## NOTICE OF FINAL RULEMAKING

**TITLE 4. PROFESSIONS AND OCCUPATIONS**

**CHAPTER 23. BOARD OF PHARMACY**

### PREAMBLE

#### 1. Articles, Parts, and Sections Affected

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<tr>
<td>R4-23-1105</td>
<td>Amend</td>
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#### 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)

3. The effective date for the rules:
   As specified under A.R.S. § 41-1032(A), the rule will be effective 60 days after the rule package is filed with the Office of the Secretary of State.
   a. If the agency selected a date earlier than the 60-day effective date as specified in A.R.S. § 41-1032(A), include the earlier date and state the reason or reasons the agency selected the earlier effective date as provided in A.R.S. § 41-1032(A)(1) through (5):
      Not applicable
   b. If the agency selected a date later than the 60-day effective date as specified in A.R.S. § 41-1032(A), include the later date and state the reason or reasons the agency selected the later effective date as provided in A.R.S. § 41-1032(B):
      Not applicable

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 final rulemaking package:
   Notice of Rulemaking Docket Opening: 24 A.A.R. 2387, August 31, 2018
   Notice of Proposed Rulemaking: 24 A.A.R. 2432, August 31, 2018

5. The agency’s contact person who can answer questions about the rulemaking:
   Name: Kamlesh Gandhi
   Address: 1616 W Adams Street, Suite 120
            Phoenix, AZ 85007
   Telephone: (602) 771-2740
   Fax: (602) 771-2749
   E-mail: kgandhi@azpharmacy.gov
   Website: www.azpharmacy.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 An agency's justification and reason why a rule should be made, amended, repealed, or renumbered, to include an explanation about the rulemaking:
   The Board is amending several rules to make them consistent with recent statutory changes, to eliminate unnecessary and burdensome provisions, or to correct rule text:
   R4-23-110 is amended to add definitions of virtual wholesaler and virtual manufacturer as required under A.R.S. § 32-1901, a requirement added under Laws 2017, Chapter 22, and to add a definition of change of ownership, as used in A.R.S. § 32-1901.01.
   R4-23-203 is amended to make it easier for individuals licensed in other jurisdictions to become licensed in Arizona.
R4-23-205 is amended to add a fee for a permit for third-party logistics provider. The new fee is specifically authorized under A.R.S. § 32-1931(C)(5), which was amended under Laws 2017, Chapter 95.

R4-23-302 is amended to remove unnecessary and burdensome requirements regarding a pharmacy intern preceptor.

R4-11-407 is amended to clarify the multiple means of communication that may be used to transfer prescription-order information between licensees and to include the prescription-order label language required under A.R.S. § 36-2525(L), which was amended by the legislature in Laws 2018, Chapter 1, § 37.

R4-23-407.1 is amended to be consistent with Laws 2017, Chapter 234, which amended A.R.S. § 32-1968 to require an opioid antagonist be dispensed under a prescription order or a standing order rather than allowing an opioid antagonist to be dispensed without a prescription order.

R4-23-411 is amended to align the date on which a licensee renews the license with the date on which the licensee renews a certificate to administer immunizations. Aligning the dates of these renewals reduces a burden on licensees who hold an immunization certificate.

R4-23-202, R4-23-301, R4-23-602, R4-23-1102, and R4-23-1103 are amended to correct internal cross references to R4-23-205. The internal cross references became incorrect when the Board amended R4-23-205 in an exempt rulemaking (See 23 A.A.R. 2383, September 1, 2017). To avoid this problem in the future, subsections are removed from the cross references.

R4-23-601 is amended to provide notice to permittees that a change of ownership, as used in A.R.S. § 32-1901.01 and defined at R4-23-110, requires a new permit application.

R4-23-603, R4-23-604, R4-23-605, R4-23-606, R4-23-607, R4-23-607, R4-23-692, and R4-23-693 are amended to delete detail regarding the application process. This is necessary to ensure the rules don’t become inconsistent with the applications.

R4-23-676 is added to address the requirements regarding third-party logistics providers established at A.R.S. § 32-1941 under Laws 2017, Chapter 95.

R4-24-1105 is amended consistent with a 5YRR approved by the Council on October 7, 2014.

Exemptions from the rulemaking moratorium were provided for this rulemaking by members of the governor’s staff on May 3, 2017, September 7, 2017, September 21, 2017, November 9, 2017, January 4, 2018, January 31, 2018, March 1, 2018, and June 12, 2018.

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 any 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:
The Board believes the economic impact of this rulemaking will be minimal for those subject to its requirements. R4-23-407 and R4-23-407.1 are amended and R4-23-676 is added to address changes made by the legislature. A fee for a third-party logistics provider permit is added to R4-23-205. The fee is specifically authorized under A.R.S. § 32-1931 and is required because of the addition of the statutory requirement that third-party logistics providers obtain a permit from the Board. Those who do so will incur the expense of paying the new fee.

Changes to R4-23-203, R4-23-302, and R4-23-411 remove burdensome requirements. Other changes clarify language and requirements and remove incorrect cross references.

10. A description of any changes between the proposed rulemaking, including supplemental notices, and the final rulemaking:
In addition to the changes identified in item 11, the Board made the following changes:

R4-23-110: Inserted the phrase “an Arizona-permitted...” as follows in the definition of “Virtual manufacturer:”

Contracts with an Arizona-permitted manufacturing entity for the physical manufacture of the drug or device:

R4-23-603(G), R4-23-604(D), R4-23-605(C), R4-23-607(C), R4-23-692, and R4-23-693: To reduce a potential regulatory burden, added language indicating notification of changes may be submitted to the Board office using the permittee’s online profile.

R4-23-607(C): Corrected an incorrect subsection label and made conforming changes throughout the Section.

11. An agency’s summary of the public or stakeholder comments made about the rulemaking and the agency response to comments:
The Board received comments from Christine Cassetta of Quarles and Brady LLC. Her comments are addressed as follows:

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<th>COMMENT</th>
<th>ANALYSIS</th>
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<tbody>
<tr>
<td>R4-23-110: The definition of “virtual manufacturer” is incorrect. A virtual manufacturer does not engage in the manufacture of drugs or devices.</td>
<td>The comment is correct.</td>
<td>The phrase “engages in the manufacture” was changed to “contracts.”</td>
</tr>
<tr>
<td>R4-23-110: The Board has no jurisdiction to require a contracting manufacturer to be licensed in Arizona. These are mostly foreign entities regulated by FDA. An Arizona licensed virtual manufacturer takes ownership of the manufactured product only after it has been approved for import.</td>
<td>The Board has determined that to fulfill its responsibility to protect public health and safety, Arizona-permitted virtual manufacturers must contract only with Arizona-permitted virtual manufacturers. This ensures the Board has jurisdiction to address issues that occur.</td>
<td>No change</td>
</tr>
<tr>
<td>R4-23-110: A private label manufacturer is, by definition, not a virtual manufacturer.</td>
<td>The comment is correct.</td>
<td>The subsection regarding a private label manufacturer was deleted and minor reformatting done.</td>
</tr>
<tr>
<td>R4-23-110: The definition of virtual manufacturer includes “a person that facilitates…” but “facilitates” is not defined.</td>
<td>The word is being used consistent with its ordinary, dictionary meaning so no definition is needed. Facilitates means to enable or assist.</td>
<td>No change</td>
</tr>
<tr>
<td>R4-23-605(G)(1)(a)(iv), (G)(2)(a)(v), and (G)(3)(a)(iv); R4-23-607(D)(3)(c): The change to these subsections is inconsistent with 21 USC 360eee-4, which prohibits states from establishing or continuing a</td>
<td>The comment is correct.</td>
<td>In each subsection, language was changed to reference the track and trace documents required under the Drug Supply Chain Security</td>
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</table>
requirement regarding tracing drug products through the distribution system if the requirement is inconsistent with, more stringent than, or in addition to those in 21 USC 353(e).

R4-23-607(A): The Board voted that a nonresident pharmacy permittee is not required to have an Arizona-licensed pharmacist-in-charge before selling or distributing into Arizona. It is sufficient if the nonresident pharmacist has a pharmacist-in-charge in the jurisdiction in which the nonresident resides.

The comment is correct.

The requirement referenced was already deleted in the Notice of Proposed Rulemaking. See struck subsection R4-23-607(C)(1)(d).

12. All agencies shall list any other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

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 licenses and permits for which fees are established under R4-23-205 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 rule in this rulemaking is more stringent than federal law. There are numerous federal laws with which individuals dealing with drugs must comply. The Drug Supply Chain Security Act requires third-party logistics providers to report to the federal government whether facilities are licensed under state law. 21 U.S.C. § 360eee-3 requires a third-party logistics provider to be licensed in the state from which a drug is distributed by the third-party logistics provider. Third-
party logistics providers will have to comply with federal law but the federal laws are not applicable to the subject of the rules in this rulemaking.

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:

No rule in the 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
R4-23-202 Licensure by Examination
R4-23-203 Licensure by Reciprocity
R4-23-205 Fees

ARTICLE 3. INTERN TRAINING AND PHARMACY INTERN PRECEPTORS

Section
R4-23-301 Intern Licensure
R4-23-302 Training Site and Pharmacy Intern Preceptors

ARTICLE 4. PROFESSIONAL PRACTICES

Section
R4-23-407 Prescription Requirements
R4-23-407.1 Dispensing an Opioid Antagonist
R4-23-411 Pharmacist-administered or Pharmacy or Graduate Intern-administered Immunizations

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

Section
R4-23-601 General Provisions
R4-23-602 Permit Application Process and Time Frames
R4-23-603 Resident-Nonprescription Drugs, Retail
R4-23-604 Resident Drug Manufacturer
R4-23-605 Resident Drug Wholesaler Permit
R4-23-606 Pharmacy Permit, Community, Hospital, and Limited Service
R4-23-607. Nonresident Permits
R4-23-676. Reserved Third-party Logistics Provider Permit
R4-23-692. Compressed Medical Gas (CMG) Distributor-Resident or Nonresident
R4-23-693. Durable Medical Equipment (DME) and Compressed Medical Gas (CMG) Supplier-Resident or Nonresident

ARTICLE 11. PHARMACY TECHNICIANS

Section
R4-23-1102. Pharmacy Technician Licensure
R4-23-1103. Pharmacy Technician Trainee Licensure
R4-23-1105. Pharmacy Technician Trainee Training Program, Pharmacy Technician Drug Compounding Training Program, and Alternative Pharmacy Technician Training
ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

In addition to definitions in A.R.S. § 32-1901, the following definitions apply to 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.

“Change of ownership,” as used in A.R.S. § 32-1901.01(A), means a change of at least 30 percent in voting stock or vested interest that has direct operational oversight.

“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 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 fax, 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.


“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 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 fax 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.


“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 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 include one or more of the following 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.

“Virtual manufacturer” means an entity that contracts for the manufacture of a drug or device for which the entity:

- Owns the New Drug Application or Abbreviated New Drug Application number, as defined by the FDA, for a drug;
- Owns the Unique Device Identification number, as defined by the FDA, for a prescription device;
- Contracts with an Arizona-permitted manufacturing entity for the physical manufacture of the drug or device; and
- Is not involved in the physical manufacture of the drug or device.

Virtual manufacturer includes an entity that may be identified as an own-label distributor, which contracts with a manufacturer to produce a drug or device and with another entity to package and label the drug or device, which is then sold under the distributor’s name or another name.

“Virtual wholesaler” means an entity that engages in the wholesale distribution of a drug or device in, into, or out of Arizona and which has title to but does not take physical possession of the drug or device. Virtual wholesaler includes entities that may be identified as:

- A broker that buys and sells goods for others; or
- A person that facilitates distribution of prescription or over-the-counter drugs and devices.
“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**

**R4-23-202. Licensure by Examination**

A. No change

   1. No change

   2. No change

   3. Complete **not less** than 1500 hours of intern training as specified in R4-23-303.

B. No change

   1. No change

      a. No change

      b. No change

         i. No change

         ii. The application fee specified in R4-23-205(C).

   2. No change

   3. No change

   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) under subsection (B)(1).

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

D. No change
   1. No change
   2. No change
   3. No change

E. No change
   1. No change
      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. No change

F. Time frames Time frames for licensure by examination.
   1. No change
      a. No change
      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. No change
   2. No change
      a. No change
      b. No change
      c. No change
   3. No change
   4. No change
      a. No change
b. No change  
c. No change  
d. No change  
e. No change  
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. No change  
   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. No change  
   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. No change  
   1. No change  
   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, and
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. No change
   1. No change
      a. No change
      b. No change
         i. No change
         ii. The reciprocity fee specified in R4-23-205(B).
   2. No change
   3. No change
   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) in subsection (B)(1).

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

D. No change
   1. No change
      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. No change

E. Time frames 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. No change
R4-23-205. Fees

A. No change
   1. No change
   2. No change

B. No change
   1. No change
      a. No change
      b. No change
   2. No change
   3. No change
      a. No change
      b. No change

C. No change
   1. No change
   2. No change
      a. No change
      b. No change
      c. No change
   3. No change
   4. No change
      a. No change
      b. No change
   5. No change
   6. No change
   7. Third-party logistics provider: $1000 biennially.

D. No change
   1. No change
   2. No change

E. No change

F. No change

G. No change
   1. No change
   2. No change
3. No change

**H. No change**
1. No change
   a. No change
   b. No change
   c. No change
d. No change
2. No change
3. No change
4. No change

**I. No change**

**J. No change**
1. No change
2. No change

**ARTICLE 3. INTERN TRAINING AND PHARMACY INTERN PRECEPTORS**

**R4-23-301. Intern Licensure**

**A. No change**

**B. No change**
1. No change
2. No change
3. No change
4. No change

**C. No change**

**D. No change**
1. No change
2. No change
3. No change

**E. No change**

**F. No change**
1. No change
2. No change

**G. No change**

**H. No change**
1. No change
   a. No change
   b. No change
      i. No change
      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. No change

I. No change
1. No change
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 before receiving the certificate of licensure.
3. No change
4. No change

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 fewer 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 from the date the Board issues the initial intern 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. No change
   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 10 days of starting or terminating training, or changing training site.
   2. No change

R4-23-302. Training Site and Pharmacy Intern Preceptors

A. No change
   1. Holds a valid Arizona pharmacy permit and employs a pharmacy intern preceptor who supervises the intern; or
   2. No change

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. No change
   1. No change
   2. Have a minimum of one year of experience as an actively practicing pharmacist before acting as a pharmacy intern preceptor; and
   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.D. 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.

**ARTICLE 4. PROFESSIONAL PRACTICES**

**R4-23-407. Prescription Requirements**

A. No change

1. A prescription order dispensed by the pharmacist uses to dispense a drug or device includes the following information:
   a. No change
   b. No change
   c. No change
   d. Name of the drug’s or device’s manufacturer or distributor of the drug or device if the prescription order is written generically or a substitution is made;
   e. No change
   f. No change
   g. No change
   h. No change
   i. No change
   j. No change
   k. No change
   l. No change

2. No change

3. No change
4. If the drug dispensed is a schedule II controlled substance that is an opioid, the drug is placed in a container that has a red cap and a warning label stating “CAUTION: OPIOID, Risk of Overdose and Addiction” or other similarly clear language indicating the possibility of overdose and addiction.

B. No change
1. No change
2. No change
3. No change
4. No change

C. No change

D. No change
1. No change
2. No change
3. No change
4. No change
   a. No change
      i. No change
         (1) No change
         (2) No change
         (3) No change
      ii. No change
         (1) No change
         (2) No change
      iii. No change
         (1) No change
         (2) No change
         (3) No change
         (4) No change
         (5) No change
         (6) No change
         (7) No change
         (8) No change
   b. No change
i. The transfer of information is communicated directly between two licensed pharmacists 
electronically, verbally, or by fax;

ii. No change
   (1) No change
   (2) No change

iii. No change
   (1) No change
   (2) No change
   (3) No change
   (4) No change
   (5) No change
   (6) No change
   (7) No change
   (8) No change

5. No change
   a. No change
   b. No change

6. No change
   a. No change
   b. No change
   c. No change
   d. No change
     i. No change
        (1) No change
        (2) No change
        (3) No change
        (4) No change
     ii. No change
        (1) No change
        (2) No change
        (3) No change
        (4) No change
        (5) No change
        (6) No change
E. Transmission of a prescription order from a medical practitioner to a pharmacy by facsimile fax 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 fax under the following conditions:
   a. No change
   b. No change
      i. No change
      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 fax of a prescription order for a patient of the facility; and
   c. No change
      i. No change
      ii. The facsimile fax 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 fax, if other than the medical practitioner.

2. No change

3. No change

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 fax machine, except a pharmacy that does not have a plain paper facsimile fax machine may make a Xerox copy of a faxed prescription order received on a non-plain paper facsimile fax 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 fax number, the medical practitioner’s signature or medical practitioner’s agent’s name, and date of authorization.

F. No change
   1. No change
   2. No change
   3. No change
   4. No change
      a. No change
      b. No change
   5. No change
   6. No change

R4-23-407.1. Dispensing an Opioid Antagonist

A. No change
   1. No change
   2. No change
   3. No change

B. Before allowing an opioid antagonist to be dispensed under A.R.S. § 32-1979, a pharmacy permit holder shall have written policies and procedures regarding: pharmacist or pharmacy intern shall provide the following education
   1. Documentation of opioid antagonists dispensed under A.R.S. § 32-1979. The documentation shall:
      a. Be maintained in a manner consistent with R4-23-407(A)(2);
      b. Include the information required under R4-23-407(A)(1)(c, d, f, and l); and
      c. Include the following:
         i. Quantity dispensed;
         ii. Directions for use; and
         iii. The patient’s name, address, telephone number, and birth date; or
         iv. Name, address, telephone number, and birth date of a family member in position to assist the individual at risk of an opioid-related overdose; or
v. Name, address, telephone number, and employer of a community member in position to assist an individual at risk of an opioid-related overdose; and
vi. Name of the individual providing the education required under subsection (B)(2);

2. Education to be provided to the individual to whom the opioid antagonist is dispensed. The education shall include:
   a.1. How to prevent an opioid-related overdose;
   b.2. How to recognize an opioid-related overdose;
   c.3. How to administer an opioid antagonist safely to an individual experiencing an opioid-related overdose;
   d.4. Precautions regarding:
      i. a. Potential side effects, and
      ii. b. Possible adverse events associated with administration of the opioid antagonist; and
   e.5. Importance of seeking emergency medical assistance for the individual experiencing an opioid-related overdose before or after administering the opioid antagonist; and


C. Before dispensing an opioid antagonist under A.R.S. § 32-1979(A), a licensed pharmacist shall:
   1. Complete an opioid prevention and treatment training program that includes the following information:
      a.1. How to recognize the symptoms of an opioid-related overdose,
      b.2. How to respond to a suspected opioid-related overdose,
      c.3. How to administer all preparations of an opioid antagonist, and
      d.4. The information needed by an individual to whom an opioid antagonist is dispensed, and
   2. Comply fully with the policies and procedures developed under subsection (B).

D. No change
   1. No change
   2. No change

E. No change

F. When dispensing an opioid antagonist on a standing order, as defined under A.R.S. § 32-1968, a pharmacist or pharmacy intern shall comply with R4-23-407 except subsection (A)(1)(b), R4-23-408, and R4-23-409.

R4-23-411. Pharmacist-administered or Pharmacy or Graduate Intern-administered Immunizations
A. Certification to administer immunizations, vaccines, and emergency medications, as defined at A.R.S. § 32-1974(N), to an eligible adult patient or eligible minor patient. As used in this Section, “eligible adult patient” means an eligible patient 13 years of age or older and “eligible minor patient” means an eligible patient at least three years of age but less than 13 years of age. A pharmacist or a pharmacy or graduate intern in the presence of and under the immediate personal supervision of a pharmacist, may administer, without a prescription, immunizations, vaccines, and emergency medications to an eligible adult patient or eligible minor patient, if:

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

B. No change
1. No change
2. No change

C. No change
1. No change
2. No change

D. No change
1. No change
2. No change
3. No change

E. No change
1. No change
2. No change
3. No change
4. No change
5. No change
6. No change

F. No change
1. No change
G. No change

H. Renewal of a certificate for pharmacist-administered immunizations. A certificate authorizing a pharmacist to administer immunizations, vaccines, and emergency medications to an eligible adult patient or eligible minor patient expires after five years. A pharmacist who wishes to continue remains in good standing to administering immunizations, vaccines, and emergency medications shall renew the certification by submitting a renewal request to the Board within the 30 days before the certificate’s expiration date and provide to the Board proof of if, at the time of license renewal under R4-23-202, the pharmacist attests the following to the Board:
   1. Current certification in basic cardiopulmonary resuscitation, and
   2. Completion of a minimum of five two contact hours (0.5 0.2 CEU) of continuing education related to immunizations during the five year biennial license 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. No change

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

R4-23-601. General Provisions

A. No change
   1. No change
   2. No change

B. No change
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 unless the Board fails to comply with the permit time-frames established in R4-23-602.

D. No change

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. No change
   b. No change
   c. No change
   d. No change

3. No change

4. No change

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.

F. At least 14 days before there is a change in ownership, as defined at R4-23-110, of a license or permit issued under this Chapter, the new licensee or permittee shall apply to the Board for a new license or permit.

R4-23-602. Permit Application Process and Time-frames

A. No change

1. No change

2. No change
   a. No change
   b. The permit fee specified in R4-23-205(D).
B. No change

C. Time frames

1. No change.
   a. No change
   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. No change

2. No change
   a. No change
   b. No change
   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 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. No change

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. No change
   a. No change
   b. No change
   c. No change
   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: 60 days.
   b. Substantive review:
      i. No change
      ii. No change
   c. Overall:
      i. No change
      ii. No change

D. No change
   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. No change

R4-23-603. Resident-Nonprescription Drugs, Retail

A. No change
   1. No change
   2. No change
   3. No change

B. No change

C. No change
   1. No change
   2. No change

D. No change
   1. No change
   2. No change

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. No change
  1. No change
     a. No change
     b. No change
     c. No change
     d. No change
  2. No change
     a. No change
     b. No change
     c. No change

G. Notification. A nonprescription drug permittee shall submit using the permittee’s online profile or provide written notice by mail, facsimile fax, or e-mail to the Board office within ten (10) days of changes involving the telephone number, facsimile or fax number, e-mail address, or mailing address, or business 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). A nonprescription drug permittee shall comply with R4-23-601(F).

I. No change

J. No change
  1. No change
  2. No change

K. Permit renewal. Permit renewal To renew a nonprescription drug permit, the permittee shall be as specified in comply with R4-23-602(D).

L. No change
  1. No change
  2. No change
  3. No change
  4. No change
  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. No change
b. No change

6. No change
   a. No change
   b. No change
   c. No change
d. No change

7. No change

8. No change

R4-23-604. Resident Drug Manufacturer

A. No change

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: and the fee specified in R4-23-205.

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 résumé 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. No change  
   1. No change  
   2. No change  
   3. No change  

D. Notification. A resident drug manufacturer permittee shall notify the Board of changes involving the drug list, ownership, address, telephone number, business name of business, or manager, including manager’s telephone number. The resident drug manufacturer permittee shall submit using the permittee’s online profile or a written notice via by mail, fax, or e-mail to the Executive Director the Board office 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). A resident drug manufacturer permittee shall comply with R4-23-601(F).

F. No change  

G. A No later than 14 days after the change occurs, a resident drug manufacturer permittee shall submit the application packet described under subsection R4-23-604(B), excluding the fee, for any change of officers in a corporation, excluding the fee and final inspection.

H. No change  
   1. No change  
      a. No change  
      b. No change  
      c. No change  
   2. No change  

I. No change  

J. Current Good Manufacturing Practice. A drug manufacturer permittee shall comply with the current is required under federal law to follow the 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. No change.
M. No change
N. No change
   1. No change
   2. No change

R4-23-605. Resident Drug Wholesaler Permit

A. No change

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: and the fee specified in R4-23-205.
   
   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. No change
   a. No change
   b. No change
   c. No change
   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 specified in the application 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, business 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 using the permittee’s online profile or a written notice via by mail, fax, or e-mail to the Executive Director Board office 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 specified in the application required in subsection (B)(4)(g)(iii). 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). A resident full-service or nonprescription drug wholesale permittee shall comply with R4-23-601(F).

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 required 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. No later than 14 days after the change occurs, a resident full-service or nonprescription drug wholesale permittee shall submit the application packet described under subsection (B), excluding the fee, for any change of officers in a corporation, excluding the fee and final inspection.

G. No change
   1. No change
      a. No change
         i. No change
         ii. No change
         iii. No change
         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) comply with the retention of track and trace documents required under the Drug Supply Chain and Security Act for all prescription-only drugs that leave the normal distribution channel as defined in A.R.S. § 32-1981.
b. No change  
  
i. No change  
  
ii. No change  
  
iii. No change  
  
2. No change  
  
a. No change  
  
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. No change  
  
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, track and trace documents required under the Drug Supply Chain and Security Act 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. No change  
  
b. No change  
  
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. No change  
  
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 that buys,
receives, or disposes of any nonprescription drug, precursor chemical, or regulated
chemical; and
v. No change
c. No change
3. No change
a. No change
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. No change
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 track and trace documents required under the Drug Supply
Chain and Security Act 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 that 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. No change
b. No change
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. No change
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. No change

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

I. No change
   1. No change
      a. No change
      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 contrabanding or suspected misbranding, counterfeiting, or contrabanding within three business days of the determination to the Board, FDA, and manufacturer or wholesale distributor from which the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical was acquired.

c. Any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical that has been opened or used, but is not adulterated, misbranded, counterfeited, or contraband or suspected of being misbranded, counterfeited, or contraband, shall be identified as opened or used, or both, and quarantined and physically separated from other narcotics or other controlled substances, prescription-only drugs or devices, nonprescription drugs, precursor chemicals, or regulated chemicals until the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired as authorized by the Board and the FDA.

d. If the conditions under which a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical has been returned cast doubt on the narcotic’s or other controlled substance’s, prescription-only drug’s or device’s, nonprescription drug’s, precursor chemical’s, or regulated chemical’s safety, identity, strength, quality, or purity of the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical, 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. No change

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 of the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical, 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. No change

2. No change

a. No change

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 contrabanding or suspected misbranding, counterfeiting, or
contrabandage contrabanding 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. No change
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 of the nonprescription drug, precursor chemical, or regulated chemical, 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, the nonprescription drug, precursor chemical, or regulated chemical 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 of the nonprescription drug, precursor chemical, or regulated chemical, 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. No change

3. No change

J. No change

1. No change

2. No change

a. No change

b. No change
3. No change
4. No change
5. No change
6. No change
7. No change
8. No change
9. No change

K. No change

1. No change
   a. No change
   b. No change
   c. No change
      i. No change
      ii. No change
      iii. No change
   d. No change
   e. No change
      i. No change
      ii. No change
      iii. No change

2. No change
   a. No change
   b. No change
   c. No change
      i. No change
      ii. No change
      iii. No change
   d. No change
   e. No change
      i. No change
      ii. Any nonprescription drug, precursor chemical, or regulated chemical that has less fewer
          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. No change
L. No change
  1. No change
  2. No change
     a. No change
     b. No change
     c. No change
     d. No change
     e. No change
     f. No change
     g. No change
     h. No change
  3. If after conducting a state and federal criminal history record check the Board determines, after conducting a state and federal criminal history record check, 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. No change
B. Application.
  1. To obtain a permit to operate a pharmacy in Arizona, a person shall submit a completed application, on a form available from the Board, and the fee as specified in R4-23-602 that includes: R4-23-205.
     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. No change
     a. No change
     b. No change
3. No change

C. Notification. A pharmacy permittee shall notify the Board office within ten (10) days of changes involving the type of pharmacy operated, telephone number, facsimile or fax number, e-mail address, or mailing address, business name of business, or staff pharmacist. A pharmacy permittee shall provide the Board office immediate notice of a change of the pharmacist-in-charge.

D. No change

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). A pharmacy permittee shall comply with R4-23-601(F).

F. No change

1. No less than 30 days before the relocation or remodel of an existing pharmacy, the pharmacy permittee shall submit, electronically or manually, a completed application for remodel or relocation electronically or manually on a using the form furnished by the Board specified under subsection (B). A fee is not required with an application for remodel or relocation.
   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 document required by subsection (B)(1)(b).

2. No change

G. Permit renewal. Permit renewal shall be as specified in R4-23-602(D). To renew a pharmacy permit, the permittee shall be as specified in comply with 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: and the fee specified in R4-23-205.

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

   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 résumé 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.C. Notification. A permittee shall submit any notification of any change required in this subsection as a written notice via using the permittee’s online profile or as a written notice by mail, fax, or e-mail to the Executive Director Board office 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, business 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, business 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, business 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 with the application under subsection (C)(3)(b) (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, business name of business, or manager, including manager’s telephone number.

F.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 appropriate application packet described under subsections (B) and (C). A nonresident permittee shall comply with R4-23-601(F).

G.E. No change
1. No change
   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. No change
      ii. No change
      iii. No change
   b. Not sell, distribute, give away, or dispose of any nonprescription drug, precursor chemical, or
      regulated chemical, to anyone in Arizona except:
      i. No change
      ii. No change
      iii. No change
   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 that 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 fewer
      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. No change
   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 that
      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 more
      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. No change
   a. No change
   b. No change
   c. Provide pedigree records track and trace documents required under the Drug Supply Chain and Security Act upon request, if immediately available, or in no less more 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. No change
   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 that 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 more 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. No change
   a. No change
   b. No change
   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 that 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 more 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. No change
   a. No change
   b. No change
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.

R4-23-676. Reserved Third-party Logistics Provider Permit

A. A person shall not provide logistics services, as described under A.R.S. § 32-1941(A), until the Board issues a third-party logistics provider permit for the facility.

B. A person that wants to provide logistics services shall obtain a Board-issued third-party logistics provider permit for each facility.

C. Application. To obtain a third-party logistics provider permit for a facility, a person shall submit a completed application, using a form available on the Board’s website, and the fee specified in R4-23-205.

D. Change of ownership. A third-party logistics provider permittee shall comply with R4-23-601(F).

E. A third-party logistics provider permittee shall renew the permit as specified under R4-23-602(D).

F. The Board shall adhere to the time frames specified under R4-23-602(C) when processing an initial or renewal application for a third-party logistics provider permit.

R4-23-692. Compressed Medical Gas (CMG) Distributor-Resident or Nonresident

A. Permit.
   1. No change
   2. No change

B. Application. To obtain a resident or nonresident CMG distributor permit, a person shall submit to the Board a completed application form and the fee as specified in R4-23-602 R4-23-205.
   1. No change
   2. No change

C. Notification. A resident or nonresident CMG distributor permittee shall submit using the permittee’s online profile or provide written notice by mail, facsimile fax, or e-mail to the Board office within ten 10 days of changes involving the telephone number, facsimile or fax number, e-mail address, or mailing address, or business 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). A resident or nonresident CMG distributor permittee shall comply with R4-23-601(F).

E. Relocation.
   1. No less than 30 days before an existing resident CMG distributor permittee relocates, the permittee shall electronically or manually submit a completed application for relocation electronically or manually on using a form furnished by the Board, and the documentation required in subsection (B). A fee is not required with an application for relocation.
   2. A nonresident CMG distributor permittee shall provide written notice by mail, facsimile fax, or e-mail to the Board office no less than ten 10 days before relocating.

F. A resident or nonresident CMG distributor permittee shall is authorized to 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. No change

H. Current Good Manufacturing Practice: A resident or nonresident CMG distributor permittee shall comply with the current is required under federal law to follow the 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:
   1. establish Implement 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.
   2. A permittee shall retain 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 Make the records required by Section R4-23-601, this Section, and 21 CFR parts 210 and 211 available on for 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.

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J. Inspection.
   1. No change
   2. Within ten 10 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 To renew a CMG distributor permit, the permittee shall comply with 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. No change
   1. The permit requirements of this Section shall do 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. No change
      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. No change
   2. No change

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 R4-23-205.
   1. No change
   2. No change

C. Notification. A resident or nonresident DME and CMG supplier permittee shall submit using the permittee’s online profile or provide written notice by mail, facsimile fax, or e-mail to the Board.
office within ten 10 days of changes involving the telephone number, facsimile or fax number, email address, or mailing address, or business 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). A resident or nonresident DME and CMG supplier permittee shall comply with R4-23-601(F).

E. Relocation.
1. No less fewer than 30 days before an existing a 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). A fee is not required with an application for relocation.
2. A nonresident DME and CMG supplier permittee shall provide written notice by mail, facsimile fax, or e-mail to the Board office no less fewer than ten 10 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 under a prescription order or medication order from a medical practitioner; and
2. A compressed medical gas only pursuant to under a compressed medical gas order from a medical practitioner.

G. Restriction. A DME and CMG supplier permit shall authorize authorizes 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 stated in subsection (J) (K).

J. Records. A resident or nonresident DME and CMG supplier permittee shall establish and implement written procedures for maintaining records pertaining to about acquisition, distribution, returns, recalls, training of personnel, maintenance, cleaning, and complaints.

K. 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 for 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.L. Inspection.

1. No change

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.M. Permit renewal. Permit renewal shall be as specified To renew a resident or nonresident DME and CMG supplier permit, the permittee shall comply with in R4-23-602(D).

M.N. 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 11. PHARMACY TECHNICIANS

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. No change
2. No change
3. No change

B. No change
1. No change
   a. No change
   b. No change
      i. No change
      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. No change

C. No change
1. No change
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 before receiving the certificate of licensure.
3. No change
4. No change

D. No change
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)(4) to vacate the suspension.
3. No change

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. No change

1. No change
   a. No change
   b. No change
      i. No change
      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. No change

C. No change

1. No change

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. No change

4. No change

5. No change

D. No change

1. No change

2. No change
   a. No change
   b. No change
   c. No change

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. Time frames for pharmacy technician trainee licensure. The Board office shall follow the time frames established in R4-23-202(F).

F. No change

R4-23-1105. Pharmacy Technician Trainee Training Program, Pharmacy Technician Drug Compounding Training Program, and Alternative Pharmacy Technician Training
A. No change

B. No change

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. No change
   b. No change
   c. No change

3. No change
   a. Document the date that a pharmacy technician trainee has successfully completed the training program, and
   b. No change

4. No change

C. No change

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. No change
   b. No change
   c. No change
      i. No change
      ii. No change
      iii. No change
      iv. No change
      v. Area clean-up cleanup;

3. No change
   a. Document the date that a pharmacy technician has successfully completed the pharmacy technician drug compounding training program, and
   b. No change

D. No change
1. No change
2. No change
3. No change
   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. No change

E. No change

F. If a pharmacy technician leaves a training program described under subsection (B), (C), or (D) before successfully completing the training program, the pharmacist-in-charge shall provide the pharmacy technician with written documentation of the hours of training completed and the tasks for which competence was demonstrated by the pharmacy technician.