



# ARIZONA STATE BOARD OF PHARMACY

MAILING ADDRESS: P.O. BOX 18520

PHOENIX, AZ 85005

BUILDING ADDRESS: 1616 W. ADAMS, SUITE 120

PHOENIX AZ 85007

PHONE: (602) 771-2727

FAX: (602) 771-2749

WWW.AZPHARMACY.GOV

## **ARIZONA REVISED STATUTES:**

PHARMACY ACT: TITLE 32 – CHAPTER 18

UNIFORM CONTROLLED SUBSTANCES ACT: TITLE 36 – CHAPTER 27

PRESCRIPTION MONITORING PROGRAM: TITLE 36 – CHAPTER 28

## **ARIZONA ADMINISTRATIVE CODE (RULES):**

TITLE 4: PROFESSIONS AND OCCUPATIONS – CHAPTER 23: BOARD OF PHARMACY

THIS PUBLICATION IS PROVIDED AS A SERVICE TO PHARMACISTS TO FOSTER VOLUNTARY COMPLIANCE WITH THE LAWS AND REGULATIONS. REASONABLE EFFORT HAS BEEN TAKEN TO ENSURE ITS ACCURACY; HOWEVER, READERS ARE REMINDED THAT THE ONLY OFFICIAL PRINTING APPEARS IN THE ARIZONA REVISED STATUTES AND THE ARIZONA ADMINISTRATIVE CODE; WHICH ARE AVAILABLE IN MOST ARIZONA LIBRARIES. YOU MAY ALSO FIND INFORMATION ONLINE AT THE ARIZONA STATE LEGISLATURE [[HTTP://WWW.AZLEG.GOV/ARIZONAREVISEDSTATUTES.ASP](http://www.azleg.gov/arizonarevisedstatutes.asp)] AND THE ARIZONA SECRETARY OF STATE [[HTTP://AZSOS.GOV/PUBLIC\\_SERVICES/TITLE\\_04/4-23.HTM](http://azsos.gov/public_services/title_04/4-23.htm)].

## **GENERAL INFORMATION**

**Arizona Health Care Cost Containment System (AHCCCS):** Effective November 1, 2012, prescriptions for Medicaid members must be written on tamper resistant prescription pads in accordance with federal regulations.

**Arizona Medical Marijuana Act (Proposition 203):** Voter passed, November 2010. For further information, please go to: <http://www.azdhs.gov/medicalmarijuana/>

### **Criminal Charges: Mandatory Reporting Requirements (A.R.S. § 32-3208):**

(A) A health professional who has been charged with a misdemeanor involving conduct that may affect patient safety or a felony after receiving or renewing a license or certificate must notify the health professional's regulatory board in writing within ten working days after the charge is filed.

(B) An applicant for licensure or certification as a health professional who has been charged with a misdemeanor involving conduct that may affect patient safety or a felony after submitting the application must notify the regulatory board in writing within ten working days after the charge is filed.

(C) On receipt of this information the regulatory board may conduct an investigation.

(D) A health professional who does not comply with the notification requirements of this section commits an act of unprofessional conduct. The health professional's regulatory board may impose a civil penalty of not more than one thousand dollars in addition to other disciplinary action it takes.

(E) The regulatory board may deny the application of an applicant who does not comply with the notification requirements of this section.

(F) On request a health profession regulatory board shall provide an applicant or health professional with a list of misdemeanors that the applicant or health professional must report.

**Prescriptive Authority of AZ Health Professionals:** is available on our website, under 'FAQ'.

## **WEBSITES**

### **Arizona Board of Pharmacy Controlled Substance Monitoring Program Login:**

<https://www.azrxreporting.com>

**Arizona Pharmacy Alliance (AzPA):** <http://azpharmacy.org>

**CDC:** <http://www.cdc.gov>

**CDC Vaccines:** <http://www.cdc.gov/vaccines/>

**DEA:** <http://www.justice.gov/dea/index.shtml>

**DEA 106:** <https://www.deadiversion.usdoj.gov/webforms/dtlLogin.jsp>

**FDA:** <http://www.fda.gov>

**My CPE Monitoring:** [www.mycpemonitor.net](http://www.mycpemonitor.net)

**PTCB:** [www.ptcb.org](http://www.ptcb.org)

**National Association of Boards of Pharmacy (NABP):** <http://www.nabp.net>

**NPI Registration:** <https://nppes.cms.hhs.gov/NPPES/Welcome.do>

# **ARIZONA STATE BOARD OF PHARMACY**



## **ARIZONA REVISED STATUTES**

- **PHARMACY ACT: TITLE 32 – CHAPTER 18**
- **UNIFORM CONTROLLED SUBSTANCES ACT:  
TITLE 36 – CHAPTER 27**
- **PRESCRIPTION MONITORING PROGRAM:  
TITLE 36 – CHAPTER 28**

## **ARIZONA ADMINISTRATIVE CODE (RULES)**

- **TITLE 4: PROFESSIONS AND OCCUPATIONS  
CHAPTER 23: BOARD OF PHARMACY**

**ARIZONA PHARMACY ACT**  
**TITLE 32 – CHAPTER 18**

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TITLE 36 – CHAPTER 28**

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# PHARMACY ACT: TITLE 32 – CHAPTER 18

## **ARTICLE 1 BOARD OF PHARMACY:**

### **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 non-disciplinary letter to notify a licensee or permittee that either:
  - (a) While there is insufficient evidence to support disciplinary action, the board believes that continuation of the activities that led to the investigation may result in further board action against the licensee or permittee.
  - (b) The violation is a minor or technical violation that is not of sufficient merit to warrant disciplinary action.
  - (c) While the licensee or permittee has demonstrated substantial compliance through rehabilitation, remediation or reeducation that has mitigated the need for disciplinary action, the board believes that repetition of the activities that led to the investigation may result in further board action against the licensee or permittee.
4. "Antiseptic", if a drug is represented as such on its label, means a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment or dusting powder or other use that involves prolonged contact with the body.
5. "Authorized officers of the law" means legally empowered peace officers, compliance officers of the state board of pharmacy and agents of the division of narcotics enforcement and criminal intelligence of the department of public safety.
6. "Board" or "Board of Pharmacy" means the Arizona State Board of Pharmacy.
7. "Color additive" means a material that either:
  - (a) Is any dye, pigment or other substance made by a process of synthesis or similar artifice, or extracted, isolated or otherwise derived, with or without intermediate or final change of identity, from any vegetable, animal, mineral or other source.
  - (b) If added or applied to a drug, or to the human body or any part of the human body, is capable of imparting color, except that color additive does not include any material that has been or may be exempted under the federal act. Color includes black, white and intermediate grays.
8. "Compounding" means the preparation, mixing, assembling, packaging or labeling of a drug by a pharmacist or an intern or pharmacy technician under the pharmacist's supervision, for the purpose of dispensing to a patient based on a valid prescription order. Compounding includes the preparation of drugs in anticipation of prescription orders prepared on routine, regularly observed prescribing patterns and the preparation of drugs as an incident to research, teaching or chemical analysis or for administration by a medical practitioner to the medical practitioner's patient and not for sale or dispensing. Compounding does not include the preparation of commercially available products from bulk compounds or the preparation of drugs for sale to pharmacies, practitioners or entities for the purpose of dispensing or distribution.
9. "Compressed medical gas distributor" means a person who holds a current permit issued by the board to distribute compressed medical gases pursuant to a compressed medical gas order to compressed medical gas suppliers and other entities that are registered, licensed or permitted to use, administer or distribute compressed medical gases.
10. "Compressed medical gas order" means an order for compressed medical gases that is issued by a medical practitioner.
11. "Compressed medical gas supplier" means a person who holds a current permit issued by the board to supply compressed medical gases pursuant to a compressed medical gas order and only to the consumer or the patient.
12. "Compressed medical gases" means gases and liquid oxygen that a compressed medical gas distributor or manufacturer has labeled in compliance with federal law.
13. "Controlled substance" means a drug, substance or immediate precursor identified, defined or listed in title 36, chapter 27, article 2.
14. "Corrosive" means any substance that when it comes in contact with living tissue will cause destruction of tissue by chemical action.

15. "Counterfeit drug" means a drug that, or the container or labeling of which, without authorization, bears the trademark, trade name or other identifying mark, imprint, number or device, or any likeness of these, of a manufacturer, distributor or dispenser other than the person who in fact manufactured, distributed or dispensed that drug.
16. "Dangerous drug" has the same meaning prescribed in section 13-3401.
17. "Decree of censure" means an official action that is taken by the board and that may include a requirement for restitution of fees to a patient or consumer.
18. "Deliver" or "delivery" means the actual, constructive or attempted transfer from one person to another whether or not there is an agency relationship.
19. "Deputy Director" means a pharmacist who is employed by the board and selected by the executive director to perform duties as prescribed by the executive director.
20. "Device", except as used in paragraph 15 of this section, section 32-1965, paragraph 4 and section 32-1967, subsection A, paragraph 15 and subsection C, means instruments, apparatus and contrivances, including their components, parts and accessories, including all such items under the federal act, intended either:
- (a) For use in the diagnosis, cure, mitigation, treatment or prevention of disease in the human body or other animals.
  - (b) To affect the structure or any function of the human body or other animals.
21. "Direct supervision of a pharmacist" means the pharmacist is present. If relating to the sale of certain items, direct supervision of a pharmacist means that a pharmacist determines the legitimacy or advisability of a proposed purchase of those items.
22. "Director" means the director of the division of narcotics enforcement and criminal investigation of the department of public safety.
23. "Dispense" means to deliver to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling or compounding necessary to prepare for that delivery.
24. "Dispenser" means a practitioner who dispenses.
25. "Distribute" means to deliver, other than by administering or dispensing.
26. "Distributor" means a person who distributes.
27. "Drug" means:
- (a) Articles recognized, or for which standards or specifications are prescribed, in the official compendium.
  - (b) Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in the human body or other animals.
  - (c) Articles other than food intended to affect the structure or any function of the human body or other animals.
  - (d) Articles intended for use as a component of any articles specified in subdivision (a), (b) or (c) of this paragraph but does not include devices or their components, parts or accessories.
28. "Drug enforcement administration" means the drug enforcement administration of the United States department of justice or its successor agency.
29. "Drug or device manufacturing" means the production, preparation, propagation or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis and includes any packaging or repackaging of substances or labeling or relabeling of its container and the promotion and marketing of the same. Drug or device manufacturing does not include compounding.
30. "Economic poison" means any substance that alone, in chemical combination or in formulation with one or more other substances is a pesticide within the meaning of the laws of this state or the federal insecticide, fungicide and rodenticide act and that is used in the production, storage or transportation of raw agricultural commodities.
31. "Established name", with respect to a drug or ingredient of a drug, means any of the following:
- (a) The applicable official name.
  - (b) If there is no such name and the drug or ingredient is an article recognized in an official compendium, 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 drug.

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

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

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

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

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

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

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

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

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

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

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

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

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

41. "Jurisprudence examination" means a board approved pharmacy law examination that is written and administered in cooperation with the National Association of Boards of Pharmacy (NABP) or another board approved pharmacy law examination. [MPJE]

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

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

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

(b) Accompanying that article.

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

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

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

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

48. "Medical practitioner" means any medical doctor, doctor of osteopathy, dentist, podiatrist, veterinarian or other person licensed and authorized by law to use and prescribe drugs and devices for the treatment of sick and injured human beings or animals or for the diagnosis or prevention of sickness in human beings or animals in this state or any state, territory or district of the United States.
49. "Medication order" means a written or verbal order from a medical practitioner or that person's authorized agent to administer a drug or device.
50. "Narcotic drug" has the same meaning prescribed in section 13-3401.
51. "New drug" means either:
- (a) Any drug the composition of which is such that the drug is not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs as safe and effective for use under the conditions prescribed, recommended or suggested in the labeling.
  - (b) Any drug the composition of which is such that the drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but that has not, other than in the investigations, been used to a material extent or for a material time under those conditions.
52. "Nonprescription drug" or "over-the-counter drug" means any nonnarcotic medicine or drug that may be sold without a prescription and is prepackaged and labeled for use by the consumer in accordance with the requirements of the laws of this state and federal law. Nonprescription drug does not include:
- (a) A drug that is primarily advertised and promoted professionally to medical practitioners and pharmacists by manufacturers or primary distributors.
  - (b) A controlled substance.
  - (c) A drug that is required to bear a label that states "Rx only."
  - (d) A drug intended for human use by hypodermic injection.
53. "Nonprescription drug wholesale permittee" means a permittee who may distribute only over-the-counter drugs and devices to pharmacies or other lawful outlets from a place devoted in whole or in part to wholesaling these items.
54. "Notice" means personal service or the mailing of a copy of the notice by certified mail addressed either to the person at the person's latest address of record in the board office or to the person's attorney.
55. "Official compendium" means the latest revision of the United States pharmacopeia and the national formulary or any current supplement.
56. "Other jurisdiction" means one of the other forty-nine states, the District of Columbia, the Commonwealth of Puerto Rico or a territory of the United States of America.
57. "Package" means a receptacle defined or described in the United States pharmacopeia and the national formulary as adopted by the board.
58. "Packaging" means the act or process of placing a drug item or device in a container for the purpose or intent of dispensing or distributing the item or device to another.
59. "Person" means an individual, partnership, corporation and association, and their duly authorized agents.
60. "Pharmaceutical care" means the provision of drug therapy and other pharmaceutical patient care services.
61. "Pharmacist" means an individual currently licensed by the board to practice the profession of pharmacy in this state.
62. "Pharmacist in charge" means the pharmacist who is responsible to the board for a licensed establishment's compliance with the laws and administrative rules of this state and of the federal government pertaining to the practice of pharmacy, the manufacturing of drugs and the distribution of drugs and devices.
63. "Pharmacist licensure examination" means a board approved examination that is written and administered in cooperation with the National Association of Boards of Pharmacy or any other board approved pharmacist licensure examination.
64. "Pharmacy" means any place:
- (a) Where drugs, devices, poisons or related hazardous substances are offered for sale at retail.
  - (b) In which the profession of pharmacy is practiced or where prescription orders are compounded and dispensed.

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

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

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

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

66. "Pharmacy technician" means a person who is licensed pursuant to this chapter.

67. "Pharmacy technician trainee" means a person who is licensed pursuant to this chapter.

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

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

(b) A toxic substance.

(c) A highly toxic substance.

(d) A corrosive substance.

(e) An irritant.

(f) A strong sensitizer.

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

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

69. "Practice of pharmacy" means furnishing the following health care services as a medical professional:

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

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

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

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

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

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

(g) Maintaining required records of drugs and devices.

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

(i) Implementing, monitoring and modifying drug therapy pursuant to a protocol-based drug therapy agreement with a provider as outlined in section 31-1970.

(j) Initiating and administering immunizations or vaccines pursuant to sections 32-1974.

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

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

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

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

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

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

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

75. "Prescription-only device" includes:

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

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

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

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

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

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

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

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

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

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

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

78. "Professionally incompetent" means:

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

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

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

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

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

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

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

**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 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 record keeping 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 permittee's permit to manufacture, sell, distribute or dispense drugs, devices, poisons, hazardous substances or precursor chemicals 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. Willfully 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, 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 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 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 licensee's license to practice pharmacy 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 the 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.

(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 that meets the elements required by the Centers for Medicare and Medicaid Services.

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 or employer as required pursuant to section 32-1926.

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

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 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 licensee's license to practice as a pharmacy technician 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 I 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 or employer as required pursuant to section 32-1926.

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

**32-1902. Arizona State Board of Pharmacy; immunity**

A. The Arizona State Board of Pharmacy is established consisting of the following members who are appointed by the governor:

1. Six pharmacists at least one of whom is a pharmacist employed by a licensed hospital and at least one of whom is employed by a community pharmacy and engaged in the day-to-day practice of pharmacy.
2. One pharmacy technician.
3. Two public members.

B. To be qualified for appointment:

1. A pharmacist must be licensed as a pharmacist in this state or any other jurisdiction for a period of at least ten years and licensed as a pharmacist and a resident in this state for a period of at least five years immediately before the date of appointment.
2. Each public member must be a resident of this state for a period of at least five years immediately before the date of appointment.
3. A pharmacy technician must be a practicing pharmacy technician in this state or any other jurisdiction for at least five years and be licensed as a pharmacy technician and a resident of this state for at least five years immediately before the date of appointment. A pharmacy technician appointed before July 1, 2009 does not have to meet the minimum five year licensure requirement of this paragraph.

C. Each pharmacist and pharmacy technician member shall serve for a term of five years. Public members may serve for a term of five years unless removed by the governor. The public members shall after the first of every year present a written report to the governor. Vacancies occurring on the board other than by expiration of term of office shall be filled for the unexpired portion of the term only.

D. On or before January 15 of each year in which a pharmacist or a pharmacy technician is to be appointed, the executive director of the pharmacy association of Arizona may submit to the governor a list of the names of at least seven of its members who have been nominated by the association, and who meet the requirements as provided in this section for the next occurring vacancy on the board. The governor may make appointments of licensed pharmacists and pharmacy technicians to the board from the nominees on the list or from others having the necessary qualifications.

E. Appointees to the board within thirty days after their appointment shall take and subscribe to an oath or affirmation, before a properly qualified officer, that they will faithfully and impartially perform the duties of their office. The executive director shall file the oath or affirmation with the secretary of state.

F. Members of the board are personally exempt from suit with respect to all acts done and actions taken in good faith and in furtherance of this chapter.

**32-1903. Organization; meetings; quorum; compensation of board; executive director; compensation; powers and duties**

A. The board shall annually elect a president and a vice-president from among its membership and select an executive director who may or may not be a member of the board. The executive director shall serve at the pleasure of the board.

B. The president of the board shall preside at all of its meetings. The vice-president shall act if the president is absent. A majority of the membership of the board constitutes a quorum.

C. The executive director is the executive officer in charge of the board's office and shall administer this chapter under the direction of the board. The executive director shall make, keep and be in charge of all records and record books required to be kept by the board, including a register of all licensees and registered businesses under this chapter. The executive director shall attend to the correspondence of the board and perform other duties the board requires. The executive director is eligible to receive compensation as determined pursuant to section 38-611.

D. Any member of the board or the executive director may administer oaths in connection with the duties of the board. The books, registers and records of the board as made and kept by the executive director or under the executive director's supervision are prima facie evidence of the matter therein recorded in any court of law. Members of the board are eligible to receive compensation in the amount of two hundred dollars for each day of actual service in the business of the board and reimbursement for all expenses necessarily and properly incurred in attending meetings of or for the board.

E. The executive director may designate the deputy director to sign claims and other documents in the executive director's absence. If the executive director dies, becomes incapacitated or resigns, the deputy director shall serve as the executive director until the board selects a new executive director.

F. The executive director may cause to be published reports summarizing judgments, decrees, court orders and board action that may have been rendered under this chapter, including the nature of charges and the disposition of the charges. The executive director may disseminate information regarding drugs, devices, poisons or hazardous substances in situations the executive director believes involve imminent danger to health or gross deception of the consumer and report the results of investigations carried out under this chapter.

## **32-1904. Powers and duties of board; immunity**

### A. The board shall:

1. Make bylaws and adopt rules that are necessary for the protection of the public and that pertain to the practice of pharmacy, the manufacturing, wholesaling or supplying of drugs, devices, poisons or hazardous substances, the use of pharmacy technicians and support personnel and the lawful performance of its duties.
2. Fix standards and requirements for the registration and reregistration of pharmacies, except as otherwise specified.
3. Investigate compliance as to the quality, label and labeling of all drugs, devices, poisons or hazardous substances and take action necessary to prevent the sale of these if they do not conform to the standards prescribed in this chapter, the official compendium or the federal act.
4. Enforce its rules. In so doing, the board or its agents have free access at all reasonable hours to any pharmacy, manufacturer, wholesaler, nonprescription drug permittee or other establishment in which drugs, devices, poisons or hazardous substances are manufactured, processed, packed or held, or to enter any vehicle being used to transport or hold such drugs, devices, poisons or hazardous substances for the purpose of:
  - (a) Inspecting the establishment or vehicle to determine if any provisions of this chapter or the federal act are being violated.
  - (b) Securing samples or specimens of any drug, device, poison or hazardous substance after paying or offering to pay for such sample.
  - (c) Detaining or embargoing a drug, device, poison or hazardous substance in accordance with section 32-1994.
5. Examine and license as pharmacists and pharmacy interns all qualified applicants as provided by this chapter.
6. Require each applicant for an initial license to submit to the board a full set of fingerprints for the purpose of obtaining a state and federal criminal records check pursuant to section 41-1750 and public law 92-544. The Department of Public Safety may exchange this fingerprint data with the Federal Bureau of Investigation. [Effective 07/22/2014]
7. Issue duplicates of lost or destroyed permits on the payment of a fee as prescribed by the board.
8. Adopt rules for the rehabilitation of pharmacists and pharmacy interns as provided by this chapter.
9. At least once every three months, notify pharmacies regulated pursuant to this chapter of any modifications on prescription writing privileges of podiatrists, dentists, doctors of medicine, registered nurse practitioners, osteopathic physicians, veterinarians, physician assistants, optometrists and homeopathic physicians of which it receives notification from the board of podiatry examiners, board of dental examiners, Arizona medical board, board of nursing, board of osteopathic examiners in medicine and surgery, veterinary medical examining board, Arizona regulatory board of physician assistants, board of optometry or board of homeopathic and integrated medicine examiners.

### B. The board may:

1. Employ chemists, compliance officers, clerical help and other employees subject to title 41, chapter 4, article 4 and provide laboratory facilities for the proper conduct of its business.
2. Provide, by education of and information to the licensees and to the public, assistance in the curtailment of abuse in the use of drugs, devices, poisons and hazardous substances.
3. Approve or reject the manner of storage and security of drugs, devices, poisons and hazardous substances.
4. Accept monies and services to assist in the enforcement of this chapter from other than licensees:
  - (a) For performing inspections and other board functions.
  - (b) For the cost of copies of the pharmacy and controlled substances laws, the annual report of the board and other information from the board.
5. Adopt rules for professional conduct appropriate to the establishment and maintenance of a high standard of integrity and dignity in the profession of pharmacy.
6. Grant permission to deviate from a state requirement for experimentation and technological advances.
7. Adopt rules for the training and practice of pharmacy interns, pharmacy technicians and support personnel.

8. Investigate alleged violations of this chapter, conduct hearings in respect to violations, subpoena witnesses and take such action as it deems necessary to revoke or suspend a license or a permit, place a licensee or permittee on probation or warn a licensee or permittee under this chapter or to bring notice of violations to the county attorney of the county in which a violation took place or to the attorney general.

9. By rule, approve colleges or schools of pharmacy.

10. By rule, approve programs of practical experience, clinical programs, internship training programs, programs of remedial academic work and preliminary equivalency examinations as provided by this chapter.

11. Assist in the continuing education of pharmacists and pharmacy interns.

12. Issue inactive status licenses as provided by this chapter.

13. Accept monies and services from the federal government or others for educational, research or other purposes pertaining to the enforcement of this chapter.

14. By rule, except from the application of all or any part of this chapter any material, compound, mixture or preparation containing any stimulant or depressant substance included in section 13-3401, paragraph 6, subdivision (c) or (d) from the definition of dangerous drug if the material, compound, mixture or preparation contains one or more active medicinal ingredients not having a stimulant or depressant effect on the central nervous system, provided that such admixtures are included in such combinations, quantity, proportion or concentration as to vitiate the potential for abuse of the substances that do have a stimulant or depressant effect on the central nervous system.

15. Adopt rules for the revocation, suspension or reinstatement of licenses or permits or the probation of licensees or permittees as provided by this chapter.

C. The executive director and other personnel or agents of the board are not subject to civil liability for any act done or proceeding undertaken or performed in good faith and in furtherance of the purposes of this chapter.

#### **32-1905. Meetings; time and place; annual report**

A. The board of pharmacy shall hold meetings to consider license and permit applications and to transact other business legally coming before it. The board must hold at least four meetings in each fiscal year.

B. The board shall designate the time and place of its meetings at least thirty days before each meeting.

C. The board shall make an annual written report to the governor and to the Arizona pharmacy association, including the names of all pharmacists, interns, pharmacy technicians, pharmacy technician trainees, pharmacies, wholesalers and manufacturers authorized to practice under this chapter and a record of licenses, permits and renewals.

#### **32-1906. Membership in national associations; official attendance at professional meetings**

A. The board may join and subscribe to state, district, regional or national organizations or publications relating to and dealing with pharmacy and manufacturing, wholesaling, and distribution of drugs, devices, poisons, and hazardous substances.

B. Members of the board, the executive director and compliance officers, if authorized by the board, and subject to legislative appropriation therefor, may attend the state, district, regional and national meetings and other educational meetings relating to any of the subjects as provided in subsection A that, in the discretion of the board, are necessary and for its best interests.

#### **32-1907. Arizona state board of pharmacy fund**

A. Except as provided in section 32-1939, the executive director shall receive and receipt for all fees and other monies provided for in this chapter and shall deposit, pursuant to sections 35-146 and 35-147, ten per cent of such monies in the state general fund and ninety per cent in the Arizona state board of pharmacy fund. All monies derived from civil penalties collected pursuant to this chapter shall be deposited, pursuant to sections 35-146 and 35-147, in the general fund.

B. Except as provided in subsection C of this section, monies deposited in the Arizona state board of pharmacy fund shall be subject to section 35-143.01.

C. From monies deposited in the Arizona state board of pharmacy fund pursuant to subsection A of this section, the executive director may transfer up to three hundred ninety-five thousand seven hundred ninety-five dollars annually to the controlled substances prescription monitoring program fund established by section 36-2605 for expenses related to the controlled substances prescription monitoring program as required by title 36, chapter 28.

#### **32-1908. Scope of chapter**

A. The provisions of this chapter regarding the selling of drugs, poisons, or hazardous substances shall be considered to include the sale, dispensing, furnishing or giving of any such article, or the supplying or applying of any such articles in the conduct of any drug, poison, or hazardous substance establishment.

B. Nothing in this chapter shall be construed to confer authority to license or regulate the collection, processing or distribution of whole human blood or its plasma, fractionations, products, derivatives or other human tissue procured, processed or distributed by federally licensed or regulated blood banks or tissue banks.

**32-1909. Prescription medication donation program; distribution; immunity; rules**

A. Pursuant to board rules and this section, the board shall establish a prescription medication donation program to accept and dispense prescription medications. Prescription medications may be donated at a physician's office, a pharmacy or a health care institution as defined in section 36-401 that elects to participate in the program and that meets the requirements of this section and board rules. Prescription medications shall be accepted or dispensed under the prescription medication donation program only in their original sealed and tamper-evident unit dose packaging. Prescription medication that is packaged in single unit doses may be accepted and dispensed even if the outside packaging is opened if the single unit dose packaging is undisturbed. The program shall not accept a donation of a prescription medication that either:

1. Expires within six months after the donation.
2. Is deemed adulterated pursuant to section 32-1966.

B. A person, manufacturer or health care institution may donate prescription medication to a physician's office, pharmacy, hospital or health care institution that volunteers to participate in the program and that meets the requirements prescribed by the board.

C. A physician's office, pharmacy, hospital or health care institution that participates in the program shall dispense donated prescription medication:

1. Either directly or through participating governmental or nonprofit private entities.
2. Only pursuant to a prescription order.
3. Only to a recipient who is a resident of this state and who meets the eligibility standards prescribed by the board by rule.

D. Before dispensing donated prescription medication, the physician's office, pharmacy, hospital or health care institutions participating in the program:

1. Shall comply with all applicable federal laws and the laws of this state dealing with the storage and distribution of dangerous drugs.
2. Shall examine the donated prescription medication to determine that it has not been adulterated and certify that the medication has been stored in compliance with the requirements of the product label.
3. May charge persons receiving donated prescription medication pursuant to this section a handling fee as prescribed by the board by rule to cover the costs of inspection, stocking and dispensing the prescription medication.

E. A pharmaceutical manufacturer is not liable for any claim or injury arising from the transfer of any prescription medication pursuant to this section including liability for failure to transfer or communicate product or consumer information regarding the transferred prescription medication, including the expiration date of the transferred prescription medication.

F. Persons and entities participating in the program as prescribed by this section and board rules are not subject to civil liability or professional disciplinary action.

G. In consultation with the director of the department of health services, the board shall adopt rules prescribing the following:

1. Eligibility criteria for physicians' offices, pharmacies, hospitals and health care institutions to receive and dispense donated prescription medication.
2. Standards and procedures for accepting, storing and dispensing donated prescription medication.
3. Standards and procedures for inspecting donated prescription medication to determine that the original unit dose packaging is sealed and tamper-evident and that the donated prescription medication is unadulterated, safe and suitable for dispensing.
4. Eligibility standards, based on economic need, for persons receiving donated prescription medication.
5. A means, such as an identification card, by which persons prove that they are eligible to receive donated prescription medication.
6. A form that each recipient shall sign before the recipient may receive donated prescription medication to confirm that the recipient understands the immunity provisions of the program.
7. A formula to determine the amount of the handling fee that a physician's office, pharmacy, hospital or health care institution may charge recipients.

8. A list of prescription medication, arranged either by category or by individual drug, that the program may accept from individuals.
  9. A list of prescription medication, arranged either by category or by individual drug, that the program shall not accept from individuals.
  10. A form each individual shall sign stating that the donor is the owner of the prescription medication and wishes to voluntarily donate the prescription medication to the program.
  11. A list of prescription medication, arranged either by category or by individual drug, that the program may accept from a health care institution.
  12. A list of prescription medication, arranged either by category or by individual drug, that the program shall not accept from a health care institution. The list shall include a statement as to why the prescription medication is ineligible for donation.
  13. Any other standards the board determines are necessary and appropriate.
- H. Notwithstanding any other law, a dispenser of donated prescription medication pursuant to this section shall not submit a claim or otherwise seek reimbursement from a public or private third party payor for the donation and a public or private third party payor shall not provide reimbursement for donations made pursuant to this section.

### **32-1910. Emergencies; continued provision of services**

- A. If a natural disaster or terrorist attack occurs and, as a consequence of the natural disaster or terrorist attack, a state of emergency is declared by the governor or by a county, city or town pursuant to its authority and the declared state of emergency results in individuals being unable to refill existing prescriptions, the board shall cooperate with this state and the county, city or town to ensure the provision of drugs, devices and professional services to the public.
- B. If a natural disaster or terrorist attack occurs in another state and, as a consequence of the natural disaster or terrorist attack, a state of emergency is declared by the governor of that state and the declared state of emergency results in individuals being temporarily relocated to Arizona and unable to refill existing prescriptions, the board shall cooperate with this state to ensure the provision of drugs, devices and professional services to the relocated individuals.
- C. When a state of emergency has been declared pursuant to this section, a pharmacist may work in the affected county, city or town and may dispense a one-time emergency refill prescription of up to a thirty-day supply of a prescribed medication if both of the following apply:
1. In the pharmacist's professional opinion the medication is essential to the maintenance of life or to the continuation of therapy.
  2. The pharmacist makes a good faith effort to reduce the information to a written prescription marked "emergency prescription" and then files and maintains the prescription as required by law.
- D. If the state of emergency declared pursuant to this section continues for at least twenty-one days after the pharmacist dispenses an emergency prescription pursuant to subsection C, the pharmacist may dispense one additional emergency refill prescription of up to a thirty day supply of the prescribed medication.
- E. A pharmacist who is not licensed in this state, but who is currently licensed in another state, may dispense prescription medications in those affected counties, cities or towns in this state during the time that a declared state of emergency exists pursuant to this section if both of the following apply:
1. The pharmacist has proof of licensure in another state.
  2. The pharmacist is engaged in a legitimate relief effort during the period of time an emergency has been declared pursuant to this section.
- F. The board may adopt rules for the provision of pharmaceutical care and drug and device delivery during a declared emergency that is the consequence of a natural disaster or terrorist attack, including the use of temporary or mobile pharmacy facilities and nonresident licensed pharmacy professionals.
- G. A pharmacist's authority to dispense prescriptions pursuant to this section ends when the declared state of emergency is terminated.

### **ARTICLE 2 LICENSURE AND PERMITS:**

#### **32-1921. Exempted acts; exemption from registration fees; definition**

- A. This chapter does not prevent:
1. The prescription and dispensing of drugs or prescription medications by a registered nurse practitioner pursuant to rules adopted by the board of nursing in consultation with the Arizona medical board, the board of osteopathic examiners in medicine and surgery and the board of pharmacy.

2. The sale of nonprescription drugs that are sold at retail in original packages by a person holding a permit issued by the board under this chapter.
3. The sale of drugs at wholesale by a wholesaler or manufacturer that holds the required permit issued by the board to a person who holds the required permit issued under this chapter.
4. The manufacturing of drugs by a person who is not a pharmacist and who holds the required permit issued by the board under this chapter.
5. The following health professionals from dispensing or personally administering drugs or devices to a patient for a condition being treated by the health professional:
  - (a) A doctor of medicine licensed pursuant to chapter 13 of this title.
  - (b) An osteopathic physician licensed pursuant to chapter 17 of this title.
  - (c) A homeopathic physician licensed pursuant to chapter 29 of this title.
  - (d) A podiatrist licensed pursuant to chapter 7 of this title.
  - (e) A dentist licensed pursuant to chapter 11 of this title.
  - (f) A doctor of naturopathic medicine who is authorized to prescribe natural substances, drugs or devices and who is licensed pursuant to chapter 14 of this title.
  - (g) An optometrist who is licensed pursuant to chapter 16 of this title and who is certified for topical or oral pharmaceutical agents.
6. A veterinarian licensed pursuant to chapter 21 of this title from dispensing or administering drugs to an animal or from dispensing or administering devices to an animal being treated by the veterinarian.
7. The use of any pesticide chemical, soil or plant nutrient or other agricultural chemical that is a color additive solely because of its effect in aiding, retarding or otherwise affecting directly or indirectly the growth or other natural physiological process of produce of the soil and thereby affecting its color whether before or after harvest.
8. A licensed practical or registered nurse employed by a person licensed pursuant to chapter 7, 11, 13, 14, 17 or 29 of this title from assisting in the delivery of drugs and devices to patients, in accordance with chapter 7, 11, 13, 14, 17 or 29 of this title.
9. The use of any mechanical device or vending machine in connection with the sale of any nonprescription drug, including proprietary and patent medicine. The board may adopt rules to prescribe conditions under which nonprescription drugs may be dispensed pursuant to this paragraph.
  - B. A person who is licensed pursuant to chapter 7, 11, 13, 14, 17 or 29 of this title and who employs a licensed practical or registered nurse who in the course of employment assists in the delivery of drugs and devices is responsible for the dispensing process.
  - C. Pursuant to a prescription order written by a physician for the physician's patients and dispensed by a licensed pharmacist, a physical therapist licensed pursuant to chapter 19 of this title, an occupational therapist licensed pursuant to chapter 34 of this title or an athletic trainer licensed pursuant to chapter 41 of this title may procure, store and administer nonscheduled legend and topical anti-inflammatories and topical anesthetics for use in phonophoresis and iontophoresis procedures and within the scope of practice of physical or occupational therapy or athletic training.
  - D. A public health facility operated by this state or a county and a qualifying community health center may dispense medication or devices to patients at no cost without providing a written prescription if the public health facility or the qualifying community health center meets all storage, labeling, safety and record keeping rules adopted by the board of pharmacy.
  - E. A person who is licensed pursuant to chapter 7, 11, 13, 14, 17 or 29 of this title, who is practicing at a public health facility or a qualifying community health center and who is involved in the dispensing of medication or devices only at a facility or center, whether for a charge or at no cost, shall register to dispense with the appropriate licensing board but is exempt from paying registration fees.
  - F. For the purposes of this section, "qualifying community health center" means a primary care clinic that is recognized as nonprofit under section 501(c)(3) of the United States internal revenue code and whose board of directors includes patients of the center and residents of the center's service area.

**32-1922. Qualifications of applicant; reciprocity; preliminary equivalency examination; honorary certificate; fee**

- A. An applicant for licensure as a pharmacist shall:
  1. Be of good moral character.
  2. Be a graduate of a school or college of pharmacy or department of pharmacy of a university recognized by the board or the accreditation council for pharmacy education, or qualify under subsection D of this section.

3. Have successfully completed, as substantiated by proper affidavits, a program of practical experience under the direct supervision of a licensed pharmacist approved by the board.
4. Pass the pharmacist licensure examination and jurisprudence examination approved by the board. An applicant who fails an examination three times shall petition the board for permission before retaking the examination. The board shall evaluate the petition and determine whether to require additional educational training before approving each additional retake of the examination.
5. Pay an application fee prescribed by the board of not more than five hundred dollars. An applicant for reciprocal licensure shall pay the fee prescribed in section 32-1924, subsection D.

B. The board may license as a pharmacist, without a pharmacist licensure examination, a person who is licensed as a pharmacist by a pharmacist licensure examination in some other jurisdiction if that person:

1. Produces satisfactory evidence to the board of having had the required secondary and professional education and training.
2. Is possessed of good morals as demanded of applicants for licensure and relicensure under this chapter.
3. Presents proof to the board's satisfaction of licensure by a pharmacist licensure examination equivalent to the pharmacist licensure examination required by the board and that the applicant has held the license in good standing for at least one year. If the applicant was examined after June 1, 1979, the applicant must present proof to the board's satisfaction of having passed the national association of boards of pharmacy licensure examination or the North American pharmacist licensure examination.
4. Presents proof to the board's satisfaction that any other license granted to the applicant by any other jurisdiction has not been suspended, revoked or otherwise restricted for any reason except nonrenewal or for failure to obtain the required continuing education credits in any jurisdiction where the applicant is currently licensed but not engaged in the practice of pharmacy.
5. Passes a board approved jurisprudence examination.

C. Subsection B of this section applies only if the jurisdiction in which the person is licensed grants, under like conditions, reciprocal licensure as a pharmacist to a pharmacist licensed by examination in this state and the applicant has held a license in good standing for at least one year issued by an active member board of the national association of boards of pharmacy.

D. If an applicant for licensure is a graduate of a pharmacy degree program at a school or college of pharmacy that was not recognized by the board at the time of the person's graduation, the applicant shall pass a preliminary equivalency examination approved by the board in order to qualify to take the examinations prescribed in subsection A of this section.

E. The preliminary equivalency examination required pursuant to subsection D of this section shall cover proficiency in English and academic areas the board deems essential to a satisfactory pharmacy curriculum.

F. An applicant who fails the preliminary equivalency examination required pursuant to subsection D of this section shall not retake the preliminary equivalency examination until the applicant files written proof with the board that the applicant has completed additional remedial academic work previously approved by the board to correct deficiencies in the applicant's education that were indicated by the results of the applicant's last preliminary equivalency examination.

G. A pharmacist who has been licensed in this state for at least fifty years shall be granted an honorary certificate of licensure by the board without the payment of the usual renewal fee, but that certificate of licensure does not confer an exemption from any other requirement of this chapter.

H. The board may require a pharmacist who has not been actively engaged in the practice of pharmacy for over one year to serve not more than four hundred hours in an internship training program approved by the board or its designee before the pharmacist may resume the active practice of pharmacy.

I. An applicant must complete the application process within twelve months after submitting the application.

### **32-1923. Interns and intern preceptors; qualifications; licensure; purpose of internship**

A. A pharmacist who meets the qualifications established by the board to supervise the training of a pharmacy intern or a graduate intern shall comply with the rules of the board and be known as a pharmacy intern preceptor.

B. A person shall not act as a pharmacy intern until that person is licensed by the board. An employer shall verify that a person is currently licensed as a pharmacy intern before the employer allows that person to act as a pharmacy intern.

C. The board shall establish the preliminary educational qualifications for all pharmacy interns which may include enrollment and attendance in a school or college of pharmacy approved by the board. The board or its designee may license as a graduate intern a graduate of a board approved college, school or program of pharmacy.

D. A pharmacy intern who is currently licensed may be employed in a pharmacy or any other place approved and authorized by the board for training interns and shall receive instruction in the practice of pharmacy, including manufacturing, wholesaling, dispensing of drugs and devices, compounding and dispensing prescription orders, clinical pharmacy, providing drug information, keeping records and making reports required by state and federal laws and other experience that, in the discretion of the board, provides the intern with the necessary experience to practice the profession of pharmacy. Pharmacy interns may compound, dispense and sell drugs, devices and poisons or perform other duties of a pharmacist only in the presence and under the immediate personal supervision of a pharmacist.

E. Intern training and licensure as a pharmacy intern under this section are for the purpose of acquiring practical experience in the practice of the profession of pharmacy before becoming licensed as a pharmacist and are not for the purpose of continued licensure under the pharmacy laws. If a pharmacy intern fails to complete pharmacy education within a period of six years, the intern is not eligible for re-licensure as an intern, without acceptable explanation to the board that the intern intends to be and is working toward becoming a pharmacist.

F. The board may accept the experience of a pharmacy intern acquired in another jurisdiction upon proper certification by the other jurisdiction.

**32-1923.01. Pharmacy technicians; pharmacy technician trainees; qualifications**

A. An applicant for licensure as a pharmacy technician must:

1. Be of good moral character.
2. Be at least eighteen years of age.
3. Have a high school diploma or the equivalent of a high school diploma.
4. Complete a training program prescribed by board rules.
5. Pass a board approved pharmacy technician examination.

B. An applicant for licensure as a pharmacy technician trainee must:

1. Be of good moral character.
2. Be at least eighteen years of age.
3. Have a high school diploma or the equivalent of a high school diploma.

**32-1924. Licenses; fees; signatures**

A. An applicant for licensure as a pharmacist who passes the board approved examinations shall pay the board an initial licensure fee of not more than five hundred dollars.

B. An applicant for licensure as a pharmacist, intern, pharmacy technician or pharmacy technician trainee shall pay a fee prescribed by the board that does not exceed fifty dollars for issuance of a wall license. On payment of a fee of not more than fifty dollars, the board may issue a replacement wall license to a licensee who requests a replacement because the original was damaged or destroyed, because of a change of name or for other good cause as prescribed by the board.

C. An applicant for licensure as an intern shall pay a fee of not more than seventy-five dollars. A license issued pursuant to this subsection expires five years after it is issued. The board shall adopt rules to prescribe the requirements for the renewal of a license that expires before the pharmacy intern completes the education or training required for licensure as a pharmacist.

D. An applicant for reciprocal licensure as a pharmacist shall pay a fee of not more than five hundred dollars for the application and expense of making an investigation of the applicant's character, general reputation and pharmaceutical standing in the jurisdiction in which the applicant is licensed.

E. All pharmacist licenses shall bear the signatures of the executive director and a majority of the members of the board.

F. An applicant for licensure as a pharmacy technician trainee shall submit with the application a fee prescribed by the board that does not exceed one hundred dollars. A license issued pursuant to this subsection expires twenty-four months after it is issued. The board shall adopt rules to allow a pharmacy technician trainee who is licensed pursuant to this chapter and who does not complete the training program and pass a board approved pharmacy technician licensure examination within the licensure period to reapply for licensure not more than one time.

G. An applicant for licensure as a pharmacy technician shall submit with the application a fee prescribed by the board that does not exceed one hundred dollars.

**32-1925. Renewal of license of pharmacists, interns and pharmacy technicians; fees; expiration dates; penalty for failure to renew; continuing education**

A. Except for interns and pharmacy technician trainees, the board shall assign all persons licensed under this chapter to one of two license renewal groups. Except as provided in section 32-4301, a holder of a license certificate 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 license certificate 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 license. The board shall vacate a suspension when the licensee pays all past

due fees and penalties. Penalties shall not exceed three hundred fifty dollars. The board may waive collection of a fee or penalty due after suspension under conditions established by a majority of the board.

B. The board shall prorate the fee for a new license for the remaining full calendar months of the respective group to which the licensee is assigned.

C. A person shall not apply for license renewal more than sixty days before the expiration date of the license.

D. A person who is licensed as a pharmacist or a pharmacy technician and who has not renewed the license for five consecutive years shall furnish to the board satisfactory proof of fitness to be licensed as a pharmacist or a pharmacy technician, in addition to the payment of all past due fees and penalties before being reinstated.

E. Biennial renewal fees for licensure shall be not more than:

1. For a pharmacist, two hundred fifty dollars.

2. For a pharmacy technician, one hundred dollars.

3. For a duplicate renewal license, twenty-five dollars.

F. 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 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 a license.

G. The board shall not renew a license for a pharmacist unless the pharmacist has complied with the mandatory continuing professional pharmacy education requirements of sections 32-1936 and 32-1937.

H. The board shall prescribe intern licensure renewal fees that do not exceed seventy-five dollars. The license of an intern who does not receive specific board approval to renew the intern license or who receives board approval to renew but who does not renew and pay all required fees before the license expiration date is suspended after the license expiration date. The board shall vacate a suspension if the licensee pays all past due fees and penalties. Penalties shall not exceed three hundred fifty dollars. The board may waive collection of a fee or penalty due after suspension under conditions established by the board.

I. The board shall not renew a license for a pharmacy technician unless that person has a current board approved license and has complied with board approved mandatory continuing professional education requirements.

### **32-1926. Notice of change of employer or home address; termination of responsibility**

A. Except as prescribed in subsection B, a pharmacist, intern, pharmacy technician or pharmacy technician trainee within ten days after changing that person's employer or home address shall give written notice to the executive director of the new employer or new home address.

B. Pursuant to board rule, a pharmacist designated as the pharmacist in charge for a permit issued under this chapter shall give immediate notice of the initiation and termination of such responsibility.

### **32-1926.01. Change in residency status; duty to report**

A. A licensee shall give written notice to the executive director of a change in the licensee's residency status authorized by the United States immigration and naturalization service.

B. If the licensee's residency status ceases to be authorized by the United States immigration and naturalization service, the licensee shall give notice to the executive director that the licensee voluntarily terminates the license.

### **32-1927. Pharmacists; pharmacy interns; graduate interns; disciplinary action**

A. A pharmacist, pharmacy intern or graduate intern is subject to disciplinary action by the board for any of the following:

1. The board determines that the licensee has committed an act of unprofessional conduct.

2. The licensee is found by psychiatric examination to be mentally unfit to practice the profession of pharmacy.

3. The licensee is found to be physically or mentally incapacitated to such a degree as to render the licensee unfit to practice the profession of pharmacy.

4. The licensee is found to be professionally incompetent to such a degree as to render the licensee unfit to practice the profession of pharmacy.

5. The license was issued through error.

B. A pharmacist, pharmacy intern or graduate intern who after a formal hearing is found by the board to be guilty of unprofessional conduct, to be mentally or physically unable safely to engage in the practice of pharmacy or to be professionally incompetent is subject to any one or combination of the following:

1. A civil penalty of not to exceed one thousand dollars for each violation of this chapter or a rule adopted under this chapter.
2. A letter of reprimand.
3. A decree of censure.
4. Completion of board designated continuing pharmaceutical education courses.
5. Probation.
6. Suspension or revocation of the license.

C. The board may charge the costs of formal hearings to the licensee whom it finds to be in violation of this chapter or a rule adopted under this chapter.

D. The board on its own motion may investigate any evidence that appears to show 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. Any person may, and a licensee or permittee of the board must, report to the board any information that appears to show 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. The board or the executive director shall notify the pharmacist, pharmacy intern or graduate intern as to the content of the complaint as soon as reasonable. Any person or entity that reports or provides information to the board in good faith is not subject to an action for civil damages. It is an act of unprofessional conduct for any pharmacist, pharmacy intern or graduate intern to fail to report as required by this subsection.

E. The pharmacy permittee or pharmacist in charge of a pharmacy located in this state must inform the board if a pharmacist, pharmacy intern or graduate intern employed by the pharmacy is terminated because of actions by the pharmacist, pharmacy intern or graduate intern that appear to show that the 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, along with a general statement of the reasons that led the pharmacy to take the action. The pharmacy permittee or pharmacist in charge of a pharmacy located in this state must inform the board if a pharmacist, pharmacy intern or graduate intern under investigation resigns or if a pharmacist, pharmacy intern or graduate intern resigns in lieu of disciplinary action by the pharmacy. Notification must include a general statement of the reasons for the resignation. A person who reports information in good faith pursuant to this subsection is not subject to civil liability.

F. The board or, if delegated by the board, the executive director shall require any combination of mental, physical, psychological, psychiatric or medical competency examinations or pharmacist licensure examinations and conduct necessary investigations including investigational interviews between representatives of the board and the pharmacist, pharmacy intern or graduate intern to fully inform itself about any information filed with the board under this section. These examinations may also include biological fluid testing. The board may require the pharmacist, pharmacy intern or graduate intern, at that person's expense, to undergo assessment by a board approved substance abuse treatment and rehabilitation program.

G. If after completing its investigation the board finds that the information provided pursuant to this section is not of sufficient seriousness to merit disciplinary action against the license of the pharmacist, pharmacy intern or graduate intern, the board may take any of the following actions:

1. Dismiss if the complaint is without merit.
2. File an advisory letter. The licensee may file a written response with the board within thirty days after receiving the advisory letter.
3. Require the licensee to complete board designated continuing pharmaceutical education courses.

H. The board shall not disclose the name of the person who provides information regarding a licensee's drug or alcohol impairment or the name of the person who files a complaint if that person requests anonymity.

I. If after completing its investigation the board believes that the information is or may be true, it may request a conference with the pharmacist, pharmacy intern or graduate intern. If the pharmacist, pharmacy intern or graduate intern refuses the invitation for a conference and the investigation indicates that grounds may exist for revocation or suspension of a license, probation, issuance of a decree of censure or a letter of reprimand or imposition of a civil penalty, the board shall issue a formal notice that a hearing be held pursuant to title 41, chapter 6, article 10.

J. If through information provided pursuant to this section or by other means the board finds that the protection of the public health, welfare and safety requires emergency action against the license of a pharmacist, pharmacy intern or graduate intern, the board may restrict a license or order a summary suspension of a license pending proceedings for revocation or other action. If the board acts pursuant to this subsection, the board shall also serve the licensee with a written notice of complaint and formal hearing that sets forth the charges and licensee's right to a formal hearing before the board or an administrative law judge on the charges within sixty days pursuant to title 41, chapter 6, article 10.

K. If after completing the conference the board finds the information provided pursuant to this section is not of sufficient seriousness to merit revocation or suspension of a license, probation, issuance of a decree of censure or a letter of reprimand or imposition of a civil penalty, it may take the following actions:

1. Dismiss if the information is without merit.
2. File an advisory letter. The licensee may file a written response with the board within thirty days after the licensee receives the advisory letter.
3. Require the licensee to complete board designated continuing pharmaceutical education courses.

L. If during a conference the board finds that the information provided pursuant to this section indicates that grounds may exist for revocation or suspension of a license, probation, issuance of a decree of censure or a letter of reprimand or imposition of a civil penalty, it may take the following actions:

1. Dismiss if the information is without merit.
2. File an advisory letter. The licensee may file a written response with the board within thirty days after the licensee receives the advisory letter.
3. Require the licensee to complete board designated continuing pharmaceutical education courses.
4. Enter into an agreement with the licensee to discipline the licensee, restrict the licensee's practice or professional activities or rehabilitate, retrain or assess the licensee in order to protect the public and ensure the licensee's ability to safely engage in the practice of pharmacy. The agreement may include at least the following:
  - (a) Issuance of a letter of reprimand.
  - (b) Issuance of a decree of censure.
  - (c) Practice or professional restrictions, such as not acting as a pharmacist in charge or pharmacy intern preceptor or working with another pharmacist.
  - (d) Rehabilitative, retraining or assessment programs, including:
    - (i) Board approved community service.
    - (ii) Successful completion of additional board designated continuing pharmaceutical education courses.
    - (iii) Successful passage of board approved pharmacist licensure examinations.
    - (iv) Successful completion of a board approved substance abuse treatment and rehabilitation program at the licensee's own expense.
  - (e) A civil penalty not to exceed one thousand dollars for each violation of this chapter or a rule adopted under this chapter.
  - (f) A period and terms of probation best adapted to protect the public health and safety and rehabilitate or educate the licensee concerned. Probation may include temporary suspension and any or all of the disciplinary actions, practice or professional restrictions, rehabilitative, retraining or assessment programs listed in this section or any other program agreed to by the board and the licensee.
- M. If the board finds that the information provided pursuant to this section and additional information provided during the conference warrants revocation or suspension of a license, probation, issuance of a decree of censure or a letter of reprimand or imposition of a civil penalty, it shall initiate formal proceedings pursuant to title 41, chapter 6, article 10.
- N. If the licensee wishes to be present at the formal hearing in person or by representation, or both, the licensee must file with the board an answer to the charges in the notice of hearing. The answer must be in writing, be verified under oath and be filed within thirty days after service of the notice of hearing. Failure to answer the board's notice of hearing is deemed an admission of the charges in the notice of hearing.
- O. An advisory letter is a nondisciplinary public document.
- P. If the board during an investigation determines that a criminal violation might have occurred, it shall disclose its investigative evidence and information to the appropriate criminal justice agency for its consideration.
- Q. In determining the appropriate disciplinary action under this section, the board shall consider all previous nondisciplinary and disciplinary actions against a licensee.
- R. The board may deny a license to an applicant for the grounds prescribed in subsection A of this section.
- S. A person licensed pursuant to this chapter or by any other jurisdiction who has a license revoked or suspended shall not obtain a license as a pharmacy intern, graduate intern, pharmacy technician or pharmacy technician trainee or work as a pharmacy intern, graduate intern, pharmacy technician or pharmacy technician trainee without the approval of the board or its designee.

**32-1927.01. Pharmacy technicians; pharmacy technician trainees; disciplinary action**

- A. A pharmacy technician or pharmacy technician trainee is subject to disciplinary action by the board for any of the following:
1. The board determines that the licensee has committed an act of unprofessional conduct.
  2. The licensee is found by psychiatric examination to be mentally unfit to safely perform the licensee's employment duties.
  3. The licensee is found to be physically or mentally incapacitated to such a degree as to render the licensee unfit to safely perform the licensee's employment duties.
  4. The licensee is found to be professionally incompetent to such a degree as to render the licensee unfit to safely perform the licensee's employment duties.
  5. The license was issued through error.

B. A pharmacy technician or pharmacy technician trainee who after a formal hearing is found by the board to be guilty of unprofessional conduct, to be mentally or physically unable safely to engage in the practice of pharmacy or to be professionally incompetent is subject to any one or combination of the following:

1. A civil penalty of not to exceed one thousand dollars for each violation of this chapter or a rule adopted under this chapter.
2. A letter of reprimand.
3. A decree of censure.
4. Completion of board designated continuing education courses.
5. Probation.
6. Suspension or revocation of the license.

C. The board may charge the costs of formal hearings to the licensee whom it finds to be in violation of this chapter or a rule adopted under this chapter.

D. The board on its own motion may investigate any evidence that appears to show 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. Any person may, and a licensee or permittee of the board must, report to the board any information that appears to show 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. The board or the executive director shall notify the pharmacy technician or pharmacy technician trainee as to the content of the complaint as soon as reasonable. Any person or entity that reports or provides information to the board in good faith is not subject to an action for civil damages. It is an act of unprofessional conduct for any pharmacy technician or pharmacy technician trainee to fail to report as required by this subsection.

E. The pharmacy permittee or pharmacist in charge of a pharmacy located in this state must inform the board if a pharmacy technician or pharmacy technician trainee employed by the pharmacy is terminated because of actions by that person that appear to show that the person 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, along with a general statement of the reasons that led the pharmacy to take the action. The pharmacy permittee or pharmacist in charge of a pharmacy located in this state must inform the board if a pharmacy technician or pharmacy technician trainee under investigation resigns or if a pharmacy technician or pharmacy technician trainee resigns in lieu of disciplinary action by the pharmacy. Notification must include a general statement of the reasons for the resignation. A person who reports information in good faith pursuant to this subsection is not subject to civil liability.

F. The board or, if delegated by the board, the executive director shall require any combination of mental, physical, psychological, psychiatric or medical competency examinations or pharmacy technician licensure examinations and conduct necessary investigations including investigational interviews between representatives of the board and the pharmacy technician or pharmacy technician trainee to fully inform itself about any information filed with the board pursuant to this section. These examinations may also include biological fluid testing. The board may require the licensee, at that person's expense, to undergo assessment by a board approved substance abuse treatment and rehabilitation program.

G. If after completing its investigation the board finds that the information provided pursuant to this section is not of sufficient seriousness to merit disciplinary action against the license of the pharmacy technician or pharmacy technician trainee, the board may take any of the following actions:

1. Dismiss if the complaint is without merit.
2. File an advisory letter. The licensee may file a written response with the board within thirty days after receiving the advisory letter.
3. Require the licensee to complete board designated continuing pharmaceutical education courses.

H. The board shall not disclose the name of the person who provides information regarding a licensee's drug or alcohol impairment or the name of the person who files a complaint if that person requests anonymity.

I. If after completing its investigation the board believes that the information is or may be true, it may request a conference with the licensee. If the licensee refuses the invitation for a conference and the investigation indicates that grounds may exist for revocation or suspension of a license, probation, issuance of a decree of censure or a letter of reprimand or imposition of a civil penalty, the board shall issue a formal notice that a hearing be held pursuant to title 41, chapter 6, article 10.

J. If through information provided pursuant to this section or by other means the board finds that the protection of the public health, welfare and safety requires emergency action against the license of a pharmacy technician or pharmacy technician trainee, the board may restrict a license or order a summary suspension of a license pending proceedings for revocation or other action. If the board acts pursuant to this subsection, the board shall also serve the licensee with a written notice of complaint and formal hearing that sets forth the charges made against the licensee and the licensee's right to a formal hearing before the board or an administrative law judge on the charges within sixty days pursuant to title 41, chapter 6, article 10.

K. If after completing the conference the board finds the information provided pursuant to this section is not of sufficient seriousness to merit revocation or suspension of a license, probation, issuance of a decree of censure or a letter of reprimand or imposition of a civil penalty, it may take the following actions:

1. Dismiss if the information is without merit.
2. File an advisory letter. The licensee may file a written response with the board within thirty days after the licensee receives the advisory letter.
3. Require the licensee to complete board designated continuing pharmaceutical education courses.

L. If during a conference the board finds that the information provided pursuant to this section indicates that grounds may exist for revocation or suspension of a license, probation, issuance of a decree of censure or a letter of reprimand or imposition of a civil penalty, it may take the following actions:

1. Dismiss if the information is without merit.
2. File an advisory letter. The licensee may file a written response with the board within thirty days after the licensee receives the advisory letter.
3. Require the licensee to complete board designated continuing pharmaceutical education courses.
4. Enter into an agreement with the licensee to discipline the licensee, restrict the licensee's practice or professional activities or rehabilitate, retrain or assess the licensee in order to protect the public and ensure the licensee's ability to safely engage in the permissible activities of a pharmacy technician or pharmacy technician trainee. The agreement may include at least the following:
  - (a) Issuance of a letter of reprimand.
  - (b) Issuance of a decree of censure.
  - (c) Practice or professional restrictions, such as doing the following only under pharmacist supervision:
    - (i) Entering prescription or patient data.
    - (ii) Initiating or accepting verbal refill authorization.
    - (iii) Counting, pouring, packaging or labeling prescription medication.
    - (iv) Compounding, reconstituting, prepackaging or repackaging drugs.
  - (d) Rehabilitative, retraining or assessment programs, including:
    - (i) Board approved community service.
    - (ii) Successful completion of additional board designated continuing pharmaceutical education courses.
    - (iii) Successful passage of board approved pharmacist technician licensure examinations.
    - (iv) Successful completion of a board approved substance abuse treatment and rehabilitation program at the licensee's own expense.
  - (e) A civil penalty not to exceed one thousand dollars for each violation of this chapter or a rule adopted under this chapter.
  - (f) A period and terms of probation best adapted to protect the public health and safety and rehabilitate or educate the licensee concerned. Probation may include temporary suspension and any or all of the disciplinary actions, practice or professional restrictions, rehabilitative, retraining or assessment programs listed in this section or any other program agreed to by the board and the licensee.

M. If the board finds that the information provided pursuant to this section and additional information provided during the conference warrants revocation or suspension of a license, probation, issuance of a decree of censure or a letter of reprimand or imposition of a civil penalty, it shall initiate formal proceedings pursuant to title 41, chapter 6, article 10.

N. If the licensee wishes to be present at the formal hearing in person or by representation, or both, the licensee must file with the board an answer to the charges in the notice of hearing. The answer must be in writing, be verified under oath and be filed within thirty days after service of the notice of hearing. Failure to answer the board's notice of hearing is deemed an admission of the charges in the notice of hearing.

O. An advisory letter is a nondisciplinary public document.

P. If the board during an investigation determines that a criminal violation might have occurred, it shall disclose its investigative evidence and information to the appropriate criminal justice agency for its consideration.

Q. In determining the appropriate disciplinary action under this section, the board shall consider all previous nondisciplinary and disciplinary actions against a licensee.

R. The board may deny a license to an applicant for the grounds prescribed in subsection A of this section.

S. A person licensed pursuant to this chapter or by any other jurisdiction who has a license revoked or suspended shall not obtain a license as a pharmacy technician or pharmacy technician trainee or work as a pharmacy technician or pharmacy technician trainee without the approval of the board or its designee.

### **32-1927.02. Permittees; disciplinary action**

A. The board may discipline a permittee if:

1. The board determines that the permittee or permittee's employee is guilty of unethical conduct pursuant to section 32-1901.01, subsection A.
2. Pursuant to a psychiatric examination, the permittee or the permittee's employee is found to be mentally unfit to safely engage in employment duties.

3. The board determines that the permittee or the permittee's employee is physically or mentally incapacitated to such a degree as to render the permittee or permittee's employee unfit to safely engage in employment duties.

4. The permit was issued through error.

5. A permittee or permittee's employee allows a person who does not possess a current license issued by the board to work as a pharmacist, pharmacy intern, graduate intern, pharmacy technician or pharmacy technician trainee.

B. A permittee who after a formal hearing is found by the board to be guilty of unethical conduct, to be mentally or physically unable safely to engage in employment duties or to be in violation of this chapter or a rule adopted under this chapter or whose employee after a formal hearing is found by the board to be guilty of unethical conduct, to be mentally or physically unable safely to engage in employment duties or to be in violation of this chapter or a rule adopted under this chapter is subject to any one or combination of the following:

1. A civil penalty not to exceed one thousand dollars for each violation of this chapter or a rule adopted under this chapter.

2. A letter of reprimand.

3. A decree of censure.

4. Completion of board designated pharmacy law continuing education courses.

5. Probation.

6. Suspension or revocation of the permit.

C. The board may charge the costs of formal hearings to the permittee whom it finds to be in violation of this chapter or a rule adopted under this chapter or whose employee it finds to be in violation of this chapter or a rule adopted under this chapter.

D. The board on its own motion may investigate 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 or is or may be in violation of this chapter or a rule adopted under this chapter. Any person may, and any licensee or permittee must, report to the board any information 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 or is or may be in violation of this chapter or a rule adopted under this chapter. The board or the executive director shall notify the permittee as to the content of the complaint as soon as reasonable. Any person or entity that reports or provides information to the board in good faith is not subject to an action for civil damages. It is an act of unethical conduct for any permittee to fail to report as required by this subsection.

E. The board or, if delegated by the board, the executive director shall require any combination of mental, physical, psychological, psychiatric or medical competency examinations and conduct necessary investigations including investigational interviews between representatives of the board and the permittee or permittee's employee to fully inform itself about any information filed with the board under subsection D of this section. These examinations may also include biological fluid testing. The board may require the permittee or permittee's employee, at that person's expense, to undergo assessment by a board approved substance abuse treatment and rehabilitation program.

F. If after completing its investigation the board finds that the information provided pursuant to subsection D of this section is not of sufficient seriousness to merit disciplinary action against the permit, the board may take any of the following actions:

1. Dismiss if the complaint is without merit.

2. File an advisory letter. The permittee may file a written response with the board within thirty days after receiving the advisory letter.

3. Require the permittee to complete board designated pharmacy law continuing education courses.

G. The board shall not disclose the name of the person who provides information regarding a permittee's or permittee's employee's drug or alcohol impairment or the name of the person who files a complaint if that person requests anonymity.

H. If after completing its investigation the board believes that the information is or may be true, it may request a conference with the permittee or permittee's employee. If the permittee or permittee's employee refuses the invitation for a conference and the investigation indicates that grounds may exist for revocation or suspension of a permit, probation, issuance of a decree of censure or a letter of reprimand or imposition of a civil penalty, the board shall issue a formal notice that a hearing be held pursuant to title 41, chapter 6, article 10.

I. If through information provided pursuant to subsection D of this section or by other means the board finds that the protection of the public health, welfare and safety requires emergency action against the permit, the board may restrict a permit or order a summary suspension of a permit pending proceedings for revocation or other action. If the board acts pursuant to this subsection, the board shall also serve the permittee with a written notice of complaint and formal hearing that sets forth the charges and the permittee's right to a formal hearing on the charges before the board or an administrative law judge within sixty days pursuant to title 41, chapter 6, article 10.

J. If after completing the conference the board finds the information provided pursuant to subsection D of this section is not of sufficient seriousness to merit revocation or suspension of a permit, probation, issuance of a decree of censure or a letter of reprimand or imposition of a civil penalty, it may take the following actions:

1. Dismiss if the information is without merit.

2. File an advisory letter. The permittee may file a written response with the board within thirty days after receiving the advisory letter.

3. Require the permittee to complete board designated pharmacy law continuing education courses.

K. If during a conference the board finds that the information provided pursuant to subsection D of this section indicates that grounds may exist for revocation or suspension of a permit, probation, issuance of a decree of censure or a letter of reprimand or imposition of a civil penalty, it may take the following actions:

1. Dismiss if the information is without merit.
2. File an advisory letter. The permittee may file a written response with the board within thirty days after the permittee receives the advisory letter.
3. Require the permittee to complete board designated pharmacy law continuing education courses.
4. Enter into an agreement with the permittee to discipline the permittee, restrict the permittee's business activities or rehabilitate or assess the permittee in order to protect the public and ensure the permittee's ability to safely engage in employment duties. The agreement may include, at a minimum, the following disciplinary actions, business activity restrictions and rehabilitative or assessment programs:
  - (a) Issuance of a letter of reprimand.
  - (b) Issuance of a decree of censure.
  - (c) Business activity restrictions, including limitations on the number, type, classification or schedule of drug, device, poison, hazardous substance, controlled substance or precursor chemical that may be manufactured, sold, distributed or dispensed.
  - (d) Successful completion of board designated pharmacy law continuing education courses.
  - (e) Rehabilitative or assessment programs, including board approved community service or successful completion of a board approved substance abuse treatment and rehabilitation program at the permittee's own expense.
  - (f) A civil penalty not to exceed one thousand dollars for each violation of this chapter or a rule adopted under this chapter.
  - (g) A period and terms of probation best adapted to protect the public health and safety and rehabilitate or assess the permittee concerned. Probation may include temporary suspension and any or all of the disciplinary actions, business practice restrictions, rehabilitative or assessment programs listed in this section or any other program agreed to by the board and the permittee.

L. If the board finds that the information provided pursuant to subsection D of this section and additional information provided during the conference indicates that grounds may exist for revocation or suspension of a permit, probation, issuance of a decree of censure or a letter of reprimand or imposition of a civil penalty, it shall initiate formal proceedings pursuant to title 41, chapter 6, article 10.

M. If the permittee wishes to be present at the formal hearing in person or by representation, or both, the permittee must file with the board an answer to the charges in the notice of hearing. The answer must be in writing, be verified under oath and be filed within thirty days after service of the notice of hearing. Failure to answer the board's notice of hearing is deemed an admission of the charges in the notice of hearing.

N. If the board, during any investigation, determines that a criminal violation might have occurred, it shall disclose its investigative evidence and information to the appropriate criminal justice agency for its consideration.

O. In determining the appropriate disciplinary action under this section, the board shall consider all previous nondisciplinary and disciplinary actions against a permittee.

P. The board may deny a permit to an applicant for the grounds prescribed in subsection A of this section.

### **32-1928. Hearings; restraining order; judicial review**

A. Except as provided in subsection B of this section, a license shall be denied, revoked or suspended or a pharmacist or pharmacy intern shall be placed on probation or censured and a civil penalty imposed only after due notice and a hearing pursuant to title 41, chapter 6, article 10. A licensee shall respond in writing to the board when the licensee receives notice of the hearing.

B. If the board has reasonable grounds to believe and finds that the licensee has been guilty of deliberate and willful violations, or that the public health, safety and welfare imperatively require immediate action, and incorporates a finding to that effect in its order, the board may order a summary suspension of the license pending a hearing. If the board issues an order of summary suspension, it shall serve the licensee with written notice of the complaint and hearing setting forth the charges and informing the licensee of the licensee's right to the hearing. The board shall institute the hearing within ten days after ordering the summary suspension. Service shall be by personal service as provided by the Arizona rules of civil procedure.

C. Except as provided in section 41-1092.08, subsection H, final decisions of the board are subject to judicial review pursuant to title 12, chapter 7, article 6.

D. With or without conditions, the board may reinstate the license of any pharmacist or pharmacy intern that it has placed on probation or whose license it has suspended or revoked.

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

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

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

C. The application for a permit to operate a pharmacy, drug manufacturing facility or wholesaling facility in this state shall be made on a form prescribed and furnished by the board which, when properly executed, indicates the ownership, trustee, receiver or other person or persons desiring the permit, including the pharmacist responsible to the board for the operation of a pharmacy or drug manufacturing facility, or other individual approved by and responsible to the board for the operation of wholesaling facilities, as well as the location, including the street name and number, and such other information as required by the board to establish identity, exact location and extent of activities, in which or from which drugs are sold, manufactured, compounded, dispensed, stocked, exposed or offered for sale.

D. The application for a permit to operate a pharmacy, drug manufacturing facility or wholesaling facility outside of this state that will dispense, sell, transfer or distribute drugs into the state shall be made on a form prescribed and furnished by the board, which, when properly executed, indicates the ownership, trustee, receiver or other person or persons desiring the permit, including the individual approved by and responsible to the board for the operation of the pharmacy, drug manufacturing facility or wholesaling facility, as well as the location including the street name and number, and such other information as required by the board to establish the identity, exact location and extent of activities, in which or from which drugs are sold, manufactured, compounded, dispensed, stocked, exposed or offered for sale.

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

### **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, full service wholesale drug, nonprescription drug wholesale and drug manufacturer's permit.

3. Drug packager or drug pre-packager 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, re-label 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.

### **32-1931. Permit fees; issuance; expiration; renewals**

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. The board shall prorate the fee for new permits for the remaining full calendar months of the respective group to which the permit is assigned.

C. 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.

D. Applications for permits shall be accompanied by the following biennial fees as determined by subsection C 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, not more than five hundred dollars.
5. A full service wholesale drug 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.

E. 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.

F. Permits issued under this section are not transferable.

G. 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.

**32-1932.01. Substance abuse treatment and rehabilitation program: private contract: funding**

A. The board may establish a program for the treatment and rehabilitation of licensees who are impaired by alcohol or drug abuse. This program shall include education, intervention, therapeutic treatment and post treatment monitoring and support.

B. The board may contract with other organizations to operate the program established pursuant to subsection A of this section. A contract with a private organization shall include the following requirements:

1. Periodic reports to the board regarding treatment program activity.
2. Pursuant to a written request by the board or its executive director, release of all treatment records.
3. Quarterly reports to the board, by case number, regarding each participant's diagnosis, prognosis and recommendations for continuing care, treatment and supervision.
4. Immediate reporting to the board of the name of an impaired licensee who the treating organization believes to be a danger to self or others.
5. Reports to the board, as soon as possible, of the name of a participant who refuses to submit to treatment or whose impairment is not substantially alleviated through treatment.

C. The board may allocate an amount of not to exceed twenty dollars from each fee it collects from biennial renewal licenses pursuant to section 32-1925 for the operation of the program established by this section.

D. A licensee who is impaired by alcohol or drug abuse may enter into a stipulation order with the board, or the licensee may be placed on probation or be subject to other action as provided by law.

**32-1933. Display of license or permit**

A. The holder of a permit granted under this chapter shall conspicuously display it in the location to which it applies.

B. A licensee shall maintain the licensee's current renewal license or duplicate current renewal license, if practicing in more than one location, in the practice site for inspection by the board or its designee or review by the public.

C. If a licensee practices in more than one place, the board may issue one or more duplicate current renewal licenses to the licensee on payment of a fee of not more than twenty-five dollars for each duplicate current renewal license.

### **32-1934. Pharmacy operated by hospital**

A. A pharmacy operating in connection with a hospital shall comply with all the provisions of this chapter requiring registration and regulation of pharmacies and with board rules.

B. A pharmacy operating in connection with a hospital shall also meet the following requirements:

1. In hospitals with fifty beds or more, the pharmacy shall be under the continuous supervision of a pharmacist during the time it is open for pharmacy services, except that the board by rule may establish requirements to allow a pharmacist who is engaged in hospital business to be in other areas of the hospital that are located outside the pharmacy.

2. In hospitals with less than fifty beds, with the written approval and recommendations of the board, the services of a pharmacist shall be required on a part-time basis according to the needs of the hospital, provided that this approval does not permit the compounding, manufacturing, dispensing, labeling, packaging or processing of drugs by other than a pharmacist.

3. In the pharmacist's absence from the hospital, the supervisory registered nurse may obtain from the pharmacy necessary doses of drugs that are ordered by a medical practitioner and that are needed by a patient in an emergency, according to procedures recommended and approved by the board for each hospital.

4. All drugs and medications furnished from the pharmacy to patients on discharge from the hospital shall be dispensed by a pharmacist and the medication shall be properly labeled.

5. The pharmacist in charge shall initiate procedures to provide for the administrative and technical guidance in all matters pertaining to the acquiring, stocking, record keeping and dispensing of drugs and devices.

### **32-1935. Approval of schools and colleges of pharmacy**

The board of pharmacy shall adopt and promulgate standards and requirements for approval of schools and colleges of pharmacy.

### **32-1936. Mandatory continuing professional pharmacy education**

A. All pharmacists licensed in this state shall satisfactorily complete approved courses of continuing professional pharmacy education or continue their education by other means in accordance with rules adopted by the board before renewing a license.

B. The board by rule shall establish the form and content of courses for continuing professional pharmacy education and the number of hours required for renewal of a license.

### **32-1937. Exceptions to continuing education requirements**

A. The requirements of continuing professional pharmacy education provided in section 32-1936 do not apply to licensees during the year of their graduation from an accredited college of pharmacy.

B. The board may make exceptions from the requirements of section 32-1936 in emergency or hardship cases or for good cause shown based on a written request for an exception from the requirements.

C. Pharmacists who are exempted from the requirements of continuing professional pharmacy education pursuant to subsection B of this section shall satisfactorily pass a written examination approved by the board for such purpose prior to license renewal.

### **32-1939. Condition of probation: repayment of inspection costs**

A. As a condition of probation, the board may require that a licensee or permittee be subject to additional compliance inspections or audits and pay the reasonable costs of these inspections and audits. These costs shall not exceed one thousand dollars. The board shall limit these additional inspections to no more than two per year.

B. Monies received pursuant to subsection A of this section shall be deposited, pursuant to sections 35-146 and 35-147, in the Arizona state board of pharmacy fund.

C. If a licensee or permittee fails to comply with a board order regarding the costs of additional inspections and audits, the board may enforce its order in the superior court in Maricopa County. The board may also impose additional sanctions against the licensee or permittee.

### **32-1940. Investigations; hearings; conferences; records; confidentiality**

A. Information received and records kept by the board in connection with investigations conducted pursuant to this chapter before a public hearing or conference are confidential and are not open to the public or subject to civil discovery.

B. Notwithstanding any other law or code of ethics regarding practitioner confidences, the physician-patient privilege between a medical practitioner and a patient, both as it relates to the competency of the witness and to the exclusion of confidential communications, does not pertain to any board investigations or other proceedings conducted pursuant to this chapter to the extent necessary to determine if a violation of this chapter has occurred. Communications or records disclosed pursuant to this subsection are confidential and may be used only in a judicial or administrative proceeding or investigation resulting from a report, investigation or hearing required or authorized under this chapter.

C. The board, its employees and agents and any other person receiving this information shall keep the identity of the patient confidential at all times.

D. The board shall report evidence of a crime uncovered during an investigation to the appropriate criminal justice agency.

E. This section does not prevent the board from disclosing investigative materials concerning a licensee's alleged violation of this chapter to the licensee or the licensee's attorney.

### **ARTICLE 3 REGULATION:**

#### **32-1961. Limitation on dispensing, compounding and sale of drugs**

A. It is unlawful for any person to compound, sell or dispense any drugs or to dispense or compound the prescription orders of a medical practitioner, unless that person is a pharmacist or a pharmacy intern acting under the direct supervision of a pharmacist, except as provided in section 32-1921. This subsection does not prevent a pharmacy technician or support personnel from assisting in the dispensing of drugs if this is done pursuant to rules adopted by the board and under the direct supervision of a licensed pharmacist.

B. It is unlawful for any person, without placing a pharmacist in active personal charge at each place of business, to:

1. Open, advertise or conduct a pharmacy.
2. Stock, expose or offer drugs for sale at retail, except as otherwise specifically provided.
3. Use or exhibit the title "drugs", "drugstore", "drug shop", "pharmacy", "apothecary" or any combination of these words or titles or any title, symbol or description of like import or any other term designed to take its place.

#### **32-1962. New drug; compliance with federal act; exception**

A. No person shall manufacture, sell, offer or hold for sale or give away any new drug or device unless it fully complies with the provisions of the federal act.

B. This section shall not apply to the nutritional supplement amygdalin, a cyano-genetic glycoside, also known as laetrile and vitamin B-17, which is processed from the seeds of certain fruits including apricots, peaches and plums.

#### **32-1963. Liability of manager, proprietor or pharmacist in charge of a pharmacy; variances in quality of drugs or devices prohibited**

A. The proprietor, manager, and pharmacist in charge of a pharmacy shall be responsible for the quality of drugs and devices sold or dispensed in the pharmacy, except those sold in original packages of the manufacturer.

B. No pharmacist or other person shall manufacture, compound, dispense, or offer for sale or cause to be manufactured, compounded, dispensed, or offered for sale any drug or device under or by a name recognized in the official compendium or the federal act which differs from the standard of strength, purity and quality specified therein as official at the time of manufacture, compounding, dispensing, or offering for sale, nor shall a pharmacist or other person manufacture, compound, dispense, or offer for sale, or cause to be manufactured, compounded, dispensed, or offered for sale, any drug or device, the strength, purity or quality of which falls below the required strength, purity or quality under which it is sold.

C. Within four working days of receiving a request, the proprietor, manager or pharmacist in charge shall provide the following documents relating to the acquisition or disposal of prescription-only and controlled substance medication if this information is requested by an authorized board agent in the course of his official duties:

1. Invoices.
2. Stock transfer documents.
3. Merchandise return memos.
4. Other related documentation.

**32-1963.01. Substitution for prescription drugs; requirements; label; definitions**

A. If a medical practitioner prescribes a brand name drug and does not indicate an intent to prevent substitution as prescribed in subsection D of this section, a pharmacist may fill the prescription with a generic equivalent drug.

B. Any pharmacy personnel shall notify the person presenting the prescription of the amount of the price difference between the brand name drug prescribed and the generic equivalent drug, if both of the following apply:

1. The medical practitioner does not indicate an intent to prevent substitution with a generic equivalent drug.
2. The transaction is not subject to third party reimbursement.

C. The pharmacist shall place on the container the name of the drug dispensed followed by the words "generic equivalent for" followed by the brand or trade name of the product that is being replaced by the generic equivalent. The pharmacist shall include the brand or trade name on the container or label of any contact lenses dispensed pursuant to this chapter.

D. A prescription generated in this state must be dispensed as written only if the prescriber writes or clearly displays "DAW", "Dispense as written", "do not substitute", "medically necessary" or any statement by the prescriber that clearly indicates an intent to prevent substitution on the face of the prescription form. A prescription from out of state or from agencies of the United States government must be dispensed as written only if the prescriber writes or clearly displays "do not substitute", "dispense as written" or "medically necessary" or any statement by the prescriber that clearly indicates an intent to prevent substitution on the face of the prescription form.

E. This section applies to all prescriptions, including those presented by or on behalf of persons receiving state or federal assistance payments.

F. An employer or agent of an employer of a pharmacist shall not require the pharmacist to dispense any specific generic equivalent drug or substitute any specific generic equivalent drug for a brand name drug against the professional judgment of the pharmacist or the order of the prescriber.

G. The liability of a pharmacist in substituting according to this section shall be no greater than that which is incurred in the filling of a generically written prescription. This subsection does not limit or diminish the responsibility for the strength, purity or quality of drugs provided in section 32-1963. The failure of a prescriber to specify that no substitution is authorized does not constitute evidence of negligence.

H. A pharmacist may not make a substitution pursuant to this section unless the manufacturer or distributor of the generic drug has shown that:

1. All products dispensed have an expiration date on the original package.
2. The manufacturer or distributor maintains recall and return capabilities for unsafe or defective drugs.

I. The labeling and oral notification requirements of this section do not apply to pharmacies serving patients in a health care institution as defined in section 36-401. However, in order for this exemption to apply to hospitals, the hospital must have a formulary to which all medical practitioners of that hospital have agreed and that is available for inspection by the board.

J. For the purposes of this section:

1. "Brand name drug" means a drug with a proprietary name assigned to it by the manufacturer or distributor.
2. "Formulary" means a list of medicinal drugs.
3. "Generic equivalent" or "generically equivalent" means a drug that has an identical amount of the same active chemical ingredients in the same dosage form, that meets applicable standards of strength, quality and purity according to the United States pharmacopeia or other nationally recognized compendium and that, if administered in the same amounts, will provide comparable therapeutic effects. Generic equivalent or generically equivalent does not include a drug that is listed by the federal food and drug administration as having unresolved bioequivalence concerns according to the administration's most recent publication of approved drug products with therapeutic equivalence evaluations.

**32-1964. Record of prescription orders; inspections; confidentiality**

A. Every proprietor, manager or pharmacist in charge of a pharmacy shall keep in the pharmacy a book or file in which that person places the original of every prescription order of drugs, devices or replacement soft contact lenses that are compounded or dispensed at the pharmacy. This information shall be serially numbered, dated and filed in the order in which the drugs, devices or replacement soft contact lenses were compounded or dispensed. A prescription order shall be kept for at least seven years. The proprietor, manager or pharmacist shall produce this book or file in court or before any grand jury on lawful order. The book or file of original prescription orders is open for inspection at all times by the prescribing medical practitioner, the board and its agents and officers of the law in performance of their duties.

B. The board, by rule, shall permit pharmacies to maintain the book or file of all original prescription orders by means of electronic media or image of the original prescription order maintained in a retrievable format in a form that contains information the board requires to provide an adequate record of drugs, devices or replacement soft contact lenses compounded or dispensed.

C. The board, by rule, shall require a similar book or file for a hospital pharmacy in a form that contains information the board requires to provide an adequate record of drugs compounded or dispensed. A prescription order or medication order must be kept for at least seven years. The administrator, manager or pharmacist must produce this book or file in court or before any grand jury on lawful order. The book or file of original prescription orders or medication orders is open for inspection at all times by the prescribing medical practitioner, the board and its agents and officers of the law in performance of their duties.

D. A pharmacist, pharmacy permittee or pharmacist in charge shall comply with applicable state and federal privacy statutes and regulations when releasing patient prescription information.

### **32-1965. Prohibited acts**

The following acts or the causing of any thereof, in addition to any others so specified in this chapter, are prohibited:

1. The manufacture, sale, holding or offering for sale of any drug, device, poison, or hazardous substance that is adulterated or misbranded.
2. The adulteration or misbranding of any drug, device, poison, or hazardous substance.
3. The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a drug, device, poison, or hazardous substance, if such act is done while such article is held for sale and results in such article being adulterated or misbranded.
4. The manufacture, sale, holding or offering for sale of a counterfeit drug or forging, counterfeiting, simulating, or falsely representing or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by rules adopted under the provisions of this chapter, or of the federal act.
5. The using, on the labeling of any drug or device, or in any advertisement, relating to such drug or device, of any representation or suggestion that such drug or device complies with the provisions of this chapter.
6. In the case of a prescription-only drug or a controlled substance that requires a prescription order by state or federal law, the failure of the manufacturer, packer, or distributor to transmit, to any medical practitioner who makes a written request for information about such drug, true and correct copies of all printed matter included in any package in which that drug is distributed or other printed matter approved under the federal act.
7. Engaging in the practice of pharmacy without first having a current license in good standing issued by the board.
8. Making or offering to make a forged, counterfeit, altered or photocopied prescription or drug order for the purpose of obtaining prescription-only or controlled substance drugs.

### **32-1966. Acts constituting adulteration of a drug or device**

A drug or device shall be deemed to be adulterated:

1. If it consists in whole or in part of any filthy, putrid or decomposed substance.
2. If it has been produced, prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or is not securely protected from dust, dirt, and, as far as may be necessary by all reasonable means, from all foreign or injurious contamination, or whereby it may have been rendered injurious to health.
3. If the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug or device meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality, which it is represented to possess.
4. If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.
5. If:
  - (a) It bears or contains a color additive which is unsafe within the meaning of the federal act.
  - (b) It is a color additive, the intended use of which in or on drugs is for the purpose of coloring only, and is unsafe within the meaning of the federal act.
6. If it is a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label.

7. If it is not subject to the provisions of paragraph 6 of this section and its strength differs from, or its purity or quality falls below that which it purports or is represented to possess.

8. If it is a drug or device to which any substance has been mixed or packed therewith so as to reduce its quality or strength, or to be substituted for it in whole or in part.

**32-1967. Acts constituting misbranding of a drug or device; exceptions; interpretation of misleading label**

A. A drug or device is misbranded:

1. If its labeling is false or misleading in any particular.

2. If in package form unless it bears a label containing both:

(a) The name and place of business of the manufacturer, packer or distributor.

(b) An accurate statement of the quantity of the contents in terms of weight, measure or numerical count.

3. If any word, statement or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed on the label or labeling. Compliance with the federal act shall be deemed compliance with this chapter except for compliance with paragraph 16 of this subsection.

4. If it is for use by humans and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marijuana, morphine, opium, paraldehyde, peyote or sulfonmethane, or any chemical derivative of such substance, which derivative or other substance has been found to be habit-forming, unless its label bears the name and quantity or proportion of such substance or derivative.

5. If it is a drug unless its label bears, to the exclusion of any other nonproprietary name, both:

(a) The established name of the drug, if there is an established name.

(b) In case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient, including the kind and quantity or proportion of any alcohol, and also including, whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glycosides, mercury, strychnine or thyroid, or derivative or preparation of any such substances, provided that the requirements for stating the quantity of the active ingredients, other than those specifically named in this subdivision, apply only to prescription drugs.

6. Unless its labeling bears both:

(a) Adequate directions for use.

(b) Adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in a manner and form as are necessary for the protection of users.

7. If it is recognized in an official compendium, unless it is packed and labeled as prescribed in such compendium, provided that the method of packing may be modified with the consent of the board.

8. If it has been found by the board to be a drug or device liable to deterioration, unless it is packaged in that form and manner, and its label bears a statement of such precautions, as the rules issued by the board require as necessary for the protection of public health.

9. If its container is so made, formed or filled as to be misleading.

10. If it is an imitation of another drug or device.

11. If it is offered for sale under the name of another drug or device.

12. If it is dangerous to health when used in the dosage, manner or with the frequency or duration prescribed, recommended or suggested in the labeling of the drug or device.

13. If it is a color additive, the intended use of which in or on drugs or devices is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive in the federal act or board rule.

14. In the case of any prescription-only drug or controlled substance distributed or offered for sale in this state, unless the manufacturer, packer or distributor of such drug or substance includes in all advertisements and other printed matter with respect to that drug a true statement of:

- (a) The established name.
- (b) The formula showing quantitatively each ingredient.
- (c) Other information in brief summary relating to side effects, contraindications or effectiveness as required in board rules or the federal act.

15. If a trademark, trade name or other identifying mark, imprint or device of another drug or device or any likeness of another drug or device has been placed on the drug or device or on its container with intent to defraud.

16. In the case of any prescription-only drug or controlled substance if in final dosage form unless it bears a label containing both:

- (a) The name and place of business of the manufacturer, and if different, the packer or distributor.
- (b) An accurate statement of the quantity of the contents in terms of weight, measure or numerical count.

B. Drugs and devices which are to be processed, labeled or repacked at establishments other than those where originally processed or packed are exempt from any labeling or packaging requirements of this chapter, provided that such drugs and devices are being delivered, manufactured, processed, labeled, repacked or otherwise held in compliance with board rules or under the federal act.

C. If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account, among other things, not only representations made or suggested by statement, word, design, device or any combination of them, but also the extent to which the labeling fails to reveal facts material in the light of such representations, or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling or under such conditions of use as are customary or usual.

**32-1968. Dispensing prescription-only drug; prescription orders; refills; labels; misbranding; dispensing soft contact lenses**

A. A prescription-only drug shall be dispensed only under one of the following conditions:

1. By a medical practitioner in conformance with section 32-1921.
2. On a written prescription order bearing the prescribing medical practitioner's manual signature.
3. On an electronically transmitted prescription order containing the prescribing medical practitioner's electronic or digital signature that is reduced promptly to writing and filed by the pharmacist.
4. On a written prescription order generated from electronic media containing the prescribing medical practitioner's electronic or manual signature. A prescription order that contains only an electronic signature must be applied to paper that uses security features that will ensure the prescription order is not subject to any form of copying or alteration.
5. On an oral prescription order that is reduced promptly to writing and filed by the pharmacist.
6. By refilling any written, electronically transmitted or oral prescription order if a refill is authorized by the prescriber either in the original prescription order, by an electronically transmitted refill order that is documented promptly and filed by the pharmacist or by an oral refill or
7. On a prescription order that the prescribing medical practitioner or the prescribing medical practitioner's agent transmits by fax or electronic mail.
8. On a prescription order that the patient transmits by fax or by email if the patient presents a written prescription order bearing the prescribing medical practitioner's manual signature when the prescription-only drug is picked up at the pharmacy.

**REMEMBER: IT IS IMPERATIVE THAT THE ORIGINAL SIGNED COPY OF THE RX BE COLLECTED BEFORE DISPENSING**

B. A prescription order shall not be refilled if it is either:

1. Ordered by the prescriber not to be refilled.
2. More than one year since it was originally ordered.

C. A prescription order shall contain the date it was issued, the name and address of the person for whom or owner of the animal for which the drug is ordered, refills authorized, if any, the legibly printed name, address and telephone number of the prescribing medical practitioner, the name, strength, dosage form and quantity of the drug ordered and directions for its use.

D. Any drug dispensed in accordance with subsection A of this section is exempt from the requirements of section 32-1967, except subsection A, paragraphs 1, 10 and 11 and the packaging requirements of subsection A, paragraphs 7 and 8, if the drug container bears a label containing the name and address of the dispenser, serial number, date of dispensing, name of the prescriber, name of the patient, or, if an animal, the name of the owner of the animal and the species of the animal, directions for use and cautionary statements, if any, contained in the order. This exemption does not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail or the internet or to a drug dispensed in violation of subsection A of this section.

E. The board may also by rule require additional information on the label of prescription medication that the board believes to be necessary for the best interest of the public's health and welfare.

F. A prescription-only drug or a controlled substance that requires a prescription order is deemed to be misbranded if, at any time before dispensing, its label fails to bear the statement "Rx only". A drug to which subsection A of this section does not apply is deemed to be misbranded if, at any time before dispensing, its label bears the caution statement quoted in this subsection.

G. A pharmacist may fill a prescription order for soft contact lenses only as provided in this chapter.

#### **32-1969. Filling foreign prescription orders; records; exception**

A. This chapter does not prohibit a pharmacist or an intern under a pharmacist's supervision from filling a new written prescription order for a drug or device issued by a medical practitioner licensed by the appropriate licensing board of a foreign country.

B. The proprietor, manager or pharmacist in charge of a pharmacy shall keep a separate record of prescriptions filled pursuant to this section.

C. A pharmacist or intern shall not fill a prescription order issued by a medical practitioner licensed by the appropriate licensing board of a foreign country for a controlled substance as defined pursuant to title 36, chapter 27, article 2.

#### **32-1970. Implementing, monitoring and modifying drug therapy and use; conditions; definitions \*REVISED\***

A. A pharmacist licensed pursuant to this chapter may implement, monitor and modify drug therapy and use only under the following circumstances:

1. The patient's drug therapy and use are pursuant to a provider.

2. The pharmacist complies with rules adopted by the state board of pharmacy.

3. The pharmacist follows the written drug therapy management protocols prescribed by the provider who made the diagnosis and implements, monitors or modifies a person's drug therapy and use only pursuant to those protocols. Each protocol developed pursuant to the drug therapy agreement shall contain detailed directions concerning the actions that the pharmacist may perform for that patient. The protocol shall specify, at a minimum, the specific drug or drugs to be managed by the pharmacist, the conditions and events for which the pharmacist must notify the provider and the laboratory tests that may be ordered. A provider who enters into a protocol-based drug therapy agreement must have a legitimate provider-patient relationship.

B. A licensee who violates this section commits an act of unprofessional conduct.

C. A pharmacist is responsible for the pharmacist's negligent acts that are the result of the pharmacist's change of medication or that relate to patient drug usage pursuant to drug therapy management protocols. This subsection does not limit a provider's liability for negligent acts that are not related to a pharmacist's change of medication pursuant to the protocols.

D. For the purposes of this section:

1. "Implement, monitor and modify" means that a pharmacist may perform specific acts as authorized by a provider pursuant to written guidelines and protocols. This does not include the selection of drug products not prescribed by the provider unless selection of the specific drug product is authorized by the written guidelines and protocols.

2. "Protocol" means a provider's written order, written standing medical order or other written order of protocol as defined by rules adopted by the Arizona medical board and the board of osteopathic examiners in medicine and surgery and that are patient, provider and pharmacist specific for prescriptions or orders given by the provider authorizing the written protocol.

3. "Provider" means a physician who is licensed pursuant to chapter 13 or 17 of this title or a registered nurse practitioner who is licensed pursuant to chapter 15 of this title and who acts as a primary care practitioner.

#### **32-1971. Single active ingredient pseudoephedrine products; location**

A permittee under this chapter shall keep products in which pseudoephedrine is the single active ingredient behind a store counter or in a locked facility that is inaccessible to customers without the assistance of the permittee or an employee of the permittee, except that this restriction does not apply to liquid, liquid capsule or gel capsule forms of these products.

**32-1972. Poison or hazardous substances; misbranding and labeling; prohibitions; exemption**

A. A poison or hazardous substance shall be misbranded unless the label bears, and accompanied information that it includes or bears, any directions for use which states conspicuously:

1. The name and address of the manufacturer or seller.
2. The common or usual name or the chemical name, if there is no common or usual name, of the poison or hazardous substance or of each component which contributes substantially to its poisonous or hazardous property, unless the board by rule permits or requires the use of a recognized generic name.
3. The signal words "poison" and "danger" and the skull and crossbones symbol on poisons or hazardous substances which are highly toxic.
4. The signal word "danger" on poisons or hazardous substances that are corrosive.
5. The signal word "warning" or "caution" on all other poisons or hazardous substances.
6. An affirmative statement as to the principal poisonous property, such as "flammable", "vapor harmful", "causes burns", "absorbed through skin", or similar wording descriptive of the poison or hazardous substance.
7. Precautionary measures describing the action to be followed or avoided.
8. Instruction, when necessary or appropriate, for first-aid treatment.
9. Instructions for handling and storage of packages which require special care in handling or storage.
10. The statement "keep out of reach of children" or its practical equivalent, or, if the poison or hazardous substance is intended for use by children, adequate directions for the protection of children from the poison or hazardous substance.
11. Directions for using the poison or hazardous substance.

B. A poison or hazardous substance is also misbranded by the reuse of a food, drug or cosmetic container, or in a container which, though not reused, is identifiable as a food, drug or cosmetic container by its labeling or by other identification, as a container for the poison or hazardous substance.

C. Any statement required on the label of a poison or hazardous substance under subsection A shall be:

1. Located prominently.
2. In the English language.
3. In conspicuous and legible type in contrast by typography, layout, or color with other printed matter on the label.

D. If the board finds that the requirements of subsections A and B are not adequate for the protection of the public health and safety in view of the special hazard presented by any particular poison or hazardous substance, it may establish by rule such reasonable variations or additional label requirements as it finds necessary, and any such poison or hazardous substance intended, or packaged in a form suitable, for use in the household or by children which fails to bear a label in accordance with such rules shall be deemed to be a misbranded poison or hazardous substance.

E. If the board finds that, because of the size of the package involved or because of the minor hazard presented by the poison or hazardous substance contained therein, or for other good and sufficient reasons, full compliance with the labeling requirements otherwise applicable under this section is impracticable or is not necessary for the adequate protection of the public health and safety, the board shall adopt rules exempting such poisons or hazardous substances from these requirements to the extent they determine to be consistent with adequate protection of the public health and safety.

F. If the board finds that the poisonous or hazardous nature of a poison or hazardous substance subject to this section is such that the labeling adequate to protect the public health and safety cannot be devised, or the poison or hazardous substance presents an imminent danger to the public health and safety, the board by rule may restrict the sale of such poison or hazardous substance or declare it to be banned and require its removal from commerce.

G. The board shall conform the rules adopted under this section as far as practicable with the regulations established pursuant to the federal hazardous substances act.

**32-1973. Pharmacies; quality assurance**

A. As prescribed by the board by rule, each pharmacy shall implement or participate in a continuous quality assurance program to review pharmacy procedures in order to identify methods for addressing pharmacy medication errors. The rules shall prescribe requirements to document compliance and any other provisions necessary for the administration of the program.

B. Records that are generated as a component of a pharmacy's ongoing quality assurance program and that are maintained for that program are peer review documents and are not subject to subpoena or discovery in an arbitration or civil proceeding. This subsection does not prohibit a patient from accessing the patient's prescription records or affect the discoverability of any records that are not generated only as a component of a pharmacy's ongoing quality assurance program and maintained only for that program.

C. A pharmacy meets the requirements of this section if it holds a current general, special or rural general hospital license from the department of health services and is any of the following:

1. Certified by the Centers for Medicare and Medicaid services to participate in the Medicare or Medicaid programs.
2. Accredited by the joint commission on the accreditation of health care organizations.
3. Accredited by the American Osteopathic Association.

**32-1974. Pharmacists: administration of immunizations, vaccines and emergency medications: certification: reporting requirements: advisory committee: definition**

A. Except as prescribed pursuant to subsection I of this section, a pharmacist who is licensed pursuant to this chapter and who meets the requirements of this section may administer the following to adults without a prescription order pursuant to rules and protocols adopted by the board pursuant to this section:

1. Immunizations or vaccines listed in the United States Centers for Disease Control and prevention's recommended adult immunization schedule.
2. Immunizations or vaccines recommended by the United States Centers for Disease control and prevention's health information for international travel.

B. A pharmacist who is licensed pursuant to this chapter and who meets the requirements of this section may administer the following to a person who is at least six years of age but under eighteen years of age without a prescription order pursuant to rules and protocols adopted by the board pursuant to this section:

1. Immunizations or vaccines for influenza.
2. Immunizations or vaccines in response to a public health emergency declared by the governor pursuant to section 36-787.

C. Pursuant to a prescription order, a pharmacist who is licensed pursuant to this chapter and who meets the requirements of this section may administer immunizations and vaccines to a person who is at least six years of age but under eighteen years of age pursuant to rules and protocols adopted by the board pursuant to this section.

D. A pharmacist who wishes to administer immunizations and vaccines pursuant to this section must be certified to do so by the board. The board shall issue a certificate to a pharmacist who meets board requirements for certification as prescribed by the board by rule.

E. A pharmacist who is certified to administer immunizations and vaccines pursuant to this section may administer emergency medication to manage an acute allergic reaction to an immunization or vaccine.

F. A pharmacist who administers an immunization, vaccine or emergency medication pursuant to this section must:

1. Report the administration to the person's primary care provider or physician, if the primary care provider or physician is available, within forty-eight hours after administering the immunization, vaccine or emergency medication and as prescribed by the board by rule.
2. Report information to any adult immunization information system or vaccine registry established by the department of health services.
3. Maintain a record of the immunization pursuant to title 12, chapter 13, article 7.1 and as prescribed by the board by rule.
4. Participate in any federal vaccine adverse event reporting system or successor database.

G. This section does not establish a cause of action against a patient's primary care provider for any adverse reaction, complication or negative outcome arising from the administration of any immunization, vaccine or emergency medication by a pharmacist to a patient pursuant to this section if it is administered without a prescription written by the patient's primary care provider.

H. The board shall adopt rules for the administration of vaccines or immunizations pursuant to this section regarding:

1. Protocols that are based on protocols approved by the United States centers for disease control and prevention and any advisory committee appointed by the board for the purpose of recommending protocols.
2. Record keeping and reporting requirements.
3. Requirements and qualifications for pharmacist certification pursuant to this section.
4. Vaccine information and educational materials for those requesting vaccines and immunizations.
5. The administration of emergency medication pursuant to this section.

I. The department of health services, by rule, shall establish and maintain a list of immunizations or vaccines that may be administered to adults by a pharmacist only pursuant to a prescription order. In adopting and maintaining this list, the department is exempt from the rule making requirements of title 41, chapter 6. The department shall adopt its initial rules within six months after receipt of the recommendations of the advisory committee appointed by the board and shall hold one public hearing before implementing the rules and any amendments to the rules. The list shall include those immunizations or vaccines listed in the United States centers for disease control and prevention's recommended adult immunization schedule or recommended by the United States centers for disease control and prevention's health information for international travel that have adverse reactions that could cause significant harm to a patient's health. A pharmacist may not administer immunizations or vaccines without a prescription order pursuant to this section before the department has established the list pursuant to this subsection. The board may not authorize a pharmacist to administer new immunizations or vaccines without a prescription order pursuant to this section until the department reviews the new immunizations and vaccines to determine if they should be added to the list established pursuant to this subsection.

J. The board may appoint an advisory committee to assist the board in adopting and amending rules and developing protocols relating to the administration of immunizations, vaccines and emergency medications and certification requirements.

K. A pharmacy intern who is certified by the board to administer immunizations and vaccines pursuant to this section may do so only in the presence and under the immediate personal supervision of a pharmacist certified as prescribed in this section.

L. This section does not prevent a pharmacist who administers an immunization or vaccine from participating in the federal vaccines for children program.

M. A pharmacist may not administer an immunization or vaccine to a minor pursuant to subsection B or C of this section without the consent of the minor's parent or guardian.

N. For the purposes of this section, "emergency medication" means emergency epinephrine and diphenhydramine.

### **32-1975. Legend drug products; listing; code identification; exemption; definitions**

A. A legend drug product in finished solid dosage form shall not be manufactured or commercially distributed within this state unless it is clearly or prominently marked or imprinted with a code imprint identifying the drug product and the manufacturer or distributor of the drug.

B. All manufacturers or distributors of legend drugs in solid dosage form shall make available on request to the board a listing of all such legend drugs identifying by code imprint the manufacturer or distributor and the specific type of drug. The listing shall at all times be kept current by all manufacturers and distributors subject to this section.

C. The board may grant exemptions from the requirements of this section on application of any drug manufacturer or distributor showing size, physical characteristics or other unique characteristics that render the application of a code imprint to a legend drug subject to this section impractical or impossible. Any exemption granted by the board shall be included by the manufacturer or distributor in the listing required by subsection B of this section, describing the physical characteristics and type of drug to which the exemption relates.

D. This section does not apply to drug products compounded by a pharmacist licensed under section 32-1924 in a pharmacy operating under a permit issued by the board.

E. For the purposes of this section:

1. "Code imprint" means a series of letters or numbers assigned by the manufacturer or distributor to a specific drug or marks or monograms unique to the manufacturer or distributor of the drug, or both.

2. "Distributor" means a person who distributes for resale a drug in solid dosage form under that person's own label even if that person is not the actual manufacturer of the drug.

3. "Legend drug" means any drug defined by section 503(b) of the federal food, drug and cosmetic act and under which definition its label is required to bear the statement "RX only".

4. "Solid dosage form" means capsules or tablets intended for oral use.

### **32-1976. Dispensing replacement soft contact lenses; prescription**

A. A prescription order for replacement soft contact lenses may be dispensed under the following conditions:

1. The prescription order shall be in the form required by this chapter and shall include the name of the prescribing physician or optometrist.

2. The prescription order contains the date of issuance.

3. The prescription order for contact lenses includes the lens brand name, type, tint and all other specifications necessary to accurately dispense the prescription.

B. The prescription shall be dispensed with the exact lenses prescribed and no substitutions shall be made. The expiration date of the prescription shall be the earlier of the expiration date provided by the prescribing physician or optometrist or one year after the date of issuance. A refill of a prescription that is within sixty days of its expiration date shall be filled with no more than the sufficient quantity of replacement soft contact lenses needed through the expiration date.

C. The prescription shall be dispensed with a written notice containing the following wording or its substantial equivalent:

Warning: If you are having any unexplained eye discomfort, watering, vision change or redness, remove your lenses immediately and consult your eye care practitioner before wearing your lenses again.

D. Any advertisement by a pharmacy or pharmacist for replacement soft contact lenses shall include all charges associated with the purchase of replacement soft contact lenses from the pharmacy or pharmacist.

**32-1977. Sale of methamphetamine precursors; electronic sales tracking system; violation; classification; state preemption**

A. A retailer shall not sell to the same person, and a person shall not purchase, products containing more than three and six-tenths grams per day or more than nine grams per thirty-day period of ephedrine or pseudoephedrine base, or their salts, isomers or salts of isomers. These limits apply to the total amount of base ephedrine and pseudoephedrine contained in the products and not to the overall weight of the products.

B. The retailer must keep nonprescription products containing pseudoephedrine or ephedrine behind the counter or in a locked case where a customer does not have direct access.

C. The retailer shall require a person purchasing a nonprescription product that contains pseudoephedrine or ephedrine to present valid government issued photo identification at the point of sale. The retailer shall record all of the following:

1. The name and address of the purchaser.
2. The name and quantity of product purchased.
3. The date and time of purchase.
4. Purchaser identification type and number.

D. Beginning January 1, 2013, before completing a sale pursuant to this section, a retailer must use an electronic sales tracking system and electronically submit the required information to the national precursor log exchange administered by the national association of drug diversion investigators if the system is available to retailers without a charge for access. For the purposes of this subsection, "available to retailers without a charge for access":

1. Includes:

- (a) Access to the web-based electronic sales tracking software, including inputting and retrieving data free of charge.
- (b) Training free of charge.
- (c) Technical support to integrate to point of sale vendors without a charge, if necessary.

2. Does not include:

- (a) Costs relating to required Internet access.
- (b) Optional hardware that a pharmacy may choose to purchase for workflow purposes.
- (c) Other equipment.

E. If a retailer that sells a nonprescription product containing pseudoephedrine or ephedrine experiences mechanical or electronic failure of the electronic sales tracking system and is unable to comply with the electronic sales tracking requirements of this section, the retailer must maintain a written log or an alternative electronic recordkeeping mechanism until the retailer is able to comply with the electronic sales tracking system requirements. A retailer that does not have Internet access to the electronic sales tracking system is compliant with the requirements of this section if the retailer maintains a written log or an alternative electronic recordkeeping mechanism.

F. The national association of drug diversion investigators shall forward state transaction records in the national precursor log exchange to the board of pharmacy each week and provide real-time access to the national precursor log exchange information through the national precursor log exchange online portal to law enforcement in this state as authorized by the board of pharmacy.

G. The system prescribed in this section must be capable of generating a stop sale alert notification that completion of the sale would result in the retailer or purchaser violating the quantity limits prescribed in this section. The retailer may not complete the sale if the system generates a stop sale alert. The electronic sales tracking system prescribed in this section must contain an override function that may be used by dispensers of ephedrine or pseudoephedrine who have a reasonable fear of imminent bodily harm if they do not complete a sale. The system must log each instance that a retailer uses the override function.

H. A person who violates this section is guilty of a class 3 misdemeanor, punishable by fine only.

I. This section does not apply to a person who obtains the product pursuant to a valid prescription order.

J. The reporting of sales of ephedrine or pseudoephedrine products is of statewide concern. The regulation of sales pursuant to this section is not subject to further regulation by a county, city, town or other political subdivision of this state.

**32-1978. Sale of dextromethorphan; age requirement; exception; violation; civil penalty; definitions**

A. It is prohibited for:

1. Any commercial entity to knowingly or wilfully sell or trade a finished drug product containing any quantity of dextromethorphan to a person who is under eighteen years of age.
2. Any person who is under eighteen years of age to purchase a finished drug product containing any quantity of dextromethorphan.
3. Any person to possess, receive or distribute unfinished dextromethorphan, unless the person is registered pursuant to the federal food, drug, and cosmetic act or is appropriately licensed with the board.

B. A person making a retail sale of a finished drug product containing any quantity of dextromethorphan must require and obtain proof of age from the purchaser before completing the sale, unless the person making the sale reasonably presumes the purchaser to be at least twenty-five years of age based on the purchaser's outward appearance.

C. Subsection A of this section does not apply to common carriers that possess, receive or distribute unfinished dextromethorphan for purposes of distributing such unfinished dextromethorphan between persons that are registered under section 510 of the federal food, drug, and cosmetic act or that are appropriately licensed with the board.

D. This section does not impose any compliance requirement on a retail entity other than manually obtaining and verifying proof of age as a condition of sale, including placement of products in a specific place within a store, other restrictions on a consumer's direct access to finished drug products or the maintenance of transaction records.

E. A person who sells or trades a finished drug product containing any quantity of dextromethorphan to a person who is under eighteen years of age shall receive a warning for a first offense and shall pay a civil penalty of fifty dollars for a second offense, unless the person provides documentation that there is an employee training program in place.

F. This section does not apply to a medication containing dextromethorphan that is sold pursuant to a valid prescription.

G. For the purposes of this section:

1. "Common carrier" means any person that holds itself out to the general public as a provider for hire of the transportation of merchandise, whether or not the person actually operates the vehicle by which the transportation is provided within, to or from the United States.
2. "Finished drug product" means a drug that is legally marketed under the federal food, drug, and cosmetic act and that is in finished dosage form.
3. "Unfinished dextromethorphan" means dextromethorphan in any form, compound, mixture or preparation that is not a finished drug product.

**ARTICLE 3.1 REGULATION OF FULL SERVICE WHOLESALE PERMITTEES:**

**32-1981. Definitions**

In this article, unless the context otherwise requires:

1. "Chain pharmacy warehouse" means a physical location for prescription-only drugs that acts as a central warehouse and that performs intracompany sales or transfers of the prescription-only drugs to a group of pharmacies that are under common ownership or control. A chain pharmacy warehouse is not limited to the distribution of prescription-only drugs under this article.
2. "Company under common ownership" has the same meaning as affiliated group as defined in 26 United States Code section 1504.
3. "Intracompany transaction" means any sale, transfer or trade between a division, subsidiary, parent or affiliated or related company under the common ownership of a person.

4. "Normal distribution channel" means the chain of custody for a prescription-only drug that begins with the delivery of the drug by a manufacturer to a wholesale distributor who then delivers the drug to a pharmacy or a practitioner for final receipt by a patient. Normal distribution channel includes the receipt of a prescription-only drug by a common carrier or other delivery service that delivers the drug at the direction of a manufacturer, full service wholesale permittee or pharmacy and that does not purchase, sell, trade or take title to any prescription-only drug.

5. "Pedigree" means a document or electronic file that contains information that records each wholesale distribution of any given prescription-only drug, from sale by a pharmaceutical manufacturer, through acquisition and sale by any wholesale distributor or repackager and until final sale to a pharmacy or other person dispensing or administering the prescription-only drug.

6. "Third party logistics provider" means a person who receives prescription-only drugs only from the original manufacturer, who delivers the prescription-only drugs at the direction of that manufacturer and who does not purchase, sell, trade or take title to prescription-only drugs.

7. "Wholesale distribution" means distribution of a drug to a person other than a consumer or patient. Wholesale distribution does not include:

(a) Any transaction or transfer between any division, subsidiary, parent or affiliated or related company under common ownership and control of a corporate entity.

(b) Selling, purchasing, distributing, transferring or trading a drug or offering to sell, purchase, distribute, transfer or trade a drug for emergency medical reasons. For the purposes of this subdivision, "emergency medical reasons" includes transferring a prescription drug by a community pharmacy or hospital pharmacy to another community pharmacy or hospital pharmacy to alleviate a temporary shortage.

(c) Drug returns if conducted by a hospital, health care entity, retail pharmacy or charitable institution in accordance with 21 Code of Federal Regulations section 203.23.

(d) The sale of prescription drugs by a pharmacy, not to exceed five per cent of the pharmacy's gross sales, to practitioners for office use.

(e) Dispensing by a retail pharmacy of prescription drugs to a patient or patient's agent pursuant to the lawful order of a practitioner.

(f) Distributing a drug sample by a manufacturer's representative.

(g) Selling, purchasing or trading blood or blood components intended for transfusion.

**32-1982. Full service wholesale permittees; bonds; designated representatives; application**

A. A full service wholesale permittee that engages in the wholesale distribution of prescription-only drugs into, within or from this state must maintain a bond and have a designated representative.

B. The designated representative of a full service wholesale permittee must:

1. Be at least twenty-one years of age.

2. Have been employed full time for at least three years in a pharmacy or with a full service wholesale permittee in a capacity related to the dispensing and distribution of, and record keeping relating to, prescription-only drugs.

3. Be employed by the full service wholesale permittee in a managerial level position.

4. Be actively involved in the daily operation of the wholesale distribution of prescription-only drugs.

5. Be physically present at the full service wholesale permittee facility during regular business hours unless the absence of the designated representative is authorized.

6. Serve as a designated representative for only one full service wholesale permittee.

7. Not have any criminal convictions under any federal, state or local laws relating to wholesale or retail prescription-only drug distribution or distribution of controlled substances.

C. The board may require the applicant's designated representative to submit a full set of fingerprints to the board. The board shall submit the fingerprints to the department of public safety for the purpose of obtaining a state and federal criminal records check pursuant to section 41-1750 and Public Law 92-544. The department of public safety may exchange the fingerprint data with the federal bureau of investigation. The board may charge each applicant a fee determined by the department of public safety. The board shall forward this fee to the department of public safety.

D. The board shall require every full service wholesale permittee that is applying for an initial permit or renewal of a permit to submit a bond of at least one hundred thousand dollars or other equivalent means of security acceptable to the board. The board may use this bond to secure payment of any fines or penalties that are imposed by the board and any fees or costs that are incurred by the board regarding the permit authorized by law and that the permittee fails to pay within thirty days after the fine, penalty or cost becomes final. The bond must cover all permits held by the permittee in this state.

E. The board may waive the bond requirement if the full service wholesale permittee has previously obtained a comparable surety bond or other equivalent means of security for the purpose of licensure in another state where the full service wholesale permittee possesses a valid license in good standing.

F. For the purposes of this article, a full service wholesale permittee does not include a hospital, chain pharmacy warehouse or third party logistics provider.

### **32-1983. Restrictions on transactions**

A. A full service wholesale permittee may accept prescription-only drug returns or exchanges from a pharmacy or chain pharmacy warehouse pursuant to the terms of an agreement between the full service wholesale permittee and the pharmacy or chain pharmacy warehouse. The full service wholesale permittee shall not accept as returns or exchanges from the pharmacy or chain pharmacy warehouse:

1. Adulterated or counterfeited prescription-only drugs.

2. An amount or quantity of a prescription-only drug that exceeds the amount or quantity that the full service wholesale permittee or another full service wholesale permittee under common ownership sold to the pharmacy or chain pharmacy warehouse.

B. A full service wholesale permittee may furnish prescription-only drugs only to a pharmacy or medical practitioner. The full service wholesale permittee must first verify that person holds a valid license or permit.

C. The full service wholesale permittee must deliver prescription-only drugs only to the premises listed on the license or permit. A full service wholesale permittee may furnish prescription-only drugs to an authorized person or agent of that premises if:

1. The full service wholesale permittee properly establishes the person's identity and authority.

2. Delivery to an authorized person or agent is used only to meet the immediate needs of a particular patient of the authorized person.

D. A full service wholesale permittee may furnish prescription-only drugs to a pharmacy receiving area if a pharmacist or authorized receiving personnel sign, at the time of delivery, a receipt showing the type and quantity of the prescription-only drug received. Any discrepancy between receipt and the type and quantity of the prescription-only drug actually received must be reported to the full service wholesale permittee by the next business day after the delivery to the pharmacy receiving area.

E. A full service wholesale permittee shall not accept payment for or allow the use of a person or entity's credit to establish an account for the purchase of prescription-only drugs from any person other than the owner of record, the chief executive officer or the chief financial officer listed on the license or permit of a person or entity legally authorized to receive prescription-only drugs. Any account established for the purchase of prescription-only drugs must bear the name of the licensee or permittee.

### **32-1984. Pedigrees; electronic files**

A. Each full service wholesale permittee must establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription-only drugs, including pedigrees for all prescription-only drugs that leave the normal distribution channel.

B. A retail pharmacy or chain pharmacy warehouse must comply with this section if the pharmacy or chain pharmacy warehouse engages in the wholesale distribution of prescription-only drugs.

C. Subsection A does not apply to:

1. The original manufacturer of the finished form of the prescription-only drug.

2. The sale, trade or transfer of a prescription-only drug between pharmacies with a common ownership or as required by an emergency.

3. Intracompany transactions.

4. The sale, trade or transfer of a prescription-only drug by a full service wholesale permittee to an entity that assists in the administration of pharmacy benefits under contracts with insurers or to a company under common ownership with that entity.

5. The sale, trade or transfer of a prescription-only drug to a pharmacy or practitioner by an entity that assists in the administration of pharmacy benefits under contracts with insurers or by a company under common ownership with that entity.

D. Each person who is engaged in the wholesale distribution of a prescription-only drug, who is in the possession of a pedigree and who attempts to further distribute that prescription-only drug must verify before any distribution of that drug occurs that each transaction listed on the pedigree has occurred.

E. The pedigree must include:

1. The name of the prescription-only drug.
2. The dosage form and strength of the prescription-only drug.
3. The size of the container.
4. The number of containers.
5. The lot number of the prescription-only drug.
6. The name of the manufacturer of the finished dosage form.
7. All necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer through acquisition and sale by any full service wholesale permittee and until final sale to a pharmacy or other person dispensing or administering the drug. At a minimum this information must include:

(a) The name, address, telephone number and, if available, the e-mail address of each owner of the prescription-only drug and each full service wholesale permittee that does not take title to the prescription-only drug.

(b) The name and address of each location from which the product was shipped, if different from the owner's.

(c) Transaction dates.

(d) Certification that each recipient has authenticated the pedigree.

8. Any other information required by the board.

F. Except as provided in subsection B, the purchaser and full service wholesale permittee must keep the information prescribed by this section for at least three years.

G. The information prescribed by this section shall be available to the board of pharmacy on request.

### **32-1985. Injunctive relief**

The board, through the appropriate county attorney or the office of the attorney general, may apply for injunctive relief in any court of competent jurisdiction or enjoin any person from committing any act in violation of this article. Injunctive proceedings are in addition to all penalties and other remedies prescribed in this chapter.

## **ARTICLE 4 ENFORCEMENT OF CHAPTER; PENALTIES:**

### **32-1991. Enforcement of chapter**

The state board of pharmacy, the division of narcotics enforcement and criminal intelligence within the department of public safety, all officers exercising police powers, and county attorneys shall enforce the provisions of this chapter, unless such enforcement is otherwise specifically delegated, and they shall cooperate with all officers and agencies charged with enforcement of laws of other states and the United States pertaining to the subject matter of this chapter.

### **32-1992. Provisions of marijuana, prescription-only drugs, narcotics, dangerous drugs or controlled substances laws not invalidated by this chapter; medicated feed not included**

A. Nothing in this chapter shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to marijuana, prescription-only drugs, narcotics, dangerous drugs or controlled substances as defined in the applicable federal and state laws relating to these drugs or substances.

B. Nothing in this chapter shall be interpreted to include medicated feed for veterinary use.

### **32-1993. Authorization to seize certain drugs, counterfeit drugs and equipment; disposition of seized equipment**

A. The following may be seized by the division of narcotics enforcement and criminal intelligence within the department of public safety and its designated agents and all officers exercising police powers when they have reasonable grounds to believe it is:

1. A drug that is a counterfeit.
2. A container of such counterfeit drug.
3. Equipment used in manufacturing, compounding, or processing a drug with respect to which drug a prohibited act within the meaning of section 32-1965 has occurred.
4. Any punch, die, plate, stone, labeling, container or other thing used or designed for use in making a counterfeit drug.
5. Any conveyance being used to transport, carry or hold a counterfeit drug in violation of section 32-1965, paragraph 4.

B. When any article, equipment, conveyance, or other thing is seized pursuant to this chapter the peace officer shall, within five days thereafter, cause to be filed in the proper court in whose jurisdiction the merchandise is seized or detained a complaint for condemnation of such merchandise as provided in this chapter.

C. Any person, firm, or corporation having an interest in the alleged article, equipment, or other thing proceeded against, or any person, firm or corporation against whom a civil or criminal liability would exist if the merchandise is in violation of section 32-1965, paragraph 4 may, within twenty days following the seizure, serve and file an answer or responsive pleading to the complaint which shall allege the interest or liability of the party filing it.

D. Any article, equipment, conveyance or other thing condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may direct and the proceeds thereof, if sold, less the legal costs and other charges shall be deposited, pursuant to sections 35-146 and 35-147, with the state treasurer.

### **32-1994. Authorization to embargo adulterated or misbranded drugs or devices; condemnation; destruction; costs**

A. When the board or its authorized agent finds or has probable cause to believe that any drug, device, poison, or hazardous substance is adulterated, or so misbranded as to be dangerous or fraudulent, within the meaning of this chapter, he shall affix to such article an appropriate marking, giving notice that such article is, or is suspected of being, adulterated or misbranded and has been detained or embargoed, and warning all persons it is unlawful to remove or dispose of such article by sale or otherwise until permission for removal or disposal is given by the board or the court.

B. When an article detained or embargoed under subsection A of this section has been found by the board to be adulterated or misbranded, it shall petition the court in whose jurisdiction the article is detained or embargoed for condemnation of such article, or if feasible, the board may permit the article to be brought into compliance with this chapter.

C. If the court finds that a detained or embargoed article is adulterated or misbranded, and it is not feasible to bring it into compliance with this chapter, such article shall be destroyed at the expense of the claimant who shall also pay all court costs, fees, storage and other proper expenses.

### **32-1995. Injunctions; restraining orders**

In addition to other remedies provided, the board may apply to the proper court for, and such court shall have jurisdiction upon hearing and for cause shown, to grant a temporary restraining order, or a temporary or permanent injunction restraining any person from violating any provision of this chapter.

### **32-1996. Violations; classification**

A. Except as provided in this section, a person who violates this chapter:

1. Without the intent to defraud or mislead is guilty of a class 2 misdemeanor.
2. With the intent to defraud or mislead is guilty of a class 5 felony.

B. A person who violates section 32-1965, paragraph 4 or article 3.1 of this chapter, is guilty of a class 2 felony.

C. Any person who secures a license or permit for that person or for another person by knowingly making a false representation, who fraudulently claims to be licensed as a pharmacist or pharmacy intern within the meaning of this chapter or who knowingly engages in the practice of pharmacy without a license is guilty of a class 2 misdemeanor.

D. A person who secures a license as a pharmacy technician or a pharmacy technician trainee for that person or for another person by knowingly making a false representation, who fraudulently claims to be licensed as a pharmacy technician or a pharmacy technician trainee or who knowingly performs the duties of a pharmacy technician or a pharmacy technician trainee without a license is guilty of a class 2 misdemeanor.

E. A person who dispenses a human growth hormone in violation of this chapter is guilty of a class 6 felony.

F. A court convicting any person for a violation of this chapter shall, immediately after the date of conviction, send a complete copy of the record of the conviction, including the person's name and offense committed, to the executive director of the board.

G. A person who violates section 32-1978 shall be issued a civil penalty only as set forth in that section.

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# UNIFORM CONTROLLED SUBSTANCES ACT: TITLE 36 – CHAPTER 27

## ARTICLE 1 GENERAL PROVISIONS:

### **36-2501. Definitions**

A. In this chapter, unless the context otherwise requires:

1. "Board" means the Arizona state board of pharmacy.

2. "Cannabis" means the following substances under whatever names they may be designated:

(a) Marijuana.

(b) All parts of any plant of the genus cannabis, whether growing or not, its seeds, the resin extracted from any part of such plant, and every compound, manufacture, salt, derivative, mixture or preparation of such plant, its seeds or resin, but shall not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake or the sterilized seed of such plant which is incapable of germination.

(c) Every compound, manufacture, salt, derivative, mixture or preparation of such resin, tetrahydrocannabinol (T.H.C.), or of such plants from which the resin has not been extracted.

3. "Controlled substance" means a drug, substance or immediate precursor in schedules I through V of article 2 of this chapter.

4. "Department" means the department of public safety.

5. "Drug dependent person" means a person who is using a controlled substance and who is in a state of psychic or physical dependence, or both, arising from the use of that substance on a continuous basis. Drug dependence is characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuing basis in order to experience its psychic effects or to avoid the discomfort caused by its absence.

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

7. "Immediate precursor" means a substance which the board has found to be and by rule designates as being the principal compound commonly used or produced primarily for use and which 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.

8. "Narcotic drug" means any of the following whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis:

(a) Opium and opiate and any salt, compound, derivation or preparation of opium or opiate.

(b) Any salt, compound, isomer, derivative or preparation which is chemically equivalent or identical with any of the substances referred to in subdivision (a) of this paragraph but not including the isoquinoline alkaloids of opium.

(c) Opium poppy and poppy straw.

(d) Coca leaves and any salt, compound, derivation or preparation of coca leaves including cocaine and its optical isomers and any salt, compound, isomer, derivation or preparation which is chemically equivalent or identical with any of these substances but not including decocainized coca leaves or extractions of coca leaves which do not contain cocaine or ecgonine.

(e) Cannabis.

9. "Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. It does not include the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

10. "Opium poppy" means the plant of the genus papaver, except its seeds.

11. "Poppy straw" means all parts, except the seeds, of the opium poppy after mowing.

12. "Production" means the manufacture, planting, cultivating, growing or harvesting of a controlled substance.

13. "Registrant" means a person registered under the provisions of the federal controlled substances act (P.L. 91-513; 84 Stat. 1242; 21 U.S.C. sec. 801 et seq.).

14. "Schedule I controlled substances" means the controlled substances identified, defined or listed in section 36-2512.

15. "Schedule II controlled substances" means the controlled substances identified, defined or listed in section 36-2513.

16. "Schedule III controlled substances" means the controlled substances identified, defined or listed in section 36-2514.

17. "Schedule IV controlled substances" means the controlled substances identified, defined or listed in section 36-2515.

18. "Schedule V controlled substances" means the controlled substances identified, defined or listed in section 36-2516.

19. "Scientific purpose" means research, teaching or chemical analysis.

20. "State", when applied to a part of the United States, means any state, district, commonwealth, territory or insular possession of the United States and any area subject to the legal authority of the United States of America.

B. Words or phrases in this chapter, if not defined in subsection A of this section, have the definitions given them in title 32, chapter 18, article 1, unless the context otherwise requires.

## **ARTICLE 2 SCHEDULES:**

### **36-2511. Nomenclature**

The controlled substances listed or to be listed in the schedules in sections 36-2512 through 36-2516 are included by whatever official, common, usual, chemical or trade name designated.

### **36-2512. Substances in schedule I \*REVISED\***

A. The following controlled substances, unless specifically excepted, are included in schedule I:

1. Any of the following, including opiates and their isomers, esters, ethers, salts and salts of isomers, esters and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation:

- (a) Acetyl-alpha-methylfentanyl.
- (b) Acetylmethadol.
- (c) Allyprodine.
- (d) Alphacetylmethadol, (except levo-alphaacetylmethadol or LAAM).
- (e) Alphameprodine.
- (f) Alphamethadol.
- (g) Alpha-methylfentanyl.
- (h) Alpha-methylthiofentanyl.
- (i) Benzethidine.
- (j) Betacetylmethadol.
- (k) Beta-hydroxyfentanyl.
- (l) Beta-hydroxy-3-methylfentanyl.
- (m) Betameprodine.
- (n) Betamethadol.
- (o) Betaprodine.
- (p) Clonitazene.
- (q) Dextromoramide.
- (r) Diampromide.
- (s) Diethylthiambutene.
- (t) Difenoxin.
- (u) Dimenoxadol.
- (v) Dimepheptanol.

- (w) Dimethylthiambutene.
- (x) Dioxaphetyl butyrate.
- (y) Dipipanone.
- (z) Ethylmethylthiambutene.
- (aa) Etonitazene.
- (bb) Etoxidine.
- (cc) Furethidine.
- (dd) Hydroxypethidine.
- (ee) Ketobemidone.
- (ff) Levomoramide.
- (gg) Levophenacymorphan.
- (hh) 3-methylfentanyl.
- (ii) 3-methylthiofentanyl.
- (jj) Morpheridine.
- (kk) MPPP (1-methyl-4-phenyl-4-propionoxypiperidine).
- (ll) Noracymethadol.
- (mm) Norlevorphanol.
- (nn) Normethadone.
- (oo) Norpipanone.
- (pp) Para-fluorofentanyl.
- (qq) PEPAP (1-(2-phenethyl)-4-phenyl-4-acetoxypiperidine).
- (rr) Phenadoxone.
- (ss) Phenampromide.
- (tt) Phenomorphan.
- (uu) Phenoperidine.
- (vv) Piritramide.
- (ww) Proheptazine.
- (xx) Properidine.
- (yy) Propiram.
- (zz) Racemoramide.
- (aaa) Thiofentanyl.
- (bbb) Tilidine.
- (ccc) Trimeperidine.

2. Any of the following opium derivatives and their salts, isomers and salts of isomers, unless specifically excepted, whenever the existence of these salts, isomers and salts of isomers is possible within the specific chemical designation:

- (a) Acetorphine.
- (b) Acetyldihydrocodeine.
- (c) Benzylmorphine.
- (d) Codeine methylbromide.
- (e) Codeine-n-oxide.
- (f) Cyprenorphine.
- (g) Desomorphine.
- (h) Dihydromorphine.
- (i) Drotebanol.
- (j) Etorphine, except hydrochloride salt.
- (k) Heroin.
- (l) Hydromorphanol.
- (m) Methyl-desorphine.
- (n) Methyl-dihydromorphine.

- (o) Morphine methylbromide.
- (p) Morphine methylsulfonate.
- (q) Morphine-n-oxide.
- (r) Myrophine.
- (s) Nicocodeine.
- (t) Nicomorphine.
- (u) Normorphine.
- (v) Pholcodine.
- (w) Thebacon.

3. Any material, compound, mixture or preparation that contains any quantity of the following hallucinogenic substances and their salts, isomers and salts of isomers, unless specifically excepted or unless listed in another schedule, whenever the existence of these salts, isomers and salts of isomers is possible within the specific chemical designation (for the purposes of this paragraph, "isomer" includes the optical, position and geometric isomers):

- (a) Alpha-ethyltryptamine (AET).
- (b) 4-bromo-2, 5-dimethoxyamphetamine.
- (c) 4-bromo-2,5-dimethoxyphenethylamine (2C-B, Nexus).
- (d) 2, 5-dimethoxyamphetamine.
- (e) 2,5-dimethoxy-4-ethylamphetamine (DOET).
- (f) 2,5-dimethoxy-4-(n)-propylthiophenethylamine (2C-T-7).
- (g) 4-methoxyamphetamine.
- (h) 5-methoxy-3, 4-methylenedioxyamphetamine.
- (i) 4-methyl-2, 5-dimethoxyamphetamine.
- (j) 3,4-methylenedioxy amphetamine.
- (k) 3, 4-methylenedioxy methamphetamine (MDMA).
- (l) 3, 4-methylenedioxy-N-ethylamphetamine (N-ethyl MDA, MDE, MDEA).
- (m) N-hydroxy-3,4-methylenedioxyamphetamine (N-hydroxy MDA).
- (n) 3, 4, 5-trimethoxy amphetamine.
- (o) 5-methoxy-N,N,-dimethyltryptamine (5-MeO-DMT).
- (p) Alpha-methyltryptamine (AMT).
- (q) Bufotenine.
- (r) Diethyltryptamine.
- (s) Dimethyltryptamine.
- (t) 5-methoxy-N,N-diisopropyltryptamine (5-MeO-DIPT).
- (u) Ibogaine.
- (v) Lysergic acid diethylamide.
- (w) Cannabis, except the synthetic isomer of delta-9-tetrahydrocannabinol.
- (x) Mescaline.
- (y) Parahexyl.
- (z) Peyote.
- (aa) N-ethyl-3-piperidyl benzilate.
- (bb) N-methyl-3-piperidyl benzilate.
- (cc) Psilocybin.
- (dd) Psilocyn
- (ee) Ethylamine analog of phencyclidine.
- (ff) Pyrrolidine analog of phencyclidine.
- (gg) 1-(1-(2-thienyl)cyclohexyl)pyrrolidine.
- (hh) Thiophene analog of phencyclidine.(ii) 4-methylmethcathinone (Mephedrone).
- (jj) 3,4-methylenedioxypropylamphetamine (MDPV).
- (kk) 2-(2,5-dimethoxy-4-ethylphenyl)ethanamine (2C-E).
- (ll) 2-(2,5-dimethoxy-4-methylphenyl)ethanamine (2C-D).

- (mm) 2-(4-chloro-2,5-dimethoxyphenyl)ethanamine (2C-C).
- (nn) 2-(4-iodo-2,5-dimethoxyphenyl)ethanamine (2C-I).
- (oo) 2-[4-(ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2).
- (pp) 2-[4-(isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4).
- (qq) 2-(2,5-dimethoxyphenyl)ethanamine (2C-H).
- (rr) 2-(2,5-dimethoxy-4-nitro-phenyl)ethanamine (2C-N).
- (ss) 2-(2,5-dimethoxy-4-(n)-propylphenyl)ethanamine (2C-P).
- (tt) 3,4,-methylenedioxy-N-methylcathinone (Methylone).
- (uu) 2-(4-iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I-NBOMe, Cimbi-5).
- (vv) 2-(4-chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe, Cimbi-82).
- (ww) 2-(4-bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-NBOMe, Cimbi-36).

4. Any material, compound, mixture or preparation which contains any quantity of cannabimimetic substances and their salts, isomers, whether optical, positional or geometric, and salts of isomers, unless specifically excepted, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation. For the purposes of this subdivision, "cannabimimetic substances" means any substances within the following structural classes:

- (a) 2-(3-hydroxycyclohexyl)phenol with substitution at the 5-position of the phenolic ring by alkyl or alkenyl, whether or not substituted on the cyclohexyl ring to any extent. Substances in the 2-(3-hydroxycyclohexyl)phenol generic definition include CP-47,497, CP-47,497 C8-Homolog, CP-55,940 and CP-56,667.
- (b) 3-(naphthoyl)indole or 3-(naphthylmethane)indole by substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the naphthoyl or naphthyl ring to any extent. Substances in the 3-(naphthoyl)indole generic definition include AM-678, AM-2201, JWH-004, JWH-007, JWH-009, JWH-015, JWH-016, JWH-018, JWH-019, JWH-020, JWH-046, JWH-047, JWH-048, JWH-049, JWH-050, JWH-070, JWH-071, JWH-072, JWH-073, JWH-076, JWH-079, JWH-080, JWH-081, JWH-082, JWH-094, JWH-096, JWH-098, JWH-116, JWH-120, JWH-122, JWH-148, JWH-149, JWH-175, JWH-180, JWH-181, JWH-182, JWH-184, JWH-185, JWH-189, JWH-192, JWH-193, JWH-194, JWH-195, JWH-196, JWH-197, JWH-199, JWH-200, JWH-210, JWH-211, JWH-212, JWH-213, JWH-234, JWH-235, JWH-236, JWH-239, JWH-240, JWH-241, JWH-242, JWH-262, JWH-386, JWH-387, JWH-394, JWH-395, JWH-397, JWH-398, JWH-399, JWH-400, JWH-412, JWH-413, JWH-414 and JWH-415.
- (c) 3-(naphthoyl)pyrrole by substitution at the nitrogen atom of the pyrrole ring, whether or not further substituted in the pyrrole ring to any extent, whether or not substituted on the naphthoyl ring to any extent. Substances in the 3-(naphthoyl)pyrrole generic definition include JWH-030, JWH-145, JWH-146, JWH-147, JWH-150, JWH-156, JWH-243, JWH-244, JWH-245, JWH-246, JWH-292, JWH-293, JWH-307, JWH-308, JWH-346, JWH-348, JWH-363, JWH-364, JWH-365, JWH-367, JWH-368, JWH-369, JWH-370, JWH-371, JWH-373 and JWH-392.
- (d) 1-(naphthylmethylene)indene by substitution of the 3-position of the indene ring, whether or not further substituted in the indene ring to any extent, whether or not substituted on the naphthyl ring to any extent. Substances in the 1-(naphthylmethylene)indene generic definition include JWH-176.
- (e) 3-(phenylacetyl)indole or 3-(benzoyl)indole by substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent, whether or not substituted on the phenyl ring to any extent. Substances in the 3-(phenylacetyl)indole generic definition include AM-694, AM-2233, JWH-167, JWH-201, JWH-202, JWH-203, JWH-204, JWH-205, JWH-206, JWH-207, JWH-208, JWH-209, JWH-237, JWH-248, JWH-250, JWH-251, JWH-253, JWH-302, JWH-303, JWH-304, JWH-305, JWH-306, JWH-311, JWH-312, JWH-313, JWH-314, JWH-315, JWH-316, RCS-4, RCS-8, SR-18 and SR-19.
- (f) 3-(cyclopropylmethanone) indole or 3-(cyclobutylmethanone) indole or 3-(cyclopentylmethanone) indole by substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent, whether or not substituted on the cyclopropyl, cyclobutyl or cyclopentyl rings to any extent. Substances in the 3-(cyclopropylmethanone) indole generic definition include UR-144, Fluoro-UR-144 and XLR-11.
- (g) Other substances:
  - (i) (6ar,10ar)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol (HU-210).
  - (ii) N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (APINACA, AKB48).
  - (iii) Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB-22).
  - (iv) Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (5F-PB-22).
  - (v) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA).
  - (vi) N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA).

5. Any of the following substances having a depressant effect on the central nervous system, including their salts, isomers and salts of isomers, unless specifically excepted or listed in another schedule, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

(a) Mecloqualone.

(b) Methaqualone.

6. Gamma-hydroxybutyric acid, any salt, hydroxybutyric compound, derivative or preparation of gamma-hydroxybutyric acid, including any isomers, esters and ethers and salts of isomers, esters and ethers of gamma-hydroxybutyric acid, except gamma-butyrolactone if the existence of the isomers, esters and salts is possible within the specific chemical designation. Notwithstanding any other provision of the federal food, drug and cosmetic act, for purposes of security requirements imposed by law or regulation on registered distributors and registered manufacturers, this substance if manufactured, distributed or processed in accordance with an exemption approved under section 505 of the federal food, drug and cosmetic act is a controlled substance in schedule III pursuant to section 36-2514.

7. Any of the following stimulants including their salts, isomers and salts of isomers, unless specifically excepted or listed in another schedule, whenever the existence of these salts, isomers and salts of isomers is possible within the specific chemical designation:

(a) Alpha-methylaminovaleophenone (Pentedrone).

(b) Alpha-pyrrolidinobutiophenone (Alpha-PBP).

(c) Alpha-pyrrolidinopropiophenone (Alpha-PPP).

(d) Alpha-pyrrolidinovaleophenone (Alpha-PVP).

(e) Aminorex.

(f) N-benzylpiperazine (BZP).

(g) Beta-keto-n-methylbenzodioxolylbutanamine (Butylone).

(h) Beta-keto-n-methylbenzodioxolylpentanamine (Pentylone).

(i) Cathinomimetic substances which are any substances derived from cathinone, (2-amino-1-phenyl-1-propanone) by any substitution at the phenyl ring, any substitution at the 3 position, any substitution at the nitrogen atom or any combination of the above substitutions.

(j) (+)cis-4-methylaminorex((+)cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine).

(k) Dihydro-5H-indeno-(5,6-d)-1,3-dioxol-6-amine (MDAI).

(l) Dimethylcathinone (Metamfepramone).

(m) Ethcathinone.

(n) Fenethylamine.

(o) 3-fluoro-N-methylcathinone (3-FMC).

(p) 4-fluoro-N-methylcathinone (4-FMC, Flephedrone).

(q) Methcathinone.

(r) Methoxy-alpha-pyrrolidinopropiophenone (MOPPP).

(s) Methoxyphenethylamine mimetic substances which are any substances derived from 2, 5-dimethoxy-phenethylamine by any substitution at the phenyl ring, any substitution at the nitrogen atom or any combination of the above substitutions.

(t) Methyl-alpha-pyrrolidinobutiophenone (MPBP).

(u) 4-methyl-alpha-pyrrolidinopropiophenone (4-MePPP).

(v) 4-methyl-N-ethylcathinone (4-MEC).

(w) Methylenedioxy-alpha-pyrrolidinopropiophenone (MDPPP).

(x) Methylenedioxyethylcathinone (Ethylone).

(y) N-ethylamphetamine.

(z) Naphthypyrovalerone (Naphyrone).

(aa) N,N-dimethylamphetamine.

B. The board may except by rule any compound, mixture or preparation containing any substance listed in this section from the application of all or any part of this chapter if the compound, mixture or preparation contains one or more active medicinal ingredients and if the admixtures are included therein in combinations, quantity, proportion or concentration that vitiates the potential for abuse.

**36-2513. Substances in schedule II \*REVISED\***

A. The following controlled substances are, unless specifically excepted, included in schedule II:

1. Any of the following substances, whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis or by combination of extraction and chemical synthesis:

- (a) Opium and opiate and any salt, compound, derivative or preparation of opium or opiate, excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, nalmefene, naloxone and naltrexone and their respective salts, but including the following:
  - (i) Raw opium.
  - (ii) Opium extracts.
  - (iii) Opium fluid extracts.
  - (iv) Powdered opium.
  - (v) Granulated opium.
  - (vi) Tincture of opium.
  - (vii) Codeine.
  - (viii) Dihydroetorphine.
  - (ix) Ethylmorphine.
  - (x) Etorphine hydrochloride.
  - (xi) Hydrocodone.
  - (xii) Hydromorphone.
  - (xiii) Metopon.
  - (xiv) Morphine.
  - (xv) Oripavine.
  - (xvi) Oxycodone.
  - (xvii) Oxymorphone.
  - (xviii) Thebaine.
- (b) Any salt, compound, derivative or preparation thereof which is chemically equivalent or identical with any of the substances referred to in subdivision (a) of this paragraph, except that these substances shall not include the isoquinoline alkaloids of opium.
- (c) Opium poppy and poppy straw.
- (d) Coca leaves and any salt, compound, derivative or preparation of coca leaves, including cocaine and ecgonine and their salts, isomers, derivatives and salts of isomers and derivatives, and any salt, compound, derivative or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine.
- (e) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid or powder form which contains the phenanthrene alkaloids of the opium poppy).

2. Any of the following opiates, including isomers, esters, ethers, salts and salts of isomers, esters, and ethers, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation, dextrorphan and levopropoxyphene excepted:

- (a) Alfentanil.
- (b) Alphaprodine.
- (c) Anileridine.
- (d) Bezitramide.
- (e) Bulk dextropropoxyphene (non-dosage forms).
- (f) Carfentanil.
- (g) Dihydrocodeine.
- (h) Diphenoxylate.
- (i) Fentanyl.
- (j) Fentanyl immediate precursor, 4-anilino-N-phenethyl-4-piperidine (ANPP).
- (k) Isomethadone.
- (l) Levo-alphaacetylmethadol (LAAM).
- (m) Levomethorphan.

- (n) Levorphanol.
- (o) Metazocine.
- (p) Methadone.
- (q) Methadone--intermediate, 4-cyano-2-dimethylamino-4, 4-diphenylbutane.
- (r) Moramide--intermediate, 2-methyl-3-morpholino-1,1-diphenylpropane-carboxylic acid.
- (s) Pethidine (meperidine).
- (t) Pethidine--intermediate--A, 4-cyano-1-methyl-4-phenylpiperidine.
- (u) Pethidine--intermediate--B, ethyl-4-phenylpiperidine-4-carboxylate.
- (v) Pethidine--intermediate--C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.
- (w) Phenazocine.
- (x) Piminodine.
- (y) Racemethorphan.
- (z) Racemorphan.
- (aa) Remifentanil.
- (bb) Sufentanil.
- (cc) Tapentadol.

3. Any material, compound, mixture or preparation which contains any quantity of the following substances having a potential for abuse associated with a stimulant effect on the central nervous system:

- (a) Amphetamine and its salts, optical isomers and salts of its optical isomers.
- (b) Methamphetamine, including its salts, isomers and salts of isomers.
- (c) Phenmetrazine and its salts.
- (d) Methylphenidate.
- (e) Phenylacetone (immediate precursor to amphetamine and methamphetamine).
- (f) Lisdexamfetamine, and its salts, isomers, and salts of isomers.

4. Any material, compound, mixture or preparation which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system, including its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

- (a) Amobarbital.
- (b) Glutethimide.
- (c) Pentobarbital.
- (d) Phencyclidine.
- (e) Phencyclidine immediate precursors:
  - (i) 1-phenylcyclohexylamine.
  - (ii) 1-piperidinocyclohexanecarbonitrile (PCC).
- (f) Secobarbital.

5. Nabilone (hallucinogenic substance).

B. The board may except by rule any compound, mixture or preparation containing any substance listed in this section from the application of all or any part of this chapter if the compound, mixture or preparation contains one or more active medicinal ingredients and if the admixtures are included therein in combinations, quantity, proportion or concentration that vitiates the potential for abuse.

**36-2514. Substances in schedule III; definition \*REVISED\***

A. The following controlled substances are, unless specifically excepted, included in schedule III:

1. Any material, compound, mixture or preparation which contains any quantity of the following substances having a potential for abuse associated with a stimulant effect on the central nervous system, including its salts, isomers, whether optical, position or geometric, and salts of such isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

- (a) Benzphetamine.

- (b) Chlorphentermine.
- (c) Clortermine.
- (d) Phendimetrazine.

2. Any material, compound, mixture or preparation which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:

- (a) Any compound, mixture or preparation containing amobarbital, secobarbital, pentobarbital or any salt thereof and one or more other active medicinal ingredients which are not listed in any schedule.
- (b) Any suppository dosage form containing amobarbital, secobarbital, pentobarbital or any salt of any of these drugs and approved by the federal act for marketing only as a suppository.
- (c) Any substance which contains any quantity of a derivative of barbituric acid or any salt thereof.
- (d) Chlorhexadol.
- (e) Embutramide.
- (f) Any drug product containing gamma hydroxybutyric acid, including its salts, isomers, and salts of isomers, for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act.
- (g) Ketamine, and its salts, isomers, and salts of isomers.
- (h) Lysergic acid.
- (i) Lysergic acid amide.
- (j) Methyprylon.
- (k) Perampanel, and its salts, isomers, and salts of isomers.
- (l) Sulfondiethylmethane.
- (m) Sulfonethylmethane.
- (n) Sulfonmethane.
- (o) Tiletamine/zolazepam (telazol) or any salt thereof.

3. Any material, compound, mixture or preparation containing the narcotic drug nalorphine or any of its salts.

4. Any material, compound, mixture or preparation containing the narcotic drug buprenorphine or any of its salts.

5. Any material, compound, mixture or preparation containing limited quantities of any of the following narcotic drugs or any salts thereof, calculated as the free anhydrous base or alkaloid:

- (a) Not more than one point eight grams of codeine, or any of its salts, per one hundred milliliters or not more than ninety milligrams per dosage unit with an equal or greater quantity of an isoquinoline alkaloid of opium.
- (b) Not more than one point eight grams of codeine, or any of its salts, per one hundred milliliters or not more than ninety milligrams per dosage unit with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
- (c) Not more than one point eight grams of dihydrocodeine, or any of its salts, per one hundred milliliters or not more than ninety milligrams per dosage unit with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
- (d) Not more than three hundred milligrams of ethylmorphine, or any of its salts, per one hundred milliliters or not more than fifteen milligrams per dosage unit with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
- (e) Not more than five hundred milligrams of opium per one hundred milliliters or per one hundred grams or not more than twenty-five milligrams per dosage unit with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
- (f) Not more than fifty milligrams of morphine, or any of its salts, per one hundred milliliters or per one hundred grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

6. Any material, compound, mixture or preparation containing any of the following anabolic steroids but not including an anabolic steroid that is expressly intended for administration through implants to cattle or other nonhuman species and that has been approved by the United States Food and Drug Administration for such administration:

- (a) 3beta, 17-dihydroxy-5a-androstane.
- (b) 3alpha, 17beta-dihydroxy-5a-androstane.
- (c) 5alpha-androstan-3, 17-dione.
- (d) 3beta, 17beta-dihydroxy-5alpha-androst-1-ene.

- (e) 3alpha, 17beta-dihydroxy-5alpha-androst-1-ene.
- (f) 4-androstenediol.
- (g) 5-androstenediol.
- (h) 1-androstenedione.
- (i) 4-androstenedione.
- (j) 5-androstenedione.
- (k) Bolasterone.
- (l) Boldenone.
- (m) Boldione.
- (n) Calusterone.
- (o) Clostebol.
- (p) Dehydrochlormethyltestosterone.
- (q) Desoxymethyltestosterone.
- (r) Delta1-dihydrotestosterone.
- (s) 4-dihydrotestosterone.
- (t) Drostanolone.
- (u) Ethylestrenol.
- (v) Fluoxymesterone.
- (w) Formebolone.
- (x) Furazabol.
- (y) 13beta-ethyl-17beta-hydroxygon-4-en-3-one.
- (z) 4-hydroxytestosterone.
- (aa) 4-hydroxy-19-nortestosterone.
- (bb) Mestanolone.
- (cc) Mesterolone.
- (dd) Methandienone.
- (ee) Methandriol.
- (ff) Methasterone.
- (gg) Methenolone.
- (hh) 17alpha-methyl-3beta, 17beta-dihydroxy-5a-androstane.
- (ii) 17alpha-methyl-3alpha, 17beta-dihydroxy-5a-androstane.
- (jj) 17alpha-methyl-3beta, 17beta-dihydroxyandrost-4-ene.
- (kk) 17alpha-methyl-4-hydroxynandrolone.
- (ll) Methyldienolone.
- (mm) Methyltrienolone.
- (nn) Methyltestosterone.
- (oo) Mibolerone.
- (pp) 17alpha-methyl-delta1-dihydrotestosterone.
- (qq) Nandrolone.
- (rr) 3beta, 17beta-dihydroxyestr-4-ene.
- (ss) 3alpha, 17beta-dihydroxyestr-4-ene.
- (tt) 3beta, 17beta-dihydroxyestr-5-ene.
- (uu) 3alpha, 17beta-dihydroxyestr-5-ene.
- (vv) 19-nor-4,9(10)-androstadienedione.
- (ww) 19-nor-4-androstenedione.
- (xx) 19-nor-5-androstenedione.
- (yy) Norbolethone.
- (zz) Norclostebol.
- (aaa) Norethandrolone.
- (bbb) Normethandrolone.
- (ccc) Oxandrolone.
- (ddd) Oxymesterone.
- (eee) Oxymetholone.
- (fff) Prostanazol.
- (ggg) Stanozolol.
- (hhh) Stenbolone.
- (iii) Testolactone.
- (jjj) Testosterone.
- (kkk) Tetrahydrogestrinone.
- (lll) Trenbolone.
- (mmm) Any salt, ester or isomer of a drug or substance described or listed in this paragraph, if that salt, ester or isomer promotes muscle growth.

7. Dronabinol, (synthetic delta-9-tetrahydrocannabinol) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved product (hallucinogenic substance).

B. If any person prescribes, dispenses, or distributes an anabolic steroid for human use that has been approved by the United States Food and Drug Administration for the express intent of administration through implants to cattle or other nonhuman species, the person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of this section.

C. The board may except by rule any compound, mixture or preparation containing any substance listed in this section from the application of all or any part of this chapter if the compound, mixture or preparation contains one or more active medicinal ingredients and if the admixtures are included therein in combinations, quantity, proportion or concentration that vitiates the potential for abuse.

D. For the purposes of this section, "anabolic steroid" means a growth promoting drug or hormonal substance that is chemically or pharmacologically related to testosterone, other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone.

**36-2515. Substances in schedule IV \*REVISED\***

A. The following controlled substances are, unless specifically excepted, included in schedule IV:

1. Any material, compound, mixture or preparation that contains any quantity of the following substances having a potential for abuse associated with a stimulant effect on the central nervous system, including its salts, isomers, whether optical, position or geometric, and salts of such isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

- (a) Cathine (+(4)-norpseudoephedrine).
- (b) Diethylpropion.
- (c) Fencamfamin.
- (d) Fenproporex.
- (e) Mazindol.
- (f) Mefenorex.
- (g) Modafinil.
- (h) Pemoline (including organometallic complexes and chelates thereof).
- (i) Phentermine.
- (j) Pipradrol.
- (k) Sibutramine.
- (l) SPA((-)-1-dimethylamino-1, 2-diphenylethane).

2. Any material, compound, mixture or preparation that contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system, including its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

- (a) Alfaxalone.
- (b) Alprazolam.
- (c) Barbitol.
- (d) Bromazepam.
- (e) Camazepam.
- (f) Carisoprodol.
- (g) Chloral betaine.
- (h) Chloral hydrate.
- (i) Chlordiazepoxide.
- (j) Clobazam.
- (k) Clonazepam.
- (l) Clorazepate.
- (m) Clotiazepam.
- (n) Cloxazolam.
- (o) Delorazepam.
- (p) Diazepam.

- (q) Dichloralphenazone.
- (r) Estazolam.
- (s) Ethchlorvynol.
- (t) Ethinamate.
- (u) Ethyl loflazepate.
- (v) Fludiazepam.
- (w) Flunitrazepam.
- (x) Flurazepam.
- (y) Fospropofol.
- (z) Halazepam.
- (aa) Haloxazolam.
- (bb) Ketazolam.
- (cc) Loprazolam.
- (dd) Lorazepam.
- (ee) Lormetazepam.
- (ff) Mebutamate.
- (gg) Medazepam.
- (hh) Meprobamate.
- (ii) Methohexital.
- (jj) Methylphenobarbital (methobarbital).
- (kk) Midazolam.
- (ll) Nimetazepam.
- (mm) Nitrazepam.
- (nn) Nordiazepam.
- (oo) Oxazepam.
- (pp) Oxazolam.
- (qq) Paraldehyde.
- (rr) Petrichloral.
- (ss) Phenobarbital.
- (tt) Pinazepam.
- (uu) Prazepam.
- (vv) Quazepam.
- (ww) Suvorexant.
- (xx) Temazepam.
- (yy) Tetrazepam.
- (zz) Triazolam.
- (aaa) Zaleplon.
- (bbb) Zolpidem.
- (ccc) Zopiclone.

3. Fenfluramine, and its salts, isomers (whether optical, position, or geometric), and its salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible.

4. Any material, compound, mixture or preparation containing any of the following narcotic drugs, or their salts, calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

- (a) Not more than one milligram of difenoxin and not less than twenty-five micrograms of atropine sulfate per dosage unit.
- (b) Dextropropoxyphene (alpha-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxybutane.
- (c) Tramadol, 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol, and its salts, optical and geometric isomers, and its salts of isomers.

5. Any material, compound, mixture or preparation that contains any quantity of the following substances, including its salts:

- (a) Pentazocine.
- (b) Butorphanol (including its optical isomers).

6. Lorcaserin, and its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible.

B. The board may except by rule any compound, mixture or preparation containing any substance listed in this section from the application of all or any part of this chapter if the compound, mixture or preparation contains one or more active medicinal ingredients and if the admixtures are included therein in combinations, quantity, proportion or concentration that vitiates the potential for abuse.

**36-2516. Substances in schedule V \*REVISED\***

The following controlled substances or controlled substance precursors are included in schedule V:

1. Any compound, mixture or preparation containing limited quantities of any of the following narcotic drugs or their salts, calculated as the free anhydrous base or alkaloid, which also contains one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

- (a) Not more than two hundred milligrams of codeine, or any of its salts, per one hundred milliliters or per one hundred grams.
- (b) Not more than one hundred milligrams of dihydrocodeine, or any of its salts, per one hundred milliliters or per one hundred grams.
- (c) Not more than one hundred milligrams of ethylmorphine, or any of its salts, per one hundred milliliters or per one hundred grams.
- (d) Not more than 2.5 milligrams of diphenoxylate and not less than twenty-five micrograms of atropine sulfate per dosage unit.
- (e) Not more than one hundred milligrams of opium per one hundred milliliters or per one hundred grams.
- (f) Not more than 0.5 milligram of difenoxin and not less than twenty-five micrograms of atropine sulfate per dosage unit.

2. Unless specifically excepted or listed in another schedule, any material, compound, mixture or preparation containing pyrovalerone.

3. Any compound or preparation containing the single active ingredient ephedrine or any of its salts.

4. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts:

- (a) Ezogabine.
- (b) Lacosamide.
- (c) Pregabalin.

**ARTICLE 3 REGULATION OF MANUFACTURE, DISTRIBUTION AND DISPENSING OF CONTROLLED SUBSTANCES:**

**36-2521. Rules**

The board may promulgate necessary and reasonable rules relating to the registration and control of the manufacture, distribution and dispensing of controlled substances within this state.

**36-2522. Registration requirements**

A. Every person who manufactures, distributes, dispenses, prescribes or uses for scientific purposes any controlled substance within this state or who proposes to engage in the manufacture, distribution, prescribing or dispensing of or using for scientific purposes any controlled substance within this state must first:

- 1. Obtain and possess a current license or permit as a medical practitioner as defined in section 32-1901 or as a pharmacy, pharmacist, manufacturer or wholesaler pursuant to title 32, chapter 18.
- 2. Be a registrant under the federal controlled substances act (P.L. 91-513; 84 Stat. 1242; 21 United States Code section 801 et seq.).

B. A person who is registered under this chapter to manufacture, distribute, dispense, prescribe or use for scientific purposes controlled substances may possess, manufacture, distribute, dispense, prescribe or use for scientific purposes those substances to the extent authorized by that person's license or permit in conformity with this chapter and title 32, chapter 18.

C. The following persons need not register and may lawfully possess controlled substances under this chapter:

1. An agent or employee of any registered manufacturer, distributor or dispenser of any controlled substance if he is acting in the usual course of his business or employment.
  2. A common or contract carrier or warehouseman or that person's employee whose possession of any controlled substance is in the usual course of business or employment.
  3. An ultimate user or a person in possession of any controlled substance pursuant to a lawful order of a medical practitioner or in lawful possession of a schedule V substance.
  4. An officer or employee of the department of public safety, a professional regulatory board established by title 32, chapter 7, 11, 13, 14, 15, 16, 17, 18, 21, 25 or 29 or the Arizona state board of pharmacy or a peace officer as defined in section 1-215 in the lawful performance of that person's duties.
- D. The board may waive by rule the requirement for registration of certain manufacturers, distributors or dispensers if the board finds waiver consistent with the public health and safety or the requirements of the United States drug enforcement administration.
- E. The board or its designee may inspect the establishment of a registrant or applicant for registration in accordance with the board's regulation if the board or its designee has information that the board or its designee believes would require an on-site inspection.

**36-2523. Records of registrants; inspection; confidentiality**

- A. Persons registered to manufacture, distribute or dispense controlled substances under this chapter shall keep records and maintain inventories in conformance with the record keeping and inventory requirements of federal law and title 32, chapter 18, and with any additional rules the board issues. Prescription orders must be filed as required by section 36-2525.
- B. A person who holds a permit to operate a pharmacy issued under title 32, chapter 18 shall inventory schedule II, III, IV and V controlled substances as prescribed by federal law. The permit holder shall conduct this inventory on May 1 of each year or as directed by the Arizona state board of pharmacy. The permit holder shall also conduct this inventory if there is a change of ownership or discontinuance of business or within ten days of a change of a pharmacist in charge.
- C. These records and inventories shall be open for inspection by peace officers in the performance of their duties. An officer shall not divulge information obtained pursuant to this subsection except in connection with a prosecution, investigation, judicial proceeding or administrative proceeding in which the person to whom the information relates is a party.

**36-2524. Order forms**

Controlled substances in schedules I and II shall be distributed by a registrant to another registrant only pursuant to an order form. Compliance with the provisions of federal law respecting order forms shall be deemed compliance with this section.

**36-2525. Prescription orders; labels**

- A. In addition to requirements in section 32-1968, pertaining to prescription orders for prescription-only drugs, the prescription order for a controlled substance shall bear the name, address and federal registration number of the prescriber. A prescription order for a schedule II controlled substance drug other than a hospital drug order for a hospital inpatient shall contain only one drug order per prescription blank. If authorized verbally by the prescriber, the pharmacist may make changes to correct errors or omissions made by the prescriber on the following parts of a written schedule II controlled substance prescription order:
1. The date issued.
  2. The strength, dosage form or quantity of drug.
  3. The directions for its use.
- B. The pharmacist must document on the original prescription order the changes that were made pursuant to the verbal authorization and record the time and date the authorization was granted.
- C. A person registered to dispense controlled substances under this chapter must keep and maintain prescription orders for controlled substances as follows:
1. Prescription orders for controlled substances listed in schedules I and II must be maintained in a separate prescription file for controlled substances listed in schedules I and II only.
  2. Prescription orders for controlled substances listed in schedules III, IV and V must be maintained either in a separate prescription file for controlled substances listed in schedules III, IV and V only or in a form that allows them to be readily retrievable from the other prescription records of the registrant. For the purposes of this paragraph, "readily retrievable" means that when the prescription is initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" in a font that is not less than one inch high and that the prescription is filed in the usual consecutively numbered

prescription file for noncontrolled substance prescriptions. The requirement to stamp the hard copy prescription with a red "C" is waived if a registrant employs an electronic data processing system or other electronic record keeping system for prescriptions that permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed and date filled.

D. Except in emergency situations in conformity with subsection E of this section, under the conditions specified in subsections F and G of this section or when dispensed directly by a medical practitioner to an ultimate user, a controlled substance in schedule II shall not be dispensed without the written prescription order in ink or indelible pencil or typewritten and manually signed by the medical practitioner. A prescription order for a schedule II substance shall not be dispensed more than ninety days after the date on which the prescription order was issued. A prescription order for a schedule II substance shall not be refilled.

E. In emergency situations, emergency quantities of schedule II substances may be dispensed on an oral prescription order of a medical practitioner. Such an emergency prescription order shall be immediately reduced to writing by the pharmacist and shall contain all the information required for schedule II drugs except for the manual signing of the order by the medical practitioner. Within seven days after authorizing an emergency oral prescription order, the prescribing medical practitioner shall cause a written prescription order manually signed for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to other requirements for prescription orders for schedule II substances, it shall have written on its face "authorization for emergency dispensing" and the date of the oral order. If the prescribing medical practitioner fails to deliver such an emergency prescription order within seven days in conformance with board rules, the pharmacist shall notify the board. Failure of the pharmacist to notify the board shall void the authority conferred by this subsection to dispense without a written, manually-signed prescription order of a medical practitioner.

F. The following may be transmitted to a pharmacy by facsimile by a patient's medical practitioner or the medical practitioner's agent:

1. A prescription order written for a schedule II controlled substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion.

2. A prescription order written for any schedule II controlled substance for a resident of a long-term care facility.

3. A prescription order written for a schedule II controlled substance for a patient enrolled in a hospice care program certified or paid for by medicare under title XVIII or a hospice program that is licensed by this state. The medical practitioner or the medical practitioner's agent must note on the prescription that the patient is a hospice patient.

G. A facsimile transmitted pursuant to subsection F of this section is the original written prescription order for purposes of this section and must be maintained as required by subsection C of this section.

H. Except when dispensed directly by a medical practitioner to an ultimate user, a controlled substance included in schedule III or IV that requires a prescription order as determined under state or federal laws shall not be dispensed without a written or oral prescription order of a medical practitioner. The prescription order shall not be filled or refilled more than six months after the date on which the prescription order was issued. A prescription order authorized to be refilled shall not be refilled more than five times. Additional quantities may only be authorized by the prescribing medical practitioner through issuance of a new prescription order that shall be treated by the pharmacist as a new and separate prescription order.

I. Except when dispensed directly by a medical practitioner to an ultimate user, a controlled substance that is included in schedule V and that requires a prescription order as determined under state or federal laws shall not be dispensed without a written or oral prescription order of a medical practitioner. The prescription order may be refilled as authorized by the prescribing medical practitioner but shall not be filled or refilled more than one year after the date of issuance.

J. A controlled substance that is listed in schedule III, IV or V and that does not require a prescription order as determined under state or federal laws may be dispensed at retail by a pharmacist, a pharmacy intern or a graduate intern under the pharmacist's supervision without a prescription order to a purchaser who is at least eighteen years of age if all of the following are true:

1. It is for a legitimate medical purpose.

2. Not more than two hundred forty cubic centimeters (eight ounces) of any such controlled substance containing opium, nor more than one hundred twenty cubic centimeters (four ounces) of any other such controlled substance, nor more than forty-eight dosage units of any such controlled substance containing opium, nor more than twenty-four dosage units of any other controlled substance may be dispensed at retail to the same purchaser in any given forty-eight hour period.

3. No more than one hundred dosage units of any single active ingredient ephedrine preparation may be sold, offered for sale, bartered, or given away to any one person in any one thirty-day period.

4. The pharmacist, pharmacy intern or graduate intern requires every purchaser of a controlled substance under this subsection not known to that person to furnish suitable identification, including proof of age where appropriate.

5. A bound record book for dispensing controlled substances under this subsection is maintained by the pharmacist and contains the name and address of the purchaser, the name and quantity of the controlled substance purchased, the date of each purchase and the name or initials of the pharmacist, pharmacy intern or graduate intern who dispensed the substance to the purchaser. Such book shall be maintained in conformity with the record keeping requirements of section 36-2523.

K. In the absence of a law requiring a prescription for a schedule V controlled substance, the board, by rules, may require, or remove the requirement of, a prescription order for a schedule V controlled substance.

L. The label on a container of a controlled substance directly dispensed by a medical practitioner or pharmacist, not for the immediate administration to the ultimate user, such as a bed patient in a hospital, shall bear the name and address of the dispensing medical practitioner or pharmacist, the serial number, date of dispensing, name of prescriber, name of patient or, if an animal, the name of the owner of the animal and the species of the animal, directions for use and cautionary statements, if any, contained in the prescription order or required by law. If the controlled substance is included in schedule II, III or IV the label shall bear a transfer warning to the effect: "Caution: federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed".

M. The board, by rule, may provide additional requirements for prescribing and dispensing controlled substances.

#### **ARTICLE 4 OFFENSES AND PENALTIES**

##### **36-2531. Prohibited acts; classification**

A. It is unlawful for any person:

1. Who is subject to article 3 of this chapter to intentionally or knowingly distribute or dispense a controlled substance in violation of section 36-2525.
2. Who is a registrant to intentionally or knowingly manufacture a controlled substance not authorized by that person's registration or to intentionally or knowingly distribute or dispense a controlled substance not authorized by that person's registration to another registrant or other authorized person.
3. To intentionally or knowingly refuse or fail to make, keep or furnish any record, notification, order form, statement, invoice or information required under this chapter.
4. To intentionally or knowingly refuse an entry into any premises for any inspection authorized by this chapter.
5. To knowingly dispense or deliver anabolic steroids without a written prescription or for a nontherapeutic use.
6. To intentionally or knowingly sell, buy, exchange or give away any preparation subject to section 36-2516, unless the preparation is to be used for a legitimate medical purpose and in compliance with this chapter.

B. Notwithstanding any other law, any person who violates any provision of subsection A of this section is guilty of a class 4 felony.

C. It is unlawful for any person intentionally or knowingly:

1. To distribute as a registrant a controlled substance classified in schedule I or II, except pursuant to an order form as required by section 36-2524.
2. To furnish false or fraudulent material information in, or omit any material information from, any application, report or other document required to be kept or filed under this chapter or any record required to be kept by this chapter.

D. A person who violates any provision of subsection C of this section is guilty of a class 4 felony.

E. A person shall not provide a false prescription for a controlled substance or knowingly or intentionally acquire or obtain possession of a controlled substance by means of forgery, fraud, deception or subterfuge, including the forgery or falsification of a prescription or the nondisclosure of a material fact. A person who violates this subsection is guilty of a class 4 felony.

F. Controlled substances, vehicles and items used or intended for use in violation of this chapter are subject to seizure and forfeiture in the manner provided in title 13, chapter 39.

#### **ARTICLE 5 ENFORCEMENT AND ADMINISTRATION**

##### **36-2541. Administrative inspections and warrants**

A. Issuance and execution of administrative inspection warrants for purposes of this chapter shall be as follows:

1. A judge of a state court of record or any justice of the peace or magistrate within his jurisdiction and upon proper oath or affirmation showing probable cause may issue warrants for the purpose of conducting administrative inspections authorized by this chapter or rules adopted pursuant to this chapter and seizures of property appropriate to the inspections. For purposes of the issuance of administrative inspection warrants, probable cause exists upon showing a valid public interest in the effective enforcement of this chapter, or rules and regulations adopted pursuant to this chapter, sufficient to justify administrative inspection of the area, premises, building or conveyance in the circumstances specified in the application for the warrant.

2. A warrant shall issue only upon an affidavit of a peace officer or a member, officer or employee of the board having knowledge of the facts alleged, sworn to before the judge or magistrate and establishing the grounds for issuing the warrant. If the judge or magistrate is satisfied that grounds for the application exist or that there is probable cause to believe they exist, such judge or magistrate shall issue a warrant identifying the area, premises, building or conveyance to be inspected, the purpose of the inspection and the type of property to be inspected, if any. The warrant shall:

(a) State the grounds for its issuance and the name of each person whose affidavit has been taken in support thereof.

(b) Be directed to a peace officer to execute it.

(c) Command the person to whom it is directed to inspect the area, premises, building or conveyance identified for the purpose specified and, if appropriate, direct the seizure of the property specified.

(d) Identify the item or types of property to be seized, if any.

(e) Direct that it be served during normal business hours and designate the judge or magistrate to whom it shall be returned.

3. A warrant issued pursuant to this section shall be executed and returned within ten days of its date unless, upon a showing of a need for additional time, the court orders otherwise. If property is seized pursuant to a warrant, a copy shall be given to the person from whom or from whose premises the property is taken, together with a receipt for the property taken. The return of the warrant shall be made promptly, accompanied by a written inventory of any property taken. The inventory shall be made in the presence of the person executing the warrant and of the person from whose possession or premises the property was taken, if present, or in the presence of at least one credible person other than the person executing the warrant. A copy of the inventory shall be delivered to the person from whom or from whose premises the property was taken and to the applicant for the warrant.

4. The judge or magistrate who has issued a warrant shall attach to such warrant a copy of the return and all papers returnable and file them with the clerk of the court in which the inspection was executed.

B. The board, its members, officers or employees and officers and employees of the department or other peace officers may make administrative inspections of controlled premises in accordance with the following provisions:

1. For purposes of this section only, "controlled premises" means:

(a) Places where persons registered or exempted from registration requirements under this chapter are required to keep records.

(b) Places including factories, warehouses, establishments and conveyances in which persons registered or exempted from registration requirements under this chapter are permitted to hold, manufacture, compound, process, sell, deliver or otherwise dispose of any controlled substance.

2. When executing an administrative inspection warrant issued pursuant to subsection A of this section a peace officer may be accompanied by a member, officer or employee of the board, and upon presenting the warrant and appropriate credentials to the owner, operator or agent in charge they may enter controlled premises for the purpose of conducting an administrative inspection.

3. When authorized by an administrative inspection warrant, such officer or employee may:

(a) Inspect and copy records required by this chapter to be kept.

(b) Inspect, within reasonable limits and in a reasonable manner, controlled premises and all pertinent equipment, finished and unfinished material, containers and labeling found in such premises and, except as provided in paragraph 5 of this subsection, all other things, including records, files, papers, processes, controls and facilities bearing on any violation of this chapter.

(c) Inventory any stock of any controlled substance and obtain samples of such substance.

4. This section does not prevent the inspection without a warrant of books and records pursuant to an administrative subpoena nor does it prevent entries and administrative inspections, including seizures of property, without a warrant:

(a) If the owner, operator or agent in charge of the controlled premises consents.

(b) In situations presenting imminent danger to health or safety.

(c) In situations involving inspection of conveyances if there is reasonable cause to believe that the mobility of the conveyance makes it impracticable to obtain a warrant.

(d) In any other exceptional or emergency circumstance where time or opportunity to apply for a warrant is lacking.

(e) In all other situations in which a warrant is not constitutionally required.

5. An inspection authorized by this section shall not extend to financial data, sales data, other than shipment data, or pricing data unless the owner, operator or agent in charge of the controlled premises consents in writing.

**36-2542. Cooperation of agencies**

A. The board and department shall cooperate with federal and other state agencies in discharging responsibilities concerning traffic in controlled substances and in suppressing the abuse of controlled substances, including the dissemination of information to law enforcement agencies relating to any person who is known to have violated or who is suspected of violating this chapter to obtain a controlled substance in violation of section 36-2531.

B. Results, information and evidence received from the United States drug enforcement administration relating to the regulatory functions of this chapter, including results of inspections conducted by it, may be relied and acted upon by the board or department in the exercise of its regulatory functions under this chapter.

**36-2543. Review**

All final civil determinations, findings and conclusions of the board or the department under this chapter are final and conclusive unless appealed pursuant to title 12, chapter 7, article 6.

**36-2544. Education; research; public notices**

A. The board and department shall cooperate with the department of health services in carrying out educational programs designed to prevent and deter misuse and abuse of narcotic drugs, dangerous drugs, marijuana and controlled substances. In connection with these programs they may:

1. Promote better recognition of the problems of misuse and abuse of narcotic drugs, dangerous drugs, marijuana and controlled substances within the regulated industry and among interested groups and organizations.
2. Assist the regulated industry and interested groups and organizations in contributing to the reduction of misuse and abuse of narcotic drugs, dangerous drugs, marijuana and controlled substances.
3. Consult with interested groups and organizations to aid them in solving administrative and organizational problems.
4. Evaluate procedures, projects, techniques and controls conducted or proposed as part of educational programs on misuse and abuse of narcotic drugs, dangerous drugs, marijuana and controlled substances.
5. Disseminate the results of research on misuse and abuse of narcotic drugs, dangerous drugs, marijuana and controlled substances to promote a better public understanding of what problems exist and what can be done to combat them.
6. Assist in the education and training of state and local law enforcement officials in their efforts to control misuse and abuse of narcotic drugs, dangerous drugs, marijuana and controlled substances.

B. The board, department and department of health services shall encourage research on misuse and abuse of narcotic drugs, dangerous drugs, marijuana and controlled substances. In connection with the research, and in furtherance of the enforcement of this chapter and title 13, chapter 34, they may:

1. Establish methods to assess accurately the effects of narcotic drugs, dangerous drugs, marijuana and controlled substances and identify and characterize those with potential for abuse.
2. Make studies and undertake programs of research to:
  - (a) Develop new or improved approaches, techniques, systems, equipment and devices to strengthen the enforcement of this chapter and title 13, chapter 34.
  - (b) Determine patterns of misuse and abuse of narcotic drugs, dangerous drugs, marijuana and controlled substances and the social effects of such misuse and abuse.
  - (c) Improve methods for preventing, predicting, understanding and dealing with the misuse and abuse of narcotic drugs, dangerous drugs, marijuana and controlled substances.
3. Enter into contracts with public agencies, institutions of higher education and private organizations or individuals for the purpose of conducting research, demonstrations or special projects which bear directly on misuse and abuse of narcotic drugs, dangerous drugs, marijuana and controlled substances.

C. The board may authorize the possession and distribution of narcotic drugs, dangerous drugs, marijuana and controlled substances for scientific purposes. Persons who obtain this authorization are exempt from state prosecution for possession and distribution of narcotic drugs, dangerous drugs, marijuana and controlled substances to the extent of the authorization.

D. The department shall prescribe the posting of a public notice designed to educate the public regarding the dangers of using anabolic steroids and human growth hormone to deter the illegal use of these drugs. The notice shall cite the laws prohibiting the use of anabolic steroids and human growth hormone and the criminal penalty for their use, distribution, unauthorized prescribing, possession and sale. The department shall require that this notice be displayed prominently in the following locations:

1. High schools, colleges and universities.
2. Professional athletic team facilities.
3. Facilities that offer, promote or provide physical fitness or body building programs to members or clients.

**ARTICLE 6 MISCELLANEOUS**

**36-2551. Pending proceedings**

All administrative proceedings pending under prior laws which are superseded by this chapter shall be continued and brought to a final determination in accord with the laws and rules in effect prior to the effective date of this chapter.

**36-2552. Continuation of rules**

Any orders and rules promulgated under any law affected by this chapter and in effect on the effective date of this chapter and not in conflict with it continue in effect until modified, superseded or repealed.

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# PRESCRIPTION MONITORING PROGRAM: TITLE 36 – CHAPTER 28

## **ARTICLE 1 GENERAL PROVISIONS:**

### **36-2601. Definitions \*EFFECTIVE UNTIL 12/31/2015\***

In this article, unless the context otherwise requires:

1. "Board" means the Arizona state board of pharmacy or its designee.
2. "Dispenser" means a medical practitioner or pharmacy that is authorized to dispense controlled substances.
3. "Licensed health care provider" means a person who is licensed pursuant to title 32, chapter 7, 11, 13, 14, 15, 16, 17, 18, 19.1, 21, 25, 29 or 33.
4. "Medical practitioner" has the same meaning prescribed in section 32-1901.
5. "Person" means an individual, partnership, corporation or association and the person's duly authorized agents.
6. "Program" means the controlled substances prescription monitoring program.

### **36-2601. Definitions \*EFFECTIVE 01/01/2016\***

In this article, unless the context otherwise requires:

1. "Board" means the Arizona state board of pharmacy or its designee.
2. "Dispenser" means a medical practitioner or pharmacy that is authorized to dispense controlled substances.
3. "Licensed health care provider" means a person who is licensed pursuant to title 32, chapter 7, 11, 13, 14, 15, 16, 17, 18, 19.1, 25, 29 or 33.
4. "Medical practitioner" means any 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 for the diagnosis or prevention of sickness in human beings in this state or any state, territory or district of the United States.
5. "Person" means an individual, partnership, corporation or association and the person's duly authorized agents.
6. "Program" means the controlled substances prescription monitoring program.

### **36-2602. Controlled substances prescription monitoring program; contracts; retention and maintenance of records**

A. The board shall adopt rules to establish a controlled substances prescription monitoring program. The program shall:

1. Include a computerized central database tracking system to track the prescribing, dispensing and consumption of schedule II, III and IV controlled substances that are dispensed by a medical practitioner or by a pharmacy that holds a valid license or permit issued pursuant to title 32. The tracking system shall not interfere with the legal use of a controlled substance for the management of severe or intractable pain.
2. Assist law enforcement to identify illegal activity related to the prescribing, dispensing and consumption of schedule II, III and IV controlled substances.
3. Provide information to patients, medical practitioners and pharmacists to help avoid the inappropriate use of schedule II, III and IV controlled substances.
4. Be designed to minimize inconvenience to patients, prescribing medical practitioners and pharmacies while effectuating the collection and storage of information.

B. The board may enter into private or public contracts, including intergovernmental agreements pursuant to title 11, chapter 7, article 3, to ensure the effective operation of the program. Each contractor must comply with the confidentiality requirements prescribed in this article and is subject to the criminal penalties prescribed in section 36-2610.

C. The board shall maintain medical records information in the program pursuant to the standards prescribed in section 12-2297.

### **36-2603. Computerized central database tracking system task force; membership**

A. The board shall appoint a task force to help it administer the computerized central database tracking system. The chairperson of the board shall chair the task force. The task force shall include the following members:

1. Pharmacists, medical practitioners and other licensed health care providers.
2. Representatives of professional societies and associations for pharmacists, medical practitioners and other licensed health care providers.

3. Representatives of professional licensing boards.
4. Representatives of the Arizona health care cost containment system administration.
5. Representatives of state and federal agencies that have an interest in the control of controlled substances.
6. Criminal prosecutors.

B. The task force shall meet to establish the procedures and conditions relating to the release of prescription information pursuant to section 36-2604. The task force shall meet at least once each year and at the call of the chairperson.

C. Task force members serve at the pleasure of the board and are not eligible to receive compensation or reimbursement of expenses.

**36-2604. Use and release of confidential information \*EFFECTIVE UNTIL 12/31/2015\***

A. Except as otherwise provided in this section, prescription information submitted to the board pursuant to this article is confidential and is not subject to public inspection. The board shall establish procedures to ensure the privacy and confidentiality of patients and that patient information that is collected, recorded and transmitted pursuant to this article is not disclosed except as prescribed in this section.

B. The board or its designee shall review the prescription information collected pursuant to this article. If the board or its designee has reason to believe an act of unprofessional or illegal conduct has occurred, the board or its designee shall notify the appropriate professional licensing board or law enforcement or criminal justice agency and provide the prescription information required for an investigation.

C. The board may release data collected by the program to the following:

1. A person who is authorized to prescribe or dispense a controlled substance, or a delegate who is authorized by the prescriber or dispenser, to assist that person to provide medical or pharmaceutical care to a patient or to evaluate a patient.
2. An individual who requests the individual's own prescription monitoring information pursuant to section 12-2293.
3. A professional licensing board established pursuant to title 32, chapter 7, 11, 13, 14, 15, 16, 17, 18, 21, 25 or 29. Except as required pursuant to subsection B of this section, the board shall provide this information only if the requesting board states in writing that the information is necessary for an open investigation or complaint.
4. A local, state or federal law enforcement or criminal justice agency. Except as required pursuant to subsection B of this section, the board shall provide this information only if the requesting agency states in writing that the information is necessary for an open investigation or complaint.
5. The Arizona health care cost containment system administration regarding persons who are receiving services pursuant to chapter 29 of this title. Except as required pursuant to subsection B of this section, the board shall provide this information only if the administration states in writing that the information is necessary for an open investigation or complaint.
6. A person who is serving a lawful order of a court of competent jurisdiction.
7. A person who is authorized to prescribe or dispense a controlled substance and who performs an evaluation on an individual pursuant to section 23-1026.

D. The board may provide data to public or private entities for statistical, research or educational purposes after removing information that could be used to identify individual patients or persons who received prescriptions from dispensers.

E. For the purposes of the section, "delegate" means a licensed health care professional who is employed in the office of or in a hospital with the prescriber or dispenser or an unlicensed medical records technician, medical assistant or office manager who is employed in the office of or in a hospital with the prescriber and who has received training regarding both the Health Insurance Portability and Accountability Act privacy standards, 45 code of federal regulations part 164, subpart E, and security standard, 45 code of federal regulations part 164, subpart C.

**36-2604. Use and release of confidential information \*EFFECTIVE 01/01/2016\***

A. Except as otherwise provided in this section, prescription information submitted to the board pursuant to this article is confidential and is not subject to public inspection. The board shall establish procedures to ensure the privacy and confidentiality of patients and that patient information that is collected, recorded and transmitted pursuant to this article is not disclosed except as prescribed in this section.

B. The board or its designee shall review the prescription information collected pursuant to this article. If the board or its designee has reason to believe an act of unprofessional or illegal conduct has occurred, the board or its designee shall notify the appropriate professional licensing board or law enforcement or criminal justice agency and provide the prescription information required for an investigation.

C. The board may release data collected by the program to the following:

1. A person who is authorized to prescribe or dispense a controlled substance, or a delegate who is authorized by the prescriber or dispenser, to assist that person to provide medical or pharmaceutical care to a patient or to evaluate a patient.
2. An individual who requests the individual's own prescription monitoring information pursuant to section 12-2293.
3. A medical practitioner regulatory board established pursuant to title 32, chapter 7, 11, 13, 14, 15, 16, 17, 18, 25 or 29. Except as required pursuant to subsection B of this section, the board shall provide this information only if the requesting board states in writing that the information is necessary for an open investigation or complaint.
4. A local, state or federal law enforcement or criminal justice agency. Except as required pursuant to subsection B of this section, the board shall provide this information only if the requesting agency states in writing that the information is necessary for an open investigation or complaint.
5. The Arizona health care cost containment system administration regarding persons who are receiving services pursuant to chapter 29 of this title. Except as required pursuant to subsection B of this section, the board shall provide this information only if the administration states in writing that the information is necessary for an open investigation or complaint.
6. A person who is serving a lawful order of a court of competent jurisdiction.
7. A person who is authorized to prescribe or dispense a controlled substance and who performs an evaluation on an individual pursuant to section 23-1026.
8. A county medical examiner or alternate medical examiner who is directing an investigation into the circumstances surrounding a death as described in section 11-593 or a delegate who is authorized by the county medical examiner or alternate medical examiner.

D. The board may provide data to public or private entities for statistical, research or educational purposes after removing information that could be used to identify individual patients or persons who received prescriptions from dispensers.

E. For the purposes of the section, "delegate" means any of the following:

1. A licensed health care professional who is employed in the office of or in a hospital with the prescriber or dispenser.
2. A unlicensed medical records technician, medical assistant or office manager who is employed in the office of or in a hospital with the prescriber or dispenser and who has received training regarding both the Health Insurance Portability and Accountability Act privacy standards, 45 code of federal regulations part 164, subpart E, and security standard, 45 code of federal regulations part 164, subpart C.
3. A forensic pathologist, medical death investigator or other qualified person who is assigned duties in connection with a death investigation pursuant to section 11-594.

**36-2605. Controlled substances prescription monitoring program fund**

A. The controlled substances prescription monitoring program fund is established consisting of legislative appropriations, transfers pursuant to section 32-1907 and any grants, gifts or donations received by the board. The board shall administer the fund. Monies in the fund are continuously appropriated and shall be used to operate the controlled substances prescription monitoring program established pursuant to section 36-2602.

B. The board may apply for grants and may accept gifts, grants or donations for the establishment and maintenance of the computerized prescription monitoring program.

**36-2606. Registration; requirements \*EFFECTIVE UNTIL 12/31/2015\***

A. Beginning November 1, 2007 and pursuant to rules adopted by the board, each medical practitioner who is issued a license pursuant to title 32 and who possesses a registration under the federal controlled substances act must have a current controlled substances prescription monitoring program registration issued by the board. The registration is:

1. Subject to biennial renewal as specified in this article.
2. Not transferable or assignable.
3. Valid only in conjunction with a valid license issued by a professional licensing board established pursuant to title 32, chapter 7, 11, 13, 14, 15, 16, 17, 21, 25 or 29.

B. An applicant for registration pursuant to this section must submit an application as prescribed by the board.

C. The board shall assign all persons registered under this article to one of two registration renewal groups. The holder of a registration ending in an even number must renew the registration biennially on or before May 1 of the next even-numbered year. The holder of a registration ending in an odd number must renew the registration biennially on or before May 1 of the next odd-numbered year. The board shall automatically suspend the registration of any registrant who fails to renew the registration on or before May 1 of the year in which the renewal is due. The board shall vacate a suspension if the registrant submits a renewal application. A suspended registrant is prohibited from accessing information in the prescription monitoring program database tracking system.

D. A registrant shall not apply for registration renewal more than sixty days before the expiration date of the registration.

E. An applicant for registration renewal pursuant to this section must submit a renewal application prescribed by the board by rule.

F. Pursuant to a fee prescribed by the board by rule, the board may issue a replacement registration to a registrant who requests a replacement because the original was damaged or destroyed, because of a change of name or for any other good cause as prescribed by the board.

**36-2606. Registration; requirements \*EFFECTIVE 01/01/2016\***

A. Beginning November 1, 2007 and pursuant to rules adopted by the board, each medical practitioner who is issued a license pursuant to title 32 and who possesses an Arizona registration under the controlled substances act (21 United States Code, Sections 801 through 904) must have a current controlled substances prescription monitoring program registration issued by the board and be granted access to the program's central database tracking system. The Arizona State Board of Pharmacy, on receipt of licensure and license renewal confirmation from a medical practitioner regulatory board established pursuant to title 32, Chapter 7, 11, 13, 14, 15, 16, 17, 25 or 29, shall register each medical practitioner who possesses an Arizona registration under the controlled substances act (21 United States Code, Sections 801 through 904) and provide the medical practitioner access to the program's central database tracking system and how to use the system. The Arizona State Board of Pharmacy shall notify each medical practitioner receiving an initial license who intends to apply for registration under the controlled substances act (21 United States Code, Sections 801 through 904) of the person's responsibility and the process to register with the Arizona State Board of Pharmacy and be granted access to the program's central database tracking system.

B. The registration is:

1. Until January 1, 2020, subject to biennial renewal as specified in this article, except for medical practitioners whose registration and renewal are provided pursuant to subsection A of this section.

2. Not transferable or assignable.

3. Valid only in conjunction with a valid license issued by a medical practitioner regulatory board established pursuant to title 32, chapter 7, 11, 13, 14, 15, 16, 17, 25 or 29.

C. An applicant for registration pursuant to this section must submit an application as prescribed by the board unless the medical practitioner's registration and renewal are provided pursuant to subsection A of this section.

D. Until January 1, 2020, the board shall assign all persons registered under this article to one of two registration renewal groups. The holder of a registration ending in an even number must renew the registration biennially on or before May 1 of the next even-numbered year. The holder of a registration ending in an odd number must renew the registration biennially on or before May 1 of the next odd-numbered year. The board shall automatically suspend the registration of any registrant who fails to renew the registration on or before May 1 of the year in which the renewal is due. The board shall vacate a suspension if the registrant submits a renewal application. A suspended registrant is prohibited from accessing information in the prescription monitoring program database tracking system. This subsection does not apply to medical practitioners whose registration and renewal are provided pursuant to subsection A of this section.

E. A registrant shall not apply for registration renewal more than sixty days before the expiration date of the registration.

F. An applicant for registration renewal pursuant to this section must submit a renewal application prescribed by the board by rule unless the medical practitioner's registration and renewal are provided pursuant to subsection A of this section.

g Pursuant to a fee prescribed by the board by rule, the board may issue a replacement registration to a registrant who requests a replacement because the original was damaged or destroyed, because of a change of name or for any other good cause as prescribed by the board.

**36-2607. Disciplinary action**

A. The registrant's professional licensing board may revoke or suspend a registrant's registration or may place the registrant on probation for any of the following:

1. The registrant's professional licensing board determines that the registration was obtained by fraudulent means.

2. The registrant's professional licensing board takes action to revoke, suspend or place on probation the registrant's license, permit or registration to prescribe or dispense drugs.

3. The registration was issued through error.
4. The registrant knowingly files with the board any application, renewal or other document that contains false or misleading information or the registrant gives false or misleading testimony to the board.
5. The registrant knowingly makes a false report or record required by this article.

B. The board may deny a registration to an applicant for the grounds prescribed in subsection A.

C. In addition to any other law, a licensed or permitted medical practitioner, pharmacist or pharmacy that fails to comply with the requirements of this article is subject to disciplinary action by the medical practitioner's, pharmacist's or pharmacy's professional licensing board. The board of pharmacy shall report to the appropriate professional licensing board the failure of a licensed or permitted medical practitioner, pharmacist or pharmacy to comply with the requirements of this article.

### **36-2608. Reporting requirements**

A. If a medical practitioner dispenses a controlled substance listed in section 36-2513, 36-2514 or 36-2515, 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 drug enforcement administration controlled substance registration number of the dispenser.
2. The name, address and date of birth of the person or, if for an animal, the owner of the animal for whom the prescription is written.
3. The name, address, telephone number and 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 or IV 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 submit the required information more frequently than once each day.

D. A dispenser who does not have an automated record keeping 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 or IV 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 or IV 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 drug enforcement administration as a narcotic treatment program and that is subject to the record keeping provisions of 21 Code of Federal Regulations section 1304.24.

**36-2609. Use of information; civil immunity**

A. An individual or entity that complies with the reporting requirements of section 36-2608 is not subject to civil liability or other civil relief for reporting the information to the board.

B. Unless a court of competent jurisdiction makes a finding of malice or criminal intent, the board, any other state agency or any person or entity in proper possession of information pursuant to this article is not subject to civil liability or other legal or equitable relief for any of the following acts or omissions:

1. Furnishing information pursuant to this article.
2. Receiving, using or relying on, or not using or relying on, information received pursuant to this article.
3. Information that was not furnished to the board.
4. Information that was factually incorrect or that was released by the board to the wrong person or entity.

**36-2610. Prohibited acts; violation; classification**

A. A person who is subject to this article and who fails to report required information pursuant to section 36-2608 is guilty of a class 2 misdemeanor.

B. A person who is subject to this article and who knowingly fails to report required information to the board in violation of section 36-2608 is guilty of a class 1 misdemeanor.

C. A person who is subject to this article and who knowingly reports information to the board that the person knows to be false or fraudulent is guilty of a class 6 felony.

D. A person who is granted access to the information maintained by the board as required by this article and who knowingly discloses the information in a manner inconsistent with a legitimate professional or regulatory purpose, a legitimate law enforcement purpose, the terms of a court order or as otherwise expressly authorized by this article is guilty of a class 6 felony.

**36-2611. Program termination \*EFFECTIVE UNTIL TO 12/31/2015\***

The program established by this chapter ends on July 1, 2017 pursuant to section 41-3102.

**36-2611. Program termination \*EFFECTIVE 01/01/2016\***

Statute is repealed.

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**ARIZONA ADMINISTRATIVE CODE – TITLE 4 PROFESSIONS & OCCUPATIONS CHAPTER 23 BOARD OF PHARMACY**

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# **ARIZONA ADMINISTRATIVE CODE – TITLE 4 PROFESSIONS & OCCUPATIONS CHAPTER 23**

## **ARTICLE 1. ADMINISTRATION:**

### **R4-23-101. General**

A. 4 A.A.C. 23 applies to all actions and proceedings of the Board and shall be deemed a part of the record in any Board action or proceeding without formal introduction of, or reference to the rules. A party to a Board action is deemed to have knowledge of the rules. The Board office shall provide a copy of the rules:

1. To each license applicant who submits a completed application packet; and
2. To each permit applicant during the final compliance inspection after the Board approves the permit application.

B. The Board, within its jurisdiction, may, in the interest of justice, excuse the failure of any person to comply with the rules.

C. The Board, within its jurisdiction, may grant an extension of time within which to comply with any rule when it deems the extension to be in the interest of justice.

### **R4-23-102. Meetings**

A. The Board shall hold not less than four meetings per fiscal year to conduct general business and interview permit and license applicants.

B. A special meeting of the Board may be held at any time subject to the call of the President or a majority of the Board members and in compliance with the notification requirements of A.R.S. § 38-431.02.

### **R4-23-103 thru R4-23-109. Repealed**

### **R4-23-110. Definitions**

In addition to definitions in A.R.S. § 32-1901, the following definitions apply to 4 A.A.C. 23:

"Active ingredient" means any component that furnishes pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or that affects the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug, that are present in the finished drug product in a modified form, and that furnish the specified activity or effect.

"AHCCCS" means the Arizona Health Care Cost Containment System.

"Annual family income" means the combined yearly gross earned income and unearned income of all adult individuals within a family unit.

"Approved course in pharmacy law" means a continuing education activity that addresses practice issues related to state or federal pharmacy statutes, rules, or regulations.

"Approved Provider" means an individual, institution, organization, association, corporation, or agency that is approved by the Accreditation Council for Pharmacy Education (ACPE) in accordance with ACPE's policy and procedures or by the Board as meeting criteria indicative of the ability to provide quality continuing education.

"Assisted living facility" means a residential care institution as defined in A.R.S. § 36-401.

"Authentication of product history" means identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other drug.

"Automated dispensing system" means a mechanical system in a long-term care facility that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications, and which collects, controls and maintains all transaction information.

"Automated storage and distribution system" means a mechanical system that performs operations or activities other than counting, compounding, or administration, relative to the storage, packaging, or distributing of drugs or devices and that collects, controls, and maintains all transaction information.

"Batch" means a specific quantity of drug that has uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

"Beyond-use date" means:

- A date determined by a pharmacist and placed on a prescription label at the time of dispensing to indicate a time beyond which the contents of the prescription are not recommended to be used; or
- A date determined by a pharmacist and placed on a compounded pharmaceutical product's label at the time of preparation as specified in R4-23-410(B)(3)(d), R4-23-410(I)(6)(e), or R4-23-410(J)(1)(d) to indicate a time beyond which the compounded pharmaceutical product is not recommended to be used.

"Biological safety cabinet" means a containment unit suitable for the preparation of low to moderate risk agents when there is a need for protection of the product, personnel, and environment, consistent with National Sanitation Foundation (NSF) standards, published in the National Sanitation Foundation Standard 49, Class II (Laminar Flow) Biohazard Cabinetry, NSF International P. O. Box 130140, Ann Arbor, MI, 48105, revised June 1987 edition, (and no future amendments or editions), incorporated by reference and on file with the Board.

"Care-giver" means a person who cares for someone who is sick or disabled or an adult who cares for an infant or child and includes a patient's husband, wife, son, daughter, mother, father, sister, brother, legal guardian, nurse, or medical practitioner.

"Community pharmacy" means any place under the direct supervision of a pharmacist where the practice of pharmacy occurs or where prescription orders are compounded and dispensed other than a hospital pharmacy or a limited service pharmacy.

"Component" means any ingredient used in compounding or manufacturing drugs in dosage form, including an ingredient that may not appear in the finished product.

"Compounding and dispensing counter" means a pharmacy counter working area defined in this Section where a pharmacist or a graduate intern, pharmacy intern, pharmacy technician, or pharmacy technician trainee under the supervision of a pharmacist compounds, mixes, combines, counts, pours, or prepares and packages a prescription medication to dispense an individual prescription order or prepackages a drug for future dispensing.

"Computer system" means an automated data-processing system that uses a programmable electronic device to store, retrieve, and process data.

"Computer system audit" means an accounting method, involving multiple single-drug usage reports and audits, used to determine a computer system's ability to store, retrieve, and process original and refill prescription dispensing information.

"Contact hour" means 50 minutes of participation in a continuing education activity sponsored by an Approved Provider.

"Container" means:

- A receptacle, as described in the official compendium or the federal act, that is used in manufacturing or compounding a drug or in distributing, supplying, or dispensing the finished dosage form of a drug; or
- A metal receptacle designed to contain liquefied or vaporized compressed medical gas and used in manufacturing, transfilling, distributing, supplying, or dispensing a compressed medical gas.

"Continuing education" means a structured learning process required of a licensee to maintain licensure that includes study in the general areas of socio-economic and legal aspects of health care; the properties and actions of drugs and dosage forms; etiology, characteristics and therapeutics of disease status; or pharmacy practice.

"Continuing education activity" means continuing education obtained through an institute, seminar, lecture, conference, workshop, mediated instruction, programmed learning course, or postgraduate study in an accredited college or school of pharmacy.

"Continuing education unit" or "CEU" means 10 contact hours of participation in a continuing education activity sponsored by an Approved Provider.

"Continuous quality assurance program" or "CQA program" means a planned process designed by a pharmacy permittee to identify, evaluate and prevent medication errors.

"Correctional facility" has the same meaning as in A.R.S. §§ 13-2501 and 31-341.

"CRT" means a cathode ray tube or other mechanism used to view information produced or stored by a computer system.

"CSPMP" means the Controlled Substances Prescription Monitoring Program established under A.R.S. Title 36, Chapter 28.

"Current good compounding practices" means the minimum standards for methods used in, and facilities or controls used for, compounding a drug to ensure that the drug has the identity and strength and meets the quality and purity characteristics it is represented to possess.

"Current good manufacturing practice" means the minimum standard for methods used in, and facilities or controls used for manufacturing, processing, packing, or holding a drug to ensure that the drug meets the requirements of the federal act as to safety, and has the identity and strength and meets the quality and purity characteristics it is represented to possess.

"Cytotoxic" means a pharmaceutical that is capable of killing living cells.

"Day" means a calendar day unless otherwise specified.

"DEA" means the Drug Enforcement Administration as defined in A.R.S. § 32-1901.

"Declared disaster areas" means areas designated by the governor or by a county, city, or town under A.R.S. § 32-1910 as those areas that have been adversely affected by a natural disaster or terrorist attack and require extraordinary measures to provide adequate, safe, and effective health care for the affected population.

"Delinquent license" means a pharmacist, pharmacy intern, graduate intern, or pharmacy technician license the Board suspends for failure to renew or pay all required fees on or before the date the renewal is due.

"Dietary supplement" means a product (other than tobacco) that:

- Is intended to supplement the diet that contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients;
- Is intended for ingestion in pill, capsule, tablet, or liquid form;
- Is not represented for use as a conventional food or as the sole item of a meal or diet; and
- Is labeled as a "dietary supplement."

"Digital signature" has the same meaning as in A.R.S. § 41-132(E).

"Dispensing pharmacist" means a pharmacist who, in the process of dispensing a prescription medication after the complete preparation of the prescription medication and before delivery of the prescription medication to a patient or patient's agent, verifies, checks, and initials the prescription medication label, as required in R4-23-402(A).

"Drug sample" means a unit of a prescription drug that a manufacturer provides free of charge to promote the sale of the drug.

"Durable medical equipment" or "DME" means technologically sophisticated medical equipment that may be used by a patient or consumer in a home or residence. DME may be prescription-only devices as defined in A.R.S. § 32-1901(75). DME includes:

Air-fluidized beds, Apnea monitors, Blood glucose monitors and diabetic testing strips, Continuous Positive Airway Pressure (CPAP) machines, Electronic and computerized wheelchairs and seating systems, Feeding pumps, Home phototherapy devices, Hospital beds, Infusion pumps, Medical oxygen and oxygen delivery systems excluding compressed medical gases, Nebulizers, Respiratory disease management devices, Sequential compression devices, Transcutaneous electrical nerve stimulation (TENS) unit, and Ventilators.

"Earned income" means monetary payments received by an individual as a result of work performed or rental property owned or leased by the individual, including: Wages, Commissions and fees, Salaries and tips, Profit from self-employment, Profit from rent received from a tenant or boarder, and Any other monetary payments received by an individual for work performed or rental of property.

"Electronic signature" has the same meaning as in A.R.S. § 44-7002.

"Eligible patient" means a patient who a pharmacist determines is eligible to receive an immunization using professional judgment after consulting with the patient regarding the patient's current health condition, recent health condition, and allergies.

"Emergency drug supply unit" means those drugs that may be required to meet the immediate and emergency therapeutic needs of long-term care facility residents and hospice inpatient facility patients, and which are not available from any other authorized source in sufficient time to prevent risk of harm to residents or patients.

"Extreme emergency" means the occurrence of a fire, water leak, electrical failure, public disaster, or other catastrophe constituting an imminent threat of physical harm to pharmacy personnel or patrons.

"Family unit" means: A group of individuals residing together who are related by birth, marriage, or adoption; or An individual who: Does not reside with another individual; or Resides only with another individual or group of individuals to whom the individual is unrelated by birth, marriage, or adoption.

"FDA" means the Food and Drug Administration, a federal agency within the United States Department of Health and Human Services, established to set safety and quality standards for foods, drugs, cosmetics, and other consumer products.

"Health care decision maker" has the same meaning as in A.R.S. § 12-2291.

"Health care institution" has the same meaning as in A.R.S. § 36-401.

"Hospice inpatient facility" means a health care institution licensed under A.R.S. § 36-401 and Article 8 that provides hospice services to a patient requiring inpatient services.

"Immediate notice" means a required notice sent by mail, facsimile, or electronic mail to the Board Office within 24 hours.

"Immunizations training program" means an immunization training program for pharmacists, pharmacy interns, and graduate interns that meets the requirements of R4-23-411(E).

"Inactive ingredient" means any component other than an "active ingredient" present in a drug.

"Internal test assessment" means performing quality assurance or other procedures necessary to ensure the integrity of a test.

"ISO Class 5 environment" means an atmospheric environment that complies with the ISO/TC209 International Cleanroom Standards, specifically ANSI/IEST/ISO-14644-1:1999: Cleanrooms and associated controlled environments--Part 1: Classification of air cleanliness, first edition dated May 1, 1999, (and no future amendments or editions), incorporated by reference and on file in the Board office.

"ISO Class 7 environment" means an atmospheric environment that complies with the ISO/TC209 International Cleanroom Standards, specifically ANSI/IEST/ISO-14644-1:1999: Cleanrooms and associated controlled environments--Part 1: Classification of air cleanliness, first edition dated May 1, 1999, (and no future amendments or editions), incorporated by reference and on file in the Board office.

"Licensed health care professional" means an individual who is licensed and regulated under A.R.S. Title 32, Chapter 7, 11, 13, 14, 15, 16, 17, 18, 25, 29, or 35.

"Limited-service correctional pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that:

- Holds a current Board permit under A.R.S. § 32-1931;
- Is located in a correctional facility; and
- Uses pharmacists, interns, and support personnel to compound, produce, dispense, and distribute drugs.

"Limited-service long-term care pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current Board-issued permit and dispenses prescription medication or prescription-only devices to patients in long-term care facilities.

"Limited-service mail-order pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current Board permit under A.R.S. § 32-1931 and dispenses a majority of its prescription medication or prescription-only devices by mailing or delivering the prescription medication or prescription-only device to an individual by the United States mail, a common or contract carrier, or a delivery service.

"Limited-service nuclear pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current Board permit under A.R.S. § 32-1931 and provides radiopharmaceutical services.

"Limited-service pharmacy permittee" means a person who holds a current limited-service pharmacy permit in compliance with A.R.S. §§ 32-1929, 32-1930, 32-1931, and A.A.C. R4-23-606.

"Limited-service sterile pharmaceutical products pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current Board permit under A.R.S. § 32-1931 and dispenses a majority of its prescription medication or prescription-only devices as sterile pharmaceutical products.

"Long-term care consultant pharmacist" means a pharmacist providing consulting services to a long-term care facility.

"Long-term care facility" or "LTCF" means a nursing care institution as defined in A.R.S. § 36-401.

"Lot" means a batch or any portion of a batch of a drug, or if a drug produced by a continuous process, an amount of drug produced in a unit of time or quantity in a manner that assures its uniformity. In either case, a lot is identified by a distinctive lot number and has uniform character and quality with specified limits.

"Lot number" or "control number" means any distinctive combination of letters or numbers, or both, from which the complete history of the compounding or manufacturing, control, packaging, and distribution of a batch or lot of a drug can be determined.

"Low-income subsidy" means Medicare-provided assistance that may partially or fully cover the costs of drugs and is based on the income of an individual and, if applicable, the individual's spouse.

"Materials approval unit" means any organizational element having the authority and responsibility to approve or reject components, in-process materials, packaging components, and final products.

"Mechanical counting device for a drug in solid, oral dosage form" means a mechanical device that counts drugs in solid, oral dosage forms for dispensing and includes an electronic balance when used to count drugs.

"Mechanical storage and counting device for a drug in solid, oral dosage form" means a mechanical device that stores and counts and may package or label drugs in solid, oral dosage forms for dispensing.

"Mediated instruction" means information transmitted via intermediate mechanisms such as audio or video tape or telephone transmission.

"Medical practitioner-patient relationship" means that before prescribing, dispensing, or administering a prescription-only drug, prescription-only device, or controlled substance to a person, a medical practitioner, as defined in A.R.S. § 32-1901, shall first conduct a physical examination of that person or have previously conducted a physical examination. This subdivision does not apply to:

- A medical practitioner who provides temporary patient supervision on behalf of the patient's regular treating medical practitioner;
- Emergency medical situations as defined in A.R.S. § 41-1831;
- Prescriptions written to prepare a patient for a medical examination; or
- Prescriptions written, prescription-only drugs, prescription-only devices, or controlled substances issued for use by a county or tribal public health department for immunization programs, emergency treatment, in response to an infectious disease investigation, public health emergency, infectious disease outbreak or act of bioterrorism. For purposes of this subsection, "bioterrorism" has the same meaning as in A.R.S. § 36-781.

"Medicare" means a federal health insurance program established under Title XVIII of the Social Security Act.

"Medication error" means any unintended variation from a prescription or medication order. Medication error does not include any variation that is corrected before the medication is dispensed to the patient or patient's care-giver, or any variation allowed by law.

"Mobile pharmacy" means a pharmacy that is self propelled or movable by another vehicle that is self propelled.

"MPJE" means Multistate Pharmacy Jurisprudence Examination, a Board-approved national pharmacy law examination written and administered in cooperation with NABP.

"NABP" means National Association of Boards of Pharmacy.

"NABPLEX" means National Association of Boards of Pharmacy Licensure Examination.

"NAPLEX" means North American Pharmacist Licensure Examination.

"Order" means either of the following: A prescription order as defined in A.R.S. § 32-1901; or A medication order as defined in A.A.C. R4-23-651.

"Other designated personnel" means a non-pharmacist individual who is permitted in the pharmacy area, for a limited time, under the direct supervision of a pharmacist, to perform non-pharmacy related duties, such as trash removal, floor maintenance, and telephone or computer repair.

"Outpatient" means an individual who is not a residential patient in a health care institution.

"Outpatient setting" means a location that provides medical treatment to an outpatient.

"Patient profile" means a readily retrievable, centrally located information record that contains patient demographics, allergies, and medication profile.

"Pharmaceutical patient care services" means the provision of drug selection, drug utilization review, drug administration, drug therapy monitoring, and other drug-related patient care services intended to achieve outcomes related to curing or preventing a disease, eliminating or reducing a patient's symptoms, or arresting or slowing a disease process, by identifying and resolving or preventing potential and actual drug-related problems.

"Pharmaceutical product" means a medicinal drug.

"Pharmacy counter working area" means a clear and continuous working area that contains no major obstacles such as a desktop computer, computer monitor, computer keyboard, external computer drive device, printer, facsimile machine, pharmacy balance, typewriter, or pill-counting machine, but may contain individual documents or prescription labels, pens, prescription blanks, refill log, pill-counting tray, spatula, stapler, or other similar items necessary for the prescription-filling process.

"Pharmacy law continuing education" means a continuing education activity that addresses practice issues related to state or federal pharmacy statutes, rules, or regulations, offered by an Approved Provider.

"Pharmacy permittee" means a person who holds a current pharmacy permit that complies with A.R.S. §§ 32-1929, 32-1930, 32-1931, 32-1934, and A.A.C. R4-23-606 and R4-23-652.

"Physician" means a medical practitioner licensed under A.R.S. Title 32, Chapter 13 or 17.

"Physician-in-charge" means a physician who is responsible to the Board for all aspects of a prescription medication donation program required in A.R.S. § 32-1909 and operated in the physician's office or in a health care institution.

"Poverty level" means the annual family income for a family unit of a particular size, as specified in the poverty guidelines updated annually in the Federal Register by the U.S. Department of Health and Human Services.

"Precursor chemical" means a precursor chemical I as defined in A.R.S. § 13-3401(26) and a precursor chemical II as defined in A.R.S. § 13-3401(27).

"Prepackaged drug" means a drug that is packaged in a frequently prescribed quantity, labeled in compliance with A.R.S. §§ 32-1967 and 32-1968, stored, and subsequently dispensed by a pharmacist or a graduate intern or pharmacy intern under the supervision of a pharmacist, who verifies at the time of dispensing that the drug container is properly labeled, in compliance with A.R.S. § 32-1968, for the patient.

"Prep area" means a specified area either within an ISO class 7 environment or adjacent to but outside an ISO class 7 environment that: Allows the assembling of necessary drugs, supplies, and equipment for compounding sterile pharmaceutical products, but does not allow the use of paper products such as boxes or bulk drug storage; Allows personnel to don personnel protective clothing, such as gown, gloves, head cover, and booties before entering the clean compounding area; and Is a room or a specified area within a room, such as an area specified by a line on the floor.

"Primary care provider" means the medical practitioner who is treating an individual for a disease or medical condition.

"Proprietor" means the owner of a business permitted by the Board under A.R.S. §§ 32-1929, 32-1930, 32-1931, and 32-1934.

"Provider pharmacy" means a pharmacy that contracts with a long-term care facility to supply prescription medication or other services for residents of a long-term care facility.

"Radiopharmaceutical" means any drug that emits ionizing radiation and includes:

- Any nonradioactive reagent kit, nuclide generator, or ancillary drug intended to be used in the preparation of a radiopharmaceutical, but does not include drugs such as carbon-containing compounds or potassium-containing salts, that contain trace quantities of naturally occurring radionuclides; and
- Any biological product that is labeled with a radionuclide or intended to be labeled with a radionuclide.

"Radiopharmaceutical quality assurance" means performing and interpreting appropriate chemical, biological, and physical tests on radiopharmaceuticals to determine the suitability of the radiopharmaceutical for use in humans and animals. Radiopharmaceutical quality assurance includes internal test assessment, authentication of product history, and appropriate record retention.

"Radiopharmaceutical services" means procuring, storing, handling, compounding, preparing, labeling, quality assurance testing, dispensing, distributing, transferring, recordkeeping, and disposing of radiochemicals, radiopharmaceuticals, and ancillary drugs. Radiopharmaceutical services include quality assurance procedures, radiological health and safety procedures, consulting activities associated with the use of radiopharmaceuticals, and any other activities required for the provision of pharmaceutical care.

"Red C stamp" means a device used with red ink to imprint an invoice with a red letter C at least one inch high, to make an invoice of a Schedule III through IV controlled substance, as defined in A.R.S. § 36-2501, readily retrievable, as required by state and federal rules.

"Refill" means other than the original dispensing of the prescription order, dispensing a prescription order in the same quantity originally ordered or in multiples of the originally ordered quantity when specifically authorized by the prescriber, if the refill is authorized by the prescriber:

- In the original prescription order;
- By an electronically transmitted refill order that the pharmacist promptly documents and files; or
- By an oral refill order that the pharmacist promptly documents and files.

"Regulated chemical" means the same as in A.R.S. § 13-3401(30).

"Remodel" means to alter structurally the pharmacy area or location.

"Remote drug storage area" means an area that is outside the premises of the pharmacy, used for the storage of drugs, locked to deny access by unauthorized persons, and secured against the use of force.

"Resident" means:

- An individual admitted to and living in a long-term care facility or an assisted living facility,
- An individual who has a place of habitation in Arizona and lives in Arizona as other than a tourist, or
- A person who owns or operates a place of business in Arizona.

"Responsible person" means the owner, manager, or other employee who is responsible to the Board for a permitted establishment's compliance with the laws and administrative rules of this state and of the federal government pertaining to distribution of drugs, devices, precursor chemicals, and regulated chemicals. Nothing in this definition relieves other individuals from the responsibility to comply with state and federal laws and administrative rules.

"Score transfer" means the process that enables an applicant to take the NAPLEX in a jurisdiction and be eligible for licensure by examination in other jurisdictions.

"Security features" means the attributes incorporated into the paper of a prescription order, referenced in A.R.S. § 32-1968(A)(4), that are approved by the Board or its staff and that includes one or more of the following features that attempt to prevent duplication or aid the authentication of a paper document: laid lines, enhanced laid lines, thermochromic ink, artificial watermark, fluorescent ink, chemical void, persistent void, penetrating numbers, high-resolution border, high-resolution latent images, micro-printing, prismatic printing, embossed images, abrasion ink, holograms, and foil stamping.

"Shared order filling" means the following:

- Preparing, packaging, compounding, or labeling an order, or any combination of these functions, that are performed by:
- A person with a current Arizona Board license, located at an Arizona pharmacy, on behalf of and at the request of another resident or nonresident pharmacy; or
- A person, located at a nonresident pharmacy, on behalf of and at the request of an Arizona pharmacy; and
- Returning the filled order to the requesting pharmacy for delivery to the patient or patient's care-giver or, at the request of this pharmacy, directly delivering the filled order to the patient.

"Shared order processing" means the following:

- Interpreting the order, performing order entry verification, drug utilization review, drug compatibility and drug allergy review, final order verification, and when necessary, therapeutic intervention, or any combination of these order processing functions, that are performed by:
- A pharmacist or intern, under pharmacist supervision, with a current Arizona Board license, located at an Arizona pharmacy, on behalf of and at the request of another resident or nonresident pharmacy; or
- A pharmacist or intern, under pharmacist supervision, located at a nonresident pharmacy, on behalf of and at the request of an Arizona pharmacy; and

- After order processing is completed, returning the processed order to the requesting pharmacy for order filling and delivery to the patient or patient's care-giver or, at the request of this pharmacy, returning the processed order to another pharmacy for order filling and delivery to the patient or patient's care-giver.

"Shared services" means shared order filling or shared order processing, or both.

"Sight-readable" means that an authorized individual is able to examine a record and read its information from a CRT, microfiche, microfilm, printout, or other method acceptable to the Board or its designee.

"Single-drug audit" means an accounting method that determines the numerical and percentage difference between a drug's beginning inventory plus purchases and ending inventory plus sales.

"Single-drug usage report" means a computer system printout of original and refill prescription order usage information for a single drug.

"Standard-risk sterile pharmaceutical product" means a sterile pharmaceutical product compounded from sterile commercial drugs using sterile commercial devices or a sterile pharmaceutical otic or ophthalmic product compounded from non-sterile ingredients.

"State of emergency" means a governmental declaration issued under A.R.S. § 32-1910 as a result of a natural disaster or terrorist attack that results in individuals being unable to refill existing prescriptions.

"Sterile pharmaceutical product" means a medicinal drug free from living biological organisms.

"Strength" means: The concentration of the drug substance (for example, weight/weight, weight/volume, or unit dose/volume basis); or The potency, that is, the therapeutic activity of a drug substance as indicated by bioavailability tests or by controlled clinical data (expressed, for example, in terms of unity by reference to a standard).

"Substantial-risk sterile pharmaceutical product" means a sterile pharmaceutical product compounded as a parenteral or injectable dosage form from non-sterile ingredients.

"Supervision" means a pharmacist is present, assumes legal responsibility, and has direct oversight of activities relating to acquiring, preparing, distributing, and selling prescription medications by pharmacy interns, graduate interns, pharmacy technicians, or pharmacy technician trainees and when used in connection with the intern training requirements means that, in a pharmacy where intern training occurs, a pharmacy intern preceptor assumes the primary responsibility of teaching the intern during the entire period of the training.

"Supplying" means selling, transferring, or delivering to a patient or a patient's agent one or more doses of:

- A nonprescription drug in the manufacturer's original container for subsequent use by the patient, or
- A compressed medical gas in the manufacturer's or compressed medical gas distributor's original container for subsequent use by the patient.

"Support personnel" means an individual, working under the supervision of a pharmacist, trained to perform clerical duties associated with the practice of pharmacy, including cashiering, bookkeeping, pricing, stocking, delivering, answering non-professional telephone inquiries, and documenting third-party reimbursement. Support personnel shall not perform the tasks of a pharmacist, pharmacy intern, graduate intern, pharmacy technician, or pharmacy technician trainee.

"Temporary pharmacy facility" means a facility established as a result of a declared state of emergency to temporarily provide pharmacy services within or adjacent to declared disaster areas.

"Tourist" means an individual who is living in Arizona but maintains a place of habitation outside of Arizona and lives outside of Arizona for more than six months during a calendar year.

"Transfill" means a manufacturing process by which one or more compressed medical gases are transferred from a bulk container to a properly labeled container for subsequent distribution or supply.

"Unearned income" means monetary payment received by an individual that is not compensation for work performed or rental of property owned or leased by the individual, including: Unemployment insurance, Workers' compensation, Disability payments, Payments from the Social Security Administration, Payments from public assistance, Periodic insurance or annuity payments, Retirement or pension payments, Strike benefits from union funds, Training stipends, Child support payments, Alimony payments, Military family allotments, Regular support payments from a relative or other individual not residing in the household, Investment income, Royalty payments, Periodic payments from estates or trusts, and Any other monetary payments received by an individual that are not: As a result of work performed or rental of property owned by the individual, Gifts, Lump-sum capital gains payments, Lump-sum inheritance payments, Lump-sum insurance payments, or Payments made to compensate for personal injury.

"Verified signature" or "signature verifying" means in relation to a Board license or permit application or report, form, or agreement, the hand-written or electronic signature of an individual who, by placing a hand-written or electronic signature on a hard-copy or electronic license or permit application or report, form, or agreement agrees with and verifies that the statements and information within or attached to the license or permit application or report, form, or agreement are true in every respect and that inaccurate reporting can result in denial or loss of a license or permit or report, form, or agreement.

"Veteran" means an individual who has served in the United States Armed Forces.

"Wholesale distribution" means distribution of a drug to a person other than a consumer or patient, but does not include:

- Selling, purchasing, or trading a drug or offering to sell, purchase, or trade a drug for emergency medical reasons. For purposes of this Section, "emergency medical reasons" includes transferring a prescription drug by a community or hospital pharmacy to another community or hospital pharmacy to alleviate a temporary shortage;
- Selling, purchasing, or trading a drug, offering to sell, purchase, or trade a drug, or dispensing a drug as specified in a prescription;
- Distributing a drug sample by a manufacturers' or distributors' representative; or
- Selling, purchasing, or trading blood or blood components intended for transfusion.

"Wholesale distributor" means any person engaged in wholesale distribution of drugs, including: manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions in the amount of at least 5% of gross sales.

#### **R4-23-111. Notice of Hearing**

A. Except as provided in A.R.S. § 32-1928(B), the Board shall revoke, suspend, place on probation, or fine a licensee or permittee only after:

1. Notice is served under this Section, and
2. A hearing is conducted under R4-23-122.

B. The Board shall give notice of hearing to a party at least 30 days before the date set for the hearing in the manner described in R4-23-115(E) and (F). The notice shall include:

1. A statement of the date, time, place, and nature of the hearing;
2. A statement of the legal authority and jurisdiction for the hearing;
3. A reference to the particular section or sections of statute and rule involved; and
4. A statement of the violation or issue asserted by the Board.

#### **R4-23-112. Ex Parte Communications**

A party shall not communicate, either directly or indirectly, with a Board member about any substantive issue in a pending matter unless:

1. All parties are present;
2. It is during a scheduled proceeding, where an absent party fails to appear after proper notice; or
3. It is by written motion with copies to all parties.

#### **R4-23-113. Motions**

A. Purpose. A party requesting a ruling from the Board shall file a motion. Motions may be made for rulings such as:

1. Continuing or expediting a hearing under R4-23-116;
2. Vacating a hearing under R4-23-117;
3. Scheduling a prehearing conference under R4-23-118;
4. Quashing a subpoena under R4-23-119;
5. Requesting telephonic testimony under R4-23-120; and
6. Reconsidering a previous order under R4-23-121.

B. Form. Unless made during a prehearing conference or hearing, motions shall be made in writing and shall conform to the requirements of R4-23-115. All motions, whether written or oral, shall state the factual and legal grounds supporting the motion, and the requested action.

C. Time limits. Absent good cause, or unless otherwise provided by law or these rules, written motions shall be filed with the Board office at least 15 days before the hearing. A party demonstrates good cause by showing that the grounds for the motion could not have been known in time, using reasonable diligence and:

1. A ruling on the motion will further administrative convenience, expedition or economy; or
2. A ruling on the motion will avoid undue prejudice to any party.

D. Response to motion. A party shall file a written response stating any objection to the motion within five days of service, or as directed by the Board.

E. Oral argument. A party may request oral argument when filing a motion or response. If necessary to develop a complete record, the Board shall grant oral argument.

F. Rulings. Rulings on motions, other than those made during a prehearing conference or the hearing, shall be in writing and served on all parties.

#### **R4-23-114. Computing Time**

In computing any time period, the Board shall exclude the day from which the designated time period begins to run. The Board shall include the last day of the period unless it falls on a Saturday, Sunday, or legal holiday. When the time period is 10 days or less, the Board shall exclude Saturdays, Sundays, and legal holidays.

#### **R4-23-115. Filing Documents**

A. Docket. The Board shall open a docket for each hearing. All documents filed in a matter with the Board shall be date stamped on the day received by the Board office and entered in the docket.

B. Definition. "Documents" include papers such as complaints, answers, motions, responses, notices, and briefs.

C. Form. A party shall state on the document the name and address of each party served and how service was made under subsection (E). A document shall contain the Board caption and the Board's docket number.

D. Signature. A document filed with the Board shall be signed by the party or the party's attorney. A signature constitutes a certification that the signer has read the document, has a good faith basis for submission of the document, and that it is not filed for the purpose of delay or harassment.

E. Filing and service. A copy of a document filed with the Board shall be served on all parties. Filing with the Board office and service shall be completed by personal delivery; first-class, certified, or express mail; or facsimile.

F. Date of filing and service. A document is filed with the Board on the date it is received by the Board office, as established by the Board office's date stamp on the face of the document. A copy of a document is served on a party as follows:

1. On the date it is personally served,
2. Five days after it is mailed by first-class or express mail,
3. On the date of the return receipt if it is mailed by certified mail, or
4. On the date indicated on the facsimile transmission.

#### **R4-23-116. Continuing or Expediting a Hearing; Reconvening a Hearing**

A. Continuing or expediting a hearing. When ruling on a motion to continue or expedite, the Board shall consider such factors as:

1. The time remaining between the filing of the motion and the hearing date;
2. The position of other parties;
3. The reasons for expediting the hearing or for the unavailability of the party, representative, or counsel on the date of the scheduled hearing;
4. Whether testimony of an unavailable witness can be taken telephonically or by deposition; and
5. The status of settlement negotiations.

B. Reconvening a hearing. The Board may recess a hearing and reconvene at a future date by a verbal ruling.

#### **R4-23-117. Vacating a Hearing**

The Board shall vacate a calendared hearing and return the matter to the Board office for further action, if:

1. The parties agree to vacate the hearing;
2. The Board dismisses the matter;
3. The non-Board party withdraws the appeal; or
4. Facts demonstrate to the Board that it is appropriate to vacate the hearing for the purpose of informal disposition, or if the action will further administrative convenience, expedition, and economy and does not conflict with law or cause undue prejudice to any party.

#### **R4-23-118. Prehearing Conference**

A. Procedure. The Board may hold a prehearing conference. The conference may be held telephonically. The Board may issue a prehearing order outlining the issues to be discussed.

B. Record. The Board may record any agreements reached during a prehearing conference by electronic or mechanical means, or memorialize them in an order.

#### **R4-23-119. Subpoenas**

A. Form. A party shall request a subpoena in writing from the Board and shall include:

1. The caption and docket number of the matter;
2. A list or description of any documents sought;
3. The full name and home or business address of the custodian of the documents sought or all persons to be subpoenaed;
4. The date, time, and place to appear or to produce documents pursuant to the subpoena; and
5. The name, address, and telephone number of the party, or the party's attorney, requesting the subpoena.

B. The Board may require a brief statement of the relevance of testimony or documents.

C. Service of subpoena. Any person who is not a party and is at least 18 years of age may serve a subpoena. The person shall serve the subpoena by delivering a copy to the person to be served. The person serving the subpoena shall provide proof of service by filing with the Board office a certified statement of the date and manner of service and the names of the persons served.

D. Objection to subpoena. A party, or the person served with a subpoena who objects to the subpoena, or any portion of it, may file an objection with the Board. The objection shall be filed within five days after service of the subpoena, or at the outset of the hearing if the subpoena is served fewer than five days before the hearing.

E. Quashing, modifying subpoenas. The Board shall quash or modify a subpoena if:

1. It is unreasonable or oppressive, or
2. The desired testimony or evidence may be obtained by an alternative method.

#### **R4-23-120. Telephonic Testimony**

The Board may grant a motion for telephonic testimony if:

1. Personal attendance by a party or witness at the hearing will present an undue hardship for the party or witness;
2. Telephonic testimony will not cause undue prejudice to any party; and
3. The proponent of the telephonic testimony pays for any cost of obtaining the testimony telephonically.

#### **R4-23-121. Rights and Responsibilities of Parties**

A. Generally. A party may present testimony and documentary evidence and argument with respect to the contested issue and may examine and cross-examine witnesses.

B. Preparation. A party shall have all witnesses, documents, and exhibits available on the date of the hearing.

C. Exhibits. A party shall provide a copy of each exhibit to all other parties at the time the exhibit is offered to the Board, unless the exhibit was previously provided to all other parties.

D. Responding to orders. A party shall comply with an order issued by the Board concerning the conduct of a hearing. Unless an objection is made orally during a pre-hearing conference or hearing, a party shall file a motion requesting the Board to reconsider the order.

#### **R4-23-122. Conduct of Hearing**

A. Public access. Unless otherwise provided by law, all hearings are open to the public and may be conducted in an informal manner as prescribed in A.R.S. § 41-1092 et seq.

B. Opening. The Board shall begin the hearing by reading the caption, stating the nature and scope of the hearing, and identifying the parties, counsel, and witnesses for the record.

C. Stipulations. The Board shall enter into the record any stipulation, settlement agreement, or consent order entered into by any of the parties before or during the hearing.

D. Opening statements. The party with the burden of proof may make an opening statement at the beginning of a hearing. All other parties may make statements in a sequence determined by the Board.

E. Order of presentation. After opening statements, the party with the burden of proof shall begin the presentation of evidence, unless the parties agree otherwise or the Board determines that requiring another party to proceed first would be more expeditious or appropriate, and would not prejudice any other party. Copies of documentary evidence may be received in the discretion of the Board. Upon request, parties shall be given an opportunity to compare the copy with the original.

F. Examination. A party shall conduct direct and cross examination of witnesses in the order and manner determined by the Board to expedite and ensure a fair hearing. The Board shall make rulings necessary to prevent argumentative, repetitive, or irrelevant questioning and to expedite the examination to the extent consistent with the disclosure of all relevant testimony and information. The Board may take notice of judicially cognizable facts. In addition, the Board may take notice of generally recognized technical or scientific facts within the Board's or its staff's specialized knowledge. A party shall be notified either before or during the hearing or by reference in preliminary reports of the material the Board notices. The Board may use the Board's or its staff's experience, technical competence, and specialized knowledge in the evaluation of the evidence.

G. Closing argument. When all evidence has been received, parties shall have the opportunity to present closing oral argument, in a sequence determined by the Board. The Board may permit or require closing oral argument to be supplemented by written memoranda. The Board may permit or require written memoranda to be submitted simultaneously or sequentially, within time periods the Board may prescribe.

H. Conclusion of hearing. Unless otherwise provided by the Board, the hearing is concluded upon the submission of all evidence, the making of final argument, and the issuing of a final decision or order of the Board.

I. Decisions and orders. Unless otherwise provided by law, any final decisions or order adverse to a party in a hearing shall be in writing or stated in the record. Any final decision shall include findings of fact and conclusions of law, separately stated. Findings of fact shall be accompanied by a concise and explicit statement of the underlying facts supporting the findings. Unless otherwise provided by law, each party shall be notified either personally or by mail to the party's last known address of record of any decision or order. Upon request, a copy of the decision or order shall be delivered or mailed to each party and to each party's attorney of record.

#### **R4-23-123. Failure of Party to Appear for Hearing**

If a party fails to appear at a hearing, the Board may proceed with the presentation of the evidence of the appearing party, or vacate the hearing and return the matter to the Board

#### **R4-23-124. Witnesses; Exclusion from Hearing**

All witnesses at the hearing shall testify under oath or affirmation. At the request of a party, or at the discretion of the Board, the Board may exclude witnesses who are not parties from the hearing room so that they cannot hear the testimony of other witnesses.

#### **R4-23-125. Proof**

A. Standard of proof. Unless otherwise provided by law, the standard of proof is a preponderance of the evidence.

B. Burden of proof. Unless otherwise provided by law:

1. The party asserting a claim, right, or entitlement has the burden of proof;
2. A party asserting an affirmative defense has the burden of establishing the affirmative defense; and
3. The proponent of a motion shall establish the grounds to support the motion.

#### **R4-23-126. Disruptions**

A person shall not interfere with access to or from the hearing room, or interfere, or threaten interference with the hearing. If a person interferes, threatens interference, or disrupts the hearing, the Board may order the disruptive person to leave or be removed.

#### **R4-23-127. Hearing Record**

A. Maintenance. The Board shall maintain the official administrative record of a matter.

B. Transfer of record. Any party requesting a copy of the administrative record or any portion of the administrative record shall make a request to the Board office and shall pay the reasonable costs of duplication.

C. Release of exhibits. Exhibits shall be released:

1. Upon the order of a court of competent jurisdiction; or
2. Upon motion of the party who submitted the exhibits if the time for judicial appeal has expired and no appeal is pending.

#### **R4-23-128. Rehearing or Review and Appeal of Decision**

A. The Board shall provide for a rehearing and review of its decisions under A.R.S. Title 41, Chapter 6, Article 10, and this Section. For purposes of these rules, the terms "contested case" and "party" are defined in A.R.S. § 41-1001.

B. A party to a contested case shall exhaust the party's administrative remedies by filing a motion for rehearing or review within 30 days after the service of the Board decision that is subject to rehearing or review in order to be eligible for judicial review under A.R.S. Title 12, Chapter 7, Article 6. The Board shall notify a party in its decision, that is subject to rehearing or review, that the party may file a motion for rehearing or review, and that failure to file a motion for rehearing or review within 30 days after service of the decision has the effect of prohibiting the party from seeking judicial review of the Board's decision.

C. A party may amend a motion for rehearing or review at any time before the Board rules on the motion.

D. The Board may grant a rehearing or review for any of the following reasons materially affecting a party's rights:

1. Irregularity in the proceedings of the Board, or any order or abuse of discretion, that deprived the moving party of a fair hearing;
2. Misconduct of the Board, its staff, its hearing officer, or the prevailing party;
3. Accident or surprise that could not have been prevented by ordinary prudence;
4. Newly discovered material evidence that could not, with reasonable diligence, have been discovered and produced at the hearing;
5. Excessive or insufficient penalty;
6. Error in the admission or rejection of evidence or other errors of law occurring at the hearing or during the progress of the proceedings;
7. That the Board's decision is a result of passion or prejudice; or
8. That the findings of fact or decision is not justified by the evidence or is contrary to law.

E. The Board may affirm or modify a decision or grant a rehearing to all or any of the parties on all or part of the issues for any of the reasons in subsection (D). An order modifying a decision or granting a rehearing shall specify with particularity the grounds for the order.

F. If a motion for rehearing or review is based upon affidavits, they shall be served with the motion. An opposing party may, within 15 days after service, serve opposing affidavits. The Board may extend this period for a maximum of 20 days, for good cause as described in subsection (I).

G. Not later than 10 days after the date of a decision, after giving parties notice and an opportunity to be heard, the Board may grant a rehearing or review on its own initiative for any reason for which it might have granted relief on the motion of a party. The Board may grant a motion for rehearing or review, timely served, for a reason not stated in the motion.

H. If a rehearing is granted, the Board shall hold the rehearing within 60 days after the order granting the rehearing is issued.

I. The Board may extend all time limits listed in this Section upon a showing of good cause. A party demonstrates good cause by showing that the grounds for the party's motion or other action could not have been known in time, using reasonable diligence, and a ruling on the motion will:

1. Further administrative convenience, expedition, or economy; or
2. Avoid undue prejudice to any party.

#### **R4-23-129. Notice of Judicial Appeal; Transmitting the Transcript**

A. Notification to the Board office. Within 10 days of filing a complaint for judicial review of a final administrative decision of the Board, the party shall file a copy of the complaint with the Board office. The Board office shall then transmit the administrative record to the Superior Court.

B. Transcript. A party requesting a transcript shall arrange for transcription at the party's expense. The Board office shall make a copy of the audio taped record available to the transcriber. The party arranging for transcription shall deliver the transcript, certified by the transcriber under oath to be a true and accurate transcription of the audio taped record, to the Board office, together with one unbound copy.

### **ARTICLE 2. PHARMACIST LICENSURE:**

#### **R4-23-201. General**

A. License required. Before practicing as a pharmacist in Arizona, a person shall possess a valid pharmacist license issued by the Board. There is no temporary licensure.

B. Methods of licensure. Licensure as a pharmacist shall be either:

1. By practical examination, using paper and pencil written testing, computer adaptive testing, or other Board-approved testing method; or

2. By reciprocity.

C. Practicing pharmacist holding a delinquent license. Before the Board reinstates an Arizona pharmacist license, a pharmacist, whose Arizona pharmacist license is delinquent for five or more years and who is practicing pharmacy outside the Board's jurisdiction with a pharmacist license issued by another jurisdiction, shall:

1. Pass the MPJE or other Board-approved jurisprudence examination,
2. Pay all delinquent annual renewal fees, and
3. Pay penalty fees.

D. Non-practicing pharmacist holding a delinquent license. Before the Board reinstates an Arizona pharmacist license, a pharmacist, whose Arizona pharmacist license is delinquent for five or more years and who did not practice pharmacy within the last 12 months before seeking reinstatement, shall:

1. Complete the requirements in subsection (C), and
2. Appear before the Board to furnish satisfactory proof of fitness to be licensed as a pharmacist.

E. Verification of license. A pharmacy permittee or pharmacist-in-charge shall not permit a person to practice as a pharmacist until the pharmacy permittee or pharmacist-in-charge verifies that the person is currently licensed by the Board as a pharmacist.

#### **R4-23-202. Licensure by Examination**

A. Eligibility. To be eligible for licensure as a pharmacist by examination, a person shall:

1. Have a degree in pharmacy from a school or college of pharmacy approved by the Board as specified in A.R.S. § 32-1935, and whose professional degree program, at the time the person graduates, is accredited by the Accreditation Council for Pharmacy Education (ACPE); or
2. Qualify under the requirements of A.R.S. § 32-1922(D); and
3. Complete not less than 1500 hours of intern training as specified in R4-23-303.

B. Application.

1. An applicant for licensure by examination shall:

- a. Submit a completed application for licensure by examination electronically or manually on a form furnished by the Board, and
- b. Submit with the application form:
  - i. The documents specified in the application form, and
  - ii. The application fee specified in R4-23-205(C).

2. The Board office shall deem an application form received on the date the Board office electronically or manually date-stamps the form.

3. An applicant for licensure by examination shall register for NAPLEX and MPJE through NABP's registration process.

4. The Board shall deem an application for licensure by examination invalid after 12 months from the date the application is received. An applicant whose application form is invalid and who wishes to continue licensure procedures, shall submit a new application form and fee as specified in R4-23-205(C).

C. Passing grade; notification; re-examination.

1. To pass the required examinations, an applicant shall obtain a score of at least 75 on both the NAPLEX and MPJE.

2. The Board office shall:

- a. Retrieve an applicant's NAPLEX and MPJE score from the NABP database no later than two weeks after the applicant's examination date; and
- b. Provide written notice by mail to an applicant who fails the NAPLEX or MPJE no later than seven days after the Board office retrieves the applicant's score from NABP.

3. An applicant who fails the NAPLEX or MPJE may register with the NABP to retake the examination within the 12-month period defined in subsection (B)(4). An applicant who fails the NAPLEX or MPJE three times shall petition the Board as specified in R4-23-401 for Board approval before retaking the examination.

4. For the purpose of licensure by examination, the Board office shall deem a passing score on the NAPLEX or MPJE invalid after 24 months from the applicant's examination date. An applicant who fails to complete the licensure process within the 24 month period, and who wishes to continue licensure procedures, shall retake the examination(s).

D. NAPLEX score transfer.

1. The Board office shall deem a score transfer received on the date the NABP transmits the applicant's official score transfer report to the Board office.
2. An applicant who receives a passing score on the NAPLEX taken in another jurisdiction shall, within 12 months from the date the Board office receives the applicant's official NABP score transfer report from the NABP, make application for licensure according to subsection (B). After 12 months, an applicant may reapply for licensure in this state under the provisions of subsection (B) or R4-23-203(B).
3. An applicant who takes the NAPLEX in another jurisdiction and fails the examination may apply for licensure in this state under the provisions of subsection (B).

E. Licensure.

1. The Board office shall issue a certificate of licensure and a wall license to a successful applicant upon receipt of:
  - a. The initial licensure fee specified in R4-23-205(A)(1)(a), and
  - b. The wall license fee specified in R4-23-205(E)(1)(a).
2. A licensee shall maintain the certificate of licensure in the practice site for inspection by the Board or its designee or review by the public.

F. Time-frames for licensure by examination.

1. The Board office shall complete an administrative completeness review within 60-days from the date the application form is received.
  - a. The Board office shall issue a written notice of administrative completeness to the applicant if no deficiencies are found in the application form.
  - b. If the application form is incomplete, the Board office shall provide the applicant with a written notice that includes a comprehensive list of the missing information. The 60-day time-frame for the Board office to finish the administrative completeness review is suspended from the date the notice of incompleteness is served until the applicant provides the Board office with all missing information.
  - c. If the Board office does not provide the applicant with written notice regarding administrative completeness, the application form shall be deemed complete 60-days after receipt by the Board office.
2. An applicant with an incomplete application form shall submit all of the missing information within 90-days of service of the notice of incompleteness.
  - a. If an applicant cannot submit all missing information within 90 days of service of the notice of incompleteness, the applicant may send a written request for an extension to the Board office postmarked or delivered no later than 90-days from service of the notice of incompleteness.
  - b. The written request for an extension shall document the reasons the applicant is unable to meet the 90-day deadline.
  - c. The Board office shall review the request for an extension of the 90-day deadline and grant the request if the Board office determines that an extension of the deadline will enable the applicant to assemble and submit the missing information. An extension shall be for no more than 30 days. The Board office shall notify the applicant in writing of its decision to grant or deny the request for an extension.
3. If an applicant fails to submit a complete application form within the time allowed, the Board office shall close the applicant's file. An applicant whose file is closed and who later wishes to obtain a license shall apply again according to subsection (B).
4. The Board office shall complete a substantive review of the applicant's qualifications in no more than 120 days from the date on which the administrative completeness review of an application is complete.
  - a. If an applicant is found to be ineligible for licensure by examination, the Board office shall issue a written notice of denial to the applicant.
  - b. If an applicant is found to be eligible to take the NAPLEX, the Board office shall notify the NABP that the applicant is eligible to test. The NABP shall issue the applicant an authorization to test letter.
  - c. If an applicant is found to be eligible to take the MPJE, the Board office shall notify the NABP that the applicant is eligible to test. The NABP shall issue the applicant an authorization to test letter.
  - d. The Board office shall deem an applicant's eligibility to test invalid after 12 months from the date the application for licensure by examination is received.
  - e. If the Board office finds deficiencies during the substantive review of an application, the Board office shall issue a written request to the applicant for additional documentation.

f. The 120 day time-frame for a substantive review of eligibility to take the NAPLEX or MPJE is suspended from the date of a written request for additional documentation until the date that all documentation is received. The applicant shall submit the additional documentation according to subsection (F)(2).

g. If the applicant and the Board office mutually agree in writing, the 120-day substantive review time-frame may be extended once for no more than 45 days.

5. For the purpose of A.R.S. § 41-1072 et seq., the Board establishes the following time-frames for licensure by examination.

a. Administrative completeness review time-frame: 60-days.

b. Substantive review time-frame: 120 days.

c. Overall time-frame: 180 days.

#### G. License Renewal

1. To renew a license, a pharmacist shall submit a completed license renewal application electronically or manually on a form furnished by the Board with the biennial renewal fee specified in R4-23-205(A)(1)(b).

2. If the biennial renewal fee is not paid by November 1 of the renewal year specified in A.R.S. § 32-1925, the pharmacist license is suspended and the licensee shall not practice as a pharmacist. The licensee shall pay a penalty as provided in A.R.S. § 32-1925 and R4-23-205(G)(1) to vacate the suspension.

3. A licensee shall maintain the renewal certificate of licensure in the practice site for inspection by the Board or its designee or review by the public.

4. Time-frames for license renewals. The Board office shall follow the time-frames established in subsection (F).

#### **R4-23-203. Licensure by Reciprocity**

A. Eligibility. A person is eligible for licensure by reciprocity who:

1. Is licensed as a pharmacist in a jurisdiction that provides reciprocity to Arizona licensees,

2. Has passed the NABPLEX or NAPLEX with a score of 75 or better or was licensed by examination in another jurisdiction having essentially the same standards for licensure as this state at the time the pharmacist was licensed,

3. Provides evidence to the Board of having completed the required secondary and professional education and training specified in R4-23-202(A),

4. Has engaged in the practice of pharmacy for at least one year or has met the internship requirements of Article 3 within the year immediately before the date of application, and

5. Has actively practiced as a pharmacist for 400 or more hours within the last calendar year or has an Arizona graduate intern license and has completed 400 hours of internship training in a Board-approved internship training site.

B. Application.

1. An applicant for licensure by reciprocity shall:

a. Submit a completed application for licensure by reciprocity electronically or manually on a form furnished by the Board, and

b. Submit with the application form:

i. The documents specified in the application form, and

ii. The reciprocity fee specified in R4-23-205(B)

2. The Board office shall deem an application form received on the date the Board office electronically or manually date-stamps the form.

3. An applicant for licensure by reciprocity shall register for MPJE through NABP's registration process.

4. The Board office shall deem an application for licensure by reciprocity invalid after 12 months from the date the application is received. An applicant whose application form is invalid and who wishes to continue licensure procedures, shall submit a new application form and fee as specified in R4-23-205(B).

C. Passing grade; notification; re-examination.

1. To pass the required examination, an applicant shall obtain a score of at least 75 on the MPJE.

2. The Board office shall:

- a. Retrieve an applicant's MPJE score from the NABP database no later than two weeks after the applicant's examination date, and
- b. Provide written notice by mail to an applicant who fails the MPJE no later than seven days after the Board office retrieves the applicant's score from NABP.

3. An applicant who fails the MPJE may register with the NABP to retake the examination within the 12-month period specified in subsection (B)(4). An applicant who fails the MPJE three times shall petition the Board as specified in R4-23-401 for Board approval before retaking the examination.

4. For the purpose of licensure by reciprocity, the Board office shall deem a passing score on the MPJE invalid after 24 months from the applicant's examination date. An applicant who fails to complete the licensure process within the 24 month period, and who wishes to continue licensure procedures, shall retake the examination.

D. Licensure.

1. The Board office shall issue a certificate of licensure and a wall license to a successful applicant upon receipt of:

- a. The initial licensure fee specified in R4-23-205(A)(1)(a), and
- b. The wall license fee specified in R4-23-205(E)(1)(a).

2. A licensee shall maintain the certificate of licensure in the practice site for inspection by the Board or its designee or review by the public.

E. Time-frames for licensure by reciprocity. The Board office shall follow the time-frames established for licensure by examination in R4-23-202(F).

F. License renewal. License renewal shall be the same as specified in R4-23-202(G).

#### **R4-23-204. Continuing Education Requirements**

A. General. In accordance with A.R.S. § 32-1925(G), the Board shall not renew a license unless the applicant has, during the two years preceding the application for renewal, participated in 30 contact hours (3.0 CEU's) of continuing education activity sponsored by an Approved Provider as defined in R4-23-110, of which at least three contact hours (0.3 CEU's) are approved courses in pharmacy law. Subject to A.R.S. § 32-1937, a pharmacist licensed for less than 24 months shall obtain continuing education units in an amount determined by multiplying 1.25 hours times the number of months between the date of initial licensure and the next license renewal date.

B. Acceptance of continuing education units (CEU's). The Board shall:

1. Only accept CEU's for continuing education activities sponsored by an Approved Provider;
2. Only accept CEU's accrued during the two-year period immediately before licensure renewal;
3. Not allow CEU's accrued in a biennial renewal period in excess of the 3.0 CEU's required to be carried forward to the succeeding biennial renewal period;
4. Allow a pharmacist who leads, instructs, or lectures to a group of health professionals on pharmacy-related topics in continuing education activities sponsored by an Approved Provider to receive CEU's for a presentation by following the same attendance procedures as any other attendee of the continuing education activity; and
5. Not accept as CEU's the performance of normal teaching duties within a learning institution by a pharmacist whose primary responsibility is the education of health professionals.

C. Continuing education records and reporting CEU's. A pharmacist shall:

1. Maintain continuing education records that:
  - a. Verify the continuing education activities the pharmacist participated in during the preceding five years; and
  - b. Consist of a statement of credit or a certificate issued by an Approved Provider at the conclusion of a continuing education activity;
2. At the time of licensure renewal, attest to the number of CEU's the pharmacist participated in during the renewal period on the biennial renewal form; and
3. When requested by the Board office, submit proof of continuing education participation within 20 days of the request.

D. The Board may revoke, suspend, or place on probation the license of a pharmacist who fails to comply with continuing education participation, recording, or reporting requirements of this Section.

E. A pharmacist who is aggrieved by any decision of the Board or its administrative staff concerning continuing education units may request a hearing before the Board.

**R4-23-205. Fees**

A. Licensure fees:

1. Pharmacist:

- a. Initial licensure [Prorated according to A.R.S. § 32-1925(B)]: \$180.
- b. Licensure renewal: \$180.

2. Pharmacy or graduate intern. Initial licensure: \$50.

3. Pharmacy technician:

- a. Initial licensure [Prorated according to A.R.S. § 32-1925(B)]: \$72.
- b. Licensure renewal: \$72.

4. Pharmacy technician trainee: \$36.

B. Reciprocity fee: \$300.

C. Application fee: \$50.

D. Vendor permit fees (Resident and nonresident) [New permits prorated according to A.R.S. § 32-1931(B)]:

1. Pharmacy: \$480 biennially (Including hospital, and limited service).

2. Drug wholesaler or manufacturer:

- a. Manufacturer: \$1000 biennially.
- b. Full-service drug wholesaler: \$1000 biennially.
- c. Nonprescription drug wholesaler: \$500 biennially.

3. Drug packager or repackager: \$1000 biennially.

4. Nonprescription drug, retail:

- a. Category I (30 or fewer items): \$120 biennially
- b. Category II (more than 30 items): \$200 biennially

5. Compressed medical gas distributor: \$200 biennially

6. Durable medical equipment and compressed medical gas supplier: \$100 biennially.

E. Other Fees:

1. Wall license.

- a. Pharmacist: \$20.
- b. Pharmacy or graduate intern: \$10.
- c. Pharmacy technician: \$10.
- d. Pharmacy technician trainee: \$10.

2. Duplicate of any Board-issued license, registration, certificate, or permit: \$10.

3. Duplicate current renewal license: \$10.

F. Fees are not refunded under any circumstances except for the Board's failure to comply with its established licensure or permit time-frames under R4-23-202 or R4-23-602.

G. Penalty fee. Renewal applications submitted after the expiration date are subject to penalty fees as provided in A.R.S. §§ 32-1925 and 32-1931.

- 1. Licensees: A fee equal to half the licensee's biennial licensure renewal fee under subsection (A) and not to exceed \$350.

2. Permittees: A fee equal to half the permittee's biennial permit fee under subsection (D) and not to exceed \$350.

### **ARTICLE 3. INTERN TRAINING AND PHARMACY INTERN PRECEPTORS:**

#### **R4-23-301. Intern Licensure**

A. Licensure as a pharmacy intern or graduate intern is for the purpose of complementing the individual's academic or experiential education in preparation for licensure as a pharmacist. An applicant may request a waiver of intern licensure requirements by submitting a written request as specified in R4-23-401 and appearing in person at a Board meeting.

B. The prerequisites for licensure as a pharmacy intern are:

1. Current enrollment, in good standing, in a Board-approved college or school of pharmacy; or
2. Graduation from a college or school of pharmacy that is not approved by the Board; and
3. Proof that the applicant is certified by the Foreign Pharmacy Graduate Examination Committee (FPGEC); or
4. By order of the Board if the Board determines the applicant needs intern training.

C. If a pharmacy intern licensee stops attending pharmacy school classes before completing the pharmacy school's requirements for graduation, the licensee shall immediately stop practicing as a pharmacy intern and surrender the pharmacy intern license to the Board or the Board's designee no later than 30 days after the date of the last attended class, unless the licensee petitions the Board as specified in R4-23-401 and receives Board approval to continue working as a pharmacy intern. A student re-entering a pharmacy program who wishes to continue internship training shall reapply for pharmacy intern licensure.

D. The prerequisites for licensure as a graduate intern are:

1. Graduation from a Board-approved college or school of pharmacy, and
2. Application for licensure as a pharmacist by examination or reciprocity, or
3. By order of the Board if the Board determines that the applicant needs intern training.

E. Experiential training. Intern training shall include the activities and services encompassed by the term "practice of pharmacy" as defined in A.R.S. § 32-1901.

F. Out-of-state experiential training. An intern shall receive credit for intern training received outside this state if the Board determines that the intern training requirements of the jurisdiction in which the training was received are equal to the minimum requirements for intern training in this state. An applicant seeking credit for intern training received outside this state shall furnish a certified copy of the records of intern training from:

1. The board of pharmacy or the intern licensing agency of the other jurisdiction where the training was received; or
2. In a jurisdiction without an intern licensing agency, the director of the applicant's Board-approved college or school of pharmacy's experiential training program.

G. Verification of license. A pharmacy permittee, or pharmacist-in-charge shall not permit a person to practice as a pharmacy or graduate intern until the pharmacy permittee or pharmacist-in-charge verifies that the person is currently licensed by the Board as a pharmacy or graduate intern.

H. Intern application.

1. An applicant for licensure as a pharmacy intern or graduate intern shall:
  - a. Submit a completed application electronically or manually on a form furnished by the Board, and
  - b. Submit with the application form:
    - i. The documents specified in the application form.
    - ii. The initial licensure fee specified in R4-23-205(A)(2), and
    - iii. The wall license fee specified in R4-23-205(E)(1)(b).

2. The Board office shall deem an application form received on the date the Board office electronically or manually date-stamps the form.

I. Licensure.

1. If an applicant is found to be ineligible for intern licensure under statute and rule, the Board office shall issue a written notice of denial to the applicant.

2. If an applicant is found to be eligible for intern licensure under statute and rule, the Board office shall issue a certificate of licensure and a wall license. An applicant who is assigned a license number and who has been granted "open" status on the Board's license verification site may begin practice as a pharmacy intern or graduate intern prior to receiving the certificate of licensure.
  3. An applicant who is assigned a license number and who has a "pending" status on the Board's license verification site shall not practice as a pharmacy intern or graduate intern until the Board office issues a certificate of licensure as specified in subsection (2).
  4. A licensee shall maintain the certificate of licensure in the practice site for inspection by the Board or its designee or review by the public.
- J. Time-frames for intern licensure. The Board office shall follow the time-frames established in R4-23-202(F).
- K. License renewal.
1. A pharmacy intern whose license expires before the intern completes the education or training required for licensure as a pharmacist but less than six years after the issuance of the initial pharmacy intern license may renew the intern license for a period equal to the difference between the expiration date of the initial intern license and six years from the issue date of the initial intern license by payment of a prorated renewal fee based on the initial license fee specified in R4-23-205(A)(2).
  2. If a pharmacy intern fails to graduate from a Board-approved college or school of pharmacy within six years for the date the Board issues the initial license, the intern is not eligible for relicensure as an intern unless the intern obtains Board approval as specified in A.R.S. § 32-1923(E) and R4-23-401. To remain in good standing, an intern who receives Board approval for relicensure shall pay a prorated renewal fee for the number of months of licensure approved by the Board based on the initial license fee specified in R4-23-205(A)(2) before the license expiration date.
  3. If an intern receives Board approval for relicensure and does not pay the renewal fee specified in subsection (2) before the license expiration date, the intern license is suspended and the licensee shall not practice as an intern. The licensee shall pay a penalty as provided in A.R.S. § 32-1925 and R4-23-205(G)(1) to vacate the suspension.
- L. Notification of training.
1. A pharmacy intern who is employed as an intern outside the experiential training program of a Board-approved college or school of pharmacy or a graduate intern shall notify the Board within ten days of starting or terminating training, or changing training site.
  2. The director of a Board-approved college or school of pharmacy's experiential training program shall provide the Board an intern training report as specified in R4-23-304(B)(3).

**R4-23-302. Training Site and Pharmacy Intern Preceptors**

- A. To receive credit for intern training hours, a pharmacy or graduate intern shall train in a site that:
1. Holds a valid Arizona pharmacy permit and employs a pharmacy intern preceptor who supervises the intern; or
  2. Is an alternative training site. For purposes of this Section, the term alternative training site is a non-pharmacy training site established and monitored by a Board-approved college or school of pharmacy or other non-pharmacy site where pharmacy related activities are performed and where an intern gains experience as specified in R4-23-301(E).
- B. The Board shall inform a pharmacy or alternative training site that an intern will not get credit for training received at the site if the Board determines that a pharmacy or alternative training site fails to provide experiential training as specified in R4-23-301(E) or violates A.R.S. Chapter 18 Title 32 or Chapter 27 Title 36 or the federal act.
- C. Pharmacy intern preceptor. To be a pharmacy intern preceptor, a pharmacist shall:
1. Hold a current unrestricted pharmacist license;
  2. Have a minimum of one year of experience as an actively practicing pharmacist before acting as a pharmacy intern preceptor;
  3. If a pharmacist has been found guilty of violating any federal or state law relating to the practice of pharmacy, drug or device distribution or recordkeeping, or unprofessional conduct, enter into an agreement satisfactory to the Board that places restrictions on the pharmacist's license; and
  4. Hold a faculty position in the experiential training program of a Board-approved college or school of pharmacy; or
  5. Be approved by the Board as being otherwise qualified as a pharmacy intern preceptor.
- D. Revocation of preceptorship privileges. The Board shall revoke a pharmacy intern preceptor's privilege to train pharmacy or graduate interns if the Board determines that a pharmacy intern preceptor fails to provide experiential training as specified in R4-23-301(E) or violates A.R.S. Title 32, Chapter 18 or Title 36, Chapter 27 or the federal act. R4-23-111 applies to revocation of preceptor privileges.
- E. Pharmacist-to-intern ratio. A pharmacy intern preceptor may supervise the training of more than one pharmacy or graduate intern during a calendar quarter. The ratio of pharmacist to intern shall not exceed one pharmacist to two interns in a community pharmacy or limited-service pharmacy setting unless approved by the Board. In considering a request to exceed the ratio, the Board will consider pharmacy space

limitations and whether exceeding the ratio poses a safety risk to the public health. Subject to R4-23-609 and the safety of public health, there is no pharmacist-to-intern ratio in a practice setting directed by a Board-approved college or school of pharmacy experiential training program.

F. Preceptor responsibilities. A pharmacy intern preceptor assumes the responsibilities of a teacher and mentor in addition to those of a pharmacist. A preceptor shall thoroughly review pharmacy policy and procedure with each intern. A preceptor is responsible for the pharmacy-related actions of an intern during the specific training period. A preceptor shall give an intern the opportunity for skill development and provide an intern with timely and realistic feedback regarding their progress.

#### **R4-23-303. Training Time**

A. Training. The minimum hours of internship training required for licensure by examination shall be 1,500.

1. After enrolling in a Board-approved college or school of pharmacy as prescribed in R4-23-301(B) and receiving a Board-issued pharmacy intern license, a pharmacy intern shall complete all required internship training as part of the pharmacy intern's Board-approved college or school of pharmacy experiential training program.

2. After receiving a Board-issued pharmacy intern license, an individual who is a graduate of a college or school of pharmacy that is not approved by the Board shall complete a minimum of 1,500 hours of internship training in a training site or sites as defined in R4-23-302(A).

3. After receiving a Board-issued graduate intern license, a graduate intern shall complete the number of internship training hours required by the Board in a training site or sites as defined in R4-23-302(A).

B. Start of training and limitation of credit. To receive credit as internship training, the practical experience shall take place in a pharmacy or an alternative training site as specified in R4-23-302(A) and under the supervision of a pharmacy intern preceptor, except for a non-pharmacy site either as part of a Board-approved college or school of pharmacy experiential training program or as approved by the Board or its designee. The Board shall credit no more than 500 hours internship training as a pharmacy or graduate intern in an alternative training site specified in R4-23-302(A)(2).

#### **R4-23-304. Reports**

A. Change of employment or mailing address. A pharmacy intern or graduate intern shall notify the Board within ten days of change of employment or mailing address.

B. Annual reports.

1. A pharmacy intern who is a graduate of a college or school of pharmacy that is not approved by the Board or is a graduate intern shall provide the Board annual intern training reports for the duration of training. The pharmacy intern shall file an annual intern training report on a report form provided by the Board by calendar year (January 1st through December 31st). An annual intern training report shall be received at the Board office no later than 30 days after the end of the calendar year. Any intern training hours reported to the Board office more than 30 days after the end of the calendar year in which the training hours were performed shall not be credited toward the total intern training hours required for licensure.

2. After graduation and before sitting for the NAPLEX or MPJE, a pharmacy intern who is a graduate of a Board-approved college or school of pharmacy shall ensure that the director of the Board-approved college or school of pharmacy's experiential training program provides the Board an intern training report that includes:

a. The dates and number of training hours experienced, by training site and total; and

b. The date signed and experiential training program director's signature verifying that the pharmacy intern successfully completed the experiential training program.

#### **ARTICLE 4. PROFESSIONAL PRACTICES:**

#### **R4-23-401. Time-frames for Board Approvals and Special Requests**

A. To request a Board approval required by this Chapter or a special request to deviate from or waive compliance with a requirement of this Chapter, a person shall send a letter by regular mail, e-mail, or facsimile to the Board office, detailing the nature of the approval or special request, including the applicable Arizona Revised Statute or administrative code citation. This Section does not apply to a request from a person regarding the probation, suspension, or revocation of a license or permit.

B. The Board office shall complete an administrative completeness review within 15 days from the date of receipt of a written request and immediately open a request file for the applicant.

1. The Board office shall issue a written notice of administrative completeness to the applicant if no deficiencies are found in the request.

2. If the request is incomplete, the Board office shall provide the applicant with a written notice that includes a comprehensive list of the missing information. The 15-day time-frame for the Board office to finish the administrative completeness review is suspended from the date the notice of incompleteness is served until the applicant provides the Board office with all missing information.

3. If the Board office does not provide the applicant with notice regarding administrative completeness, the request is deemed complete 15 days after receipt by the Board office.

- C. An applicant with an incomplete request shall submit all of the missing information within 30 days of service of the notice of incompleteness.
1. If an applicant cannot submit all missing information within 30 days of service of the notice of incompleteness, the applicant may send a written request for an extension to the Board office post-marked or delivered no later than 30 days from service of the notice of incompleteness.
  2. The written request for an extension shall document the reasons the applicant cannot meet the 30-day deadline.
  3. The Board office shall review the request for an extension of the 30-day deadline and grant the request if the Board office determines that an extension of the deadline will enable the applicant to assemble and submit the missing information. An extension shall be for no more than 30 days. The Board office shall notify the applicant in writing of its decision to grant or deny the request for an extension. An applicant who requires an additional extension shall submit an additional written request according to subsections (C)(1) and (C)(2).
- D. If an applicant fails to submit a complete request within the time allowed, the Board office shall close the applicant's request file. An applicant whose request file is closed and who later wishes to obtain an approval or special request shall apply again according to subsection (A).
- E. From the date on which the administrative completeness review of a request is finished, the Board shall complete a substantive review of the applicant's request in no more than 120 days.
1. The Board shall:
    - a. Approve the request,
    - b. Deny the request, or
    - c. If the Board determines deficiencies exist, request that the applicant produce additional documentation.
  2. If the Board approves or denies, the Board office shall issue a written approval or denial.
  3. If the Board finds deficiencies during the substantive review of a request, the Board office shall issue a written request to the applicant for additional documentation.
  4. The 120-day time-frame for a substantive review of a request for approval or special request is suspended from the date of a written request for additional documentation until the date of the next Board meeting after all documentation is received. The applicant shall submit the additional documentation according to subsection (C).
  5. If the applicant and the Board office mutually agree in writing, the 120-day substantive review time-frame may be extended once for no more than 30 days.
- F. If the applicant fails to submit the additional information requested within the time allowed, the Board office shall close the applicant's request file. An applicant whose request file is closed and who later wishes to obtain an approval or special request shall apply again according to subsection (A).
- G. For the purpose of A.R.S. § 41-1072 et seq., the Board establishes the following time-frames for a Board approval required by this Chapter or a special request to deviate from or waive compliance with a requirement of this Chapter:
1. Administrative completeness review time-frame: 15 days;
  2. Substantive review time-frame: 120 days; and
  3. Overall time-frame: 135 days.

**R4-23-402. Pharmacist, Graduate Intern, and Pharmacy Intern**

- A. A pharmacist or a graduate intern or pharmacy intern under the supervision of a pharmacist shall perform the following professional practices in dispensing a prescription medication from a prescription order:
1. Receive, reduce to written form, and manually initial oral prescription orders;
  2. Obtain and record the name of an individual who communicates an oral prescription order;
  3. Obtain, or assume responsibility to obtain, from the patient, patient's agent, or medical practitioner and record, or assume responsibility to record, in the patient's profile, the following information:
    - a. Name, address, telephone number, date of birth (or age), and gender;
    - b. Individual history including known diseases and medical conditions, known drug allergies or drug reactions, and if available a comprehensive list of medications currently taken and medical devices currently used;
  4. Record, or assume responsibility to record, in the patient's profile, a pharmacist's, graduate intern's, or pharmacy intern's comments relevant to the patient's drug therapy, including other information specific to the patient or drug;
  5. Verify the legality and pharmaceutical feasibility of dispensing a drug based upon:

- a. A patients' allergies,
  - b. Incompatibilities with a patient's currently-taken medications,
  - c. A patient's use of unusual quantities of dangerous drugs or narcotics,
  - d. A medical practitioner's signature, and
  - e. The frequency of refills;
6. Verify that a dosage is within proper limits;
  7. Interpret the prescription order, which includes exercising professional judgment in determining whether to dispense a particular prescription;
  8. Compound, mix, combine, or otherwise prepare and package the prescription medication needed to dispense individual prescription orders;
  9. Prepackage or supervise the prepackaging of drugs by a pharmacy technician or pharmacy technician trainee under R4-23-1104. For drugs prepackaged by a pharmacy technician or pharmacy technician trainee, a pharmacist shall:
    - a. Verify the drug to be prepackaged;
    - b. Verify that the label meets the official compendium's standards;
    - c. Check the completed prepackaging procedure and product; and
    - d. Manually initial the completed label; or
    - e. For automated packaging systems, manually initial the completed label or a written log or initial a computer-stored log;
  10. Check prescription order data entry to ensure that the data input:
    - a. Is for the correct patient by verifying the patient's name, address, telephone number, gender, and date of birth or age;
    - b. Is for the correct drug by verifying the drug name, strength, and dosage form;
    - c. Communicates the prescriber's directions precisely by verifying dose, dosage form, route of administration, dosing frequency, and quantity; and
    - d. Is for the correct medical practitioner by verifying the medical practitioner's name, address, and telephone number;
  11. Make a final accuracy check on the completed prescription medication and manually initial the finished label. Manual initialing of a finished label is not required if the pharmacy's computer system complies with the computer documentation requirements of R4-23-408(B)(4);
  12. Record, or assume responsibility to record, a prescription serial number and date dispensed on the original prescription order;
  13. Obtain, or assume responsibility to obtain, permission to refill a prescription order and record, or assume responsibility to record on the original prescription order:
    - a. Date dispensed,
    - b. Quantity dispensed, and
    - c. Name of medical practitioner or medical practitioner's agent who communicates permission to refill the prescription order;
  14. Reduce to written or printed form, or assume responsibility to reduce to written or printed form, a new prescription order received by:
    - a. Facsimile,
    - b. Computer modem, or
    - c. Other means of communication;
  15. Verify, or assume responsibility to verify, that a completed prescription medication is sold only to the correct patient, patient's care-giver, or authorized agent;
  16. Record on the original prescription order the name or initials of the pharmacist, graduate intern, or pharmacy intern who originally dispenses the prescription order; and
  17. Record on the original prescription order the name or initials of the pharmacist, graduate intern, or pharmacy intern who dispenses each refill.

B. Only a pharmacist, graduate intern, or pharmacy intern shall provide oral consultation about a prescription medication to a patient or patient's care-giver in an outpatient setting, including a patient discharged from a hospital. The oral consultation is required whenever the following occurs:

1. The prescription medication has not been previously dispensed to the patient in the same strength or dosage form or with the same directions;
2. The pharmacist, through the exercise of professional judgment, determines that oral consultation is warranted; or
3. The patient or patient's care-giver requests oral consultation.

C. Oral consultation shall include:

1. Reviewing the name and strength of a prescription medication or name of a prescription-only device and the labeled indication of use for the prescription medication or prescription-only device;
2. Reviewing the prescription's directions for use;
3. Reviewing the route of administration; and
4. Providing oral information regarding special instructions and written information regarding side effects, procedure for missed doses, or storage requirements.

D. When, in the professional judgement of the pharmacist or graduate intern or pharmacy intern under the supervision of a pharmacist, or when circumstance precludes it, oral consultation may be omitted if the pharmacist, graduate intern, or pharmacy intern:

1. Personally provides written information to the patient or patient's care-giver that summarizes the information that would normally be orally communicated;
2. Documents, or assumes responsibility to document, both the circumstance and reason for not providing oral consultation by a method approved by the Board or its designee; and
3. Offers the patient or patient's care-giver the opportunity to communicate with a pharmacist, graduate intern, or pharmacy intern at a later time and provides a method for the patient or patient's care-giver to contact a pharmacist, graduate intern, or pharmacy intern at the pharmacy.

E. The pharmacist or graduate intern or pharmacy intern under the supervision of a pharmacist, through the exercise of professional judgment, may provide oral consultation that includes:

1. Common severe adverse effects, interactions, or therapeutic contraindications, and the action required if they occur;
2. Techniques of self-monitoring drug therapy;
3. The duration of the drug therapy; and
4. Prescription refill information.

F. Nothing in subsection (B) requires a pharmacist, graduate intern, or pharmacy intern to provide oral consultation if a patient or patient's care-giver refuses the consultation.

G. Using a method approved by the Board or its designee, a pharmacist, graduate intern, or pharmacy intern shall document, or assume responsibility to document, that oral consultation is or is not provided.

H. Oral consultation documentation. When oral consultation is required as specified in subsection (B), a pharmacist, graduate intern, or pharmacy intern shall:

1. Document, or assume responsibility to document, that oral consultation is provided; or
2. When a patient refuses oral consultation or a person other than the patient or patient's care-giver picks up a prescription and oral consultation is not provided, document, or assume responsibility to document, that oral consultation is not provided; or
3. When a pharmacist, graduate intern, or pharmacy intern determines to omit oral consultation under subsection (D) and oral consultation is not provided, document, or assume responsibility to document, both the circumstance and reason that oral consultation is not provided; and
4. Document, or assume responsibility to document, the name, initials, or identification code of the pharmacist, graduate intern, or pharmacy intern who did or did not provide oral consultation.

I. When a prescription is delivered to the patient or patient's care-giver outside the immediate area of a pharmacy and a pharmacist is not present, the prescription shall be accompanied by written or printed patient medication information that, in addition to the requirements in subsection (C), includes:

1. Approved use for the prescription medication;

2. Possible adverse reactions;
  3. Drug-drug, food-drug, or disease-drug interactions;
  4. Missed dose information; and
  5. Telephone number of the dispensing pharmacy or another method approved by the Board or its designee that allows a patient or patient's care-giver to consult with a pharmacist.
- J. A prescription medication or prescription-only device, delivered to a patient at a location where a licensed health care professional is responsible for administering the prescription medication to the patient, is exempt from the requirement of subsection (C).
- K. A pharmacist, graduate intern, or pharmacy intern shall wear a badge indicating name and title while on duty.
- L. Nothing in this Section prevents a hospital pharmacist from accepting a prescription order according to rules pertaining specifically to hospital pharmacies.

**R4-23-403. Repealed**

**R4-23-404. Unethical Practices**

A. Rebates prohibited. A pharmacist or pharmacy permittee shall not offer, deliver, receive, or accept any unearned rebate, refund, commission, preference, patronage dividend, discount, or other unearned consideration, whether in the form of money or otherwise, as compensation or inducement to refer a patient, client, or customer to any person, except for a rebate or premium paid completely and directly to a patient. A pharmacist or pharmacy permittee shall not

1. Make payment to a medical practitioner in money or other consideration for a prescription order prescribed by the medical practitioner; or
2. Make payment to a long-term care or assisted living facility or other health care institution in money, discount, rental, or other consideration in an amount above the prevailing rate for:
  - a. Prescription medication or devices dispensed or sold for a patient or resident of the facility or institution; or
  - b. Drug selection or drug utilization review services, drug therapy management services, or other pharmacy consultation services provided for a patient or resident of the facility or institution.

B. Prescription order-blank advertising prohibited. A pharmacist or pharmacy permittee shall not:

1. Directly or indirectly furnish to a medical practitioner a prescription order-blank that refers to a specific pharmacist or pharmacy in any manner; or
2. Actively or passively participate in any arrangement or agreement where a prescription order-blank is prepared, written, or issued in a manner that refers to a specific pharmacist or pharmacy.

C. Fraudulent claim for service. A pharmacist or pharmacy permittee shall not claim the performance of a service that the pharmacist or pharmacy permittee knows or should know was not performed, such as, claiming to dispense a prescription medication that is not dispensed.

D. Fraudulent claim for a fee. A pharmacist or pharmacy permittee:

1. Shall not claim a fee for a service that is not performed or earned;
2. May divide a prescription order into two or more portions of prescription medication at the request of a patient, or for some other ethical reason, and charge a dispensing fee for the additional service; and
3. Shall not divide a prescription order merely to obtain an additional fee.

E. Prohibiting a prescription-only drug or device from being dispensed over the counter. A pharmacist shall ensure that:

1. A prescription-only drug or device is dispensed only after receipt of a valid prescription order from a licensed medical practitioner;
2. The dispensed prescription-only drug or device is properly prepared, packaged, and labeled according to this Chapter; and
3. The prescription order is filed according to this Chapter.

F. Drugs dispensed in the course of the conduct of a business of dispensing drugs through diagnosis by mail or the internet.

1. A pharmacist shall not dispense a drug from a prescription order if the pharmacist has knowledge, or reasonably should know under the circumstances, that the prescription order was issued on the basis of an internet-based questionnaire or an internet-based consultation without a medical practitioner-patient relationship as defined in R4-23-110.

2. A pharmacist who dispenses a prescription-only drug, prescription-only device, or controlled substance in violation of this Section is engaging in unethical conduct in violation of A.R.S. § 32-1901.01.

#### **R4-23-405. Change of Responsibility**

A pharmacist designated as the pharmacist-in-charge for a pharmacy, manufacturer, or other establishment shall give immediate notice, as defined in R4-23-110, when:

1. The pharmacist's responsibility as a pharmacist-in-charge is terminated; or
2. The pharmacist knows of a pending termination of the pharmacist's responsibility as the pharmacist-in-charge.

#### **R4-23-406. Repealed**

#### **R4-23-407. Prescription Requirements**

A. Prescription orders. A pharmacist shall ensure that:

1. A prescription order dispensed by the pharmacist includes the following information:
    - a. Date of issuance;
    - b. Name and address of the patient for whom or the owner of the animal for which the drug or device is dispensed;
    - c. Drug name, strength, and dosage form or device name;
    - d. Name of the drug's or device's manufacturer or distributor if the prescription order is written generically or a substitution is made;
    - e. Prescribing medical practitioner's directions for use;
    - f. Date of dispensing;
    - g. Quantity prescribed and if different, quantity dispensed;
    - h. For a prescription order for a controlled substance, the medical practitioner's address and DEA number;
    - i. For a written prescription order, the medical practitioner's signature;
    - j. For an electronically transmitted prescription order, the medical practitioner's digital or electronic signature;
    - k. For an oral prescription order, the medical practitioner's name and telephone number; and
    - l. Name or initials of the dispensing pharmacist;
  2. A prescription order is kept by the pharmacist or pharmacy permittee as a record of the dispensing of a drug or device for seven years from the date the drug or device is dispensed, except for a drug or device personally administered by a medical practitioner to the medical practitioner's patient; and
  3. The dispensing of a drug or device complies with the packaging requirements of the official compendium and state and federal law.
- B. Prescription refills. A pharmacist shall ensure that the following information is recorded on the back of a prescription order when it is refilled:
1. Date refilled,
  2. Quantity dispensed,
  3. Name or approved abbreviation of the manufacturer or distributor if the prescription order is written generically or a substitution is made, and
  4. The name or initials of the dispensing pharmacist.
- C. A pharmacist may furnish a copy of a prescription order to the patient for whom it is prescribed or to the authorized representative of the patient if the copy is clearly marked "COPY FOR REFERENCE PURPOSES ONLY" or other similar statement. A copy of a prescription order is not a valid prescription order and a pharmacist shall not dispense a drug or device from the information on a copy.
- D. Transfer of prescription order information. For a transfer of prescription order information to be valid, a pharmacy permittee or pharmacist-in-charge shall ensure that:
1. Both the original and the transferred prescription order are maintained for seven years after the last dispensing date;

2. The original prescription order information for a Schedule III, IV, or V controlled substance is transferred only as specified in 21 CFR 1306.25, published April 1, 2008, and no future amendments or editions, incorporated by reference, and on file with the Board, and available from the U.S. Government Printing Office, U.S. Superintendent of Documents, Washington, DC 20402-0001;
3. The original prescription order information for a non-controlled substance drug is transferred without limitation only up to the number of originally authorized refills;
4. For a transfer within Arizona:
  - a. The transfer of original prescription order information for a non-controlled substance drug meets the following conditions:
    - i. The transfer of information is communicated directly between:
      - (1) Two licensed pharmacists,
      - (2) A licensed pharmacist and a licensed pharmacy or graduate intern, or
      - (3) Two licensed pharmacy or graduate interns;
    - ii. The following information is recorded by the transferring pharmacist or pharmacy or graduate intern:
      - (1) The word "void" is written on the face of the invalidated original prescription unless it is an electronic or oral transfer and the transferred prescription order information is invalidated in the transferring pharmacy's computer system; and
      - (2) The name and identification code, number, or address and telephone number of the pharmacy to which the prescription is transferred, the name of the receiving pharmacist or pharmacy or graduate intern, the date of transfer, and the name of the transferring pharmacist or pharmacy or graduate intern is written on the back of the prescription or entered into the transferring pharmacy's computer system; and
    - iii. The following information is recorded by the receiving pharmacist or pharmacy or graduate intern on the transferred prescription order:
      - (1) The word "transfer;"
      - (2) Date of issuance of the original prescription order;
      - (3) Original number of refills authorized on the original prescription order;
      - (4) Date of original dispensing;
      - (5) Number of valid refills remaining and the date of the last refill;
      - (6) Name and identification code, number, or address, telephone number, and original prescription number of the pharmacy from which the prescription is transferred;
      - (7) Name of the transferring pharmacist or pharmacy or graduate intern; and
      - (8) Name of the receiving pharmacist or pharmacy or graduate intern;
  - b. The transfer of original prescription order information for a Schedule III, IV, or controlled substance meets the following conditions:
    - i. The transfer of information is communicated directly between two licensed pharmacists;
    - ii. The following information is recorded by the transferring pharmacist:
      - (1) The word "void" is written on the face of the invalidated original prescription order unless it is an electronic or oral transfer and the transferred prescription order information is invalidated in the transferring pharmacy's computer system; and
      - (2) The name, address, and DEA number of the pharmacy to which the prescription is transferred, the name of the receiving pharmacist, the date of transfer, and the name of the transferring pharmacist is written on the back of the prescription order or entered into the transferring pharmacy's computer system; and
    - iii. The following information is recorded by the receiving pharmacist on the transferred prescription order:
      - (1) The word "transfer;"
      - (2) Date of issuance of original prescription order;
      - (3) Original number of refills authorized on the original prescription order;

- (4) Date of original dispensing;
- (5) Number of valid refills remaining and the date of the last refill;
- (6) Name, address, DEA number, and original prescription number of the pharmacy from which the prescription is transferred;
- (7) Name of the transferring pharmacist; and
- (8) Name of the receiving pharmacist;

5. For a transfer from out-of-state:

- a. The transfer of original prescription order information for a non-controlled substance drug meets the conditions in subsections (D)(4)(a)(i) and (D)(4)(a)(iii); and
- b. The transfer of original prescription order information for a Schedule III, IV, or V controlled substance meets the conditions in subsections (D)(4)(b)(i) and (D)(4)(b)(iii); and

6. For an electronic transfer, the electronic transfer of original prescription order information meets the following conditions:

- a. The electronic transfer is between pharmacies owned by the same company using a common or shared database;
- b. The electronic transfer of original prescription order information for a non-controlled substance drug is performed by a pharmacist or a pharmacy or graduate intern, pharmacy technician trainee, or pharmacy technician under the supervision of a pharmacist;
- c. The electronic transfer of original prescription order information for a controlled substance is performed between two licensed pharmacists;
- d. The electronic transfer of original prescription order information for a non-controlled substance drug meets the following conditions:

- i. The transferring pharmacy's computer system:

- (1) Invalidates the transferred original prescription order information;
    - (2) Records the identification code, number, or address of the pharmacy to which the prescription order information is transferred;
    - (3) Records the name or identification code of the receiving pharmacist, pharmacy or graduate intern, pharmacy technician trainee, or pharmacy technician; and
    - (4) Records the date of transfer; and

- ii. The receiving pharmacy's computer system;

- (1) Records that a prescription transfer occurred;
    - (2) Records the date of issuance of the original prescription order;
    - (3) Records the original number of refills authorized on the original prescription order;
    - (4) Records the date of original dispensing;
    - (5) Records the number of valid refills remaining and the date of the last refill;
    - (6) Records the identification code, number, or address and original prescription number of the pharmacy from which the prescription is transferred;
    - (7) Records the name or identification code of the receiving pharmacist or pharmacy or graduate intern, pharmacy technician trainee, or pharmacy technician; and
    - (8) Records the date of transfer;

- e. The electronic transfer of original prescription order information for a controlled substance meets the following conditions:

- i. The transferring pharmacy's computer system:

- (1) Invalidates the transferred original prescription order information;
    - (2) Records the identification code, number, or address, and DEA number of the pharmacy to which the prescription order information is transferred;

- (3) Records the name or identification code of the receiving pharmacist;
- (4) Records the date of transfer; and
- (5) Records the name or identification code of the transferring pharmacist; and

ii. The electronic prescription order information received by the computer system of the receiving pharmacy includes the information required in subsection (D)(4)(b)(iii); and

f. In addition to electronic documentation of a transferred prescription order in the computer system, an original prescription order containing the requirements of this Section is filed in compliance with A.R.S. § 32-1964.

E. Transmission of a prescription order from a medical practitioner to a pharmacy by facsimile machine.

1. A medical practitioner or medical practitioner's agent may transmit a prescription order for a Schedule III, IV, or V controlled substance, prescription-only drug, or nonprescription drug to a pharmacy by facsimile under the following conditions:

a. The prescription order is faxed only to the pharmacy of the patient's choice;

b. The faxed prescription order:

i. Contains all the information required for a prescription order in A.R.S. §§ 32-1968 and 36-2525; and

ii. Is only faxed from the medical practitioner's practice location, except that a nurse in a hospital, long-term care facility, or inpatient hospice may send a facsimile of a prescription order for a patient of the facility; and

c. The faxed prescription order shall contain the following additional information:

i. The date the prescription order is faxed;

ii. The facsimile number of the prescribing medical practitioner or the facility from which the prescription order is faxed, and the telephone number of the facility; and

iii. The name of the person who transmits the facsimile, if other than the medical practitioner.

2. A medical practitioner or medical practitioner's agent may fax a prescription order for a Schedule II controlled substance for information purposes only, unless the faxed prescription order meets the requirements of A.R.S. § 36-2525(F) and (G).

3. A pharmacy may receive a faxed prescription order for a Schedule II controlled substance for information purposes only, except a faxed prescription order for a Schedule II controlled substance that meets the requirements of A.R.S. § 36-2525(F) and (G) may serve as the original written prescription order.

4. To meet the seven-year record retention requirement of A.R.S. § 32-1964, a pharmacy shall receive a faxed prescription order on a plain paper facsimile machine, except a pharmacy that does not have a plain paper facsimile machine may make a Xerox copy of a faxed prescription order received on a non-plain paper facsimile machine.

5. A medical practitioner or the medical practitioner's agent may fax refill authorizations to a pharmacy if the faxed authorization includes the medical practitioner's telephone number and facsimile number, the medical practitioner's signature or medical practitioner's agent's name, and date of authorization.

F. Electronic transmission of a prescription order from a medical practitioner to a pharmacy.

1. Unless otherwise prohibited by law, a medical practitioner or medical practitioner's agent may transmit a prescription order by electronic means, directly or through an intermediary, including an E-prescribing network, to the dispensing pharmacy as specified in A.R.S. § 32-1968.

2. For electronic transmission of a Schedule II, III, IV, or V controlled substance prescription order, the medical practitioner and pharmacy shall ensure that the transmission complies with any security or other requirements of federal law.

3. The medical practitioner and pharmacy shall ensure that all electronic transmissions comply with all the security requirements of state or federal law related to the privacy of protected health information.

4. In addition to the information required to be included on a prescription order as specified in A.R.S. § 32-1968, an electronically transmitted prescription order shall include:

a. The date of transmission; and

b. If the individual transmitting the prescription is not the medical practitioner, the name of the medical practitioner's authorized agent who transmits the prescription order.

5. A pharmacy receiving an electronically transmitted prescription order shall maintain the prescription order as specified in A.R.S. § 32-1964.

6. A medical practitioner or medical practitioner's agent shall transmit an electronic prescription order only to the pharmacy of the patient's choice.

#### **R4-23-408. Computer Records**

A. Systems manual. A pharmacy permittee or pharmacist-in-charge shall:

1. Develop, implement, and comply with policies and procedures for the following operational aspects of a computer system:
  - a. Examples of all output documentation provided by the computer system that contains original or refill prescription order or patient profile information;
  - b. Steps a pharmacy employee follows when the computer system is not operational due to scheduled or unscheduled system interruption;
  - c. Regular and routine backup file procedure and file maintenance, including secure storage of backup files;
  - d. Audit procedures, personnel code assignments, and personnel responsibilities; and
  - e. Quality assurance mechanism for data entry validation;
2. Review biennially and, if necessary, revise the policies and procedures required under this Section;
3. Document the review required under subsection (A)(2);
4. Assemble the policies and procedures as a written manual or by another method approved by the Board or its designee; and
5. Make the policies and procedures available within the pharmacy for reference by pharmacy personnel and inspection by the Board or its designee.

B. Computer system data storage and retrieval. A pharmacy permittee or pharmacist-in-charge shall ensure that the computer system is capable of:

1. Producing sight-readable information on all original and refill prescription orders and patient profiles;
2. Providing online retrieval (via CRT display or hard-copy printout) of original prescription order information required in A.R.S. § 32-1968(C), R4-23-402(A), and R4-23-407(A);
3. Providing online retrieval (via CRT display or hard-copy printout) of patient profile information required in R4-23-402(A);
4. Providing documentation identifying the pharmacist responsible for dispensing each original or refill prescription order, except a pharmacy permittee with a computer system that is in use before the effective date of this Section that cannot provide documentation identifying the dispensing pharmacist may continue to use the computer system by providing manual documentation identifying the dispensing pharmacist;
5. Producing a printout of all prescription order information, including a single-drug usage report that contains:
  - a. The name of the prescribing medical practitioner;
  - b. The name and address of the patient;
  - c. The quantity dispensed on each original or refill prescription order;
  - d. The date of dispensing for each original or refill prescription order;
  - e. The name or identification code of the dispensing pharmacist; and
  - f. The serial number of each prescription order; and
6. Providing a printout of requested prescription order information to an individual pharmacy within 72 hours of the request if prescription order information is maintained in a centralized computer record system.

C. A pharmacy permittee or pharmacist-in-charge of a pharmacy that uses a pharmacy computer system:

1. Shall notify the D.E.A. and the Board in writing that original and refill prescription information and patient profiles are stored in a pharmacy computer system;
2. Shall comply with this Section if the pharmacy computer system's refill records are used as an alternative to the manual refill records required in R4-23-407(B);
3. Is exempt from the manual refill recordkeeping requirements of R4-23-407(B), if the pharmacy computer system complies with the requirements of this Section; and

4. Shall ensure that documentation of the accuracy of original and refill information entered into a computer system is provided by each pharmacist using the computer system and kept on file in the pharmacy for seven years from the date of the last refill. Documentation includes one of the following:

a. A hard-copy printout of each day's original and refill data that:

- i. States original and refill data for prescriptions dispensed by each pharmacist is reviewed for accuracy;
- ii. Includes the printed name of each dispensing pharmacist; and
- iii. Is signed and initialed by each dispensing pharmacist; or

b. A log book or separate file of daily statements that:

- i. States original and refill data for prescriptions dispensed by each pharmacist is reviewed for accuracy;
- ii. Includes the printed name of each dispensing pharmacist; and
- iii. Is signed and initialed by each dispensing pharmacist.

D. If a pharmacy computer system does not comply with the requirements of subsections (A), (B), and (F), the pharmacy permittee or pharmacist-in-charge shall bring the computer system into compliance within three months of a notice of noncompliance or violation letter. If the computer system is still noncompliant with subsection (A), (B), or (F) after three months, the pharmacy permittee or pharmacist-in-charge shall immediately comply with the manual recordkeeping requirements of R4-23-402 and R4-23-407.

E. If a pharmacy's personnel perform manual recordkeeping under subsection (D), the pharmacy's personnel shall continue manual recordkeeping until the pharmacist-in-charge sends proof, verified by a Board compliance officer, that the computer system complies with subsections (A), (B), and (F).

F. Security. To maintain the confidentiality of patient records, a pharmacy permittee or pharmacist-in-charge shall ensure that:

1. The computer system has security and systems safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription order information and patient profiles; and
2. After a prescription order is dispensed, any alteration of prescription order information is documented, including the identification of the pharmacist responsible for the alteration.

G. A computer system that does not comply with all the requirements of subsections (A), (B), and (F) may be used in a pharmacy if:

1. The computer system was in use in the pharmacy before July 11, 2001, and
2. The pharmacy complies with the manual recordkeeping requirements of R4-23-402 and R4-23-407.

H. Prescription records and retention.

1. Instead of filing the original hard-copy prescription as required in A.R.S. § 32-1964, a pharmacy permittee or pharmacist-in-charge may use an electronic imaging recordkeeping system, if:

- a. The system is capable of capturing, storing, and reproducing the exact image of a prescription, including the reverse side of the prescription if necessary;
- b. Any notes of clarification of and alterations to a prescription are directly associated with the electronic image of the prescription;
- c. The prescription image and any associated notes of clarification to or alterations to a prescription are retained for a period not less than seven years from the date the prescription is last dispensed;
- d. The original hard-copy prescription is maintained for no less than 30 days after the date dispensed;
- e. Policies and procedures for the use of an electronic imaging recordkeeping system are developed, implemented, reviewed, and revised in the same manner described in subsection (A) and complied with; and
- f. The prescription is not for a schedule II controlled substance.

2. If a pharmacy's computer system fields are automatically populated by an electronically transmitted prescription order, the automated record constitutes the original prescription and a hard-copy or electronic image is not required if the computer system is capable of maintaining, printing, and providing all the prescription information required in A.R.S. §§ 32-1968 and 36-2525 and R4-23-407(A) within 72 hours of a request by the Board, the Board's compliance officers, other authorized regulatory board agents, or authorized officers of the law.

#### **R4-23-409. Returning Drugs and Devices**

A. After a person for whom a drug is prescribed or the person's agent takes the drug from the premises where sold, distributed, or dispensed, a pharmacist or pharmacy permittee shall not accept the drug for return or exchange for the purpose of resale unless the pharmacist determines that:

1. The drug is in its original, manufacturer's, unopened container; and
2. The drug or its container has not been subjected to contamination or deterioration.

B. The provisions of subsection (A) of this Section do not apply to a drug dispensed to:

1. A hospital inpatient as defined in R4-23-651; or
2. A resident of a long-term care facility where a licensed health care professional administers the drug, and the pharmacist ensures and documents that the drug:
  - a. Has been stored in compliance with the requirements of the official compendium; and
  - b. Is not obviously contaminated or deteriorated.

C. After a person for whom a device is prescribed or the person's agent takes the device from the premises where sold, distributed, or dispensed, a pharmacist or pharmacy permittee shall not accept the device for return or exchange for the purpose of resale or reuse unless the pharmacist determines that:

1. The device is inspected and is free of defects;
2. The device is rendered incapable of transferring disease; and
3. The device, if resold or reused, is not claimed to be new or unused.

#### **R4-23-410. Current Good Compounding Practices**

A. This Section establishes the current good compounding practices to be used by a pharmacist licensed by the Board, in a pharmacy permitted by the Board, and in compliance with applicable federal and state law governing the practice of pharmacy.

B. A pharmacy permittee shall ensure compliance with the provisions in this subsection.

1. All substances for compounding that are received, stored, or used by the pharmacy permittee:

- a. Meet official compendium requirements;
- b. Are of high quality, such as Chemically Pure (CP), Analytical Reagent (AR), certified American Chemical Society (ACS), or Food Chemical Codex (FCC) grade; or
- c. Are obtained from a source that, in the professional judgment of the pharmacist, is acceptable and reliable.

2. Before compounding a pharmaceutical product in excess of the quantity dispensed in anticipation of receiving valid prescriptions for the pharmaceutical product, a pharmacist, employed by the pharmacy permittee, shall establish a history of compounding valid prescriptions for the pharmaceutical product.

3. Neither the pharmacy permittee nor a pharmacist employed by the pharmacy permittee provides a compounded pharmaceutical product to a pharmacy, medical practitioner, or other person for dispensing or distributing except that a compounded pharmaceutical product may be provided to a medical practitioner to administer to a patient of the medical practitioner if each container is accompanied by the written list required in subsection (l)(5) and has a label that includes the following:

- a. The pharmacy's name, address, and telephone number;
- b. The pharmaceutical product's name and the information required in subsection (l)(4);
- c. A lot or control number;
- d. A beyond-use-date based upon the pharmacist's professional judgment, but not more than the maximum guidelines recommended in the Pharmacy Compounding Practices chapter of the official compendium unless there is published or unpublished stability test data that shows a longer period is appropriate;
- e. The statement "Not For Dispensing;" and
- f. The statement "For Office or Hospital Administration Only."

4. A pharmacy or pharmacist may advertise or otherwise promote the fact that the pharmacy or pharmacist provides prescription compounding services.

C. A pharmacy permittee shall ensure compliance with the organization, training, and personnel issues in this subsection.

1. Before dispensing a compounded pharmaceutical product, a pharmacist:

a. Inspects and approves or rejects, or assumes responsibility for inspecting and approving or rejecting, components, pharmaceutical product containers and closures, in-process materials, and labeling;

b. Prepares or assumes responsibility for preparing all compounding records;

c. Reviews all compounding records to ensure that no errors occur in the compounding process;

d. Ensures the proper use, cleanliness, and maintenance of all compounding equipment; and

e. Documents by hand-written initials or signature in the compounding record the completion of the requirements of subsections (C)(1)(a), (b), (c), and (d).

2. A pharmacist engaged in compounding:

a. Complies with the current good compounding practices and applicable state pharmacy laws;

b. Maintains compounding proficiency through current awareness, training, and continuing education; and

c. Ensures that personnel engaged in compounding wear:

i. Clean clothing appropriate to the work performed; and

ii. Protective apparel, such as coats, aprons, gowns, gloves or masks to protect the personnel from chemical exposure and prevent pharmaceutical product contamination.

D. A pharmacy permittee shall ensure the security, safety, and quality of a compounded pharmaceutical product by conforming with the following standards:

1. Implement procedures to exclude from direct contact with components, pharmaceutical product containers and closures, in-process materials, labeling, and pharmaceutical products, any person with an apparent illness or open lesion that may adversely affect the safety or quality of a compounded pharmaceutical product, until the illness or lesion, as determined by competent medical personnel, does not jeopardize the safety or quality of a compounded pharmaceutical product; and

2. Require all personnel to inform a pharmacist of any health condition that may adversely affect a compounded pharmaceutical product.

E. A pharmacy permittee shall provide compounding facilities that conform with the standards in this subsection.

1. In addition to the minimum area requirements of R4-23-609, R4-23-655, or R4-23-673, the compounding area:

a. Complies with the requirements in R4-23-611; and

b. Has sufficient space to permit efficient pharmacy practice, free movement of personnel, and visual surveillance by a pharmacist.

2. If sterile pharmaceutical product or radiopharmaceutical product compounding is performed, the compounding area complies with the requirements of R4-23-670, R4-23-681, and R4-23-682.

3. A clean, dry, and temperature-controlled area and, if required, a refrigerated area, in which to store properly labeled containers of bulk drugs, chemicals, and materials used in compounding, that complies with state statutes and rules.

F. To protect pharmaceutical product safety, identity, strength, quality, and purity, a pharmacy permittee shall ensure that equipment and utensils used in pharmaceutical product compounding are:

1. Of appropriate design, adequate size, and suitably located for proper operation, cleaning, and maintenance;

2. Made of material that is not reactive, additive, or absorptive when exposed to components, in-process materials, or pharmaceutical products;

3. Cleaned and protected from contamination before use;

4. Inspected and determined suitable for use before initiation of compounding operations; and

5. Routinely inspected, calibrated, or checked to make proper performance certain.

G. A pharmacy permittee shall ensure that the pharmacist-in-charge establishes, implements, and complies with procedures to prevent cross-contamination when pharmaceutical products that require special precautions to prevent cross-contamination, such as penicillin, are used in a

compounding procedure. The procedures shall include either the dedication of equipment or the meticulous cleaning of contaminated equipment before its use in compounding other pharmaceutical products.

H. A pharmacy permittee shall ensure that the pharmacist-in-charge establishes, implements, and complies with control procedures for components and pharmaceutical product containers and closures, either written or electronically stored with printable documentation, that conform with the standards in this subsection.

1. Components and pharmaceutical product containers and closures are:

- a. Stored off the floor,
- b. Handled and stored to prevent contamination, and
- c. Rotated so the oldest approved stock is used first.

2. Container closure systems comply with official compendium standards.

3. Pharmaceutical product containers and closures are clean and made of material that is not reactive, additive, or absorptive.

I. A pharmacy permittee shall ensure that the pharmacist-in-charge establishes, implements, and complies with pharmaceutical product compounding controls that conform with the standards in this subsection.

1. Pharmaceutical product compounding procedures are available in either written form or electronically stored with printable documentation:

- a. To ensure that a finished pharmaceutical product has the identity, strength, quality, and purity it is purported or represented to possess, the procedures include, for each pharmaceutical product compounded, a description of:
  - i. The components, their manufacturer, lot number, expiration date, and amounts, the order of component addition, if applicable, and the compounding process;
  - ii. The equipment and utensils used; and
  - iii. The pharmaceutical product container and closure system proper for the sterility and stability of the pharmaceutical product as it is intended to be used.

b. To test the pharmaceutical product being compounded, the procedures monitor the output and validate the performance of compounding processes that may cause variability in the final pharmaceutical product, including assessing:

- i. Dosage form weight variation;
- ii. Adequacy of mixing to ensure uniformity and homogeneity; and
- iii. Clarity, completeness, and pH of solutions, if applicable.

2. Components for pharmaceutical product compounding are accurately weighed, measured, or subdivided. To ensure that each weight, measure, or subdivision is correct as stated in the compounding procedures, a pharmacist:

- a. Checks and rechecks, or assumes responsibility for checking and re-checking, the operations at each stage of the compounding process; and
- b. Documents by hand-written initials or signature the completion and accuracy of the compounding process.

3. Compounding equipment and utensils are properly cleaned and maintained.

4. In addition to the labeling requirements of A.R.S. § 32-1968(D), the label contains:

- a. A statement, symbol, designation, or abbreviation that the pharmaceutical product is a compounded pharmaceutical product, and
- b. A beyond-use-date as specified in subsection (B)(3)(d).

5. A written list of the compounded pharmaceutical product's active ingredients is given to the patient at the time of dispensing.

6. When a component is removed from its original container and transferred to another container, the new container label contains, in full text or an abbreviated code system, the following:

- a. The component name,
- b. The manufacturer's or supplier's name,
- c. The lot or control number,

- d. The weight or measure,
- e. The beyond-use-date as specified in subsection (B)(3)(d), and
- f. The transfer date.

J. A pharmacy permittee shall ensure that the pharmacist-in-charge stores any quantity of compounded pharmaceutical product produced in excess of the quantity dispensed in accordance with subsection (B):

- 1. In an appropriate container with a label that contains:
  - a. A complete list of components or the pharmaceutical product's name;
  - b. The preparation date;
  - c. The assigned lot or control number; and
  - d. A beyond-use-date as specified in subsection (B)(3)(d); and
- 2. Under conditions, dictated by the pharmaceutical product's composition and stability characteristics, that ensure its strength, quality, and purity.

K. A pharmacy permittee shall ensure that the pharmacist-in-charge establishes, implements, and complies with recordkeeping procedures that comply with this subsection:

- 1. Pharmaceutical product compounding procedures and other records required by this Section are maintained by the pharmacy for not less than seven years, and
- 2. Pharmaceutical product compounding procedures and other records required by this Section are readily available for inspection by the Board or its designee.

**R4-23-411. Pharmacist-administered or Pharmacy or Graduate Intern-administered Immunizations**

A. Certification to administer immunizations, vaccines, and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient or eligible minor patient. As used in this Section, "eligible adult patient" means an eligible patient 18 years of age or older and "eligible minor patient" means an eligible patient at least 6 years of age but under 18 years of age. A pharmacist or a pharmacy or graduate intern, in the presence of and under the immediate personal supervision of a certified pharmacist, may administer, without a prescription, immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient or eligible minor patient, if:

- 1. The pharmacist or pharmacy or graduate intern meets the qualifications and standards specified by A.R.S. § 32-1974 and this Section.
- 2. The Board certifies the pharmacist or pharmacy or graduate intern as specified in subsection (D).
- 3. For an eligible adult patient, the immunization or vaccine is listed in the United States Centers for Disease Control and Prevention's Recommended Adult Immunization Schedule; or the immunization or vaccine is recommended in the United States Centers for Disease Control and Prevention's Health Information for International Travel.
- 4. For an eligible adult patient, the immunization or vaccine is not on the Arizona Department of Health Services list specified in A.A.C. R9-6-1301 as required under A.R.S. § 32-1974 and subsection (I).
- 5. For an eligible minor patient, the immunization or vaccine is for influenza.
- 6. For an eligible minor patient, any immunizations or vaccines other than influenza are administered in response to a public health emergency declared by the Governor under A.R.S. § 36-787.

B. A pharmacist or a pharmacy or graduate intern, in the presence of and under the immediate personal supervision of a certified pharmacist, may administer, with a prescription, any immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient or eligible minor patient, if:

- 1. The pharmacist or pharmacy or graduate intern meets the qualifications and standards specified by A.R.S. § 32-1974 and this Section.
- 2. The Board certifies the pharmacist or pharmacy or graduate intern as specified in subsection (D).

C. A pharmacist or pharmacy or graduate intern who is certified to administer immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient or eligible minor patient shall:

- 1. Not delegate the authority to any other pharmacist, pharmacy or graduate intern, or employee; and
- 2. Maintain their current certificate for inspection by the Board or its designee or review by the public.

D. Qualifications for certification to administer immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient or eligible minor patient. After receipt of a completed application form, the Board shall issue a certificate authorizing the

administration of immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient or eligible minor patient to a pharmacist or pharmacy or graduate intern who meets the following qualifications:

1. Has a current license to practice pharmacy in this state,
2. Successfully completes a training program specified in subsection (E), and
3. Has a current certificate in basic cardiopulmonary resuscitation.

E. Immunizations training program requirements. A training program for pharmacists or pharmacy or graduate interns to administer immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient or eligible minor patient shall include the following courses of study:

1. Basic immunology and the human immune response;
2. Mechanics of immunity, adverse effects, dose, and administration schedule of available vaccines;
3. Response to an emergency situation as a result of the administration of an immunization, including administering epinephrine and diphenhydramine to counteract the adverse effects of an immunization given based on a patient-specific prescription order received before administering the immunization;
4. Administration of intramuscular injections;
5. Other immunization administration methods; and
6. Recordkeeping and reporting requirements specified in subsection (F).

F. Recordkeeping and reporting requirements.

1. A pharmacist or pharmacy or graduate intern granted certification under this Section to administer immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible patient shall provide to the pharmacy the following information and documentation regarding each immunization or vaccine administered:

- a. The name, address, and date of birth of the patient;
- b. The date of administration and site of injection;
- c. The name, dose, manufacturer's lot number, and expiration date of the vaccine, epinephrine, or diphenhydramine;
- d. The name and address of the patient's primary care provider or physician, as identified by the patient;
- e. The name of the pharmacist or pharmacy or graduate intern administering the immunization;
- f. A record of the pharmacist's or pharmacy or graduate intern's consultation with the patient determining that the patient is an eligible patient as defined in R4-23-110;
- g. The date and time that the written report specified in subsection (F)(2) was sent to the patient's primary care provider or physician;
- h. Consultation or other professional information provided to the patient by the pharmacist or pharmacy or graduate intern;
- i. The name and date of the vaccine information sheet provided to the patient; and
- j. For immunizations or vaccines given to an eligible minor patient, a consent form signed by the minor's parent or guardian.

2. The pharmacist or pharmacy or graduate intern shall provide a written report to the patient's primary care provider or physician containing the documentation required in subsection (F)(1) within 48 hours after the immunization. The pharmacy shall make the required records specified in subsection (F)(1) and a record of compliance with this subsection available in the pharmacy for inspection by the Board or its designee.

3. A pharmacy's pharmacist-in-charge shall maintain the records required in subsection (F)(1) in the pharmacy for a minimum of seven years from the immunization's administration date.

G. Confidentiality of records. A pharmacist, pharmacy or graduate intern, pharmacy permittee, or pharmacist-in-charge shall comply with applicable state and federal privacy statutes and rules when releasing patient health information.

H. Renewal of a certificate for pharmacist-administered immunizations. A certificate authorizing a pharmacist to administer immunizations or vaccines and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient or eligible minor patient shall be renewed every five years by submitting a renewal request within the 30 days before the certificate's expiration date. A pharmacist desiring to renew the certificate shall provide to the Board proof of the following:

1. Current certification in basic cardiopulmonary resuscitation, and

2. Completion of a minimum of five contact hours (0.5 CEU) of continuing education related to immunizations during the five-year renewal period. A pharmacist may use the continuing education hours required in this subsection as part of the total continuing education hours required for pharmacist license renewal.

I. Pharmacist-administered or pharmacy or graduate intern-administered adult immunizations that require a prescription order. A pharmacist or pharmacy or graduate intern certified by the Board to administer adult immunizations or vaccines shall not administer any immunization or vaccine listed in A.A.C. R9-6-1301 without a prescription order. In addition to filing a prescription order as required in A.R.S. § 32-1964, a pharmacist or pharmacy or graduate intern who administers an immunization or vaccine listed in A.A.C. R9-6-1301 shall comply with the recordkeeping requirements of subsection (F)(1).

#### **R4-23-412. Emergency Refill Prescription Dispensing**

A. When a state of emergency is declared under A.R.S. § 32-1910(A) or (B) and the state of emergency results in individuals being unable to refill existing prescriptions, a pharmacist may work in the affected county, city, or town and may dispense a one-time emergency refill prescription of up to a 30-day supply of a prescribed medication to an affected individual if both of the following apply:

1. In the pharmacist's professional opinion the medication is essential to the maintenance of life or to the continuation of therapy, and
2. The pharmacist makes a good faith effort to reduce the information to a written prescription marked "emergency prescription" and files and maintains the prescription as required by law.

B. If the state of emergency declared under A.R.S. § 32-1910(A) or (B) continues for at least 21-days after the pharmacist dispenses an emergency prescription under subsection (A), the pharmacist may dispense one additional emergency refill prescription of up to a 30-day supply of the prescribed medication if the pharmacist complies with subsection (A)(2).

C. A pharmacist's authority to dispense emergency prescriptions under this Section ends when the declared state of emergency is terminated.

#### **R4-23-413. Temporary Recognition of Nonresident Licensure**

A. When a state of emergency is declared under A.R.S. § 32-1910(A) or (B):

1. A pharmacist who is not licensed in this state, but who is currently licensed in another state, may dispense prescription medications in those affected counties, cities, or towns in this state during the time that a declared state of emergency exists under A.R.S. § 32-1910(A) or (B) if both of the following apply:

- a. The pharmacist provides proof of current licensure in another state, and
- b. The pharmacist is engaged in a relief effort during a state of emergency.

2. Acting under the direct supervision of a pharmacist, a pharmacy technician or pharmacy intern not licensed in this state, but currently licensed or registered in another state, may assist a pharmacist in dispensing prescription medications in affected counties, cities, or towns in this state during the time that a declared state of emergency exists under A.R.S. § 32-1910(A) or (B) if both of the following apply:

- a. The pharmacy technician or pharmacy intern provides proof of current licensure or registration in another state, and
- b. The pharmacy technician or pharmacy intern is engaged in a relief effort during a state of emergency.

B. The recognition of nonresident licensure or registration shall end with the termination of the declared state of emergency.

#### **R4-23-414. Reserved**

#### **R4-23-415. Impaired Licensees - Treatment and Rehabilitation**

A. The Board may contract with qualified organizations to operate a program for the treatment and rehabilitation of licensees impaired as the result of alcohol or other drug abuse, pursuant to A.R.S. § 32-1932.01.

B. Participants in the program are either "confidential" or "known." Confidential participants are self-referred and may remain unidentified to the Board, subject to maintaining compliance with their program contract. Known participants are under Board order to complete a minimum tenure in the program. After a known participant completes the minimum tenure, the Board may terminate the Board order and reinstate the participant's license to practice pharmacy.

C. The program contract with a qualified organization shall include as a minimum the following:

1. Duties and responsibilities of each party.
2. Duration, not to exceed two years, of contract and terms of compensation.
3. Quarterly reports from the program administrator to the Board indicating:

- a. Identity of participants;
  - i. By name, if a known participant; or
  - ii. By case number, if a confidential participant;
- b. Status of each participant, including;
  - i. Clinical findings;
  - ii. Diagnosis and treatment recommendations;
  - iii. Program activities; and
  - iv. General recovery and rehabilitation program information.

4. The program administrator shall report immediately to the Board the name of any impaired licensee who poses a danger to self or others.

5. The program administrator shall report to the Board, as soon as possible, the name of any impaired licensee:

- a. Who refuses to submit to treatment,
- b. Whose impairment is not substantially alleviated through treatment, or
- c. Who violates the terms of their contract.

6. The program administrator shall periodically provide informational programs to the profession, including approved continuing education programs on the topic of drug and chemical impairment, treatment, and rehabilitation.

D. Under A.R.S. § 32-1903(F), the Board may publish the names of participants under current Board orders.

E. The Board or its executive director may request the treatment records for any participant. The program administrator shall provide treatment records within 10 working days of receiving a written request from the Board or its executive director for such records. Upon request of the program administrator or the Board or its executive director, a program participant shall authorize a drug and alcohol treatment facility or program or a private practitioner or treatment program to release the participant's records to the program administrator or the Board or its executive director.

F. On the recommendation of the program administrator or a Board member and by mutual consent, the program administrator, Board member, Board staff, and program participant may meet informally to discuss program compliance.

**R4-23-416. Thru R4-23-420. Reserved**

**R4-23-421. Thru R4-23-429. Repealed**

**ARTICLE 5. CONTROLLED SUBSTANCES PRESCRIPTION MONITORING PROGRAM:**

**R4-23-501. Controlled Substances Prescription Monitoring Program Registration**

A. Under A.R.S. § 36-2606, a medical practitioner who is issued a license under A.R.S. Title 32, Chapter 7, 11, 13, 14, 15, 16, 17, 21, 25, or 29 and possesses a current DEA registration under the Federal Controlled Substances Act shall have a current CSPMP registration issued by the Board.

B. Application. To obtain a CSPMP registration, a person shall submit a completed application on a form furnished by the Board that includes:

- 1. Applicant's name, address, mailing address, if different, e-mail address, telephone number, facsimile number, license number issued under A.R.S. Title 32, Chapter 7, 11, 13, 14, 15, 16, 17, 21, 25, or 29, and DEA registration number;
- 2. Whether the applicant's license and DEA registration listed in subsection (B)(1) are current and in good standing, and if not, the status of the license and registration; and
- 3. Date signed and applicant's verified signature.

C. Registration. Within seven business days of receipt of a completed application specified in subsection (B), the Board office shall determine whether an application is complete. If the application is complete, the Board office shall issue a registration number and mail a current renewal receipt to the applicant. If the application is incomplete, the Board office shall issue a notice of incompleteness. An applicant with an incomplete application shall comply with the requirements of R4-23-202(F)(2) and (3).

D. Registration renewal. As specified in A.R.S. § 36-2606(C), the Board shall automatically suspend the registration of any registrant that fails to renew the registration on or before May 1 of the year in which the renewal is due. The Board shall vacate a suspension if the registrant submits a renewal application. A suspended registrant is prohibited from accessing information in the prescription monitoring program database.

#### E. CSPMP database access

1. A medical practitioner that chooses to use the CSPMP database shall request access from the CSPMP Director on forms provided on the Board's website. Upon receipt of the request, the CSPMP Director or designee shall issue access credentials provided the medical practitioner is in compliance with the registration requirements of this section and has completed the Board's CSPMP Online Training Program.

2. A pharmacist that chooses to use the CSPMP database shall request access from the CSPMP Director on forms provided on the Board's website. Upon receipt of the request, the CSPMP Director or designee shall issue access credentials provided the pharmacist has a current active pharmacist license and has completed the Board's CSPMP Online Training Program.

#### **R4-23-502. Requirements for Data Format and Transmission**

A. Each dispenser shall submit to the Board or its designee by electronic means information regarding each prescription dispensed for a controlled substance listed in Schedules II, III, and IV of A.R.S. Title 36, Chapter 27, the Arizona Uniform Controlled Substances Act. The information reported shall conform to the August 31, 2005 Version 003, Release 000 ASAP Rules-based Standard Implementation Guide for Prescription Monitoring Programs published by the American Society for Automation in Pharmacy as specified in A.R.S. § 36-2608(B). The information submitted for each prescription shall include:

1. The name, address, telephone number, prescription number, and DEA registration number of the dispenser;
2. The name, address, gender, date of birth, and telephone number of the person or, if for an animal, the owner of the animal for whom the prescription is written;
3. The name, address, telephone number, and DEA registration number of the prescribing medical practitioner;
4. The quantity and National Drug Code (NDC) number of the Schedule II, III, or IV controlled substance dispensed;
5. The date the prescription was dispensed;
6. The number of refills, if any, authorized by the medical practitioner;
7. The date the prescription was issued;
8. The method of payment identified as cash or third party; and
9. Whether the prescription is new or a refill.

B. A dispenser shall submit the required information electronically unless the Board approves a waiver as specified in subsection (D).

C. A dispenser's electronic data transfer equipment including hardware, software, and internet connections shall meet the privacy and security standards of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and A.R.S. § 12-2292, in addition to common internet industry standards for privacy and security. A dispenser shall ensure that each electronic transmission meets the following data protection requirements:

1. Data shall be at least 128-bit encryption in transmission and at rest; and
2. Data shall be transmitted via secure e-mail, telephone modem, diskette, CD-ROM, tape, secure File Transfer Protocol (FTP), Virtual Private Network (VPN), or other Board-approved media.

D. A dispenser who does not have an automated recordkeeping system capable of producing an electronic report in the Board 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 supplied by the Board or its designee.

E. Unless otherwise approved by the Board, a dispenser shall report by the close of business on each Friday the required information for the previous week, Sunday through Saturday. If a Friday falls on a state holiday, the dispenser shall report the information on the following business day. The Board may approve a less frequent reporting period if a dispenser makes a showing that a less frequent reporting period will not reduce the effectiveness of the system or jeopardize the public health.

#### **R4-23-503. Access to Controlled Substances Prescription Monitoring Program Data**

A. Except as provided in A.R.S. § 36-2604(B) and (C) and this Section, prescription information submitted to the Board or its designee is confidential and is not subject to public inspection.

B. The Board or its designee shall review the prescription information collected under A.R.S. Title 36, Chapter 28 and R4-23-502. If the Board or its designee has reason to believe an act of unprofessional or illegal conduct has occurred, the Board or its designee shall notify the appropriate professional licensing board or law enforcement or criminal justice agency and provide the prescription information required for an investigation.

C. The Board or its designee is authorized to release data collected by the program to the following:

1. A person who is authorized to prescribe or dispense a controlled substance to assist that person to provide medical or pharmaceutical care to a patient or to evaluate a patient;

2. An individual who requests the individual's own controlled substance prescription information under A.R.S. § 12-2293;
  3. A professional licensing board established under A.R.S. Title 32, Chapter 7, 11, 13, 14, 15, 16, 17, 18, 21, 25, or 26. Except as required under subsection (B), the Board or its designee shall provide this information only if the requesting board states in writing that the information is necessary for an open investigation or complaint;
  4. A local, state, or federal law enforcement or criminal justice agency. Except as required under subsection (B), the Board or its designee shall provide this information only if the requesting agency states in writing that the information is necessary for an open investigation or complaint;
  5. The Arizona Health Care Cost Containment System Administration regarding individuals who are receiving services under A.R.S. Title 36, Chapter 29. Except as required under subsection (B), the Board or its designee shall provide this information only if the Administration states in writing that the information is necessary for an open investigation or complaint;
  6. A person serving a lawful order of a court of competent jurisdiction; and
  7. The Board staff for purposes of administration and enforcement of A.R.S. Title 36, Chapter 28 and this Article.
- D. The Board or its designee may provide data to public or private entities for statistical, research, or educational purposes after removing information that could be used to identify individual patients or persons who received prescriptions from dispensers.

**R4-23-504. Computerized Central Database Tracking System Task Force**

- A. The Board shall appoint a task force to help it administer the computerized central database tracking system as specified in A.R.S. § 36-2603.
- B. The Task Force shall meet at least once each year and at the call of the chairperson to establish the procedures and conditions relating to the release of prescription information specified in A.R.S. § 36-2604 and R4-23-503.
- C. The Task Force shall determine:
1. The information to be screened;
  2. The frequency and thresholds for screening; and
  3. The parameters for using the information to notify medical practitioners, patients, and pharmacies to educate and provide for patient management and treatment options.
- D. The Board shall review and approve the procedures and conditions established by the Task Force as needed but at least once every calendar year.

**R4-23-505. Reports**

- A. Before releasing prescription monitoring program data, the Board or its designee shall receive a written request for controlled substance prescription information.
- B. A person authorized to access CSPMP data under R4-23-503(C)(1) through (6) shall submit a written request that:
1. Specifies the information requested for the report;
  2. For a medical practitioner, provides a statement that the report's purpose is to provide medical or pharmaceutical care to a patient or to evaluate a patient;
  3. For an individual obtaining the individual's own controlled substance prescription information, provides a form of non-expired government-issued identification;
  4. For a professional licensing board, states that the information is necessary for an open investigation or complaint;
  5. For a local, state, or federal law enforcement or criminal justice agency, states that the information is necessary for an open investigation or complaint;
  6. For the AHCCCS Administration, states that the information is necessary for an open investigation or complaint; and
  7. For a person serving a lawful order of a court of competent jurisdiction, provides a copy of the court order.
- C. The Board or its designee may provide reports through U.S. mail, other common carrier, facsimile, or secured electronic media or may allow reports to be picked up in-person at the Board office.

**R4-23-506. Repealed**

## **ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS:**

### **R4-23-601. General Provisions**

A. Permit required to sell a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical. A person shall have a current Board permit to:

1. Sell a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical in Arizona; or
2. Sell a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical from outside Arizona and ship the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical into Arizona.

B. A medical practitioner is exempt from subsection (A) to administer a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical for the emergency needs of a patient.

C. Permit fee. Permits are issued biennially on an odd- and even- year expiration based on the assigned permit number. The fee, specified in R4-23-205, is not refundable under any circumstances except the Board's failure to comply with the permit time-frames established in R4-23-602.

D. Record of receipt and disposal of narcotics or other controlled substances, prescription-only drugs or devices, nonprescription drugs, precursor chemicals, or regulated chemicals.

1. Every person manufacturing a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical, including repackaging or relabeling, shall prepare and retain for not less than three years the manufacturing, repackaging, or relabeling date for each narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical.
2. Every person receiving, selling, delivering, or disposing of a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical shall record and retain for not less than three years the following information:
  - a. The name, strength, dosage form, and quantity of each narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical received, sold, delivered, or disposed;
  - b. The name, address, and license or permit number, if applicable, of the person from whom each narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is received;
  - c. The name, address, and license or permit number, if applicable, of the person to whom each narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is sold or delivered, or of the person who disposes of each narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical; and
  - d. The receipt, sale, deliver, or disposal date of each narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical.
3. The record required in this subsection shall be available for inspection by the Board or its compliance officer during regular business hours.
4. If the record required in this subsection is stored in a centralized recordkeeping system and not immediately available for inspection, a permittee, manager, or pharmacist-in-charge shall provide the record within four working days of the Board's or its compliance officer's request.

E. Narcotics or other controlled substances, prescription-only drugs or devices, nonprescription drugs, precursor chemicals, or regulated chemicals damaged by water, fire, or from human or animal consumption or use. No person shall sell or offer to sell any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical damaged by water, fire, or from human or animal consumption or use.

### **R4-23-602. Permit Application Process and Time-frames**

A. A person applying for a permit shall:

1. Submit a completed application for the desired permit electronically or manually on a form furnished by the Board, and
2. Submit with the application form:
  - a. The documents specified in the application form, and
  - b. The permit fee specified in R4-23-205(D).

B. The Board office shall deem an application form received on the date the Board office electronically or manually date-stamps the form.

C. Time-frames for permits.

1. The Board office shall finish an administrative completeness review within 60 days from the date the application form is received.
  - a. The Board office shall issue a written notice of administrative completeness to the applicant if no deficiencies are found in the application form.
  - b. If the application form is incomplete, the Board office shall provide the applicant with a written notice that includes a comprehensive list of the missing information. The 60-day time-frame for the Board office to finish the administrative completeness review is suspended from the date the notice of incompleteness is served until the applicant provides the Board office with all missing information.
  - c. If the Board office does not provide the applicant with written notice regarding administrative completeness, the application form shall be deemed complete 60 days after receipt by the Board office.
2. An applicant with an incomplete application form shall submit to the Board office all of the missing information within 90 days of service of the notice of incompleteness.
  - a. If an applicant cannot submit all missing information within 90 days of service of the notice of incompleteness, the applicant may send a written request for an extension to the Board office postmarked or delivered no later than 90 days from service of the notice of incompleteness;
  - b. The written request for an extension shall document the reasons the applicant is unable to meet the 90-day deadline; and
  - c. The Board Office office shall review the request for an extension of the 90-day deadline and grant the request if the Board Office office determines that an extension of the 90-day deadline will enable the applicant to assemble and submit the missing information. An extension shall be for no more than 30 days. The Board office shall notify the applicant in writing of its decision to grant or deny the request for an extension.
3. If an applicant fails to submit a complete application form within the time allowed, the Board office shall close the applicant's file. An applicant whose file is closed and who later wishes to obtain a permit shall submit a new application and fee as specified in subsection (A).
4. For a nonprescription drug permit applicant, a compressed medical gas distributor permit applicant, and a durable medical equipment and compressed medical gas supplier permit applicant, the Board office shall issue a permit on the day that the Board office determines an administratively complete application form is received.
5. Except as described in subsection (C)(4), from the date on which the administrative completeness review of an application form is finished, the Board office shall complete a substantive review of the applicant's qualifications in no more than 120 days.
  - a. If an applicant is found to be ineligible, the Board office shall issue a written notice of denial to the applicant.
  - b. If an applicant is found to be eligible, the Board office shall recommend to the Board that the applicant be issued a permit. Upon receipt of the Board office's recommendation, the Board shall either issue a permit to the applicant or if the Board determines the applicant does not meet eligibility requirements, return the matter to the Board office.
  - c. If the Board office finds deficiencies during the substantive review of the application form, the Board office shall issue a written request to the applicant for additional documentation.
  - d. The 120-day time-frame for a substantive review for the issuance or denial of a permit is suspended from the date of the written request for additional documentation until the date that all documentation is received. The applicant shall submit the additional documentation according to subsection (C)(2).
  - e. If the applicant and the Board office mutually agree in writing, the 120-day substantive review time-frame may be extended once for no more than 45 days.
6. For the purpose of A.R.S. § 41-1072 et seq., the Board establishes the following time-frames for permits:
  - a. Administrative completeness review time-frame: 60 days.
  - b. Substantive review time-frame:
    - i. Nonprescription drug permit, compressed medical gas distributor permit, and durable medical equipment and compressed medical gas supplier permit: none.
    - ii. Except as described in subsection (C)(6)(b)(i): 120 days.
  - c. Overall time-frame:
    - i. Nonprescription drug permit, compressed medical gas distributor permit, and durable medical equipment and compressed medical gas supplier permit: 60 days.
    - ii. Except as described in subsection (C)(6)(c)(i): 180 days.

**D. Permit renewal.**

1. To renew a permit, a permittee shall submit a completed application for permit renewal electronically or manually on a form furnished by the Board with the biennial renewal fee specified in R4-23-205(D).

2.If the biennial renewal fee is not paid by November 1 of the renewal year specified in A.R.S. § 32-1931, the permit is suspended. The permittee shall pay a penalty fee as provided in A.R.S. § 32-1931 and R4-23-205(G)(2) to vacate the suspension.

3. Time-frames for permit renewals. The Board office shall follow the time-frames established in subsection (C).

E. Display of permit. A permittee shall conspicuously display the permit in the location to which it applies.

#### **R4-23-603. Nonprescription Drugs, Retail**

A. Permit. A person, including the following, shall not sell or distribute a nonprescription drug without a current Board-issued permit:

1. A grocer;
2. Other non-pharmacy retail outlet; or
3. Mobile or non-fixed location retailer, such as a swap-meet vendor.

B. A medical practitioner licensed under A.R.S. Title 32 is exempt from the requirements of subsection (A).

C. Application. To obtain a permit to sell a nonprescription drug, a person shall submit:

1. A completed application form and fee as specified in R4-23-602; and
2. Documentation of compliance with local zoning laws, if required by the Board.

D. Drug sales. A nonprescription drug permittee:

1. Shall sell a drug only in the original container packaged and labeled by the manufacturer; and
2. Shall not package, repack, label, or relabel any drug.

E. Inspection. A nonprescription drug permittee shall consent to inspection during business hours by a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(5).

F. Quality control. A nonprescription drug permittee shall:

1. Ensure that all drugs stocked, sold, or offered for sale are:
  - a. Kept clean;
  - b. Protected from contamination, excessive heat, cold, sunlight, and other deteriorating factors;
  - c. In compliance with federal law; and
  - d. Received from a supplier with a current Board-issued permit as specified in R4-23-601(A).
2. Develop and implement a program to ensure that:
  - a. Any expiration-dated drug is reviewed regularly;
  - b. Any drug, that exceeds its expiration date, is deteriorated or damaged, or does not comply with federal law, is moved to a quarantine area and not sold or distributed; and
  - c. Any quarantined drug is destroyed or returned to its source of supply.

G. Notification. A nonprescription drug permittee shall provide written notice by mail, facsimile, or e-mail to the Board office within ten days of changes involving the telephone number, facsimile number, e-mail address, mailing address, or name of business.

H. Change of ownership. No less than 14 days before a change of ownership occurs that involves changes of stock ownership of 30% or more of the voting stock of a corporation or an existing and continuing corporation that is not actively traded on any securities market or over-the-counter market, the prospective owner shall submit a completed application form and fee as specified in subsection (C).

I. Relocation. No less than 30 days before an existing nonprescription drug permittee relocates, the permittee shall submit a completed application for relocation electronically or manually on a form furnished by the Board, and the documentation required in subsection (C).

J. Records. A nonprescription drug permittee shall:

1. Retain records of the receipt and disposal of nonprescription drugs as required in R4-23-601(D), and
2. Comply with the requirements of A.R.S. § 32-1977 and federal law for the retail sale of methamphetamine precursors.

K. Permit renewal. Permit renewal shall be as specified in R4-23-602(D).

L. Nonprescription drug vending machine outlet. In addition to the requirements of R4-23-601, R4-23-602, and subsections (A) through (K), a person selling or distributing a nonprescription drug in a vending machine shall comply with the following requirements:

1. Each individual vending machine is considered an outlet and shall have a Board-issued nonprescription drug permit;
2. Each nonprescription-drug-permitted vending machine shall display in public view an identification seal, furnished by the Board, containing the permit number, vending machine's serial number, owner's name and telephone contact number;
3. Each nonprescription-drug-permitted vending machine is assigned a specific location that is within a weather-tight structure, protected from direct sunlight, and maintained at a temperature not less than 59° F and not greater than 86° F;
4. Each nonprescription drug sold in a vending machine is packaged and labeled in the manufacturer's original FDA-approved container;
5. A nonprescription-drug-permitted vending machine is subject to inspection by a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(5) as follows:
  - a. The owner, manager, or other staff of the nonprescription drug permittee shall provide access to the contents of the vending machine within 24 hours of a request from a Board compliance officer or other authorized officer of the law; or
  - b. The Board compliance staff shall have independent access to the vending machine;
6. Before relocating or retiring a nonprescription-drug-permitted vending machine, the owner or manager shall notify the Board in writing. The notice shall include:
  - a. Permit number;
  - b. Vending machine's serial number;
  - c. Action planned (relocate or retire); and
  - d. If retiring a vending machine, the disposition of the nonprescription drug contents of the vending machine;
7. The sale or distribution of a precursor chemical or regulated chemical in a vending machine is prohibited; and
8. Under no circumstance may expired drugs be sold or distributed.

**R4-23-604. Resident Drug Manufacturer**

A. Permit. A person shall not manufacture, package, repackage, label, or relabel any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical without a current Board-issued drug manufacturer permit.

B. Application. To obtain a permit to operate a drug manufacturing firm in Arizona, a person shall submit a completed application, on a form furnished by the Board, that includes:

1. Business name, address, mailing address, if different, telephone number, and facsimile number;
2. Owner's name, if corporation or partnership, officers or partners, including address and title, and any other trade or business names used;
3. Whether the owner, corporation, or partnership has conducted a similar business in any other jurisdiction and if so, indicate under what name and location;
4. Whether the owner, any officer, or active partner has ever been convicted of an offense involving moral turpitude, a felony offense, or any drug-related offense or has any currently pending felony or drug-related charges, and if so, indicate charge, conviction date, jurisdiction, and location;
5. Whether the owner, any officer, or active partner has ever been denied a drug manufacturer permit in this state or any other jurisdiction, and if so, indicate where and when;
6. A copy of the drug list required by the FDA;
7. Plans or construction drawings showing facility size and security for the proposed business;
8. Applicant's and manager's name, address, emergency telephone number, and resumé indicating educational or experiential qualifications related to drug manufacturer operation;
9. The applicant's current FDA drug manufacturer or repackager registration number and expiration date;
10. Documentation of compliance with local zoning laws;

11. For an application submitted because of ownership change, the former owner's name and business name, if different;

12. Date signed, and applicant's, corporate officer's, partner's, or manager's, verified signature and title; and

13. Fee specified in R4-23-205.

C. Before issuing a drug manufacturer permit, the Board shall:

1. Receive and approve a completed permit application;

2. Interview the applicant and manager, if different from the applicant, at a Board meeting; and

3. Receive a satisfactory compliance inspection report on the facility from a Board compliance officer.

D. Notification. A resident drug manufacturer permittee shall notify the Board of changes involving the drug list, ownership, address, telephone number, name of business, or manager, including manager's telephone number. The resident drug manufacturer permittee shall submit a written notice via mail, fax, or e-mail to the Executive Director within 24 hours of the change, except any change of ownership requires that the resident drug manufacturer permittee comply with subsection (E).

E. Change of ownership. Before a change of ownership occurs that involves changes of stock ownership of more than 30% of the voting stock of a corporation or an existing and continuing corporation that is not actively traded on any securities market or over-the-counter market, the prospective owner shall submit the application packet described under subsection R4-23-604(B).

F. Before an existing resident drug manufacturer permittee relocates, the drug manufacturer permittee shall submit the application packet described in subsection R4-23-604(B), excluding the fee. The facility at the new location shall pass a final inspection by a Board compliance officer before operations begin.

G. A resident drug manufacturer permittee shall submit the application packet described under subsection R4-23-604(B) for any change of officers in a corporation, excluding the fee and final inspection.

H. Manufacturing and distribution.

1. A drug manufacturer permittee shall manufacture and distribute a drug only:

a. To a pharmacy, drug manufacturer, or full-service or nonprescription drug wholesaler currently permitted by the Board;

b. To a medical practitioner currently licensed as a medical practitioner as defined in A.R.S. § 32-1901; or

c. To a properly permitted, registered, licensed, or certified person or firm of another jurisdiction; and

2. Before manufacturing and distributing a drug that is not listed on a drug manufacturer's permit application, the drug manufacturer permittee shall send to the Board office a written request to amend the permit application, including documentation of FDA approval to manufacture the drug not listed on the original permit application. If a request to amend a permit application includes the documentation required in this subsection, the Board or its designee shall approve the request to amend within 30 days of receipt.

I. A drug manufacturer permit is subject to denial, suspension, probation, or revocation under A.R.S. § 32-1927.02.

J. Current Good Manufacturing Practice. A drug manufacturer permittee shall comply with the current good manufacturing practice requirements of 21 CFR 210 through 211, (Revised April 1, 2011, incorporated by reference and on file with the Board and available at [www.gpo.gov](http://www.gpo.gov). This incorporated material includes no future editions or amendments.)

K. Records. A drug manufacturer permittee shall:

1. Establish and implement written procedures for maintaining records pertaining to production, process control, labeling, packaging, quality control, distribution, complaints, and any information required by federal or state law;

2. Retain the records required by this Article and 21 CFR 210 through 211 as incorporated in subsection (J) for at least two years after distribution of a drug or one year after the expiration date of a drug, whichever is longer; and

3. Make the records required by this Article and 21 CFR 210 through 211 as incorporated in subsection (J) available within 48 hours for review by a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(5).

L. Inspections. A drug manufacturer permittee shall make the drug manufacturer's facility available for inspection by the Board or its compliance officer under A.R.S. § 32-1904.

M. Nonresident drug manufacturer. A nonresident drug manufacturer shall comply with the requirements of R4-23-607.

N. Manufacturing radiopharmaceuticals. Before manufacturing a radiopharmaceutical, a drug manufacturer permittee shall:

1. Comply with the regulatory requirements of the Arizona Radiation Regulatory Agency, the U.S. Nuclear Regulatory Commission, the FDA, and this Section; and

2. Hold a current Arizona Radiation Regulatory Agency Radioactive Materials License. If a drug manufacturer permittee who manufactures radiopharmaceuticals fails to maintain a current Arizona Radiation Regulatory Agency Radioactive Materials License, the permittee's drug manufacturer permit shall be immediately suspended pending a hearing by the Board.

#### **R4-23-605. Resident Drug Wholesaler Permit**

A. Permit. A person shall not operate a business or firm for the wholesale distribution of any drug, device, precursor chemical, or regulated chemical without a current Board-issued full-service or nonprescription drug wholesale permit.

B. Application.

1. To obtain a permit to operate a full-service or nonprescription drug wholesale firm in Arizona, a person shall submit a completed application on a form furnished by the Board that includes:

- a. Whether the application is for a full-service or nonprescription drug wholesale permit;
- b. Business name, address, mailing address, if different, telephone number, and facsimile number;
- c. Owner's name, if corporation or partnership, officers or partners, including address and title, and any other trade or business names used;
- d. Whether the owner, corporation, or partnership has conducted a similar business in any other jurisdiction and if so, indicate under what name and location;
- e. Whether the owner, any officer or active partner has ever been convicted of an offense involving moral turpitude, a felony offense, or any drug-related offense or has any currently pending felony or drug-related charges, and if so, indicate charge, conviction date, jurisdiction, and location;
- f. Whether the owner or any officer or active partner has ever been denied a drug wholesale permit in this state or any other jurisdiction, and if so, indicate where and when;
- g. For a full-service drug wholesale firm:
  - i. The designated representative's name, address, and emergency telephone number;
  - ii. Documentation that the designated representative meets the requirements of A.R.S. § 32-1982(B) and the following as specified in A.R.S. § 32-1982(C):
    - (1) A full set of fingerprints from the designated representative; and
    - (2) The state and federal criminal history record check fee specified by and made payable to the Arizona State Department of Public Safety by money order, certified check, or bank draft; and
  - iii. A \$100,000 bond as specified in A.R.S. § 32-1982(D) submitted on a form supplied by the Board;
- h. The type of drugs, whether nonprescription, prescription-only, controlled substances, human, or veterinary, the applicant will distribute;
- i. Plans or construction drawings showing facility size and security for the proposed business;
- j. Documentation of compliance with local zoning laws;
- k. For a nonprescription drug wholesale firm, the manager's or designated representative's name, address, emergency telephone number, and resumé indicating educational or experiential qualifications related to drug wholesale operation;
- l. For an application submitted because of ownership change, the former owner's name and business name, if different;
- m. Date signed, and applicant's, corporate officer's, partner's, manager's, or designated representative's verified signature and title; and
- n. Fee specified in R4-23-205.

2. Before issuing a full-service or nonprescription drug wholesale permit, the Board shall:

- a. Receive and approve a completed permit application;
- b. Interview the applicant and the designated representative, if different from the applicant, at a Board meeting;
- c. Receive a satisfactory compliance inspection report on the facility from a Board compliance officer; and
- d. For a full-service drug wholesale permit, issue a fingerprint clearance to a qualified designated representative, as specified in subsection (L). If the fingerprint clearance of a designated representative for a full-service drug wholesale permit applicant is denied, the full-service drug wholesale permit applicant shall appoint another designated representative and submit the documentation, fingerprints, and fee required in subsection (B)(1)(g)(ii).

C. Notification. A resident full-service or nonprescription drug wholesale permittee shall notify the Board of changes involving the type of drugs sold or distributed, ownership, address, telephone number, name of business, or manager or designated representative, including the manager's or designated representative's telephone number.

1. The resident full-service or nonprescription drug wholesale permittee shall submit a written notice via mail, fax, or e-mail to the Executive Director within 10 days of the change, except any change of ownership requires that the resident full-service or nonprescription drug wholesale permittee comply with subsection (D).

2. For a change of designated representative, a resident full-service drug wholesale permittee shall submit the documentation, fingerprints, and fee required in subsection (B)(1)(g)(ii). If the fingerprint clearance of a designated representative for a full-service drug wholesale permit applicant is denied, the full-service drug wholesale permit applicant shall appoint another designated representative and submit the documentation, fingerprints, and fee required in subsection (B)(1)(g)(ii).

D. Change of ownership. Before a change of ownership occurs that involves changes of stock ownership of more than 30% of the voting stock of a corporation or an existing and continuing corporation that is not actively traded on any securities market or over-the-counter market, the prospective owner shall submit the application packet described under subsection (B).

E. Before an existing resident full-service or nonprescription drug wholesaler permittee relocates, the resident full-service or nonprescription drug wholesale permittee shall submit the application packet described under subsection (B), excluding the fee. The facility at the new location shall pass a final inspection by a Board compliance officer before operations begin.

F. A resident full-service or nonprescription drug wholesale permittee shall submit the application packet described under subsection (B) for any change of officers in a corporation, excluding the fee and final inspection.

G. Distribution restrictions. In addition to the requirements of this subsection, a resident full-service wholesale permittee shall comply with the distribution restrictions specified in A.R.S. § 32-1983.

#### 1. Records.

a. A full-service drug wholesale permittee shall:

i. Maintain records to ensure full accountability of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical including dates of receipt and sales, names, addresses, and DEA registration numbers, if required, of suppliers or sources of merchandise, and customer names, addresses, and DEA registration numbers, if required;

ii. File the records required in subsection (G)(1)(a)(i) in a readily retrievable manner for a minimum of three years;

iii. Make the records required in subsection (G)(1)(a)(i) available upon request during regular business hours for inspection by a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(5). Records kept at a central location apart from the business location and not electronically retrievable shall be made available within two business days; and

iv. In addition to the records requirements of subsection (G)(1)(a)(i), provide a pedigree as specified in A.R.S. § 32-1984(E) for all prescription-only drugs that leave the normal distribution channel as defined in A.R.S. § 32-1981.

b. A nonprescription drug wholesale permittee shall:

i. Maintain records to ensure full accountability of any nonprescription drug, precursor chemical, or regulated chemical including dates of receipt and sales, names, addresses, and DEA registration numbers, if required, of suppliers or sources of merchandise, and customer names, addresses, and DEA registration numbers, if required;

ii. File the records required in subsection (G)(1)(b)(i) in a readily retrievable manner for a minimum of three years; and

iii. Make the records required in subsection (G)(1)(b)(i) available upon request during regular business hours for inspection by a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(5). Records kept at a central location apart from the business location and not electronically retrievable shall be made available within two business days.

#### 2. Drug sales.

a. A full-service drug wholesale permittee shall:

i. Not sell, distribute, give away, or dispose of, any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical, except in the original container packaged and labeled by the manufacturer or repackager;

ii. Not package, repackage, label, or relabel any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical;

iii. Not sell, distribute, give away, or dispose of, any narcotic or other controlled substance, or prescription-only drug or device, to anyone except a pharmacy, drug manufacturer, or full-service drug wholesaler currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;

iv. Not sell, distribute, give away, or dispose of, any nonprescription drug, precursor chemical, or regulated chemical, to anyone except a pharmacy, drug manufacturer, full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;

v. Provide pedigree records upon request, if immediately available, or within two business days from the date of a request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(5);

vi. Maintain a copy of the current permit or license of each person or firm who buys, receives, or disposes of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical; and

vii. Provide permit and license records upon request, if immediately available, or within two business days from the date of the request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(5).

b. A nonprescription drug wholesale permittee shall:

i. Not sell, distribute, give away, or dispose of any nonprescription drug, precursor chemical, or regulated chemical, except in the original container packaged and labeled by the manufacturer or repackager;

ii. Not package, repackage, label, or relabel any nonprescription drug, precursor chemical, or regulated chemical;

iii. Not sell or distribute any nonprescription drug, precursor chemical, or regulated chemical, to anyone except a pharmacy, drug manufacturer, full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;

iv. Maintain a record of the current permit or license of each person or firm who buys, receives, or disposes of any nonprescription drug, precursor chemical, or regulated chemical; and

v. Provide permit and license records upon request, if immediately available, or within two business days from the date of the request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(5).

c. Nothing in this subsection shall be construed to prevent the return of a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical to the original source of supply.

3. Out-of-state drug sales.

a. A full-service drug wholesale permittee shall:

i. Not sell, distribute, give away, or dispose of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical, except in the original container packaged and labeled by the manufacturer or repackager;

ii. Not package, repackage, label, or relabel any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical;

iii. Not sell, distribute, give away, or dispose of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical, to anyone except a person or firm that is properly permitted, registered, licensed, or certified in another jurisdiction;

iv. Provide pedigree records upon request, if immediately available, or within two business days from the date of the request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(5);

v. Maintain a copy of the current permit, registration, license, or certificate of each person or firm who buys, receives, or disposes of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical; and

vi. Provide permit, registration, license, and certificate records upon request, if immediately available, or within two business days from the date of the request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(5); and

b. A nonprescription drug wholesale permittee shall:

i. Not sell, distribute, give away, or dispose of any nonprescription drug, precursor chemical, or regulated chemical, except in the original container packaged and labeled by the manufacturer or repackager;

ii. Not package, repackage, label, or relabel any nonprescription drug, precursor chemical, or regulated chemical;

iii. Not sell or distribute any nonprescription drug, precursor chemical, or regulated chemical, to anyone except a person or firm that is properly permitted, registered, licensed, or certified in another jurisdiction;

iv. Maintain a record of the current permit, registration, license, or certificate of each person or firm who buys, receives, or disposes of any nonprescription drug, precursor chemical, or regulated chemical; and

v. Provide permit, registration, license, or certificate records upon request, if immediately available, or within two business days from the date of the request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(5).

4. Cash-and-carry sales.

a. A full-service drug wholesale permittee shall complete a cash-and-carry sale or distribution of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical, only after:

i. Verifying the validity of the order;

ii. Verifying the identity of the pick-up person for each transaction by confirming that the person or firm represented placed the cash-and-carry order; and

iii. For a prescription-only drug order, verifying that the cash-and-carry sale or distribution is used only to meet the immediate needs of a particular patient of the person or firm who placed the cash-and-carry order; and

b. A nonprescription drug wholesale permittee shall complete a cash-and-carry sale or distribution of any nonprescription drug, precursor chemical, or regulated chemical, only after:

i. Verifying the validity of the order; and

ii. Verifying the identity of the pick-up person for each transaction by confirming that the person or firm represented placed the cash-and-carry order.

H. Prescription-only drug returns or exchanges. A full-service drug wholesale permittee shall ensure that any prescription-only drug returned or exchanged by a pharmacy or chain pharmacy warehouse under A.R.S. § 32-1983(A) meets the following criteria:

1. The prescription-only drug is not adulterated or counterfeited, except an adulterated or counterfeited prescription-only drug that is the subject of an FDA or manufacturer recall may be returned for destruction or subsequent return to the manufacturer;

2. The quantity of prescription-only drug returned or exchanged does not exceed the quantity of prescription-only drug that the full-service drug wholesale permittee or a full-service drug wholesale permittee under common ownership sold to the pharmacy or chain pharmacy warehouse; and

3. The pharmacy or chain pharmacy warehouse provides documentation that:

a. Lists the name, strength and manufacturer, of the prescription-only drug being returned or exchanged; and

b. States that the prescription-only drug was maintained in compliance with storage conditions prescribed on the drug label or manufacturer's package insert.

I. Returned, outdated, damaged, deteriorated, adulterated, misbranded, counterfeited, and contraband drugs.

1. Except as specified in subsection (H)(1) for a prescription-only drug, a full-service drug wholesale permittee shall ensure that the return of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical meets the following criteria.

a. Any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical that is outdated, damaged, deteriorated, adulterated, misbranded, counterfeited, or contraband or suspected of being adulterated, misbranded, counterfeited, or contraband, or otherwise deemed unfit for human or animal consumption shall be quarantined and physically separated from other narcotics or other controlled substances, prescription-only drugs or devices, nonprescription drugs, precursor chemicals, or regulated chemicals until the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired as authorized by the Board and the FDA.

b. Any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical whose immediate or sealed outer or secondary containers or product labeling are misbranded, counterfeited, or contraband or suspected of being misbranded, counterfeited, or contraband shall be quarantined and physically separated from other narcotics or other controlled substances, prescription-only drugs or devices, nonprescription drugs, precursor chemicals, or regulated chemicals until the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired as authorized by the Board and the FDA. When the immediate or sealed outer or secondary containers or product labeling are determined to be misbranded, counterfeited, or contraband or suspected of being misbranded, counterfeited, or contraband, the full-service drug wholesale permittee shall provide notice of the misbranding, counterfeiting, or contrabandage or suspected misbranding, counterfeiting, or contrabandage within three business days of the determination to the Board, FDA, and manufacturer or wholesale distributor from which the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical was acquired.

c. Any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical that has been opened or used, but is not adulterated, misbranded, counterfeited, or contraband or suspected of being misbranded, counterfeited, or contraband, shall be identified as opened or used, or both, and quarantined and physically separated from other narcotics or other controlled substances, prescription-only drugs or devices, nonprescription drugs, precursor chemicals, or regulated chemicals until the

narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired as authorized by the Board and the FDA.

d. If the conditions under which a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical has been returned cast doubt on the narcotic's or other controlled substance's, prescription-only drug's or device's, nonprescription drug's, precursor chemical's, or regulated chemical's safety, identity, strength, quality, or purity, the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical shall be quarantined and physically separated from other narcotics or other controlled substances, prescription-only drugs or devices, nonprescription drugs, precursor chemicals, or regulated chemicals until the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired as authorized by the Board and the FDA, except as provided in subsection (1)(1)(d)(i).

i. If examination, testing, or other investigation proves that the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical meets appropriate standards of safety, identity, strength, quality, and purity, it does not have to be destroyed or returned to the manufacturer or wholesale distributor.

ii. In determining whether the conditions under which a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical has been returned cast doubt on the narcotic's or other controlled substance's, prescription-only drug's or device's, nonprescription drug's, precursor chemical's, or regulated chemical's safety, identity, strength, quality, or purity, the full-service drug wholesale permittee shall consider, among other things, the conditions under which the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical has been held, stored, or shipped before or during its return and the condition of the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical and the condition of its container, carton, or product labeling as a result of storage or shipping.

e. For any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical identified under subsections (1)(1)(a) or (b), the full-service drug wholesale permittee shall ensure that the identified item or items and other evidence of criminal activity, and accompanying documentation is retained and not destroyed until its disposition is authorized by the Board and the FDA.

2. A nonprescription drug wholesale permittee shall ensure that the return of any nonprescription drug, precursor chemical, or regulated chemical meets the following criteria.

a. Any nonprescription drug, precursor chemical, or regulated chemical that is outdated, damaged, deteriorated, adulterated, misbranded, counterfeited, or contraband or suspected of being adulterated, misbranded, counterfeited, or contraband, or otherwise deemed unfit for human or animal consumption shall be quarantined and physically separated from other nonprescription drugs, precursor chemicals, or regulated chemicals until the nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired as authorized by the Board and the FDA.

b. Any nonprescription drug, precursor chemical, or regulated chemical whose immediate or sealed outer or secondary containers or product labeling are misbranded, counterfeited, or contraband or suspected of being misbranded, counterfeited, or contraband shall be quarantined and physically separated from other nonprescription drugs, precursor chemicals, or regulated chemicals until the nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired as authorized by the Board and the FDA. When the immediate or sealed outer or secondary containers or product labeling are determined to be misbranded, counterfeited, or contraband or suspected of being misbranded, counterfeited, or contraband, the nonprescription drug wholesale permittee shall provide notice of the misbranding, counterfeiting, or contrabandage or suspected misbranding, counterfeiting, or contrabandage within three business days of the determination to the Board, FDA, and manufacturer or wholesale distributor from which the nonprescription drug, precursor chemical, or regulated chemical was acquired.

c. Any nonprescription drug, precursor chemical, or regulated chemical that has been opened or used, but is not adulterated, misbranded, counterfeited, or contraband or suspected of being misbranded, counterfeited, or contraband, shall be identified as opened or used, or both, and quarantined and physically separated from other nonprescription drugs, precursor chemicals, or regulated chemicals until the nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired as authorized by the Board and the FDA.

d. If the conditions under which a nonprescription drug, precursor chemical, or regulated chemical has been returned cast doubt on the nonprescription drug's, precursor chemical's, or regulated chemical's safety, identity, strength, quality, or purity, the nonprescription drug, precursor chemical, or regulated chemical shall be quarantined and physically separated from other nonprescription drugs, precursor chemicals, or regulated chemicals until the nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired as authorized by the Board and the FDA, except as provided in subsection (1)(2)(d)(i).

i. If examination, testing, or other investigation proves that the nonprescription drug, precursor chemical, or regulated chemical meets appropriate standards of safety, identity, strength, quality, and purity, it does not need to be destroyed or returned to the manufacturer or wholesale distributor.

ii. In determining whether the conditions under which a nonprescription drug, precursor chemical, or regulated chemical has been returned cast doubt on the nonprescription drug's, precursor chemical's, or regulated chemical's safety, identity, strength, quality, or purity, the nonprescription drug wholesale permittee shall consider, among other things, the conditions under which the nonprescription drug, precursor chemical, or regulated chemical has been held, stored, or shipped before or during its return and the condition of the nonprescription drug, precursor chemical, or regulated chemical and the condition of its container, carton, or product labeling as a result of storage or shipping.

e. For any nonprescription drug, precursor chemical, or regulated chemical identified under subsections (l)(2)(a) or (b), the nonprescription drug wholesale permittee shall ensure that the identified item or items and other evidence of criminal activity, and accompanying documentation is retained and not destroyed until its disposition is authorized by the Board and the FDA.

3. A full-service drug wholesale permittee and nonprescription drug wholesale permittee shall comply with the recordkeeping requirements of subsection (G) for all outdated, damaged, deteriorated, adulterated, misbranded, counterfeited and contraband narcotics or other controlled substances, prescription-only drugs or devices, nonprescription drugs, precursor chemicals, or regulated chemicals.

J. Facility. A full-service or nonprescription drug wholesale permittee shall:

1. Ensure that the facility occupied by the full-service or nonprescription drug wholesale permittee is of adequate size and construction, well-lighted inside and outside, adequately ventilated, and kept clean, uncluttered, and sanitary;

2. Ensure that the permittee's warehouse facility:

a. Is secure from unauthorized entry; and

b. Has an operational security system designed to provide protection against theft;

3. In a full-service drug wholesale facility, ensure that only authorized personnel may enter areas where any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is kept;

4. In a nonprescription drug wholesale facility, ensure that only authorized personnel may enter areas where any nonprescription drug, precursor chemical, or regulated chemical is kept;

5. In a full-service drug wholesale facility, ensure that any thermolabile narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is stored in an area where room temperature is maintained in compliance with storage conditions prescribed on the product label;

6. In a nonprescription drug wholesale facility, ensure that any thermolabile nonprescription drug, precursor chemical, or regulated chemical is stored in an area where room temperature is maintained in compliance with storage conditions prescribed on the product label;

7. Make the facility available for inspection by a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(5) during regular business hours;

8. In a full-service drug wholesale facility, provide a quarantine area for storage of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical that is outdated, damaged, deteriorated, adulterated, misbranded, counterfeited, or contraband or suspected of being adulterated, misbranded, counterfeited, or contraband, otherwise deemed unfit for human or animal consumption, or that is in an open container; and

9. In a nonprescription drug wholesale facility, provide a quarantine area for storage of any nonprescription drug, precursor chemical, or regulated chemical that is outdated, damaged, deteriorated, adulterated, misbranded, counterfeited, or contraband or suspected of being adulterated, misbranded, counterfeited, or contraband, otherwise deemed unfit for human or animal consumption, or that is in an open container.

K. Quality controls.

1. A full-service drug wholesale permittee shall:

a. Ensure that any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical that meets the criteria specified in subsection (l)(1) is not sold, distributed, or delivered to any person for human or animal consumption;

b. Ensure that a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is not manufactured, packaged, repackaged, labeled, or relabeled by any of its employees;

c. Ensure that any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical stocked, sold, offered for sale, or delivered is:

i. Kept clean,

ii. Protected from contamination and other deteriorating environmental factors, and

iii. Stored in a manner that complies with applicable federal and state law and official compendium storage requirements;

d. Maintain manual or automatic temperature and humidity recording devices or logs to document conditions in areas where any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is stored; and

e. Develop and implement a program to ensure that:

i. Any expiration-dated narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is reviewed regularly;

ii. Any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical that has less than 120 days remaining on the expiration date, or is deteriorated, damaged, or does not comply with federal law, is moved to a quarantine area and not sold or distributed; and

iii. Any quarantined narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired.

2. A nonprescription drug wholesale permittee shall:

a. Ensure that any nonprescription drug, precursor chemical, or regulated chemical that meets the criteria specified in subsection (1)(2) is not sold, distributed, or delivered to any person for human or animal consumption;

b. Ensure that a nonprescription drug, precursor chemical, or regulated chemical is not manufactured, packaged, repackaged, labeled, or relabeled by any of its employees;

c. Ensure that any nonprescription drug, precursor chemical, or regulated chemical stocked, sold, offered for sale, or delivered is:

i. Kept clean,

ii. Protected from contamination and other deteriorating environmental factors, and

iii. Stored in a manner that complies with applicable federal and state law and official compendium storage requirements;

d. Maintain manual or automatic temperature and humidity recording devices or logs to document conditions in areas where any nonprescription drug, precursor chemical, or regulated chemical is stored; and

e. Develop and implement a program to ensure that:

i. Any expiration-dated nonprescription drug, precursor chemical, or regulated chemical is reviewed regularly;

ii. Any nonprescription drug, precursor chemical, or regulated chemical that has less than 120 days remaining on the expiration date, or is deteriorated, damaged, or does not comply with federal law, is moved to a quarantine area and not sold or distributed; and

iii. Any quarantined nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired.

L. Fingerprint clearance.

1. After receiving the state and federal criminal history record of a designated representative, the Board shall compare the record with the list of criminal offenses that preclude a designated representative from receiving a fingerprint clearance. If the designated representative's criminal history record does not contain any of the offenses listed in subsection (L)(2), the Board shall issue the designated representative a fingerprint clearance.

2. The Board shall not issue a fingerprint clearance to a designated representative who is awaiting trial for or who has been convicted of committing or attempting or conspiring to commit one or more of the following offenses in this state or the same or similar offenses in another state or jurisdiction:

a. Unlawfully administering intoxicating liquors, controlled substances, dangerous drugs, or prescription-only drugs;

b. Sale of peyote;

c. Possession, use, or sale of marijuana, dangerous drugs, prescription-only drugs, or controlled substances;

d. Manufacture or distribution of an imitation controlled substance;

e. Manufacture or distribution of an imitation prescription-only drug;

f. Possession or possession with intent to use an imitation controlled substance;

g. Possession or possession with intent to use an imitation prescription-only drug; or

h. A felony offense involving sale, distribution, or transportation of, offer to sell, transport, or distribute, or conspiracy to sell, transport, or distribute marijuana, dangerous drugs, prescription-only drugs, or controlled substances.

3. If after conducting a state and federal criminal history record check the Board determines that it is not authorized to issue a fingerprint clearance, the Board shall notify the full-service drug wholesale applicant or permittee that employs the designated representative that the Board is not authorized to issue a fingerprint clearance. This notice shall include the criminal history information on which the denial was based. This criminal history information is subject to dissemination restrictions under A.R.S. § 41-1750 and federal law.

4. The issuance of a fingerprint clearance does not entitle a person to employment.

#### **R4-23-606. Resident Pharmacy Permit: Community, Hospital, and Limited Service**

A. Permit. A person shall not operate a pharmacy in Arizona without a current Board-issued pharmacy permit.

B. Application.

1. To obtain a permit to operate a pharmacy in Arizona, a person shall submit a completed application form and fee as specified in R4-23-602 that includes:

- a. Documentation of compliance with local zoning laws, if required by the Board;
- b. A detailed floor plan showing proposed pharmacy area including size and security;
- c. A copy of the lease agreement, if applicable; and;
- d. A disclosure statement indicating whether a medical practitioner will receive compensation, either directly or indirectly, from the pharmacy;

2. Before issuing a pharmacy permit, the Board shall:

- a. Receive and approve a completed permit application; and
- b. Receive a satisfactory compliance inspection report on the facility from a Board compliance officer.

3. Before issuing a pharmacy permit, the Board may interview the applicant and the pharmacist-in-charge, if different from the applicant, at a Board meeting based on the need for additional information.

C. Notification. A pharmacy permittee shall notify the Board office within ten days of changes involving the type of pharmacy operated, telephone number, facsimile number, e-mail address, mailing address, name of business, or staff pharmacist. A pharmacy permittee shall provide the Board of immediate notice of a change of the pharmacist-in-charge.

D. If any nonprescription drugs are sold outside the pharmacy area when the pharmacy area is closed, the pharmacy permittee shall ensure that the business has a current, Board-issued nonprescription drug permit as required in Section R4-23-603.

E. Change of ownership. No less than 14 days before a change of ownership occurs that involves changes of stock ownership of 30% or more of the voting stock of a corporation or an existing and continuing corporation that is not actively traded on any securities market or over-the-counter market, the prospective owner shall submit a completed application form and fee as specified in subsection (B).

F. Relocation or remodel.

1. No less than 30 days before the relocation or remodel of an existing pharmacy, the pharmacy permittee shall submit a completed application for remodel or relocation electronically or manually on a form furnished by the Board.

- a. An application for relocation shall include the documents required by subsections (B)(1)(a) through (d).
- b. An application for remodel shall include the documents required by subsection (B)(1)(b).

2. The new or remodeled facility shall pass a final inspection by a Board compliance officer before operations begin.

G. Permit renewal. Permit renewal shall be as specified in R4-23-602(D).

#### **R4-23-607. Nonresident Permits**

A. Permit. A person who is not a resident of Arizona shall not sell or distribute any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical into Arizona without:

1. Processing a current Board-issued nonresident pharmacy permit, nonresident manufacturer permit, nonresident full-service or nonprescription drug wholesale permit, or nonresident nonprescription drug permit;
2. Possessing a current equivalent license or permit issued by the licensing authority in the jurisdiction where the person or firm resides;
3. For a nonresident pharmacy, employing a pharmacist who is designated as the pharmacist-in-charge and who possesses a current Arizona Board-issued pharmacist license; and
4. For a nonresident pharmacy permit issued before April 7, 2007, complying with subsection (A)(3) and submitting to the Board the pharmacist-in-charge's name, current Arizona Board-issued pharmacist license number, and telephone number by November 1, 2007.

B. Application. To obtain a nonresident pharmacy, nonresident manufacturer, nonresident full-service or nonprescription drug wholesale, or nonprescription drug permit, a person shall submit a completed application, on a form furnished by the Board, that includes:

1. Business name, address, mailing address, if different, telephone number, and facsimile number;

2. Owner's name, if corporation or partnership, officers or partners, including address and title, and any other trade or business names used;
  3. Whether the owner, corporation, or partnership has conducted a similar business in any other jurisdiction and if so, indicate under what name and location;
  4. Whether the owner, any officer, or active partner has ever been convicted of an offense involving moral turpitude, a felony offense, or any drug-related offense or has any currently pending felony or drug-related charges, and if so, indicate charge, conviction date, jurisdiction, and location;
  5. A copy of the applicant's current equivalent license or permit, issued by the licensing authority in the jurisdiction where the person or firm resides and required by subsection (A)(2);
  6. For an application submitted because of ownership change, the former owner's name and business name, if different;
  7. Date signed, and applicant's, corporate officer's, partner's, manager's, administrator's, pharmacist-in-charge's, or designated representative's verified signature and title; and
  8. Fee specified in R4-23-205.
- C. In addition to the requirements of subsection (B), the following information is required on the application:
1. Nonresident pharmacy.
    - a. The type of pharmacy;
    - b. Whether the owner, any officer, or active partner has ever been denied a pharmacy permit in this state or any other jurisdiction, and if so, indicate where and when;
    - c. If applying for a hospital pharmacy permit, the number of beds, manager's or administrator's name, and a copy of the hospital's current equivalent license or permit issued by the licensing authority in the jurisdiction where the person or firm resides;
    - d. Pharmacist-in-charge's name, current Arizona Board-issued pharmacist license number, and telephone number; and
    - e. For an application submitted because of ownership change, the former pharmacy's name, address, and permit number; and
  2. Nonresident manufacturer.
    - a. Whether the owner, any officer, or active partner has ever been denied a drug manufacturer permit in this state or any other jurisdiction, and if so, indicate where and when;
    - b. A copy of the drug list required by the FDA;
    - c. Manager's or responsible person's name, address, and emergency telephone number; and
    - d. The firm's current FDA drug manufacturer or repackager registration number and expiration date; and
  3. Nonresident full-service drug wholesaler.
    - a. The designated representative's name, address, and emergency telephone number;
    - b. Documentation that the designated representative meets the requirements of A.R.S. § 32-1982(B) and the following as specified in A.R.S. § 32-1982(C):
      - i. A full set of fingerprints from the designated representative; and
      - ii. The state and federal criminal history record check fee specified by and made payable to the Arizona State Department of Public Safety by money order, certified check, or bank draft; and
    - c. A \$100,000 bond as specified in A.R.S. § 32-1982(D) submitted on a form supplied by the Board; and
  4. Nonresident full-service or nonprescription drug wholesaler.
    - a. The type of drug wholesale permit;
    - b. Whether the owner, any officer, or active partner has ever been denied a drug wholesale permit in this state or any other jurisdiction, and if so, indicate where and when;
    - c. The types of drugs, nonprescription, prescription-only, controlled substances, human, or veterinary, the applicant will distribute;
    - d. Manager's or designated representative's name, address, emergency telephone number, and resumé indicating educational or experiential qualifications related to drug wholesale operation; and

5. Nonresident nonprescription drug retailer.

a. Whether applying for Category I or Category II permit;

b. Date business started or planned opening date; and

c. Type of business, such as convenience, drug, grocery, or health food store, swap-meet vendor, or vending machine.

D. Before issuing a nonresident full-service drug wholesale permit, the Board shall:

1. Receive and approve a completed permit application; and

2. Issue a fingerprint clearance to a qualified designated representative, as specified in R4-23-605(L). If a nonresident full-service drug wholesale permit applicant's designated representative's fingerprint clearance is denied, the nonresident full-service drug wholesale permit applicant shall appoint another designated representative and submit the documentation, fingerprints, and fee required in subsection (C)(3)(b).

E. Notification. A permittee shall submit any notification of change required in this subsection as a written notice via mail, fax, or e-mail to the Executive Director within 10 days of the change, except any change of ownership requires that the nonresident permittee comply with subsection (F).

1. Nonresident pharmacy. A nonresident pharmacy permittee shall notify the Board of changes involving the type of pharmacy operated, ownership, address, telephone number, name of business, or pharmacist-in-charge.

2. Nonresident manufacturer. A nonresident manufacturer permittee shall notify the Board of changes involving listed drugs, ownership, address, telephone number, name of business, or manager, including manager's telephone number.

3. Nonresident drug wholesaler. A nonresident full-service or nonprescription drug wholesale permittee shall notify the Board of changes involving the types of drugs sold or distributed, ownership, address, telephone number, name of business, or manager or designated representative, including the manager's or designated representative's telephone number. For a change of designated representative, a nonresident full-service drug wholesale permittee shall submit the documentation, fingerprints, and fee required in subsection (C)(3)(b). If a nonresident full-service drug wholesale permit applicant's designated representative's fingerprint clearance is denied, the nonresident full-service drug wholesale permittee shall appoint another designated representative and submit the documentation, fingerprints, and fee required in subsection (C)(3)(b).

4. Nonresident nonprescription drug retailer. A nonresident nonprescription drug permittee shall notify the Board of changes involving permit category, ownership, address, telephone number, name of business, or manager, including manager's telephone number.

F. Change of ownership. Before a change of ownership occurs that involves changes of stock ownership of more than 30% of the voting stock of a corporation or an existing and continuing corporation that is not actively traded on any securities market or over-the-counter market, the prospective owner shall submit the appropriate application packet described under subsections (B) and (C).

G. Drug sales.

1. Nonresident pharmacy. A nonresident pharmacy permittee shall:

a. Not sell, distribute, give away, or dispose of any narcotic or other controlled substance or prescription-only drug or device, to anyone in Arizona except:

i. A pharmacy, drug manufacturer, or full-service drug wholesaler currently permitted by the Board;

ii. A medical practitioner currently licensed under A.R.S. Title 32; or

iii. An Arizona resident upon receipt of a valid prescription order for the resident;

b. Not sell, distribute, give away, or dispose of any nonprescription drug, precursor chemical, or regulated chemical, to anyone in Arizona except:

i. A pharmacy, drug manufacturer, full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board;

ii. A medical practitioner currently licensed under A.R.S. Title 32; or

iii. An Arizona resident either upon receipt of a valid prescription order for the resident or in the original container packaged and labeled by the manufacturer;

c. Except for a drug sale that results from the receipt and dispensing of a valid prescription order for an Arizona resident, maintain a copy of the current permit or license of each person or firm in Arizona who buys, receives, or disposes of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical; and

d. Provide permit and license records upon request, if immediately available, or in no less than two business days from the date of the request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(5).

2. Nonresident manufacturer. A nonresident manufacturer permittee shall:

- a. Not sell, distribute, give away, or dispose of any narcotic or other controlled substance or prescription-only drug or device, to anyone in Arizona except, a pharmacy, drug manufacturer, or full-service drug wholesaler currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;
- b. Not sell, distribute, give away, or dispose of any nonprescription drug, precursor chemical, or regulated chemical, to anyone in Arizona except, a pharmacy, drug manufacturer, full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;
- c. Maintain a copy of the current permit or license of each person or firm in Arizona who buys, receives, or disposes of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical; and
- d. Provide permit and license records upon request, if immediately available, or in no less than two business days from the date of the request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(5).

3. Nonresident full-service drug wholesaler. In addition to complying with the distributions restrictions specified in A.R.S. § 32-1983, a nonresident full-service drug wholesale permittee shall:

- a. Not sell, distribute, give away, or dispose of, any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical to anyone in Arizona, except in the original container, packaged and labeled by the manufacturer or repackager;
- b. Not package, repackage, label, or relabel any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical for shipment or delivery to anyone in Arizona;
- c. Provide pedigree records upon request, if immediately available, or in no less than two business days from the date of the request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(5);
- d. Not sell, distribute, give away, or dispose of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical to anyone in Arizona except a pharmacy, drug manufacturer, or full-service drug wholesaler currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;
- e. Not sell, distribute, give away, or dispose of, any nonprescription drug, precursor chemical, or regulated chemical, to anyone in Arizona except, a pharmacy, drug manufacturer, full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;
- f. Maintain a copy of the current permit or license of each person or firm in Arizona who buys, receives, or disposes of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical; and
- g. Provide permit and license records upon request, if immediately available, or in no less than two business days from the date of the request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(5).

4. Nonresident nonprescription drug wholesaler. A nonresident nonprescription drug wholesale permittee shall:

- a. Not sell, distribute, give away, or dispose of any nonprescription drug, precursor chemical, or regulated chemical to anyone in Arizona, except in the original container, packaged and labeled by the manufacturer or repackager;
- b. Not package, repackage, label, or relabel any nonprescription drug, precursor chemical, or regulated chemical for shipment or delivery to anyone in Arizona;
- c. Not sell, distribute, give away, or dispose of, any nonprescription drug, precursor chemical, or regulated chemical, to anyone in Arizona except, a pharmacy, drug manufacturer, full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;
- d. Maintain a copy of the current permit or license of each person or firm in Arizona who buys, receives, or disposes of any nonprescription drug, precursor chemical, or regulated chemical; and
- e. Provide permit and license records upon request, if immediately available, or in no less than two business days from the date of the request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(5).

5. Nonresident nonprescription drug retailer. A nonresident nonprescription drug permittee shall not:

- a. Sell, distribute, give away, or dispose of a nonprescription drug, precursor chemical, or regulated chemical to anyone in Arizona except in the original container packaged and labeled by the manufacturer;
- b. Package, repackage, label, or relabel any drug, precursor chemical, or regulated chemical for shipment or delivery to anyone in Arizona; or
- c. Sell, distribute, give away, or dispose of any drug, precursor chemical, or regulated chemical to anyone in Arizona that exceeds its expiration date, is contaminated or deteriorated from excessive heat, cold, sunlight, moisture, or other factors, or does not comply with federal law.

H. When selling or distributing any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical into Arizona, a nonresident pharmacy, nonresident manufacturer, nonresident full-service or nonprescription drug wholesale, or nonprescription drug permittee shall comply with federal law, the permittee's resident state drug law, and this Section.

#### **R4-23-608. Change of Personnel and Responsibility**

A. A community, hospital, or limited-service pharmacy permittee shall give the Board:

1. Notice by mail, facsimile, or electronic mail within ten days of employing or terminating a pharmacist; and
2. Immediate notice of designating or terminating a pharmacist-in-charge.

B. Responsibility of ownership and management. The owner and management of a pharmacy shall:

1. Ensure that pharmacists, interns, and other pharmacy employees comply with state and federal laws and administrative rules; and
2. Not overrule a pharmacist in matters of pharmacy ethics and interpreting laws pertaining to the practice of pharmacy or the distribution of drugs and devices.

C. The Board may suspend or revoke a pharmacy permit if the owner or management of a pharmacy violates subsection (B).

#### **R4-23-609. Pharmacy Area of Community Pharmacy**

A. Minimum area of community pharmacy. The minimum area of a community pharmacy, the actual area primarily devoted to stocking drugs restricted to pharmacists, and to the compounding and dispensing of prescription medication, exclusive of office area or other support function area, shall not be less than 300 square feet. A maximum of three pharmacy personnel may practice or work simultaneously in the minimum area. The pharmacy permittee shall provide an additional 60 square feet of floor area for each additional pharmacist, graduate intern, pharmacy intern, pharmacy technician, pharmacy technician trainee, or support personnel who may practice or work simultaneously. All of the allotted square footage area, including adequate shelving, shall lend itself to efficient pharmaceutical practice and permit free movement and visual surveillance of personnel by the pharmacist.

B. Compounding and dispensing counter. On or after January 6, 2004, a pharmacy permit applicant or remodel or relocation applicant shall provide a compounding and dispensing counter that provides a minimum of three square feet of pharmacy counter working area of not less than 16 inches in depth and 24 inches in length for the practice of one pharmacist, graduate intern, pharmacy intern, pharmacy technician, or pharmacy technician trainee. For each additional pharmacist, graduate intern, pharmacy intern, pharmacy technician, or pharmacy technician trainee practicing simultaneously, there shall be an additional three square feet of pharmacy counter working area of not less than 16 inches in depth and 24 inches in length. The Board shall determine a pharmacy's total required compounding and dispensing counter area by multiplying the maximum number of personnel allowed in the pharmacy area using the requirements specified in subsection (A) by three square feet per person. A pharmacy permittee or pharmacist-in-charge may operate the pharmacy with a total pharmacy counter working area specified in subsection (A) that is equal to the actual maximum number of pharmacists, graduate interns, pharmacy interns, pharmacy technicians, and pharmacy technician trainees, working simultaneously in the pharmacy area times three square feet per person.

C. Working area for compounding and dispensing counter. The aisle floor area used by the pharmacist, graduate intern, pharmacy intern, pharmacy technician, or pharmacy technician trainee at the compounding and dispensing counter shall extend the full length of the counter and be clear and continuous for a minimum of 36 inches from any counter, fixture, or structure.

D. Area for patient counseling. On or after April 1, 1995, a pharmacy permit applicant or remodel or relocation applicant shall provide a separate and distinct patient counseling area that provides patient privacy. This subsection does not apply to a pharmacy exempt from the requirements of R4-23-402(B).

E. Narcotic cabinet or safe. To prevent diversion, narcotics and other controlled substances may be:

1. Kept in a separate locked cabinet or safe, or
2. Dispersed throughout the pharmacy's prescription-only drug stock.

F. Building security standard of community pharmacy area.

The pharmacy area shall be enclosed by a permanent barrier or partition from floor or counter to structural ceiling or roof, with entry doors that can be securely locked. The barrier shall be designed so that only a pharmacist can access the area where prescription-only drugs, narcotics, and other controlled substances are stored, compounded and dispensed. The permanent barrier may be constructed of other than a solid material. If constructed of a material other than a solid, the openings or interstices of the material shall not be large enough to permit removal of items in the pharmacy area through the barrier. Any material used in the construction of the permanent barrier must be of sufficient strength and thickness that it cannot be readily or easily removed, penetrated, or bent. The pharmacy permittee shall submit plans and specifications of the permanent barrier to the Board for approval.

G. Drug storage and security.

1. The pharmacy permittee shall ensure that drugs and devices are stored in a dry, well-lit, ventilated, and clean and orderly area. The pharmacy permittee shall maintain the drug storage area at temperatures that ensure the integrity of the drugs before dispensing as stated in the official compendium defined in A.R.S. § 32-1901(55) or the manufacturer's or distributor's labeling.

2. If the pharmacy permittee needs additional storage area for drugs that are restricted to sale by a pharmacist, the pharmacy permittee shall ensure that the area is contained by a permanent barrier from floor or counter to structural ceiling or roof. The pharmacy permittee shall lock all doors and gates to the drug storage area. Only a pharmacist with a key is permitted to enter the storage area, except in an extreme emergency.

H. A pharmacy permittee or pharmacist-in-charge shall ensure that the pharmacy working counter area is protected from unauthorized access while the pharmacy is open for business by a barrier not less than 66 inches in height or another method approved by the Board or its designee.

#### **R4-23-610. Community Pharmacy Personnel and Security Procedures**

A. Every pharmacy shall have a pharmacist designated as the "pharmacist-in-charge."

1. The pharmacist-in-charge shall ensure the communication and compliance of Board directives to the management, other pharmacists, interns, and technicians of the pharmacy.

2. The pharmacist-in-charge shall:

a. Ensure that all pharmacy policies and procedures required under 4 A.A.C. 23 are prepared, implemented, and complied with;

b. Review biennially and, if necessary, revise all pharmacy policies and procedures required under 4 A.A.C. 23;

c. Document the review required under subsection (A)(2)(b);

d. Ensure that all pharmacy policies and procedures required under 4 A.A.C. 23 are assembled as a written or electronic manual; and

e. Make all pharmacy policies and procedures required under 4 A.A.C. 23 available in the pharmacy for employee reference and inspection by the Board or its staff.

B. Personnel permitted in the pharmacy area of a community pharmacy include pharmacists, graduate interns, pharmacy interns, compliance officers, drug inspectors, peace officers acting in their official capacity, other persons authorized by law, pharmacy technicians, pharmacy technician trainees, support personnel, and other designated personnel. Pharmacy interns, graduate interns, pharmacy technicians, pharmacy technician trainees, support personnel, and other designated personnel shall be permitted in the pharmacy area only when a pharmacist is on duty, except in an extreme emergency as defined in R4-23-110.

1. The pharmacist-in-charge shall comply with the minimum area requirements as described in R4-23-609 for a community pharmacy and for compounding and dispensing counter area.

2. A pharmacist employed by a pharmacy shall ensure that the pharmacy is physically secure while the pharmacist is on duty.

C. In a community pharmacy, a pharmacist shall ensure that the pharmacy area, and any additional storage area for drugs that is restricted to access only by a pharmacist is locked when a pharmacist is not present, except in an extreme emergency.

D. A pharmacist is the only person permitted by the Board to unlock the pharmacy area or any additional storage area for drugs restricted to access only by a pharmacist, except in an extreme emergency.

E. A pharmacy permittee or pharmacist-in-charge shall ensure that any prescription-only drugs and controlled substances received in an area outside the pharmacy area are immediately transferred unopened to the pharmacy area. The pharmacist-in-charge shall ensure that any prescription-only drug and controlled substance shipments are opened and marked by pharmacy personnel in the pharmacy area under the supervision of a pharmacist, graduate intern, or pharmacy intern.

F. A pharmacy permittee or pharmacist-in-charge may provide a small opening or slot through which a written prescription order or prescription medication container to be refilled may be left in the prescription area when the pharmacist is not present.

G. A pharmacist shall ensure that prescription medication is not left outside the prescription area or picked up by the patient when the pharmacist is not present by either:

1. Delivering the prescription medication to the patient, or

2. Securing the prescription medication inside the locked pharmacy, except when using an automated storage and distribution system that complies with the requirements of R4-23-614.

#### **R4-23-611. Pharmacy Facilities**

A. Facilities. A pharmacy permittee or pharmacist-in-charge shall ensure that:

1. A pharmacy's facilities are constructed according to state and local laws and ordinances;

2. A pharmacy facility's:

a. Walls, ceilings, windows, floors, shelves, and equipment are clean and in good repair and order; and

b. Counters, shelves, aisles, and open spaces are not cluttered;

3. Adequate trash receptacles are provided and emptied periodically during the day;
  4. A pharmacy facility of any pharmacy permit issued or pharmacy remodeled after February 01, 2014 provides access toilet facilities either:
    - a. Within the pharmacy area, or
    - b. No further than a walking distance of 100 feet from the pharmacy area or an alternative distance approved by the Board or its designee;
  5. The toilet facilities are maintained in a sanitary condition and in good repair;
  6. All professional personnel and staff of the pharmacy keep themselves and their apparel clean while in the pharmacy area;
  7. No animals, except licensed assistant animals and guard animals, are allowed in the pharmacy;
  8. The pharmacy facility is kept free of insects and rodents; and
  9. There is a sink with hot and cold running water, other than a sink in a toilet facility, within the pharmacy area for use in preparing drug products.
- B. Supply of drugs and chemicals. A pharmacy permittee or pharmacist-in-charge shall ensure that:
1. A pharmacy maintains a stock of drugs and chemicals that:
    - a. Are sufficient to meet the normal demands of the trading area or patient base the pharmacy serves; and
    - b. Meet all standards of strength and purity as established by the official compendiums;
  2. All stock, materials, drugs, and chemicals held for ultimate sale or supply to the consumer are not contaminated;
  3. Policies and procedures are developed, implemented, and complied with to prevent the sale or use of a drug or chemical:
    - a. That exceeds its expiration date;
    - b. That is deteriorated or damaged by reason of age, heat, light, cold, moisture, crystallization, chemical reaction, rupture of coating, disintegration, solidification, separation, discoloration, change of odor, precipitation, or other change as determined by organoleptic examination or by other means;
    - c. That is improperly labeled;
    - d. Whose container is defective; or
    - e. That does not comply with federal law; and
  4. The policies and procedures described in subsection (B)(3):
    - a. Are made available in the pharmacy for employee reference and inspection by the Board or its designee; and
    - b. Provide the following:
      - i. Any expiration-dated drug or chemical is reviewed regularly;
      - ii. Any drug or chemical that exceeds its expiration date, is deteriorated or damaged, improperly labeled, has a defective container, or does not comply with federal law, is moved to a quarantine area and not sold or distributed; and
      - iii. Any quarantined drug or chemical is properly destroyed or returned to its source of supply.

**R4-23-612. Equipment**

A pharmacy permittee or pharmacist-in-charge shall ensure that a pharmacy has the necessary equipment to allow a pharmacist to practice the profession of pharmacy, including the following:

1. Adequate refrigeration equipment dedicated to the storage of drugs and biologicals;
2. A C-V controlled substance register, if C-V controlled substances are sold without an order of a medical practitioner;
3. Graduates in assorted sizes;
4. One mortar and pestle, not required if the pharmacy permittee states in the application that compounding will not be performed in the pharmacy;
5. Spatulas of assorted sizes including one nonmetallic;

6. Prescription balance, Class A with weights or an electronic balance of equal or greater accuracy, not required if the pharmacy permittee states in the application that compounding will not be performed in the pharmacy;
7. One ointment tile or equivalent, not required if the pharmacy permittee states in the application that compounding will not be performed in the pharmacy;
8. A current hard-copy or access to a current electronic-copy of the Arizona Pharmacy Act and administrative rules and Arizona Controlled Substance Act;
9. A professional reference library consisting of a minimum of one current reference or text, in hard-copy or electronic media, addressing the following subject areas:
  - a. Pharmacology or toxicology,
  - b. Therapeutics,
  - c. Drug compatibility, and
  - d. Drug product equivalency;
10. An assortment of labels, including prescription labels, transfer labels for controlled substances, and cautionary and warning labels;
11. A red C stamp as defined in R4-23-110, if C-III, C-IV, and C-V controlled substance invoices are not filed separately from other invoices;
12. Current antidote and drug interaction information; and
13. Regional poison control phone number prominently displayed in the pharmacy area.

**R4-23-613. Procedure for Discontinuing a Pharmacy**

A. A pharmacy permittee or pharmacist-in-charge shall provide written notice to the Board and the Drug Enforcement Administration (D.E.A.) at least 14 days before discontinuing operation of the pharmacy. The notice shall contain the following information:

1. Name, address, pharmacy permit number, and D.E.A. registration number of the pharmacy discontinuing business;
  2. Name, address, pharmacy permit number (if applicable), and D.E.A. registration number (if applicable) of the licensee, permittee, or registrant to whom any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical will be sold or transferred;
  3. Name and address of the location where the discontinuing pharmacy's records of purchase and disbursement of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical will be kept and the person responsible for the records. These records shall be kept for a minimum of three years from the date the pharmacy is discontinued;
  4. Name and address of the location where the discontinuing pharmacy's prescription files and patient profiles will be kept and the person responsible for the files and profiles. These records shall be kept for a minimum of seven years from the date the last original or refill prescription was dispensed; and
  5. The proposed date of discontinuing business operations.
- B. The pharmacy permittee shall ensure that all pharmacy signs and symbols are removed from both the inside and outside of the premises.
- C. The pharmacy permittee or pharmacist-in-charge shall ensure that all state permits and certificates of registration are returned to the Board office and that D.E.A. registration certificates and unused D.E.A. Schedule II order forms are returned to the D.E.A. Regional Office in Phoenix.
- D. The pharmacist-in-charge of the pharmacy discontinuing business shall ensure that:
1. Only a pharmacist has access to the prescription-only drugs and controlled substances until they are transferred to the licensee, permittee, or registrant listed in subsection (A)(2);
  2. All narcotics or other controlled substances, prescription-only drugs or devices, nonprescription drugs, precursor chemicals, or regulated chemicals are removed from the premises on or before the date the pharmacy is discontinued; and
  3. All controlled substances are transferred as follows:
    - a. Take an inventory of all controlled substances that are transferred using the procedures in R4-23-1003;
    - b. Include a copy of the inventory with the controlled substances that are transferred;
    - c. Keep the original of the inventory with the discontinued pharmacy's records of narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical purchase and disbursement for a minimum of three years from the date the pharmacy is discontinued;

d. Use a D.E.A. form 222 to transfer any Schedule II controlled substances; and

e. Transfer controlled substances that need destruction in the same manner as all other controlled substances.

E. Upon receipt of outdated or damaged controlled substances from a discontinued pharmacy, the licensee, permittee, or registrant described in subsection (A)(2) shall contact a D.E.A. registered reverse distributor for proper destruction of outdated or damaged controlled substances. If there are controlled substances a reverse distributor will not accept, the licensee, permittee, or registrant shall then contact the Board office and request an inspection for the purpose of drug destruction.

F. During the three-year record retention period specified in subsection (A)(3), the person described in subsection (A)(3) shall provide to the Board upon its request a discontinued pharmacy's records of the purchase and disbursement of narcotics or other controlled substances, prescription-only drugs or devices, nonprescription drugs, precursor chemicals, or regulated chemicals.

G. During the seven-year record retention period specified in subsection (A)(4), the person described in subsection (A)(4) shall provide to the Board upon its request a discontinued pharmacy's records of prescription files and patient profiles.

#### **R4-23-614. Automated Storage and Distribution System**

A. Before using an automated storage and distribution system, a pharmacy permittee or pharmacist-in-charge shall:

1. Ensure that the automated storage and distribution system and the policies and procedures comply with subsection (B); and

2. Notify the Board in writing of the intent to use an automated storage and distribution system, including the type or name of the system.

B. A pharmacy permittee or pharmacist-in-charge shall establish policies and procedures for appropriate performance and use of the automated storage and distribution system that:

1. Ensure that the automated storage and distribution system is in good working order while maintaining appropriate recordkeeping and security safeguards;

2. Ensure that an automated storage and distribution system used by the pharmacy that allows access to drugs or devices by a patient:

a. Only contains prescriptions that:

i. Do not require oral consultation as specified in R4-23-402(B); and

ii. Are properly labeled and verified by a pharmacist before placement into the automated storage and distribution system and subsequent release to patients;

b. Allows a patient to choose whether or not to use the system;

c. Is located either in a wall of a properly permitted pharmacy or within 20 feet of a properly permitted pharmacy if the automated storage and distribution system is secured against the wall or floor in such a manner that prevents the automated storage and distribution system's unauthorized removal;

d. Provides a method to identify the patient and only release that patient's prescriptions;

e. Is secure from access and removal of drugs or devices by unauthorized individuals;

f. Provides a method for a patient to obtain a consultation with a pharmacist if requested by the patient; and

g. Does not allow the system to dispense refilled prescriptions if a pharmacist determines that the patient requires oral counseling as specified in R4-23-402(B);

3. Ensure that an automated storage and distribution system used by the pharmacy that allows access to drugs or devices only by authorized licensed personnel for the purposes of administration based on a valid prescription order or medication order:

a. Provides for adequate security to prevent unauthorized individuals from accessing or obtaining drugs or devices; and

b. Provides for the filling, stocking, or restocking of all drugs or devices in the system only by a Board licensee or other authorized licensed personnel; and

4. Implement an ongoing quality assurance program that monitors compliance with the established policies and procedures of the automated storage and distribution system and federal and state law.

C. A pharmacy permittee or pharmacist-in-charge shall:

1. Ensure that the policies and procedures required under subsection (B) are prepared, implemented, and complied with;

2. Review biennially and, if necessary, revise the policies and procedures required under subsection (B);

3. Document the review required under subsection (C)(2);
4. Assemble the policies and procedures as a written or electronic manual; and
5. Make the policies and procedures available for employee reference and inspection by the Board or its staff within the pharmacy and at any location outside the pharmacy where the automated storage and distribution system is used.

D. The Board may prohibit a pharmacy permittee or pharmacist-in-charge from using an automated storage and distribution system if the pharmacy permittee or the pharmacy permittee's employees do not comply with the requirements of subsections (A), (B), or (C).

#### **R4-23-615. Mechanical Storage and Counting Device for a Drug in Solid, Oral Dosage Form**

A. A pharmacy permittee or pharmacist-in-charge shall ensure that a mechanical storage and counting device for a drug in a solid, oral dosage form that is used by a pharmacist or a pharmacy intern, graduate intern, pharmacy technician, or pharmacy technician trainee under the supervision of a pharmacist complies with the following method to identify the contents of the device:

1. The drug name and strength are affixed to the front of each cell or cassette of the device;
2. A paper or electronic log is kept for each cell or cassette that contains:
  - a. An identification of the cell or cassette by the drug name and strength or the number of the cell or cassette;
  - b. The drug's manufacturer or National Drug Code (NDC) number;
  - c. The expiration date and lot number from the manufacturer's stock bottle that is used to fill the cell or cassette. If multiple lot numbers of the same drug are added to a cell or cassette, each lot number and expiration date shall be documented, and the earliest expiration date shall become the expiration date of the mixed lot of drug in the cell or cassette;
  - d. The date the cell or cassette is filled;
  - e. Documentation of the identity of the licensee who placed the drug into the cell or cassette; and
  - f. If the licensee who filled the cell or cassette is not a pharmacist, documentation of the identity of the pharmacist who supervised the non-pharmacist licensee who filled the cell or cassette; and
3. The paper or electronic log is available in the pharmacy for inspection by the Board or its designee for not less than two years.

B. A pharmacy permittee or pharmacist-in-charge shall ensure that any drug previously counted by a mechanical storage and counting device for a drug in a solid, oral dosage form that has not left the pharmacy is not returned to the drug's cell, cassette, or stock bottle, unless the drug return method is approved by the Board or its designee as specified in subsection (G). This subsection does not prevent a pharmacy permittee or pharmacist-in-charge from using a manual or mechanical counting device to count and dispense a previously counted drug that has not left the pharmacy if the previously counted drug is dispensed before its beyond-use-date.

C. A pharmacy permittee or pharmacist-in-charge shall ensure the accuracy of any mechanical storage and counting device for a drug in a solid, oral dosage form that is used by a pharmacist or a pharmacy intern, graduate intern, pharmacy technician, or pharmacy technician trainee under the supervision of a pharmacist by documenting completion of the following:

1. Training in the maintenance, calibration, and use of the mechanical storage and counting device for each employee who uses the mechanical storage and counting device;
2. Maintenance and calibration of the mechanical storage and counting device as recommended by the device's manufacturer; and
3. Routine quality assurance and accuracy validation testing for each mechanical storage and counting device.

D. A pharmacy permittee or pharmacist-in-charge shall ensure that the documentation required in subsection (C) is available for inspection by the Board or its designee.

E. A pharmacy permittee or pharmacist-in-charge shall:

1. Ensure that policies and procedures for the performance and use of a mechanical storage and counting device for a drug in a solid, oral dosage form are prepared, implemented, and complied with;
2. Review biennially and, if necessary, revise the policies and procedures required under subsection (E)(1);
3. Document the review required under subsection (E)(2);
4. Assemble the policies and procedures as a written or electronic manual; and
5. Make the policies and procedures available within the pharmacy for employee reference and inspection by the Board or its staff.

F. The Board may prohibit a pharmacy permittee or pharmacist-in-charge from using a mechanical storage and counting device for a drug in a solid, oral dosage form if the pharmacy permittee or the pharmacy permittee's employees do not comply with the requirements of subsections (A), (B), (C), (D), or (E).

G. Returning a drug previously counted by a mechanical storage and counting device for a drug in a solid, oral dosage form that has not left the pharmacy to the drug's cell or cassette.

1. Before returning a drug previously counted by a mechanical storage and counting device that has not left the pharmacy to the drug's cell or cassette, a pharmacy permittee or pharmacist-in-charge shall:

- a. Apply for approval from the Board or its designee for the drug return method to be used in returning the drug;
- b. Develop a drug return method that uses technology, such as bar coding, to prevent drug return errors;
- c. Provide documentation depicting the drug return method;
- d. Demonstrate the drug return method for a Board Compliance Officer; and
- e. Receive approval from the Board or its designee for the drug return method to be used in returning the drug.

2. Before approving a request to waive the drug return prohibition in subsection (B), the Board or its designee shall:

- a. Receive a request in writing from the pharmacy permittee or pharmacist-in-charge;
- b. Review the documentation of the drug return method; and
- c. Receive a satisfactory inspection report from a Board Compliance Officer that the drug return method uses technology to prevent drug return errors.

#### **R4-23-616. Mechanical Counting Device for a Drug in Solid, Oral Dosage Form**

A. A pharmacy permittee or pharmacist-in-charge shall ensure the accuracy of any mechanical counting device for a drug in a solid, oral dosage form that is used by a pharmacist or a pharmacy intern, graduate intern, pharmacy technician, or pharmacy technician trainee under the supervision of a pharmacist by documenting completion of the following:

1. Training in the maintenance, calibration, and use of the mechanical counting device for each employee who uses the mechanical counting device;
2. Maintenance and calibration of the mechanical counting device as recommended by the device's manufacturer; and
3. Routine quality assurance and accuracy validation testing for each mechanical counting device.

B. A pharmacy permittee or pharmacist-in-charge shall ensure that the documentation required in subsection (A) is available for inspection by the Board or its designee.

C. A pharmacy permittee or pharmacist-in-charge shall:

1. Ensure that policies and procedures for the performance and use of a mechanical counting device for a drug in a solid, oral dosage form are prepared, implemented, and complied with;
2. Review biennially and, if necessary, revise the policies and procedures required under subsection (C)(1);
3. Document the review required under subsection (C)(2);
4. Assemble the policies and procedures as a written or electronic manual; and
5. Make the policies and procedures available within the pharmacy for employee reference and inspection by the Board or its staff.

D. The Board may prohibit a pharmacy permittee or pharmacist-in-charge from using a mechanical counting device for a drug in a solid, oral dosage form if the pharmacy permittee or the pharmacy permittee's employees do not comply with the requirements of subsections (A), (B), or (C).

#### **R4-23-617. Temporary Pharmacy Facilities or Mobile Pharmacies**

A. Pharmacies located in declared disaster areas, nonresident pharmacies, and pharmacies licensed or permitted in another state but not licensed or permitted in this state, if necessary to provide pharmacy services during a declared state of emergency, may arrange to temporarily locate to a temporary pharmacy facility or mobile pharmacy or relocate to a temporary pharmacy facility or mobile pharmacy if the pharmacist-in-charge of the temporary pharmacy facility or mobile pharmacy ensures that:

1. The pharmacy is under the control and management of the pharmacist-in-charge or a supervising pharmacist designated by the pharmacist-in-charge;

2. The pharmacy is located within or adjacent to the declared disaster area;
  3. The Board is notified of the pharmacy's location;
  4. The pharmacy is properly secured to prevent theft and diversion of drugs;
  5. The pharmacy's records are maintained in accordance with Arizona statutes and rules; and
  6. The pharmacy stops providing pharmacy services when the declared state of emergency ends, unless it possesses a current resident pharmacy permit issued by the Board under A.R.S. §§ 32-1929, 32-1930, and 32-1931.
- B. The Board shall have the authority to approve or deny temporary pharmacy facilities, mobile pharmacies, and shall make arrangements for appropriate monitoring and inspection of the temporary pharmacy facilities and mobile pharmacies on a case-by-case basis.
- C. A temporary pharmacy facility wishing to permanently operate at its temporary site shall apply for and have received a permit issued under A.R.S. §§ 32-1929, 32-1930, and 32-1931 by following the application process under R4-23-606.
- D. A mobile pharmacy, placed in operation during a declared state of emergency, shall not operate permanently.

**R4-23-618. Thru R4-23-619. Reserved**

**R4-23-620. Continuous Quality Assurance Program**

A. Each pharmacy permittee shall implement or participate in a continuous quality assurance (CQA) program. A pharmacy permittee meets the requirements of this Section if it holds a current general, special or rural general hospital license from the Arizona Department of Health Services and is any of the following:

1. Certified by the Centers for Medicare and Medicaid Services to participate in the Medicare or Medicaid programs;
2. Accredited by the Joint Commission on the Accreditation of Healthcare Organizations; or
3. Accredited by the American Osteopathic Association.

B. A pharmacy permittee or the pharmacist-in-charge shall ensure that:

1. The pharmacy develops, implements, and utilizes a CQA program consistent with the requirements of this Section and A.R.S. § 32-1973;
2. The medication error data generated by the CQA program is utilized and reviewed on a regular basis, as required by subsection (D); and
3. Training records, policies and procedures, and other program records or documents, other than medication error data, are maintained for a minimum of two years in the pharmacy or in a readily retrievable manner.

C. A pharmacy permittee or pharmacist-in-charge shall:

1. Ensure that policies and procedures for the operation and management of the pharmacy's CQA program are prepared, implemented, and complied with;
2. Review biennially and, if necessary, revise the policies and procedures required under subsection (C)(1);
3. Document the review required under subsection (C)(2);
4. Assemble the policies and procedures as a written or electronic manual; and
5. Make the policies and procedures available within the pharmacy for employee reference and inspection by the Board or its staff.

D. The policies and procedures shall address a planned process to:

1. Train all pharmacy personnel in relevant phases of the CQA program;
2. Identify and document medication errors;
3. Record, measure, and analyze data collected to:
  - a. Assess the causes and any contributing factors relating to medication errors, and
  - b. Improve the quality of patient care;
4. Utilize the findings from subsections (D)(2) and (3) to develop pharmacy systems and workflow processes designed to prevent or reduce medication errors; and
5. Communicate periodically, and at least annually, with pharmacy personnel to review CQA program findings and inform pharmacy personnel of any changes made to pharmacy policies, procedures, systems, or processes as a result of CQA program findings.

E. The Board's regulatory oversight activities regarding a pharmacy's CQA program are limited to inspection of the pharmacy's CQA policies and procedures and enforcing the pharmacy's compliance with those policies and procedures.

F. A pharmacy's compliance with this Section shall be considered by the Board as a mitigating factor in the investigation and evaluation of a medication error.

#### **R4-23-621. Shared Services**

A. Before participating in shared services, a pharmacy shall have either a current resident or non-resident pharmacy permit issued by the Board.

B. A pharmacy may provide or utilize shared services functions only if the pharmacies involved:

1. Have the same owner; or
2. Have a written contract or agreement that outlines the services provided and the shared responsibilities of each party in complying with federal and state pharmacy statutes and rules, and
3. Share a common electronic file or technology that allows access to information necessary or required to perform shared services in conformance with the pharmacy act and the Board's rules.

C. Notifications to patients.

1. Before using shared services provided by another pharmacy, a pharmacy permittee shall:

a. Notify patients that their orders may be processed or filled by another pharmacy; and

b. Provide the name of that pharmacy or, if the pharmacy is part of a network of pharmacies under common ownership and any of the network pharmacies may process or fill the order, notify the patient of this fact. The notification may be provided through a one-time written notice to the patient or through use of a sign in the pharmacy.

2. If an order is delivered directly to the patient by a filling pharmacy and not returned to the requesting pharmacy, the filling pharmacy permittee shall ensure that the following is placed on the prescription container or on a separate sheet delivered with the prescription container:

a. The local, and if applicable, the toll-free telephone number of the pharmacy utilizing shared services that has access to the patient's records; and

b. A statement that conveys to the patient or patient's care-giver the following information: *"Written information about this prescription has been provided for you. Please read this information before you take the medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions at (insert the local and toll-free telephone numbers of the pharmacy utilizing shared services that has access to the patient's records)."*

3. The provisions of subsection (C) do not apply to orders delivered to patients in facilities where a licensed health care professional is responsible for administering the prescription medication to the patient.

D. A pharmacy permittee engaged in shared services shall:

1. Maintain manual or electronic records that identify, individually for each order processed, the name, initials, or identification code of each pharmacist, graduate intern, pharmacy intern, pharmacy technician, and pharmacy technician trainee who took part in the order interpretation, order entry verification, drug utilization review, drug compatibility and drug allergy review, final order verification, therapeutic intervention, or refill authorization functions performed at that pharmacy;

2. Maintain manual or electronic records that identify, individually for each order filled or dispensed, the name, initials, or identification code of each pharmacist, graduate intern, pharmacy intern, pharmacy technician, and pharmacy technician trainee who took part in the filling, dispensing, and counseling functions performed at that pharmacy;

3. Report to the Board as soon as practical the results of any disciplinary action taken by another state's pharmacy regulatory agency involving shared services;

4. Maintain a mechanism for tracking the order during each step of the processing and filling procedures performed at the pharmacy;

5. Provide for adequate security to protect the confidentiality and integrity of patient information; and

6. Provide for inspection of any required record or information within 72 hours of any request by the Board or its designee.

E. Each pharmacy permittee that provides or utilizes shared services shall develop, implement, review, revise, and comply with joint policies and procedures for shared services in the manner described in R4-23-610(A)(2). Each pharmacy permittee is required to maintain only those portions of the joint policies and procedures that relate to that pharmacy's operations. The policies and procedures shall:

1. Outline the responsibilities of each of the pharmacies;

2. Include a list of the name, address, telephone numbers, and all license and permit numbers of the pharmacies involved in shared services; and
  3. Include policies and procedures for:
    - a. Notifying patients that their orders may be processed or filled by another pharmacy and providing the name of that pharmacy;
    - b. Protecting the confidentiality and integrity of patient information;
    - c. Dispensing orders when the filled order is not received or the patient comes in before the order is received;
    - d. Maintaining required manual or electronic records to identify the name, initials, or identification code and specific activity or activities of each pharmacist, graduate intern, pharmacy intern, pharmacy technician, or pharmacy technician trainee who performed any shared services;
    - e. Complying with federal and state laws; and
    - f. Operating a continuous quality improvement program for shared services, designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.
- F. Nothing in this Section shall prohibit an individual pharmacist licensed in Arizona, who is an employee of or under contract with a pharmacy, or an Arizona-licensed graduate intern, pharmacy intern, pharmacy technician, or pharmacy technician trainee, working under the supervision of the pharmacist, from accessing that pharmacy's electronic database from inside or outside the pharmacy and performing the order processing functions permitted by the pharmacy act, if both of the following conditions are met:
1. The pharmacy establishes controls to protect the confidentiality and integrity of patient information; and
  2. None of the database is duplicated, downloaded, or removed from the pharmacy's electronic database.

**R4-23-622. Thru R4-23-650. Reserved**

**R4-23-651. Definitions (*The following definitions apply to R4-23-651 through R4-23-659*):**

"Administration" means the giving of a dose of medication to a patient as a result of an order of a medical practitioner.

"Direct copy" means an electronic, facsimile or carbonized copy.

"Dispensing for hospital inpatients" means the interpreting, evaluating, and implementing a medication order including preparing for delivery a drug or device to an inpatient or inpatient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, an inpatient (hereafter referred to as "dispensing").

"Drug distribution" means the delivery of drugs other than "administering" or "dispensing."

"Emergency medical situation" means a condition of emergency in which immediate drug therapy is required for the preservation of health, life, or limb of a person or persons.

"Floor stock" means a supply of essential drugs not labeled for a specific patient and maintained and controlled by the pharmacy at a patient care area for the purpose of timely administration to a patient of the hospital.

"Formulary" means a continually revised compilation of pharmaceuticals (including ancillary information) that reflects the current clinical judgment of the medical staff.

"Hospital pharmacy" means a pharmacy, as defined in A.R.S. § 32-1901, that holds a current permit issued by the Board pursuant to A.R.S. § 32-1931, and is located in a hospital as defined in A.R.S. § 32-1901.

"Inpatient" means any patient who receives non-self-administered drugs from a hospital pharmacy for use while within a facility owned by the hospital.

"Intravenous admixture" means a sterile parenteral solution to which one or more additional drug products have been added.

"Medication order" means a written, electronic, or verbal order from a medical practitioner or a medical practitioner's authorized agent for administration of a drug or device.

"On-call" means a pharmacist is available to:

- Consult or provide drug information regarding drug therapy or related issues; or
- Dispense a medication order and review a patient's medication order for pharmaceutical and therapeutic feasibility under R4-23-653(E)(2) before any drug is administered to a patient, except as specified in R4-23-653(E)(1).

"Patient care area" means any area for the primary purpose of providing a physical environment that is owned by or operated in conjunction with a hospital, for a patient to obtain health care services, except those areas where a physician, dentist, veterinarian, osteopath, or other medical practitioner engages primarily in private practice.

"Repackaged drug" means a drug product that is transferred by pharmacy personnel from an original manufacturer's container to another container properly labeled for subsequent dispensing.

"Satellite pharmacy" means a work area in a hospital setting under the direction of a pharmacist that is a remote extension of a centrally licensed hospital pharmacy and owned by and dependent upon the centrally licensed hospital pharmacy for administrative control, staffing, and drug procurement.

"Single unit" means a package of medication that contains one discrete pharmaceutical dosage form.

"Supervision" means the process by which a pharmacist directs the activities of hospital pharmacy personnel to a sufficient degree to ensure that all activities are performed accurately, safely, and without risk of harm to patients.

#### **R4-23-652. Hospital Pharmacy Permit**

A. The following rules are applicable to all hospitals as defined by A.R.S. § 32-1901 and hospital pharmacies as defined by R4-23-651.

B. Before opening a hospital pharmacy, a person shall obtain a pharmacy permit as specified in R4-23-602 and R4-23-606.

C. Discontinued hospitals. If a hospital license is discontinued by the state Department of Health Services, the pharmacy permittee or pharmacist-in-charge shall follow the procedures described in R4-23-613 for discontinuing a pharmacy.

#### **R4-23-653. Personnel: Professional or Technician**

A. Each hospital pharmacy shall be directed by a pharmacist who is licensed to engage in the practice of pharmacy in Arizona and is referred to as the Director of Pharmacy. The Director of Pharmacy shall be the pharmacist-in-charge, as defined in A.R.S. § 32-1901 or shall appoint a pharmacist-in-charge. The Director of Pharmacy and the pharmacist-in-charge, if a different individual, shall:

1. Be responsible for all the activities of the hospital pharmacy and for meeting the requirements of the Arizona Pharmacy Act and these rules;
2. Ensure that the policies and procedures required by these rules are prepared, implemented, and complied with;
3. Review biennially and, if necessary, revise the policies and procedures required under these rules;
4. Document the review required under subsection (A)(3);
5. Assemble the policies and procedures as a written manual or by another method approved by the Board or its designee; and
6. Make the policies and procedures available within the pharmacy for employee reference and inspection by the Board or its designee.

B. In all hospitals, a pharmacist shall be in the hospital during the time the pharmacy is open for pharmacy services, except for an extreme emergency as defined in R4-23-110. Pharmacy services shall be provided for a minimum of 40 hours per week, unless an exception for less than the minimum hours is made upon written request by the hospital and with express permission of the Board or its designee.

C. In a hospital where the pharmacy is not open 24 hours per day for pharmacy services, a pharmacist shall be "on-call" as defined in R4-23-651 when the pharmacy is closed.

D. The Director of Pharmacy may be assisted by other personnel approved by the Director of Pharmacy in order to operate the pharmacy competently, safely, and adequately to meet the needs of the hospital's patients.

E. Pharmacists. A pharmacist or a pharmacy intern or graduate intern under the supervision of a pharmacist shall perform the following professional practices:

1. Verify a patient's medication order before administration of a drug to the patient, except:
  - a. In an emergency medical situation; or
  - b. In a hospital where the pharmacy is open less than 24 hours a day for pharmacy services, a pharmacist shall verify a patient's medication order within four hours of the time the pharmacy opens for pharmacy services;
2. Verify a medication order's pharmaceutical and therapeutic feasibility based upon:
  - a. The patient's medical condition,
  - b. The patient's allergies,
  - c. The pharmaceutical and therapeutic incompatibilities, and
  - d. The recommended dosage limits;

3. Measure, count, pour, or otherwise prepare and package a drug needed for dispensing, except a pharmacy technician or pharmacy technician trainee may measure, count, pour, or otherwise prepare and package a drug needed for dispensing under the supervision of a pharmacist according to written policies and procedures approved by the Board or its designee
4. Compound, admix, combine, or otherwise prepare and package a drug needed for dispensing, except a pharmacy technician may compound, admix, combine, or otherwise prepare and package a drug needed for dispensing under the supervision of a pharmacist according to written policies and procedures approved by the Board or its designee;
5. Verify the accuracy, correct procedure, compounding, admixing, combining, measuring, counting, pouring, preparing, packaging, and safety of a drug prepared and packaged by a pharmacy technician or pharmacy technician trainee according to subsections (E)(3) and (4) and according to the policies and procedures in subsection (G);
6. Supervise drug repackaging and check the completed repackaged product as specified in R4-23-402(A);
7. Supervise training and education in aseptic technique and drug incompatibilities for all personnel involved in the admixture of parenteral products within the hospital pharmacy;
8. Consult with the medical practitioner regarding the patient's drug therapy or medical condition;
9. When requested by a medical practitioner, patient, patient's agent, or when the pharmacist deems it necessary, provide consultation with a patient regarding the medication order, patient's profile, or overall drug therapy;
10. Monitor a patient's drug therapy for safety and effectiveness;
11. Provide drug information to patients and health care professionals;
12. Manage the activities of pharmacy technicians, pharmacy technician trainees, other personnel, and systems to ensure that all activities are performed accurately, safely, and without risk of harm to patients;
13. Verify the accuracy of all aspects of the original, completed medication order; and
14. Ensure compliance by pharmacy personnel with a quality assurance program developed by the hospital.

F. Pharmacy technicians and pharmacy technician trainees. Before working as a pharmacy technician or pharmacy technician trainee, an individual shall meet the eligibility and licensure requirements prescribed in 4 A.A.C. 23, Article 11.

G. Pharmacy technician policies and procedures. Before employing a pharmacy technician or pharmacy technician trainee, a Director of Pharmacy or pharmacist-in-charge shall develop the policies and procedures required under R4-23-1104.

H. Pharmacy technician training program.

1. A Director of Pharmacy or pharmacist-in-charge shall comply with the training program requirements of R4-23-1105 based on the needs of the hospital pharmacy;

2. A pharmacy technician or pharmacy technician trainee shall:

- a. Perform only those tasks for which training and competency have been demonstrated; and

- b. Not perform professional practices reserved for a pharmacist, graduate intern, or pharmacy intern in subsection (E), except as specified in subsections (E)(3) and (4).

I. Supervision. A hospital pharmacy's Director of Pharmacy and the pharmacist-in-charge, if a different individual, shall supervise all of the activities and operations of a hospital pharmacy. A pharmacist shall supervise all functions and activities of pharmacy technicians, pharmacy technician trainees, and other hospital pharmacy personnel to ensure that all functions and activities are performed competently, safely, and without risk of harm to patients.

#### **R4-23-654. Absence of Pharmacist**

A. If a pharmacist will not be on duty in the hospital, the Director of Pharmacy or pharmacist-in-charge shall arrange, before the pharmacist's absence, for the medical staff and other authorized personnel of the hospital to have access to drugs in the remote drug storage area defined in R4-23-110 or in the hospital pharmacy if a drug is not available in a remote drug storage area and is required to treat the immediate needs of a patient. A pharmacist shall be on-call during all absences.

B. If a pharmacist will not be on duty in the hospital pharmacy, the Director of Pharmacy or pharmacist-in-charge shall arrange, before the pharmacist's absence, for the medical staff and other authorized personnel of the hospital to have telephone access to an on-call pharmacist.

C. The hospital pharmacy permittee shall ensure that the hospital pharmacy is not without a pharmacist on duty in the hospital for more than 72 consecutive hours.

D. Remote drug storage area. The Director of Pharmacy or pharmacist-in-charge shall, in consultation with the appropriate committee of the hospital:

1. Develop and maintain an inventory listing of the drugs to be included in a remote drug storage area; and
  2. Develop, implement, review, and revise in the same manner described in R4-23-653(A) and comply with policies and procedures that ensure proper storage, access, and accountability for drugs in a remote drug storage area.
- E. Access to hospital pharmacy. If a drug is not available from a remote drug storage area and the drug is required to treat the immediate needs of a patient whose health may be compromised, the drug may be obtained from the hospital pharmacy according to the requirements of this subsection.
1. The Director of Pharmacy or pharmacist-in-charge shall, in consultation with the appropriate committee of the hospital, develop, implement, review, and revise in the same manner described in R4-23-653(A) and comply with policies and procedures to ensure that access to the hospital pharmacy during the pharmacist's absence conforms to the following requirements:
    - a. Access is delegated to only one supervisory nurse in each shift;
    - b. The policy and name of supervisory nurse is communicated in writing to the medical staff of the hospital;
    - c. Access is delegated only to a nurse who has received training from the Director of Pharmacy, pharmacist-in-charge, or Director's designee in the procedures required for proper access, drug removal, and recordkeeping; and
    - d. Access is delegated by the supervisory nurse to another nurse only in an emergency.
  2. If a nurse to whom authority is delegated to access the hospital pharmacy removes a drug from the hospital pharmacy, the nurse shall:
    - a. Record the following information on a form or by another method approved by the Board or its designee:
      - i. Patient's name;
      - ii. Drug name, strength, and dosage form;
      - iii. Quantity of drug removed; and
      - iv. Date and time of removal;
    - b. Sign or initial, if a corresponding signature is on file in the hospital pharmacy, the form recording the drug removal;
    - c. Attach the original or a direct copy of the medication order for the drug to the form recording the drug removal; and
    - d. Place the form recording the drug removal conspicuously in the hospital pharmacy.
  3. Within four hours after a pharmacist returns from an absence, the pharmacist shall verify all records of drug removal that occurred during the pharmacist's absence according to R4-23-653(E).

**R4-23-655. Physical Facility**

- A. General. A hospital pharmacy permittee shall ensure that the hospital pharmacy has sufficient equipment and physical facilities for proper compounding, dispensing, and storage of drugs, including parenteral preparations.
- B. Minimum area of hospital pharmacy. The minimum area of a hospital pharmacy depends on the type of hospital, the number of beds, and the pharmaceutical services provided. Any hospital pharmacy permit issued or hospital pharmacy remodeled after January 31, 2003 shall provide a minimum hospital pharmacy area, the actual area primarily devoted to drug dispensing and preparation functions, exclusive of bulk drug storage, satellite pharmacy, and office areas that is not less than 500 square feet. The minimum area requirement, not including unusable area, may be varied upon approval by the Board for out-of-the-ordinary conditions or for systems that require less space.
- C. The Board may also require that a hospital pharmacy permittee or applicant provide:
1. More than the minimum area if equipment, inventory, personnel, or other factors cause crowding to a degree that interferes with safe pharmacy practice;
  2. Additional dispensing, preparation, or storage areas because of the increased number of specific drugs prescribed per day, the increased use of intravenous and irrigating solutions, and the increased use of disposable and prepackaged products;
  3. Additional dispensing, preparation, or storage areas to handle investigational drugs, emergency drug kits, chemotherapeutics, alcohol and other flammables, poisons, external preparations, and radioisotopes, and to accommodate quality control procedures; and
  4. Additional office space to provide for an increased number of personnel, a drug information library, a poison information library, research support, teaching and conferences, and a waiting area.
- D. Hospital pharmacy area. A hospital pharmacy permittee shall ensure that the hospital pharmacy area is enclosed by a permanent barrier or partition from floor to ceiling with entry doors that can be securely locked, constructed according to R4-23-609(F).

E. Hospital pharmacy storage areas. The hospital pharmacy permittee, Director of Pharmacy, or pharmacist-in-charge shall ensure that all undispensed or undistributed drugs are stored in designated areas within the hospital pharmacy or other locked areas under the control of a pharmacist that ensure proper sanitation, temperature, light, ventilation, moisture control, segregation, and security.

#### **R4-23-656. Sanitation and Equipment**

A hospital pharmacy permittee or Director of Pharmacy shall ensure that a hospital pharmacy:

1. Has a professional reference library consisting of hard-copy or electronic media appropriate for the scope of pharmacy services provided by the hospital;
2. Has a sink, other than a sink in a toilet facility, that:
  - a. Has hot and cold running water;
  - b. Is within the hospital pharmacy area for use in preparing drug products; and
  - c. Is maintained in a sanitary condition and in good repair;
3. Maintains a room temperature within a range compatible with the proper storage of drugs;
4. Has a refrigerator and freezer with a temperature maintained within a range compatible with the proper storage of drugs requiring refrigeration or freezing; and
5. Has a designated area for a laminar air flow hood and other supplies required for the preparation of sterile products as specified in R4-23-670.

#### **R4-23-657. Security**

A. Personnel security standards. A Director of Pharmacy shall ensure that:

1. No one is permitted in the pharmacy unless a pharmacist is present except as provided in this Section and R4-23-654. If only one pharmacist is on duty in the pharmacy and that pharmacist must leave the pharmacy for an emergency or patient care duties, nonpharmacist personnel may remain in the pharmacy to perform duties as outlined in R4-23-653, provided that all C-II controlled substances are secured to prohibit access by other than a pharmacist, and that the pharmacist remains available in the hospital;
2. All hospital pharmacy areas are kept locked by key or programmable lock to prevent access by unauthorized personnel; and
3. Pharmacists, pharmacy or graduate interns, pharmacy technicians, pharmacy technician trainees, and other personnel working in the pharmacy wear identification badges, including name and position, whenever on duty.

B. Prescription blank security. The Director of Pharmacy shall develop, implement, review, and revise in the same manner described in R4-23-653(A) and comply with policies and procedures for the safe distribution and control of prescription blanks bearing identification of the hospital.

#### **R4-23-658. Drug Distribution and Control**

A. General. The Director of Pharmacy or pharmacist-in-charge shall in consultation with the medical staff, develop, implement, review, and revise in the same manner described in R4-23-653(A) and comply with written policies and procedures for the effective operation of a drug distribution system that optimizes patient safety.

B. Responsibility. The Director of Pharmacy is responsible for the safe and efficient procurement, dispensing, distribution, administration, and control of drugs, including the following:

1. In consultation with the appropriate department personnel and medical staff committee, develop a medication formulary for the hospital;
2. Proper handling, distribution, and recordkeeping of investigational drugs; and
3. Regular inspections of drug storage and preparation areas within the hospital.

C. Physician orders. A Director of Pharmacy or pharmacist-in-charge shall ensure that:

1. Drugs are dispensed from the hospital pharmacy only upon a written order, direct copy or facsimile of a written order, or verbal order of an authorized medical practitioner; and
2. A pharmacist reviews the original, direct or facsimile copy, or verbal order before an initial dose of medication is administered, except as specified in R4-23-653(E)(1).

D. Labeling. A Director of Pharmacy or pharmacist-in-charge shall ensure that all drugs distributed or dispensed by a hospital pharmacy are packaged in appropriate containers and labeled as follows:

1. For use inside the hospital.

a. Labels for all single unit packages contain at a minimum, the following information:

- i. Drug name, strength, and dosage form;
- ii. Lot number and beyond-use-date; and
- iii. Appropriate auxiliary labels;

b. Labels for repackaged preparations contain at a minimum the following information:

- i. Drug name, strength, and dosage form;
- ii. Lot number and beyond-use-date;
- iii. Appropriate auxiliary labels; and
- iv. Mechanism to identify pharmacist accountable for repackaging;

c. Labels for all intravenous admixture preparations contain at a minimum the following information:

- i. Patient's name and location;
- ii. Name and quantity of the basic parenteral solution;
- iii. Name and amount of drug added
- iv. Date of preparation;
- v. Beyond-use-date and time;
- vi. Guidelines for administration;
- vii. Appropriate auxiliary label or precautionary statement; and
- viii. Initials of pharmacist responsible for admixture preparation; and

2. For use outside the hospital. Any drug dispensed to a patient by a hospital pharmacy that is intended for self-administration outside of the hospital is labeled as specified in A.R.S. §§ 32-1963.01(C) and 32-1968(D) and A.A.C. R4-23-402.

E. Controlled substance accountability. A Director of Pharmacy or pharmacist-in-charge shall ensure that effective policies and procedures are developed, implemented, reviewed, and revised in the same manner described in R4-23-653(A) and complied with regarding the use, accountability, and recordkeeping of controlled substances in the hospital, including the use of locked storage areas when controlled substances are stored in patient care areas.

F. Emergency services dispensing. If a hospital permits dispensing of drugs from the emergency services department when the pharmacy is unable to provide this service, the Director of Pharmacy, in consultation with the appropriate department personnel and medical staff committee shall develop, implement, review, and revise in the same manner described in R4-23-653(A) and comply with written policies and procedures for dispensing drugs for outpatient use from the hospital's emergency services department. The policies and procedures shall include the following requirements:

- 1. Drugs are dispensed only to patients who have been admitted to the emergency services department;
- 2. Drugs are dispensed only by an authorized medical practitioner, not a designee or agent;
- 3. The nature and type of drugs available for dispensing are designed to meet the immediate needs of the patients treated within the hospital;
- 4. Drugs are dispensed only in quantities sufficient to meet patient needs until outpatient pharmacy services are available;
- 5. Drugs are prepackaged by a pharmacist or a pharmacy intern, graduate intern, pharmacy technician, or pharmacy technician trainee under the supervision of a pharmacist in suitable containers and appropriately pre-labeled with the drug name, strength, dosage form, quantity, manufacturer, lot number, beyond-use-date, and any appropriate auxiliary labels;
- 6. Upon dispensing, the authorized medical practitioner completes the label on the prescription container that complies with the requirements of R4-23-658(D); and
- 7. The hospital pharmacy maintains a dispensing log, hard-copy prescription, or electronic record, approved by the Board or its designee and includes the patient name and address, drug name, strength, dosage form, quantity, directions for use, medical practitioner's signature or identification code, and DEA registration number, if applicable.

#### **R4-23-659. Administration of Drugs**

A. Self-administration. A hospital shall not allow self-administration of medications by a patient unless the Director of Pharmacy or pharmacist-in-charge, in consultation with the appropriate department personnel and medical staff committee, develops, implements, reviews, and revises in the same manner described in R4-23-653(A) and complies with policies and procedures for self-administration of medications by a patient. The policies and procedures shall specify that self-administration of medications, if allowed, occurs only when:

1. Specifically ordered by a medical practitioner, and
2. The patient is educated and trained in the proper manner of self-administration.

B. Drugs brought in by a patient. If a hospital allows a patient to bring a drug into the hospital and before a patient brings a drug into the hospital, the Director of Pharmacy or pharmacist-in-charge shall, in consultation with the appropriate department personnel and medical staff committee, develop, implement, review, and revise in the same manner described in R4-23-653(A) and comply with policies and procedures for a patient-owned drug brought into the hospital. The policies and procedures shall specify the following criteria for a patient-owned drug brought into the hospital:

1. When policy allows the administration of a patient-owned drug, the drug is not administered to the patient unless:
  - a. A pharmacist or medical practitioner identifies the drug, and
  - b. A medical practitioner writes a medication order specifying administration of the identified patient-owned drug; and
2. If a patient-owned drug will not be used during the patient's hospitalization, the hospital pharmacy's personnel shall:
  - a. Package, seal, and give the drug to the patient's agent for removal from the hospital; or
  - b. Package, seal, and store the drug for return to the patient at the time of discharge from the hospital.

C. Drug samples. The Director of Pharmacy or pharmacist-in-charge is responsible for the receipt, storage, distribution, and accountability of drug samples within the hospital, including developing, implementing, reviewing, and revising in the same manner described in R4-23-653(A) and complying with specific policies and procedures regarding drug samples.

#### **R4-23-660. Investigational Drugs**

The Director of Pharmacy or pharmacist-in-charge shall ensure that:

1. The following information concerning an investigational drug is available for use by hospital personnel:
  - a. Composition,
  - b. Pharmacology,
  - c. Adverse reactions,
  - d. Administration guidelines, and
  - e. All other available information concerning the drug, and
2. An investigational drug is:
  - a. Properly stored in, labeled, and dispensed from the pharmacy, and
  - b. Not dispensed before the drug is approved by the appropriate medical staff committee of the hospital.

#### **R4-23-661. Thru R4-23-664. Repealed**

#### **R4-23-665. Thru R4-23-669. Reserved**

#### **R4-23-670. Sterile Pharmaceutical Products**

A. In addition to the minimum area requirement of R4-23-609(A) and R4-23-655(B) and before compounding a sterile pharmaceutical product, a pharmacy permittee, limited-service pharmacy permittee, or applicant shall provide a minimum sterile pharmaceutical product compounding area that is not less than 100 square feet of contiguous floor area, except any pharmacy permit issued or pharmacy remodeled before November 1, 2006 may continue to use a sterile pharmaceutical product compounding area that is not less than 60 square feet of contiguous floor area, until a pharmacy ownership change occurs that requires issuance of a new permit or the pharmacy is remodeled. The pharmacy permittee or the pharmacist-in-charge shall ensure that the sterile pharmaceutical product compounding area:

1. Is dedicated to the purpose of preparing and compounding sterile pharmaceutical products;
2. Is isolated from other pharmacy functions;

3. Restricts entry or access;
4. Is free from unnecessary disturbances in air flow;
5. Is made of non-porous and cleanable floor, wall, and ceiling material; and
6. Meets the minimum air cleanliness standards of an ISO Class 7 environment as defined in R4-23-110, except an ISO class 7 environment is not required if all sterile pharmaceutical product compounding occurs within an ISO class 5 environment isolator, such as a glove box, pharmaceutical isolator, barrier isolator, pharmacy isolator, or hospital pharmacy isolator.

B. In addition to the equipment requirements in R4-23-611 and R4-23-612 or R4-23-656 and before compounding a sterile pharmaceutical product, a pharmacy permittee, limited-service pharmacy permittee, or applicant shall ensure that a pharmacist who compounds a sterile pharmaceutical product has the following equipment:

1. Environmental control devices capable of maintaining a compounding area environment equivalent to an "ISO class 5 environment" as defined in R4-23-110. Devices capable of meeting these standards include: laminar airflow hoods, hepa filtered zonal airflow devices, glove boxes, pharmaceutical isolators, barrier isolators, pharmacy isolators, hospital pharmacy isolators, and biological safety cabinets;
2. Disposal containers designed for needles, syringes, and other material used in compounding sterile pharmaceutical products and if applicable, separate containers to dispose of cytotoxic, chemotherapeutic, and infectious waste products;
3. Freezer storage units with thermostatic control and thermometer, if applicable;
4. Packaging or delivery containers capable of maintaining official compendial drug storage conditions;
5. Infusion devices and accessories, if applicable; and
6. In addition to the reference library requirements of R4-23-612, a current reference pertinent to the preparation of sterile pharmaceutical products.

C. Before compounding a sterile pharmaceutical product, the pharmacy permittee, limited-service pharmacy permittee, or pharmacist-in-charge shall:

1. Prepare, implement, and comply with policies and procedures for compounding and dispensing sterile pharmaceutical products,
2. Review biennially and if necessary revise the policies and procedures required under subsection (C)(1),
3. Document the review required under subsection (C)(2),
4. Assemble the policies and procedures as a written manual or by another method approved by the Board or its designee, and
5. Make the policies and procedures available in the pharmacy for employee reference and inspection by the Board or its designee.

D. The assembled policies and procedures shall include, where applicable, the following subjects:

1. Supervisory controls and verification procedures to ensure the quality and safety of sterile pharmaceutical products;
2. Clinical services and drug monitoring procedures for:
  - a. Patient drug utilization reviews;
  - b. Inventory audits;
  - c. Patient outcome monitoring;
  - d. Drug information; and
  - e. Education of pharmacy and other health professionals;
3. Controlled substances;
4. Supervisory controls and verification procedures for:
  - a. Cytotoxics handling, storage, and disposal;
  - b. Disposal of unused supplies and pharmaceutical products; and
  - c. Handling and disposal of infectious wastes;
5. Pharmaceutical product administration, including guidelines for the first dosing of a pharmaceutical product;

6. Drug and component procurement;
  7. Pharmaceutical product compounding, dispensing, and storage;
  8. Duties and qualifications of professional and support staff;
  9. Equipment maintenance;
  10. Infusion devices and pharmaceutical product delivery systems;
  11. Investigational drugs and their protocols;
  12. Patient profiles;
  13. Patient education and safety;
  14. Quality management procedures for:
    - a. Adverse drug reactions;
    - b. Drug recalls;
    - c. Expired pharmaceutical products;
    - d. Beyond-use-dating for both standard-risk and substantial-risk sterile pharmaceutical products consistent with the requirements of R4-23-410(B)(3)(d);
    - e. Temperature and other environmental controls;
    - f. Documented process and product validation testing; and
    - g. Semi-annual certification of the laminar air flow hood or other ISO class 5 environment, other equipment, and the ISO class 7 environment, including documentation of routine cleaning and maintenance for each laminar air flow hood or other ISO class 5 environment, other equipment, and the ISO class 7 environment; and
  15. Sterile pharmaceutical product delivery requirements for:
    - a. Shipment to the patient;
    - b. Security; and
    - c. Maintaining official compendial storage conditions.
- E. Standard-risk sterile pharmaceutical product compounding. Before compounding a standard-risk sterile pharmaceutical product, a pharmacy permittee or pharmacist-in-charge shall ensure compliance with the following minimum standards:
1. Compounding occurs only in an ISO class 5 environment within an ISO class 7 environment, and the ISO class 7 environment may have a specified prep area inside the environment;
  2. Compounding sterile pharmaceutical products from sterile commercial drugs or sterile pharmaceutical otic or ophthalmic products from non-sterile ingredients occurs using procedures that involve only a few closed-system, basic, simple aseptic transfers and manipulations;
  3. Each person who compounds wears adequate personnel protective clothing for sterile preparation that includes gown, gloves, head cover, and booties. Each person who compounds is not required to wear personnel protective clothing when all sterile pharmaceutical compounding occurs within an ISO class 5 environment isolator, and the ISO Class 5 environment isolator is not inside an ISO Class 7 environment; and
  4. Each person who compounds completes an annual media-fill test to validate proper aseptic technique.
- F. Substantial-risk sterile pharmaceutical product compounding. Before compounding a substantial-risk sterile pharmaceutical product, a pharmacy permittee or pharmacist-in-charge shall ensure compliance with the following minimum standards:
1. Compounding parenteral or injectable sterile pharmaceutical products from non-sterile ingredients occurs only in an ISO class 5 environment within an ISO class 7 environment and the ISO class 7 environment shall not have a prep area inside the environment;
  2. Each person who compounds wears adequate personnel protective clothing for sterile preparation that includes gown, gloves, head cover, and booties. Each person who compounds is not required to wear personnel protective clothing when all sterile pharmaceutical compounding occurs within an ISO class 5 environment isolator, and the ISO Class 5 environment isolator is not inside an ISO Class 7 environment; and
  3. Each person who compounds completes a semi-annual media-fill test that simulates the most challenging or stressful conditions for compounding using dry non-sterile media to validate proper aseptic technique.

#### **R4-23-671. General Requirements for Limited-Service Pharmacy**

A. Before opening a limited-service pharmacy, a person shall obtain a permit in compliance with A.R.S. §§ 32-1929, 32-1930, 32-1931, and R4-23-606.

B. The limited-service pharmacy permittee shall secure the limited-service pharmacy by conforming with the following standards:

1. Permit no one to be in the limited-service pharmacy unless the pharmacist-in-charge or a pharmacist authorized by the pharmacist-in-charge is present;
2. Require the pharmacist-in-charge to designate in writing, by name, title, and specific area, those persons who will have access to particular areas of the limited-service pharmacy;
3. Implement procedures to guard against theft or diversion of drugs, including controlled substances; and
4. Require all persons working in the limited-service pharmacy to wear badges, with their names and titles, while on duty.

C. To obtain permission to deviate from the minimum area requirement set forth in R4-23-609, R4-23-673, or R4-23-682, a limited-service pharmacy permittee shall submit a written request to the Board and include documentation that the deviation will facilitate experimentation or technological advances in the practice of pharmacy as defined in A.R.S. § 32-1901. If the Board determines the requested deviation from the minimum area requirement will enhance the practice of pharmacy and benefit the public, the Board shall grant the requested deviation.

D. The Board shall require more than the minimum area in a limited-service pharmacy when the Board determines that equipment, personnel, or other factors in the limited-service pharmacy cause crowding that interferes with safe pharmacy practice.

E. Before dispensing from a limited-service pharmacy, the limited-service pharmacy permittee or pharmacist-in-charge shall:

1. Prepare, implement, and comply with written policies and procedures for pharmacy operations and drug dispensing and distribution,
2. Review biennially and if necessary revise the policies and procedures required under subsection (E)(1),
3. Document the review required under subsection (E)(2),
4. Assemble the policies and procedures as a written manual or by another method approved by the Board or its designee, and
5. Make the policies and procedures available in the pharmacy for employee reference and inspection by the Board or its designee.

#### **R4-23-672. Limited-Service Correctional Pharmacy**

A. The limited-service pharmacy permittee shall ensure that the limited-service correctional pharmacy complies with the standards for area, personnel, security, sanitation, equipment, drug distribution and control, administration of drugs, drug source, quality assurance, investigational drugs, and inspections as set forth in R4-23-608, R4-23-609(A) through (D) and (F) through (H), R4-23-610(A), R4-23-611, R4-23-612, R4-23-653(E), R4-23-658(B) through (E), R4-23-659, and R4-23-660.

B. The pharmacist-in-charge of a limited-service correctional pharmacy shall authorize only pharmacists, interns, pharmacy technicians, pharmacy technician trainees, compliance officers, drug inspectors, peace officers, and correctional officers acting in their official capacities, other persons authorized by law, support personnel, and other designated personnel to be in the limited-service correctional pharmacy.

C. When no pharmacist will be on duty in the correctional facility, the pharmacist-in-charge shall arrange, before there is no pharmacist on duty, for the medical staff and other authorized personnel of the correctional facility to have access to drugs in remote drug storage areas or, if a drug is not available in a remote drug storage area and is required to treat the immediate needs of a patient, in the limited-service correctional pharmacy.

1. The pharmacist-in-charge shall, in consultation with the appropriate committee of the correctional facility, develop and implement procedures to ensure that remote drug storage areas:

- a. Contain only properly labeled drugs that might reasonably be needed and can be administered safely during the pharmacist's absence,
- b. Contain drugs packaged only in amounts sufficient for immediate therapeutic requirements,
- c. Are accessible only with a physician's written order,
- d. Provide a written record of each drug withdrawn,
- e. Are inventoried at least once each week, and
- f. Are audited for compliance with the requirements of this rule at least once each month.

2. The pharmacist-in-charge shall, in consultation with the appropriate committee of the correctional facility, develop and implement procedures to ensure that access to the limited-service correctional pharmacy when no pharmacist is on duty conforms to the following requirements:

- a. Is delegated to only one nurse, who is in a supervisory position;

- b. Is communicated in writing to medical staff of the correctional facility;
- c. Is delegated only to a nurse who has received training from the pharmacist-in-charge in proper methods of access, removal of drugs, and recordkeeping procedures; and
- d. Is delegated by the supervisory nurse to another nurse only in an emergency.

3. When a nurse to whom authority to access the limited-service correctional pharmacy is delegated removes a drug from the limited-service correctional pharmacy, the nurse shall:

a. Record the following information on a form:

- i. Patient's name,
- ii. Name of the drug and its strength and dosage form,
- iii. Dose prescribed,
- iv. Amount of drug removed, and
- v. Date and time of removal;

b. Sign the form recording the drug removal;

c. Attach the original or a direct copy of a physician's written order for the drug to the form recording the drug removal; and

d. Place the form recording the drug removal conspicuously in the limited-service correctional pharmacy.

4. Within four hours after a pharmacist in the limited-service correctional pharmacy returns to duty following an absence in which the limited-service correctional pharmacy was accessed by a nurse to whom authority had been delegated, the pharmacist shall verify all records of drug removal according to R4-23-402.

D. When no pharmacist will be on duty in the correctional facility, the pharmacist-in-charge shall arrange, before there is no pharmacist on duty, for the medical staff and other authorized personnel of the correctional facility to have telephone access to a pharmacist.

E. The limited-service pharmacy permittee shall ensure that the limited-service correctional pharmacy is not without a pharmacist on duty for more than 96 consecutive hours.

F. In addition to the requirements of R4-23-671, the limited-service pharmacy permittee shall secure the limited-service correctional pharmacy as follows:

1. Permit no one to be in the limited-service correctional pharmacy unless a pharmacist is on duty except:

a. As provided in subsection (C)(3) when a pharmacist is not on duty; or

b. A pharmacy technician or pharmacy technician trainee may remain to perform duties in R4-23-1104(A), when a pharmacist is on duty and available in the correctional facility but temporarily absent from the pharmacy, provided:

- i. All controlled substances are secured in a manner that prohibits access by persons other than a pharmacist;
- ii. Activities performed by a pharmacy technician or pharmacy technician trainee while the pharmacist is temporarily absent are verified by the pharmacist immediately upon returning to the pharmacy;
- iii. Any drug measured, counted, poured, or otherwise prepared and packaged by a pharmacy technician or pharmacy technician trainee while the pharmacist is temporarily absent is verified by the pharmacist immediately upon returning to the pharmacy; and
- iv. Any drug that has not been verified by a pharmacist for accuracy is not dispensed, supplied, or distributed while the pharmacist is temporarily absent from the pharmacy; and

2. Provide keyed or programmable locks to all areas of the limited-service correctional pharmacy.

G. The pharmacist-in-charge of a limited-service correctional pharmacy shall ensure that the written policies and procedures for pharmacy operations and drug distribution within the correctional facility include the following:

- 1. Physicians' orders, prescription orders, or both;
- 2. Authorized abbreviations;
- 3. Formulary system;
- 4. Clinical services and drug utilization management including:

- a. Participation in drug selection,
- b. Drug utilization reviews,
- c. Inventory audits,
- d. Patient outcome monitoring,
- e. Committee participation,
- f. Drug information, and
- g. Education of pharmacy and other health professionals;
5. Duties and qualifications of professional and support staff;
6. Products of abuse and contraband medications;
7. Controlled substances;
8. Drug administration;
9. Drug product procurement;
10. Drug compounding, dispensing, and storage;
11. Stop orders;
12. Pass or discharge medications;
13. Investigational drugs and their protocols;
14. Patient profiles;
15. Quality management procedures for:
  - a. Adverse drug reactions;
  - b. Drug recalls;
  - c. Expired and beyond-use-date drugs;
  - d. Medication or dispensing errors;
  - e. Drug storage; and
  - f. Education of professional staff, support staff, and patients;
16. Recordkeeping;
17. Sanitation;
18. Security;
19. Access to remote drug storage areas by non-pharmacists; and
20. Access to limited-service correctional pharmacy by non-pharmacists.

**R4-23-673. Limited-Service Mail-order Pharmacy**

- A. The limited-service pharmacy permittee shall design and construct the limited-service mail-order pharmacy to conform with the following requirements:
1. A dispensing area devoted to stocking, compounding, and dispensing prescription medications, which is physically separate from a non-dispensing area devoted to non-dispensing pharmacy services;
  2. A dispensing area of at least 300 square feet if three or fewer persons work in the dispensing area simultaneously;
  3. A dispensing area that provides 300 square feet plus 60 square feet for each person in excess of three persons if more than three persons work in the dispensing area simultaneously;

4. Space in the dispensing area permits efficient pharmaceutical practice, free movement of personnel, and visual surveillance by the pharmacist;
  5. A non-dispensing area of at least 30 square feet for each person working simultaneously in the non-dispensing area; and
  6. Space in the non-dispensing area permits free movement of personnel and visual surveillance by the pharmacist; or
- B. The limited-service pharmacy permittee shall design and construct the limited-service mail-order pharmacy to conform with the following requirements:
1. A contiguous area in which both dispensing and non-dispensing pharmacy services are provided;
  2. A contiguous area of at least 300 square feet if three or fewer persons work in the area simultaneously;
  3. A contiguous area that provides 300 square feet plus 60 square feet for each person in excess of three persons if more than three persons work in the area simultaneously; and
  4. Space in the contiguous area permits efficient pharmaceutical practice, free movement of personnel, and visual surveillance by the pharmacist.
- C. The limited-service pharmacy permittee shall ensure that the limited-service mail-order pharmacy complies with the standards for area, personnel, security, sanitation, and equipment set forth in R4-23-608, R4-23-609(B) through (H), R4-23-610 (A) and (C) through (F), R4-23-611, and R4-23-612.
- D. The pharmacist-in-charge of a limited-service mail-order pharmacy shall authorize only pharmacists, interns, pharmacy technicians, pharmacy technician trainees, compliance officers, drug inspectors, peace officers acting in their official capacities, support personnel, other persons authorized by law, and other designated personnel to be in the limited-service mail-order pharmacy.
- E. The pharmacist-in-charge of a limited-service mail-order pharmacy shall ensure that prescription medication is delivered to the patient or locked in the dispensing area when a pharmacist is not present in the pharmacy.
- F. In addition to the delivery requirements of R4-23-402, the limited-service pharmacy permittee shall, during regular hours of operation but not less than five days and a minimum 40 hours per week, provide toll-free telephone service to facilitate communication between patients and a pharmacist who has access to patient records at the limited-service mail-order pharmacy. The limited-service pharmacy permittee shall disclose this toll-free number on a label affixed to each container of drugs dispensed from the limited-service mail-order pharmacy.
- G. The pharmacist-in-charge of a limited-service mail-order pharmacy shall ensure that the written policies and procedures for pharmacy operations and drug distribution include the following:
1. Prescription orders;
  2. Clinical services and drug utilization management for:
    - a. Drug utilization reviews,
    - b. Inventory audits,
    - c. Patient outcome monitoring,
    - d. Drug information, and
    - e. Education of pharmacy and other health professionals;
  3. Duties and qualifications of professional and support staff;
  4. Controlled substances;
  5. Drug product procurement;
  6. Drug compounding, dispensing, and storage;
  7. Patient profiles;
  8. Quality management procedures for:
    - a. Adverse drug reactions,
    - b. Drug recalls,
    - c. Expired and beyond-use-date drugs,

- d. Medication or dispensing errors, and
- e. Education of professional and support staff;
- 9. Recordkeeping;
- 10. Sanitation;
- 11. Security;
- 12. Drug delivery requirements for:
  - a. Transportation,
  - b. Security,
  - c. Temperature and other environmental controls,
  - d. Emergency provisions, and
- 13. Patient education.

**R4-23-674. Limited-Service Long-Term Care Pharmacy**

A. A limited-service pharmacy permittee shall ensure that the limited-service long-term care pharmacy complies with:

- 1. The general requirements of R4-23-671;
- 2. The professional practice standards of Article 4 and Article 11; and
- 3. The permits and drug distribution standards of R4-23-606 through R4-23-612, R4-23-670, and this Section.

B. If a limited-service long-term care pharmacy permittee contracts with a long-term care facility as a Provider Pharmacy, as defined in R4-23-110, the limited-service long-term care pharmacy permittee shall ensure that the long-term care consultant pharmacist and the pharmacist-in-charge of the limited-service long-term care pharmacy comply with R4-23-701, R4-23-701.01, R4-23-701.02, R4-23-701.03, R4-23-701.04 and this Section.

C. The limited-service long-term care pharmacy permittee or pharmacist-in-charge shall ensure that prescription medication is delivered to the patient's long-term care facility or locked in the dispensing area of the pharmacy when a pharmacist is not present in the pharmacy.

D. The pharmacist-in-charge of a limited-service long-term care pharmacy shall authorize only those individuals listed in R4-23-610(B) to be in the limited-service long-term care pharmacy.

E. In consultation with the long-term care facility's medical director and director of nursing, the long-term care consultant pharmacist and pharmacist-in-charge of the long-term care facility's provider pharmacy may develop, if necessary, a medication formulary for the long-term care facility that ensures the safe and efficient procurement, dispensing, distribution, administration, and control of drugs in the long-term care facility.

F. The limited-service long-term care pharmacy permittee or pharmacist-in-charge shall ensure that the written policies and procedures required in R4-23-671(E) include the following:

- 1. Clinical services and drug utilization management for:
  - a. Drug utilization reviews,
  - b. Inventory audits,
  - c. Patient outcome monitoring,
  - d. Drug information, and
  - e. Education of pharmacy and other health professionals;
- 2. Controlled substances;
- 3. Drug compounding, dispensing, and storage;
- 4. Drug delivery requirements for:
  - a. Transportation,

- b. Security,
- c. Temperature and other environmental controls, and
- d. Emergency provisions;
- 5. Drug product procurement;
- 6. Duties and qualifications of professional and support staff;
- 7. Emergency drug supply unit procedures;
- 8. Formulary, including development, review, modification, use, and documentation, if applicable;
- 9. Patient profiles;
- 10. Patient education;
- 11. Prescription orders, including:
  - a. Approved abbreviations
  - b. Stop-order procedures, and
  - c. Leave-of-absence and discharge prescription order procedures;
- 12. Quality management procedures for:
  - a. Adverse drug reactions,
  - b. Drug recalls,
  - c. Expired and beyond-use-date drugs,
  - d. Medication or dispensing errors, and
  - e. Education of professional and support staff;
- 13. Recordkeeping;
- 14. Sanitation; and
- 15. Security.

**R4-23-675. Limited-Service Sterile Pharmaceutical Products Pharmacy**

A. The limited-service pharmacy permittee or the pharmacist-in-charge shall ensure that the limited-service sterile pharmaceutical products pharmacy complies with the standards for area, personnel, security, sanitation, equipment, sterile pharmaceutical products, and limited-service pharmacies established in R4-23-608, R4-23-609, R4-23-610, R4-23-611, R4-23-612, R4-23-670, and R4-23-671.

B. The pharmacist-in-charge of a limited-service sterile pharmaceutical products pharmacy shall authorize only pharmacists, interns, compliance officers, peace officers acting in their official capacities, pharmacy technicians, pharmacy technician trainees, support personnel, and other designated personnel to be in the limited-service sterile pharmaceutical products pharmacy.

C. The pharmacist-in-charge of a limited-service sterile pharmaceutical products pharmacy shall ensure that prescription medication is delivered to the patient or locked in the dispensing area when a pharmacist is not present in the pharmacy.

D. In addition to the delivery requirements of R4-23-402, the limited-service pharmacy permittee shall, during regular hours of operation, but not less than a minimum 40 hours per week, provide toll-free telephone service to facilitate communication between patients and a pharmacist who has access to patient records at the limited-service sterile pharmaceutical products pharmacy. The limited-service pharmacy permittee shall disclose this toll-free number on a label affixed to each container dispensed from the limited-service sterile pharmaceutical products pharmacy.

E. The limited-service pharmacy permittee or the pharmacist-in-charge shall ensure development, implementation, review and revision in the same manner described in R4-23-671(E) and compliance with policies and procedures for pharmacy operations, including pharmaceutical product compounding, dispensing, and distribution, that comply with the requirements of R4-23-402, R4-23-410, R4-23-670, and R4-23-671.

F. The non-dispensing roles of the pharmacist may include chart reviews, audits, drug therapy monitoring, committee participation, drug information, and in-service training of pharmacy and other health professionals.

**R4-23-676. Thru 4-23-680. Reserved**

**R4-23-681. General Requirements for Limited-Service Nuclear Pharmacy**

A. To be an authorized nuclear pharmacist, a pharmacist shall:

1. Hold a current pharmacist license issued by the Board; and

2. Be certified as a nuclear pharmacist by:

a. The Board of Pharmaceutical Specialties, or

b. A similar group recognized by the Arizona State Board of Pharmacy; or

3. Satisfy each of the following requirements:

a. Meet minimal standards of training for status as an authorized user of radioactive material, as specified by the Arizona Radiation Regulatory Agency and the United States Nuclear Regulatory Commission;

b. Submit certification of completion of a Board-approved nuclear pharmacy training program or other training program recognized by the Arizona Radiation Regulatory Agency, with 200 hours of didactic training in the following areas:

i. Radiation physics and instrumentation,

ii. Radiation protection,

iii. Mathematics pertaining to the use and measurement of radioactivity,

iv. Radiation biology, and

v. Radiopharmaceutical chemistry;

c. Submit evidence of a minimum of 500 hours of clinical/practical nuclear pharmacy training under the supervision of an authorized nuclear pharmacist in the following areas:

i. Procuring radioactive materials;

ii. Compounding radiopharmaceuticals;

iii. Performing routine quality control procedures;

iv. Dispensing radiopharmaceuticals;

v. Distributing radiopharmaceuticals;

vi. Implementing basic radiation protection procedures; and

vii. Consulting and educating the nuclear medicine community, patients, pharmacists, other health professionals, and the general public; and

d. Submit written certification, signed by a preceptor who is an authorized nuclear pharmacist, that the above training was satisfactorily completed.

B. Radiopharmaceuticals are prescription-only drugs that require specialized techniques in their handling and testing, to obtain optimum results and minimize hazards.

1. A person shall not sell, barter, or otherwise dispose of, or be in possession of any radiopharmaceutical except under the conditions detailed in A.R.S. § 32-1929.

2. A person shall not manufacture, compound, sell, or dispense any radiopharmaceutical unless the person is a pharmacist or a pharmacy intern acting under the direct supervision of a pharmacist in accordance with A.R.S. § 32-1961 and these rules, with the exception of the following, if the following are licensed by the Arizona Radiation Regulatory Agency to use radiopharmaceuticals in compliance with A.R.S. § 30-673;

a. A medical practitioner who administers a radiopharmaceutical to the medical practitioner's patient as provided in A.R.S. § 32-1921(A),

b. A hospital nuclear medicine department, and

c. A medical practitioner's office.

3. The Board shall cooperate with the Arizona Radiation Regulatory Agency and other interested state and federal agencies, in the enforcement of these rules for the protection of the public. This cooperation may include exchange of licensing and other information, joint inspections, and other activities where indicated.

C. In addition to compliance with all the applicable federal and state laws and rules governing drugs, whether radioactive or not, a limited-service nuclear pharmacy permittee shall comply with all laws and rules of the Arizona Radiation Regulatory Agency and the U.S. Nuclear Regulatory Commission, including emergency and safety provisions.

D. A limited-service nuclear pharmacy permittee shall comply with the education, experience, and licensing requirements of the Arizona Radiation Regulatory Agency.

E. A limited-service nuclear pharmacy permittee shall ensure that radiopharmaceuticals are transferred only to a person or firm that holds a current Radioactive Materials License issued by the Arizona Radiation Regulatory Agency.

#### **R4-23-682. Limited-Service Nuclear Pharmacy**

A. Before operating a limited-service nuclear pharmacy, a person shall obtain a permit in compliance with A.R.S. §§ 32-1929, 32-1930, and 32-1931, and R4-23-606.

B. A permit to operate a limited-service nuclear pharmacy shall be issued only to a person who is or employs an authorized nuclear pharmacist and holds a current Arizona Radiation Regulatory Agency Radioactive Materials License. A limited-service nuclear pharmacy permittee that fails to maintain a current Arizona Radiation Regulatory Agency Radioactive Materials License shall be immediately suspended pending revocation by the Board. A limited-service nuclear pharmacy permittee shall have copies of Arizona Radiation Regulatory Agency inspection reports available upon request for Board inspection.

1. A limited-service nuclear pharmacy permittee shall designate an authorized nuclear pharmacist as the pharmacist-in-charge. The pharmacist-in-charge shall be responsible to the Board:

- a. For the operations of the pharmacy related to the practice of pharmacy and distribution of drugs and devices;
- b. For communicating Board directives to the management, pharmacists, interns, and other personnel of the pharmacy; and
- c. For the pharmacy's compliance with all federal and state pharmacy laws and rules.

2. An authorized nuclear pharmacist shall directly supervise all personnel performing tasks in the preparation and distribution of radiopharmaceuticals and ancillary drugs.

3. An authorized nuclear pharmacist shall be present whenever the limited-service nuclear pharmacy is open for business.

C. A limited-service nuclear pharmacy permittee shall ensure that the limited-service nuclear pharmacy complies with the standards for personnel, area, security, sanitation, and general requirements in R4-23-608, R4-23-609, R4-23-610, R4-23-611, and R4-23-671.

1. A limited-service nuclear pharmacy shall contain separate areas for:

- a. Preparing and dispensing radiopharmaceuticals,
- b. Receiving and shipping radiopharmaceuticals,
- c. Storing radiopharmaceuticals, and
- d. Decaying radioactive waste.

2. The Board may require more than the minimum area in instances where equipment, inventory, personnel, or other factors cause crowding to a degree that interferes with safe pharmacy practice.

D. The pharmacist-in-charge shall designate in writing, by title and specific area, the persons who may have access to particular pharmacy areas.

E. A limited-service nuclear pharmacy permittee shall maintain records of acquisition, inventory, and disposition of radiopharmaceuticals, other radioactive substances, and other drugs in accordance with federal and state statutes and rules.

1. A prescription order, in addition to the requirements in A.R.S. § 32-1968(C) and R4-23-407(A), shall contain:

- a. The date and time of calibration of the radiopharmaceutical,
- b. The name of the procedure for which the radiopharmaceutical is prescribed, and
- c. The words "Physician's Use Only" instead of the name of the patient if the radiopharmaceutical is nontherapeutic or for a nonblood product.

2. The lead container used to store and transport a radio-pharmaceutical shall have a label that, in addition to the requirements in A.R.S. § 32-1968(D), includes:

- a. The date and time of calibration of the radiopharmaceutical,
- b. The name of the radiopharmaceutical,
- c. The molybdenum 99 content to USP limits,
- d. The name of the procedure for which the radiopharmaceutical is prescribed,
- e. The words "Physician's Use Only" instead of the name of the patient if the radiopharmaceutical is nontherapeutic or for a nonblood product,
- f. The words "Caution: Radioactive Material," and
- g. The standard radiation symbol.

3. The radiopharmaceutical container shall have a label that includes:

- a. The date and time of calibration of the radiopharmaceutical;
- b. The name of the patient, recorded before dispensing, if the radiopharmaceutical is therapeutic or for a blood product;
- c. The words "Physician's Use Only" instead of the name of the patient if the radiopharmaceutical is nontherapeutic or for a nonblood product;
- d. The name of the radiopharmaceutical;
- e. The dose of radiopharmaceutical;
- f. The serial number;
- g. The words "Caution: Radioactive Material"; and
- h. The standard radiation symbol.

F. The following minimum requirements are in addition to the requirements of the Arizona Radiation Regulatory Agency, the applicable U.S. Nuclear Regulatory Commission regulations, and the applicable regulations of the federal Food and Drug Administration. A limited-service nuclear pharmacy permittee shall provide:

1. In addition to the minimum pharmacy area requirements in R4-23-609:

- a. An area for the storing, compounding, and dispensing of radiopharmaceuticals completely separate from pharmacy areas for nonradioactive drugs;
- b. A minimum of 80 sq. ft. for a hot lab and storage area; and
- c. A minimum of 300 sq. ft. of compounding and dispensing area;

2. The following equipment:

- a. Fume hood, approved by the Arizona Radiation Regulatory Agency;
- b. Laminar flow hood;
- c. Dose calibrator;
- d. Refrigerator;
- e. Prescription balance, Class A, and weights or an electronic balance of equal or greater accuracy;
- f. Well scintillation counter;
- g. Incubator oven;
- h. Microscope;
- i. An assortment of labels, including prescription labels and cautionary and warning labels;
- j. Glassware necessary for compounding and dispensing radiopharmaceuticals as required by the Arizona Radiation Regulatory Agency;
- k. Other equipment necessary for radiopharmaceutical quality control for products compounded or dispensed as required by the Arizona Radiation Regulatory Agency;
- l. Current antidote and drug interaction information; and

- m. Regional poison control phone number prominently displayed in the pharmacy area;
- 3. Supplies necessary for compounding and dispensing radiopharmaceuticals as required by the Arizona Radiation Regulatory Agency;
- 4. A professional reference library consisting of a minimum of one current reference or text addressing each of the following subject areas:
  - a. Therapeutics,
  - b. Nuclear pharmacy practice, and
  - c. Imaging;
- 5. Current editions and supplements of:
  - a. A.R.S. §§ 30-651 through 30-696 pertaining to the Arizona Radiation Regulatory Agency,
  - b. Rules of the Arizona Radiation Regulatory Agency,
  - c. Regulations of the federal Food and Drug Administration pertaining to radioactive drugs,
  - d. Arizona Pharmacy Act and rules,
  - e. Arizona Uniform Controlled Substances Act, and
  - f. Radiological Health Handbook.
- G. The pharmacist-in-charge of a limited-service nuclear pharmacy shall prepare, implement, review, and revise in the same manner described in R4-23-671(E) and comply with written policies and procedures for pharmacy operations and drug distribution.
- H. The written policies and procedures of a limited-service nuclear pharmacy shall include the following:
  - 1. Prescription orders;
  - 2. Clinical services and drug utilization management including:
    - a. Drug utilization reviews,
    - b. Inventory audits,
    - c. Patient outcome monitoring,
    - d. Drug information, and
    - e. Education of pharmacy and other health professionals;
  - 3. Duties and qualifications of professional and support staff;
  - 4. Radioactive material handling, storage, and disposal;
  - 5. Drug product procurement;
  - 6. Drug compounding, dispensing, and storage;
  - 7. Investigational drugs and their protocols;
  - 8. Patient profiles;
  - 9. Quality management procedures for:
    - a. Adverse drug reaction reports;
    - b. Drug recall;
    - c. Expired and beyond-use-date drugs;
    - d. Medication or dispensing errors;
    - e. Radiopharmaceutical quality assurance;
    - f. Radiological health and safety;

- g. Drug storage and disposition; and
- h. Education of professional staff, support staff, and patients;
- 10. Recordkeeping;
- 11. Sanitation;
- 12. Security;
- 13. Drug delivery requirements for:
  - a. Transportation,
  - b. Security,
  - c. Radiological health and safety procedures,
  - d. Temperature and other environmental controls, and
  - e. Emergency provisions; and
- 14. Patient education.

**R4-23-683. Thru R4-23-690. Reserved**

**R4-23-691. Repealed**

**R4-23-692. Compressed Medical Gas Distributor**

**A. Permit.**

1. A person shall not manufacture, process, transfill, package, or label a compressed Medical in Arizona, or manufacture, process, transfill, package, or label a compressed medical gas outside Arizona and ship into Arizona without a current Board-issued resident or nonresident compressed medical gas distributor permit.

2. Before operating as a compressed medical gas distributor, a person shall register with the FDA as a medical gas manufacturer and comply with the drug listing requirements of the federal act.

**B. Application.** To obtain a resident or nonresident CMG distributor permit, a person shall submit a completed application form and fee as specified in R4-23-602.

1. A resident CMG distributor permit applicant shall include documentation of compliance with local zoning laws, if required by the Board.

2. A nonresident CMG distributor permit applicant that resides in a jurisdiction that issues an equivalent license or permit shall include a copy of the equivalent license or permit.

**C. Notification.** A resident or nonresident CMG distributor permittee shall provide written notice by mail, facsimile, or e-mail to the Board office within ten days of changes involving the telephone number, facsimile number, e-mail address, mailing address, or name of business.

**D. Change of ownership.** No less than 14 days before a change of ownership occurs that involves changes of stock ownership of 30% or more of the voting stock of a corporation or an existing and continuing corporation that is not actively traded on any securities market or over-the-counter market, the prospective owner shall submit a completed application form and fee as specified in subsection (B).

**E. Relocation.**

1. No less than 30 days before an existing resident CMG distributor permittee relocates, the permittee shall submit a completed application for relocation electronically or manually on a form furnished by the Board, and the documentation required in subsection (B).

2. A nonresident CMG distributor permittee shall provide written notice by mail, facsimile, or e-mail to the Board office no less than ten days before relocating.

**F. A resident or nonresident CMG distributor permittee shall sell or distribute a compressed medical gas pursuant to a compressed medical gas order only to durable medical equipment and compressed medical gas suppliers and other entities that are registered, licensed, or permitted to use, administer, or distribute compressed medical gases.**

**G. Facility.** A resident or nonresident CMG distributor permittee shall ensure the facility is clean, uncluttered, sanitary, temperature controlled, and secure from unauthorized access.

H. Current Good Manufacturing Practice: A resident or nonresident CMG distributor permittee shall comply with the current good manufacturing practice requirements of 21 CFR parts 210 and 211, (Revised April 1, 2013, incorporated by reference and on file with the Board and available at [www.gpo.gov](http://www.gpo.gov). This incorporated material includes no future editions or amendments).

I. Records: A resident or nonresident CMG distributor permittee shall establish and implement written procedures for maintaining records pertaining to production, transfilling, process control, labeling, packaging, quality control, distribution, returns, recalls, training of personnel, complaints, and any information required by federal or state law.

1. A permittee shall retain the records required by Section R4-23-601, this Section, and 21 CFR parts 210 and 211 for not less than three years or one year after the expiration date of the compressed medical gas, whichever is longer.

2. A permittee shall make the records required by Section R4-23-601, this Section, and 21 CFR parts 210 and 211 available on inspection by the Board or its compliance officer, or if stored in a centralized recordkeeping system apart from the inspection location and not electronically retrievable, shall provide the records within four working days of a request by the Board or its compliance officer.

J. Inspection.

1. A resident CMG distributor permittee shall make the CMG distributor's facility available for inspection by the Board or its compliance officers under A.R.S. § 32-1904.

2. Within ten days from the date of a request by the Board or its staff, a nonresident CMG distributor permittee shall provide a copy of the most recent inspection report completed by the permittee's resident licensing authority or the FDA, or a copy of the most recent inspection report completed by a third-party auditor approved by the permittee's resident licensing authority or the Board or its designee. The Board may inspect, or may employ a third-party auditor to inspect, a nonresident permittee as specified in A.R.S. § 32-1904.

K. Permit renewal. Permit renewal shall be as specified in R4-23-602(D).

L. Nothing in this Section shall be construed to prohibit the emergency administration of oxygen by licensed health care personnel, emergency medical technicians, first responders, fire fighters, law enforcement officers, and other emergency personnel trained in the proper use of emergency oxygen.

#### **R4-23-693. Durable Medical Equipment (DME) and Compressed Medical Gas (CMG) Supplier-Resident or Nonresident**

A. Permit. A person shall not sell, lease, or supply durable medical equipment or a compressed medical gas to a patient or consumer in Arizona for use in a home or residence without a current Board-issued resident or nonresident durable medical equipment and compressed medical gas supplier permit.

1. The permit requirements of this Section shall not apply to the following unless there is a separate business entity engaged in the business of providing durable medical equipment or a compressed medical gas to a patient or consumer for use in a home or residence:

a. A medical practitioner licensed under A.R.S. Title 32;

b. A hospital, long-term care facility, hospice, or other health care facility using durable medical equipment or a compressed medical gas in the normal course of treating a patient; and

c. A pharmacy.

2. Nothing in this Section shall be construed to prohibit a person with a current Board-issued nonprescription drug permit from the retail sale of nonprescription drugs or devices.

B. Application. To obtain a resident or nonresident DME and CMG supplier permit, a person shall submit a completed application form and fee as specified in R4-23-602.

1. A resident DME and CMG supplier permit applicant shall include documentation of compliance with local zoning laws, if required by the Board.

2. A nonresident DME and CMG supplier permit applicant that resides in a jurisdiction that issues an equivalent license or permit shall include a copy of the equivalent license or permit.

C. Notification. A resident or nonresident DME and CMG supplier permittee shall provide written notice by mail, facsimile, or e-mail to the Board office within ten days of changes involving the telephone number, facsimile number, email address, mailing address, or name of business.

D. Change of ownership. No less than 14 days before a change of ownership occurs that involves changes of stock ownership of 30% or more of the voting stock of a corporation or an existing and continuing corporation that is not actively traded on any securities market or over-the-counter market, the prospective owner shall submit a completed application form and fee as specified in subsection (B).

E. Relocation.

1. No less than 30 days before an existing resident DME and CMG supplier permittee relocates, the permittee shall submit a completed application for relocation electronically or manually on a form furnished by the Board, and the documentation required in subsection (B).

2. A nonresident DME and CMG supplier permittee shall provide written notice by mail, facsimile, or e-mail to the Board office no less than ten days before relocating.

F. Orders. A resident or nonresident DME and CMG supplier shall sell, lease, or provide:

1. Durable medical equipment that is a prescription-only device as defined in A.R.S. § 32-1901(75) only pursuant to a prescription order or medication order from a medical practitioner; and

2. A compressed medical gas only pursuant to a compressed medical gas order from a medical practitioner.

G. Restriction. A DME and CMG supplier permit shall authorize the permittee to procure, possess, and provide a prescription-only device or compressed medical gas to a patient or consumer as specified in subsection (F). A DME and CMG supplier permit does not authorize the permittee to procure, possess, or provide narcotics or other controlled substances, prescription-only drugs other than compressed medical gases, precursor chemicals, or regulated chemicals.

H. Facility. A resident or nonresident DME and CMG supplier permittee shall ensure the facility is clean, uncluttered, sanitary, temperature controlled, and secure from unauthorized access. A permittee shall maintain separate and identified storage areas in the facility and in the delivery vehicles for clean, dirty, contaminated, or damaged durable medical equipment or compressed medical gases.

I. A resident or nonresident DME and CMG supplier permittee shall not manufacture, process, transfill, package, or label a compressed medical gas, except as set forth in subsection (J).

J. Records. A resident or nonresident DME and CMG supplier permittee shall establish and implement written procedures for maintaining records pertaining to acquisition, distribution, returns, recalls, training of personnel, maintenance, cleaning, and complaints. A permittee shall:

1. Ensure that a prescription order, medication order, or compressed medical gas order is obtained as specified in subsection (F);

2. Ensure that each compressed medical gas container supplied by the permittee contains a label bearing the name and address of the permittee;

3. Ensure that all appropriate warning labels are present on the durable medical equipment or compressed medical gas;

4. Retain the records required by Section R4-23-601 and this Section for not less than three years, or if supplying a compressed medical gas, one year after the expiration date of the compressed medical gas, whichever is longer; and

5. Make the records required by Section R4-23-601 and this Section available on inspection by the Board or its compliance officer, or if stored in a centralized recordkeeping system apart from the inspection location and not electronically retrievable for inspection, shall provide the records within four working days of a request by the Board or its staff.

K. Inspection.

1. A resident DME and CMG supplier permittee shall make the DME and CMG supplier's facility available for inspection by the Board or its compliance officers under A.R.S. § 32-1904.

2. Within ten days from the date of a request by the Board or its staff, a nonresident DME and CMG supplier permittee shall provide a copy of the most recent inspection report completed by the permittee's resident licensing authority, or a copy of the most recent inspection report completed by a third-party auditor approved by the permittee's resident licensing authority or the Board or its designee. The Board may inspect, or may employ a third-party auditor to inspect, a nonresident permittee as specified in A.R.S. § 32-1904.

L. Permit renewal. Permit renewal shall be as specified in R4-23-602(D).

M. Nothing in this Section shall be construed to prohibit the emergency administration of oxygen by licensed health care personnel, emergency medical technicians, first responders, fire fighters, law enforcement officers, and other emergency personnel trained in the proper use of emergency oxygen.

#### **ARTICLE 7. NON-PHARMACY LICENSED OUTLETS - GENERAL PROVISIONS:**

##### **R4-23-701. Long-Term Care Facilities Pharmacy Services: Consultant Pharmacist**

A. The long-term care consultant pharmacist as defined in R4-23-110 shall:

1. Possess a valid Arizona pharmacist license issued by the Board;

2. Ensure the provision of pharmaceutical patient care services as defined in R4-23-110;

3. Review the distribution and storage of drugs and devices and assist the facility in establishing policies and procedures for the distribution and storage of drugs and devices.

4. Provide resident evaluation programs that relate to monitoring the therapeutic response and utilization of all drugs and devices prescribed or administered to residents, using as guidelines the most current indicators established by the Centers for Medicare and Medicaid Services, United States Department of Health and Human Services as required in 42 CFR 483.60 (revised October 1, 2010, incorporated by reference and on file with the Board. This incorporated material contains no future editions or amendments.).

5. Serve as a resource for pharmacy-related education services within the facility;
6. Participate in quality management of resident care in the facility;
7. Communicate with the provider pharmacy regarding areas of mutual concern and resolution.

B. A long-term care consultant pharmacist shall ensure that:

1. When a provider pharmacy is not open for business, arrangements are made in advance by the long-term care consultant pharmacist, in cooperation with the pharmacist-in-charge of the provider pharmacy and the director of nursing and medical staff of the long-term care facility, for providing emergency drugs for the licensed nursing staff to administer to the residents of the facility using an emergency drug supply unit located at the facility;
2. The label and packaging of prescription-only and nonprescription drugs intended for use within a long-term care facility complies with state and federal law; and
3. The long-term care facility:
  - a. Stores controlled substances listed in A.R.S. § 36-2513 in a separately locked and permanently affixed compartment, unless the facility uses a single-unit package medication distribution system, and
  - b. Maintains accurate records of controlled substance administration or ultimate disposition.

C. The long-term care consultant pharmacist shall:

1. Ensure availability of records and reports designed to provide the data necessary to evaluate the drug use of each long-term care facility resident that include the following:
  - a. Provider pharmacy patient profiles and long-term care facility medication administration records;
  - b. Reports of suspected adverse drug reactions;
  - c. Inspection reports of drug storage areas with emphasis on detecting outdated drugs; and
  - d. Accountability reports, that include:
    - i. Date and time of administration,
    - ii. Name of the person who administered the drug,
    - iii. Documentation and verification of any wasted or partial doses,
    - iv. Exception reports for refused doses, and
    - v. All drug destruction forms; and
2. Identify and report drug irregularities and dispensing errors to the prescriber, the director of nursing of the facility, and the provider pharmacy.

D. A long-term care consultant pharmacist or pharmacist-in-charge of a provider pharmacy shall ensure that:

1. Discontinued or outdated drugs, including controlled substances, are destroyed or disposed of in a timely manner using methods consistent with federal, state, and local requirements and subject to review by the Board or its staff; and
2. Drug containers with illegible or missing labels are:
  - a. Identified; and
  - b. Replaced or relabeled by a pharmacist employed by the pharmacy that dispensed the prescription medication.

#### **R4-23-701.01. Long-Term Care Facilities Pharmacy Services: Provider Pharmacy**

The limited-service pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall ensure that:

1. A prescription medication is provided only by a valid prescription order for an individual long-term care facility resident, properly labeled for that resident, as specified in this subsection. Nothing in this Section shall prevent a provider pharmacy from supplying nonprescription drugs in a manufacturer's unopened container or emergency drugs using an emergency drug supply unit as specified in R4-23-701.02;
2. A prescription medication label for a long-term care facility resident complies with A.R.S. § 32-1968, and A.R.S. § 36-2525 and contains:
  - a. The drug name, strength, dosage form, and quantity; and

b. The beyond-use-date;

3. Only a pharmacist employed by the pharmacy that dispensed the prescription medication may, through the exercise of professional judgment, re-label or alter a prescription medication label that is illegible or missing;

4. The provider pharmacy develops and implements drug recall policies and procedures that protect the health and safety of facility residents. The drug recall procedures shall include immediate discontinuation of any patient level recalled drug and notification of the prescriber and director of nursing of the facility; and

5. Drugs previously dispensed to a resident of the long-term care facility by another pharmacy, and drugs previously dispensed by the provider pharmacy, are not repackaged.

#### **R4-23-701.02. Long-Term Care Facilities Pharmacy Services: Emergency Drugs**

A. The limited-service pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall ensure that:

1. An emergency drug supply unit is available within the long-term care facility,

2. Drugs contained in an emergency drug supply unit remain the property of the provider pharmacy, and

3. Controlled substance drugs contained in an emergency drug supply unit are included in all inventories required under A.R.S. § 36-2523(B) and R4-23-1003(A).

B. An emergency drug supply unit shall meet the following criteria:

1. The drugs are necessary to meet the immediate and emergency therapeutic needs of long-term care facility residents as determined by the provider pharmacy's pharmacist-in-charge in consultation with the long-term care facility's medical director and nursing director;

2. The purpose of the emergency drug supply unit in a long-term care facility is not to relieve a provider pharmacy of the responsibility for timely provision of the resident's routine drug needs, but to ensure that an emergency drug supply unit is available for facility residents in need of immediate and emergency therapeutic drugs; and

3. The drugs are provided in a manufacturer's unit of package or are prepackaged and labeled to include the drug name, strength, dosage form, manufacturer, lot number, and expiration date and provider pharmacy's name, address, telephone number, and pharmacist's initials.

C. The limited-service pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall ensure that an emergency drug supply unit:

1. Is stored in an area that:

a. Is temperature controlled; and

b. Prevents unauthorized access;

2. Contains on the exterior of the emergency drug supply unit a label to indicate that the contents are for emergency use only;

3. Contains on the exterior of the emergency drug supply unit a complete list of the contents of the unit by drug name, strength, dosage form, and quantity and the provider pharmacy's name, address, and telephone number;

4. Contains on the exterior of the emergency drug supply unit a label that indicates the date of the earliest drug expiration date;

5. Contains on the exterior of the emergency drug supply unit a label that indicates the date of and pharmacist responsible for the last inspection of the emergency drug supply unit; and

6. Is secured with a tamper-evident seal, or is locked and sealed in a manner that obviously reveals when the unit has been opened or tampered with.

D. The limited-service pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall:

1. Prepare, implement, review, and revise in the same manner described in R4-23-671(E) and comply with written policies and procedures for the storage and use of an emergency drug supply unit in a long-term care facility;

2. Make the policies and procedures available in the provider pharmacy and long-term care facility for employee reference and inspection by the Board or its staff;

3. Ensure that the written policies and procedures include the following:

a. Drug removal procedures that requires:

i. The long-term care facility's personnel receive a valid prescription order for each drug removed from the emergency drug supply unit,

- ii. The long-term care facility's personnel notify the provider pharmacy when a drug is removed from the emergency drug supply unit, and
- b. Outdated drug replacement procedures, and
- c. Security and inspection procedures;
- 4. Exchange or restock the emergency drug supply unit weekly, or more often as necessary, to ensure the availability of an adequate supply of emergency drugs within the long-term care facility. Restocking of the emergency drug supply unit at the facility shall be completed by an Arizona licensed pharmacist employed by the provider pharmacy, or by an Arizona licensed intern, technician or technician trainee under the direct on-site supervision of an Arizona licensed pharmacist; and
- 5. Educate pharmacy and long-term care facility personnel in the storage and use of an emergency drug supply unit.
- E. In addition to the requirements of subsections (A) through (D), an automated emergency drug supply unit may be used, provided:
  - 1. The pharmacy permittee or pharmacist-in-charge of the provider pharmacy notifies the Board or its staff in writing of the intent to use an automated emergency drug supply unit, including the name and type of unit;
  - 2. The provider pharmacy is notified electronically when the automated emergency drug supply unit has been accessed;
  - 3. All events involving the access of the automated emergency drug supply unit are recorded electronically and maintained for not less than two years;
  - 4. The provider pharmacy is capable of producing a report of all transactions of the automated emergency drug supply unit including a single drug usage report as required in R4-23-408(B)(5) on inspection by the Board or its staff;
  - 5. The provider pharmacy develops written policies and procedures for:
    - a. Accessing the automated emergency drug supply unit in the event of a system malfunction or downtime,
    - b. Authorizing and modifying user access,
  - c. An ongoing quality assurance program that includes:
    - i. Training in the use of the automated emergency drug supply unit for all authorized users,
    - ii. Maintenance and calibration of the automated emergency drug supply unit as recommended by the device manufacturer; and
  - 6. Documentation of the requirements of subsection (E)(5)(c)(ii) is maintained for inspection by the Board or its staff for not less than two years.
- F. The Board may prohibit a pharmacy permittee or pharmacist-in-charge of a provider pharmacy from using an automated emergency drug supply unit if the pharmacy permittee or pharmacy permittee's employees do not comply with the requirements of subsections (A) through (E).

**R4-23-701.03. Long-Term Care Facilities Pharmacy Services: Emergency Drug Prescription Order**

The limited-service pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall ensure that every emergency drug prescription order is evaluated according to the requirements of R4-23-402(A) by a pharmacist within 72 hours of the first dose of drug administered by long-term care facility personnel under the emergency drug prescription order.

**R4-23-701.04. Long-Term Care Facilities Pharmacy Services: Automated Dispensing Systems**

A. Before using an automated dispensing system as defined in R4-23-110, a pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall:

- 1. Notify the Board or its staff in writing of the intent to use an automated dispensing system, including the name and type of system;
- 2. Obtain a separate controlled substances registration at the location of each long-term care facility at which an automated dispensing system containing controlled substances will be located as required by federal law; and
- 3. Maintain copies of the registrations required under subsection (A)(2) at the provider pharmacy for inspection by the Board or its staff.

B. A pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall ensure:

- 1. Drugs contained in an automated dispensing system remain the property of the provider pharmacy,
- 2. Controlled substance drugs contained in an automated dispensing system are included in all inventories required under A.R.S. 36-2523(B) and R4-23-1003(A),
- 3. Schedule II drugs are not stocked in an automated dispensing system, and

4. A separate emergency drug supply unit is available in the long-term care facility to meet the requirements of R4-23-701.02.

C. A pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall:

1. Ensure that policies and procedures as required in subsection (D) for the use of an automated dispensing system in a long-term care facility are prepared, implemented, and complied with;
2. Review biennially and, if necessary, revise the policies and procedures required under subsection (D);
3. Document the review required under subsection (C)(2);
4. Assemble the policies and procedures as a written or electronic manual; and
5. Make the policies and procedures available for employee reference and inspection by the Board or its staff within the pharmacy and at any location outside of the pharmacy where the automated dispensing system is used.

D. A pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall ensure the written policies and procedures include:

1. Drug removal procedures that include the following:

- a. A drug is provided only by a valid prescription order for an individual long-term care facility resident;
- b. A drug is dispensed from an automated dispensing system only after a pharmacist has:
  - i. Reviewed and verified the resident's prescription order as required by R4-23-402(A), and
  - ii. Electronically authorized the access for that drug for that particular resident, and

c. The automated dispensing system labels each individual drug packet with a resident specific label that complies with R4-23-701.01(2) and contains the resident's room number or facility identification number; and

2. Security procedures that include the following:

- a. The pharmacy permittee or pharmacist-in-charge of the provider pharmacy is responsible for authorizing user access, including adding and removing users and modifying user access;
- b. Each authorized user is a licensee of the Board or authorized licensed personnel of the long-term care facility; and
- c. The automated dispensing system is secured at the long-term care facility by electronic or mechanical means or a combination thereof designed to prevent unauthorized access;

3. Drug stocking procedures that include the following:

a. Automated dispensing systems that use non-removable containers that do not allow prepackaging of the container as set out in subsection (D)(3)(b):

- i. Are stocked at the long-term care facility by an Arizona licensed pharmacist employed by the provider pharmacy, or by an Arizona licensed intern, graduate intern, technician or technician trainee under the direct onsite supervision of an Arizona licensed pharmacist; and
- ii. Utilize barcode or other technologies to ensure the correct drug is placed in the correct canister or container; and

b. Automated dispensing systems that use removable containers may be stocked at the long-term care facility by an authorized user provided:

- i. The prepackaging of the container occurs at the provider pharmacy;
- ii. A pharmacist verifies the container has been properly filled and labeled, and the container is secured with a tamper-evident seal;
- iii. The individual containers are transported to the long-term care facility in a secure, tamper-evident shipping container; and
- iv. The automated dispensing system uses microchip, bar-coding, or other technologies to ensure the containers are accurately loaded in the automated dispensing system; and

4. Record-keeping and report procedures that include the following:

- a. All events involving the access of the automated dispensing system are recorded electronically and maintained for not less than two years;
- b. The provider pharmacy is capable of producing a report of all transactions of the automated dispensing system including:
  - i. A single drug usage report that complies with R4-23-408(B)(5); and

- ii. An authorized user history including date and time of access and type of transaction; and
- c. The provider pharmacy has procedures to safeguard the storage, packaging, and distribution of drugs by monitoring:
- i. Current inventory;
  - ii. Expiration dates;
  - iii. Controlled substance dispensing;
  - iv. Re-dispense requests; and
  - v. Wastage.
- E. A pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall:
1. Ensure that an electronic log is kept for each container fill that includes:
    - a. An identification of the container by drug name and strength, and container number;
    - b. The drug's manufacturer or National Drug Code (NDC) number;
    - c. The expiration date and lot number from the manufacturer's stock bottle that is used to fill the container. If multiple lot numbers of the same drug are added to a container, each lot number and expiration date shall be documented;
    - d. The date the container is filled;
    - e. Documentation of the identity of the licensee who placed the drug into the container; and
    - f. If the licensee who filled the container is not a pharmacist, documentation of the identity of the pharmacist who supervised the non-pharmacist licensee; and
  2. Maintain the electronic log for inspection by the Board or its staff for not less than two years.
- F. A pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall:
1. Implement an ongoing quality assurance program that monitors performance of the automated dispensing system and compliance with the established policies and procedures that includes:
    - a. Training in the use of the automated dispensing system for all authorized users,
    - b. Maintenance and calibration of the automated dispensing system as recommended by the device manufacturer,
    - c. Routine accuracy validation testing no less than every three months, and
    - d. Downtime and malfunction procedures to ensure the timely provision of medication to the long-term care facility resident, and
  2. Maintain documentation of the requirements of subsections (F)(1)(b) and (F)(1)(c) for inspection by the Board or its staff for not less than two years.
- G. The Board may prohibit a pharmacy permittee or pharmacist-in-charge from using an automated dispensing system in a long-term care facility if the pharmacy permittee or the pharmacy permittee's employees do not comply with the requirements of subsections (A) through (F).

**R4-23-702. Hospice Inpatient Facilities**

- A. If a pharmacy permittee contracts to provide pharmacy services to the patients of a hospice inpatient facility as defined in R4-23-110, the pharmacy permittee shall ensure that:
1. A prescription medication is provided only by a valid prescription order for an individual hospice inpatient facility patient, properly labeled for that patient, as specified in this subsection. Nothing in this section shall prevent a provider pharmacy from supplying non-prescription drugs in a manufacturer's unopened container;
  2. A prescription medication label for a hospice inpatient facility patient complies with A.R.S. §§ 32-1968 and 36-2525 and contains:
    - a. The drug name, strength, dosage form, and quantity; and
    - b. The beyond-use date; and
  3. If the label on the hospice inpatient facility patient's drug container becomes damaged or soiled, a pharmacist employed by the pharmacy that dispensed the drug container, through the exercise of professional judgment, may re-label the drug container. Only a pharmacist is permitted to label a drug container or alter the label of a drug container.

B. A pharmacist may help hospice inpatient facility personnel develop written policies and procedures for the procurement, administration, storage, control, recordkeeping, and disposal of drugs in the facility.

C. The provider pharmacy may contract with the hospice inpatient facility to provide pharmacist services at the facility that include evaluation of the patient's response to medication therapy, identification of potential adverse drug reactions, and recommended appropriate corrective action.

D. A provider pharmacy that places an emergency drug supply unit at a hospice inpatient facility shall comply with the requirements of R4-23-701.02.

E. A pharmacy shall not place an automated dispensing system as defined in R4-23-701.04 in a hospice inpatient facility.

F. Drugs previously dispensed to a patient of the hospice inpatient facility by another pharmacy, and drugs previously dispensed by the provider pharmacy, shall not be repackaged.

#### **R4-23-703. Assisted Living Facilities**

A. Assisted living facilities are licensed by the state Department of Health Services.

B. A pharmacy shall:

1. Only dispense, sell, or deliver a prescription or nonprescription drug to an assisted living facility resident after receiving a prescription order for the drug from the resident's medical practitioner;

2. Label, in accordance with A.R.S. §§ 32-1963.01, 32-1968, and 36-2525, all drugs dispensed, sold, or delivered to an assisted living facility resident;

3. Obtain a copy of the current Arizona Department of Health Services license issued to an assisted living facility before dispensing drugs to that facility's resident; and

4. Maintain, for inspection by a Board compliance officer, a file containing the license copy required in subsection (B)(3).

C. In addition to the labeling requirements of A.R.S. §§ 32-1963.01, 32-1968 and 36-2525, the label on a prescription medication for an assisted living facility resident shall include the name, strength, and quantity of the drug and a beyond-use date.

D. If the label on an assisted living facility resident's drug container becomes damaged or soiled, a pharmacist employed by the pharmacy that dispensed the drug container, through the exercise of professional judgment, may re-label the drug container. Only a pharmacist is permitted to label a drug container or alter the label of a drug container.

E. A pharmacist may help assisted living facility personnel to develop written policies and procedures for the procurement, administration, storage, control, recordkeeping, and disposal of drugs in the facility and provide other information concerning drugs that assisted living facilities should have for safe and effective supervision of drug self-administration.

F. A pharmacy shall not place an emergency drug supply unit as defined in R4-23-701.02 or an automated dispensing system in R4-23-701.04 in an assisted living facility.

G. Drug previously dispensed to a resident of the assisted living facility by another pharmacy, and drugs previously dispensed by the provider pharmacy, shall not be repackaged.

#### **R4-23-704. Customized Patient Medication Packages**

In lieu of dispensing two or more prescribed drugs in separate containers, a pharmacist may, with the consent of the patient, the patient's caregiver, the prescriber, or the facility caring for the patient, provide a customized patient medication package. The pharmacist preparing a customized patient medication package shall abide by the guidelines set forth in the current edition of the official compendium for labeling, packaging and record-keeping, and state and federal law.

#### **R4-23-705. Thru R4-23-709. Repealed**

#### **ARTICLE 8. DRUG CLASSIFICATION:**

#### **R4-23-801. Dietary Supplements**

A person who sells, distributes, or provides a product that is labeled as a dietary supplement and is labeled or marketed as a treatment for any deficiency disease, for the correction of any symptom of disease, or for the prevention, mitigation, or cure of any disease, either by direct statement or by inference, is selling, distributing, or providing a drug and is subject to the requirements of A.R.S. Title 32, Chapter 18 and 4 A.A.C. 23.

#### **R4-23-802. Veterinary**

Veterinary preparation: A veterinary drug manufacturer or supplier may distribute:

1. A prescription-only veterinary drug to:

- a. A veterinary medical practitioner licensed under A.R.S. Title 32, Chapter 21,
  - b. A full-service drug wholesaler permitted under A.R.S. Title 32, Chapter 18, or
  - c. A pharmacy permitted under A.R.S. Title 32, Chapter 18, and
2. A nonprescription veterinary drug to:
- a. A veterinary medical practitioner licensed under A.R.S. Title 32, Chapter 21,
  - b. A nonprescription drug retailer permitted under A.R.S. Title 32, Chapter 18,
  - c. A full-service or nonprescription drug wholesaler permitted under A.R.S. Title 32, Chapter 18, or
  - d. A pharmacy permitted under A.R.S. Title 32, Chapter 18.

**R4-23-803. Thru R4-23-804. Repealed**

**ARTICLE 9. PENALTIES AND MISCELLANEOUS:**

**R4-23-901. Penalty for Violations**

Any person, firm, or corporation violating any provision of 4 A.A.C. 23 is subject to the penalties in A.R.S. § 32-1996. In addition, a license or permit issued under the provisions of A.R.S. Title 32, Chapter 18 is subject to suspension or revocation for violation of 4 A.A.C. 23.

**ARTICLE 10. UNIFORM CONTROLLED SUBSTANCES AND DRUG OFFENSES:**

**R4-23-1001.Thru R4-23-1002. Repealed**

**R4-23-1003. Records and Order Forms**

A. Records.

1. If the pharmacist-in-charge of a pharmacy is replaced by another pharmacist-in-charge, the new pharmacist-in-charge shall complete an inventory of all controlled substances in the pharmacy within 10 days of assuming the responsibility. This inventory and any other required controlled substance inventory shall:

- a. Include an exact count of all Schedule II controlled substances;
- b. Include an exact count of all Schedule III through Schedule V controlled substances or an estimated count if the stock container contains fewer than 1001 units;
- c. Indicate the date the inventory is taken and whether the inventory is taken before opening of business or after close of business for the pharmacy;
- d. Be signed by:
  - i. The pharmacist-in-charge; or
  - ii. For other required inventories, the pharmacist who does the inventory;

e. Be kept separately from all other records; and

f. Be available in the pharmacy for inspection by the Board or its designee for not less than three years.

2. A loss of a controlled substance shall be reported:

- a. Within 10 days of discovery;
- b. On a DEA form 106;
- c. By the pharmacist-in-charge of a pharmacy or a manufacturer;
- d. By the permittee or designated representative of a full-service wholesaler; and

e. To the federal Drug Enforcement Administration (DEA), the Narcotic Division of the Department of Public Safety (DPS), and the Board of Pharmacy. A copy of the DEA form 106 shall be kept on file by the pharmacy permittee. The DEA form 106 shall state whether the police investigated the loss.

3. Every person manufacturing any controlled substance, including repackaging or relabeling, shall record and retain for not less than three years the manufacturing, repackaging, or relabeling date for each controlled substance.

4. Every person receiving, selling, delivering, or disposing of any controlled substance shall record and retain for not less than three years the following information:

- a. The name, strength, dosage form, and quantity of each controlled substance received, sold, delivered, or disposed;
- b. The name, address, and DEA registration number of the person from whom each controlled substance is received;
- c. The name, address, and DEA registration number of the person to whom each controlled substance is sold or delivered or who disposes of each controlled substance; and
- d. The date of each transaction.

5. A full-service drug wholesale permittee or the designated representative shall complete an inventory of all controlled substances in the manner prescribed in subsection (A)(1). The permittee or designated representative shall conduct this inventory:

- a. On May 1 of each year or as directed by the Board; and
- b. If there is a change of ownership, or discontinuance of business, or within 10 days of a change of a designated representative.

6. A drug manufacturer permittee or the pharmacist-in-charge shall complete an inventory of all controlled substances in the manner prescribed in subsection (A)(1). The permittee or pharmacist-in-charge shall conduct this inventory:

- a. On May 1 of each year or as directed by the Board; and
- b. If there is a change of ownership, or discontinuance of business, or within 10 days of a change of a pharmacist-in-charge.

B. Order form. For purposes of A.R.S. § 36-2524, "Order Form" means DEA Form 222c.

#### **R4-23-1004. Repealed**

#### **R4-23-1005. Substances Excepted from the Schedules of Controlled Substances**

A. All over-the-counter non-narcotic substances containing limited amounts of controlled substances that are excluded from all controlled substance schedules by 21 CFR § 1308.22 (Revised April 1, 2012, incorporated by reference and on file with the Board. This incorporated material contains no future editions or amendments.), are excluded from all controlled substance schedules in Arizona.

B. All chemical preparations or mixtures containing one or more controlled substances listed in any schedule that are exempted from all controlled substance schedules by 21 CFR § 1308.24 (Revised April 1, 2012, incorporated by reference and on file with the Board. This incorporated material contains no future editions or amendments.), are exempted from all controlled substance schedules in Arizona.

C. All prescription-only drugs that are exempted by 21 CFR § 1308.32 (Revised April 1, 2012, incorporated by reference and on file with the Board. This incorporated material contains no future editions or amendments.), are exempted from all controlled substance schedules in Arizona.

#### **R4-23-1006. Substances Excepted from Drug Offenses**

The following materials, compounds, mixtures, or preparations containing any stimulant or depressant substance included in A.R.S. §§ 13-3401(6)(b) or 13-3401(6)(c) are excepted from the definition of dangerous drugs under the authority of A.R.S. § 32-1904(B)(14):

1. Over-the-counter drugs excepted in R4-23-1005(A).
2. Chemical preparations excepted in R4-23-1005(B).
3. Prescription-only drugs excepted in R4-23-1005(C).

### **ARTICLE 11. PHARMACY TECHNICIANS:**

#### **R4-23-1101. Licensure and Eligibility**

A. License required. A person shall not work as a pharmacy technician or pharmacy technician trainee in Arizona, unless the person possesses a pharmacy technician or pharmacy technician trainee license issued by the Board.

B. Eligibility.

1. To be eligible for licensure as a pharmacy technician trainee, a person shall:
  - a. Be of good moral character,
  - b. Be at least 18 years of age, and
  - c. Have a high school diploma or the equivalent of a high school diploma.

2. To be eligible for licensure as a pharmacy technician, a person shall:

- a. Meet the requirements of subsection (B)(1),
- b. Complete a pharmacy technician training program that meets the standards prescribed in R4-23-1105, and
- c. Pass the Pharmacy Technician Certification Board (PTCB) examination or another Board-approved pharmacy technician examination.

C. A pharmacy technician delinquent license. Before an Arizona pharmacy technician license will be reinstated, a pharmacy technician whose Arizona pharmacy technician license is delinquent for five or more consecutive years shall furnish to the Board satisfactory proof of fitness to be licensed as a pharmacy technician and pay all past due biennial renewal fees and penalty fees. Satisfactory proof includes:

1. For a person with a delinquent license who is practicing as a pharmacy technician out-of-state with a pharmacy technician license issued by another jurisdiction:

- a. Proof of current, unrestricted pharmacy technician licensure in another jurisdiction; and
- b. Proof of employment as a pharmacy technician during the last 12 months; or

2. For a person with a delinquent license who did not practice as a pharmacy technician within the last 12 months:

- a. Take and pass a Board-approved pharmacy technician examination, and
- b. Complete 20 contact hours or two CEUs of continuing education activity sponsored by an approved provider, including at least two contact hours or 0.2 CEUs of continuing education activity in pharmacy law.

#### **R4-23-1102. Pharmacy Technician Licensure**

A. Eligibility. An applicant for licensure as a pharmacy technician shall provide the Board proof that the applicant is eligible under R4-23-1101(B)(2), including documentation that the applicant:

1. Completed a pharmacy technician training program that meets the standards prescribed in R4-23-1105(B)(2); and
2. Passed the Pharmacy Technician Certification Board (PTCB) examination or another Board-approved pharmacy technician examination; or
3. Meets the requirements of R4-23-1105(D)(1) or (2).

B. Application.

1. An applicant for licensure as a pharmacy technician shall:

- a. Submit a completed application electronically or manually on a form furnished by the Board, and
- b. Submit with the application form:
  - i. The documents specified in the application form,
  - ii. The initial licensure fee specified in R4-23-205(A)(3)(a), and
  - iii. The wall license fee specified in R4-23-205(E)(1)(c).

2. The Board office shall deem an application form received on the date the Board office electronically or manually date-stamps the form.

C. Licensure.

1. If an applicant is found to be ineligible for pharmacy technician licensure under statute and rule, the Board office shall issue written notice of denial to the applicant.

2. If an applicant is found to be eligible for pharmacy technician licensure under statute and rule, the Board office shall issue a certificate of licensure and a wall license. An applicant who is assigned a license number and who has been granted "open" status on the Board's license verification site may begin practice as a pharmacy technician prior to receiving the certificate of licensure.

3. An applicant who is assigned a license number and who has a "pending" status on the Board's license verification site shall not practice as a pharmacy technician until the Board office issues a certificate of licensure as specified in subsection (2).

4. A licensee shall maintain the certificate of licensure in the practice site for inspection by the Board or its designee or review by the public.

D. License renewal.

1. To renew a license, a pharmacy technician shall submit a completed license renewal application electronically or manually on a form furnished by the Board with the biennial renewal fee specified in R4-23-205(A)(3)(b).

2. If the biennial renewal fee is not paid by November 1 of the renewal year specified in A.R.S. § 32-1925, the pharmacy technician license is suspended and the licensee shall not practice as a pharmacy technician. The licensee shall pay a penalty as provided in A.R.S. § 32-1925 and R4-23-205(G)(1) to vacate the suspension.

3. A licensee shall maintain the renewal certificate of licensure in the practice site for inspection by the Board or its designee or review by the public.

E. Time-frames for pharmacy technician licensure and license renewal. The Board office shall follow the time-frames established in R4-23-202(F).

F. Verification of license. A pharmacy permittee or pharmacist-in-charge shall not permit a person to practice as a pharmacy technician until the pharmacy permittee or pharmacist-in-charge verifies that the person is currently licensed by the Board as a pharmacy technician.

#### **R4-23-1103. Pharmacy Technician Trainee Licensure**

A. Eligibility. An applicant for licensure as a pharmacy technician trainee shall provide the Board proof that the applicant is eligible under R4-23-1101(B)(1).

B. Application.

1. An applicant for licensure as a pharmacy technician trainee shall:

a. Submit a completed application electronically or manually on a form furnished by the Board, and

b. Submit with the application form:

i. The documents specified in the application form.

ii. The licensure fee specified in R4-23-205(A)(4), and

iii. The wall license fee specified in R4-23-205(E)(1)(d).

2. The Board office shall deem an application form received on the date the Board office electronically or manually date-stamps the form.

C. Licensure.

1. If an applicant is found to be ineligible for pharmacy technician trainee licensure under statute and rule, the Board office shall issue a written notice of denial to the applicant.

2. If an applicant is found to be eligible for pharmacy technician trainee licensure under statute and rule, the Board office shall issue a certificate of licensure and a wall license. An applicant who is assigned a license number and who has been granted "open" status on the Board's license verification site may begin practice as a pharmacy technician trainee prior to receiving the certificate of licensure.

3. An applicant who is assigned a license number and who has a "pending" status on the Board's license verification site shall not practice as a pharmacy technician trainee until the Board office issues a certificate of licensure as specified in subsection (2).

4. A licensee shall maintain the certificate of licensure in the practice site for inspection by the Board or its designee or review by the public.

5. A pharmacy technician trainee license is valid for 24 months from the date issued. A pharmacy technician trainee who does not complete the prescribed training program and pass the Pharmacy Technician Certification Board (PTCB) examination or another Board-approved pharmacy technician examination before the pharmacy technician trainee's license expires is not eligible for licensure as a pharmacy technician and shall not practice as a pharmacy technician or pharmacy technician trainee.

D. Re-application for licensure

1. The Board may allow a pharmacy technician trainee whose license expires before the pharmacy technician trainee completes the prescribed training program and passes the Pharmacy Technician Certification Board (PTCB) examination or another Board-approved pharmacy technician examination to reapply for licensure not more than one time. A pharmacy technician trainee whose license has expired may make a special request to the Board under R4-23-401 for approval to reapply for licensure.

2. The Board shall base its decision to grant or deny a special request to reapply for licensure on an assessment of:

a. The reasons the pharmacy technician trainee did not complete a pharmacy technician training program and the likelihood that the pharmacy technician trainee will complete a pharmacy technician training program within the next 24 months,

b. The reasons the pharmacy technician trainee failed the pharmacy technician examination and the likelihood that the pharmacy technician trainee will pass the pharmacy technician examination within the next 24 months, and

c. Other extenuating circumstances.

3. A pharmacy technician trainee that receives Board approval to reapply for licensure shall submit a completed application manually on a form furnished by the Board and pay the licensure fee specified in R4-23-205(A)(4).

E. Time-frames for pharmacy technician trainee licensure. The Board office shall follow the time-frames established in R4-23-202(F).

F. Verification of license. A pharmacy permittee or pharmacist-in-charge shall not permit a person to practice as a pharmacy technician trainee until the pharmacy permittee or pharmacist-in-charge verifies that the person is currently licensed by the Board as a pharmacy technician trainee.

#### **R4-23-1104. Pharmacy Technicians and Pharmacy Technician Trainees**

A. Permissible activities of a pharmacy technician trainee. Acting in compliance with all applicable statutes and rules and under the supervision of a pharmacist, a pharmacy technician trainee may assist a graduate intern, pharmacy intern, or pharmacist with the following when applicable to the pharmacy practice site:

1. Record on the original prescription order the prescription serial number and date dispensed;
2. Initiate or accept verbal or electronic refill authorization from a medical practitioner or medical practitioner's agent and record, on the original prescription order or by an alternative method approved by the Board or its designee, the medical practitioner's name, patient name, name and quantity of prescription medication, specific refill information, and name of medical practitioner's agent, if any;
3. Record information in the refill record or patient profile;
4. Type and affix a label for a prescription medication or enter information for a new or refill prescription medication into a computer, if a pharmacist verifies the accuracy and initials in handwriting or by another method approved by the Board or its designee the finished label prepared by the technician before the prescription medication is dispensed to the patient;
5. Reconstitute a prescription medication, if a pharmacist checks the ingredients and procedure before reconstitution and verifies the final product after reconstitution;
6. Retrieve, count, or pour a prescription medication, if a pharmacist verifies the contents of the prescription medication against the original prescription medication container or by an alternative drug identification method approved by the Board or its designee;
7. Prepackage drugs in accordance with R4-23-402(A); and
8. Measure, count, pour, or otherwise prepare and package a drug needed for hospital inpatient dispensing, if a pharmacist verifies the accuracy, measuring, counting, pouring, preparing, packaging, and safety of the drug before the drug is delivered to a patient care area.

B. Permissible activities of a pharmacy technician. Acting in compliance with all applicable statutes and rules and under the supervision of a pharmacist, a pharmacy technician may:

1. Perform the activities listed in subsection (A); and
2. After completing a pharmacy technician drug compounding training program developed by the pharmacy permittee or pharmacist-in-charge under R4-23-1105(C), assist a pharmacist, graduate intern, or pharmacy intern in compounding prescription medications and sterile or non-sterile pharmaceuticals in accordance with written policies and procedures, if the preparation, accuracy, and safety of the final product is verified by a pharmacist before dispensing.

C. When performing the activities listed in subsections (A) and (B) for which the pharmacy technician or pharmacy technician trainee has been trained, the pharmacy technician or pharmacy technician trainee shall perform those functions accurately.

D. Prohibited activities. A pharmacy technician or pharmacy technician trainee shall not perform a function reserved for a pharmacist, graduate intern, or pharmacy intern in accordance with R4-23-402 or R4-23-653.

E. A pharmacy technician or pharmacy technician trainee shall wear a badge indicating name and title while on duty.

F. Before employing a pharmacy technician or pharmacy technician trainee, a pharmacy permittee or pharmacist-in-charge shall develop, implement, review, and revise in the same manner described in R4-23-653(A) and comply with policies and procedures for pharmacy technician and pharmacy technician trainee activities as specified in subsection (G).

G. The policies and procedures shall include the following:

1. For all practice sites:
  - a. Supervisory controls and verification procedures to ensure the quality and safety of pharmaceutical service;
  - b. Employment performance expectations for a pharmacy technician and pharmacy technician trainee;
  - c. The activities a pharmacy technician or pharmacy technician trainee may perform as specified in R4-23-1104(A) and (B);
  - d. Pharmacist and patient communication;
  - e. Reporting, correcting, and avoiding medication and dispensing errors;
- f. Security procedures for:

- i. Confidentiality of patient prescription records, and
  - ii. The pharmacy area;
- g. Automated medication distribution system;
- h. Compounding procedures for pharmacy technicians; and
- i. Brief overview of state and federal pharmacy statutes and rules;
- 2. For community and limited-service pharmacy practice sites:
  - a. Prescription dispensing procedures for:
    - i. Accepting a new written prescription,
    - ii. Accepting a refill request,
    - iii. Selecting a drug product,
    - iv. Counting and pouring,
    - v. Labeling, and
    - vi. Obtaining refill authorization;
  - b. Computer data entry procedures for:
    - i. New and refill prescriptions,
    - ii. Patient's drug allergies,
    - iii. Drug-drug interactions,
    - iv. Drug-food interactions,
    - v. Drug-disease state contraindications,
    - vi. Refill frequency,
    - vii. Patient's disease and medical condition,
    - viii. Patient's age or date of birth and gender, and
    - ix. Patient profile maintenance; and
- 3. For hospital pharmacy practice sites:
  - a. Medication order procurement and data entry,
  - b. Drug preparation and packaging,
  - c. Outpatient and inpatient drug delivery, and
  - d. Inspection of drug storage and preparation areas and patient care areas.

**R4-23-1105. Pharmacy Technician Trainee Training Program, Pharmacy Technician Drug Compounding Training Program, and Alternative Pharmacy Technician Training**

A. Nothing in this Section prevents additional offsite training of a pharmacy technician.

B. Pharmacy technician trainee training program.

1. A pharmacy permittee or pharmacist-in-charge shall develop, implement, review, and revise in the same manner described in R4-23-653(A) and comply with a pharmacy technician trainee training program based on the needs of the individual pharmacy.

2. A pharmacy permittee or pharmacist-in-charge shall ensure that the pharmacy technician trainee training program includes training guidelines that:

- a. Define the specific tasks a pharmacy technician trainee is expected to perform,

- b. Specify how and when the pharmacist-in-charge will assess the pharmacy technician trainee's competency, and
- c. Address the policies and procedures specified in R4-23-1104(G) and the permissible activities specified in R4-23-1104(A).

3. A pharmacist-in-charge shall:

- a. Document the date that a pharmacy technician trainee has successfully completed the training program, and
  - b. Maintain the documentation required in this subsection for inspection by the Board or its designee
4. A pharmacy technician trainee shall perform only those tasks, listed in R4-23-1104(A), for which training and competency has been demonstrated.

C. Pharmacy technician drug compounding training program.

1. A pharmacy permittee or pharmacist-in-charge shall develop, implement, review, and revise in the same manner described in R4-23-653(A) and comply with a pharmacy technician drug compounding training program based on the needs of the individual pharmacy;

2. A pharmacy permittee or pharmacist-in-charge shall ensure that the pharmacy technician drug compounding training program includes training guidelines that:

- a. Define the specific tasks a pharmacy technician is expected to perform,
- b. Specify how and when the pharmacist-in-charge will assess the pharmacy technician's competency, and
- c. Address the following procedures and tasks:

- i. Area preparation,
- ii. Component preparation,
- iii. Aseptic technique and product preparation,
- iv. Packaging and labeling, and
- v. Area clean up;

3. A pharmacist-in-charge shall:

- a. Document the date that a pharmacy technician has successfully completed the pharmacy technician drug compounding training program, and
- b. Maintain the documentation required in this subsection for inspection by the Board or its designee.

D. Alternative pharmacy technician training.

1. An individual who has passed the required Board-approved pharmacy technician examination, but has not followed the normal path to pharmacy technician licensure by obtaining a pharmacy technician trainee license and working while completing a pharmacy technician trainee training program as specified in subsection B, may obtain a pharmacy technician license, if the individual has employment in pharmacy and completes an on-the-job training program as part of the individual's employment orientation that includes: reading and discussing with the pharmacist-in-charge of the pharmacy where employed, the Board rules concerning pharmacy technicians and pharmacy technician trainees, the pharmacy technician and pharmacy technician trainee job description, and the policies and procedures manual of that pharmacy.

2. An individual who has completed a pharmacy technician certificate program and has passed the required Board-approved pharmacy technician examination, but has not followed the normal path to pharmacy technician licensure by obtaining a pharmacy technician trainee license and working while completing a pharmacy technician trainee training program as specified in subsection (B), may obtain a pharmacy technician license, if the individual has employment in pharmacy and completes an on-the-job training program as part of the individual's employment orientation that includes: reading and discussing with the pharmacist-in-charge of the pharmacy where employed, the Board rules concerning pharmacy technicians and pharmacy technician trainees, the pharmacy technician and pharmacy technician trainee job description, and the policies and procedures manual of that pharmacy.

3. A pharmacist-in-charge shall:

- a. Document the date that an individual licensed under subsection (D)(1) or (2) has successfully completed the on-the-job training program as part of the individual's employment orientation as required under subsection (D)(1) or (2), and
- b. Maintain the documentation required in this subsection for inspection by the Board or its designee.

E. A pharmacy technician shall perform only those tasks, listed in R4-23-1104(B), for which training and competency has been demonstrated.

#### **R4-23-1106. Continuing Education Requirements**

A. General. According to A.R.S. § 32-1925(l), the Board shall not renew a pharmacy technician license unless the applicant has during the two years preceding the application for renewal:

1. Participated in 20 contact hours or two CEUs of continuing education activity sponsored by an Approved Provider defined in R4-23-110, and
2. At least two of the contact hours or 0.2 of the CEUs are approved courses in pharmacy law. For a pharmacy technician licensed less than 24 months the continuing education contact hours are calculated by multiplying 0.83 hours times the number of months between the date of initial licensure and the licensee's next license renewal date.

B. Valid CEUs. The Board shall:

1. Only accept CEUs for continuing education activities sponsored by an Approved Provider;
2. Only accept CEUs accrued during the two-year period immediately before licensure renewal;
3. Not allow CEUs accrued in a biennial renewal period in excess of the required two CEUs to be carried forward to the succeeding biennial renewal period;
4. Allow a pharmacy technician who leads, instructs, or lectures to a group of health professionals on pharmacy-related topics in continuing education activities sponsored by an Approved Provider to receive CEUs for a presentation by following the same attendance procedures as any other attendee of the continuing education activity; and
5. Not accept as a CEU a pharmacy technician's normal teaching duties within a learning institution if the pharmacy technician's primary responsibility is the education of health professionals.

C. Continuing education records and reporting CEUs. A pharmacy technician shall:

1. Maintain continuing education records that:
  - a. Verify the continuing education activities the pharmacy technician participated in during the preceding five years; and
  - b. Consist of a statement of credit or a certificate issued by an Approved Provider at the conclusion of a continuing education activity;
2. At the time of licensure renewal, attest to the number of CEUs the pharmacy technician participated in during the renewal period on the biennial renewal form; and
3. When requested by the Board office, submit proof of continuing education participation within 20 days of the request.

D. The Board shall deem a pharmacy technician's failure to comply with the continuing education participation, recording, or reporting requirements of this Section as unprofessional conduct and grounds for disciplinary action by the Board under A.R.S. § 32-1927.01.

E. A pharmacy technician who is aggrieved by any decision of the Board concerning continuing education units may request a hearing before the Board.

#### **ARTICLE 12. PRESCRIPTION MEDICATION DONATION PROGRAM:**

##### **R4-23-1201. Eligibility Requirements for Participation in the Program**

A physician's office, a pharmacy, or a health care institution may participate in the prescription medication donation program, under A.R.S. § 32-1909, if all of the following requirements, as applicable, are met:

1. The physician-in-charge of the participating physician's office has a current license issued under A.R.S. Title 32, Chapter 13 or 17;
2. The pharmacy has a current permit issued under A.R.S. Title 32, Chapter 18;
3. The health care institution has a current license issued under A.R.S. Title 36, Chapter 4 and has a physician-in-charge or pharmacist-in-charge of dispensing; and
4. The physician's office, the pharmacy, or the health care institution complies with all federal and state drug laws, rules, and regulations.

##### **R4-23-1202. Donating Medications**

A. The following may donate an eligible prescription medication, as specified in R4-23-1203, to a physician's office, a pharmacy, or a health care institution that participates in the prescription medication donation program:

1. An individual for whom the prescription medication was prescribed on a patient-specific prescription order or that individual's health care decision maker;
2. A manufacturer that has a current permit issued under A.R.S. Title 32, Chapter 18; or

3. A health care institution that has a current license issued under A.R.S. Title 36, Chapter 4.

B. An individual or health care decision maker electing to donate an eligible prescription medication shall not have taken possession of the prescription medication before the donation and shall make the donation through a medical practitioner, pharmacy, or health care institution.

#### **R4-23-1203. Eligible Prescription Medications**

A prescription medication may be donated to a physician's office, a pharmacy, or a health care institution that participates in the prescription medication donation program if the prescription medication:

1. Is not a:

a. Controlled substance;

b. Drug sample; or

c. Drug that can only be dispensed to a patient registered with the drug's manufacturer, because donation could prevent the manufacturer from maintaining required patient registration data;

2. Is in its original sealed and tamper-evident unit dose packaging that is unopened or has only its outside packaging opened and its single unit dose packaging undisturbed;

3. Has been in the possession of a licensed health care professional, manufacturer, pharmacy, or health care institution and not in the possession of the individual specified in R4-23-1202(A)(1);

4. Has been stored according to federal and state drug law and the requirements of the manufacturer's package insert;

5. Has an expiration date or beyond-use-date later than six months after the date of donation;

6. Is in packaging that shows the lot number and expiration date or beyond-use-date of the prescription medication;

7. Does not have any physical signs of tampering or adulteration; and

8. Is in packaging that does not have any physical signs of tampering, except for the outside packaging as specified in subsection (2).

#### **R4-23-1204. Eligibility Requirements to Receive Donated Prescription Medications**

An individual is eligible to receive donated prescription medications from the prescription medication donation program if the individual:

1. Is a resident of Arizona;

2. Has an annual family income that is less than or equal to 300% of the poverty level;

3. Satisfies one of the following:

a. Has no health insurance coverage;

b. Has health insurance coverage that does not pay for the prescription medication prescribed;

c. Is an American or Alaska Native who:

i. Is eligible for, but chooses not to use, the Indian Health Service to receive prescription medications; and

ii. Either has no other health insurance coverage or has health insurance coverage that does not pay for the prescription medication prescribed; or

d. Is a veteran who:

i. Is eligible for, but chooses not to use, Veterans Health Administration benefits to receive prescription medications; and

ii. Either has no other health insurance coverage or has health insurance coverage that does not pay for the prescription medication prescribed;

4. Is ineligible for enrollment in AHCCCS; and

5. If eligible for Medicare, is ineligible for a full low-income subsidy.

#### **R4-23-1205. Donor Form**

A. Before donating a prescription medication, a donor shall sign a form that includes:

1. A statement attesting that the donor is one of the entities identified in R4-23-1202(A) and intends to voluntarily donate the prescription medication to the prescription medication donation program;
  2. If the donor is the individual named on the prescription or the individual's health care decision maker:
    - a. The individual's name and address;
    - b. The name of the individual's health care decision maker, if applicable;
    - c. The name of the medical practitioner, pharmacy, or health care institution through which the donation is being made;
    - d. The following information about the donated prescription medication:
      - i. The brand name or generic name of the prescription medication donated;
      - ii. If a generic medication, the name of the manufacturer or the national drug code number of the prescription medication donated;
      - iii. The strength of the prescription medication donated;
      - iv. The quantity of the prescription medication donated;
      - v. The lot number of the prescription medication donated; and
      - vi. The expiration date or beyond-use-date of the prescription medication donated;
    - e. A statement attesting that the individual or the individual's health care decision maker has not had possession of the donated prescription medication;
    - f. The dated signature of the individual or the individual's health care decision maker;
    - g. If the donation is an ongoing donation as authorized under subsection (B), a statement that conforms to subsection (B);
    - h. A statement by the medical practitioner, pharmacy, or health care institution attesting that the medical practitioner, pharmacy, or health care institution through which the donation is being made has stored the donated prescription medication as required in R4-23-1203(4);
    - i. A statement by the medical practitioner, pharmacy, or health care institution attesting that the drugs being donated meet the specific requirements of R4-23-1203(1); and
    - j. The dated signature of the medical practitioner or of an authorized agent for the pharmacy or health care institution through which the donation is being made;
  3. If the donor is a manufacturer:
    - a. The name and address of the manufacturer;
    - b. The information about the donated prescription medication specified in subsection (A)(2)(d);
    - c. A statement by the manufacturer that the manufacturer has stored the donated prescription medication as required in R4-23-1203(4); and
    - d. The dated signature of the manufacturer's authorized agent; and
  4. If the donor is a health care institution:
    - a. The name and address of the health care institution;
    - b. The information about the donated prescription medication specified in subsection (A)(2)(d);
    - c. A statement attesting that the health care institution has stored the donated prescription medication as required in R4-23-1203(4);
    - d. A statement by the health care institution attesting that the drugs being donated meet the specific requirements of R4-23-1203(1); and
    - e. The dated signature of the health care institution's authorized agent.
- B. An individual who resides in a health care institution, or the individual's health care decision maker, may elect to make an ongoing donation of future unused eligible prescription medication:
1. When future unused eligible prescription medication is a result of the individual's prescription medication being changed or discontinued by the individual's primary care provider; and
  2. By indicating the following on a donor form that complies with subsection (A): "From this day forward, I wish to donate all my remaining unused prescription medications that are eligible, under R4-23-1203, to the prescription medication donation program."

C. To stop an ongoing donation, an individual who resides in a health care institution, or the individual's health care decision maker, shall submit written notice to the receiving physician's office, pharmacy, or health care institution indicating the individual's, or the health care decision maker's, desire to stop the ongoing donation.

#### **R4-23-1206. Recipient Form**

Before receiving a donated prescription medication from the prescription medication donation program, a recipient of a donated prescription medication shall sign a form:

1. Identifying the physician's office, pharmacy, or health care institution that is dispensing the donated prescription medication;
2. Stating that the recipient has been advised of and understands the immunity provisions of the program under A.R.S. § 32-1909(E) and (F);
3. Attesting that the recipient meets the eligibility requirements specified in R4-23-1204: and
4. Including the following:
  - a. The brand name or generic name of the prescription medication received;
  - b. If a generic medication, the name of the manufacturer or the national drug code number of the prescription medication received;
  - c. The strength of the prescription medication received;
  - d. The quantity of the prescription medication received;
  - e. The recipient's name and address; and
  - f. The dated signature of the recipient.

#### **R4-23-1207. Recordkeeping**

A. Before transferring possession of a prescription medication donated by an individual or an individual's health care decision maker, a medical practitioner, pharmacy, or health care institution that has possession of the donated prescription medication and through which the donation is being made shall create an invoice that includes the following:

1. The name and address of the medical practitioner, pharmacy, or health care institution that has possession of the donated prescription medication;
2. The name of the individual who made the donation;
3. The brand name or generic name of the prescription medication transferred;
4. If a generic medication, the name of the manufacturer or the national drug code number of the prescription medication transferred;
5. The strength of the prescription medication transferred;
6. The quantity of the prescription medication transferred;
7. The lot number of the prescription medication transferred;
8. The expiration date or beyond-use-date of the prescription medication transferred;
9. The date the prescription medication is transferred to a participating physician's office, pharmacy, or health care institution; and
10. The name and address of the participating physician's office, pharmacy, or health care institution to which the donated prescription medication is transferred.

B. Before transferring possession of a prescription medication donated by a manufacturer, the manufacturer shall create an invoice that includes the manufacturer's name and address and the information described in subsections (A)(3) through (10).

C. Before transferring possession of a prescription medication donated by a health care institution, the health care institution shall create an invoice that includes the health care institution's name and address and the information described in subsections (A)(3) through (10).

D. A medical practitioner, pharmacy, health care institution, or manufacturer required to create an invoice under subsection (A), (B), or (C) shall:

1. Transmit a copy of the invoice and the donor form required under R4-23-1205 to the participating physician's office, pharmacy, or health care institution to which a donated prescription medication is transferred;
2. Maintain a copy of the invoice for a minimum of three years from the date of the invoice;
3. Maintain a copy of the donor form for a minimum of three years from the date signed; and

4. Make a copy of the invoice or donor form available upon request for inspection by the Board, its designee, or other authorized officers of the law.

E. A physician's office, a pharmacy, or a health care institution that participates in the prescription medication donation program shall:

1. Maintain:

a. The documents required under R4-23-1206 for a minimum of three years from the date signed; and

b. Each invoice and donor form received under subsection (D)(1) for a minimum of three years from the date received; and

2. Make the documents required under R4-23-1206 and subsection (D)(1) available upon request for inspection by the Board, its designee, or other authorized officers of the law.

#### **R4-23-1208. Handling Fee**

A physician's office, a pharmacy, or a health care institution that dispenses a donated prescription medication may charge a recipient of a donated prescription medication a handling fee of no more than \$4.50 per prescription to cover inspection, stocking, and dispensing costs.

#### **R4-23-1209. Policies and Procedures**

A physician's office, a pharmacy, or a health care institution that participates in the prescription medication donation program shall:

1. Develop, implement, and comply with policies and procedures for the receipt, storage, and distribution of prescription medications donated to the physician's office, the pharmacy, or the health care institution;

2. Review biennially and, if necessary, revise the policies and procedures required under this Section;

3. Document the review required under subsection (2);

4. Assemble the policies and procedures as a written manual or in a readily accessible electronic format;

5. Make the policies and procedures available for reference by a physician's office, pharmacy, or health care institution personnel and, upon request, for inspection by the Board or its designee; and

6. Ensure that the written or electronic policies and procedures required under subsection (1) include provisions to ensure:

a. That each transferred prescription medication meets the eligibility requirements of Sections R4-23-1202 and R4-23-1203;

b. That each individual who receives a donated prescription medication under the prescription medication donation program signs the recipient form specified in R4-23-1206;

c. Compliance with the applicable requirements for recordkeeping in Section R4-23-1207;

d. Compliance with the requirements of Section R4-23-1210; and

e. Compliance with the requirements of Section R4-23-1211.

#### **R4-23-1210. Dispensing Donated Prescription Medications**

A. Before dispensing a donated prescription medication under the program, a participating physician's office, pharmacy, or health care institution shall:

1. Obtain and maintain a current drug identification reference or text in hard-copy or electronic media format;

2. Inspect the donated prescription medication to ensure that the prescription medication has not been adulterated;

3. Certify that the donated prescription medication has been stored in compliance with the requirements of the manufacturer's package insert;

4. Comply with all federal and state laws regarding storage and distribution of a donated prescription medication;

5. Obtain a prescription order of a licensed medical practitioner for the recipient to receive the donated prescription medication; and

6. Properly label the donated prescription medication to be dispensed.

B. As specified in subsection (C) a participating physician's office, pharmacy, or health care institution may transfer a prescription medication donated under this Article to another participating physician's office, pharmacy, or health care institution, but the donated prescription medication shall not be resold.

C. A participating physician's office, pharmacy, or health care institution may transfer a donated prescription medication to another participating physician's office, pharmacy, or health care institution, if:

1. The transferring physician's office, pharmacy, or health care institution has available a prescription medication that the receiving physician's office, pharmacy, or health care institution needs;
2. The transferring physician's office, pharmacy, or health care institution prepares an invoice that includes its name and address and the information described in R4-23-1207(B)(3) through (10);
3. A copy of the invoice required in subsection (C)(2) is sent to the receiving physician's office, pharmacy, or health care institution with the transferred prescription medication; and
4. The transferring physician's office, pharmacy, or health care institution and the receiving physician's office, pharmacy, or health care institution each:
  - a. Keep a copy of the invoice required in subsection (C)(2) on file for three years from the date of transfer; and
  - b. Make the invoice records available, upon request, for inspection by the Board or its designee.

**R4-23-1211. Responsibilities of the Physician-in-charge or Pharmacist-in-charge of a Participating Physician's Office, Pharmacy, or Health Care Institution**

The physician-in-charge of a participating physician's office; the pharmacist-in-charge of a participating pharmacy; or the physician-in-charge or pharmacist-in-charge of dispensing for a participating health care institution shall, either personally or through a designee:

1. Coordinate the receipt of prescription medications donated by manufacturers or health care institutions or through medical practitioners, pharmacies, or health care institutions from eligible donors;
2. Check each donated prescription medication against the invoice and any additional alternate record and resolve any discrepancies;
3. Store and secure donated prescription medications as required by federal and state law;
4. Inspect each donated prescription medication for adulteration;
5. Certify that each donated prescription medication has been stored in compliance with the manufacturer's package insert;
6. Ensure that expired, adulterated, or unidentifiable donated prescription medication is not dispensed;
7. Ensure that prescription medications identified under subsection (6) are destroyed within 30 days of identification as specified in subsection (9);
8. Ensure safety in drug recalls by destroying any donated prescription medication that may be subject to recall if its lot number cannot exclude it from recall;
9. Ensure destruction of expired, adulterated, unidentifiable, and recalled donated prescription medication by:
  - a. Following federal, state, and local guidelines for drug destruction;
  - b. Creating a list of expired, adulterated, unidentifiable, or recalled donated prescription medications to be destroyed;
  - c. Following the destruction, signing the list described in subsection (9)(b) and having the list signed by a witness verifying the destruction; and
  - d. Keeping the list described in subsection (9)(b) on file for three years from the date of destruction;
10. Redact or remove all previous patient or pharmacy labeling on a donated prescription medication before dispensing the donated prescription medication;
11. Ensure that all dispensed donated prescription medications comply with the labeling requirements of A.R.S. § 32-1968(D);
12. Place on the label of each dispensed donated prescription medication a beyond-use-date that does not exceed the beyond-use-date or expiration date from the original label of the donated prescription medication or, if the dispensed donated prescription medication comes from multiple packages, the earliest beyond-use-date or expiration date from the donated prescription medication packages; and
13. Maintain the records required in this Article.

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