

House Engrossed Senate Bill
pharmacy board; virtual manufacturers

State of Arizona
Senate
Fifty-sixth Legislature
Second Regular Session
2024

SENATE BILL 1234

AN ACT

AMENDING SECTION 32-1901, ARIZONA REVISED STATUTES; AMENDING TITLE 32, CHAPTER 18, ARTICLE 3, ARIZONA REVISED STATUTES, BY ADDING SECTION 32-1980; RELATING TO THE ARIZONA STATE BOARD OF PHARMACY.

(TEXT OF BILL BEGINS ON NEXT PAGE)

1 Be it enacted by the Legislature of the State of Arizona:

2 Section 1. 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 directly applying a controlled substance,
7 prescription-only drug, dangerous drug or narcotic drug, whether by
8 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
11 the practitioner.

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

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

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

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

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

38 6. "Automated prescription-dispensing kiosk" means a mechanical
39 system that is operated as an extension of a pharmacy, that maintains all
40 transaction information within the pharmacy operating system, that is
41 separately permitted from the pharmacy and that performs operations that
42 either:

43 (a) Accept a prescription or refill order, store prepackaged or
44 repackaged medications, label and dispense patient-specific prescriptions
45 and provide counseling on new or refilled prescriptions.

1 (b) Dispense or deliver a prescription or refill that has been
2 prepared by or on behalf of the pharmacy that oversees the automated
3 prescription-dispensing kiosk.

4 7. "Board" or "board of pharmacy" means the Arizona state board of
5 pharmacy.

6 8. "Certificate of composition" means a list of a product's
7 ingredients.

8 9. "Certificate of free sale" means a document that authenticates a
9 product that is generally and freely sold in domestic or international
10 channels of trade.

11 10. "Color additive" means a material that either:

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

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

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

32 12. "Compressed medical gas distributor" means a person that holds
33 a current permit issued by the board to distribute compressed medical
34 gases to compressed medical gas suppliers and other entities that are
35 registered, licensed or permitted to use, administer or distribute
36 compressed medical gases.

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

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

42 15. "Compressed medical gas supplier" means a person that holds a
43 current permit issued by the board to supply compressed medical gases
44 pursuant to a compressed medical gas order and only to the consumer or the
45 patient.

1 16. "Controlled substance" means a drug, substance or immediate
2 precursor that is identified, defined or listed in title 36, chapter 27,
3 article 2 or the rules adopted pursuant to title 36, chapter 27,
4 article 2.

5 17. "Corrosive" means any substance that when it comes in contact
6 with living tissue will cause destruction of the tissue by chemical
7 action.

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

13 19. "Dangerous drug" has the same meaning prescribed in section
14 13-3401.

15 20. "Day" means a business day.

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

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

22 23. "Deputy director" means a pharmacist who is employed by the
23 board and selected by the executive director to perform duties as
24 prescribed by the executive director.

25 24. "Device", except as used in paragraph 18 of this section,
26 section 32-1965, paragraph 4 and section 32-1967, subsection A, paragraph
27 15 and subsection C, means an instrument, apparatus or contrivance,
28 including its components, parts and accessories, including all such items
29 under the federal act, that is intended either:

30 (a) For use in diagnosing, curing, mitigating, treating or
31 preventing disease in the human body or other animals.

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

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

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

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

44 28. "Dispenser" means a practitioner who dispenses.

- 1 29. "Distribute" means to deliver, other than by administering or
2 dispensing.
- 3 30. "Distributor" means a person who distributes.
- 4 31. "Drug" means:
- 5 (a) Articles that are recognized, or for which standards or
6 specifications are prescribed, in the official compendium.
- 7 (b) Articles that are intended for use in the diagnosis, cure,
8 mitigation, treatment or prevention of disease in the human body or other
9 animals.
- 10 (c) Articles other than food that are intended to affect the
11 structure or any function of the human body or other animals.
- 12 (d) Articles that are intended for use as a component of any
13 articles specified in subdivision (a), (b) or (c) of this paragraph but
14 does not include devices or their components, parts or accessories.
- 15 32. "Drug enforcement administration" means the drug enforcement
16 administration of the United States department of justice or its successor
17 agency.
- 18 33. "Drug or device manufacturing" means producing, preparing,
19 propagating or processing a drug or device, either directly or indirectly,
20 by extraction from substances of natural origin or independently by means
21 of chemical synthesis and includes any packaging or repackaging of
22 substances or labeling or relabeling of its container and promoting and
23 marketing the same. Drug or device manufacturing does not include
24 compounding.
- 25 34. "Durable medical equipment" means technologically sophisticated
26 medical equipment as prescribed by the board in rule that a patient or
27 consumer may use in a home or residence and that may be a
28 prescription-only device.
- 29 35. "Durable medical equipment distributor":
- 30 (a) Means a person that stores or distributes durable medical
31 equipment other than to the patient or consumer.
- 32 (b) Includes a virtual durable medical equipment distributor as
33 prescribed in rule by the board.
- 34 36. "Durable medical equipment supplier":
- 35 (a) Means a person that sells, leases or supplies durable medical
36 equipment to the patient or consumer.
- 37 (b) Includes a virtual durable medical equipment supplier as
38 prescribed in rule by the board.
- 39 37. "Economic poison" means any substance that alone, in chemical
40 combination with or in formulation with one or more other substances is a
41 pesticide within the meaning of the laws of this state or the federal
42 insecticide, fungicide and rodenticide act and that is used in producing,
43 storing or transporting raw agricultural commodities.
- 44 38. "Enteral feeding" means nourishment that is provided by means
45 of a tube inserted into the stomach or intestine.

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

3 (a) The applicable official name.

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

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

9 40. "Executive director" means the executive director of the board
10 of pharmacy.

11 41. "Federal act" means the federal laws and regulations that
12 pertain to drugs, devices, poisons and hazardous substances and that are
13 official at the time any drug, device, poison or hazardous substance is
14 affected by this chapter.

15 42. "Full-service wholesale permittee":

16 (a) Means a permittee who may distribute prescription-only drugs
17 and devices, controlled substances and over-the-counter drugs and devices
18 to pharmacies or other legal outlets from a place devoted in whole or in
19 part to wholesaling these items.

20 (b) Includes a virtual wholesaler as defined in rule by the board.

21 43. "Good manufacturing practice" means a system for ensuring that
22 products are consistently produced and controlled according to quality
23 standards and covering all aspects of design, monitoring and control of
24 manufacturing processes and facilities to ensure that products do not pose
25 any risk to the consumer or public.

26 44. "Highly toxic" means any substance that falls within any of the
27 following categories:

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

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

40 (c) Produces death within fourteen days in half or more than half
41 of a group of ten or more rabbits tested in a dosage of two hundred
42 milligrams or less per kilogram of body weight, if administered by
43 continuous contact with the bare skin for twenty-four hours or less. If
44 the board finds that available data on human experience with any substance
45 indicate results different from those obtained on animals in the dosages

1 or concentrations prescribed in this paragraph, the human data shall take
2 precedence.

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

6 46. "Intern" means a pharmacy intern.

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

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

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

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

21 51. "Labeling" means all labels and other written, printed or
22 graphic matter that either:

23 (a) Is on any article or any of its containers or wrappers.

24 (b) Accompanies that article.

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

30 53. "Limited service pharmacy" means a pharmacy that is approved by
31 the board to practice a limited segment of pharmacy as indicated by the
32 permit issued by the board.

33 54. "Manufacture" or "manufacturer":

34 (a) Means every person who prepares, derives, produces, compounds,
35 processes, packages or repackages or labels any drug in a place, other
36 than a pharmacy, that is devoted to manufacturing the drug.

37 (b) Includes a virtual manufacturer ~~as defined in rule by the~~
38 ~~board.~~

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

40 56. "Medical practitioner" means any medical doctor, doctor of
41 osteopathic medicine, dentist, podiatrist, veterinarian or other person
42 who is licensed and authorized by law to use and prescribe drugs and
43 devices to treat sick and injured human beings or animals or to diagnose
44 or prevent sickness in human beings or animals in this state or any state,
45 territory or district of the United States.

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

4 58. "Narcotic drug" has the same meaning prescribed in section
5 13-3401.

6 59. "New drug" means either:

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

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

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

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

25 (b) A controlled substance.

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

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

28 61. "Nonprescription drug wholesale permittee":

29 (a) Means a permittee who may distribute only over-the-counter
30 drugs and devices to pharmacies or other lawful outlets from a place
31 devoted in whole or in part to wholesaling these items.

32 (b) Includes a virtual wholesaler as defined in rule by the board.

33 62. "Notice" means personal service or the mailing of a copy of the
34 notice by certified mail and email addressed either to the person at the
35 person's latest address of record in the board office or to the person and
36 the person's attorney using the most recent information provided to the
37 board in the board's licensing database.

38 63. "Nutritional supplementation" means vitamins, minerals and
39 caloric supplementation. Nutritional supplementation does not include
40 medication or drugs.

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

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

1 66. "Package" means a receptacle that is defined or described in
2 the United States pharmacopeia and the national formulary as adopted by
3 the board.

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

7 68. "Parenteral nutrition" means intravenous feeding that provides
8 an individual with fluids and essential nutrients the individual needs
9 while the individual is unable to receive adequate fluids or feedings by
10 mouth or by enteral feeding.

11 69. "Person" means an individual, partnership, corporation and
12 association, and their duly authorized agents.

13 70. "Pharmaceutical care" means the provision of drug therapy and
14 other pharmaceutical patient care services.

15 71. "Pharmacist" means an individual who is currently licensed by
16 the board to practice the profession of pharmacy in this state.

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

22 73. "Pharmacist licensure examination" means a board-approved
23 examination that is written and administered in cooperation with the
24 national association of boards of pharmacy or any other board-approved
25 pharmacist licensure examination.

26 74. "Pharmacy" means:

27 (a) Any place where drugs, devices, poisons or related hazardous
28 substances are offered for sale at retail or where prescription orders are
29 dispensed by a licensed pharmacist.

30 (b) Any place that displays on or in the place or that displays a
31 sign on the place the words "pharmaceutical chemist", "apothecary",
32 "druggist", "pharmacy", "drugstore", "drugs" or "drug sundries", any
33 combination of these words, or any words of similar meaning in any
34 language.

35 (c) Any place where the characteristic symbol of pharmacy or the
36 characteristic prescription sign "Rx" is exhibited.

37 (d) Any building or other structure or portion of a building or
38 other structure that is leased, used or controlled by a permittee to
39 conduct the business authorized by the board at the address specified on
40 the permit issued to the permittee.

41 (e) A remote dispensing site pharmacy.

42 (f) A remote hospital-site pharmacy.

43 (g) A satellite pharmacy.

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

1 76. "Pharmacy technician" means a person who is licensed pursuant
2 to this chapter.

3 77. "Pharmacy technician trainee" means a person who is licensed
4 pursuant to this chapter.

5 78. "Poison" or "hazardous substance" includes any of the following
6 if intended and suitable for household use or use by children:

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

12 (b) A toxic substance.

13 (c) A highly toxic substance.

14 (d) A corrosive substance.

15 (e) An irritant.

16 (f) A strong sensitizer.

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

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

34 79. "Practice of pharmacy":

35 (a) Means furnishing the following health care services as a
36 medical professional:

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

39 (ii) Compounding drugs pursuant to or in anticipation of a
40 prescription order.

41 (iii) Labeling drugs and devices in compliance with state and
42 federal requirements.

43 (iv) Participating in drug selection and drug utilization reviews,
44 drug administration, drug or drug-related research and drug therapy
45 monitoring or management.

1 (v) Providing patient counseling necessary to provide
2 pharmaceutical care.

3 (vi) Properly and safely storing drugs and devices in anticipation
4 of dispensing.

5 (vii) Maintaining required records of drugs and devices.

6 (viii) Offering or performing acts, services, operations or
7 transactions that are necessary to conduct, operate, manage and control a
8 pharmacy.

9 (ix) Providing patient care services pursuant to a collaborative
10 practice agreement with a provider as outlined in section 32-1970.

11 (x) Initiating and administering immunizations or vaccines pursuant
12 to section 32-1974.

13 (b) Does not include initiating a prescription order for any
14 medication, drug or other substance used to induce or cause a medication
15 abortion as defined in section 36-2151.

16 80. "Practitioner" means any physician, dentist, veterinarian,
17 scientific investigator or other person who is licensed, registered or
18 otherwise permitted to distribute, dispense, conduct research with respect
19 to or administer a controlled substance in the course of professional
20 practice or research in this state, or any pharmacy, hospital or other
21 institution that is licensed, registered or otherwise permitted to
22 distribute, dispense, conduct research with respect to or administer a
23 controlled substance in the course of professional practice or research in
24 this state.

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

27 82. "Precursor chemical" means a substance that is:

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

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

34 83. "Prescription" means either a prescription order or a
35 prescription medication.

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

39 85. "Prescription-only device" includes:

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

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

44 86. "Prescription-only drug" does not include a controlled
45 substance but does include:

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

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

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

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

14 87. "Prescription order" means any of the following:

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

18 (b) An order that is transmitted to a pharmacist through word of
19 mouth, telephone or other means of communication directed by that medical
20 practitioner. Prescription orders received by word of mouth, telephone or
21 other means of communication shall be maintained by the pharmacist
22 pursuant to section 32-1964, and the record so made by the pharmacist
23 constitutes the original prescription order to be dispensed by the
24 pharmacist. This paragraph does not alter or affect laws of this state or
25 any federal act requiring a written prescription order.

26 (c) An order that is initiated by a pharmacist pursuant to a
27 collaborative practice agreement with a provider as outlined in section
28 32-1970, or immunizations or vaccines administered by a pharmacist
29 pursuant to section 32-1974.

30 (d) A diet order or an order for enteral feeding, nutritional
31 supplementation or parenteral nutrition that is initiated by a registered
32 dietitian or other qualified nutrition professional in a hospital pursuant
33 to section 36-416.

34 88. "Professionally incompetent" means:

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

38 (b) When considered with other indications of professional
39 incompetence, a pharmacist or pharmacy intern who fails to obtain a
40 passing score on a board-approved pharmacist licensure examination or a
41 pharmacy technician or pharmacy technician trainee who fails to obtain a
42 passing score on a board-approved pharmacy technician licensure
43 examination.

44 89. "Radioactive substance" means a substance that emits ionizing
45 radiation.

1 90. "Remote dispensing site pharmacy" means a pharmacy where a
2 pharmacy technician or pharmacy intern prepares, compounds or dispenses
3 prescription medications under remote supervision by a pharmacist.

4 91. "Remote hospital-site pharmacy" means a pharmacy located in a
5 satellite facility that operates under the license issued by the
6 department of health services to the hospital of which it is a satellite.

7 92. "Remote supervision by a pharmacist" means that a pharmacist
8 directs and controls the actions of pharmacy technicians and pharmacy
9 interns through the use of audio and visual technology.

10 93. "Revocation" or "revoke" means the official cancellation of a
11 license, permit, registration or other approval authorized by the board
12 for a period of two years unless otherwise specified by the board. A
13 request or new application for reinstatement may be presented to the board
14 for review before the conclusion of the specified revocation period upon
15 review of the executive director.

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

21 95. "Satellite facility" has the same meaning prescribed in section
22 36-422.

23 96. "Satellite pharmacy" means a work area located within a
24 hospital or on a hospital campus that is not separated by other commercial
25 property or residential property, that is under the direction of a
26 pharmacist, that is a remote extension of a centrally licensed hospital
27 pharmacy, that is owned by and dependent on the centrally licensed
28 hospital pharmacy for administrative control, staffing and drug
29 procurement and that is not required to be separately permitted.

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

33 98. "Third-party logistics provider" means an entity that provides
34 or coordinates warehousing or other logistics services for the following
35 items, but that does not take ownership of the items, and that distributes
36 those items as directed by a manufacturer, wholesaler, dispenser or
37 durable medical equipment supplier that is permitted by the board:

- 38 (a) Narcotic drugs or other controlled substances.
- 39 (b) Dangerous drugs as defined in section 13-3401.
- 40 (c) Prescription-only drugs and devices.
- 41 (d) Nonprescription drugs and devices.
- 42 (e) Precursor chemicals.
- 43 (f) Regulated chemicals as defined in section 13-3401.

1 99. "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.

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

8 101. "VIRTUAL MANUFACTURER" MEANS AN ENTITY THAT CONTRACTS FOR THE
9 MANUFACTURE OF A DRUG OR DEVICE, INCLUDING A PRIVATE LABEL DISTRIBUTOR AS
10 DEFINED IN 21 CODE OF FEDERAL REGULATIONS PART 207.1, AND THAT MEETS ALL
11 OF THE FOLLOWING:

12 (a) OWNS EITHER:

13 (i) THE NEW DRUG APPLICATION OR ABBREVIATED NEW DRUG APPLICATION
14 NUMBER AS DEFINED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION FOR A
15 DRUG.

16 (ii) THE UNIQUE DEVICE IDENTIFICATION NUMBER AS DEFINED BY THE
17 UNITED STATES FOOD AND DRUG ADMINISTRATION FOR A PRESCRIPTION DEVICE.

18 (b) IS NOT INVOLVED IN THE PHYSICAL MANUFACTURE OF THE DRUG OR
19 DEVICE.

20 (c) CONTRACTS WITH A UNITED STATES FOOD AND DRUG ADMINISTRATION
21 REGISTERED MANUFACTURING ENTITY FOR THE PHYSICAL MANUFACTURE OF THE DRUG
22 OR DEVICE.

23 Sec. 2. Title 32, chapter 18, article 3, Arizona Revised Statutes,
24 is amended by adding section 32-1980, to read:

25 32-1980. Virtual manufacturers; oversight and contracting
26 requirements

27 A. A VIRTUAL MANUFACTURER LOCATED IN THIS STATE OR LOCATED IN
28 ANOTHER JURISDICTION THAT IS RESPONSIBLE FOR THE SHIPMENT OF PRESCRIPTION
29 DRUGS OR DEVICES INTO THIS STATE SHALL MAKE PROFESSIONALLY REASONABLE
30 EFFORTS TO ENSURE THAT THE UNITED STATES FOOD AND DRUG ADMINISTRATION
31 REGISTERED MANUFACTURING ENTITY FOR THE PHYSICAL MANUFACTURE OF A
32 PRESCRIPTION DRUG OR PRESCRIPTION DEVICE COMPLIES WITH CURRENT GOOD
33 MANUFACTURING PRACTICES AS DESCRIBED IN 21 CODE OF FEDERAL REGULATIONS
34 PART 210, 211, 212, 314, 808, 812 OR 820, AS APPLICABLE.

35 B. A VIRTUAL MANUFACTURER OF PRESCRIPTION DRUGS SHALL CONTRACT WITH
36 A DRUG MANUFACTURER THAT IS PERMITTED BY THIS STATE.