



**PHARMACY RULES COMMITTEE
of the
PHARMACY EXAMINING BOARD**

**Room 121A, 1400 East Washington Avenue, Madison, WI 53703
Contact: Dan Williams (608) 266-2112
September 23, 2015**

*Notice: The following agenda describes the issues that the Committee plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. A **quorum of the Board may be present during any committee meetings.***

AGENDA

8:00 A.M.

OPEN SESSION – CALL TO ORDER

A. Approval of Agenda (1)

B. Legislation and Rule Matters – Discussion and Consideration

- 1) Phar 2, 4 Relating to Application and Examination **(2-3)**
- 2) Phar 5 Relating to Renewal and Reinstatement **(4-7)**
- 3) Phar 6 Relating to Temperature and Humidity Controls **(8-10)**
- 4) Phar 14 Relating to Home Medical Oxygen Providers **(11-27)**
- 5) Phar 15 Relating to Compounding **(28-38)**
- 6) Update on Legislation and Pending or Possible Rulemaking Projects

C. Public Comments

ADJOURNMENT

MEETINGS AND HEARINGS ARE OPEN TO THE PUBLIC, AND MAY BE CANCELLED
WITHOUT NOTICE.

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held at 1400 East Washington Avenue, Madison, Wisconsin, unless otherwise noted. In order to confirm a meeting or to request a complete copy of the board's agenda, please call the listed contact person. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of disciplinary hearings may be changed by the examiner for the convenience of the parties. Interpreters for the hearing impaired provided upon request by contacting the Affirmative Action Officer, 608-266-2112.

TEXT OF RULE

SECTION 1. Phar 1.02(6m) is created to read:

Phar 1.02(6m) “NABP” means the National Association of Boards of Pharmacy.

SECTION 2. Phar 2.01 is repealed.

SECTION 3. Phar 2.02 (1) (intro) and (a) are amended to read:

Phar 2.02 Application procedure for original licensure. (1) Each applicant for original licensure as a pharmacist shall submit ~~a completed notarized application prior to the examination date on forms provided by the board. The application shall include~~ all of the following:

(a) ~~The~~ Completed application form with the signature of the applicant.

SECTION 4. Phar 2.02 (f) and (g) are created to read:

Phar 2.02 (f) Evidence of having passed the NAPLEX.

(g) Evidence of having passed the multi-state pharmacy jurisprudence examination with Wisconsin as primary state.

SECTION 5. Phar 2.03 and 2.04 is repealed.

SECTION 6. Phar 2.05 repealed and recreated:

Phar 2.05 Application procedure for persons licensed in another state. Each applicant licensed as a pharmacist in another state shall submit all of the following:

- (1) Completed application and fee as determined by the department under s. 440.05, Stats.
- (2) NABP Clearinghouse license transfer application.
- (3) Evidence of having passed the multi-state pharmacy jurisprudence examination with Wisconsin as primary state.

SECTION 7. Phar 2.06 is repealed.

SECTION 8. Phar 4.01 is repealed.

SECTION 9. Phar 4.03 is amended to read:

Phar 4.03 Passing scores. (1) The passing scores set by the board represent the minimum competency required to protect public health and safety. The board may adopt the recommended passing score of the examination provider.

SECTION 10. Phar 4.03(3) is repealed.

SECTION 11. Phar 4.04, 4.045, 4.046 and 4.05 are repealed.

SECTION 12. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

TEXT OF RULE

SECTION 1. Phar 5.01 (1) is amended to read:

Phar 5.01 Requirements. (1) Pharmacists, pharmacies, manufacturers, ~~and~~ distributors and home medical oxygen providers licensed under ch. 450, Stats., and otherwise qualified for renewal, may continue to be licensed biennially by applying for renewal and paying the fee ~~specified in s. 440.08(2), Stats.~~ as determined by the department under s. 440.03(9)(a), Stats..

SECTION 2. Phar 5.01 (3) is amended to read:

Phar 5.01(3) No pharmacy, manufacturer, ~~or~~ distributor or home medical oxygen provider may operate without a current license.

SECTION 3. Phar 5.04 is amended to read:

Phar 5.04 Renewal prohibited; relicensure. Any person whose license is currently suspended or revoked may not renew his or her license. ~~A person whose license has been suspended or revoked and subsequently reinstated by the board, and who is otherwise qualified for renewal, may renew his or her license upon completion of a renewal form and filing of the required renewal fee.~~

SECTION 4. Phar 5.05 is repealed and recreated to read:

Phar 5.05 Renewal. (1) GENERAL. A person with an expired credential may not reapply for a credential using the initial application process.

(2) RENEWAL WITHIN 5 YEARS. A person renewing the license within 5 years shall do all of the following:

(a) Pay the renewal fee as determined by the department under s. 440.03(9)(a), Stats. and any applicable late renewal fee.

(b) Certify the completion of 30 hours of continuing education during the last biennium.

(3) RENEWAL AFTER EXPIRATION DATE. Notwithstanding par. (2), if a pharmacist fails to obtain renewal on or before the applicable renewal date, the board may suspend the pharmacist's license and may require the pharmacist to pass an examination to the satisfaction of the board to restore that license.

(4) RENEWAL AFTER 5 YEARS. This subsection does not apply to license holders who have unmet disciplinary requirements or whose license has been surrendered or revoke. A person renewing the credential after 5 years shall do all of the following:

(a) Pay the renewal fee as determined by the department under s. 440.03(9)(a), Stats. and the renewal late fee.

(b) Evidence of having passed the multi-state pharmacy jurisprudence examination with Wisconsin as primary state.

OPTIONS:

Discussed at last committee meeting	<p>(c) If the person renewing the credential does not have 2000 hours of practice as a pharmacist within last 24 months of submitting the application for renewal, the person shall meet one of the following requirements:</p> <ol style="list-style-type: none"> 1. If the license has been expired for at least 5 years but not more than 10 years, the person shall submit evidence of all of the following: <ol style="list-style-type: none"> a. Completion of 160 hours of internship for each year the pharmacist license was expired, not to exceed 1000 hours. b. Completion of 15 hours of continuing education for each year the pharmacist license was expired or within the last two years passage of the NAPLEX. 2. If the license has been expired for more than 10 years, the person shall submit evidence of all of the following: <ol style="list-style-type: none"> a. Completion of 160 hours of internship for each year the pharmacist license was expired, not to exceed 1000 hours. b. Passage of the NAPLEX.
Illinois	<p>License expired for more than 5 years (and not practicing in another state) shall submit proof of completion of:</p> <ol style="list-style-type: none"> 1. 30 hours of continuing education 2. 600 hours of clinical practice under the supervision of a licensed pharmacist completed within 2 years prior to renewal or successful completion of the Pharmacist Assessment for Remediation Evaluation (PARE). To be successful, must receive an overall score of 80 or higher, as well as a minimum score of 75 in each of the 3 content areas on the PARE.
Iowa	<p>License has been inactive for more than 5 years (and not practicing in another state) shall do one or more of the following:</p> <ol style="list-style-type: none"> 1. Successfully pass all components of the licensure examination required for initial licensure. 2. Complete 160 internship for each year the pharmacist was on inactive status (not to exceed 1,000 hours). 3. Obtain one and one-half times the number of continuing education credits required for each renewal period the pharmacist was inactive. 4. Complete a Continuing Professional Development portfolio identifying minimum of 45 learning outcomes for each renewal period the pharmacist was inactive.
Michigan	<p>License expired for at least 3 years but not more than 8 years shall do all of the following:</p> <ol style="list-style-type: none"> 1. Completion of 30 hours of continuing education within the 2 years preceding the application for renewal. 2. Pass the jurisprudence examination. 3. Complete within 6 months of renewal, not less than 200 clock hours under the personal charge of a currently licensed pharmacist. Practical pharmacy experience shall include: pharmacy administration and management; drug distribution, use and control; legal requirements; providing health information services and advising patients; pharmacist's ethical and professional responsibilities; and drug and product information.

	<p>License lapsed for at least 8 years shall comply with all of the following:</p> <ol style="list-style-type: none"> 1. Completion of 30 hours of continuing education within the 2 years preceding the application for renewal. 2. Pass the jurisprudence examination. 3. Complete within 6 months of renewal, not less than 400 clock hours under the personal charge of a currently licensed pharmacist. Practical pharmacy experience shall include: pharmacy administration and management; drug distribution, use and control; legal requirements; providing health information services and advising patients; pharmacist's ethical and professional responsibilities; and drug and product information. 4. Pass the NAPLEX <p>May be granted a temporary, nonrenewable license to complete the practical experience.</p>
Minnesota	<p>Lapsed license more than 2 years (and not practicing in another state) meet one of the following set of requirements:</p> <ol style="list-style-type: none"> 1. Evidence of all of the following: <ol style="list-style-type: none"> a. Payment of back renewal fees and penalty fees up to a maximum of \$1000. b. Completion of at least 60 hours of continuing education within the last two years. c. Successful passing of the Minnesota version of the MPJE. d. Successful passing of the NAPLEX e. Completion of 400 hours of work as a pharmacist intern. f. Statement that they have not been charged with or convicted of a felony or misdemeanor involving controlled substance abuse, habitual indulgence of intoxicating liquor or of moral turpitude or have been found by any licensing agency to have engaged in unprofessional conduct. 2. Evidence of all of the following: <ol style="list-style-type: none"> a. Successful passing of the Minnesota version of the MPJE. b. Successful passing of the NAPLEX c. Completion of 1,600 hours as a pharmacist-intern. d. Statement that they have not been charged with or convicted of a felony or misdemeanor involving controlled substance abuse, habitual indulgence of intoxicating liquor or of moral turpitude or have been found by any licensing agency to have engaged in unprofessional conduct.

SECTION 5. Phar 5.06 is created to read:

Phar 5.06 Reinstatement. A licensee who has unmet disciplinary requirements and failed to renew the license within 5 years or whose license has been surrendered or revoked may apply to have the license reinstated in accordance with all of the following:

- (1) Evidence of completion of the requirements in Phar 5.05(4) if the license has not been active within 5 years
- (2) Evidence of completion of the disciplinary requirements, if applicable.
- (3) Evidence of rehabilitation or change in circumstances warranting reinstatement.

SECTION 6. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

Current Phar 6.07 Storage Rule

Phar 6.07 Storage. (1) The professional service area shall have a refrigerator adequate for the storage of biological and other drugs requiring refrigeration.

(2) The professional service area shall have sufficient shelf, drawer or cabinet space for the proper storage of a representative stock of prescription labels, an assorted stock of prescription containers, and an adequate stock of prescription drugs, chemicals and required pharmacy equipment.

(3) Controlled substances shall be stored in a securely locked, substantially-constructed cabinet or dispersed throughout the inventory of non-controlled substances in a manner that obstructs theft.

Considerations submitted by Philip

Definitions

Drug Products - Medicines, including marketed human and veterinary prescription finished dosage medications, in-process/intermediate/bulk materials, drug product samples, clinical trial materials, over-the-counter products.

Mean Kinetic Temperature - The single calculated temperature at which the total amount of degradation over a particular period is equal to the sum of the individual degradations that would occur at various temperatures.

Freezer: A place in which the temperature is maintained between -13 and 14 degrees Fahrenheit.

Refrigerator: A cold place in which the temperature is maintained between 36 and 46 degrees Fahrenheit.

Cold: Any temperature not exceeding 46 Fahrenheit.

Cool: Any temperature between 46 and 59 Fahrenheit.

Controlled room temperature: The temperature maintained thermostatically that encompasses a usual and customary working environment of 68 to 77 degrees Fahrenheit.

Dry place: The term "dry place" denotes a place that does not exceed 40% average relative humidity at 68 Fahrenheit or the equivalent water vapor pressure at other temperatures.

Warm: Any temperature between 86 and 104 degrees Fahrenheit.

Excessive heat: Any temperature above 104 degrees Fahrenheit.

NIST: National Institute for Standards and Technology

Phar 6.07 Storage

- Drug product storage areas shall maintain temperature and humidity limits as defined in the drug product monograph or label.
- A monthly record shall be maintained that includes the minimum and maximum temperature of each storage area and average relative humidity each day a pharmacy is operating and actions taken when temperatures are outside of conditions as defined in the drug product monograph or label. This record shall be maintained for 3 years.
- Temperature monitoring devices shall conform to specifications that are traceable to a NIST standard and shall be calibrated to be accurate within plus or minus 1 degree Fahrenheit and shall record temperatures at least every 15 minutes.

Neighboring States and NABP Model

Illinois

Refrigerators shall be for the exclusive use of prescription drugs. No personal or food items shall be stored in the refrigerator. Refrigeration shall be capable fo maintaining temperature within a range compatible with the proper storage of drugs requiring refrigeration or freezing.

Iowa

Temperature is only mentioned in regards to Compounding.

Storage areas. Controlled temperature storage areas within the pharmacy shall be monitored at least once daily and the results documented on a temperature log. Temperature-sensing mechanisms shall be suitably placed within the storage space to accurately reflect the area's temperature.

Michigan

Wholesale Distributor shall have storage areas that are designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment and security conditions. All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with label requirements or in accordance with requirements set forth n the current edition of the official compendium. If storage requirements are not established for a prescription rug, the drug may be held at controlled room temperature to help ensure that its identity, strength, quality, and purity are not adversely affected. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices or logs shall be utilized to document the proper storage of prescription drugs. The recordkeeping requirements shall be followed for all stored prescription drugs.

Compounding address temperature as it relates to compounding practices.

Minnesota

Each pharmacy must have a refrigerator used only for drug storage or a separate compartment used only for drug storage within a general use refrigerator, manual, electromechanical, or electronic temperature recording equipment devices, or logs shall be used to document proper storage of legend drugs every business day.

Delivery: Use adequate storage or shipping containers and shipping processes to ensure drug stability and potency. The shipping processes must include the use of appropriate packaging material and devices, according to the recommendations of the manufacturer or the United States Pharmacopeia Chapter 1079, in order to ensure that the drug is kept at appropriate storage temperatures throughout the delivery process to maintain the integrity of the medication; develop and implement policies and procedures to ensure accountability, safe delivery, and compliance with temperature requirements. The policies and procedures must address when

drugs do not arrive at their destination in a timely manner or when there is evidence that the integrity of a drug has been compromised during shipment. In these instances, the pharmacy must make provisions for the replacement of the drugs.

Hospital Service Policies: Drug Handling and Storage.

At least the following provisions for the safe handling and secure storing of drugs shall be observed. Storage areas shall be safeguarded by an effective security system, with the pharmacist responsible for maintaining security. Drugs shall be protected from contamination. Drugs shall be stored at temperatures recommended by the U.S.P./N.F. or by the individual drug label or package insert.

Compounding practices are to follow 795 and 797 Standards.

NABP Model Rule

General Pharmacy

All areas where Drugs and Devices are stored shall be dry, well lighted, well ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures which will ensure the integrity of the Drugs prior to their Dispensing as stipulated by the United States Pharmacopeia–National Formulary (USP-NF) and/or the Manufacturer’s or Distributor’s Product Labeling unless otherwise indicated by the Board.

Wholesale Distributor

All Prescription Drugs and Devices shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the Product Labeling of such Prescription Drugs and Devices, or with requirements in the current edition of an official compendium such as the USP-NF.

- (a) If no storage requirements are established for a Prescription Drug, the Prescription Drug may be held at “controlled” room temperature, as defined in an official compendium such as USP-NF, to help ensure that its identity, strength, quality, and purity are not adversely affected.
- (b) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment and/or logs shall be utilized to document proper storage of Prescription Drugs and Devices.
- (c) Packaging of the Prescription Drugs and Devices should be in accordance with an official compendium such as USP-NF and identify any compromise in the integrity of the Prescription Drugs or Devices due to tampering or adverse storage conditions.
- (d) Controlled substance Drugs should be isolated from non-controlled substance Drugs and stored in a secure area in accordance with Drug Enforcement Administration security requirements and standards.
- (e) The record keeping requirements in Section 10 (Record Keeping) shall be followed for the Wholesale Distribution of all Prescription Drugs and Devices.

Chapter Phar 14
HOME MEDICAL OXYGEN PROVIDERS

Phar 14.01 Application. Each applicant for licensure as a home medical oxygen provider shall submit all of the following:

- (1) Submits an application for licensure on a form provided by the board.
- (2) Pays the fee specified in s. 440.05(1).
- (3) Evidence of accreditation by an organization deemed an accreditation organization for suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) by the United States department of health and human services, centers for medicare and medicaid services.

Phar 14.02 Standards of Professional Conduct. Licensed home medical oxygen providers and their employees and agents shall do all of the following:

- (1) Comply with all transportation rules and regulations regarding transporting oxygen in cylinder or liquid form.
- (2) Comply with the food and drug administration regarding transporting medical oxygen systems.
- (3) Demonstrate that oxygen provided to cylinder or liquid form meets purity standards for medical grade oxygen.
- (4) Meet safety inspection requirements including all of the following:
 - (a) Maintain documentation demonstrating each piece of oxygen or respiratory equipment has been checked, is free of defect and operates within the manufacturer's specifications.
 - (b) Equipment shall not be modified to the extent that the modification may reasonably cause harm.
 - (c) Maintain all electrical components so that they do not present a fire or shock hazard.
 - (d) Ensure that all appropriate warning labels, including tags, are present on the equipment provided.
- (5) Maintain recall procedures including all of the following:
 - (a) Ensure that lot numbers and expiration dates are affixed to each cylinder delivered.
 - (b) Maintain a tracking system for all medical oxygen and gas delivered.
 - (c) Document all equipment serial numbers and model numbers to ensure that equipment can be retrieved if a recall is initiated.
 - (d) Maintain records for equipment that requires food and drug administration tracking.
- (6) Comply with the all of the following maintenance and cleaning requirements:
 - (a) Maintain documentation demonstrating that a function and safety check of equipment was performed prior to set up.
 - (b) Maintain an established protocol for cleaning and disinfecting equipment which address both aerobic and anaerobic pathogens.
 - (c) Maintain a material safety data sheet on file for solutions and products used in cleaning and disinfecting procedures.

- (d) Maintain segregated areas on the premises and in delivery vehicles for clean, dirty and contaminated equipment.
 - (e) Clean and disinfect equipment according to manufacturers' specifications.
 - (f) Instruct the patient on proper cleaning techniques as specified by the manufacturer.
- (7) Implement a comprehensive preventative maintenance program which includes all of the following
- (a) Procedures for problem reporting, tracking, recall and resolution.
 - (b) Performance of service as specified by the manufacturer and the documentation of such performance in the service records.
 - (c) Routine inspection, service, and maintenance of equipment located in the patient's or customer's residence according to manufacturers' specifications.
- (8) Maintain repair logs to document repair and maintenance of equipment, including oxygen concentrators, infant monitors and mechanical ventilators. The repair log shall include all of the following:
- (a) Type of equipment.
 - (b) Manufacturer.
 - (c) Model.
 - (d) Serial number.
 - (e) Date of repair.
 - (f) Specific repair made.
 - (g) Name of person or company performing the repair.
- (9) Maintain testing equipment to ensure accurate calibration. Testing equipment shall be appropriate for the level of service offered. Scales used to weigh liquid oxygen reservoirs shall be properly maintained to ensure accuracy.
- (10) Provide counseling including all of the following:
- (a) Utilize orientation checklists for review of all of the following:
 1. Instructions for use of the equipment.
 2. Safety precautions.
 3. Cleaning procedures.
 4. Maintenance procedures.
 5. Return demonstrations on back up oxygen systems.
 - (b) Instruct the patient about emergency and routine contact procedures.
 - (c) Deliver and review written instruction materials to ensure that the patient receives information regarding the operation of the equipment.
- (11) Develop, implement and document a written plan of services in the patient record, including an assessment of the safety of the home environment, the caregiver or patient ability to comply with the prescription and the caregiver or patient ability to operate and clean the equipment as instructed.
- (12) Maintain all required home medical oxygen records for a period of 5 years.

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.¹⁵⁵
- (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.

¹⁵⁵ 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.

- (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:¹⁵⁶
 - (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

¹⁵⁶ 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.

- (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.¹⁵⁷
- (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).

¹⁵⁷ 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.

- (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;¹⁵⁸
 - (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.

¹⁵⁸ 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.

- (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 distributor 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:¹⁵⁹
 - (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:¹⁶⁰
 - (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,

¹⁵⁹ The Board may refer to the following industry guideline: CGA M-7, *Guideline for Qualifying Suppliers Used by Medical Gas Manufacturers and Distributors*.

¹⁶⁰ Record retention requirements are determined based on cryogenic and liquefied gas product profiles.

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, barter, 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.

15.01 Definitions. In this chapter:

- (1) Active pharmaceutical ingredient (API) means any substance or mixture of substances intended to be used in the compounding of a drug preparation and that, when used in the compounding of a drug preparation, becomes an active ingredient in the preparation intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease in humans and animals or affecting the structure and function of the body.
- (2) Added substances means ingredients that are necessary to compound a drug preparation that are not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation.
- (3) Beyond Use Date (BUD) means the date after which a non-sterile compounded preparation shall not be used, or the date after which a sterile compounded preparation shall not be stored or transported.
- (4) Component means any, active pharmaceutical ingredient, or added substances used in the compounding of a drug preparation.
- (5) Compounding means the preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug delivery device, or a device in accordance with a prescription, medication order or initiative. Compounding includes any of the following:
 - (a) Preparation of drug dosage forms for both human and animal patients.
 - (b) Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.
 - (c) Reconstitution or manipulation of commercial products that may require the addition of one or more ingredients. Notwithstanding this paragraph, the reconstitution or mixing that is performed pursuant to the directions contained in approved labeling provided by the manufacturer of a commercially available product is not compounding.
 - (d) Preparation of drugs or devices for the purposes of, or as an incident to, research, teaching or chemical analysis.
- (6) Controlled room temperature means a temperature maintained thermostatically that encompasses the usual and customary working environment of 68 degrees to 77 degrees Fahrenheit.
- (7) Refrigerator means a cold place in which the temperature is maintained between 36 degrees and 46 degrees Fahrenheit
- (8) Stability means the extent to which a compounded preparation retains, within specified limits and throughout its period of storage and use, the same properties and characteristics that it possessed at the time of compounding.
 - (a) Chemical stability means each active pharmaceutical ingredient retains its chemical integrity and labeled potency, within specified limits.
 - (b) Physical stability means the original physical properties, including appearance, palatability, uniformity, dissolution, and suspendability, are retained.
 - (c) Microbiological stability means sterility or resistance to microbial growth is retained according to specified requirements and antimicrobial agents that are present retain effectiveness within specified limits.
 - (d) Therapeutic stability means the therapeutic effect remains unchanged.
 - (e) Toxicological stability means no significant increase in toxicity occurs.

Freezer means a place in which the temperature is maintained between -11 degrees and 14 degrees Fahrenheit

Excursions between 59 degrees and 86 degrees Fahrenheit are allowed provided the mean kinetic temperature does not exceed 77 degrees Fahrenheit.

Dry Place means a place that does not exceed 40% average relative humidity at 68 degrees Fahrenheit or the equivalent water vapor pressure at other temperatures.

SUBCHAPTER I – General

15.10 Facilities. A pharmacist engaged in compounding shall ensure all of the following:

- (1) An area designated for compounding.
- (2) Orderly placement of compounding equipment, materials, and components in order to minimize the potential for compounding errors.
- (3) The compounding area is well-lighted.
- (4) The compounding area is maintained in a clean and sanitary condition.
- (5) Heating, ventilation and air conditioning systems are controlled to avoid decomposition and contamination of all components.
- (6) The compounding area is easily accessible to all of the following:
 - (a) Hot and cold running water, exclusive of the bathroom sink.
 - (b) Soap or detergent.
 - (c) Single-use towels.
- (7) All compounding equipment, materials and components shall be stored off the floor and in a manner to prevent contamination and permit inspection and cleaning of the compounding and storage areas

15.11 Equipment and Drug Preparation Containers.

- (1) A pharmacy shall possess equipment and drug preparation containers or packaging appropriate to the type of compounding performed at the pharmacy.
- (2) Equipment and drug preparation containers or packaging used in compounding shall be of appropriate design and capacity, and shall be suitably stored in a manner to facilitate use, cleaning, maintenance, and protect it from contamination.
- (3) Equipment and drug preparation containers/packaging used in compounding drug products shall be of suitable composition. Equipment surfaces that contact components may not be reactive, additive or adsorptive so as to alter the stability of the compounded preparation.
- (4) Equipment used in compounding shall be thoroughly cleaned and sanitized after each use, and when necessary, prior to use, according to written policies and procedures, in order to reduce bioburden and reduce the opportunity for cross-contamination.
- (5) All equipment utilized in compounding preparations shall be inspected, maintained, calibrated and validated at appropriate intervals, consistent with manufacturer's recommendations, to ensure the accuracy and reliability of equipment performance. Records shall be kept indicating

15.12 Records. The managing pharmacist shall ensure written or electronic compounding documentation to systematically trace, evaluate, and replicate the compounding steps throughout the process of a preparation. The compounding documentation shall be maintained for a period

of 5 years after the date of the last refill. The compounding documentation shall include all of the following:

- (1) Master Formulation Record including all of the following:
 - (a) Official or assigned name, strength, and dosage form of the preparation.
 - (b) Calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients.
 - (c) Description of all ingredients and their quantities.
 - (d) Compatibility and stability information, including references or laboratory testing
 - (e) Equipment needed to prepare the preparation.
 - (f) Mixing instructions including all of the following:
 1. Order of mixing.
 2. Mixing temperatures or other environmental controls.
 3. Duration of mixing.
 4. Other factors pertinent to the replication of the preparation as compounded.
 - (f) Sample labeling information, including all of the following:
 1. Name and quantity or concentration of each active ingredient.
 2. Assigned BUD.
 3. Storage conditions.
 4. Prescription or control number.
 - (g) Container used in dispensing.
 - (h) Packaging and storage requirements.
 - (i) Description of final preparation.
 - (j) Quality control procedures and expected results.
- (2) Compounding Record including all of the following:
 - (a) Official or assigned name, strength, and dosage of the preparation.
 - (b) Maser Formulation Record reference for the preparation.
 - (c) Names and quantities of all components.
 - (d) Sources, lot numbers and expiration dates of all components.
 - (e) Total quantity compounded.
 - (f) Name of the person who prepared the preparation.
 - (g) Name of the person who performed the quality control procedures.
 - (h) Name of the person who approved the preparation.
 - (i) Date of preparation.
 - (j) Assigned control or prescription number.
 - (k) Assigned BUD.
 - (L) Duplicate label as described in the Master Formulation Record.
 - (m) Description of the final product.
 - (n) Results of quality control procedures.
 - (o) Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver.

15.13 Quality control.

(1) The pharmacist shall do a final check and review each procedure in the compounding process. A final check shall include verification of all the following:

- (a) The master formulation record, compounding record and written procedures were followed in the execution of the compounding process. Any deviation in procedures shall be documented.
 - (b) There was a check and recheck of each procedure at each stage of the process.
 - (c) The tests or examinations conducted on the compounded preparation to ensure their uniformity and integrity followed established written procedures.
 - (d) The performance of compounding processes and equipment that may be responsible for causing variability in the final compounded preparations.
- (2) The pharmacist shall observe the finished preparation to ensure that it appears as expected.
- (3) The pharmacist shall investigate any discrepancies and take appropriate corrective action before the prescription is dispensed to the patient.
- (4) The pharmacist completing the final check is solely responsible for the finished preparation.

15.14 Training. All personnel involved in the compounding, evaluation, packaging, and dispensing of compounded preparations shall be properly trained and competency is assessed for the type of compounding conducted. It is the responsibility of the managing pharmacist to ensure and document that all training and competency assessments.

15.15 Adverse Event Reporting. A pharmacy or pharmacist that becomes aware of an adverse event attributed to a compounded preparation shall report the adverse event to the department, using the form provided by the department, not later than 10 calendar days after becoming aware of the adverse event.

SUBCHAPTER II – Non-sterile Compounding

15.20 Definitions. In this subchapter:

- (1) Office use

MICHIGAN: A pharmacist or pharmacy shall not compound pharmaceuticals for a prescriber or health facility to administer to the prescriber's or facility's patients without a prescription, unless the pharmaceutical compounded by the pharmacist or pharmacy complies with the most recent guidance on pharmacy compounding of human drug products under 2 USC 353c and is authorized by the board to compound nonsterile pharmaceuticals for a prescriber or health facility to administer to the prescriber or facility's patients in limited quantities without a prescription. An application for approval shall include all of the following:

- (a) The name and license number of the pharmacist or pharmacy requesting authorization to compound under this subsection.
- (b) The name of the specific prescriber or health facility that is requesting compounded pharmaceuticals and an affidavit from the prescriber or designated agent of the health facility attesting to the need and that the compounded pharmaceuticals are only for patients located in this state or in states immediately adjacent to this state.
- (c) The pharmaceuticals to be compounded and the reason for the need to compound the pharmaceuticals.

- (d) The anticipated quantities of pharmaceuticals to be compounded each month and the frequency of the need to compound before receipt of a prescription or documentation supporting the anticipated quantities.
- (e) The conditions of operation including practices consistent with USP standards and requirements for sterility testing.

TEXAS: A reasonable quantity of a compounded non-sterile preparation to a practitioner's office for office use by the practitioner.

15.21 Component Selection.

- (1) A pharmacist shall use components manufactured in a FDA registered facility. If a component is unavailable from a FDA registered facility, the pharmacist may utilize a component that has been tested by a FDA approved vendor and the component has been determined to be pure and safe documented by a Certificate of Analysis.
- (2) Components with an expiration date from the manufacturer or distributor may be used before the expiration date provided all of the following:
 - (a) The component is stored in its original container under conditions to avoid decomposition
 - (b) There is minimal exposure of the remaining component each time component is withdrawn from the container.
 - (c) When any withdrawals from the container are performed by those trained in the proper handling of the component.
- (3) Components without an expiration date assigned by the manufacturer or supplier, shall be labeled with the date of receipt and assigned a conservative expiration date, not to exceed three years after receipt, based upon the nature of the component and its degradation mechanism, the container in which it is packaged and the storage conditions.
- (4) Components transferred to another container which shall provide integrity that is minimally equivalent to the original container and shall be identified with all of the following:
 - (a) Component name.
 - (b) Original supplier.
 - (c) Lot or control number.
 - (d) Transfer date.
 - (e) Expiration date.
- (5) Manufactured drug products utilized as the source of active pharmaceutical ingredients shall be manufactured in an FDA registered facility and the manufacturer's product container shall be labeled with a lot number and expiration date.
- (6) A pharmacist compounding for human use may not use components that have been withdrawn or removed from the market for safety or efficacy reasons by the FDA. A pharmacist compounding for food producing animal use may not use components prohibited for use in food producing animals.

15.21 Assigning BUD.

- (1) The BUD shall not be later than the expiration date on the container of any component.

- (2) In the absence of stability information that is applicable to a specific drug product and preparation, the maximum BUD for a non-sterile compounded drug preparation that is packaged in a tight, light-resistant container as follows:
- (a) For nonaqueous formulations stored at controlled room temperature, the BUD shall not be later than the time remaining until the earliest expiration date of any active pharmaceutical ingredient or 6 months, whichever is earlier.
 - (b) For water-containing oral formulations, the BUD shall not be later than 14 days when stored at in a refrigerator
 - (c) For water-containing semisolid, mucosal liquid, topical or dermal formulations, stored at controlled room temperature, the BUD shall not be later than 30 days.
- (3) Assignment of BUD shall include an assessment of the need for antimicrobial agents and or storage in a refrigerator to protect against bacteria, yeast, and mold contamination introduced during or after the compounding process.

SUBCHAPTER III – Sterile Compounding

15.01 Definitions. In this chapter:

- (1) Active pharmaceutical ingredient (API) means any substance or mixture of substances intended to be used in the compounding of a drug preparation, thereby becoming the active ingredient in the preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease in humans and animals or affecting the structure and function of the body.
- (2) Beyond Use Date (BUD) means the date after which a compounded preparation should not be used. This definition captures the BUD definition for non-sterile products only. A definition for sterile compounding will need to be added.
- (3) Component means any ingredient used in the compounding of a drug preparation.
- (4) Compounding means the preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug delivery device, or a device in accordance with a prescription, medication order or initiative. Compounding includes any of the following:
 - (a) Preparation of drug dosage forms for both human and animal patients.
 - (b) Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.
 - (c) Reconstitution or manipulation of commercial products that may require the addition of one or more ingredients. Notwithstanding this paragraph, the reconstitution or mixing that is performed pursuant to the directions contained in approved labeling provided by the manufacturer of a commercially available product is not compounding.
 - (d) Preparation of drugs or devices for the purposes of, or as an incident it, research, teaching or chemical analysis.{NOTE: Unresolved - Preparation of drugs and devices for prescriber's office use}
- (5) Stability means the extent to which a preparation retains, within specified limits and throughout its period of storage and use, the same properties and characteristics that it possessed at the time of compounding.

SUBCHAPTER I – General

- 15.10 Facilities.** (1) A pharmacy engaged in compounding shall ensure all of the following:
- (a) An area shall provide for safe and orderly compounding of drug products.
 - (b) An area shall provide for the orderly placement of equipment and materials in order to minimize the potential for errors.
 - (c) The area is well-lighted and ventilated. (1)(c) How will this be enforced?
 - (d) The area is maintained in a clean and sanitary condition.
 - (e) Heating and air conditioning systems are controlled to avoid decomposition and contamination of chemicals. Suggest removing if revisions to Phar 6 capture this.
 - (f) Sewage, trash and other refuse in and from the pharmacy and immediate drug compounding area are maintained, and disposed of, in a timely, safe and sanitary manner.
 - (g) The area is easily accessible to all of the following:
 1. Hot and cold running water, exclusive of the bathroom sink.
 2. Soap or detergent.

3. Air dryers or single source towels. *Air dryers will be removed in the next USP 797 update*
- (h) Areas for sterile preparations shall be separated and distinct from non-sterile compounding areas. *Except in the event that an isolator is in place.*

15.11 Equipment. (1) A pharmacy shall possess equipment appropriate to the type of compounding performed at the pharmacy. *Equipment section is applicable to sterile but not complete for sterile requirements (ie lacks ISO 5)*

(2) Equipment used in compounding drug products shall be of appropriate design and capacity, and shall be suitably located to facilitate operations for the intended use, cleaning and maintenance of the equipment.

(3) Equipment used in compounding drug products shall be of suitable composition. Equipment surfaces that contact components shall be reactive, additive or adsorptive so as to alter the safety, identity, strength, quality and purity of the compounded product. *Edit to second sentence: shall NOT be reactive*

(4) Equipment used in compounding drug products shall be thoroughly cleaned and sanitized after each use, and when necessary, prior to use, in order to prevent cross-contamination of ingredients and preparations.

(5) Equipment used in compounding drug products shall be stored in a manner to prevent cross-contamination of ingredients and preparations.

(6) Automated, mechanical or electronic equipment may be used in compounding non-sterile preparations. All equipment utilized in compounding preparations shall be inspected, maintained and validated at appropriate intervals, consistent with manufacturer's recommendations, to ensure the accuracy and reliability of equipment performance. *Add requirements for sterile preparations*

15.12 Records. A pharmacist shall maintain written or electronic documentation to systematically trace, evaluate, and replicate the steps throughout the process of a compounded preparation. The records shall include all of the following:

- (1) Master Formulation Record shall include all of the following:
- (a) Official or assigned name, strength, and dosage form on the preparation.
 - (b) Calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients.
 - (c) Description of all ingredients and their quantities.
 - (d) Equipment needed to prepare the preparation.
 - (e) Mixing instructions including all of the following: *...where applicable*
 - 1. Order of mixing.
 - 2. Mixing temperatures or other environmental controls.
 - 3. Duration of mixing.
 - 4. Other factors pertinent to the replication of the preparation as compounded.
 - (f) Sample labeling information, including all of the following:
 - 1. Name and quantity of concentration of each active ingredient.
 - 2. Assigned BUD.
 - 3. Storage conditions.
 - 4. Prescription or control number.

- (g) Container used in dispensing.
- (h) Packaging and storage requirements.
- (i) Description of final preparation.
- (j) Quality control procedures and expected results. ...where applicable
...where applicable

(2) Compounding Record shall include all of the following:

- (a) Official or assigned name, strength, and dosage of the preparation.
- (b) Maser Formulation Record reference for the preparation.
- (c) Names and quantities of all components.
- (d) Sources, lot numbers and expiration dates of all components.
- (e) Total quantity compounded.
- (f) Name of the person who prepared the preparation.
- (g) Name of the person who performed the quality control procedures.
- (h) Name of the person who approved the preparation.
- (i) Date of preparation.
- (j) Assigned control or prescription number.
- (k) Assigned BUD.
- (L) ~~Duplicate label as described in the Master Formulation Record.~~
- (m) Description of the final product.
- (n) Results of quality control procedures.
- (o) Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver.

Master

(2)(f)-(h): Consider allowing name or initials or personal identifier. This could be the same person.

Use lower case "l"

Change to "copy of label used to label dispense final product"

15.13 Quality control. (1) The pharmacist shall do a final check and review each procedure in the compounding process. A final check shall include verification of all the following:

- (a) The master formulation record, compounding record and written procedures were followed in the execution of the compounding process. Any deviation in procedures shall be documented.
- (b) There was a check and recheck of each procedure at each stage of the process.
- (c) The tests or examinations conducted on the compounded preparation to ensure their uniformity and integrity followed established written procedures.
- (d) The performance of compounding processes and equipment that may be responsible for causing variability in the final compounded preparations.

(2) The pharmacist shall observe the finished preparation to ensure that it appears as expected.

(3) The pharmacist shall investigate any discrepancies and take appropriate corrective action before the prescription is dispensed to the patient.

15.14 Training. All personnel involved in the compounding, evaluation, packaging, and dispensing of compounded preparations shall be properly trained for the type of compounding conducted. It is the responsibility of the pharmacist to ensure and document that a training program has been implemented and that it is ongoing.

15.15 Adverse Event Reporting. A pharmacy or pharmacist that becomes aware of an adverse event attributed to the integrity of the product of a compounded pharmaceutical shall report the

adverse event to the department not later than 10 calendar days after becoming aware of the adverse event. For purposes of this section, an adverse event does not include an isolated allergic reaction to a substance included in the compound.

SUBCHAPTER II – Non-sterile Compounding

15.20 Component Selection. (1) A pharmacist shall use components manufactured in a FDA registered facility. If a component is unavailable from a FDA registered facility, the pharmacist may utilize a component that has been tested by a ~~FDA approved vendor~~ and the component has been determined to be pure and safe documented by a Certificate of Analysis.

(2) Components with an expiration date from the ~~manufacture or distribute~~ ^{manufacturer or distributor} may be used before the expiration date provided all of the following:

- (a) The material is stored in its original container under conditions to avoid decomposition of the chemicals.
- (b) There is minimal exposure of the remaining material each time material is withdrawn from the container.
- (c) When any withdrawals from the container are performed by those trained in the proper handling of the material.

(3) Components without an expiration date assigned by the manufacturer or supplier, shall be labeled with the date of receipt and assigned an expiration date, not to exceed three years after receipt, based upon the nature of the component and its degradation mechanism, the container in which it is packaged and the storage conditions.

(4) Components transferred to another container which shall provide integrity that is minimally equivalent to the original container and shall be identified with all of the following:

- (a) Component name.
- (b) Original supplier.
- (c) Lot or control number.
- (d) Transfer date.
- (e) Expiration date.

(5) Manufactured drug products utilized as the source of active ingredients shall be manufactured in an FDA registered facility and the manufacturer's product container shall be labeled with a lot number and expiration date.

(6) A pharmacist compounding for human use may not use components that have been withdrawn or removed from the market for safety or efficacy reasons by the FDA. A pharmacist compounding for food producing animal use may not use components prohibited for use in food producing animals.

(7) All components shall be stored off the floor, handled and stored to prevent contamination, ~~and rotated so that the oldest stock is used first.~~

15.21 Assigning BUD. (1) The BUD shall not be later than the expiration date on the container of any component.

(2) In the absence of stability information that is applicable to a specific drug product and preparation, the maximum BUD for a non-sterile compounded drug preparation that is packaged in a tight, light-resistant container and stored at controlled room temperature is one of the following:

(a) For nonaqueous liquids and solid formulations, the BUD shall not be later than the time remaining until the earliest expiration date of any active pharmaceutical ingredient or 6 months, whichever is earlier.

(b) For water-containing oral formulations, the BUD shall not be later than 14 days when stored at cold temperatures {NOTE: Define “cold temperatures”}

(c) For water-containing semisolid, mucosal liquid, topical or dermal formulations, the BUD shall not be later than 30 days.