STATE OF OHIO BOARD OF PHARMACY

Medical Oxygen, Nitrous Oxide, Medical Gases and Dialysis Solutions – CSI Comments - Board Response

Rule	Commenter	Comment	Board Response
4729:5-17-01	Northwind Corp	On August 1, 1995, a policy was adopted by the Ohio Board of Pharmacy to exclude emergency oxygen sold over the counter without a prescription for the purpose of a medical emergency. Emergency oxygen would be used by laypeople and do not pose a danger to the public. The policy clearly states that it was in the best interest of the citizens of the state of Ohio if such devices continue to be readily available in emergency situations which may occur in such places such as the workplace, schools and churches. The federal Food and Drug Administration's compliance Policy Guide 7124.10 dated October 10, 1980 provides that the devices intended for the administration of medical oxygen in an emergency may be sold over the counter without a prescription such devices are designed so that they do not pose a danger to the public if used by laypersons. The document further states, that the Board of Pharmacy does not recognize such a dangerous drug provided that the device is labelled	Incorporated FDA policy guidance and resolution into rule. See paragraph (H) of rule.

		and/or meets the following criteria: 1. The device is promoted and sold for the use of non-medical personnel in the event of an emergency. 2. The device is designed so that it delivers 6lpm set flow for at least 15 minutes whither any adjustments needed by medically trained personnel. 3. The device contains no more than 80 minutes (480 liters) of USP Oxygen; and BE IT FURTHER RESOLVED that such devices may be purchased and sold without a prescription by persons not registered with the Board of Pharmacy as a dangerous drug distributor. This policy was voted upon and passed. On May 7, 2018, the Common Sense Initiative passed new regulations in regards to oxygen. My questions: 1. Does the new regulations of 4729:5-17-01 to 4729:5-17-05 exclude emergency oxygen? If the answer is YES, then there is no reason to address the comments below.	

		If it does not, please help me understand the following: The average EMS response time in Central Ohio is 10-14 minutes and rural parts of Ohio is over 20 minutes, the cardiac arrest save rate in Ohio hovers around 7.8%, basically we ONLY save 4 people out of 50 per day. Should we not be training the citizens of Ohio on how to help the EMS so that we save more people in need of emergency medical care and should we not be supporting laypersons to use emergency equipment that can drammatically improve life saving (like we do an AED). In Kings County, WA, the EMS have a 62% cardiac arrest save rate, they must be doing things right. There is no supporting evidence that indicates that 60 minutes of emergency oxygen at a fixed 6lpm administered to a person can cause harm. On the flip side, there is endless evidence that emergency oxygen saves lives of persons suffering from heart attacks, strokes, trauma, shock etc. My question: 1. Is it the goal of the State of Ohio to keep our cardiac arrest save rate low as it has been for over 30 years? If not, what are you doing so dramatically different to change this fact?	

4729:5-17-02, 4729:5-17-03	Ohio Veterinary Medical Association	With respect to this rule package we have one principle observation as to a modification. In 4729:5-17-02 (B) and 4725-17-03 (B) the criteria for storage and maintenance reflect the containers being in an indoor setting ("dry" for example). While this would be the case for most veterinary facilities we are aware of at least one which has oxygen in a large outdoor storage unit/area. This certainly might be the situation in large human medical facilities as well. If you would like me to share a picture of an outdoor oxygen storage tank area I would be happy to do so. Adding the word "interior" to this definition and criteria is suggested.	Removed dry provision and required conditions in accordance with manufacturer's instructions in all three rules.

New Changes/Modifications = Yellow

Note: All rule text of the package is provided regardless if any new changes or modifications have been made.

4729:5-17-01 – Medical Oxygen, Nitrous Oxide, Medical Gases and Dialysis Solutions – Definitions.

As used in Chapter 4729:5-17 of the Administrative Code:

(A) "Licensed health professional authorized to prescribe drugs" or "prescriber" has the same meaning as in rule 4729:5-1-02 of the Administrative Code.

(B) "Peritoneal dialysis solution" or “dialysis solution” means a commercially available, unopened, sterile solution whose only purpose is to be instilled into the peritoneal cavity during the medical procedure known as peritoneal dialysis.

(C) “Readily retrievable” means that records maintained in accordance with this chapter shall be kept in such a manner that, upon request, they can be produced for review no later than three business days to an agent, officer or inspector of the board.

(D) "Responsible person" has the same meaning as defined in rule 4729:5-2-01 of the Administrative Code and is responsible for the supervision and control of dangerous drugs and medical gases as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and medical gases and maintaining all drug records otherwise required.

(E) "Tamper-evident" means a package, storage container or other physical barrier is sealed or secured in such a way that access to the medical gases or dangerous drugs stored within is not possible without leaving visible proof that such access has been attempted or made.

4729:5-17-02 – Medical Oxygen – General Provisions.

(A) Except as provided in paragraph (H) of this rule, each person, whether located within or outside of this state, who conducts retail sales of oxygen in original packages labeled as required by the "Federal Food, Drug, and Cosmetic Act" in this state shall obtain a limited category II terminal distributor of dangerous drugs license. The requirements of this paragraph do not apply to persons currently licensed to purchase, possess, and sell unlimited category II dangerous drugs at retail.

(B) All areas where medical oxygen is stored shall be maintained in a clean and orderly condition. Storage areas shall be maintained at conditions and temperatures which will ensure the integrity of the medical oxygen prior to use as stipulated by the manufacturer's or distributor's labeling.

(C) Medical oxygen shall be secured in a tamper-evident manner to deter and detect unauthorized access.

(D) All retail sellers of oxygen shall maintain records of purchase of oxygen at wholesale and sale of oxygen at retail for three years at the licensed location. All records shall be readily retrievable.

(1) A terminal distributor intending to maintain records, described in this rule, at a location other than the place licensed by the state board of pharmacy must notify the board in a manner determined by the board.

(2) Any such alternate location shall be secured and accessible only to representatives of the terminal distributor of dangerous drugs.

(E) A terminal distributor of dangerous drugs shall report the theft or significant loss of medical oxygen pursuant to rule 4729:5-3-02 of the Administrative Code.

(F) Except as provided in paragraphs (G) and (H) of this rule, prior to making an initial sale of medical oxygen to a patient, a terminal distributor must have an order issued by a prescriber.

(1) The order must include the full name and address of the patient, the signature of the prescriber, the manually printed, typewritten, electronically generated or preprinted full name and address of the prescriber, the telephone number where the prescriber can be personally contacted during normal business hours, the date of issuance and documentation of need.

(2) The prescriber's order may be transmitted electronically to the retail seller.

(3) All orders issued in accordance with this paragraph are valid for a period of one year from the date of issuance.

(G) S.C.U.B.A. divers who hold a valid certificate in the following nationally recognized S.C.U.B.A. diving certifying organization programs may purchase, possess, and use medical oxygen for the purpose of emergency care or treatment at the scene of a diving emergency pursuant to section 4729.541 of the Revised Code:

(1) Diver alert network (DAN): oxygen first aid for scuba diving injuries;

(2) International association of nitrox and technical divers: oxygen provider course;

(3) Professional association of diving instructors (PADI): emergency first response;

(4) PADI: PADI oxygen first aid;

(5) PADI: rescue diver course;

(6) PADI: tec deep diver;

(7) Scuba schools international: medic first aid emergency oxygen administration;

(8) Technical diving international-S.C.U.B.A. diving international: diver advanced development program as a CPROX administrator;

(9) YMCA: slam rescue;

(10) National association of underwater instructors (NAUI) first aid;

(11) NAUI rescue scuba diver;

(12) NAUI advanced rescue scuba diver;

(13) NAUI first aid instructor;

(14) NAUI oxygen administration; and

(15) NAUI instructor.

(H)

(1) In accordance with policy guidance issued by the United States food and drug administration, oxygen equipment intended for emergency use may be sold without a prescription.

(a) Such equipment shall deliver a minimum flow rate of 6 liters of oxygen per minute for a minimum of 15 minutes.

(b) Labeling for emergency oxygen may not contain references to heart attacks, strokes, shock or any other medical condition amenable to diagnosis or treatment only by a licensed practitioner.

(c) Oxygen units delivering a minimum flow rate of less than 6 liters of oxygen per minute for a period less than 15 minutes and labeled for emergency use are considered adulterated and misbranded.

(d) If the units are not intended for emergency use and provide less than 6 liters/minute or are labeled for human use for other than emergency use, such units are regarded as a dangerous drug and shall bear the prescription legend.

(e) The units shall contain no more than 80 minutes (480 liters) of USP oxygen.

(2) Persons that only sell oxygen equipment intended for emergency use that meet the criteria listed in paragraph (H)(1) of this rule shall not be required to obtain licensure as a terminal distributor of dangerous drugs in accordance with paragraph (A) of this rule.

(3) Persons that possess and administer oxygen equipment intended for emergency use that meet the criteria listed in paragraph (H)(1) of this rule shall not be required to obtain licensure as a terminal distributor of dangerous drugs.

4729:5-17-03 – Nitrous Oxide – General Provisions.

(A) Each person located within this state who seeks to purchase and possess nitrous oxide for the purpose of using it as a direct ingredient of food, pursuant to Title 21 CFR 184.1545 (04/1/2017), shall obtain a limited category II terminal distributor of dangerous drugs license.

(B) All areas where nitrous oxide is stored shall be maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures and conditions which will ensure the integrity of the nitrous oxide oxygen prior to use as stipulated by the manufacturer's or distributor's labeling.

(C) Nitrous oxide shall be secured in a tamper-evident manner to deter and detect unauthorized access.

(D) All food processors and retail sellers of food licensed in accordance with this rule shall maintain records of purchase at wholesale and use in processing food for three years at the licensed years at the licensed location. All records shall be readily retrievable.

(1) A terminal distributor intending to maintain records, described in this rule, at a location other than the place licensed by the state board of pharmacy must notify the board in a manner determined by the board.

(2) Any such alternate location shall be secured and accessible only to representatives of the terminal distributor of dangerous drugs.

(E) A terminal distributor of dangerous drugs shall report the theft or significant loss of nitrous oxide pursuant to rule 4729:5-3-02 of the Administrative Code.

4729:5-17-04 – Compressed Medical Gasses – General Provisions and Safety Program.

(A) Each person, whether located within or outside this state, who seeks to possess or sell compressed medical gases in this state shall obtain a wholesale distributor of dangerous drugs or terminal distributor of dangerous drugs license.

(B) Wholesale or terminal distributors of dangerous drugs who fill containers with compressed medical gases must comply with the current good manufacturing practice regulations issued pursuant to the federal Food, Drug and Cosmetic Act (4/1/2017) and the current regulations and guidelines issued pursuant to Title 21 CFR 10.90 (4/1/2017).

(C) Records required by state and federal laws, rules or regulations issued pursuant to such laws governing the sale of dangerous drugs and the filling of containers with compressed medical gases shall be maintained for a period of three years at the licensed location for inspection. All records shall be readily retrievable.

(1) A terminal distributor intending to maintain records, described in this rule, at a location other than the place licensed by the state board of pharmacy must notify the board in a manner determined by the board.

(2) Any such alternate location shall be secured and accessible only to representatives of the terminal distributor of dangerous drugs.

(D) A terminal distributor of dangerous drugs shall report the theft or significant loss of compressed medical gasses pursuant to rule 4729:5-3-02 of the Administrative Code.

(E) A wholesale distributor of dangerous drugs shall report the theft or significant loss of compressed medical gasses pursuant to rule 4729:6-3-02 of the Administrative Code.

(F) A medical gases safety program developed pursuant to section 4729.70 of the Revised Code shall comply with the following requirements:

(1) The instructors shall have the appropriate education and experience to teach a program in medical gas safety.

(2) The program shall be presented to all individuals who fill, install, connect, or disconnect medical gases contained in cryogenic vessels that are portable and intended for use in administering direct treatment to one or more individuals.

(3) Successful participation and demonstrated competency in a program must be completed prior to an individual filling, installing, connecting, or disconnecting a medical gas contained within a cryogenic vessel.

(4) The program must include at least the following:

(a) The description of a cryogenic vessel including at least the following:

(i) Valve inlet and outlet connections.

(ii) Safety systems associated with each outlet.

(iii) Proper labeling.

(iv) Color coding.

(v) Gas identification.

(b) A review of each medical gas listed in division (C)(2) of section 4729.70 of the Revised Code that may be contained in a cryogenic vessel including the following:

(i) A description of the properties of the gas and liquid.

(ii) The precautions and warnings associated with the gas and liquid.

(iii) Procedures for handling exposure to the gas or liquid.

(iv) Procedures to handling the gas or liquid during an emergency.

(c) The proper installation of cryogenic vessels including the following:

(i) Connecting and disconnecting supply lines.

(ii) Recognizing silver-brazed fittings or other acceptable mechanical means that make the connection a permanent and integral part of the valve.

(iii) Recognizing that changing or adapting the fittings for another gas service is strictly prohibited unless pursuant to paragraph (H) of this rule.

(iv) Recognizing the appropriate devices through which medical gases are delivered from cryogenic vessels.

(v) Detecting and reporting leaks.

(vi) Transporting cryogenic vessels appropriately within a facility.

(vii) Appropriate storage of cryogenic vessels.

(5) The program instructor must document the participation of an individual in a medical gases safety program. The documentation must be maintained by the individual's employer for a period of at least three years and made readily retrievable.

(6) Individuals who install, connect, or disconnect medical gases from cryogenic vessels must attend a medical gases safety program at least once every two years.

(G) No person shall modify a cryogenic vessel, connection, or valve or adapt a connection for another gas service pursuant to division (D) of section 4729.70 of the Revised Code.

(H) Paragraph (G) of this rule does not apply to an employee or agent of a firm owning the cryogenic vessel and is charged with the responsibility of conducting applicable vessel maintenance, changing service from one medical gas to another, or bringing a vessel into compliance with section 4729.70 of the Revised Code.

(1) Such employee or agent shall meet at least the following requirements:

(a) Successful completion of a medical gases safety program pursuant to paragraph (F) of this rule.

(b) Successful participation and demonstrated competency in a cryogenic vessel modification program administered by an instructor with the appropriate education and experience. The program must be based on written and validated procedures. The employee or agent must participate in the program annually and it must include the following procedures:

(i) Removing, adding, or adapting cryogenic vessel connections and valves.

(ii) Modifying cryogenic vessels.

(iii) Conducting cryogenic vessel maintenance.

(iv) Changing the cryogenic vessel from one medical gas to another.

(v) Bringing a cryogenic vessel into compliance with section 4729.70of the Revised Code.

(vi) Silver brazing or welding techniques and certification of the individual if applicable.

(vii) Removing and adding suitable mechanical means to make a connection a permanent and integral part of the valve.

(2) The employer must document the successful participation and demonstrated competency of an employee or agent in a cryogenic vessel modification program. The documentation must be maintained by the employer for a period of at least three years and made available, upon request, to those business entities receiving service and to the state board of pharmacy.

4729:5-17-05 – Dialysis Solutions – General Provisions.

(A) Each person, whether located within or outside this state, who sells peritoneal dialysis solutions in original packages labeled as required by the "Federal Food, Drug, and Cosmetic Act" to persons residing in this state shall obtain a limited category II terminal distributor of dangerous drugs license. The requirements of this paragraph do not apply to persons currently licensed to purchase, possess, and sell unlimited category II dangerous drugs at retail.

(B) All areas where dialysis solution is stored shall be dry, well-lighted, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures and conditions which will ensure the integrity of the dialysis solutions prior to use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.

(C) Dialysis solutions shall be secured in a tamper-evident manner to deter and detect unauthorized access.

(D) All retail sellers of peritoneal dialysis solutions shall maintain records of purchase of dialysis solutions at wholesale and sale of dialysis solutions at retail for three years at the licensed location. All records shall be readily retrievable.

(E) Before making an initial sale of dialysis solutions to a patient, a terminal distributor must have an order issued by a prescriber.

(1) The order must include the full name and address of the patient, the signature of the prescriber, the manually printed, typewritten, electronically generated or preprinted full name and address of the prescriber, the telephone number where the prescriber can be personally contacted during normal business hours, the date of issuance and the complete and accurate identification of each such product to be provided to the patient.

(2) The prescriber's order may be transmitted electronically to the retail seller.

(3) All orders issued in accordance with this paragraph are valid for a period of one year from the date of issuance.

(F) A terminal distributor of dangerous drugs shall report the theft or significant loss of dialysis solution pursuant to rule 4729:5-3-02 of the Administrative Code.