**TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING**
**CHAPTER 19 PHARMACISTS**
**PART 14 DEVICES; MEDICAL GAS REPACKAGERS AND SELLERS**

**16.19.14.1 ISSUING AGENCY:** Board of Pharmacy.
[16.19.14.1 NMAC – Rp, 16.19.14.1 NMAC, 02/28/2023]

**16.19.14.2 SCOPE:** All individuals and entities subject to the New Mexico Drug, Device and Cosmetic Act, Chapter 26, Article I NMSA 1978.
[16.19.14.2 NMAC – Rp, 16.19.14.2 NMAC, 02/28/2023]

**16.19.14.3 STATUTORY AUTHORITY:** Paragraph 7 of Subsection A of Section 61-11-6 NMSA 1978 authorizes the Board to enforce the provisions of all state laws pertaining to the practice of pharmacy and the manufacture, production, sale or distribution of drugs, cosmetics or poisons, including the New Mexico Drug, Device and Cosmetic Act. Paragraphs 18 and 19 of Subsection B of Section 61-11-14 authorize the Board to license and otherwise establish minimum standards for medical gas sellers and repackagers. Section 26-1-18 of the Drug, Device and Cosmetic Act authorizes the Board to promulgate regulations for the efficient enforcement of the Act.
[16.19.14.3 NMAC – Rp, 16.19.14.3 NMAC, 02/28/2023]

**16.19.14.4 DURATION:** Permanent.
[16.19.14.4 NMAC – Rp, 16.19.14.4 NMAC, 02/28/2023]

**16.19.14.5 EFFECTIVE DATE:** February 15, 1996, unless a different date is cited at the end of a Section or Paragraph. This Part reformatted for inclusion into the New Mexico Administrative Code (NMAC) effective 2-15-96.
[16.19.14.5 NMAC – Rp, 16.19.14.5 NMAC, 02/28/2023]

**16.19.14.6 OBJECTIVE:** The objective of Part 14 of Chapter 19 is to establish mandatory controls and performance standards for health care devices so as to minimize the risk of injury from the distribution and use of adulterated or misbranded devices-,and to establish standards for the repackaging and selling of medical gases, so as to minimize the risk of injury from the distribution and use of adulterated or misbranded medical gases.
[16.19.14.6 NMAC – Rp, 16.19.14.6 NMAC, 02/28/2023]

**16.19.14.7 DEFINITIONS:**

**A**. **"Device",** as used in the New Mexico Drug and Cosmetic Act, is any health care product that does not achieve any of its principal intended purpose through chemical action within or on the body of man or other animal and which is not dependent upon being metabolized for achievement of any of its principal intended purposes.

**B.** **"Board"** means the New Mexico board of pharmacy.

**C.** **"Distribution of medical gases"** means the distribution of medical gas, to persons other than consumers or patients.

**D.** **"Drug order"** means a prescription drug order issued by a licensed prescriber for medical gas.

**E.** **"FDA"** means the United States Food and Drug Administration.

**F.** **"Federal Act"** means the Federal Food, Drug and Cosmetic Act.

**G.** **"Medical gas"** means:

**(1)** a drug that is manufactured or stored in a liquefied, nonliquefied, or cryogenic state and is administered as a gas; and

**(2)** that is labeled for medical use in compliance with federal law and is otherwise a designated medical gas as defined at 21 U.S.C. Section 360ddd(1) of the Federal Act, including each of the following that meets the standards set forth in an official compendium: oxygen, nitrogen, nitrous oxide, carbon dioxide, helium, and medical air.

**H.** "Medical gas repackager" means a person that manufactures or repackages a medical gas, which includes producing, cascading, distributing, filling, mixing, purifying, separating, transferring, and transfilling medical gases. This includes original manufacturers as defined by the FDA that repackage medical gas and have a valid registration as a drug establishment with the FDA. A medical gas manufacturer shall be issued the license type medical gas repackager.

**I.** **"Medical gas seller"** means a person licensed to distribute a medical gas to a person other than a consumer or patient, or to supply medical gases on drug orders to a patient or ultimate user.

**J.** **"Repackage"** means persons or entities manufacturing bulk medical gases or transferring gas or liquefied gas product from one container to another (e.g., liquid to gas, gas to gas, liquid to liquid).

[16.19.14.7 NMAC – Rp, 16.19.14.7 NMAC, 02/28/2023]

**16.19.14.8 CLASSIFICATION OF DEVICES:** Three regulatory classes are established based on the extent of control necessary to ensure safety and effectiveness of each device:

**A.** Class I -- General Controls

**(1)** prohibiting adulteration or misbranding

**(2)** requiring federal registration and listing by the manufacturer

**(3)** requiring notification of risks, repairs, replacement or refund

**(4)** requirement restricting sale, distribution or use

**(5)** requirement with respect to good manufacturing practices, record keeping, reports and inspections

**(6)** authority to ban the device

**B.** Class II -- Performance Standards

**(1)** general controls not sufficient to assure safety and effectiveness

**(2)** performance standards required by federal FDA

**(3)** FDA regulations establishing the performance standard.

**C.** Class III -- Pre-Market Approval

**(1)** represents life sustaining, life-supporting or implanted in the body or which presents a potential unreasonable risk of illness or injury.

**(2)** requires investigational device exemption for research (IDE under federal act Sec. 520 (g)).

[16.19.14.8 NMAC – Rp, 16.19.14.8 NMAC, 02/28/2023]

**16.19.14.9 ADULTERATION:** A device may be considered to be adulterated:

**A.** It is subject to a performance standard and does not comply with all requirements of such standard.

**B.** Class II device FDA pre-market approval is not completed.

**C.** It is a banned device.

**D.** It is in violation of good manufacturing practice requirements.

**E.** It fails to comply with the IDE (Investigational Device Exemption) protocol.

[16.19.14.9 NMAC – Rp, 16.19.14.9 NMAC, 02/28/2023]

**16.19.14.10 MISBRANDING:** A device may be deemed to be misbranded if:

**A.** Manufactured in a nonregistered establishment pursuant to federal requirements.

**B.** If advertising and description literature fails to meet minimum requirements for disclosure of product information.

**C.** Devices subject to performance standards set by FDA, whose labeling fails to meet those prescribed in the standard.

**D.** Devices that fail or whose manufacturer refuses to comply with requirements relating to notification and other remedies and requirements or fails to maintain adequate records and necessary reports as required under the federal act Section 518-519.

**E.** If its label does not bear adequate directions for use and adequate warning against unsafe use.

**F.** If the labeling is false or misleading.

**G.** If it is a restricted device and fails to bear required labeling.

[16.19.14.10 NMAC – Rp, 16.19.14.10 NMAC, 02/28/2023]

**16.19.14.11 RESTRICTED DEVICE (PRESCRIPTION STATUS):**

**A.** FDA requirements may restrict the sale, distribution, or use of a device if there cannot be reasonable assurance of its safety and effectiveness.

**B.** Prescription status devices are determined on the basis of its intended use and whether or not the device can be adequately labeled as usable by the layman (i.e., pacemaker, hearing aids, hear valves, etc.).

**C.** Labeling must contain certain information such as name of device, statement of intended use, relevant warnings, precaution, side effects and contraindications.

**D.** Labeling of a restricted device, other than surgical instruments, shall bear:

**(1)** "CAUTION: Federal law restricts this device to sale by or on the order of a _____:, physician, dentist, veterinarian, or with the descriptive designation of any other practitioner licensed by the laws of this State to prescribe or use the device in his practice.

**(2)** The method of its application or use.

**(3)** The label meets all other requirements under CFR Title 21, Section 801.109 (c) and (d) and (e).

[16.19.14.11 NMAC – Rp, 16.19.14.11 NMAC, 02/28/2023]

**16.19.14.12 CUSTOM DEVICES:**

**A.** A custom device is one which is sometimes ordered from manufacturers by practitioners to conform to their own special needs or to those of their patients (i.e. prosthetic devices, dental devices and specially designed orthopedic footwear).

**B.** Custom devices are exempt from performance standards or pre-market approval requirements; however, they are subject to FDA requirements for investigational use, banning, restriction of distribution, adulteration and misbranding.

**C.** The exemption applied only to devices which are not generally available in finished form for dispensing, or on prescription, or for commercial distribution or generally available to other practitioners.

[03-07-80...08-27-90; 16.19.14.12 NMAC - Rn, 16 NMAC 19.14.12, 03-30-02]

**16.19.14.13 PROCEDURE FOR LICENSURE OF BUSINESS FOR MEDICAL GAS REPACKAGER OR SELLER AND FOR TRANSFER OF OWNERSHIP OF LICENSED BUSINESSES**:

**A.** An applicant shall submit required application and fee to the board. Applications for a license or license renewal under this section shall be made on a form furnished by the board. The board may require such information as it deems is reasonably necessary to carry out the purposes of this part.

**B.** After preliminary approval of a new application for licensure, an applicant that is located in New Mexico shall submit a request for inspection and the inspection fee, where applicable, in advance of fourteen days of the requested date for inspection. All subsequent requests for inspection shall be submitted in advance of fourteen days of the requested date for inspection.

**C.** The license provided for herein shall terminate upon the sale or transfer of ownership. Operation of a business subsequent to the date of such transfer or sale without a new application and approval by the board shall constitute a violation of the law under Subsection I of Section 61-11-14 NMSA 1978, and is subject to the penalties contained in the Pharmacy Act.

[16.19.14.13 NMAC – N, 02/28/2023]

**16.19.14.14 LICENSE REQUIREMENTS MEDICAL GAS REPACKAGER OR SELLER:**

**A.** Every medical gas repackager or seller, wherever located, shall be licensed by the board in accordance with the laws and regulations of this state before engaging in repackaging, distribution or selling of medical gases in this state.

**B.** Repackagers and sellers cannot operate from a place of residence. No primary business location will be operated out of a storage unit. Use of a storage unit shall be consistent with accrediting body approval and allowance.

**C.** Where operations are conducted at more than one location, each such location shall be licensed by the board.

**D.** A manufacturer or wholesale drug distributor licensed by the board may distribute medical gas without the requirement of a separate medical gas license. Said licensees shall distribute only to an entity licensed to receive medical gas. A pharmacy, dentist, or licensed prescriber's license verifies their authority to receive prescription only medical gases.

**E.** A pharmacy licensed by the board may provide medical gas pursuant to a drug order, or to nearby emergency medical services, i.e., ambulance companies and firefighting organizations in the same state or same

marketing or service area, or nearby licensed practitioners allowed to prescribe medical gases for use in the treatment of acutely ill or injured persons; to nearby or contracted nursing homes or home care services; or to another pharmacy to alleviate a temporary shortage without the requirement of a separate medical gas license.

**F.** The Board may prohibit a person or entity from receiving or maintaining licensure if the person or entity:

**(1)** has been convicted of any felony for conduct relating to manufacturing or distribution, any felony violation of Subsection (i) or (k) of section 301, or any felony violation of Section 1365 of title 18, United States Code, relating to product tampering; or

**(2)** has been found by the board to have violated the requirements of this part, or state requirements for licensure.

**G.** The board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be consistent with the public health and safety.

[16.19.14.14 NMAC – N, 02/28/2023].

**16.19.14.15 MINIMUM QUALIFICATIONS MEDICAL GAS REPACKAGER OR SELLER:**

**A.** Compliance with federal, state, and local law. Repackagers and sellers shall operate in compliance with all applicable federal, state, and local laws and regulations.

**B.** Every person or entity subject to this part shall meet the federal requirements to handle medical gas, the Prescription Drug Marketing Act at 21 U.S.C., Sec. 331 et seq., and any other applicable federal, state, or local laws and regulations. Said applicants and licensees shall be registered with the FDA, if required.

**C.** Every person or entity subject to this part must conform to the Compressed Medical Gases Guidelines published by the FDA.

**D.** Personnel. As a condition of receiving and retaining a license under this part, the licensee or applicant shall require each person employed in any medical gas related activity to have education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the medical gas quality, safety and security will at all times be maintained by law.

[16.19.14.15 NMAC – N, 02/28/2023]

**16.19.14.16 MINIMUM REQUIREMENTS:**

**A.** Written policies and procedures. Repackagers and sellers shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the proper receipt, security, storage, handling, repackaging, labeling, inventory, distribution, quarantine, return or disposition of medical gases, for identifying, recording and reporting losses or thefts, for correcting all errors and inaccuracies in inventories, for maintenance of required drug records in proper form, and handling recalls.

**B.** The facility shall be of suitable size and construction, with adequate lighting, environmental control, quarantine, cleanliness and pest control.

**C.** The facility shall be secure from unauthorized entry.

**D.** Recordkeeping. Medical gas repackagers and sellers shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of medical gas.

**E.** Inventories and records shall be made available for inspection and copying by Board inspectors for a period of at least three (3) years.

**F.** All repackagers or sellers in New Mexico must publicly display or have readily available all required licenses and the most recent inspection report administered by the board.

**G.** Medical gas repackagers shall distribute only to an entity licensed to receive medical gas. A pharmacy, dentist, or licensed prescriber's license verifies their authority to receive prescription only medical gases.

[16.19.14.16 NMAC – N, 02/28/2023]

**16.19.14.17 CHANGE IN LOCATION OF A MEDICAL GAS REPACKAGER OR SELLER**:

Before any person or entity subject to this part located in New Mexico changes the location of the facility, a new application shall be submitted to the board, setting forth such changes. Upon approval and completion of the change, a request for inspection will be submitted to the board. There will be no charge for the new application, but the inspection will carry the same fee as applies for a new facility inspection.

[16.19.14.17 NMAC – N, 02/28/2023]

**16.19.14.18 TRANSFER OF OWNERSHIP**: A transfer of ownership occurs upon.

**A.** The sale of the facility to another individual or individuals by the present owner.

**B.** The addition or deletion of one or more partners in a partnership.

**C.** The death of a singular or sole owner.

**D.** The change of ownership of thirty percent or more of the voting stock of a corporation since the issuance of the license or last renewal application.

**E.** A new license application will be required to be filed in each of the above circumstances. As stated in the Pharmacy Act, Subsection I of Section 61-11-14 NMSA 1978, licenses are not transferable, and shall expire on December 31 of every other year unless renewed.

[16.19.14.18 NMAC – N, 02/28/2023]

**16.19.14.19 PRESCRIPTION REQUIREMENT**:

**A.** Prescription requirement, in general: A designated medical gas shall be subject to the requirements of 21 U.S.C. section 353(b)(1) unless the Secretary of the FDA exercises the authority provided in section 353(b)(3) to remove such medical gas from the requirements of section 353(b)(1), the gas is approved for use without a prescription pursuant to an application under 21 U.S.C. section 355 or 360b, or the use in question is authorized pursuant to another provision of this part relating to use of medical products in emergencies.

**B.** Oxygen, no prescription required for certain uses: oxygen may be provided without a prescription for the following uses:

**(1)** for use in the event of depressurization or other environmental oxygen deficiency; and

**(2)** for oxygen deficiency or for use in emergency resuscitation, when administered by properly trained personnel.

**(3)** Labeling - For oxygen provided pursuant to this Subsection B., the requirements of section 353(b)(4) of 21 U.S.C. shall be deemed to have been met if its labeling bears a warning that the oxygen can be used for emergency use only and for all other medical applications a prescription is required.

**C.** Prescription requirement. Except as provided above, medical gas sellers shall not supply medical gas to a patient or consumer without a drug order.

**(1)** An original or copy of a prescription drug order must be kept at the licensed location supplying the medical gas.

**(2)** A prescription drug order shall be valid for a period of time consistent with the indication for which it was prescribed. Prescription drug orders shall be maintained for three years and be readily retrievable and available at inspection.

[16.19.14.19 NMAC – N, 02/28/2023]

**16.19.14.20 REPORT OF ROBBERY, FIRE AND FLOOD:** When a medical gas repackager or seller located in New Mexico is involved in a robbery, fire, flood or any unusual event in which medical gases might be missing or damaged, the owner shall immediately file with the Board, a signed statement of the circumstances of such occurrence and evidence that local authorities were notified, if applicable.

[16.19.14.20 NMAC – N, 02/28/2023]

**HISTORY OF 16.19.14 NMAC:**

**Pre-NMAC History:** The material in this part was derived from that previously filed with the State Records Center and Archives:

Regulation No. 14, Devices, 11-25-80.
Regulation No. 14, Devices, 10-24-85.
Regulation No. 14, Devices, 2-2-87.
Regulation No. 14, Devices, 7-27-90.

**History of Repealed Material:** 16.19.4 NMAC, Devices filed 3/30/2002, was repealed and renamed as 16.19.14 Devices; Medical Gas Repackers and Sellers, effective 2/28/2023.

**Other History:**

16 NMAC 19.14, Pharmacists - Devices, filed 02-02-1996, reformatted and renumbered to 16.19.14 NMAC, Devices, effective 03-30-2002.