NOTICES OF FINAL EXEMPT RULEMAKING

This section of the *Arizona Administrative Register* contains Notices of Final Exempt Rulemaking.

The Office of the Secretary of State is the filing office and publisher of these rules. Questions about the interpretation of the final exempt rule should be addressed to the agency proposing them. Refer to Item #5 to contact the person charged with the rulemaking.

NOTICE OF FINAL EXEMPT RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

[R16-180]

PREAMBLE

1. Article, Part, or Section Affected (as applicable) — **Rulemaking Action**

R4-23-110	Amend
R4-23-205	Amend

2. Citations to the agency's statutory rulemaking authority to include both the authorizing statute (general) and the implementing statute (specific):

Authorizing statute: A.R.S. § 32-1904(A)(1)

Implementing statute: A.R.S. § 32-1904(B)(17)

Statute or session law authorizing the exemption:Laws 2016, Chapter 284, Section 3

3. The effective date for the rules and the reason the agency selected the effective date:

August 31, 2016. Under the exemption provided by Laws 2016, Chapter 284, Section 3, the rulemaking will be effective when filed with the Office of the Secretary of State.

4. Citation to all related notices published in the *Register* to include the Register as specified in R1-1-409(A) that pertain to the record of the exempt rulemaking:

None

5. The agency's contact person who can answer questions about the rulemaking:

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1616 W Adams, Suite 120
Phoenix, AZ 85007
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6. An agency's justification and reason why a rule should be made, amended, repealed, or renumbered, to include an explanation about the rulemaking:

During the last legislative session, the legislature amended A.R.S. § 32-1904 to authorize the Board to issue a certificate of free sale to a person licensed by the Board as a manufacturer (See Laws 2016, Chapter 284). The certificate of free sale allows the person to sell food supplements of dietary supplements internationally. A certificate of free sale indicates a product is marketed in the U.S. and eligible for export. A certificate of good manufacturing practices indicates a food or dietary supplement is manufactured in a manner that results in the product meeting standards regarding safety, identity and strength, and quality and purity.

The amended statute authorizes the Board to establish an inspection process for issuance of certificates of free sale or good manufacturing practice and expressly authorizes the Board to establish the new fees in this rulemaking. Statute also requires the Board to define “food supplements” and “dietary supplements” in rule.

An exemption from EO2016-03 was provided to the Board in an e-mail from Christina Corieri, Policy Advisor for Health and Human Services in the Governor’s office, dated May 23, 2016.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The Board did not review or rely on a study in its evaluation of or justification for the rule in this rulemaking.

8. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. A summary of the economic, small business, and consumer impact, if applicable:

A person licensed by the Board that wishes to obtain a certificate of free sale or good manufacturing practice will incur the cost of paying the fee established in this rulemaking. However, the person will have the benefit of being able to export food supplements or dietary supplements. When a manufacturer of food or dietary supplements wishes to export the products, the foreign government or customer may require a certificate, preferably from a state regulatory agency, regarding the product's regulatory and marketing status.

The Board estimates four or five manufacturers may apply for certificates of free sale or good manufacturing practice. A separate certificate is needed for each shipment of products to a foreign country. The Board estimates it may collect approximately $15,000 in fees and contribute $1,500 to the state's general fund.

10. A description of any changes between the proposed rulemaking, including supplemental notices, and the final rulemaking (if applicable):

None

11. An agency's summary of the public or stakeholder comments made about the rulemaking and the agency response to comments, if applicable:

None

12. Other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. When applicable, matters shall include, but not be limited to:

None

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:

The certificates established in statute and for which fees are established in this rulemaking are general permits consistent with A.R.S. § 41-1037 because they are issued to qualified individuals or entities to conduct activities that are substantially similar in nature.

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

No federal law is applicable to this rulemaking. There are, however, federal laws with which a manufacturer or distributor of food supplements or dietary supplements must comply. These include the Dietary Supplement Health and Education Act, 21 CFR, Chapter 1, Subchapter B, Part 111, and the Federal Food, Drug and Cosmetic Act.

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:

No analysis was submitted.

13. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rule:

None

14. Whether the rule was previously made, amended, or repealed as an emergency rule. If so, cite the notice published in the Register as specified in R1-1-409(A). Also, the agency shall state where the text was changed between the emergency and the final rulemaking packages:

None of the rules in this rulemaking was previously made, amended, or repealed as an emergency rule.

15. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 1. ADMINISTRATION

Section
R4-23-110. Definitions

ARTICLE 2. PHARMACIST LICENSURE

Section
R4-23-205. Fees

ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

In addition to definitions in A.R.S. § 32-1901, the following definitions apply to ~~4 A.A.C. 23~~ this Chapter:

"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 or food 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~~ humans 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" or "food supplement."

"Digital signature" has the same meaning as in A.R.S. § 41-132(E).

"Dispensing pharmacist" means a pharmacist who, in the process of dispensing a prescription medication after the complete preparation of the prescription medication and before delivery of the prescription medication to a patient or patient's agent, verifies, checks, and initials the prescription medication label, as required in R4-23-402(A).

"Drug sample" means a unit of a prescription drug that a manufacturer provides free of charge to promote the sale of the drug.

"Durable medical equipment" or "DME" means technologically sophisticated medical equipment that may be used by a patient or consumer in a home or residence. DME may be prescription-only devices as defined in A.R.S. § 32-1901(75). DME includes:

Air-fluidized beds,

Apnea monitors,

Blood glucose monitors and diabetic testing strips,

Continuous Positive Airway Pressure (CPAP) machines,

Electronic and computerized wheelchairs and seating systems,

Feeding pumps,

Home phototherapy devices,

Hospital beds,

Infusion pumps,

Medical oxygen and oxygen delivery systems excluding compressed medical gases,

Nebulizers,

Respiratory disease management devices,

Sequential compression devices,

Transcutaneous electrical nerve stimulation (TENS) unit, and

Ventilators.

"Earned income" means monetary payments received by an individual as a result of work performed or rental property owned or leased by the individual, including:

Wages,

Commissions and fees,

Salaries and tips,

Profit from self-employment,

Profit from rent received from a tenant or boarder, and

Any other monetary payments received by an individual for work performed or rental of property.

"Electronic signature" has the same meaning as in A.R.S. § 44-7002.

"Eligible patient" means a patient who a pharmacist determines is eligible to receive an immunization using professional judgment after consulting with the patient regarding the patient's current health condition, recent health condition, and allergies.

"Emergency drug supply unit" means those drugs that may be required to meet the immediate and emergency therapeutic needs of long-term care facility residents and hospice inpatient facility patients, and which are not available from any other authorized source in sufficient time to prevent risk of harm to residents or patients.

"Extreme emergency" means the occurrence of a fire, water leak, electrical failure, public disaster, or other catastrophe constituting an imminent threat of physical harm to pharmacy personnel or patrons.

"Family unit" means:

A group of individuals residing together who are related by birth, marriage, or adoption; or

An individual who:

Does not reside with another individual; or

Resides only with another individual or group of individuals to whom the individual is unrelated by birth, marriage, or adoption.

"FDA" means the Food and Drug Administration, a federal agency within the United States Department of Health and Human Services, established to set safety and quality standards for foods, drugs, cosmetics, and other consumer products.

"Health care decision maker" has the same meaning as in A.R.S. § 12-2291.

"Health care institution" has the same meaning as in A.R.S. § 36-401.

"Hospice inpatient facility" means a health care institution licensed under A.R.S. § 36-401 and Article 8 that provides hospice services to a patient requiring inpatient services.

"Immediate notice" means a required notice sent by mail, facsimile, or electronic mail to the Board Office within 24 hours.

"Immunizations training program" means an immunization training program for pharmacists, pharmacy interns, and graduate interns that meets the requirements of R4-23-411(E).

"Inactive ingredient" means any component other than an "active ingredient" present in a drug.

"Internal test assessment" means performing quality assurance or other procedures necessary to ensure the integrity of a test.

"ISO Class 5 environment" means an atmospheric environment that complies with the ISO/TC209 International Cleanroom Standards, specifically ANSI/IEST/ISO-14644-1:1999: Cleanrooms and associated controlled environments--Part 1: Classification of air cleanliness, first edition dated May 1, 1999, (and no future amendments or editions), incorporated by reference and on file in the Board office.

"ISO Class 7 environment" means an atmospheric environment that complies with the ISO/TC209 International Cleanroom Standards, specifically ANSI/IEST/ISO-14644-1:1999: Cleanrooms and associated controlled environments--Part 1: Classification of air cleanliness, first edition dated May 1, 1999, (and no future amendments or editions), incorporated by reference and on file in the Board office.

"Licensed health care professional" means an individual who is licensed and regulated under A.R.S. Title 32, Chapter 7, 11, 13, 14, 15, 16, 17, 18, 25, 29, or 35.

"Limited-service correctional pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that:

Holds a current Board permit under A.R.S. § 32-1931;

Is located in a correctional facility; and

Uses pharmacists, interns, and support personnel to compound, produce, dispense, and distribute drugs.

"Limited-service long-term care pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current Board-issued permit and dispenses prescription medication or prescription-only devices to patients in long-term care facilities.

"Limited-service mail-order pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current Board permit under A.R.S. § 32-1931 and dispenses a majority of its prescription medication or prescription-only devices by mailing or delivering the prescription medication or prescription-only device to an individual by the United States mail, a common or contract carrier, or a delivery service.

"Limited-service nuclear pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current Board permit under A.R.S. § 32-1931 and provides radiopharmaceutical services.

"Limited-service pharmacy permittee" means a person who holds a current limited-service pharmacy permit in compliance with A.R.S. §§ 32-1929, 32-1930, 32-1931, and A.A.C. R4-23-606.

"Limited-service sterile pharmaceutical products pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current Board permit under A.R.S. § 32-1931 and dispenses a majority of its prescription medication or prescription-only devices as sterile pharmaceutical products.

"Long-term care consultant pharmacist" means a pharmacist providing consulting services to a long-term care facility.

"Long-term care facility" or "LTCF" means a nursing care institution as defined in A.R.S. § 36-401.

"Lot" means a batch or any portion of a batch of a drug, or if a drug produced by a continuous process, an amount of drug produced in a unit of time or quantity in a manner that assures its uniformity. In either case, a lot is identified by a distinctive lot number and has uniform character and quality with specified limits.

"Lot number" or "control number" means any distinctive combination of letters or numbers, or both, from which the complete history of the compounding or manufacturing, control, packaging, and distribution of a batch or lot of a drug can be determined.

"Low-income subsidy" means Medicare-provided assistance that may partially or fully cover the costs of drugs and is based on the income of an individual and, if applicable, the individual's spouse.

"Materials approval unit" means any organizational element having the authority and responsibility to approve or reject components, in-process materials, packaging components, and final products.

"Mechanical counting device for a drug in solid, oral dosage form" means a mechanical device that counts drugs in solid, oral dosage forms for dispensing and includes an electronic balance when used to count drugs.

"Mechanical storage and counting device for a drug in solid, oral dosage form" means a mechanical device that stores and counts and may package or label drugs in solid, oral dosage forms for dispensing.

"Mediated instruction" means information transmitted via intermediate mechanisms such as audio or video tape or telephone transmission.

"Medical practitioner-patient relationship" means that before prescribing, dispensing, or administering a prescription-only drug, prescription-only device, or controlled substance to a person, a medical practitioner, as defined in A.R.S. § 32-1901, shall first conduct a physical examination of that person or have previously conducted a physical examination. This subdivision does not apply to:

A medical practitioner who provides temporary patient supervision on behalf of the patient's regular treating medical practitioner;

Emergency medical situations as defined in A.R.S. § 41-1831;

Prescriptions written to prepare a patient for a medical examination; or

Prescriptions written, prescription-only drugs, prescription-only devices, or controlled substances issued for use by a county or tribal public health department for immunization programs, emergency treatment, in response to an infectious disease investigation, public health emergency, infectious disease outbreak or act of bioterrorism. For purposes of this subsection, "bioterrorism" has the same meaning as in A.R.S. § 36-781.

"Medicare" means a federal health insurance program established under Title XVIII of the Social Security Act.

"Medication error" means any unintended variation from a prescription or medication order. Medication error does not include any variation that is corrected before the medication is dispensed to the patient or patient's care-giver, or any variation allowed by law.

"Mobile pharmacy" means a pharmacy that is ~~self-propelled~~ self-propelled or movable by another vehicle that is ~~self-propelled~~ 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 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~~ include one or more of the following ~~features that attempt~~ designed 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 optic 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, administering, 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.

ARTICLE 2. PHARMACIST LICENSURE

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. Certificate fees:
1. Certificate of free sale: $200 per certificate.
2. Certificate of good manufacturing practice: $200 per certificate.
3. Annual inspection fee calculated at the average hourly rate of a pharmacy inspector multiplied by the duration of the inspection measured in 10-minute increments or portion of a 10-minute increment.

~~E.~~F. Other ~~Fees~~ 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.
4. Permit or certificate verification: $15.

~~F.~~ G. Fees are not refunded under any circumstances except for the Board's failure to comply with its established licensure or permit ~~time-frames~~ time frames under R4-23-202 or R4-23-602.

~~G.~~ H. Penalty ~~fee~~. Renewal applications submitted after the expiration date are subject to a penalty ~~fees~~ as provided in A.R.S. §§ 32-1925 and 32-1931.
1. Licensees: A ~~fee~~ penalty equal to half the licensee's biennial licensure renewal fee under subsection (A) and not to exceed $350.
2. Permittees: A ~~fee~~ penalty equal to half the permittee's biennial permit fee under subsection (D) and not to exceed $350.

NOTICE OF FINAL EXEMPT RULEMAKING

TITLE 7. EDUCATION

CHAPTER 2. STATE BOARD OF EDUCATION

[R16-181]

PREAMBLE

1. Article, Part, or Section Affected (as applicable) — **Rulemaking Action**

R7-2-612.01	New Section
R7-2-614	Amend

2. Citations to the agency's statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific), and the statute or session law authorizing the exemption:

Authorizing statute: A.R.S. §§ 15-203 (A) (1) and 15-203 (A) (14)

Implementing statute: Not applicable

3. The effective date of the rules and the agency's reason it selected the effective date:

August 22, 2016

4. A list of all notices published in the *Register* as specified in R1-1-409(A) that pertains to the record of the exempt rulemaking:

N/A

5. The agency's contact person who can answer questions about the rulemaking:

Name: Dr. Karol Schmidt, Executive Director
Address: State Board of Education
1700 W. Washington, Suite 300
Phoenix, AZ 85007
Telephone: (602) 542-5057
Fax: (602) 542-3046
E-mail: inbox@azsbe.az.gov

6. An agency's justification and reason why a rule should be made, amended, repealed, or renumbered to include an explanation about the rulemaking:

A.R.S. § 15-203(A)(14) authorizes the State Board to supervise and control the certification of educators. SB 1502 provided an additional pathway for CTE certification. A new section was added to conform to these changes in R7-2-612.01. SB 1208 included clarifying language regarding teaching intern certificates and placements for student teaching. Conforming changes are made to R7-2-614(E).

7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

N/A

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

N/A

9. The summary of the economic, small business and consumer impact, if applicable:
The rules are not expected to have significant, if any, economic impact on small businesses.

10. A description of the changes between the proposed rules, including supplemental notices and final rules (if applicable):
N/A

11. A summary of the comments made regarding the rule and the agency response to them:
At its August 1, 2016 special meeting, the Board initiated emergency rulemaking, finding that the proposed amendment to R7-2-614(E) and the proposed rule R7-2-612.01 were necessary as an emergency measure to avoid serious prejudice to the public interest or the interest of the parties concerned, especially those individuals seeking certification or seeking to hire individuals consistent with the provisions of SB 1208 or SB 1502. No public comment was received.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:
N/A

13. Incorporations by reference and their location in the rules:
N/A

14. Was this rule previously made as an emergency rule? If so, please indicate the *Register* citation:
N/A

15. The full text of the rule follows:

TITLE 7. EDUCATION

CHAPTER 2. STATE BOARD OF EDUCATION

ARTICLE 6. CERTIFICATION

Section
R7-2-612.01. Standard Specialized Career and Technical Education (CTE) Certificates – grades K-12
R7-2-614. Other Teaching Certificates

ARTICLE 6. CERTIFICATION

R7-2-612.01. Standard Specialized Career and Technical Education (CTE) Certificates – grades K-12

A. Standard Specialized CTE certificates are subject to the general certification provisions in R7-2-607 and the renewal requirements in R7-2-619.

B. The certificate is valid for eight years.
1. The holder is qualified to teach CTE Agriculture, CTE Business and Marketing, CTE Education and Training, CTE Family and Consumer Sciences, CTE Health Careers, or CTE Industrial and Emerging Technologies as specified on the certificate.
2. The requirements are:
   a. A valid fingerprint clearance card issued by the Arizona Department of Public Safety.
   b. Demonstration of expertise in the specified CTE area through one of the following:
      i. A Bachelor's or more advanced degree in the specified CTE area; or
      ii. A Bachelor's or more advanced degree and completion of twenty-four semester hours of coursework in the specified CTE area; or
      iii. An Associate's degree in the specified CTE area; or
      iv. An industry certification, license, or credential in the specified CTE area approved by the appropriate Department of Education Career and Technical Education Program Specialist or Career and Technical Education Program Services Director.
   c. Verification of five years of work experience in the specified CTE occupational area.

R7-2-614. Other Teaching Certificates

A. No change
B. No change
1. No change
2. No change
3. No change
4. No change
5. No change
6. No change
7. No change

C. No change
1. No change
2. No change
3. No change
4. No change
5. No change
   a. No change
   b. No change
   c. No change
6. No change
   a. No change
   b. No change
   c. No change

D. No change
1. No change
2. No change
3. No change
4. No change
5. No change
   a. No change
   b. No change
   c. No change
   d. No change
      i. No change
      ii. No change
6. No change

E. No change
1. No change
2. No change
3. The teaching intern certificate entitles the holder to enter into a teaching contract while completing the requirements for an Arizona ~~provisional~~ teaching certificate. During the valid period of the intern certificate the holder may teach in a Structured English Immersion classroom, or in any subject area in which the holder has passed the appropriate Arizona Teacher Proficiency Assessment. Teaching Intern certificate holders who teach in a Structured English Immersion classroom shall hold a valid Provisional or full Structured English Immersion Endorsement, an English as a Second Language Endorsement, or a Bilingual Endorsement. The candidate shall be enrolled in a Board authorized alternative path to certification program or a Board approved teacher educator preparation program.
4. No change
5. No change
   a. No change
   b. A passing score on one or more subject knowledge portions of the Arizona Teacher Proficiency Assessment that corresponds to the ~~applicant's teaching assignment(s)~~ Board approved alternative path to certification program, or Board approved educator preparation program, in which the applicant is enrolled;
   c. No change
   d. No change
6. No change
   a. No change
   b. No change
   c. No change
   ~~d. Completion of the requirements for a Provisional or full Structured English Immersion endorsement.~~
7. The holder of the teaching intern certificate may apply for an Arizona ~~Provisional~~ Teaching Certificate upon completion of the following:
   a. No change
   b. No change
   c. No change
   d. No change
   ~~e. Completion of the requirements for a full Structured English Immersion endorsement.~~
8. Placement decisions of teaching intern certificate holders shall only be based on agreements between the educator preparation provider, the provider's partner organizations and the local education agency except as otherwise provided in R7-2-614(E).

F. No change
1. No change
2. No change
   a. No change
   b. No change
3. No change
   a. No change
   b. No change
      i. No change
      ii. No change
      iii. No change
   c. No change

G. No change
1. No change
2. No change
3. No change
   a. No change
   b. No change
   c. No change

H. No change
1. No change
2. No change
3. No change
   a. No change
   b. No change
      i. No change
      ii. No change
      iii. No change
      iv. No change
      v. No change
   c. No change
   d. No change
4. No change
   a. No change
   b. No change

I. No change
1. No change
2. No change
3. No change
   a. No change
   b. No change
   c. No change
   d. No change
4. No change

J. No change
1. No change
2. No change
3. No change
   a. No change
   b. No change
4. No change