Fifty-first Legislature
Second Regular Session

COMMITTEE ON HEALTH

HOUSE OF REPRESENTATIVES AMENDMENTS TO S.B. 1043

(Reference to Senate engrossed bill)

Page 10, between lines 14 and 15, insert:

"Sec. 3. Section 32-1901, Arizona Revised Statutes, is amended to read:

32-1901. Definitions

In this chapter, unless the context otherwise requires:

1. "Administer" means the direct application of a controlled substance, prescription-only drug, dangerous drug or narcotic drug, whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject by a practitioner or by the practitioner's authorized agent or the patient or research subject at the direction of the practitioner.

2. "Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or that are likely to induce, directly or indirectly, the purchase of drugs, devices, poisons or hazardous substances.

3. "Advisory letter" means a nondisciplinary letter to notify a licensee or permittee that either:

(a) While there is insufficient evidence to support disciplinary action, the board believes that continuation of the activities that led to the investigation may result in further board action against the licensee or permittee.

(b) The violation is a minor or technical violation that is not of sufficient merit to warrant disciplinary action.

(c) While the licensee or permittee has demonstrated substantial compliance through rehabilitation, remediation or reeducation that has mitigated the need for disciplinary action, the board believes that repetition of the activities that led to the investigation may result in further board action against the licensee or permittee.

4. "Antiseptic", if a drug is represented as such on its label, means a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment or dusting powder or other use that involves prolonged contact with the body.

5. "Authorized officers of the law" means legally empowered peace officers, compliance officers of the state board of pharmacy and agents of the division of narcotics enforcement and criminal intelligence of the department of public safety.

6. "Board" or "board of pharmacy" means the Arizona state board of pharmacy.

7. "Color additive" means a material that either:

(a) Is any dye, pigment or other substance made by a process of synthesis or similar artifice, or extracted, isolated or otherwise derived, with or without intermediate or final change of identity, from any vegetable, animal, mineral or other source.

(b) If added or applied to a drug, or to the human body or any part of the human body, is capable of imparting color, except that color additive does not include any material that has been or may be exempted under the federal act. Color includes black, white and intermediate grays.

8. "Compounding" means the preparation, mixing, assembling, packaging or labeling of a drug by a pharmacist or an intern or pharmacy technician under the pharmacist's supervision, for the purpose of dispensing to a patient based on a valid prescription order. Compounding includes the preparation of drugs in anticipation of prescription orders prepared on routine, regularly observed prescribing patterns and the preparation of drugs as an incident to research, teaching or chemical analysis or for administration by a medical practitioner to the medical practitioner's patient and not for sale or dispensing. Compounding does not include the preparation of commercially available products from bulk compounds or the preparation of drugs for sale to pharmacies, practitioners or entities for the purpose of dispensing or distribution.

9. "Compressed medical gas distributor" means a person who holds a current permit issued by the board to distribute compressed medical gases pursuant to a compressed medical gas order to compressed medical gas suppliers and other entities that are registered, licensed or permitted to use, administer or distribute compressed medical gases.

10. "Compressed medical gas order" means an order for compressed medical gases that is issued by a medical practitioner.

11. "Compressed medical gas supplier" means a person who holds a current permit issued by the board to supply compressed medical gases pursuant to a compressed medical gas order and only to the consumer or the patient.

12. "Compressed medical gases" means gases and liquid oxygen that a compressed medical gas distributor or manufacturer has labeled in compliance with federal law.

13. "Controlled substance" means a drug, substance or immediate precursor identified, defined or listed in title 36, chapter 27, article 2.

14. "Corrosive" means any substance that when it comes in contact with living tissue will cause destruction of tissue by chemical action.

15. "Counterfeit drug" means a drug that, or the container or labeling of which, without authorization, bears the trademark, trade name or other identifying mark, imprint, number or device, or any likeness of these, of a manufacturer, distributor or dispenser other than the person who in fact manufactured, distributed or dispensed that drug.

16. "Dangerous drug" has the same meaning prescribed in section 13-3401.

17. "Decree of censure" means an official action that is taken by the board and that may include a requirement for restitution of fees to a patient or consumer.

18. "Deliver" or "delivery" means the actual, constructive or attempted transfer from one person to another whether or not there is an agency relationship.

19. "Deputy director" means a pharmacist WHO IS employed by the board and selected by the executive director to perform duties as prescribed by the executive director.

20. "Device", except as used in paragraph 15 of this section, section 32-1965, paragraph 4 and section 32-1967, subsection A, paragraph 15 and subsection C, means instruments, apparatus and contrivances, including their components, parts and accessories, including all such items under the federal act, intended either:

(a) For use in the diagnosis, cure, mitigation, treatment or prevention of disease in the human body or other animals.

(b) To affect the structure or any function of the human body or other animals.

21. "Direct supervision of a pharmacist" means the pharmacist is present. If relating to the sale of certain items, direct supervision of a pharmacist means that a pharmacist determines the legitimacy or advisability of a proposed purchase of those items.

22. "Director" means the director of the division of narcotics enforcement and criminal investigation of the department of public safety.

23. "Dispense" means to deliver to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling or compounding necessary to prepare for that delivery.

24. "Dispenser" means a practitioner who dispenses.

25. "Distribute" means to deliver, other than by administering or dispensing.

26. "Distributor" means a person who distributes.

27. "Drug" means:

(a) Articles recognized, or for which standards or specifications are prescribed, in the official compendium.

(b) Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in the human body or other animals.

(c) Articles other than food intended to affect the structure or any function of the human body or other animals.

(d) Articles intended for use as a component of any articles specified in subdivision (a), (b) or (c) of this paragraph but does not include devices or their components, parts or accessories.

28. "Drug enforcement administration" means the drug enforcement administration of the United States department of justice or its successor agency.

29. "Drug or device manufacturing" means the production, preparation, propagation or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis and includes any packaging or repackaging of substances or labeling or relabeling of its container and the promotion and marketing of the same. Drug or device manufacturing does not include compounding.

30. "Economic poison" means any substance that alone, in chemical combination or in formulation with one or more other substances is a pesticide within the meaning of the laws of this state or the federal insecticide, fungicide and rodenticide act and that is used in the production, storage or transportation of raw agricultural commodities.

31. "Established name", with respect to a drug or ingredient of a drug, means any of the following:

(a) The applicable official name.

(b) If there is no such name and the drug or ingredient is an article recognized in an official compendium, ~~then~~ the official title in an official compendium.

(c) If neither subdivision (a) nor (b) of this paragraph applies, ~~then~~ the common or usual name of such drug.

32. "Executive director" means the executive director of the board of pharmacy.

33. "Federal act" means the federal laws and regulations that pertain to drugs, devices, poisons and hazardous substances and that are official at

the time any drug, device, poison or hazardous substance is affected by this chapter.

34. "Full service wholesale permittee" means a permittee who may distribute prescription-only drugs and devices, controlled substances and over-the-counter drugs and devices to pharmacies or other legal outlets from a place devoted in whole or in part to wholesaling these items.

35. "Graduate intern" means a person who has graduated from a college, school or program of pharmacy approved by the board and who meets the qualifications and experience for a pharmacy intern as provided in section 32-1923.

36. "Highly toxic" means any substance that falls within any of the following categories:

(a) Produces death within fourteen days in half or more than half of a group of ten or more laboratory white rats each weighing between two hundred and three hundred grams, at a single dose of fifty milligrams or less per kilogram of body weight, when orally administered.

(b) Produces death within fourteen days in half or more than half of a group of ten or more laboratory white rats each weighing between two hundred and three hundred grams, if inhaled continuously for a period of one hour or less at an atmospheric concentration of two hundred parts per million by volume or less of gas or vapor or two milligrams per liter by volume or less of mist or dust, provided the concentration is likely to be encountered by humans if the substance is used in any reasonably foreseeable manner.

(c) Produces death within fourteen days in half or more than half of a group of ten or more rabbits tested in a dosage of two hundred milligrams or less per kilogram of body weight, if administered by continuous contact with the bare skin for twenty-four hours or less.

If the board finds that available data on human experience with any substance indicate results different from those obtained on animals in the dosages or concentrations prescribed in this paragraph, the human data shall take precedence.

37. "Hospital" means any institution for the care and treatment of the sick and injured that is approved and licensed as a hospital by the department of health services.

38. "Intern" means a pharmacy intern and a graduate intern.

39. "Internship" means the practical, experiential, hands-on training of a pharmacy intern under the supervision of a preceptor.

40. "Irritant" means any substance, other than a corrosive, that on immediate, prolonged or repeated contact with normal living tissue will induce a local inflammatory reaction.

41. "Jurisprudence examination" means a board approved pharmacy law examination that is written and administered in cooperation with the national association of boards of pharmacy or another board approved pharmacy law examination.

42. "Label" means a display of written, printed or graphic matter on the immediate container of any article that, unless easily legible through the outside wrapper or container, also appears on the outside wrapper or container of the article's retail package. For the purposes of this paragraph, the immediate container does not include package liners.

43. "Labeling" means all labels and other written, printed or graphic matter either:

(a) On any article or any of its containers or wrappers.

(b) Accompanying that article.

44. "Letter of reprimand" means a disciplinary letter that is a public document issued by the board and that informs a licensee or permittee that the licensee's or permittee's conduct violates state or federal law and may require the board to monitor the licensee or permittee.

45. "Limited service pharmacy" means a pharmacy THAT IS approved by the board to practice a limited segment of pharmacy as indicated by the permit issued by the board.

46. "Manufacture" or "manufacturer" means every person who prepares, derives, produces, compounds, processes, packages or repackages or labels any drug in a place, other than a pharmacy, devoted to manufacturing the drug.

47. "Marijuana" has the same meaning prescribed in section 13-3401.

48. "Medical practitioner" means any medical doctor, doctor of osteopathy, dentist, podiatrist, veterinarian or other person licensed and authorized by law to use and prescribe drugs and devices for the treatment of sick and injured human beings or animals or for the diagnosis or prevention of sickness in human beings or animals in this state or any state, territory or district of the United States.

49. "Medication order" means a written or verbal order from a medical practitioner or that person's authorized agent to administer a drug or device.

50. "Narcotic drug" has the same meaning prescribed in section 13-3401.

51. "New drug" means either:

(a) Any drug the composition of which is such that the drug is not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs as safe and effective for use under the conditions prescribed, recommended or suggested in the labeling.

(b) Any drug the composition of which is such that the drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but that has not, other than in the investigations, been used to a material extent or for a material time under those conditions.

52. "Nonprescription drug" or "over-the-counter drug" means any nonnarcotic medicine or drug that may be sold without a prescription and is prepackaged and labeled for use by the consumer in accordance with the requirements of the laws of this state and federal law. Nonprescription drug does not include:

(a) A drug that is primarily advertised and promoted professionally to medical practitioners and pharmacists by manufacturers or primary distributors.

(b) A controlled substance.

(c) A drug that is required to bear a label that states "Rx only."

(d) A drug intended for human use by hypodermic injection.

53. "Nonprescription drug wholesale permittee" means a permittee who may distribute only over-the-counter drugs and devices to pharmacies or other lawful outlets from a place devoted in whole or in part to wholesaling these items.

54. "Notice" means personal service or the mailing of a copy of the notice by certified mail addressed either to the person at the person's latest address of record in the board office or to the person's attorney.

55. "Official compendium" means the latest revision of the United States pharmacopeia and the national formulary or any current supplement.

56. "Other jurisdiction" means one of the other forty-nine states, the District of Columbia, the Commonwealth of Puerto Rico or a territory of the United States of America.

57. "Package" means a receptacle defined or described in the United States pharmacopeia and the national formulary as adopted by the board.

58. "Packaging" means the act or process of placing a drug item or device in a container for the purpose or intent of dispensing or distributing the item or device to another.

59. "Person" means an individual, partnership, corporation and association, and their duly authorized agents.

60. "Pharmaceutical care" means the provision of drug therapy and other pharmaceutical patient care services.

61. "Pharmacist" means an individual currently licensed by the board to practice the profession of pharmacy in this state.

62. "Pharmacist in charge" means the pharmacist who is responsible to the board for a licensed establishment's compliance with the laws and administrative rules of this state and of the federal government pertaining to the practice of pharmacy, the manufacturing of drugs and the distribution of drugs and devices.

63. "Pharmacist licensure examination" means a board approved examination that is written and administered in cooperation with the national

association of boards of pharmacy or any other board approved pharmacist licensure examination.

64. "Pharmacy" means any place:

(a) Where drugs, devices, poisons or related hazardous substances are offered for sale at retail.

(b) In which the profession of pharmacy is practiced or where prescription orders are compounded and dispensed.

(c) That has displayed on it or in it the words~~,~~ "pharmacist," "pharmaceutical chemist," "apothecary," "druggist," "pharmacy," "drugstore," "drugs~~,~~" OR "drug sundries" or any of these words or combinations of these words, or words of similar import either in English or any other language, or that is advertised by any sign containing any of these words.

(d) Where the characteristic symbols of pharmacy or the characteristic prescription sign "Rx" is exhibited.

(e) Or a portion of any building or structure that is leased, used or controlled by the permittee to conduct the business authorized by the board at the address for which the permit was issued and that is enclosed and secured when a pharmacist is not in attendance.

65. "Pharmacy intern" means a person who has all of the qualifications and experience prescribed in section 32-1923.

66. "Pharmacy technician" means a person WHO IS licensed pursuant to this chapter.

67. "Pharmacy technician trainee" means a person WHO IS licensed pursuant to this chapter.

68. "Poison" or "hazardous substance" includes, but is not limited to, any of the following if intended and suitable for household use or use by children:

(a) Any substance that, according to standard works on medicine, pharmacology, pharmacognosy or toxicology, if applied to, introduced into or developed within the body in relatively small quantities by its inherent action uniformly produces serious bodily injury, disease or death.

(b) A toxic substance.

(c) A highly toxic substance.

(d) A corrosive substance.

(e) An irritant.

(f) A strong sensitizer.

(g) A mixture of any of the substances described in this paragraph, if the substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.

(h) A substance designated by the board to be a poison or hazardous substance. This subdivision does not apply to radioactive substances, economic poisons subject to the federal insecticide, fungicide and rodenticide act or the state pesticide act, foods, drugs and cosmetics subject to state laws or the federal act or substances intended for use as fuels when stored in containers and used in the heating, cooking or refrigeration system of a house. This subdivision applies to any substance or article that is not itself an economic poison within the meaning of the federal insecticide, fungicide and rodenticide act or the state pesticide act, but that is a poison or hazardous substance within the meaning of this paragraph by reason of bearing or containing an economic poison or hazardous substance.

69. "Practice of pharmacy" means FURNISHING THE FOLLOWING HEALTH CARE SERVICES AS A MEDICAL PROFESSIONAL:

(a) Interpreting, evaluating and dispensing prescription orders in the patient's best interests.

(b) Compounding drugs pursuant to or in anticipation of a prescription order.

(c) Labeling of drugs and devices in compliance with state and federal requirements.

(d) Participating in drug selection and drug utilization reviews, drug administration, drug or drug-related research and drug therapy monitoring or management.

(e) Providing patient counseling necessary to provide pharmaceutical care.

(f) Properly and safely storing drugs and devices in anticipation of dispensing.

(g) Maintaining required records of drugs and devices.

(h) Offering or performing of acts, services, operations or transactions necessary in the conduct, operation, management and control of a pharmacy.

(i) IMPLEMENTING, MONITORING AND MODIFYING DRUG THERAPY PURSUANT TO A PROTOCOL-BASED DRUG THERAPY AGREEMENT WITH A PROVIDER AS OUTLINED IN SECTION 32-1970.

(j) INITIATING AND ADMINISTERING IMMUNIZATIONS OR VACCINES PURSUANT TO SECTION 32-1974.

70. "Practitioner" means any physician, dentist, veterinarian, scientific investigator or other person WHO IS licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or administer a controlled substance in the course of professional practice or research in this state, or any pharmacy, hospital or other institution THAT IS licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or administer a controlled substance in the course of professional practice or research in this state.

71. "Preceptor" means a pharmacist who is serving as the practical instructor of an intern and complies with section 32-1923.

72. "Precursor chemical" means a substance that is:

(a) The principal compound that is commonly used or that is produced primarily for use and that is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail or limit manufacture.

(b) Listed in section 13-3401, paragraph 26 or 27.

73. "Prescription" means either a prescription order or a prescription medication.

74. "Prescription medication" means any drug, including label and container according to context, that is dispensed pursuant to a prescription order.

75. "Prescription-only device" includes:

(a) Any device that is limited by the federal act to use under the supervision of a medical practitioner.

(b) Any device required by the federal act to bear on its label essentially the legend "Rx only".

76. "Prescription-only drug" does not include a controlled substance but does include:

(a) Any drug that because of its toxicity or other potentiality for harmful effect, the method of its use, or the collateral measures necessary to its use is not generally recognized among experts, qualified by scientific training and experience to evaluate its safety and efficacy, as safe for use except by or under the supervision of a medical practitioner.

(b) Any drug that is limited by an approved new drug application under the federal act or section 32-1962 to use under the supervision of a medical practitioner.

(c) Every potentially harmful drug, the labeling of which does not bear or contain full and adequate directions for use by the consumer.

(d) Any drug, other than a controlled substance, required by the federal act to bear on its label the legend "Rx only".

77. "Prescription order" means any of the following:

(a) An order to a pharmacist for drugs or devices issued and signed by a duly licensed medical practitioner in the authorized course of the practitioner's professional practice.

(b) An order transmitted to a pharmacist through word of mouth, telephone or other means of communication directed by that medical practitioner. Prescription orders received by word of mouth, telephone or other means of communication shall be maintained by the pharmacist pursuant to section 32-1964, and the record so made by the pharmacist constitutes the original prescription order to be dispensed by the pharmacist. This

paragraph does not alter or affect laws of this state or any federal act requiring a written prescription order.

(c) An order initiated by a pharmacist pursuant to a protocol-based drug therapy agreement with a provider as outlined in section 32-1970, or immunizations or vaccines administered by a pharmacist pursuant to section 32-1974.

78. "Professionally incompetent" means:

(a) Incompetence based on a variety of factors including a lack of sufficient pharmaceutical knowledge or skills or experience to a degree likely to endanger the health of patients.

(b) When considered with other indications of professional incompetence, a pharmacist, pharmacy intern or graduate intern who fails to obtain a passing score on a board approved pharmacist licensure examination or a pharmacy technician or pharmacy technician trainee who fails to obtain a passing score on a board approved pharmacy technician licensure examination.

79. "Radioactive substance" means a substance that emits ionizing radiation.

80. "Safely engage in employment duties" means that a permittee or the permittee's employee is able to safely engage in employment duties related to the manufacture, sale, distribution or dispensing of drugs, devices, poisons, hazardous substances, controlled substances or precursor chemicals.

81. "Symbol" means the characteristic symbols that have historically identified pharmacy, including "show globes", "mortar and pestle" and the sign "Rx".

82. "Toxic substance" means a substance, other than a radioactive substance, that has the capacity to produce injury or illness in humans through ingestion, inhalation or absorption through any body surface.

83. "Ultimate user" means a person who lawfully possesses a drug or controlled substance for that person's own use, for the use of a member of that person's household or for administering to an animal owned by that person or by a member of that person's household."

Renumber to conform

Page 12, between lines 26 and 27, insert:

"Sec. 5. Section 32-1929, Arizona Revised Statutes, is amended to read:

32-1929. Biennial registration of pharmacies, wholesalers, manufacturers and similar places; application

A. Except as provided in section 32-4301, the board shall require and provide for biennial registration of every pharmacy, wholesaler~~,~~ AND manufacturer and any other place in which or from which drugs are sold, compounded, dispensed, stocked, exposed, manufactured or offered for sale.

B. Any person desiring to operate, maintain, open or establish a pharmacy, wholesaling firm~~,~~ OR manufacturing plant, or any other place in which or from which drugs are manufactured, compounded, dispensed, stocked, exposed, sold~~,~~ or offered for sale, shall apply to the board for a permit before engaging in any such activity.

C. The application for a permit TO OPERATE A PHARMACY, DRUG MANUFACTURING FACILITY OR WHOLESALING FACILITY IN THIS STATE shall be made on a form prescribed and furnished by the board, which, when properly executed, ~~shall indicate~~ INDICATES the ownership, trustee, receiver or other person or persons desiring the permit, including the pharmacist responsible to the board for the operation of a pharmacy or drug manufacturing facility, or other individual approved by and responsible to the board for the operation of wholesaling facilities, as well as the location, including the street name and number, and such other information as required by the board to establish THE identity, exact location~~,~~ and extent of activities, in which or from which drugs are sold, manufactured, compounded, dispensed, stocked, exposed or offered for sale.

D. THE APPLICATION FOR A PERMIT TO OPERATE A PHARMACY, DRUG MANUFACTURING FACILITY OR WHOLESALING FACILITY OUTSIDE OF THIS STATE THAT WILL DISPENSE, SELL, TRANSFER OR DISTRIBUTE DRUGS INTO THIS STATE SHALL BE MADE ON A FORM PRESCRIBED AND FURNISHED BY THE BOARD, WHICH, WHEN PROPERLY EXECUTED, INDICATES THE OWNERSHIP, TRUSTEE, RECEIVER OR OTHER PERSON OR PERSONS DESIRING THE PERMIT, INCLUDING THE INDIVIDUAL APPROVED BY AND

RESPONSIBLE TO THE BOARD FOR THE OPERATION OF THE PHARMACY, DRUG MANUFACTURING FACILITY OR WHOLESALING FACILITY, AS WELL AS THE LOCATION, INCLUDING THE STREET NAME AND NUMBER, AND SUCH OTHER INFORMATION AS REQUIRED BY THE BOARD TO ESTABLISH THE IDENTITY, EXACT LOCATION AND EXTENT OF ACTIVITIES, IN WHICH OR FROM WHICH DRUGS ARE SOLD, MANUFACTURED, COMPOUNDED, DISPENSED, STOCKED, EXPOSED OR OFFERED FOR SALE.

~~D.~~ E. If it is desired to operate, maintain, open or establish more than one pharmacy, or any other place of business in which or from which drugs are sold, manufactured, compounded, dispensed, stocked, exposed or offered for sale, a separate application shall be made and a separate permit shall be issued for each place, business~~,~~ or outlet."

Renumber to conform

Amend title to conform

and, as so amended, it do pass

HEATHER CARTER
Chairman

1043-health
3/12/14
12:20 PM
H:laa

1043hc2
03/11/2014
09:20 AM
C: mjh

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