

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 Repealed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, 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.

NEW "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

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 (I)(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 (I)(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.

<http://www.cdc.gov/vaccines>

<http://wwwnc.cdc.gov/travel/page/yellowbook-home-2014>

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

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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. 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 wholesaler 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 wholesaler permittee shall comply with the distribution restrictions specified in A.R.S. § 32-1983.

1. Records.

a. A full-service drug wholesaler 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 wholesaler 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 wholesaler 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, repack, 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 wholesaler 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, repack, 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,

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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 (I)(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 (I)(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 (I)(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 (I)(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,

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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 (I)(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 (I)(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 of 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 100feet 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, an
 - 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;

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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 radiopharmaceutical 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. 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).

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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(I), 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

13. Maintain the records required in this Article.

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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