State of Arizona
House of Representatives
Fifty-third Legislature
Second Regular Session
2018

CHAPTER 227

HOUSE BILL 2040

AN ACT

AMENDING SECTIONS 32-1901, 32-1901.01, 32-1930, 32-1931 AND 36-2608, ARIZONA REVISED STATUTES; RELATING TO THE ARIZONA STATE BOARD OF PHARMACY.

(TEXT OF BILL BEGINS ON NEXT PAGE)

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

Section 1. 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 board of pharmacy and agents of the division of narcotics enforcement and criminal intelligence of the department of public safety.

6. "AUTOMATED PRESCRIPTION-DISPENSING KIOSK" MEANS A MECHANICAL SYSTEM THAT IS OPERATED AS AN EXTENSION OF A PHARMACY, THAT MAINTAINS ALL TRANSACTION INFORMATION WITHIN THE PHARMACY OPERATING SYSTEM, THAT IS SEPARATELY PERMITTED FROM THE PHARMACY AND THAT PERFORMS OPERATIONS THAT EITHER:

(a) ACCEPT A PRESCRIPTION OR REFILL ORDER, STORE PREPACKAGED OR REPACKAGED MEDICATIONS, LABEL AND DISPENSE PATIENT-SPECIFIC PRESCRIPTIONS AND PROVIDE COUNSELING ON NEW OR REFILLED PRESCRIPTIONS.

(b) DISPENSE OR DELIVER A PRESCRIPTION OR REFILL THAT HAS BEEN PREPARED BY OR ON BEHALF OF THE PHARMACY THAT OVERSEES THE AUTOMATED PRESCRIPTION-DISPENSING KIOSK.

~~6.~~ 7. "Board" or "board of pharmacy" means the Arizona state board of pharmacy.

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

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

~~9.~~ 10. "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.

~~10.~~ 11. "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.

~~11.~~ 12. "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.

~~12.~~ 13. "Compressed medical gases" means gases and liquid oxygen that a compressed medical gas distributor or manufacturer has labeled in compliance with federal law.

~~13.~~ 14. "Compressed medical gas order" means an order for compressed medical gases that is issued by a medical practitioner.

~~14.~~ 15. "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.

~~15.~~ 16. "Controlled substance" means a drug, substance or immediate precursor that is identified, defined or listed in title 36, chapter 27, article 2.

~~16.~~ 17. "Corrosive" means any substance that when it comes in contact with living tissue will cause destruction of tissue by chemical action.

~~17.~~ 18. "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.

~~18.~~ 19. "Dangerous drug" has the same meaning prescribed in section 13-3401.

20. "DAY" MEANS A BUSINESS DAY.

~~19.~~ 21. "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.

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

~~21.~~ 23. "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.

~~22.~~ 24. "Device", except as used in paragraph ~~17~~ 18 of this section, section 32-1965, paragraph 4 and section 32-1967, subsection A, paragraph 15 and subsection C, means instruments, ~~apparatus~~ APPARATUSES 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.

~~23.~~ 25. "Director" means the director of the division of narcotics enforcement and criminal investigation of the department of public safety.

~~24.~~ 26. "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.

~~25.~~ 27. "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.

~~26.~~ 28. "Dispenser" means a practitioner who dispenses.

~~27.~~ 29. "Distribute" means to deliver, other than by administering or dispensing.

~~28.~~ 30. "Distributor" means a person who distributes.

~~29.~~ 31. "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.

~~30.~~ 32. "Drug enforcement administration" means the drug enforcement administration of the United States department of justice or its successor agency.

~~31.~~ 33. "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.

~~32.~~ 34. "Economic poison" means any substance that alone, in chemical combination WITH 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.

~~33.~~ 35. "Enteral feeding" means nourishment provided by means of a tube inserted into the stomach or intestine.

~~34.~~ 36. "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, the official title in an official compendium.

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

~~35.~~ 37. "Executive director" means the executive director of the board of pharmacy.

~~36.~~ 38. "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.

~~37.~~ 39. "Full service wholesale permittee":

(a) 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.

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

~~38.~~ 40. "Good manufacturing practice" means a system for ensuring that products are consistently produced and controlled according to quality standards and covering all aspects of design, monitoring and control of manufacturing processes and facilities to ensure that products do not pose any risk to the consumer or public.

~~39.~~ 41. "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.

~~40.~~ 42. "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.

~~41.~~ 43. "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.

~~42.~~ 44. "Intern" means a pharmacy intern and a graduate intern.

~~43.~~ 45. "Internship" means the practical, experiential, hands-on training of a pharmacy intern under the supervision of a preceptor.

~~44.~~ 46. "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.

~~45.~~ 47. "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.

~~46.~~ 48. "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.

~~47.~~ 49. "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.

~~48.~~ 50. "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.

~~49.~~ 51. "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.

~~50.~~ 52. "Manufacture" or "manufacturer":

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

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

~~51.~~ 53. "Marijuana" has the same meaning prescribed in section 13-3401.

~~52.~~ 54. "Medical practitioner" means any medical doctor, doctor of ~~osteopathy~~ OSTEOPATHIC MEDICINE, dentist, podiatrist, veterinarian or other person who is 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.

~~53.~~ 55. "Medication order" means a written or verbal order from a medical practitioner or that person's authorized agent to administer a drug or device.

~~54.~~ 56. "Narcotic drug" has the same meaning prescribed in section 13-3401.

~~55.~~ 57. "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.

~~56.~~ 58. "Nonprescription drug" or "over-the-counter drug" means any nonnarcotic medicine or drug that may be sold without a prescription and THAT 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 that is intended for human use by hypodermic injection.

~~57.~~ 59. "Nonprescription drug wholesale permittee":

(a) 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.

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

~~58.~~ 60. "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.

~~59.~~ 61. "Nutritional supplementation" means vitamins, minerals and caloric supplementation. Nutritional supplementation does not include medication or drugs.

~~60.~~ 62. "Official compendium" means the latest revision of the United States pharmacopeia and the national formulary or any current supplement.

~~61.~~ 63. "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.

~~62.~~ 64. "Package" means a receptacle defined or described in the United States pharmacopeia and the national formulary as adopted by the board.

~~63.~~ 65. "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.

~~64.~~ 66. "Parenteral nutrition" means intravenous feeding that provides a person with fluids and essential nutrients the person needs while the person is unable to receive adequate fluids or feedings by mouth or by enteral feeding.

~~65.~~ 67. "Person" means an individual, partnership, corporation and association, and their duly authorized agents.

~~66.~~ 68. "Pharmaceutical care" means the provision of drug therapy and other pharmaceutical patient care services.

~~67.~~ 69. "Pharmacist" means an individual who is currently licensed by the board to practice the profession of pharmacy in this state.

~~68.~~ 70. "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.

~~69.~~ 71. "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.

~~70.~~ 72. "Pharmacy":

(a) Means any place:

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

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

~~(c)~~ (iii) 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)~~ (iv) Where the characteristic symbols of pharmacy or the characteristic prescription sign "Rx" is exhibited.

~~(e)~~ (v) 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.

(b) INCLUDES A SATELLITE PHARMACY.

~~71.~~ 73. "Pharmacy intern" means a person who has all of the qualifications and experience prescribed in section 32-1923.

~~72.~~ 74. "Pharmacy technician" means a person who is licensed pursuant to this chapter.

~~73.~~ 75. "Pharmacy technician trainee" means a person who is licensed pursuant to this chapter.

~~74.~~ 76. "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 that is 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.

~~75.~~ 77. "Practice of pharmacy":

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

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

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

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

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

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

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

(vii) Maintaining required records of drugs and devices.

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

(ix) Initiating, monitoring and modifying drug therapy pursuant to a protocol-based drug therapy agreement with a provider as outlined in section 32-1970.

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

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

~~76.~~ 78. "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.

~~77.~~ 79. "Preceptor" means a pharmacist who is serving as the practical instructor of an intern and complies with section 32-1923.

~~78.~~ 80. "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.

~~79.~~ 81. "Prescription" means either a prescription order or a prescription medication.

~~80.~~ 82. "Prescription medication" means any drug, including label and container according to context, that is dispensed pursuant to a prescription order.

~~81.~~ 83. "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".

~~82.~~ 84. "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".

~~83.~~ 85. "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.

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

~~84.~~ 86. "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.

~~85.~~ 87. "Radioactive substance" means a substance that emits ionizing radiation.

88. "REVOCATION" OR "REVOKE" MEANS THE OFFICIAL CANCELLATION OF A LICENSE, PERMIT, REGISTRATION OR OTHER APPROVAL AUTHORIZED BY THE BOARD FOR A PERIOD OF TWO YEARS UNLESS OTHERWISE SPECIFIED BY THE BOARD. A REQUEST OR NEW APPLICATION FOR REINSTATEMENT MAY BE PRESENTED TO THE BOARD FOR REVIEW BEFORE THE CONCLUSION OF THE SPECIFIED REVOCATION PERIOD UPON REVIEW OF THE EXECUTIVE DIRECTOR.

~~86.~~ 89. "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.

90. "SATELLITE PHARMACY" MEANS A WORK AREA LOCATED WITHIN A HOSPITAL OR ON A HOSPITAL CAMPUS THAT IS NOT SEPARATED BY OTHER COMMERCIAL PROPERTY OR RESIDENTIAL PROPERTY, THAT IS UNDER THE DIRECTION OF A PHARMACIST, THAT IS A REMOTE EXTENSION OF A CENTRALLY LICENSED HOSPITAL PHARMACY AND THAT IS OWNED BY AND DEPENDENT ON THE CENTRALLY LICENSED HOSPITAL PHARMACY FOR ADMINISTRATIVE CONTROL, STAFFING AND DRUG PROCUREMENT AND THAT IS NOT REQUIRED TO BE SEPARATELY PERMITTED.

~~87.~~ 91. "Symbol" means the characteristic symbols that have historically identified pharmacy, including show globes and mortar and pestle, and the sign "Rx".

~~88.~~ 92. "Third-party logistics provider" means an entity that provides or coordinates warehousing or other logistics services for a prescription or over-the-counter dangerous drug or dangerous device in intrastate or interstate commerce on behalf of a manufacturer, wholesaler or dispenser of the prescription or over-the-counter dangerous drug or dangerous device but that does not take ownership of the prescription or over-the-counter dangerous drug or dangerous device or have responsibility to direct its sale or disposition.

~~89.~~ 93. "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.

~~90.~~ 94. "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.

Sec. 2. Section 32-1901.01, Arizona Revised Statutes, is amended to read:

32-1901.01. Definition of unethical and unprofessional conduct; permittees; licensees

A. In this chapter, unless the context otherwise requires, for the purposes of disciplining a permittee, "unethical conduct" means the following, whether occurring in this state or elsewhere:

1. Committing a felony, whether or not involving moral turpitude, or a misdemeanor involving moral turpitude or any drug-related offense. In either case, conviction by a court of competent jurisdiction or a plea of no contest is conclusive evidence of the commission.

2. Committing an act that is substantially related to the qualifications, functions or duties of a permittee and that demonstrates either a lack of good moral character or an actual or potential unfitness to hold a permit in light of the public's safety.

3. Working under the influence of alcohol or other drugs.

4. ~~Addiction~~ BEING ADDICTED to the use of alcohol or other drugs to such a degree as to render the permittee unfit to perform the permittee's employment duties.

5. Violating a federal or state law or administrative rule relating to the manufacture, sale or distribution of drugs, devices, poisons, hazardous substances or precursor chemicals.

6. Violating a federal or state law or administrative rule relating to marijuana, prescription-only drugs, narcotics, dangerous drugs, controlled substances or precursor chemicals.

7. Violating state or federal reporting or recordkeeping requirements on transactions relating to precursor chemicals.

8. Failing to report in writing to the board any evidence that a pharmacist, pharmacy intern or graduate intern is or may be professionally incompetent, is or may be guilty of unprofessional conduct or is or may be mentally or physically unable safely to engage in the practice of pharmacy.

9. Failing to report in writing to the board any evidence that a pharmacy technician or pharmacy technician trainee is or may be professionally incompetent, is or may be guilty of unprofessional conduct or is or may be mentally or physically unable safely to engage in the permissible activities of a pharmacy technician or pharmacy technician trainee.

10. Failing to report in writing to the board any evidence that appears to show that a permittee or permittee's employee is or may be guilty of unethical conduct, is or may be mentally or physically unable safely to engage in employment duties related to manufacturing, selling, distributing or dispensing of drugs, devices, poisons, hazardous substances, controlled substances or precursor chemicals or is or may be in violation of this chapter or a rule adopted under this chapter.

11. Intending to sell, transfer or distribute, or to offer for sale, transfer or distribution, or selling, transferring, distributing or dispensing or offering for sale, transfer or distribution an imitation controlled substance, imitation over-the-counter drug or imitation prescription-only drug as defined in section 13-3451.

12. ~~Denial or discipline of a~~ HAVING THE permittee's permit to manufacture, sell, distribute or dispense drugs, devices, poisons, hazardous substances or precursor chemicals DENIED OR DISCIPLINED in another jurisdiction ~~and the permit was not reinstated~~.

13. Committing an offense in another jurisdiction that if committed in this state would be grounds for discipline.

14. Obtaining or attempting to obtain a permit or a permit renewal by fraud, by misrepresentation or by knowingly taking advantage of the mistake of another person or an agency.

15. Wilfully making a false report or record required by this chapter, required by federal or state laws pertaining to drugs, devices, poisons, hazardous substances or precursor chemicals or required for the payment for drugs, devices, poisons or hazardous substances or precursor chemicals or for services pertaining to such drugs or substances.

16. Knowingly filing with the board any application, renewal or other document that contains false or misleading information.

17. Providing false or misleading information or omitting material information in any communication to the board or the board's employees or agents.

18. Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, this chapter.

19. Violating a formal order, terms of probation, a consent agreement or a stipulation issued or entered into by the board or its executive director pursuant to this chapter.

20. Failing to comply with a board subpoena or failing to comply in a timely manner with a board subpoena without providing any explanation to the board for not complying with the subpoena.

21. Failing to provide the board or its employees or agents or an authorized federal or state official conducting a site investigation, inspection or audit with access to any place for which a permit has been issued or for which an application for a permit has been submitted.

22. Failing to notify the board of a change of ownership, management or pharmacist in charge.

23. Failing to promptly produce on the request of the official conducting a site investigation, inspection or audit any book, record or document.

24. Overruling or attempting to overrule a pharmacist in matters of pharmacy ethics or interpreting laws pertaining to the practice of pharmacy or the distribution of drugs or devices.

25. Distributing premiums or rebates of any kind in connection with the sale of prescription medication, other than to the prescription medication recipient.

26. Failing to maintain effective controls against the diversion of CONTROLLED SUBSTANCES OR precursor chemicals to unauthorized persons or entities.

27. Fraudulently claiming to have performed a service.

28. Fraudulently charging a fee for a service.

29. Advertising drugs or devices, or services pertaining to drugs or devices, in a manner that is untrue or misleading in any particular, and that is known, or that by the exercise of reasonable care should be known, to be untrue or misleading.

B. In this chapter, unless the context otherwise requires, for the purposes of disciplining a pharmacist, pharmacy intern or graduate intern, "unprofessional conduct" means the following, whether occurring in this state or elsewhere:

1. ~~Addiction~~ BEING ADDICTED to the use of alcohol or other drugs to such a degree as to render the licensee unfit to practice the profession of pharmacy.

2. Violating any federal or state law, rule or regulation relating to the manufacture or distribution of drugs and devices or the practice of pharmacy.

3. Dispensing a different drug or brand of drug in place of the drug or brand of drug ordered or prescribed without the express permission in each case of the orderer, or in the case of a prescription order, the medical practitioner. The conduct prohibited by this paragraph does not apply to substitutions authorized pursuant to section 32-1963.01.

4. Obtaining or attempting to obtain a license to practice pharmacy or a license renewal by fraud, by misrepresentation or by knowingly taking advantage of the mistake of another person or an agency.

5. ~~Denial or discipline of a~~ HAVING THE licensee's license to practice pharmacy DENIED OR DISCIPLINED in another jurisdiction ~~and the license was not reinstated~~.

6. Claiming professional superiority in compounding or dispensing prescription orders.

7. Failing to comply with the mandatory continuing professional pharmacy education requirements of sections 32-1936 and 32-1937 and rules adopted by the board.

8. Committing a felony, whether or not involving moral turpitude, or a misdemeanor involving moral turpitude or any drug-related offense. In either case, conviction by a court of competent jurisdiction or a plea of no contest is conclusive evidence of the commission.

9. Working under the influence of alcohol or other drugs.

10. Violating a federal or state law or administrative rule relating to marijuana, prescription-only drugs, narcotics, dangerous

drugs, controlled substances or precursor chemicals when determined by the board or by conviction in a federal or state court.

11. Knowingly dispensing a drug without a valid prescription order as required pursuant to section 32-1968, subsection A.

12. Knowingly dispensing a drug on a prescription order that was issued in the course of the conduct of business of dispensing drugs pursuant to diagnosis by mail or the internet, unless the order was any of the following:

(a) Made by a physician who provides temporary patient supervision on behalf of the patient's regular treating licensed health care professional or provides a consultation requested by the patient's regular treating licensed health care professional.

(b) Made in an emergency medical situation as defined in section 41-1831.

(c) Written to prepare a patient for a medical examination.

(d) Written or the prescription medications were issued for use by a county or tribal public health department for immunization programs or emergency treatment or in response to an infectious disease investigation, a public health emergency, an infectious disease outbreak or an act of bioterrorism. For the purposes of this subdivision, "bioterrorism" has the same meaning prescribed in section 36-781.

(e) Written or antimicrobials were dispensed by the prescribing or dispensing physician to a contact as defined in section 36-661 who is believed to have had significant exposure risk as defined in section 36-661 with another person who has been diagnosed with a communicable disease as defined in section 36-661.

(f) Written or the prescription medications were issued for administration of immunizations or vaccines listed in the United States centers for disease control and prevention's recommended immunization schedule to a household member of a patient.

(g) For epinephrine auto-injectors that are written or dispensed for a school district or charter school and that are to be stocked for emergency use pursuant to section 15-157 or for an authorized entity to be stocked pursuant to section 36-2226.01.

(h) Written by a licensee through a telemedicine program that is covered by the policies and procedures adopted by the administrator of a hospital or outpatient treatment center.

(i) Written pursuant to a physical or mental health status examination that was conducted during a real-time telemedicine encounter with audio and video capability.

(j) For naloxone hydrochloride or any other opioid antagonist approved by the United States food and drug administration and written or dispensed for use pursuant to section 36-2228 or 36-2266.

13. Failing to report in writing to the board any evidence that a pharmacist, pharmacy intern or graduate intern is or may be professionally

incompetent, is or may be guilty of unprofessional conduct or is or may be mentally or physically unable to safely engage in the practice of pharmacy.

14. Failing to report in writing to the board any evidence that a pharmacy technician or pharmacy technician trainee is or may be professionally incompetent, is or may be guilty of unprofessional conduct or is or may be mentally or physically unable to safely engage in the permissible activities of a pharmacy technician or pharmacy technician trainee.

15. Failing to report in writing to the board any evidence that a permittee or a permittee's employee is or may be guilty of unethical conduct or is or may be in violation of this chapter or a rule adopted under this chapter.

16. Committing an offense in another jurisdiction that if committed in this state would be grounds for discipline.

17. Knowingly filing with the board any application, renewal or other document that contains false or misleading information.

18. Providing false or misleading information or omitting material information in any communication to the board or the board's employees or agents.

19. Violating or attempting to violate, directly or indirectly, or assisting in or abetting in the violation of, or conspiring to violate, this chapter.

20. Violating a formal order, terms of probation, a consent agreement or a stipulation issued or entered into by the board or its executive director pursuant to this chapter.

21. Failing to comply with a board subpoena or failing to comply in a timely manner with a board subpoena without providing any explanation to the board for not complying with the subpoena.

22. Refusing without just cause to allow authorized agents of the board to examine documents that are required to be kept pursuant to this chapter or title 36.

23. Participating in an arrangement or agreement to allow a prescription order or a prescription medication to be left at, picked up from, accepted by or delivered to a place that is not licensed as a pharmacy. This paragraph does not prohibit a pharmacist or a pharmacy from using an employee or a common carrier to pick up prescription orders at or deliver prescription medications to the office or home of a medical practitioner, the residence of a patient or a patient's hospital.

24. Paying rebates or entering into an agreement for the payment of rebates to a medical practitioner or any other person in the health care field.

25. Providing or causing to be provided to a medical practitioner prescription order blanks or forms bearing the pharmacist's or pharmacy's name, address or other means of identification.

26. Fraudulently claiming to have performed a professional service.

27. Fraudulently charging a fee for a professional service.

28. Failing to report a change of the licensee's home address, contact information, employer or employer's address as required by section 32-1926.

29. Failing to report a change in the licensee's residency status as required by section 32-1926.01.

30. FAILING TO MAINTAIN EFFECTIVE CONTROLS AGAINST THE DIVERSION OF CONTROLLED SUBSTANCES OR PRECURSOR CHEMICALS TO UNAUTHORIZED PERSONS OR ENTITIES.

C. In this chapter, unless the context otherwise requires, for the purposes of disciplining a pharmacy technician or pharmacy technician trainee, "unprofessional conduct" means the following, whether occurring in this state or elsewhere:

1. ~~Addiction~~ BEING ADDICTED to the use of alcohol or other drugs to such a degree as to render the licensee unfit to perform the licensee's employment duties.

2. Violating a federal or state law or administrative rule relating to the manufacture or distribution of drugs or devices.

3. Obtaining or attempting to obtain a pharmacy technician or pharmacy technician trainee license or a pharmacy technician license renewal by fraud, by misrepresentation or by knowingly taking advantage of the mistake of another person or an agency.

4. ~~Denial or discipline of a~~ HAVING THE licensee's license to practice as a pharmacy technician DENIED OR DISCIPLINED in another jurisdiction ~~and the license was not reinstated~~.

5. Failing to comply with the mandatory continuing professional education requirements of section 32-1925, subsection H and rules adopted by the board.

6. Committing a felony, whether or not involving moral turpitude, or a misdemeanor involving moral turpitude or any drug-related offense. In either case, conviction by a court of competent jurisdiction or a plea of no contest is conclusive evidence of the commission.

7. Working under the influence of alcohol or other drugs.

8. Violating a federal or state law or administrative rule relating to marijuana, prescription-only drugs, narcotics, dangerous drugs, controlled substances or precursor chemicals when determined by the board or by conviction in a federal or state court.

9. Failing to report in writing to the board any evidence that a pharmacist, pharmacy intern or graduate intern is or may be professionally incompetent, is or may be guilty of unprofessional conduct or is or may be mentally or physically unable to safely engage in the practice of pharmacy.

10. Failing to report in writing to the board any evidence that a pharmacy technician or pharmacy technician trainee is or may be professionally incompetent, is or may be guilty of unprofessional conduct or is or may be mentally or physically unable to safely engage in the permissible activities of a pharmacy technician or pharmacy technician trainee.

11. Failing to report in writing to the board any evidence that a permittee or a permittee's employee is or may be guilty of unethical conduct or is or may be in violation of this chapter or a rule adopted under this chapter.

12. Committing an offense in another jurisdiction that if committed in this state would be grounds for discipline.

13. Knowingly filing with the board any application, renewal or other document that contains false or misleading information.

14. Providing false or misleading information or omitting material information in any communication to the board or the board's employees or agents.

15. Violating or attempting to violate, directly or indirectly, or assisting in or abetting in the violation of, or conspiring to violate, this chapter.

16. Violating a formal order, terms of probation, a consent agreement or a stipulation issued or entered into by the board or its executive director pursuant to this chapter.

17. Failing to comply with a board subpoena or failing to comply in a timely manner with a board subpoena without providing any explanation to the board for not complying with the subpoena.

18. Failing to report a change of the licensee's home address, contact information, employer or employer's address as required by section 32-1926.

19. Failing to report a change in the licensee's residency status as required by section 32-1926.01.

Sec. 3. Section 32-1930, Arizona Revised Statutes, is amended to read:

32-1930. Types of permits; restrictions on permits; discontinuance of pharmacy permit

A. On application, the board may issue the following classes or kinds of permits:

1. A nonprescription drug permit to sell, retail, stock, expose or offer for sale at retail nonprescription drugs in the original package. A permittee is not required to conduct business in any fixed place.

2. If approved by the board, a pharmacy, limited service pharmacy, AUTOMATED PRESCRIPTION-DISPENSING KIOSK, full service wholesale drug, third-party logistics provider, nonprescription drug wholesale and drug manufacturer's permit.

3. Drug packager or drug prepackager permit to an individual or establishment that is currently listed by the United States federal food and drug administration and has met the requirements of that agency to purchase, repackage, relabel or otherwise alter the manufacturer's original package of an approved drug product with the intent of reselling these items to persons or businesses authorized to possess or resell the repackaged, prepackaged or relabeled drug.

4. A compressed medical gas distributor permit and a durable medical equipment and compressed medical gas supplier permit.

B. The board shall deny or revoke a pharmacy permit if a medical practitioner receives compensation, either directly or indirectly, from a pharmacy as a result of the practitioner's prescription orders. This does not include compensation to a medical practitioner who is the owner of a building where space is leased to a pharmacy at the prevailing rate, not resulting in a rebate to the medical practitioner.

C. If a pharmacy permanently discontinues operation, the permittee shall immediately surrender the permit to the executive director. The permittee shall remove all drug signs and symbols, either within or without the premises, and shall remove or destroy all drugs, devices, poisons and hazardous substances.

D. AN AUTOMATED PRESCRIPTION-DISPENSING KIOSK MAY NOT CONTAIN OR DISPENSE A CONTROLLED SUBSTANCE AS DEFINED IN SECTION 36-2501 AND THE CONTROLLED SUBSTANCES ACT (P.L. 91-513; 84 STAT. 1242; 21 UNITED STATES CODE SECTION 802).

Sec. 4. Section 32-1931, Arizona Revised Statutes, is amended to read:

32-1931. Permit fees; issuance; expiration; renewals; online profiles

A. The board shall assign the permit of all persons or firms issued under this chapter to one of two permit renewal groups. Except as provided in section 32-4301, a holder of a permit ending in an even number shall renew it biennially on or before November 1 of the even-numbered year, two years from the last renewal date. Except as provided in section 32-4301, a holder of a permit ending in an odd number shall renew it biennially on or before November 1 of the odd-numbered year, two years from the last renewal date. Failure to renew and pay all required fees on or before November 1 of the year in which the renewal is due suspends the permit. The board shall vacate a suspension when the permittee pays penalties of not to exceed three hundred fifty dollars and all past due fees. The board may waive collection of a fee or penalty due after suspension under conditions established by a majority of the board.

B. Permit fees that are designated to be not more than a maximum amount shall be set by the board for the following two fiscal years beginning November 1. The board shall establish the fees approximately proportionate to the maximum fee allowed to cover the board's anticipated

expenditures for the following two fiscal years. Variation in a fee is not effective except at the expiration date of the permit.

C. Applications for permits shall be accompanied by the following biennial fees as determined by subsection B of this section:

1. A nonprescription drug permit, not more than two hundred dollars. Permittees stocking thirty different nonprescription drug products or less shall be classified as category I retailers. Permittees stocking more than thirty different nonprescription drug products shall be classified as category II retailers. Both categories are subject to biennial permit fees established by the board pursuant to this chapter.

2. A drug manufacturer's permit, not more than one thousand dollars.

3. A pharmacy permit, not more than five hundred dollars.

4. A limited service pharmacy permit OR AN AUTOMATED PRESCRIPTION-DISPENSING KIOSK PERMIT, not more than five hundred dollars.

5. A full service wholesale drug permit or a third-party logistics provider permit, not more than one thousand dollars.

6. A nonprescription drug wholesale permit, not more than five hundred dollars.

7. A drug repackager's permit, not more than one thousand dollars.

8. A compressed medical gas distributor permit, not more than two hundred dollars.

9. A durable medical equipment and compressed medical gas supplier permit, not more than one hundred dollars.

D. If an applicant is found to be satisfactory to the board, the executive director shall issue to the applicant a permit for each pharmacy, manufacturer, wholesaler or other place of business in which drugs are sold, manufactured, compounded, dispensed, stocked, exposed or offered for sale, for which application is made.

E. Permits issued under this section are not transferable.

F. If a permittee does not apply for renewal, the permit expires pursuant to subsection A of this section. A person may activate and renew an expired permit by filing the required application and fee. Renewal thirty days after the expiration date of a permit may be made only on payment of the required biennial renewal fee, all past due fees and a penalty of one-half of the amount of the applicable biennial renewal fee. The board may waive the collection of a fee or penalty due after suspension pursuant to conditions prescribed by the board.

G. A permittee shall create an online profile using the board's licensing software.

Sec. 5. Section 36-2608, Arizona Revised Statutes, is amended to read:

36-2608. Reporting requirements; waiver; exceptions

A. If a medical practitioner dispenses a controlled substance listed in section 36-2513, 36-2514, 36-2515 or 36-2516, or if a

prescription for a controlled substance listed in any of those sections is dispensed by a pharmacy in this state, a health care facility in this state for outpatient use or a board-permitted nonresident pharmacy for delivery to a person residing in this state, the medical practitioner, health care facility or pharmacy must report the following information as applicable and as prescribed by the board by rule:

1. The name, address, telephone number, prescription number and United States drug enforcement administration controlled substance registration number of the dispenser.

2. The name, address and date of birth of the person for whom the prescription is written.

3. The name, address, telephone number and United States drug enforcement administration controlled substance registration number of the prescribing medical practitioner.

4. The name, strength, quantity, dosage and national drug code number of the schedule II, III, IV or V controlled substance dispensed.

5. The date the prescription was dispensed.

6. The number of refills, if any, authorized by the medical practitioner.

B. Except as provided in subsection D of this section, a dispenser must use the September 28, 2011 version 4, release 2 standard implementation guide for prescription monitoring programs published by the American society for automation in pharmacy or any subsequent version or release of that guide to report the required information.

C. The board shall allow the reporter to transmit the required information by electronic data transfer if feasible or, if not feasible, on reporting forms as prescribed by the board. The ~~board shall not require the~~ reporter ~~to~~ SHALL submit the required information ~~more frequently than~~ once each day.

D. A dispenser who does not have an automated recordkeeping system capable of producing an electronic report in the established format may request a waiver from electronic reporting by submitting a written request to the board. The board shall grant the request if the dispenser agrees in writing to report the data by submitting a completed universal claim form as prescribed by the board by rule.

E. The board by rule may prescribe the prescription form to be used in prescribing a schedule II, III, IV or V controlled substance if the board determines that this would facilitate the reporting requirements of this section.

F. The reporting requirements of this section do not apply to the following:

1. A controlled substance administered directly to a patient.

2. A controlled substance dispensed by a medical practitioner at a health care facility licensed by this state if the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of seventy-two hours with not more than two seventy-two-hour cycles within any fifteen-day period.

3. A controlled substance sample.

4. The wholesale distribution of a schedule II, III, IV or V controlled substance. For the purposes of this paragraph, "wholesale distribution" has the same meaning prescribed in section 32-1981.

5. A facility that is registered by the United States drug enforcement administration as a narcotic treatment program and that is subject to the recordkeeping provisions of 21 Code of Federal Regulations section 1304.24.

APPROVED BY THE GOVERNOR APRIL 17, 2018.

FILED IN THE OFFICE OF THE SECRETARY OF STATE APRIL 17, 2018.