5/7/2018

The following information is being provided pursuant to the requirements of Executive Order 2011-01K and Senate Bill 2 of the 129th General Assembly, which require state agencies, including the State of Ohio Board of Pharmacy, to draft rules in collaboration with stakeholders, assess and justify an adverse impact on the business community (as defined by S.B. 2), and provide an opportunity for the affected public to provide input on the following rules.

New

- 4729:5-17-01- Definition section for medical oxygen, nitrous oxide, medical gases and dialysis solutions rule chapter.
- 4729:5-17-02- Establishes the requirements for terminal distributors of medical oxygen.
- 4729:5-17-03- Establishes the requirements for terminal distributors of nitrous oxide.
- 4729:5-17-04- Establishes the requirements for terminal or wholesale distributors of compressed medical gasses.
- 4729:5-17-05- Establishes the requirements for terminal distributors of dialysis solutions.

Rescind

- Chapter 4729-21- Establishes the requirements for terminal or wholesale distributors of compressed medical gasses.
- Chapter 4729-22- Establishes the requirements for terminal distributors of medical oxygen.
- Chapter 4729-25- Establishes the requirements for terminal distributors of nitrous oxide.
- Chapter 4729-27- Establishes the requirements for terminal distributors of dialysis solutions.

Comments on the proposed rules will be accepted until close of business on **May 25, 2018**. Please send all comments to the following email address: **Ali.Simon@pharmacy.ohio.gov**

In addition, please copy your comments to: **CSIPublicComments@governor.ohio.gov**

CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: **State of Ohio Board of Pharmacy**

Regulation/Package Title: **Oxygen, Nitrous, Medical Gases and Dialysis Solution**

Rule Number(s):

New

- 4729:5-17-01
- 4729:5-17-02
- 4729:5-17-03
- 4729:5-17-04
- 4729:5-17-05

Rescind

- Chapter 4729-21
- Chapter 4729-22
- Chapter 4729-25
- Chapter 4729-27

Date: **5/7/2018**

Rule Type:

New	5-Year Review
Amended	**Rescinded**

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

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Regulatory Intent

1. Please briefly describe the draft regulation in plain language.

New

- 4729:5-17-01- Definition section for medical oxygen, nitrous oxide, medical gases and dialysis solutions rule chapter.
- 4729:5-17-02- Establishes the requirements for terminal distributors of medical oxygen.
- 4729:5-17-03- Establishes the requirements for terminal distributors of nitrous oxide.
- 4729:5-17-04- Establishes the requirements for terminal or wholesale distributors of compressed medical gasses.
- 4729:5-17-05- Establishes the requirements for terminal distributors of dialysis solutions.

Rescind

- Chapter 4729-21- Establishes the requirements for terminal or wholesale distributors of compressed medical gasses.
- Chapter 4729-22- Establishes the requirements for terminal distributors of medical oxygen.
- Chapter 4729-25- Establishes the requirements for terminal distributors of nitrous oxide.
- Chapter 4729-27- Establishes the requirements for terminal distributors of dialysis solutions.

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

The proposed rules are authorized by sections 4729.26 and 4729.70 of the Ohio Revised Code.

3. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?

These rules do not implement a federal requirement.

4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

This rule package exceeds federal requirements because the regulation of dangerous drugs has traditionally been done at the state level by legislatively created state boards of pharmacy.

5. **What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

Section 4729.26 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules governing the distribution of dangerous drugs.

Section 4729.70 of the Ohio Revised Code requires the Board to adopt rules to implement a medical gases safety program.

Without these regulations, the Board of Pharmacy would not be able to ensure the licensure and safe operation of entities selling oxygen, nitrous oxide, medical gases and dialysis solutions.

6. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

The success of the regulations will be measured by having rules written in plain language, licensee compliance with the rules, and minimal questions from licensees regarding the provisions of the rule.

Development of the Regulation

7. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**

This rule package was distributed for initial public comment by posting the rule package to the Board's proposed rules website.

Prior to filing with CSI, the rules were reviewed and approved by the Board of Pharmacy.

8. **What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

The Board did not receive any feedback from stakeholders on the contents of the rule package.

9. **What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

Scientific data was not used to develop or review this rule package.

10. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

As the regulations are essential to protecting the public's safety by ensuring uniform standards for the safe handling of medical gasses and the distribution of dangerous drugs, the State of Ohio Board of Pharmacy did not consider any regulatory alternatives.

11. Did the Agency specifically consider a performance-based regulation? Please explain. ***Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.***

The agency did not consider a performance-based regulation for this rule package. It is the Board's responsibility to ensure uniform practice standards across Ohio. At this juncture, it was the determination of the Board that the rule package did not lend itself to performance-based regulations.

12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

The Board of Pharmacy's Director of Policy and Communications reviewed the proposed rules to ensure that the regulations do not duplicate another State of Ohio Board of Pharmacy regulation.

13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

The rules will be posted on the Board of Pharmacy's web site, information concerning the rules will be included in materials e-mailed to licensees, and notices will be sent to associations, individuals and groups. Board of Pharmacy staff are also available via phone or email to answer questions regarding implementation of the rules. In addition, the Board's compliance agents are trained to educate licensees on current and/or new regulations during on-site inspections.

Board of Pharmacy staff receive regular updates on rules via a monthly internal newsletter, biannual staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, email updates and quarterly webinars from the Director of Policy and feedback from the Board's legal department for every citation submitted.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community;

The rule package impacts the following:

- Terminal distributors of dangerous drugs with a classification to sell oxygen, nitrous, medical gases and dialysis solutions.

b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and

Violation of these rules may result in administrative licensure discipline for a terminal distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, monetary fine and/or revocation of a license.

c. Quantify the expected adverse impact from the regulation.

New

- 4729:5-17-01- Definition section for medical oxygen, nitrous oxide, medical gases and dialysis solutions rule division. This rule is definitional and should not have any adverse impact.
- 4729:5-17-02- Establishes the requirements for terminal distributors of medical oxygen. Licensure as a terminal distributor of dangerous drugs costs $160 annually. The application takes between 30-60 minutes to complete.
- 4729:5-17-03- Establishes the requirements for terminal distributors of nitrous oxide. Licensure as a terminal distributor of dangerous drugs costs $160 annually. The application takes between 30-60 minutes to complete.
- 4729:5-17-04- Establishes the requirements for terminal or wholesale distributors of compressed medical gasses. Licensure as a terminal distributor of dangerous drugs costs $160 annually. Licensure as a wholesale distributor of dangerous drugs costs $950 annually. Both applications take between 30-60 minutes to complete.
- 4729:5-17-05- Establishes the requirements for terminal distributors of dialysis solutions. Licensure as a terminal distributor of dangerous drugs costs $160 annually. The application takes between 30-60 minutes to complete.

15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The Board believes that the regulatory intent justifies the impact on business because the regulations are intended to protect and promote public safety. The rules ensure uniform regulations protect the health and safety of patients receiving medical gases or dialysis solutions.

Regulatory Flexibility

16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

The rule package does not provide any exemptions or alternative means of compliance for small businesses. The law does not differentiate on the size of the business and therefore the regulations are uniform across Ohio.

17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

The State of Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations. However, any failure of a standard of care in the distribution of dangerous drugs is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

18. What resources are available to assist small businesses with compliance of the regulation?

Board of Pharmacy staff is available by telephone and e-mail to answer questions. Board staff members also provide presentations to groups and associations who seek updates on current regulations and host regional meetings to discuss changes to Ohio laws and rules. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

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

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 section 4729.01 of the Revised 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.

(D) "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, drugs or hypodermics 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) 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 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 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) Before 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.

(F) 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.

(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.

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 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 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.

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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 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.