OHIO STATE BOARD OF PHARMACY

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-Equal Opportunity Employer and Service Provider-

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11/06/14

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 Ohio State 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.

Rescinded Rules

- 4729 Chapter 8 (to be replaced with new rules – see New Rules section below)

New Rules

- 4729-8-01: Definitions for a new OAC section that closely mirrors recently adopted Drug Enforcement Administration Rules that permit registrants to collect unwanted and unused prescription drugs from ultimate users for disposal.

- 4729-8-02: Authorizes approved collectors, other than law enforcement agencies, to collect unwanted and unused prescription drugs from ultimate users via mail-back programs and drug collection receptacles pursuant to federal regulations.

- 4729-8-03: Provides the requirements for law enforcement agencies to collect unwanted and unused prescription drugs from ultimate users via mail-back programs, drug collection receptacles and drug take-back days.

- 4729-8-04: Provides the procedure that shall be followed for the destruction of drugs collected pursuant to Chapter 8.

No Change (5 Year Review)

- 4729-12-01: Provides a standard definition of ephedrine.

- 4729-12-02: Requires registration and licensure for entities selling or manufacturing ephedrine.
- 4729-12-03: Permits the sale of products containing ephedrine in accordance with existing Ohio drug laws.
- 4729-12-04: Requires licensees to conduct an annual inventory of all ephedrine products.
- 4729-12-05: Requires licensees keep records pursuant to Chapter 3719. of the Revised Code and Chapters 4729-9 and 4729-11 of the Administrative Code.
- 4729-12-08: Provides a process whereby the Board of Pharmacy can exempt ephedrine-containing products from classification as schedule V controlled substances.
- 4729-12-09: Exempts specific products from classification as a schedule V controlled substance.
- 4729-12-10: Provides the criteria to be considered in denying a petition for exemption or removing an ephedrine drug product exemption.
- 4729-15-01: Provides definitions for the regulation of nuclear pharmacies.
- 4729-21-01: Requires those who possess and sell compressed medical gasses register either as a wholesale distributor or terminal distributor of dangerous drugs.
- 4729-21-02: Requires compressed medical gas fillers to comply with FDA regulations.
- 4729-21-04: Provides requirements for cryogenic medical gases safety programs.
- 4729-21-05: Prohibits the modification of cryogenic vessels, connections, adapters and valves.
- 4729-22-01: Requires licensure for persons selling medical oxygen.
- 4729-22-02: Permits medical oxygen to be sold at retail to patients only with an order from a prescriber in the course of professional practice.
- 4729-22-03: Requires retail sellers of medical oxygen to maintain records for three years.
- 4729-25-01: Requires any person who possesses or purchases nitrous oxide to be licensed as a terminal distributor of dangerous drugs.
- 4729-25-02: Requires food processors and retail sellers of food to purchase, store, and use nitrous oxide in accordance with federal and state law and regulations.
- 4729-25-03: Requires food processors and retail sellers of nitrous oxide to maintain records for three years.
- 4729-25-04: Requires food processors and retail sellers of nitrous oxide to report the loss of any nitrous oxide to the Board of Pharmacy.
- 4729-29-02: States that any actions initiated as a result of a consult agreement whereby the consulting pharmacist is not the dispensing pharmacist or the person administering

the dosage ordered, the consulting pharmacist shall be deemed to be acting as the agent of the consulting physician unless the physician has specified otherwise in the consult agreement.

Comments on the proposed rules will be accepted until close of business on **November 20, 2014**. Please send all comments to the following email address:

Cameron.mcnamee@bop.ohio.gov

In addition, please copy your comments to:

CSIPublicComments@governor.ohio.gov

CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio State Board of Pharmacy

Regulation/Package Title: Drug Take Back / Nuclear Pharmacies / Compressed Medical Gases / Ephedrine and Ephedrine-Containing Products / Oxygen / Nitrous Oxide / Management of Drug Therapy under Consult Agreement with Physician

Rule Number(s): New: 4729-8-01, 4729-8-02, 4729-8-03 & 4729-8-04

No Change: 4729-12-01, 4729-12-02, 4729-12-03, 4729-12-04, 4729-12-05, 4729-12-08, 4729-12-09, 4729-12-10, 4729-15-01, 4729-21-01, 4729-21-02, 4729-21-04, 4729-21-05, 4729-22-01, 4729-22-02, 4729-22-03, 4729-25-01, 4729-25-02, 4729-25-03, 4729-25-04, 4729-29-02

Rescinded: 4729-8-01, 4729-8-02, 4729-8-03 & 4729-8-04

Date: 11/6/2014

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.

Regulatory Intent

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

Rescinded Rules

- 4729 Chapter 8: This chapter is being rescinded due to new federal regulations published by the Drug Enforcement Administration that allow for additional locations (pharmacies, hospitals with pharmacies, long-term care facilities, reverse distributers, etc.) to collect unwanted and unused prescription drugs from the public. The new Chapter 8 will include terminology that closely mirrors the federal regulations to reduce any confusion amongst entities wishing to collect and destroy prescription drugs.

New Rules

- 4729-8-01: Definitions for a new OAC section that closely mirrors recently adopted Drug Enforcement Administration Rules that permit registrants to collect unwanted and unused prescription drugs from ultimate users for disposal.

- 4729-8-02: Authorizes approved collectors, other than law enforcement agencies, to collect unwanted and unused prescription drugs from ultimate users via mail-back programs and drug collection receptacles pursuant to federal regulations.

- 4729-8-03: Provides the requirements for law enforcement agencies to collect unwanted and unused prescription drugs from ultimate users via mail-back programs, drug collection receptacles and drug take-back days.

- 4729-8-04: Provides the procedure that shall be followed for the destruction of drugs collected pursuant to Chapter 8.

No Change (5 Year Review)

- 4729-12-01: Provides a standard definition of ephedrine.
- 4729-12-02: Requires registration and licensure for entities selling or manufacturing ephedrine.
- 4729-12-03: Permits the sale of products containing ephedrine in accordance with existing Ohio drug laws.
- 4729-12-04: Requires licensees to conduct an annual inventory of all ephedrine products.
- 4729-12-05: Requires licensees keep records pursuant to Chapter 3719. of the Revised Code and Chapters 4729-9 and 4729-11 of the Administrative Code.
- 4729-12-08: Provides a process whereby the Board of Pharmacy can exempt ephedrine-containing products from classification as schedule V controlled substance.

- 4729-12-09: Exempts specific products from classification as a schedule V controlled substance.
- 4729-12-10: Provides the criteria to be considered in denying a petition for exemption or removing an ephedrine drug product exemption.
- 4729-15-01: Provides definitions for the regulation of nuclear pharmacies.
- 4729-21-01: Requires those who possess and sell compressed medical gasses register either as a wholesale distributor or terminal distributor of dangerous drugs.
- 4729-21-02: Requires compressed medical gas fillers to comply with FDA regulations.
- 4729-21-04: Provides requirements for cryogenic medical gases safety programs.
- 4729-21-05: Prohibits the modification of cryogenic vessels, connections, adapters and valves.
- 4729-22-01: Requires licensure for persons selling medical oxygen.
- 4729-22-02: Permits medical oxygen to be sold at retail to patients only with an order from a prescriber in the course of professional practice.
- 4729-22-03: Requires retail sellers of medical oxygen to maintain records for three years.
- 4729-25-01: Requires any person who possesses or purchases nitrous oxide to be licensed as a terminal distributor of dangerous drugs.
- 4729-25-02: Requires food processors and retail sellers of food to purchase, store, and use nitrous oxide in accordance with federal and state law and regulations.
- 4729-25-03: Requires food processors and retail sellers of nitrous oxide to maintain records for three years.
- 4729-25-04: Requires food processors and retail sellers of nitrous oxide to report the loss of any nitrous oxide to the Board of Pharmacy.
- 4729-29-02: States that any actions initiated as a result of a consult agreement whereby the consulting pharmacist is not the dispensing pharmacist or the person administering the dosage ordered, the consulting pharmacist shall be deemed to be acting as the agent of the consulting physician unless the physician has specified otherwise in the consult agreement.

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

The proposed rules are authorized by sections 3715.69, 4729.39, 3719.28 and 4729.26 of the Ohio Revised Code. The following sections of the Ohio Revised Code are also considered authorizing statutes for this rule package: 3719.01, 4729.01, 3719.03, 3719.05, 3719.07, 3719.09, 3719.13, 3719.15, 3719.16, 3719.27, 4729.28, 4729.54, 4729.55, 4729.51, 4729.39

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?

The rule does not implement a federal requirement. However, the new OAC Chapter 8 will include terminology that closely mirrors newly adopted federal regulations to reduce any confusion amongst entities wishing to collect and destroy prescription drugs.

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 the pharmacy profession has traditionally been done at the state level by legislatively created state boards of pharmacy, such as the Ohio State Board of Pharmacy. The Ohio State Board of Pharmacy regulates all aspects of pharmacy practice and drug storage. While the Food and Drug Administration closely regulates the manufacture and distribution of prescription drugs, the day-to-day practice of pharmacy, including the following, is regulated by the Board:

- collection of dangerous drugs, including controlled substances;
- pharmacists practicing under a consult agreement;
- licensure of entities possessing and storing dangerous drugs, including ephedrine;
- oversight of radiopharmaceuticals at nuclear pharmacies; and
- regulation of medical gases.

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 state board of pharmacy to adopt rules governing the practice of pharmacy, which includes establishing licensing requirements for locations that store dangerous drugs (such as epinephrine and medical gasses), pharmacies, and locations that collect unwanted or unused prescription drugs.

Section 3715.69 of the Ohio Revised Code authorizes the state board of pharmacy to adopt rules for the administration of Chapter 3715, Ohio's Pure Food and Drug Act.

Section 3719.28 of the Ohio Revised Code requires the state board of pharmacy to adopt rules for the administration and enforcement of Chapter 3719. of the Revised Code in order to prescribe the manner of keeping and the form and content of records to be kept by persons

authorized to manufacture, distribute, dispense, conduct research in, prescribe, administer, or otherwise deal with controlled substances.

Section 4729.39 of the Ohio Revised Code requires the state board of pharmacy to adopt rules to be followed by pharmacists that establish standards and procedures for entering into a consult agreement and managing an individual's drug therapy under a consult agreement.

Section 4729.69 of the Ohio Revised Code requires the state board of pharmacy, in collaboration with the director of mental health and addiction services and attorney general, to adopt rules regarding drug take-back programs under which drugs are collected from the community for the purpose of destruction or disposal of the drugs. In addition to this section, section 3719.28 of the Ohio Revised Code authorizes the state board of pharmacy to adopt rules to prevent the improper acquisition or use of controlled substances or their diversion into illicit channels.

The rules proposed under this statutory authority are necessary to facilitate compliance with the provisions in Chapters 4729, 4776, 5903 and 3719 of the Ohio Revised Code to promote the public's safety. Without these regulations, the Ohio State Board of Pharmacy would not be able to:

- Provide proper record keeping requirements for medical gasses (including oxygen).
- Provide uniform drug collection and destruction procedures for entities authorized under state and federal law.
- Uniformly regulate the sale of products containing ephedrine.
- Provide uniform licensing and record keeping requirements for the sale of medical gasses.
- Clarify that a consulting pharmacist is an agent of a prescriber pursuant to a consult agreement.

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 and prescribers of dangerous drugs regarding the provisions of the rules.

Development of the Regulation

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

The rules were reviewed and approved by the Ohio State Board of Pharmacy's Rules Review Committee on August 14, 2014. The committee is comprised of a broad array of stakeholders from various aspects of the pharmacy profession including:

- OhioHealth
- Trumbull Memorial Hospital
- Kroger
- Hock's Pharmacy
- Northeast Ohio Medical University
- Nationwide Children's Hospital
- Giant Eagle
- Absolute Pharmacy
- St Ann's Hospital
- Akron General
- Cedarville University

The drug collection rules (OAC Chapter 8) were reviewed by the Ohio Attorney General's Office, Ohio EPA and the Ohio Department of Mental Health and Addiction Services.

The rules were subject to final approval by the state board of pharmacy prior to filing with the Common Sense Initiative and JCARR.

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

The Ohio EPA recommended updating the rule language in 4729-8-02 & 8-03 to remove the phrase hazardous drugs and replace it with specific types of drugs that should not be collected via a mail back program, collection event or drug collection receptacle. This provides additional clarity on what types of drugs are prohibited since hazardous could be perceived differently depending on the entity collecting the drugs.

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 the rules.

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 regulations throughout Ohio, the Ohio State 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 performance-based regulations for the rules in this package. It is the Board's responsibility to ensure that regulations are consistent throughout the state. 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 Legal Affairs and Pharmacist Compliance Supervisor reviewed the proposed rules to ensure that the regulations do not duplicate another Ohio State 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 Pharmacy Board'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. Pharmacy Board 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.

Pharmacy Board staff receive regular updates on rules via a quarterly internal newsletter, biannual staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, monthly email updates from the legislative affairs liaison and feedback from the Board's legal director 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:

- Retail sellers of compressed gasses and medical oxygen;
- Pharmacies;
- Pharmacists;
- Law enforcement agencies;
- Reverse distributors;
- Hospitals with on-site pharmacies;
- Long-term care facilities;
- Entities that purchase and possess ephedrine products;
- Entities that purchase and possess nitrous oxide.

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

Violation of the rules may result in administrative licensure discipline for a pharmacist or location licensed as a terminal distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, required course work, monetary penalty and/or revocation of a license.

Additional adverse impact of the rule package may include employer time for compliance and licensure (for sellers of ephedrine products and medical gasses).

c. Quantify the expected adverse impact from the regulation.

- 4729-8-01: Definitions for a new OAC section that closely mirrors recently adopted Drug Enforcement Administration Rules that permit registrants to collect unwanted and unused prescription drugs for from ultimate users disposal. This is a definitional section and should have no adverse impact.

- 4729-8-02: Authorizes approved collectors, other than law enforcement agencies, to collect unwanted and unused prescription drugs from ultimate users via mail-back programs and drug collection receptacles pursuant to federal regulations. Requires

collectors to be authorized by the Drug Enforcement Agency. This requires the submission of an application to the DEA to modify their registrant status. This application takes approximately 1 hour to complete and there is no associated cost. The additional record keeping requirements for the authorized collectors (required by federal regulations) will also result in additional employer time to ensure compliance. Further, violation of these regulations may result in sanctions by the Board against an Ohio licensee.

- 4729-8-03: Provides the requirements for law enforcement agencies to collect unwanted and unused prescription drugs from ultimate users via mail-back programs, drug collection receptacles and drug take-back days. This should only impact law enforcement agencies that choose to operate drug collection receptacles, mail-back programs or collection events. It will require record keeping pursuant to the agency's record keeping requirements and compliance with federal and state destruction laws. This may result in increased administrative costs to ensure compliance.

- 4729-8-04: Provides the procedure that shall be followed for the destruction of drugs collected pursuant to OAC Chapter 8. This rule requires any authorized entity that collects unwanted or unused drugs to destroy the drugs pursuant to all applicable laws and ensure the confidentiality of the individual disposing of the drugs. Compliance with all applicable laws regarding drug destruction may result in increased administrative costs and may also result in additional expenses to dispose of the drugs.

- 4729-12-01: Provides a standard definition of ephedrine. This is a definitional section and should not result in any adverse impact.

- 4729-12-02: Requires registration and licensure for entities selling or manufacturing ephedrine. The fee for a category III terminal distributor license is $150 per year. The initial application for a terminal distributor license takes about one hour to complete. Online renewal of the license takes about 10 minutes.

- 4729-12-03: Permits the sale of products containing ephedrine in accordance with existing Ohio drug laws. Adherence to these laws may result in increased administrative costs to ensure compliance.

- 4729-12-04: Requires licensees to conduct an annual inventory of all ephedrine products. Annual inventories of ephedrine products will result in increased administrative costs.

The time required to conduct an inventory depends on the amount of ephedrine products stored at each location.

- 4729-12-05: Requires licensees keep records pursuant to Chapter 3719. of the Revised Code and Chapters 4729-9 and 4729-11 of the Administrative Code. This will result in increased administrative costs on the part of the licensees to maintain these records for the required time period.

- 4729-12-08: Provides a process whereby the Board of Pharmacy can exempt ephedrine-containing products from classification as schedule V controlled substances. While there is no monetary cost to request an exemption from the Board of Pharmacy, it is estimated that assembling the request may take between one to two hours.

- 4729-12-09: Exempts specific products from classification as a schedule V controlled substance. This rule has no adverse impact as it exempts products from regulations.

- 4729-12-10: Provides the criteria to be considered in denying a petition for exemption or removing an ephedrine drug product exemption. This rule has no adverse impact as it provides the criteria to be considered by the Board.

- 4729-15-01: Provides definitions for the regulation of nuclear pharmacies. This is a definitional section and does not have an adverse impact.

- 4729-21-01: Requires those who possess and sell compressed medical gasses to register either as a wholesale distributor or terminal distributor of dangerous drugs. The terminal distributor license fee, depending on the type of other drugs stored by the facility, ranges from $112.50 to $150 per year. The initial application for a terminal distributor license takes about one hour to complete. Online renewal of the license takes about 10 minutes. The wholesale distributor of dangerous drugs license fee ranges from $750 to $787.50. It also takes approximately one hour to complete the license application and online renewal takes about ten minutes.

- 4729-21-02: Requires compressed medical gas fillers to comply with FDA regulations. Compliance with FDA guidelines and submission of documentation to the FDA will result in increased administrative costs for compressed medical gas fillers.

- 4729-21-04: Provides requirements for cryogenic medical gases safety programs. Development of a medical gases safety program will result in costs to compressed medical gas fillers to implement a training program to all of their employees. There will also be additional administrative costs to maintain all training records for a minimum of three years.

- 4729-21-05: Prohibits the modification of cryogenic vessels, connections, adapters and valves. Compressed medical gas fillers may experience increased administrative costs to ensure any employee meets the requirements to make modifications of cryogenic vessels, connections, adapters and valves. In addition, the filler must maintain documentation of meeting the requirements for a minimum of three years.

- 4729-22-01: Requires licensure as a category II terminal distributor of dangerous drugs for persons selling medical oxygen. The license fee is $112.50 per year. The initial application for a terminal distributor license takes about one hour to complete. Online renewal of the license takes about 10 minutes.

- 4729-22-02: Permits medical oxygen to be sold at retail to patients only with an order from a prescriber in the course of professional practice. May result in increased administrative costs to verify orders are from a licensed prescriber.

- 4729-22-03: Requires retail sellers of medical oxygen to maintain records for three years. This will result in increased administrative costs on the part of the licensees to maintain these records for the required time period.

- 4729-25-01: Requires any person who possesses or purchases nitrous oxide to be licensed as a category II terminal distributor of dangerous drugs. The license fee is $112.50 per year. The initial application for a terminal distributor license takes about one hour to complete. Online renewal of the license takes about 10 minutes.

- 4729-25-02: Requires food processors and retail sellers of food to purchase, store, and use nitrous oxide in accordance with federal and state law and regulations. Adherence to federal and state laws and regulations will result in increased administrative costs to ensure compliance.

- 4729-25-03: Requires food processors and retail sellers of nitrous oxide to maintain records for three years. This will result in increased administrative costs on the part of the licensees to maintain these records for the required time period.

- 4729-25-04: Requires food processors and retail sellers of nitrous oxide to report the loss of any nitrous oxide to the Board of Pharmacy. The time it would take to report theft or loss to the Board and local law enforcement would be the adverse impact of this regulation.

- 4729-29-02: States that any actions initiated as a result of a consult agreement whereby the consulting pharmacist is not the dispensing pharmacist or the person administering the dosage ordered, the consulting pharmacist shall be deemed to be acting as the agent of the consulting physician unless the physician has specified otherwise in the consult agreement. May result in increased administrative costs if a consulting pharmacist is required to present documentation at the request of a dispensing pharmacist or person administering the dosage ordered. Failure to produce the requested documentation could also result in administrative sanctions against the consulting pharmacist.

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

The Ohio State Board of Pharmacy believes that the regulatory intent of the proposed rules is necessary in order to protect the health and safety of all Ohioans by providing uniform regulations to ensure the following:

- Safety standards for medical gases.
- Procedures for the collection and disposal of unused and unwanted medication.
- Safe use of ephedrine products.
- Uniform implementation of pharmacist consult agreements.

Regulatory Flexibility

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

These rules do 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 Ohio State Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations. However, any failure of a standard of care 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 an update on current regulations. Additionally, field staff (i.e. compliance officers) is trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

New Rules

4729-8-01 DEFINITIONS.

As used in Chapter 4729-8 of the Administrative Code:

(A) “Authorized collector” means a registered manufacturer, distributor, reverse distributor, narcotic treatment program, hospital/clinic with an on-site pharmacy, or retail pharmacy that is authorized by the United States drug enforcement administration to receive controlled substances for the purpose of destruction.

(B) "Controlled substances" has the same meaning as defined in division (C) of section 3719.01 of the Revised Code.

(C) "Dangerous drugs" has the same meaning as defined in division (F) of section 4729.01 of the Revised Code.

(D) "Drug collection receptacle" means a secured, lined receptacle into which prescription medications, including controlled substances, dangerous drugs, and over-the-counter medications can be deposited by ultimate users for the purposes of collecting unused or expired drugs. Except for a law enforcement agency, a drug collection receptacle shall meet the requirements specified in 21 CFR 1317.75 (10/09/2014).

(E) "Drug" has the same meaning as defined in division (E) of section 4729.01 of the Revised Code.

(F) "Law enforcement agency" means a government entity that employs peace officers to perform law enforcement duties or a federal law enforcement agency.

(G) “Law enforcement officer” has the same meaning as 21 CFR 1300.05 (10/09/2014).

(H) “Mail-back program” means a program operated by an authorized collector or law enforcement agency that accepts prescription medications, including controlled substances, dangerous drugs, and over-the-counter medications from ultimate users through the mail for purposes of collecting unused or expired drugs. Except for a law enforcement agency, a mail-back program shall meet the requirements specified in 21 CFR 1317.70 (10/09/2014).

(I) “Non-retrievable” means the condition or state to which a drug shall be rendered following a process that permanently alters that drug’s physical or chemical condition or state through irreversible means and thereby renders the drug unavailable and unusable for all practical purposes.

(J) "Take-back event" means a one-day program operated by a law enforcement agency through

which ultimate users may safely dispose of unused or expired prescription medications, including controlled substances, dangerous drugs, and over-the-counter medications. A take-back event shall meet the requirements specified in 21 CFR 1317.65 (10/09/2014).

(K) "Ultimate user" means a person who has lawfully obtained, and who possesses, a pharmaceutical drug for their own use or for the use of a member of their household or for an animal owned by an individual or a member of their household. It also includes any person lawfully entitled to dispose of a decedent's property.

4729-8-02 APPROVED COLLECTORS.

(A) An authorized collector may operate a drug collection receptacle if they meet all of the requirements specified in 21 CFR Part 1300, 21 CFR Part 1301, 21 CFR Part 1304, 21 CFR Part 1305, 21 CFR Part 1307 and 21 CFR Part 1317 (10/09/2014).

(B) If an authorized collector operates a drug collection receptacle for the collection of non-controlled substances only, they shall meet all of the requirements specified in paragraph (A) of this rule.

(C) A long-term care facility may dispose of prescription medications, including controlled substances, dangerous drugs, and over-the-counter medications on behalf of an ultimate user who resides, or has resided, at that long-term care facility pursuant to 21 CFR 1317.80.

(D) An authorized collector may operate a mail-back program if they meet all of the requirements specified in 21 CFR Part 1300, 21 CFR Part 1301, 21 CFR Part 1304, 21 CFR Part 1305, 21 CFR Part 1307 and 21 CFR Part 1317 (10/09/2014).

(E) If an authorized collector operates a mail-back program for the collection of non-controlled substances only, they shall meet all of the requirements specified in paragraph (A) of this rule.

(F) An authorized collector shall not collect any of the following in a drug collection receptacle or through a mail-back program:

(1) No medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers);

(2) Schedule I controlled substances; or

(3) The authorized collector's inventory or stock of controlled substances, dangerous drugs or over-the-counter medications.

(G) An authorized collector shall maintain the confidentiality of the ultimate user pursuant to all applicable state and federal laws, rules, and regulations.

(H) An authorized collector shall not operate a take-back event as defined in rule 4729-8-01 of the Administrative Code.

(I) A law enforcement agency may take possession of drugs collected from ultimate users through a collection receptacle operated by an authorized collector for the purpose of destruction if all of the following apply:

(1) The authorized collector appropriately documents the transfer of the sealed inner liners to the law enforcement agency and maintains the documentation for three years. The documentation should include the following information:

(a) The date each sealed inner liner is transferred to the law enforcement agency for destruction, the name of the law enforcement officer who collected each sealed inner liner, the address of the law enforcement agency to whom each sealed inner liner was transferred, the unique identification number and the size (e.g., 5-gallon, 10-gallon, etc.) of each sealed inner liner transferred, and the names and signatures of the two employees that transferred each sealed inner liner to the law enforcement agency.

(2) Each sealed inner liner shall be transported by a law enforcement officer from the authorized collector's location. Authorized collectors shall not transport or mail seal inner liners to law enforcement agencies.

(3) The law enforcement agency processes and stores the collected drugs pursuant to rule 4729-8-03 of the Administrative Code.

(4) The law enforcement agency destroys the collected drugs pursuant to rule 4729-8-04 of the Administrative Code and 21 CFR Part 1317.90 (10/09/2014).

4729-8-03 LAW ENFORCEMENT AGENCIES.

(A) Law enforcement agencies may operate a drug collection receptacle if all of the following apply:

(1) The receptacle is located inside the premises of the law enforcement agency.

(2) The receptacle is placed in a location that is accessible to the public during posted hours.

(3) The receptacle is placed within reasonable view of law enforcement personnel or under

continuous video surveillance.
(4) The receptacle is securely fastened to a permanent structure so that it cannot be removed and must be locked to prevent the unauthorized retrieval of its contents.

(5) The receptacle is clearly marked indicating the following information:

(a) No needles, syringes, or lancets shall be placed in the receptacle.

(b) No iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers) shall be placed in the receptacle.

(6) If a law enforcement agency chooses to limit the types of drugs that are acceptable for return, such limitations shall be clearly stated on or near the drug collection receptacle.

(7) The law enforcement agency shall check the drug collection receptacle regularly and remove deposits to prevent the receptacle from reaching capacity.

(8) The law enforcement shall maintain the confidentiality of the ultimate user disposing of the drugs pursuant to all applicable state and federal laws, rules, and regulations.

(9) The drugs shall be stored in a manner that prevents the diversion of controlled substances and is consistent with that agency's standard procedures for storing illicit controlled substances.

(10) The law enforcement agency shall maintain custody and control of the contents deposited in the drug collection receptacle until the drugs are destroyed pursuant to 4729-8-04 of the Administrative Code.

(11) The law enforcement agency shall maintain any records of removal, storage, or destruction of the drugs collected in a manner that is consistent with that agency's recordkeeping requirements for illicit controlled substances evidence.

(B) Law enforcement agencies may conduct a mail-back program if all of the following apply:

(1) Packages are made available (for sale or for free) for the collection of pharmaceutical drugs by common or contract carrier.

(2) The packages made available meet the following specifications:

(a) The package must be nondescript and shall not include any markings or other information that might indicate that the package contains pharmaceutical drugs;

(b) The package must be water- and spill-proof; tamper-evident; tear-resistant; and sealable;

(c) The package must be preaddressed with and delivered to the participating law enforcement's physical address;

(d) The cost of shipping the package shall be postage paid;

(e) The package must include instructions for the user that indicate the process for mailing back the package, the substances that can be sent, notice that packages may only be mailed from within the customs territory of the United States (the 50 States, the District of Columbia, and Puerto Rico), and notice that only packages provided by the collector will be accepted for destruction.

(f) The instructions for the package shall indicate the following information:

(i) No medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers) shall be placed in the package;

(g) If a law enforcement agency chooses to limit the types of drugs that are acceptable for return, such limitations shall be clearly stated on the package instructions.

(3) The law enforcement agency shall maintain custody and control of the sealed packages until the packages are disposed of pursuant to rule 4729-8-04 of the Administrative Code.

(4) The law enforcement agency shall maintain the confidentiality of the ultimate user disposing of the drugs pursuant to all applicable state and federal laws, rules, and regulations.

(5) The mail-back packages shall be stored in a manner that prevents the diversion of controlled substances and is consistent with that agency's standard procedures for storing illicit controlled substances.

(6) The law enforcement agency shall maintain any records of removal, storage, or destruction of the drugs collected in a manner that is consistent with that agency's recordkeeping requirements for illicit controlled substances evidence.

(C) Law enforcement agencies may operate a take-back event if all of the following apply:

(1) A law enforcement agency shall appoint a law enforcement officer employed by the agency to oversee the collection. Law enforcement officers employed and authorized by the law enforcement agency or law enforcement component of a Federal agency conducting a take-back event shall maintain control and custody of the collected drugs from the time the drugs are collected from the ultimate user until secure transfer, storage, or destruction of the drugs has

occurred.

(2) Each take-back event shall have at least one receptacle for the collection of drugs. The collection receptacle should be a securely locked, substantially constructed container with an outer container and a removable inner liner.

(3) Ultimate users disposing of unused or expired drugs shall place them directly into the drug collection receptacle or hand them directly to a law enforcement officer.

(4) No needles, syringes or lancets shall be collected. A bulk sharps disposal container may be provided at each take-back event for the disposal of sharps.

(5) No iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (e.g., cancer chemotherapy drugs, cytotoxic drugs), compressed cylinders or aerosols (e.g., asthma inhalers) shall be collected.

(6) At the conclusion of the collection event, the drugs shall be removed from the event location and either:

(i) Stored in a manner that prevents the diversion of controlled substances and is consistent with that agency's standard procedures for storing illicit controlled substances; or

(ii) Destroyed pursuant to rule 4729-8-04 of the Administrative Code.

(7) The law enforcement agency shall maintain any records of removal, storage, or destruction of the drugs collected in a manner that is consistent with that agency's recordkeeping requirements for illicit controlled substances evidence.

(J) The law enforcement agency shall ensure that the confidentiality of the ultimate user is maintained pursuant to applicable state and federal laws, rules, and regulations.

(K) Law enforcement agencies that participate in take-back event pursuant to this rule are not subject to rule 4729-9-06 of the Administrative Code.

4729-8-04 PROCEDURE FOR DESTRUCTION OF COLLECTED DRUGS.

(A) All drugs collected pursuant to this chapter shall be destroyed in compliance with applicable Federal, State, tribal, and local laws and regulations and shall be rendered non-retrievable.

(B) The method of destruction shall ensure that the confidentiality of the ultimate user is maintained pursuant to applicable state and federal laws, rules, and regulations.

The Following Rules would be Rescinded:

4729-8-01
4729-8-02
4729-8-03
4729-8-04

No Change (5-Year Review)

4729-12-01 DEFINITION OF EPHEDRINE.

Ephedrine is a -[-(Methylamino)ethyl]benzene-methanol; a -[1-(methylamino) ethyl]benzyl alcohol; 2-methylamino-1-phenyl-1-propanol; 1-phenyl-1-hydroxy-2-methylaminopropane; 1-phenyl-2- methylaminopropanol; a - hydroxy-b -methylaminopropylbenzene; a product which occurs in the Chinese herb Ma Huang (Ephedra vulgaris, Ephedra sinica Stapf., Ephedra equisetina Bunge, Gnetaceae) and in several other Ephedra spp. Isomeric forms include d- and l-ephedrine as well as d- and l-pseudoephedrine with l-ephedrine and d-pseudoephedrine as the naturally occurring isomers.

4729-12-02 REGISTRATION AND LICENSURE.

(A) Any person who manufactures, sells at wholesale or retail, dispenses, imports or exports products containing ephedrine, its salts or isomers, or who proposes to engage in such activities, shall submit an application for registration as a wholesaler of dangerous drugs and controlled substances or for licensure as a category III terminal distributor of dangerous drugs to conduct such activities in accordance with Chapters 3719. and 4729. of the Revised Code.

(B) This rule does not apply if the ephedrine product is a food product or a dietary supplement that is specifically excepted in division (K) (2) of section 3719.44 of the Revised Code.

4729-12-03 SECURITY, STORAGE, AND SALE.

(A) Schedule V products containing ephedrine may be sold at wholesale or retail, and must be maintained in accordance with Chapters 3719. and 4729. of the Revised Code and Chapters 4729-9 and 4729-11 of the Administrative Code.

(B) This rule does not apply if the ephedrine product is a food product or a dietary supplement that is specifically excepted in division (K)(2) of section 3719.44 of the Revised Code.

4729-12-04 INVENTORY.

(A) Every registrant or licensee required to keep records who possesses any quantity of ephedrine or schedule V drug products containing ephedrine shall take an inventory pursuant to rules 4729-9-14 and 4729-9-16 of the Administrative Code.

(B) This rule does not apply if the ephedrine product is a food product or a dietary supplement that is specifically excepted in division (K)(2) of section 3719.44 of the Revised Code.

4729-12-05 RECORDS.

(A) All practitioners, registrants, and licensees required to keep records pursuant to Chapter 3719. of the Revised Code and Chapters 4729-9 and 4729-11 of the Administrative Code shall maintain such records for ephedrine and schedule V drug products containing ephedrine.

(B) This rule does not apply if the ephedrine product is a food product or a dietary supplement that is specifically excepted in division (K)(2) of section 3719.44 of the Revised Code.

4729-12-08 PETITIONS FOR EXCEPTION OF EPHEDRINE-CONTAINING PRODUCTS.

(A) A petition requesting that a drug product containing ephedrine be excepted by the board of pharmacy from being legally classified as a schedule V controlled substance stimulant may be submitted by any person engaged in the legitimate manufacture or wholesale sale of such products in the United States. The petition shall include the following information:

(1) Full name, address, and telephone number of the manufacturer.

(a) If incorporated, the petition must include copies of the incorporation papers and the names, dates of birth, addresses, and social security numbers of the officers of the corporation and all stockholders holding more than ten per cent of the stock.

(b) If a proprietorship, the petition must include the name, address, date of birth, and social security number of the owner(s).

(c) If a partnership, the petition must include the names, addresses, dates of birth, and social security numbers of the partners.

(2) A description of the package sizes and the manner of packaging the drug product.

(3) A limited number of samples of each dosage form marketed in the final marketed packages.

(4) The manner of distribution, advertising, and promotion of the product, including but not limited to:

(a) The full name and address of all accounts located in Ohio to which the products have been or will be distributed at wholesale based on other products marketed by the petitioner.

(b) Copies of all advertisements used to promote the product within the last twelve months shall be included with the petition. A list of the publications in which the advertisements appeared or will appear if not presently marketed. If the product has not yet been marketed, copies of other products marketed by the petitioner shall be submitted with the petition.

(5) A listing of all ingredients in the product, indicating the quantity of each ingredient, whether or not it has any therapeutic value, and its purpose for being included in the product. Documentation of the therapeutic value of all active ingredients in the product shall be included with the petition.

(6) A list of all names the product is marketed or will be marketed under in the United States or any other country.

(7) Any information regarding the product's abuse or potential for abuse in the United States or other countries where the product is marketed or will be marketed under any of the names listed in paragraph (A)(6) of this rule.

(B) This rule does not apply if the ephedrine product is a food product or a dietary supplement that is specifically excepted in division (K)(2) of section 3719.44 of the Revised Code.

4729-12-09 EXCEPTIONS.

Pursuant to division (K) of section 3719.44 of the Revised Code, each of the following products containing ephedrine, its salts, its isomers, or the salts of its isomers is declared to be excepted from classification as a schedule V controlled substance:

(A) All products that contain the isomer known as pseudoephedrine or its salts, but do not also contain any of the isomer known as ephedrine or its salts.

(B) "Breathe Easy TM" herb tea.

(C) "Bronkaid TM Dual Action" caplets.

(D) "Hydrosal TM" hemorrhoidal ointment.

(E) "Primatene TM Dual Action Formula" tablets.

(F) "Primatene TM" tablets.

(G) "SnoreStop TM" tablets.

4729-12-10 CRITERIA TO BE CONSIDERED IN DENYING A PETITION FOR EXEMPTION OR REMOVING A DRUG PRODUCT EXEMPTION.

(A) The board shall consider the following factors in determining whether a particular over-the-counter (OTC) drug product containing the schedule V controlled substance ephedrine is manufactured and distributed for legitimate use in a manner consistent with the pertinent OTC tentative or final monograph issued by the federal food and drug administration and in a manner that reduces the likelihood of inappropriate use and/or abuse:

(1) The package size and the manner of packaging;

(2) distribution, advertising, and promotion of the product;

(3) labeling and the name of the product;

(4) the potential, duration, scope, and significance of inappropriate use and/or abuse;

(5) other facts as may be relevant to and consistent with the public health and safety.

(B) The board shall remove a drug product exception for a particular drug product if it determines that the drug product is not manufactured and distributed for legitimate use and in a manner that reduces the likelihood of abuse.

4729-15-01 DEFINITIONS.

As used in Chapter 4729-15 of the Administrative Code:

(A) "Class 100 environment" means an atmospheric environment that contains no more than one hundred particles of 0.5 microns in diameter or larger per cubic foot of air according to "Federal Standard 209E". A class 100 environment is equivalent to ISO class 5.

(B) "Class 100,000 environment" means an atmospheric environment that contains no more than one hundred thousand particles of 0.5 microns in diameter or larger per cubic foot of air according to "Federal Standard 209E". A class 100,000 environment is equivalent to ISO class 8.

(C) "Nuclear pharmacist" shall be a licensed pharmacist holding a current identification card in the state of Ohio, and meets the following standards:

(1) Be certified as a nuclear pharmacist by the "Board of Pharmaceutical Specialties"; or

(2) Meet minimal standards of training for an "authorized user" of radioactive material or for an "authorized nuclear pharmacist (ANP)" designation by the proper nuclear regulatory agency, the United States nuclear regulatory commission, or the appropriate state agency including:

(a) Have received a minimum of two hundred contact hours of didactic instruction in nuclear pharmacy and the safe handling and use of radioactive materials from an accredited college of pharmacy or a program approved by the nuclear regulatory commission, with emphasis in the following areas:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics of radioactivity;

(iv) Radiation biology;

(v) Radiopharmaceutical chemistry.

(b) Attain a minimum of five hundred hours of clinical nuclear pharmacy training under the supervision of a pharmacist trained in nuclear pharmacy and who is an "authorized user" or an "authorized nuclear pharmacist" as defined by the nuclear regulatory commission.

(D) "Nuclear pharmacy" is a pharmacy where prescriptions for radiopharmaceuticals are filled or where radiopharmaceuticals are compounded or dispensed by a pharmacist licensed by the proper authorities to receive, possess, and use such drugs. A nuclear pharmacy shall be licensed by the United States nuclear regulatory commission or the appropriate state nuclear regulatory agencies, other appropriate state agencies, and by the state board of pharmacy.

(E) "Radiopharmaceutical," a dangerous drug as defined in division (F) of section 4729.01 of the Revised Code, shall include any article that exhibits spontaneous decay or disintegration of an unstable atomic nucleus, usually accompanied by the emission of ionizing radiation and any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such article.

4729-21-01 REGISTRATION/LICENSURE.

No person, whether located within or outside this state, shall possess or sell compressed medical gases in Ohio unless they are registered as a wholesale distributor of dangerous drugs or licensed as a category II or category III terminal distributor of dangerous drugs with the board.

4729-21-02 COMPRESSED MEDICAL GAS FILLERS.

All dangerous drug distributors, wholesale and terminal, who fill containers with compressed medical gases must comply with the current good manufacturing practice regulations issued by the federal "Food and Drug Administration (F.D.A.)" pursuant to the "Federal Food, Drug and Cosmetic Act" and the current guidelines issued pursuant to Title 21 CFR 10.90 . Any deviation

from the current guidelines issued by the federal F.D.A. must be submitted to the federal F.D.A. for written approval before implementation. Documentation that the different procedures have been approved shall be maintained by dangerous drug distributors for review and copying by agents of the board.

4729-21-04 REQUIREMENTS FOR A CRYOGENIC MEDICAL GASES SAFETY PROGRAM.

(A) A medical gases safety program developed pursuant to section 4729.70 of the Revised Code shall meet at least the following requirements:

(1) The instructors shall have the appropriate education and experience to teach a program in medical gases 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 at least 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) What to do when there is an exposure to the gas or liquid.

(iv) What to do in an emergency hazardous material situation with the gas or liquid.

(c) The proper installation of cryogenic vessels including at least 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 rule 4729-21-05 of the Administrative Code.

(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.

(B) 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 available, upon request, to those business entities receiving service and to the state board of pharmacy.

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

4729-21-05 MODIFYING CRYOGENIC VESSELS, CONNECTIONS, ADAPTORS, AND VALVES.

(A) 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.

(B) Paragraph (A) 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 rule 4729-21-04 of the Administrative Code.

(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 at least 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 4729.70 of 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.

4729-22-01 LICENSURE.

Each person, whether located within or outside this state, who sells oxygen 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 from the board of pharmacy pursuant to the provisions of sections 4729.54 and 4729.55 of the Revised Code. A person who is a nonresident and is selling medical oxygen at retail to Ohio residents must also comply with the requirements in Chapter 4729-10 of the Administrative Code. This requirement shall not apply to persons already licensed to purchase, possess, and sell unlimited category II dangerous drugs at retail.

4729-22-02 SECURITY, STORAGE, AND SALE.

Medical oxygen may be sold only at retail to patients pursuant to an order from a prescriber in the course of their professional practice. Medical oxygen may be sold at retail and must be

maintained in accordance with Chapters 3715. and 4729. of the Revised Code; rules 4729-9-05 , 4729-9-11 , 4729-9-12 , and Chapter 4729-21 of the Administrative Code; and the "Federal Food, Drug and Cosmetic Act".

4729-22-03 RECORDS.

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 for inspection and copying by board of pharmacy agents.

4729-25-01 LICENSURE.

Each person located within this state who wishes 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 , shall obtain a limited category II terminal distributor of dangerous drugs license from the board of pharmacy pursuant to the provisions of sections4729.54 and 4729.55 of the Revised Code.

4729-25-02 SECURITY, STORAGE, AND USE.

Food processors and retail sellers of food must purchase, store, and use nitrous oxide in accordance with Chapters 3715. and 4729. of the Revised Code; rules 4729-9-05 , 4729-9-11 , 4729-9-12 , and Chapter 4729-21 of the Administrative Code; and the "Federal Food, Drug and Cosmetic Act".

4729-25-03 RECORDS.

All food processors and retail sellers of nitrous oxide shall maintain records of purchase at wholesale and use in processing food for three years at the licensed location for inspection and copying by board of pharmacy agents.

4729-25-04 REPORT OF THEFT OR LOSS.

Each food processor and retail seller of food shall, upon discovery of the theft or significant loss of any nitrous oxide, notify the board of pharmacy and local law enforcement authorities pursuant to section 2921.22 of the Revised Code. Thefts of nitrous oxide must be reported whether or not the nitrous oxide is subsequently recovered and/or the responsible parties are identified and action taken against them.

4729-29-02 PHARMACIST AS AGENT.

For the purpose of implementing any actions initiated as a result of a consult agreement whereby the consulting pharmacist is not the dispensing pharmacist or the person administering the dosage ordered, the consulting pharmacist shall be deemed to be acting as the agent of the

consulting physician as the term agent is used in rules 4729-5-21 and 4729-5-30 of the Administrative Code unless the physician has specified otherwise in the consult agreement. The pharmacist's copy of the signed consult agreement shall be made available to the dispensing pharmacist or the person administering the dosage ordered if it is requested in order to prove the right of the pharmacist to act in this manner.