

ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

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

“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.

ARTICLE 2. PHARMACIST LICENSURE

R4-23-205. Fees

A. Licensure fees:

1. Pharmacist:
 - a. Initial licensure [Prorated according to A.R.S. § 32-1925(B)]: \$180.
 - b. Licensure renewal: \$180.
2. Pharmacy or graduate intern. Initial licensure: \$50.
3. Pharmacy technician:
 - a. Initial licensure [~~prorated~~ Prorated according to A.R.S. § 32-1925(B)]: \$72.
 - b. Licensure renewal: \$72.
4. Pharmacy technician trainee: \$36.

B. Reciprocity fee: \$300.

C. Application fee: \$50.

D. Vendor permit fees (Resident and nonresident) [New permits prorated according to A.R.S. § 32-1931(B)]:

1. Pharmacy: \$480 biennially (Including hospital, and limited service).
2. Drug wholesaler or manufacturer:
 - a. Manufacturer: \$1000 biennially.
 - b. Full-service drug wholesaler: \$1000 biennially.
 - c. Nonprescription drug wholesaler: \$500 biennially.
3. Drug packager or repackager: \$1000 biennially.
4. Nonprescription drug, retail:

- a. Category I (30 or fewer items): \$120 biennially.
- b. Category II (more than 30 items): \$200 biennially.
5. Compressed medical gas distributor: \$200 biennially.
6. ~~Compressed medical gas supplier~~ Durable medical equipment and compressed medical gas supplier: \$100 biennially.

E. Other Fees:

1. Wall license.
 - a. Pharmacist: \$20.
 - b. Pharmacy or graduate intern: \$10.
 - c. Pharmacy technician: \$10.
 - d. Pharmacy technician trainee: \$10.
2. Duplicate of any Board-issued license, registration, certificate, or permit: \$10.
3. Duplicate current renewal license: \$10.

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

G. Penalty fee. Renewal applications submitted after the expiration date are subject to penalty fees as provided in A.R.S. §§ 32-1925 and 32-1931.

1. Licensees: A fee equal to half the licensee's biennial licensure renewal fee under subsection (A) and not to exceed \$350.
2. Permittees: A fee equal to half the permittee's biennial permit fee under subsection (D) and not to exceed \$350.

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

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

- A. A person applying for a permit shall ~~submit to the Board Office an application packet consisting of:~~
1. ~~A Submit a completed application ~~form~~ for the desired permit ~~signed by the applicant; electronically or manually on a form furnished by the Board, and~~~~
 2. ~~A cashier's, certified, business, or personal check, or money order for the applicable biennial permit fee; and Submit with the application form:~~
 - a. The documents specified in the application form, and
 - b. The permit fee specified in R4-23-205(D).
 3. ~~Other information or documents required by R4-23-603, R4-23-604, R4-23-605, R4-23-606, R4-23-607, or R4-23-671.~~
- B. The Board ~~Office~~ office shall deem an application ~~packet received on the date that the Board Office stamps on the packet immediately upon receipt~~ form received on the date the Board office electronically or manually date-stamps the form.
- C. ~~The Board office shall finish an administrative completeness review within 20 days from the date of receipt of an application packet. Time-frames for permits.~~
1. The Board office shall finish an administrative completeness review within 60 days from the date the application form is received.
 - 1-a. The Board ~~Office~~ office shall issue a written notice of administrative completeness to the applicant if no deficiencies are found in the application ~~packet~~ form.
 - 2-b. If the application ~~packet~~ form is incomplete, the Board ~~Office~~ office shall

provide the applicant with a written notice that includes a comprehensive list of the missing information. The ~~20~~ 60-day time-frame for the Board ~~Office~~ 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~~ office with all missing information.

- ~~3.c.~~ If the Board ~~Office~~ office does not provide the applicant with written notice regarding administrative completeness, the application ~~packet~~ form shall be deemed complete ~~20~~ 60 days after receipt by the Board ~~Office~~ office.
- ~~D.2.~~ An applicant with an incomplete application ~~packet~~ form shall submit to the Board ~~Office~~ office all of the missing information within ~~60~~ 90 days of service of the notice of incompleteness.

 - ~~1.a.~~ If an applicant cannot submit all missing information within ~~60~~ 90 days of service of the notice of incompleteness, the applicant may ~~obtain an extension by submitting a written request to the Board Office postmarked or delivered within 60 days of service of the notice of incompleteness.~~ send a written request for an extension to the Board office postmarked or delivered no later than 90 days from service of the notice of incompleteness;
 - ~~2.b.~~ The written request for an extension shall document the reasons the applicant is unable to meet the ~~60~~ 90-day deadline; and
 - ~~3.c.~~ The Board ~~Office~~ office shall review the request for an extension of the ~~60~~ 90-day deadline and grant the request if the Board ~~Office~~ office determines that an extension of the ~~60~~ 90-day deadline will enable the applicant to assemble and submit the missing information. An extension ~~of the 60-day deadline~~ shall be

for no more than ~~60~~ 30 days. ~~An applicant that requires an additional extension shall submit an additional written request in accordance with this subsection.~~

The Board ~~Office~~ office shall notify the applicant in writing of its decision to grant or deny the request for an extension.

~~E.3.~~ If an applicant fails to submit a complete application ~~packet~~ form within the time allowed, the Board ~~Office~~ office shall close the applicant's file. An applicant whose file ~~has been~~ is closed and who later wishes to obtain a permit shall ~~apply again in accordance with subsection (A)~~ submit a new application and fee as specified in subsection (A).

~~F.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~~ office shall issue a permit on the day that the Board ~~Office~~ office determines an administratively complete application ~~packet~~ form is received.

~~G.5.~~ Except as described in subsection ~~(F)~~ (C)(4), from the date on which the administrative completeness review of an application ~~packet~~ form is finished, the Board ~~Office~~ office shall complete a substantive review of the applicant's qualifications in no more than 120 days.

~~1.a.~~ If an applicant is found to be ineligible, the Board ~~Office~~ office shall issue a written notice of denial to the applicant;

~~2.b.~~ If an applicant is found to be eligible, the Board ~~Office~~ office shall recommend to the Board that the applicant be issued a permit. Upon receipt of the Board ~~Office's~~ office's recommendation, the Board shall either issue a permit to the

applicant or if the Board determines the applicant does not meet eligibility requirements, return the matter to the Board ~~Office~~ office.

- ~~3.c.~~ If the Board ~~Office~~ office finds deficiencies during the substantive review of the application ~~packet~~ form, the Board ~~Office~~ office shall issue a written request to the applicant for additional documentation.
 - ~~4.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).
 - ~~5.e.~~ ~~When~~ If the applicant and the Board ~~Office~~ office mutually agree in writing, the 120-day substantive review time-frame may be extended once for no more than ~~35~~ 45 days.
- ~~H.6.~~ For the purpose of A.R.S. § 41-1072 et seq., the Board establishes the following time-frames for permits:
- ~~1.a.~~ Administrative completeness review time-frame: ~~20~~ 60 days.
 - ~~2.b.~~ Substantive review time-frame:
 - ~~a.i.~~ Nonprescription drug permit, compressed medical gas distributor permit, and durable medical equipment and compressed medical gas supplier permit: none.
 - ~~b.ii.~~ Except as described in subsection ~~(H)(2)(a)~~ (C)(6)(b)(i): 120 days.
 - ~~3.c.~~ Overall time-frame:
 - ~~a.i.~~ Nonprescription drug permit: 20 days; Nonprescription drug permit, compressed medical gas distributor permit, and durable medical

equipment and compressed medical gas supplier permit: 60 days.

b-ii. Except as described in subsection (H)(3)(a): 140 days (C)(6)(c)(i): 180 days.

D. Permit renewal.

1. To renew a permit, a permittee shall submit a completed application for permit renewal electronically or manually on a form furnished by the Board with the biennial renewal fee specified in R4-23-205(D).
2. If the biennial renewal fee is not paid by November 1 of the renewal year specified in A.R.S. § 32-1931, the permit is suspended. The permittee shall pay a penalty fee as provided in A.R.S. § 32-1931 and R4-23-205(G)(2) to vacate the suspension.
3. Time-frames for permit renewals. The Board office shall follow the time-frames established in subsection (C).

E. Display of permit. A permittee shall conspicuously display the permit in the location to which it applies.

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

- A. Permit.** A person, including the following, shall not sell or distribute a nonprescription drug without a current Board-issued permit:
1. A grocer;
 2. Other non-pharmacy retail outlet; or
 3. Mobile or non-fixed location retailer, such as a swap-meet vendor.
- B.** A medical practitioner licensed under A.R.S. Title 32 is exempt from the requirements of subsection (A).
- C. Application.** To obtain a permit to sell a nonprescription drug, a person shall submit a

completed application, on a form furnished by the Board, that includes:

1. ~~Whether applying for Category I or Category II permit; A completed application form and fee as specified in R4-23-602; and~~
2. ~~Business name, address, mailing address, if different, telephone number, and facsimile number; Documentation of compliance with local zoning laws, if required by the Board.~~
3. ~~Owner's name, if corporation or partnership, officers or partners, including address and title;~~
4. ~~Date business started or planned opening date;~~
5. ~~Documentation of compliance with local zoning laws;~~
6. ~~Type of business, such as convenience, drug, grocery, or health food store, swap-meet vendor, or vending machine;~~
7. ~~If application is submitted because of ownership change, former owner's name and business name, if different;~~
8. ~~Date signed, applicant's verified signature; and~~
9. ~~Fee specified in R4-23-205.~~

D. Drug sales: A nonprescription drug permittee:

1. Shall sell a drug only in the original container packaged and labeled by the manufacturer; and
2. Shall not package, repackage, label, or relabel any drug.

E. Inspection. A nonprescription drug permittee shall consent to inspection during business hours by a Board compliance officer or other authorized officer of the law as defined in A.R.S. § ~~32-1901(4)~~ 32-1901(5).

- F.** Quality control. A nonprescription drug permittee shall:
1. Ensure that all drugs stocked, sold, or offered for sale are:
 - a. Kept clean;
 - b. Protected from contamination, excessive heat, cold, sunlight, and other deteriorating factors; ~~and~~
 - c. ~~Comply~~ In compliance with federal law; and
 - d. Received from a supplier with a current Board-issued permit as specified in R4-23-601(A).
 2. Develop and implement a program to ensure that:
 - a. Any expiration-dated drug is reviewed regularly;
 - b. Any drug, that exceeds its expiration date, is deteriorated or damaged, or does not comply with federal law, is moved to a quarantine area and not sold or distributed; and
 - c. Any quarantined drug is destroyed or returned to its source of supply.
- G.** Notification. A nonprescription drug permittee shall provide written notice by mail, facsimile, or e-mail to the Board office within ten days of changes involving the telephone number, facsimile number, e-mail address, mailing address, or name of business.
- H.** Change of ownership. No less than 14 days before a change of ownership occurs that involves changes of stock ownership of 30% or more of the voting stock of a corporation or an existing and continuing corporation that is not actively traded on any securities market or over-the-counter market, the prospective owner shall submit a completed application form and fee as specified in subsection (C).
- I.** Relocation. No less than 30 days before an existing nonprescription drug permittee

relocates, the permittee shall submit a completed application for relocation electronically or manually on a form furnished by the Board, and the documentation required in subsection (C).

J. Records. A nonprescription drug permittee shall:

1. Retain records of the receipt and disposal of nonprescription drugs as required in R4-23-601(D), and
2. Comply with the requirements of A.R.S. § 32-1977 and federal law for the retail sale of methamphetamine precursors.

K. Permit renewal. Permit renewal shall be as specified in R4-23-602(D).

G.L. Nonprescription drug vending machine outlet. In addition to the requirements of R4-23-601, R4-23-602, and subsections (A) through ~~(F)~~ (K), a person selling or distributing a nonprescription drug in a vending machine shall comply with the following requirements:

1. Each individual vending machine is considered an outlet and shall have a Board-issued nonprescription drug permit;
2. Each nonprescription-drug-permitted vending machine shall display in public view an identification seal, furnished by the Board, containing the permit number, vending machine's serial number, owner's name, and telephone contact number, ~~and permit expiration date~~;
3. Each nonprescription-drug-permitted vending machine is assigned a specific location that is within a weather-tight structure, protected from direct sunlight, and maintained at a temperature not less than 59° F and not greater than 86° F;
4. Each nonprescription drug sold in a vending machine is packaged and labeled in the manufacturer's original FDA-approved container;

5. A nonprescription-drug-permitted vending machine is subject to inspection by a Board compliance officer or other authorized officer of the law as defined in A.R.S. § ~~32-1901(4)~~ 32-1901(5) as follows:
 - a. The owner, manager, or other staff of the nonprescription drug permittee shall provide access to the contents of the vending machine within 24 hours of a request from a Board compliance officer or other authorized officer of the law; or
 - b. The Board compliance staff shall have independent access to the vending machine;
6. Before relocating or retiring a nonprescription-drug-permitted vending machine, the owner or manager shall notify the Board in writing. The notice shall include:
 - a. Permit number;
 - b. Vending machine's serial number;
 - c. Action planned (relocate or retire); and
 - d. If retiring a vending machine, the disposition of the nonprescription drug contents of the vending machine;
7. The sale or distribution of a precursor chemical or regulated chemical in a vending machine is prohibited ~~unless the nonprescription drug permittee provides written proof to the Board of compliance with the requirements of A.R.S. §§ 13-3401, 13-3404, and 13-3404.01;~~ and
8. Under no circumstance may expired drugs be sold or distributed ~~for human or animal consumption.~~

R4-23-606. Resident Pharmacy Permit; Community, Hospital, and Limited Service

- A. Permit. A person shall not operate a pharmacy in Arizona without a current Board-issued

pharmacy permit.

B. Application.

1. To obtain a permit to operate a ~~new pharmacy or change ownership, relocate, or remodel an existing~~ pharmacy in Arizona, a person shall submit a completed application, ~~on a form furnished by the Board,~~ form and fee as specified in R4-23-602 that includes:
 - a. ~~The type of pharmacy~~ Documentation of compliance with local zoning laws, if required by the Board;
 - b. ~~Business name, address, mailing address, if different, telephone number, and facsimile number~~ A detailed floor plan showing proposed pharmacy area including size and security;
 - c. ~~Owner's name, if corporation or partnership, officers or partners, including address and title, and any other trade or business names used;~~ A copy of the lease agreement, if applicable; and
 - 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;~~ A disclosure statement indicating whether a medical practitioner will receive compensation, either directly or indirectly, from the pharmacy.
 - 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, 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;~~

- ~~g. Whether the owner, any officer, or partner is a medical practitioner;~~
 - ~~h. Name and telephone number of individual to contact before opening;~~
 - ~~i. If applying for a hospital pharmacy permit, the hospital's Department of Health Services license number, number of beds, and manager's or administrator's name;~~
 - ~~j. Planned opening, change of ownership, relocation, or remodel date;~~
 - ~~k. Plans or construction drawings showing pharmacy size and security for the proposed business;~~
 - ~~l. Documentation of compliance with local zoning laws;~~
 - ~~m. Lease agreement and a disclosure statement indicating whether a medical practitioner receives income from the lease;~~
 - ~~n. Pharmacist in charge's name;~~
 - ~~o. For an application submitted because of ownership change, the former pharmacy's name, address, owner's name, and permit number;~~
 - ~~p. Date signed, applicant's, corporate officer's, partner's, manager's, administrator's, or pharmacist in charge's verified signature and title; and~~
 - ~~q. Fee specified in R4-23-205.~~
2. Before issuing a pharmacy permit, the Board shall:
- a. Receive and approve a completed permit application; and
 - b. Receive a satisfactory compliance inspection report on the facility from a Board compliance officer.

3. Before issuing a pharmacy permit, the Board may interview the applicant and the pharmacist-in-charge, if different from the applicant, at a Board meeting based on the need for additional information.
- C. Notification. A pharmacy permittee shall notify the Board office within ten days of changes involving the type of pharmacy operated, ~~pharmacy area, ownership, address,~~ telephone number, facsimile number, e-mail address, mailing address, name of business, ~~pharmacist-in-charge,~~ or staff pharmacist. A pharmacy permittee shall provide the Board office immediate notice of a change of the pharmacist-in-charge.
- D. If any nonprescription drugs are sold outside the pharmacy area when the pharmacy area is closed, the pharmacy permittee shall ensure that the business has a current, Board-issued nonprescription drug permit as required in ~~Sections R4-23-602 and~~ Section R4-23-603.
- E. Change of ownership. ~~Before any change of ownership occurs, a prospective owner shall submit the application packet described under subsection R4-23-606(B), except for changes of stock ownership of less than 30% of the voting stock of a corporation or an existing and continuing corporation that is actively traded on any securities market or over the counter market. No less than 14 days before a change of ownership occurs that involves changes of stock ownership of 30% or more of the voting stock of a corporation or an existing and continuing corporation that is not actively traded on any securities market or over-the-counter market, the prospective owner shall submit a completed application form and fee as specified in subsection (B).~~
- F. ~~Before the relocation or remodel of an existing pharmacy, the pharmacy permittee shall submit the application packet described under subsection R4-23-606(B), except a fee is not required. The new or remodeled facility shall pass a final inspection by a Board compliance~~

~~officer before operations begin.~~ Relocation or remodel.

1. No less than 30 days before the relocation or remodel of an existing pharmacy, the pharmacy permittee shall submit a completed application for remodel or relocation electronically or manually on a form furnished by the Board.

a. An application for relocation shall include the documents required by subsections (B)(1)(a) through (d).

b. An application for remodel shall include the document required by subsection (B)(1)(b).

2. The new or remodeled facility shall pass a final inspection by a Board compliance officer before operations begin.

G. ~~A pharmacy permittee shall submit the application packet described under subsection R4-23-606(B) for any change of officers in a corporation, except a fee and final inspection are not required.~~ Permit renewal. Permit renewal shall be as specified in R4-23-602(D).

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

A. Permit:

1. A person shall not manufacture, process, transfill, package, or label a compressed medical gas ~~before a compressed medical gas distributor permit is issued by the Board or its designee following a satisfactory final inspection by a Board compliance officer.~~ in Arizona, or manufacture, process, transfill, package, or label a compressed medical gas outside Arizona and ship into Arizona without a current Board-issued resident or nonresident compressed medical gas distributor permit.

2. Before operating as a compressed medical gas distributor, a person shall register with the FDA as a medical gas manufacturer and comply with the drug listing

- requirements of the federal act.
3. ~~To obtain a compressed medical gas distributor permit a person shall submit a completed application, on a form furnished by the Board, to the Board's office.~~
 4. ~~A compressed medical gas distributor permittee shall distribute a compressed medical gas only:~~
 - a. ~~Pursuant to a compressed medical gas order; and~~
 - b. ~~If the compressed medical gas is listed on the distributor's permit application. To receive approval to distribute an additional compressed medical gas, the permittee shall request that the permit application be amended.~~
 - i. ~~The permittee shall send a written request to amend the permit application to the Board office.~~
 - ii. ~~The request shall include documentation that the FDA has approved manufacture of the additional compressed medical gas not listed on the original permit application.~~
 - iii. ~~If a request to amend an original permit application includes the documentation referenced in subsection (A)(4)(b)(ii) and if the Board or its designee determines that the amendment is in the interest of public health and safety, the Board or its designee shall approve the request to amend within 30 days of receipt.~~
 5. ~~A compressed medical gas distributor permit is subject to denial, suspension, or revocation under A.R.S. § 32-1927.02.~~
- B.** ~~Current Good Manufacturing Practice: A compressed medical gas distributor permittee shall comply with the current good manufacturing practice requirements of 21 CFR 210~~

~~through 211, published April 1, 2011, (and no future amendments or editions), incorporated by reference and on file with the Board.~~

~~C. Records: A compressed medical gas distributor permittee shall establish and implement written procedures for maintaining records pertaining to production, transfilling, process control, labeling, packaging, quality control, distribution, complaints, and any information required by federal or state law.~~

~~1. A permittee shall retain the records required by this Article and 21 CFR 210 through 211 for at least two years after distribution of the compressed medical gas or one year after the expiration date of the compressed medical gas, whichever is longer.~~

~~2. A permittee shall make the records required by this Article and 21 CFR 210 through 211 available within 48 hours for review by the Board, its compliance officers, or the FDA.~~

~~D. Inspections: A permittee shall make the compressed medical gas distributor's facility available for inspection by the Board or its compliance officers under A.R.S. § 32-1904.~~

B. Application. To obtain a resident or nonresident CMG distributor permit, a person shall submit a completed application form and fee as specified in R4-23-602.

1. A resident CMG distributor permit applicant shall include documentation of compliance with local zoning laws, if required by the Board.

2. A nonresident CMG distributor permit applicant that resides in a jurisdiction that issues an equivalent license or permit shall include a copy of the equivalent license or permit.

C. Notification. A resident or nonresident CMG distributor permittee shall provide written notice by mail, facsimile, or e-mail to the Board office within ten days of changes

involving the telephone number, facsimile number, e-mail address, mailing address, or name of business.

D. Change of ownership. No less than 14 days before a change of ownership occurs that involves changes of stock ownership of 30% or more of the voting stock of a corporation or an existing and continuing corporation that is not actively traded on any securities market or over-the-counter market, the prospective owner shall submit a completed application form and fee as specified in subsection (B).

E. Relocation.

1. No less than 30 days before an existing resident CMG distributor permittee relocates, the permittee shall submit a completed application for relocation electronically or manually on a form furnished by the Board, and the documentation required in subsection (B).

2. A nonresident CMG distributor permittee shall provide written notice by mail, facsimile, or e-mail to the Board office no less than ten days before relocating.

F. A resident or nonresident CMG distributor permittee shall sell or distribute a compressed medical gas pursuant to a compressed medical gas order only to durable medical equipment and compressed medical gas suppliers and other entities that are registered, licensed, or permitted to use, administer, or distribute compressed medical gases.

G. Facility. A resident or nonresident CMG distributor permittee shall ensure the facility is clean, uncluttered, sanitary, temperature controlled, and secure from unauthorized access.

H. Current Good Manufacturing Practice: A resident or nonresident CMG distributor permittee shall comply with the current good manufacturing practice requirements of 21 CFR parts 210 and 211, (Revised April 1, 2013, incorporated by reference and on

file with the Board and available at www.gpo.gov. This incorporated material includes no future editions or amendments).

I. Records: A resident or nonresident CMG distributor permittee shall establish and implement written procedures for maintaining records pertaining to production, transfilling, process control, labeling, packaging, quality control, distribution, returns, recalls, training of personnel, complaints, and any information required by federal or state law.

1. A permittee shall retain the records required by Section R4-23-601, this Section, and 21 CFR parts 210 and 211 for not less than three years or one year after the expiration date of the compressed medical gas, whichever is longer.

2. A permittee shall make the records required by Section R4-23-601, this Section, and 21 CFR parts 210 and 211 available on inspection by the Board or its compliance officer, or if stored in a centralized recordkeeping system apart from the inspection location and not electronically retrievable, shall provide the records within four working days of a request by the Board or its compliance officer.

J. Inspection.

1. A resident CMG distributor permittee shall make the CMG distributor's facility available for inspection by the Board or its compliance officers under A.R.S. § 32-1904.

2. Within ten days from the date of a request by the Board or its staff, a nonresident CMG distributor permittee shall provide a copy of the most recent inspection report completed by the permittee's resident licensing authority or the FDA, or a copy of the most recent inspection report completed by a third-party auditor approved by the permittee's resident licensing authority or the Board or its designee. The Board may

inspect, or may employ a third-party auditor to inspect, a nonresident permittee as specified in A.R.S. § 32-1904.

K. Permit renewal. Permit renewal shall be as specified in R4-23-602(D).

L. Nothing in this Section shall be construed to prohibit the emergency administration of oxygen by licensed health care personnel, emergency medical technicians, first responders, fire fighters, law enforcement officers, and other emergency personnel trained in the proper use of emergency oxygen.

R4-23-693. ~~Compressed Medical Gas Supplier~~ Durable Medical Equipment (DME) and Compressed Medical Gas (CMG) Supplier-Resident or Nonresident

A. Permit:

- ~~1. A person shall not supply a compressed medical gas before a compressed medical gas supplier permit is issued by the Board or its designee following a satisfactory final inspection by a Board compliance officer.~~
- ~~2. To obtain a compressed medical gas supplier permit a person shall submit a completed application, on a form furnished by the Board, to the Board's office.~~
- ~~3. A compressed medical gas supplier permittee shall supply a compressed medical gas only:-~~
 - ~~a. Pursuant to a compressed medical gas order, and~~
 - ~~b. To the consumer, patient, or agent of the consumer or patient for whom the compressed medical gas order is written.~~
- ~~4. A compressed medical gas supplier permittee shall not manufacture, process, transfill, package, or label a compressed medical gas, except as set forth in subsection (B)(2).~~

B. Records: A compressed medical gas supplier permittee shall establish and implement

~~written procedures for maintaining records pertaining to acquisition and distribution of, and complaints related to, compressed medical gases.~~

- ~~1. A permittee shall ensure that a compressed medical gas order is obtained and filed for each compressed medical gas container supplied by the permittee.~~
- ~~2. A permittee shall ensure that each compressed medical gas container supplied by the permittee contains a label bearing the name and address of the compressed medical gas supplier.~~
- ~~3. A permittee shall retain the records required by this Article for at least two years after supplying the compressed medical gas or one year after the expiration date of the compressed medical gas, whichever is longer.~~
- ~~4. A permittee shall make the records required by this Article available within 48 hours for review by the Board or its compliance officers.~~

~~C. Inspections: A permittee shall make the compressed medical gas supplier's facility available for inspection by the Board or its compliance officers under A.R.S. § 32-1904.~~

A. Permit. A person shall not sell, lease, or supply durable medical equipment or a compressed medical gas to a patient or consumer in Arizona for use in a home or residence without a current Board-issued resident or nonresident durable medical equipment and compressed medical gas supplier permit.

1. The permit requirements of this Section shall not apply to the following unless there is a separate business entity engaged in the business of providing durable medical equipment or a compressed medical gas to a patient or consumer for use in a home or residence:
 - a. A medical practitioner licensed under A.R.S. Title 32;

E. Relocation.

1. No less than 30 days before an existing resident DME and CMG supplier permittee relocates, the permittee shall submit a completed application for relocation electronically or manually on a form furnished by the Board, and the documentation required in subsection (B).
2. A nonresident DME and CMG supplier permittee shall provide written notice by mail, facsimile, or e-mail to the Board office no less than ten days before relocating.

F. Orders. A resident or nonresident DME and CMG supplier shall sell, lease, or provide:

1. Durable medical equipment that is a prescription-only device as defined in A.R.S. § 32-1901(75) only pursuant to a prescription order or medication order from a medical practitioner; and
2. A compressed medical gas only pursuant to a compressed medical gas order from a medical practitioner.

G. Restriction. A DME and CMG supplier permit shall authorize the permittee to procure, possess, and provide a prescription-only device or compressed medical gas to a patient or consumer as specified in subsection (F). A DME and CMG supplier permit does not authorize the permittee to procure, possess, or provide narcotics or other controlled substances, prescription-only drugs other than compressed medical gases, precursor chemicals, or regulated chemicals.

H. Facility. A resident or nonresident DME and CMG supplier permittee shall ensure the facility is clean, uncluttered, sanitary, temperature controlled, and secure from unauthorized access. A permittee shall maintain separate and identified storage areas in the

facility and in the delivery vehicles for clean, dirty, contaminated, or damaged durable medical equipment or compressed medical gases.

I. A resident or nonresident DME and CMG supplier permittee shall not manufacture, process, transfill, package, or label a compressed medical gas, except as set forth in subsection (J).

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

A permittee shall:

1. Ensure that a prescription order, medication order, or compressed medical gas order is obtained as specified in subsection (F);
2. Ensure that each compressed medical gas container supplied by the permittee contains a label bearing the name and address of the permittee;
3. Ensure that all appropriate warning labels are present on the durable medical equipment or compressed medical gas;
4. Retain the records required by Section R4-23-601 and this Section for not less than three years, or if supplying a compressed medical gas, one year after the expiration date of the compressed medical gas, whichever is longer; and
5. Make the records required by Section R4-23-601 and this Section available on inspection by the Board or its compliance officer, or if stored in a centralized recordkeeping system apart from the inspection location and not electronically retrievable for inspection, shall provide the records within four working days of a request by the Board or its staff.

K. Inspection.

1. A resident DME and CMG supplier permittee shall make the DME and CMG supplier's facility available for inspection by the Board or its compliance officers under A.R.S. § 32-1904.
2. Within ten days from the date of a request by the Board or its staff, a nonresident DME and CMG supplier permittee shall provide a copy of the most recent inspection report completed by the permittee's resident licensing authority, or a copy of the most recent inspection report completed by a third-party auditor approved by the permittee's resident licensing authority or the Board or its designee. The Board may inspect, or may employ a third-party auditor to inspect, a nonresident permittee as specified in A.R.S. § 32-1904.

L. Permit renewal. Permit renewal shall be as specified in R4-23-602(D).

M. Nothing in this Section shall be construed to prohibit the emergency administration of oxygen by licensed health care personnel, emergency medical technicians, first responders, fire fighters, law enforcement officers, and other emergency personnel trained in the proper use of emergency oxygen.