

PROPOSED

HOUSE OF REPRESENTATIVES AMENDMENTS TO S.B. 1043

(Reference to Senate engrossed bill)

1 Page 10, between lines 14 and 15, insert:

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

4 32-1901. Definitions

5 In this chapter, unless the context otherwise requires:

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

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

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

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

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

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

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

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

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

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

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

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

26 8. "Compounding" means the preparation, mixing, assembling, packaging  
27 or labeling of a drug by a pharmacist or an intern or pharmacy technician  
28 under the pharmacist's supervision, for the purpose of dispensing to a  
29 patient based on a valid prescription order. Compounding includes the  
30 preparation of drugs in anticipation of prescription orders prepared on  
31 routine, regularly observed prescribing patterns and the preparation of drugs  
32 as an incident to research, teaching or chemical analysis or for

1 administration by a medical practitioner to the medical practitioner's  
2 patient and not for sale or dispensing. Compounding does not include the  
3 preparation of commercially available products from bulk compounds or the  
4 preparation of drugs for sale to pharmacies, practitioners or entities for  
5 the purpose of dispensing or distribution.

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

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

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

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

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

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

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

29 16. "Dangerous drug" has the same meaning prescribed in section  
30 13-3401.

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

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

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

10           20. "Device", except as used in paragraph 15 of this section, section  
11 32-1965, paragraph 4 and section 32-1967, subsection A, paragraph 15 and  
12 subsection C, means instruments, apparatus and contrivances, including their  
13 components, parts and accessories, including all such items under the federal  
14 act, intended either:

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

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

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

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

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

29           24. "Dispenser" means a practitioner who dispenses.

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

32           26. "Distributor" means a person who distributes.

1           27. "Drug" means:

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

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

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

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

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

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

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

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

27           (a) The applicable official name.

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

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

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

3           33. "Federal act" means the federal laws and regulations that pertain  
4 to drugs, devices, poisons and hazardous substances and that are official at  
5 the time any drug, device, poison or hazardous substance is affected by this  
6 chapter.

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

11           35. "Graduate intern" means a person who has graduated from a college,  
12 school or program of pharmacy approved by the board and who meets the  
13 qualifications and experience for a pharmacy intern as provided in section  
14 32-1923.

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

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

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

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

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

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

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

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

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

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

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

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

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

25           (b) Accompanying that article.

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

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

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

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

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

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

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

15           51. "New drug" means either:

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

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

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



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

4 (b) A controlled substance.

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

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

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

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

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

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

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

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

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

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

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

30 62. "Pharmacist in charge" means the pharmacist who is responsible to  
31 the board for a licensed establishment's compliance with the laws and  
32 administrative rules of this state and of the federal government pertaining

1 to the practice of pharmacy, the manufacturing of drugs and the distribution  
2 of drugs and devices.

3 63. "Pharmacist licensure examination" means a board approved  
4 examination that is written and administered in cooperation with the national  
5 association of boards of pharmacy or any other board approved pharmacist  
6 licensure examination.

7 64. "Pharmacy" means any place:

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

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

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

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

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

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

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

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

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

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

5 (b) A toxic substance.

6 (c) A highly toxic substance.

7 (d) A corrosive substance.

8 (e) An irritant.

9 (f) A strong sensitizer.

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

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

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

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

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

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

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

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

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

10 (g) Maintaining required records of drugs and devices.

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

14 (i) IMPLEMENTING, MONITORING AND MODIFYING DRUG THERAPY PURSUANT TO A  
15 PROTOCOL-BASED DRUG THERAPY AGREEMENT WITH A PROVIDER AS OUTLINED IN SECTION  
16 32-1970.

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

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

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

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

30 (a) The principal compound that is commonly used or that is produced  
31 primarily for use and that is an immediate chemical intermediary used or

1 likely to be used in the manufacture of a controlled substance, the control  
2 of which is necessary to prevent, curtail or limit manufacture.

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

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

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

9 75. "Prescription-only device" includes:

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

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

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

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

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

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

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

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

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

1 (b) An order transmitted to a pharmacist through word of mouth,  
2 telephone or other means of communication directed by that medical  
3 practitioner. Prescription orders received by word of mouth, telephone or  
4 other means of communication shall be maintained by the pharmacist pursuant  
5 to section 32-1964, and the record so made by the pharmacist constitutes the  
6 original prescription order to be dispensed by the pharmacist. This  
7 paragraph does not alter or affect laws of this state or any federal act  
8 requiring a written prescription order.

9 (c) An order initiated by a pharmacist pursuant to a protocol-based  
10 drug therapy agreement with a provider as outlined in section 32-1970, or  
11 immunizations or vaccines administered by a pharmacist pursuant to section  
12 32-1974.

13 78. "Professionally incompetent" means:

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

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

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

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

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

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

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

8 Renumber to conform

9 Amend title to conform

HEATHER CARTER

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