nabp
National Association of Boards of Pharmacy
1600 Feehanville Drive • Mount Prospect, IL 60056-6014
Tel: 847/391-4406 • Fax: 847/391-4502
Web Site: www.nabp.net

May 13, 2013

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

[Submitted electronically via *www.regulations.gov/*]

RE: Docket No. FDA-2013-N-0260
Provisions of the Food and Drug Administration Safety and Innovation Act Related to Medical Gases; Request for Comments Regarding Regulations

Dear Sir or Madam:

Thank you for the opportunity to provide comments to the Food and Drug Administration (FDA) pursuant to the Request for Comments published in the *Federal Register* on March 22, 2013.

The National Association of Boards of Pharmacy (NABP), founded in 1904, is the independent, international, and impartial association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

In concert with NABP's mission of protecting the public health, NABP supports FDA's efforts to address whether changes to federal drug regulations are necessary for medical gases and would like to offer the following comments:

In January 2012, NABP's Committee on Law Enforcement/Legislation recommended and the NABP Executive Committee subsequently approved to amend the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* by adding separate rules for the licensure of medical gas and medical gas related equipment wholesale distributors, a copy of which is attached. NABP believes that separate federal regulations pertaining to the wholesale distribution of medical gases are necessary as existing regulations, in many instances, do not apply to medical gases.

Existing regulations focus on the risk of diversion and adulteration, which are generally not concerns for medical gases, and therefore provisions relating to pedigrees, counterfeits and contraband were removed from the *Model Act*. Additionally, the depth of personal identification information and the qualifications for the designated representative required for licensure of

wholesale distributors of medical gases or medical gas related equipment were adjusted from those required of wholesale distributors of prescription drugs. The *Model Act* amendments also eliminated provisions pertaining to facility details such as square footage, lease details, and temperature and humidity controls as they do not apply to wholesale distributors of medical gases. Please note that additional controls in the handling, security, and policies and procedures provisions were added for nitrous oxide in order to decrease the potential of theft for nonmedical purposes.

Thank you for the opportunity to provide comments on this issue. We look forward to continuing to work with the FDA on this important issue. If you have any questions or require additional information, please contact Melissa Madigan, NABP policy and communications director, at 847/391-4400 or mmadigan@nabp.net.

Sincerely,

NATIONAL ASSOCIATION OF
BOARDS OF PHARMACY

Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary

Enclosure: *Model Rules for the Licensure of Medical Gas and Medical Gas Related Equipment Wholesale Distributors*

cc: NABP Executive Committee

Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy

August 2012

Published by:
National Association of Boards of Pharmacy
1600 Feehanville Drive
Mount Prospect, IL 60056
847/391-4406

Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary

Model Rules for the Licensure of Medical Gas and Medical Gas Related Equipment Wholesale Distributors

Section 1. Definitions.

(a) "Adulterated Medical Gas or Medical Gas Related Equipment." A Medical Gas or Medical Gas Related Equipment shall be deemed to be Adulterated:

(1) if:

(i) it consists in whole or in part of any impurities or deleterious substances exceeding normal specifications;

(ii) it has been produced, prepared, packed, or held under conditions whereby the medical gas may have been contaminated causing it to be rendered injurious to health; or if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practices to ensure that the medical gas meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess; or

(iii) its container interior is contaminated with any poisonous or deleterious substance that may render the contents injurious to health; or

(2) if it purports to be or is represented as a Medical Gas, the name of which is recognized in the United States Pharmacopeia–National Formulary (USP-NF), and its strength differs from, or its quality or purity falls below, the standard set forth in the USP-NF. Such a determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the USP-NF, or validated equivalent, or in the absence of or inadequacy of these tests or methods of assay, those prescribed under authority of the Federal Act. No medical gas defined in USP-NF shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefore set forth in the compendium, if its difference in strength, quality, or purity from that standard is plainly stated on its label; or

(3) if it is not subject to paragraph (2) and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

(b) "Authorized Distributor of Record of Medical Gases or Medical Gas Related Equipment" means a distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products. An ongoing relationship is deemed to exist between such wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in Section 1504 of the Internal Revenue Code, complies with the following:

(1) the wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; and

(2) the wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which must be updated by the manufacturer when changes are made.

(c) "Common Carrier of Medical Gases or Medical Gas Related Equipment" means any person or entity who undertakes, whether directly or by any other arrangement, to transport, load, or offload property including Medical Gas or Medical Gas Related Equipment for compensation.

(d) "Designated Representative of Medical Gas or Medical Gas Related Equipment Wholesale Distributors" means any and all individuals designated by the Wholesale Distributor of Medical Gases or Medical Gas Related Equipment who will serve as a responsible individual of such Wholesale Distributor with the Board who is actively involved in and aware of the actual daily operation of such Wholesale Distributor.

(e) "Distribute Medical Gas or Medical Gas Related Equipment" or "Distribution of Medical Gas or Medical Gas Related Equipment" means to sell, offer to sell, deliver, offer to deliver, broker, give away, or transfer a Medical Gas or Medical Gas Related Equipment, whether by passage of title, physical movement, or both. The term does not include:
  (1) to Dispense or Administer; or
  (2) delivering or offering to deliver a Medical Gas or Medical Gas Related Equipment by a common carrier in the usual course of business as a common carrier.

(f) "Emergency Medical Reasons for the Distribution of Medical Gases or Medical Gas Related Equipment" include, but are not limited to, transfers of a Medical Gas or Medical Gas Related Equipment between a Wholesale Distributor of Medical Gases or Medical Gas Related Equipment or Pharmacy to alleviate a temporary shortage of a Medical Gas or Medical Gas Related Equipment arising from delays in or interruption of regular distribution schedules; sales to nearby emergency medical services, ie, ambulance companies and firefighting organizations in the same state or same marketing or service area, or nearby licensed Practitioners allowed to dispense Medical Gases or Medical Gas Related Equipment for use in the treatment of acutely ill or injured Persons; provision of minimal emergency supplies of Medical Gases or Medical Gas Related Equipment to nearby nursing homes for use in emergencies or during hours of the day when necessary Medical Gases or Medical Gas Related Equipment cannot be obtained; and transfers of Medical Gases or Medical Gas Related Equipment by a retail Pharmacy to another retail Pharmacy to alleviate a temporary shortage.

(g) "Emergency Use Oxygen" means Oxygen USP administered in emergency situations without a prescription. The container must be labeled in accordance with federal FDA requirements: "For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Rx Only."

(h) "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 Drugs, food, cosmetics, and other consumer products.

(i) "Federal Act" means the Federal Food, Drug, and Cosmetic Act.

(j) "Health Care Entity" means any Person that provides diagnostic, medical, surgical, dental treatment, or rehabilitative care, including home respiratory care providers and (in the case of Oxygen USP) to an authorized administrator of "Emergency Use Oxygen," but does not include any retail Pharmacy or Wholesale Distributor.

(k) "Immediate Container for Medical Gases" means compressed gas cylinders and liquid containers containing a Medical Gas, but does not include large bulk liquid or high

pressure containers such as storage tanks, vehicle mounted vessels, trailers, and/or railcars.

(l) "Intracompany Transaction" means any transaction between a division, subsidiary, parent, and/or affiliated or related company under the common ownership and control of a corporate entity.

(m) "Label for Medical Gases" means a display of written, printed, or graphic matter upon the immediate container of any Medical Gas.

(n) "Label for Medical Gas Related Equipment" means a display of written, printed, or graphic matter upon the immediate container of any Medical Gas Related Equipment.

(o) "Legally Authorized to Receive" means persons that are licensed Manufacturers of Medical Gases or Medical Gas Related Equipment, Wholesale Distributors of Medical Gases or Medical Gas Related Equipment, home respiratory care companies, and Pharmacies. Also includes Health Care Entities, persons authorized to receive Emergency Use Oxygen without a prescription, and companies that require the use of a Medical Gas in the installation and refurbishment of piping and equipment, including Medical Gas Related Equipment that will be used to distribute or contain a Medical Gas.

(p) "Medical Gas" means gases (including liquefied gases) classified by FDA as drugs or devices that are used for medical applications and which may be stored and administered through the use of Medical Gas Related Equipment, which may or may not be required under Federal or State law for the immediate container to bear the label, "Rx only" or "Caution: Federal or State law prohibits dispensing without a prescription."

(q) "Manufacturer of Medical Gases" means persons manufacturing bulk medical gases or persons transferring gas or liquefied gas product from one container to another (eg, liquid to gas, gas to gas, liquid to liquid).

(r) "Medical Gas Related Equipment" means a device used as a component part or accessory used to contain or control the flow, delivery, and/or pressure during the administration of a medical gas (eg, liquid oxygen base and portable units, pressure regulators and flow meters, oxygen concentrators, etc).

(s) "Misbranded Medical Gas or Medical Gas Related Equipment" means a Medical Gas or Medical Gas Related Equipment shall be deemed to be misbranded if the label is false or misleading in any particular; or the label does not bear the name and address of the Manufacturer, packer, or Distributor and does not have an accurate statement of the quantities of the active ingredients in the case of a Medical Gas; or the label does not show an accurate monograph for the Medical Gas.

(t) "Prescription Medical Gas" means a Medical Gas which is required under law to be labeled with the following statement: "Rx Only."

(u) "Product Labeling" means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article.

(v) "USP Standards" means standards published in the current official United States Pharmacopeia or National Formulary.

(w) "Wholesale Distribution of Medical Gases or Medical Gas Related Equipment" means the Distribution of Medical Gas or Medical Gas Related Equipment, by Wholesale Distributors of Medical Gases or Medical Gas Related Equipment to Persons other than consumers or patients. To the extent permitted by the Prescription Drug Marketing Act,

Wholesale Distribution of Medical Gases, or Medical Gas Related Equipment does not include:

(1) the sale, purchase, or trade of a Medical Gas or Medical Gas Related Equipment, an offer to sell, purchase, or trade a Prescription Drug or Device, or the Dispensing of a Medical Gas or Medical Gas Related Equipment pursuant to a Prescription;

(2) the sale, purchase, or trade of a Medical Gas or Medical Gas Related Equipment or an offer to sell, purchase, or trade a Medical Gas or Medical Gas Related Equipment for Emergency Medical Reasons;

(3) intracompany Transactions, unless in violation of own use provisions;

(4) the sale, purchase, or trade of a Medical Gas or Medical Gas Related Equipment or an offer to sell, purchase, or trade a Medical Gas or Medical Gas Related Equipment among hospitals, Pharmacies, or other health care entities that are under common control;

(5) the sale, purchase, or trade of a Medical Gas or Medical Gas Related Equipment or the offer to sell, purchase, or trade a Medical Gas or Medical Gas Related Equipment by a charitable organization described in 503(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(6) the purchase or other acquisition by a hospital or other similar health care entity that is a member of a group purchasing organization of a Medical Gas or Medical Gas Related Equipment for its own use from the group purchasing organization or from other hospitals or similar health care entities that are members of these organizations;

(7) the return of residual Medical Gas that may be reprocessed in accordance with Manufacturer's procedures, or the return of recalled, expired, damaged, or otherwise non-salable Medical Gas or Medical Gas Related Equipment, when conducted by a hospital, health care entity, Pharmacy, or charitable institution in accordance with the Board's regulations; or

(8) other transactions excluded from the definition of "wholesale distribution" under 21 CFR 203.3(CC), including any amendments thereto.

(x) "Wholesale Distributor of Medical Gases or Medical Gas Related Equipment" means any Person engaged in Wholesale Distribution of Medical Gas or Medical Gas Related Equipment in or into the State, including but not limited to Manufacturers, own-label distributors, private-label distributors, warehouses, including Manufacturers' and Distributors' warehouses, and Wholesale Medical Gas or Medical Gas Related Equipment warehouses.

Section 2. Requirements for Licensure.

Wholesale Distributors of Medical Gases or Medical Gas Related Equipment that reside in this state and provide services within this state or other states shall be licensed by the Board and shall periodically renew their license with the Board using an application provided by the Board. Wholesale Distributors of Medical Gases or Medical Gas Related Equipment that provide services within this state though are not residents of this state shall maintain a valid license with the state Board in which they reside and in all states in which they distribute, if required.

Wholesale Distributors cannot operate from a place of residence, except when that place of residence is used for "on call" delivery of homecare oxygen and oxygen related equipment by a home respiratory care technician. Where Wholesale Distribution operations are conducted at more than one location within this state, each such location shall be licensed by the Board of Pharmacy.

(a) Subject to the Federal Act and all applicable federal law and regulations, an FDA-registered Medical Gas or Medical Gas Related Equipment manufacturer, including its affiliates, subsidiaries, agents, and other entities under common ownership and control of the manufacturer, that exclusively distributes its own Medical Gas or Medical Gas Related Equipment, may be exempted from the requirements for licensure.

(b) Every Wholesale Distributor who engages in the Wholesale Distribution of Medical Gases or Medical Gas Related Equipment shall license with the Board by application and provide information required by the Board on an application approved by the Board, including but not limited to:

  (1) all trade or business names used by the licensee (includes "doing business as (dba)" and "formerly known as"), which cannot be identical to the name used by another unrelated Wholesale Distributor licensed to purchase Medical Gas or Medical Gas Related Equipment in the State;

  (2) name(s) of the owner and operator of the licensee (if not the same person), including:

    (i) if a Person: the name, business address, Social Security number, and date of birth;

    (ii) if a partnership: the name, business address, and Social Security number, and date of birth of each partner, the name of the partnership, and federal employer identification number;

    (iii) if a corporation: the name, business address, and title of each corporate officer and director, the corporate names, the state of incorporation, federal employer identification number, and the name and business address of the parent company, if any;

    (iv) if a sole proprietorship: the full name and business address of the sole proprietor and the name and federal employer identification number of the business entity;

    (v) if a limited liability company: the name, business address, and title of each company officer, the name of the limited liability company and federal employer identification number, and the name of the state in which the limited liability company was organized; and

    (vi) any other relevant information that the Board requires.

  (3) name(s), business address(es), and telephone number(s) of a person(s) to serve as the Designated Representative(s) for each facility of the Wholesale Distributor that engages in the Wholesale Distribution of Medical Gas /or Medical Gas Related Equipment and additional information as required in Section 10 (Record Keeping);

  (4) a list of all State and Federal licenses, registrations, or permits, including the license, registration, or permit numbers issued to the Wholesale Distributor by any other state and federal authority that authorizes the Wholesale Distributor to

purchase, possess, and Wholesale Distributes Medical Gas or Medical Gas Related Equipment in this state;

(5) a list of all disciplinary actions pertinent to Wholesale Distributors of Medical Gases or Medical Gas Related Equipment by any State and Federal agencies against the Wholesale Distributor distributing Medical Gas or Medical Gas Related Equipment into the state as well as any such actions against principals, owners, directors, or officers;

(6) an address and description of each facility and warehouse, including all locations utilized for Medical Gas or Medical Gas Related Equipment storage or Wholesale Distribution including a description of the security system;

(7) information regarding general and product liability insurance, including copies of relevant policies;

(8) a description of import and export activities;

(9) a copy of the Wholesale Distributor's written policies and procedures as required in Section 11 (Policies and Procedures); and

(10) the information collected by the Board pursuant to Section 1(a)(6) shall be made available only to the Board, a third party recognized by the Board, and to State and Federal law enforcement officials. The Board shall make provisions for protecting the confidentiality of the information collected under this section.

(c) A "surety" bond of not less than $100,000, or other equivalent means of security acceptable to the Board or a third party recognized by the Board such as insurance, an irrevocable letter of credit, or funds deposited in a trust account or financial institution, to secure payment of any administrative penalties imposed by the Board and any fees or costs incurred by the Board regarding that licensee when those penalties, fees, or costs are authorized under state law and the licensee fails to pay thirty (30) days after the penalty, fee, or costs becomes final. A separate "surety" bond or other equivalent means of security is not required for each company's separate locations or for affiliated companies/groups when such separate locations or affiliated companies/groups are required to apply for or renew their Wholesale Distributor of Medical Gases or Medical Gas Related Equipment license with the Board. The Board may make a claim against such bond or other equivalent means of security until one year after the Wholesale Distributor's license ceases to be valid or until sixty (60) days after any administrative or legal proceeding before or on behalf of the Board that involves the Wholesale Distributor is concluded, including any appeal, whichever occurs later. Manufacturers of Medical Gases shall be exempt from securing a "surety" bond or other equivalent means of security acceptable to the Board. The Board may waive the bond requirement, if the Wholesale Distributor of Medical Gases or Medical Gas Related Equipment:

(1) has previously obtained a comparable surety bond or other equivalent means of security for the purpose of licensure in another state, where the wholesale distributor possesses a valid license in good standing; or

(2) is a publicly held company.

(d) Every Wholesale Distributor of Medical Gases or Medical Gas Related Equipment who engages in Wholesale Distribution of Medical Gases or Medical Gas Related Equipment shall submit a reasonable fee to be determined by the Board.

(e) Manufacturing facilities of Medical Gases are exempt from inspection by the Board, if the Manufacturing facilities:
  (1) are currently registered with FDA in accordance with Section 510 of the Federal Act and can provide proof of such registration, such as a copy of the online verification page; and
  (2) can provide proof of inspection by the FDA, or other regulatory body within the past three (3) years.

(f) The Board may require each facility that engages in Wholesale Distribution of Medical Gases or Medical Gas Related Equipment to undergo an inspection in accordance with Section 15 of this rule and in accordance with a schedule to be determined by the Board. Wholesale Distributors of Medical Gas or Medical Gas Related Equipment do not qualify for the Verified-Accredited Wholesale Distributors (VAWD) accreditation program.

(g) All Wholesale Distributors of Medical Gases or Medical Gas Related Equipment must publicly display or have readily available all state licenses and the most recent inspection report administered by the Board.

(h) Changes in any information in this Section shall be submitted to the Board, or to a third party recognized by the Board, within 30 days of such change (unless otherwise noted).

(i) Information submitted by the Wholesale Distributor of Medical Gases or Medical Gas Related Equipment to the Board or a third party recognized by the Board that is considered trade secret or proprietary information, as defined under this State's privacy and trade secret/proprietary statutes, shall be maintained by the Board or a third party recognized by the Board as private or trade secret/proprietary information and be exempt from public disclosure.

Section 3. Minimum Qualifications.

(a) The Board will consider the following factors in determining the eligibility for, and renewal of, licensure of Persons who engage in the Wholesale Distribution of Medical Gas or Medical Gas Related Equipment:
  (1) any findings by the Board that the applicant has violated or been disciplined by a regulatory agency in any state for violating any Federal, State, or local laws relating to or the Wholesale Distribution of Medical Gases or Medical Gas Related Equipment;
  (2) any criminal convictions of the applicant under Federal, State, or local laws;
  (3) the applicant's past experience in the Manufacture or Wholesale Distribution of Medical Gases or Medical Gas Related Equipment;
  (4) the furnishing by the applicant of false or fraudulent material in any application made in connection with the or Manufacturing or Wholesale Distribution of Medical Gases or Medical Gas Related Equipment;
  (5) Suspension, sanction, or Revocation by federal, State, or local government against any license currently or previously held by the applicant or any of its owners for violations of State or Federal laws regarding Medical Gas or Medical Gas Related Equipment;
  (6) compliance with previously granted licenses of any kind;
  (7) compliance with the requirements to maintain and/or make available to the Board licensing authority or to Federal, State, or local law enforcement officials those

records required to be maintained by Wholesale Distributors of Medical Gases or Medical Gas Related Equipment; and

(8) any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

(b) The Board shall consider the results of a criminal and financial background check of the applicant, including but not limited to, all key personnel involved in the operations of the Wholesale Distributor of Medical Gases or Medical Gas Related Equipment, including the most senior Person responsible for facility operations, purchasing, and inventory control and the Person or Persons they report to; and all company officers, key management, principals, and owners with ten percent (10%) or greater ownership interest in the company (applying to non-publicly held companies only) to determine if an applicant or others associated with the ownership, management, or operations of the Wholesale Distributor of Medical Gases or Medical Gas Related Equipment have committed criminal acts that would constitute grounds for denial of licensure. The background check will be conducted in compliance with any applicable state and Federal laws, at the applicant's expense, and will be sufficient to include all states of residence since the Person has been an adult. Manufacturers of Medical Gases or Medical Gas Related Equipment shall be exempt from criminal and financial background checks.

(c) The applicant shall provide, and attest to, a statement providing a complete disclosure of any past criminal convictions and violations of the State and Federal laws regarding Medical Gases or Medical Gas Related Equipment or an affirmation and attestation that the applicant has not been involved in, or convicted of, any criminal or prohibited acts.

Section 4. Personnel.

Each Person that is issued an initial or renewal license as a Wholesale Distributor of Medical Gases or Medical Gas Related Equipment, whether in state or out of state, must designate in writing, Person(s) for each facility to serve as Designated Representatives of such Wholesale Distributor. The members of the quality control unit, per 21 CFR 211.22, shall act as the Designated Representatives for the Wholesale Distributer.

(a) To be certified as a Designated Representative for a Wholesale Distributor of Medical Gases or Medical Gas Related Equipment, a Person:

(1) must have the appropriate amount of education, training and experience or any combination thereof to perform the functions required to serve as the Designated Representative of such Wholesale Distributor; and

(2) must be actively involved in and aware of the daily operations of the Wholesale Distributor location(s) including all policies and procedures pertaining to those operations and may cover multiple locations. The Designated Representative is therefore not required to be present at each site during normal business hours.

(b) The information collected pursuant to Section 3(a) shall be made available only to the Board, a third party recognized by the Board, and to State and Federal law enforcement officials. The Board and a third party recognized by the Board shall make provisions for protecting the confidentiality of the information collected under this section.

(c) Each licensed Wholesale Distributor of Medical Gases or Medical Gas Related Equipment located outside of this State that Wholesale Distributes Medical Gases or Medical Gas Related Equipment in this State shall designate a registered agent in this

State for service of process. Any licensed Wholesale Distributor of Medical Gases or Medical Gas Related Equipment that does not so designate a registered agent shall be deemed to have designated the Secretary of State of this State to be its true and lawful attorney, upon who may be served all legal processes in any action or proceeding against such licensed Wholesale Distributor growing out of or arising from such Wholesale Distribution. A copy of any such service of process shall be mailed to such Wholesale Distributor by the Board by certified mail, return receipt requested, postage prepaid, at the address such licensed Wholesale Distributor has designated on its application for licensure in this State. If any such Wholesale Distributor is not licensed in this State, service on the Secretary of State only shall be sufficient service.

(d) A Designated Representative must complete either:
   (1) continuing education programs specified by the Board regarding Federal and State laws in regard to the Wholesale Distribution, handling, and storage of Medical Gases or Medical Gas Related Equipment; or
   (2) training programs that address applicable Federal and State laws and are provided by qualified in-house specialists, outside counsel, or consulting specialists with capabilities to help ensure compliance.

Section 5. Minimum Requirements for the Storage and Handling of Medical Gases or Medical Gas Related Equipment and for Establishment and Maintenance of Medical Gas or Medical Gas Related Equipment Records.

The following are required for the storage, handling, transport, and shipment of Medical Gases or Medical Gas Related Equipment and for the establishment and maintenance of Wholesale Distribution records by Wholesale Distributors of Medical Gases and Medical Gas Related Equipment and their officers, agents, representatives, and employees.

(a) All facilities at which a Medical Gas or Medical Gas Related Equipment is received, stored, warehoused, handled, held, offered, marketed, displayed, or transported from shall:
   (1) be of suitable construction to ensure that all Medical Gases or Medical Gas Related Equipment in the facilities are maintained in accordance with the Product Labeling of such Medical Gas or Medical Gas Related Equipment, or in compliance with official compendium standards such as the USP-NF;
   (2) be of suitable size and construction to facilitate cleaning, maintenance, and proper Wholesale Distribution operations;
   (3) have adequate storage areas with appropriate lighting, ventilation, sanitation, space, equipment, and security conditions;
   (4) have a quarantine area for storage of Medical Gas or Medical Gas Related Equipment that are suspected of being outdated, Misbranded, or Adulterated, or otherwise unfit for Distribution or Wholesale Distribution;
   (5) be maintained in a clean and orderly condition;
   (6) be free from infestation that may impact the identity, strength, quality, or purity of the Medical Gas;
   (7) be a commercial location and not a personal dwelling or residence, except when that personal dwelling is used for “on call” delivery of Oxygen USP and oxygen related equipment for homecare use;

(8) provide for the secure and confidential storage of information with restricted access and policies and procedures to protect the integrity and confidentiality of the information; and
(9) provide and maintain appropriate inventory controls in order to detect and document any theft of nitrous oxide.

Section 6. Security.

(a) All facilities used for Wholesale Distribution of Medical Gases or Medical Gas Related Equipment shall be secure from unauthorized entry:
  (1) access from outside the premises shall be kept to a minimum and be well-controlled;
  (2) the outside perimeter of the premises shall be well-lighted; and
  (3) entry into areas where Medical Gas or Medical Gas Related Equipment are held shall be limited to authorized personnel; all facilities shall be equipped with a system to detect or deter entry after hours.
(b) All facilities shall be equipped with a system that will provide suitable protection against theft. When appropriate, the system shall provide protection against theft that is facilitated or hidden by tampering with computers or electronic records.
(c) All facilities shall be equipped with inventory management and control systems that protect against, detect, and document any instances of theft of nitrous oxide.
(d) Where Wholesale Distributors of Medical Gases or Medical Gas Related Equipment use electronic distribution records, they shall employ, train, and document the training of personnel in the proper use of such technology and equipment.
(e) All facilities shall be equipped with security systems to protect the integrity and confidentiality of data and documents and make such data and documents readily available to the Board and other state and federal law enforcement officials.
(f) Vehicles utilized for on-call delivery of Oxygen USP and oxygen related equipment for home care use by home care providers may be parked at a place of residence and shall be locked and equipped with an audible alarm while not attended.
(g) All Wholesale Distributors of Medical Gases or Medical Gas Related Equipment shall maintain records documenting from whom Medical Gases or Medical Gas Related Equipment are received and to whom Medical Gases and/or Medical Gas Related Equipment are distributed with information sufficient to perform a recall of Medical Gases or Medical Gas Related Equipment received and distributed in compliance with 21 CFR 150b, 21 CFR 211.196, and 21 CFR 820.160b.

Section 7. Storage.

All Medical Gases or Medical Gas Related Equipment shall be stored under appropriate conditions in accordance with regulations or, in the absence of regulations, in accordance with applicable industry standards, and the manufacturers' recommendations on the product labeling.
(a) Packaging of the Medical Gas or Medical Gas Related Equipment should be in accordance with an official compendium such as USP-NF, if applicable.
(b) The record keeping requirements in Section 10 (Record Keeping) shall be followed for the Wholesale Distribution of all Medical Gases or Medical Gas Related Equipment.

Section 8. Examination of Materials.

(a) Upon receipt, each Medical Gas container and related equipment shall be visually examined for identity and to determine if it is damaged or otherwise unfit for Wholesale Distribution. This examination shall be adequate to reveal container damage that would suggest possible Adulteration or Misbranding.

(b) The Medical Gas or Medical Gas Related Equipment found to be unacceptable under paragraph (a) should be quarantined from the rest of stock until the examination and determination that the Medical Gas or Medical Gas Related Equipment are not Misbranded or Adulterated.

(c) Each outgoing shipment shall be carefully inspected for identity of the Medical Gas or Medical Gas Related Equipment and to ensure that there is no Delivery of Medical Gas or Medical Gas Related Equipment that have been damaged in storage or held under improper conditions.

(d) Upon receipt, a Wholesale Distributor of Medical Gases or Medical Gas Related Equipment must review records for the acquisition of Medical Gases or Medical Gas Related Equipment for accuracy and completeness.

(e) The record keeping requirements in Section 10 (Record Keeping) shall be followed for all incoming and outgoing Medical Gases or Medical Gas Related Equipment.

Section 9. Returned, Damaged, and Outdated Medical Gases or Medical Gas Related Equipment.

(a) Medical Gas that has left the control of the Wholesale Distributor may be returned to the Wholesale Distributor or Manufacturer from which it was acquired but may not be resold as a Medical Gas even if the integrity of the product is maintained, unless it is reprocessed by the Manufacturer employing proper and adequate controls to ensure the identity, strength, quality, and purity of the reprocessed Medical Gas.

(b) Reusable Medical Gas Related Equipment that has left the control of the Wholesale Distributor may be returned to Wholesale Distributor or Manufacturer for inspection. The Medical Gas Related Equipment may be repaired and or refurbished, if necessary, provided the Manufacturer or Wholesale Distributor employs proper and adequate controls to return the Medical Gas Related Equipment to proper condition.

(c) Any Medical Gas, including its container, that is damaged, Misbranded, or Adulterated shall be quarantined and physically separated from other Medical Gases until it is destroyed or returned to either the Manufacturer or Wholesale Distributor from which it was acquired. External contamination to Medical Gas containers or closure system, not impacting the integrity of the Medical Gas, is not considered damage or Adulteration for purposes of this paragraph. When Medical Gas or Medical Gas Related Equipment are Adulterated, Misbranded, or suspected of being Adulterated, or Misbranded, notice of the Adulteration, Misbranding, or suspected Adulteration, or Misbranding shall be provided to the manufacturer or wholesale distributer from which they were acquired and also the appropriate boards and federal regulatory bodies.

(d) Any Medical Gas container that has been opened or used, but is not Adulterated or Misbranded, shall be considered empty, quarantined and physically separated from non-

empty Medical Gas containers and returned to the Manufacturer for destruction or reprocessing.

(e) Any Medical Gas, its container, or Medical Gas Related Equipment including its associated documentation or labeling, suspected of being involved in a criminal activity shall be retained and not destroyed until its disposition is authorized by the Board, or applicable law enforcement agency.

(f) The record keeping requirements in Section 10 (Record Keeping) of this rule shall be followed for all Misbranded or Adulterated Medical Gases.

Section 10. Due Diligence.

A Wholesale Distributor of Medical Gases or Medical Gas Related Equipment licensed in accordance with these Rules shall comply with the following Due Diligence requirements:

(a) Prior to the initial Wholesale Distribution or acquisition of a Medical Gases or Medical Gas Related Equipment to or from any Wholesale Distributor (or prior to any Wholesale Distribution to a Wholesale Distributor by a Manufacturer), the Distributing Wholesale Distributor (or Manufacturer) shall provide the following information to the acquiring Wholesale Distributor:

(1) If a Manufacturer is distributing to a wholesale distributor, evidence that the manufacturer is registered, and the Medical Gas or Medical Gas Related Equipment is listed with FDA;

(2) If a Wholesale Distributor is distributing to a wholesale distributor, evidence that the wholesale distributor supplying the Medical Gas or Medical Gas Related Equipment is licensed to provide product into the State, if required by the State;

(3) the name(s) of the responsible facility contact person(s) at the supplying Manufacturer or Wholesale Distributor; and

(4) a certification that the Manufacturer or Wholesale Distributor's policies and procedures comply with this Act.

(b) A Manufacturer or Wholesale Distributor that Wholesale Distributes or acquires Medical Gases or Medical Gas Related Equipment to or from another Wholesale Distributor of Medical Gases or Medical Gas Related Equipment shall provide to or obtain from the distributing or acquiring entities as applicable the information set forth in Section 10 (Record Keeping).

(c) Wholesale Distributors of Medical Gases or Medical Gas Related Equipment are exempt from inspecting and obtaining the information from Manufacturers of Medical Gases or Medical Gas Related Equipment as required in Section 9 (Due Diligence) when the Manufacturer is registered with FDA in accordance with Section 510 of the Federal Act and can:

(1) provide proof of such registration; and

(2) either:

(i) can provide proof of inspection by the FDA, or other regulatory body within the past three (3) years; or

(ii) in the event that no regulatory body has inspected within the past three (3) years, conformance with industry standards or guidelines, as identified by the Board.

Section 11. Record Keeping.

(a) Wholesale Distributors of Medical Gases or Medical Gas Related Equipment shall establish and maintain records of all transactions regarding the receipt and Wholesale Distribution or other disposition of Medical Gases or Medical Gas Related Equipment. These records shall include:
  (1) dates of receipt and Wholesale Distribution or other disposition of the Medical Gas or Medical Gas Related Equipment; and
  (2) Information sufficient to perform a recall of Medical Gases or Medical Gas Related Equipment received and distributed.

(b) Such records shall be made available for inspection and photocopying by any authorized official of any State, Federal, or local governmental agency for a period of:
  (1) three (3) years following their creation date for high pressure Medical Gases;
  (2) one (1) year following their creation date for cryogenic or refrigerated liquid Medical Gases; and
  (3) three (3) years following their creation date for Medical Gas Related Equipment.

(c) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of any State or Federal governmental agency charged with enforcement of these rules.

(d) Wholesale Distributors and Manufacturers of Medical Gases or Medical Gas Related Equipment should maintain an ongoing list of Persons from whom they receive or to whom they distribute Medical Gases or Medical Gas Related Equipment.

(e) Wholesale Distributors of Medical Gases or Medical Gas Related Equipment shall maintain a system for the mandatory reporting of any theft, suspected theft, or other significant loss of Nitrous Oxide to the Board and other appropriate law enforcement agencies.

Section 12. Policies and Procedures.

Wholesale Distributors of Medical Gases or Medical Gas Related Equipment shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, transport, and shipping and Wholesale Distribution of Medical Gases or Medical Gas Related Equipment, including policies and procedures for maintaining inventories, identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories associated with nitrous oxide. Wholesale Distributors of Medical Gases or Medical Gas Related Equipment shall include in their written policies and procedures the following:

(a) A procedure to be followed for handling recalls and withdrawals of Medical Gases or Medical Gas Related Equipment. Such procedure shall be adequate to deal with recalls and withdrawals due to:
  (1) Any action initiated at the request of FDA or any other federal, state, or local law enforcement or other government agency, including the Board of Pharmacy; or

(2) Any volunteer action by the Manufacturer of Medical Gases or Medical Gas Related Equipment to remove defective or potentially defective Medical Gases or Medical Gas Related Equipment from the market.

(b) A procedure to ensure that Wholesale Distributors of Medical Gases or Medical Gas Related Equipment prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of a strike, fire, flood, or other natural disaster, or other situations of local, State, or national emergency.

(c) A procedure for reporting criminal or suspected criminal activities involving the inventory of nitrous oxide to the Board, and applicable law enforcement agencies, within three (3) business days of becoming aware of the criminal or suspect criminal activity.

(d) A procedure for verifying security provisions of Common Carriers.

Section 13. Prohibited Acts.

It is unlawful for a Person to knowingly and willfully perform or cause the performance of or aid and abet any of the following acts in this State:

(a) the Manufacture, Repackaging, sale, delivery, or holding or offering for sale any Medical Gas or Medical Gas Related Equipment that is Adulterated, Misbranded, or has otherwise been rendered unfit for Distribution or Wholesale Distribution;

(b) the Adulteration, or Misbranding of any Medical Gas or Medical Gas Related Equipment;

(c) the receipt of any Medical Gas or Medical Gas Related Equipment that is Adulterated, Misbranded, stolen, obtained by fraud or deceit, or the delivery or proffered delivery of such Medical Gas or Medical Gas Related Equipment for pay or otherwise;

(d) the Alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the Product Labeling of a Medical Gas or Medical Gas Related Equipment or the willful commission of any other act with respect to a Medical Gas or Medical Gas Related Equipment that results in the Medical Gas or Medical Gas Related Equipment being Misbranded;

(e) the purchase or receipt of a Medical Gas or Medical Gas Related Equipment from a Person that is not licensed to Wholesale Distribute Medical Gas or Medical Gas Related Equipment to that purchaser or recipient;

(f) the sale or transfer of a Medical Gas or Medical Gas Related Equipment to a Person who is not legally authorized to receive a Medical Gas or Medical Gas Related Equipment;

(g) the failure to maintain or provide records as required by this Act and Rules;

(h) providing the Board or any of its representatives or any state or federal official with false or fraudulent records or making false or fraudulent statements regarding any matter within the provisions of this Act and Rules;

(i) the Wholesale Distribution of any Medical Gas or Medical Gas Related Equipment that was:

(1) purchased by a public or private hospital or other health care entity;

(2) donated or supplied at a reduced price to a charitable organization; or

(3) stolen or obtained by fraud or deceit.

(j) the failure to obtain a license or operating without a valid license when a license is required;

(k) the Obtaining of or attempting to obtain a Medical Gas or Medical Gas Related Equipment by fraud, deceit, misrepresentation, or engaging in misrepresentation or fraud in the Distribution or Wholesale Distribution of a Medical Gas/or Medical Gas Related Equipment;
(l) the Distributing of a Medical Gas or Medical Gas Related Equipment to a patient without a Prescription or Prescription Order from a Practitioner licensed by law to use or prescribe the Medical Gas or Medical Gas Related Equipment;
(m) the Distributing or Wholesale Distributing of a Medical Gas or Medical Gas Related Equipment that was previously dispensed by a Pharmacy or distributed by a Practitioner;
(n) the Distributing of a Medical Gas or Medical Gas Related Equipment to a patient without providing appropriate information and counseling on use, storage, and disposal;
(o) the failure to report any Prohibited Act as listed in these Rules; or
(p) the failure to exercise Due Diligence as provided in Section 9 (Due Diligence) of these regulations.

Section 14. Criminal Acts.

(a) A Person who, with intent to defraud or deceive, performs the act of Adulteration or Misbranding of any Medical Gas or Medical Gas Related Equipment commits a felony of the third degree.
(b) A Person who engages in the Wholesale Distribution and knowingly purchases or receives Medical Gas or Medical Gas Related Equipment from a Person, not legally authorized to Wholesale Distribute Medical Gas or Medical Gas Related Equipment, in Wholesale Distribution commits a felony of the third degree.
(c) A Person who engages in the Wholesale Distribution and knowingly sells, barters, brokers, or transfers Medical Gases or Medical Gas Related Equipment to a Person not legally authorized to purchase Medical Gases or Medical Gas Related Equipment, under the jurisdiction in which the Person receives the Medical Gas or Medical Gas Related Equipment in Wholesale Distribution, commits a felony of the third degree.
(d) A Person who knowingly falsely creates any Label for a Medical Gas or Medical Gas Related Equipment or who falsely represents any factual matter contained in any Label of a Medical Gas or Medical Gas Related Equipment commits a felony of the third degree.
(e) A Person found guilty of any offense under this section, under the authority of the Court convicting and sentencing the Person, shall be ordered to forfeit to the State any real or Personal property:
    (1) used or intended to be used to commit, to facilitate, or to promote the commission of such offense; and
    (2) constituting, derived from, or traceable to the gross proceeds that the defendant obtained directly or indirectly as a result of the offense. Any property or assets subject to forfeiture under this section may be seized pursuant to a warrant obtained in the same manner as a search warrant or as otherwise permitted by law, and held until the case against a defendant is adjudicated. Monies ordered forfeited, or proceeds from the sale of other assets ordered forfeited, shall be equitably divided between the Board and other agencies involved in the investigation and prosecution that led to the conviction. Other property ordered forfeited after conviction of a defendant may, at the discretion of the investigating

agencies, be placed into official use by the Board or the agencies involved in the investigation and prosecution that led to the conviction.

Section 15. Salvaging and Reprocessing.

(a) Medical Gas or Medical Gas Related Equipment that has been subjected to improper conditions such as a fire, accident or natural disaster, shall not be Salvaged or Reprocessed;

(b) Medical Gas product in a Medical Gas container that has left the control of the Wholesale Distributor may be returned to the Manufacturer and reprocessed provided the Manufacture employs proper and adequate controls to assure the identity, strength, quality, and purity of the reprocessed Medical Gas; and

(c) Reusable Medical Gas Related Equipment that has left the control of the Wholesale Distributor may be returned to the Wholesale Distributor or Manufacturer for inspection. The Medical Gas Related Equipment may be repaired and or refurbished (servicing), if necessary, provided the Manufacturer or Wholesale Distributor employs proper and adequate controls to ensure the Medical Gas Related Equipment complies with the manufacturers' design and performance specifications following completion of servicing.

Section 16. Inspection.

(a) The Board shall have the authority to recognize a third party to inspect Wholesale Distributors of Medical Gases or Medical Gas Related Equipment in that State or in other State(s).

(b) The Board shall have the authority to recognize other State(s) inspections of Wholesale Distributors of Medical Gases or Medical Gas Related Equipment operations in other State(s), if such state's laws are deemed to be substantially equivalent.

(c) The Board may license by reciprocity, a Wholesale Distributor of Medical Gases or Medical Gas Related Equipment that is licensed under the laws of another state, if the requirements of that State are deemed by the Board to be substantially equivalent;.

(d) Any applicant that is denied a license due to an inspection shall have the right of review of the Board's decision.

(e) The Board shall ensure that the proprietary information obtained during the inspection process remains confidential and privileged.

(f) The Board may waive requirements of this Chapter.

Comments

Section 1(c). Comment.

Common carriers frequently use the terms “to load,” which means placing property from the shipping location onto the transport vehicle, and “to offload,” which means removing property from the transport vehicle at the delivery location.

Section 2(b)(2). Comment.

The risk of diversion and adulteration are not concerns for medical gases. With this in mind, the depth of personal identification information required for licensure of Wholesale Distributors of Medical Gases or Medical Gas Related Equipment is less than that of Wholesale Distributors of Prescription Drugs. In addition, the provision of facility details such as square footage, lease details, and temperature and humidity controls is not required as it is for Wholesale Distributors of Prescription Drugs.

Section 2(f). Comment.

Although a Board may allow a firm to be third-party accredited, Wholesale Distributors of Medical Gases or Medical Gas Related Equipment do not qualify for the NABP Verified-Accredited Wholesale Distributors (VAWD) accreditation program as the inspection criteria is not applicable to Medical Gas or Medical Gas Equipment Related operations.

Section 5(a)(7). Comment.

Some home respiratory care providers provide “on call” services to patients. This requires home respiratory care technicians to keep parked at their personal dwelling the company vehicle stocked with Medical Gases or Medical Gas Related Equipment.

Section 10(c). Comment.

The Board may refer to the following industry guideline: CGA M-7, *Guideline for Qualifying Suppliers Used by Medical Gas Manufacturers and Distributors.*

Section 11(b). Comment.

Record retention requirements are determined based on cryogenic and liquefied gas product profiles.