OHIO STATE BOARD OF PHARMACY

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-Equal Opportunity Employer and Service Provider-

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10/9/14

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.

New Rule

- 4729-7-10: Outlines Board of Pharmacy provisions relating to the licensure of veterans and military families. Includes all Board policies regarding fee waivers, continuing education and license renewal extensions for veterans and military families.

Amended Rules

- 4729-5-12: Requires pharmacists and pharmacy interns to submit to a criminal records check prior to initial licensure. Also requires an applicant who lets their license lapse for more than three years to submit to a criminal background check if requesting a pharmacist or pharmacy intern license.
- 4729-5-21: Provides the manner in which a prescription must be processed in a pharmacy. Allows a pharmacy to document the administration of an immunization on a prescription form in order to allow the pharmacy to bill an individual's health insurance.

Amended Rules (5 Year Review)

- 4729-21-06: Provides the approved courses that divers must complete before they are allowed to purchase and utilize medical oxygen. Authorizes individuals who have completed courses from the National Association of Underwater Instructors to purchase and possess medical oxygen for the purpose of emergency care or treatment at the scene of a diving emergency.

- 4729-15-03: Sets the minimum standards for a nuclear pharmacy. Updates a cross-reference to a new drug compounding chapter (Chapter 16). This chapter will be in effect prior to the effective date of this rule.
- 4729-5-27: Provides the record keeping requirements for the practice of pharmacy in an outpatient setting. Updates the rule to reflect current technology.
- 4729-5-30: Provides the manner in which a valid prescription must be issued by a prescriber in order to be dispensed by a pharmacy. Updates a cross-reference to a new drug compounding chapter (Chapter 16). This chapter will be in effect prior to the effective date of this rule.
- 4729-21-03: Requires sellers of compressed medical gas to keep records for three years. Updates current terminology to match other record keeping sections of the Administrative Code.
- 4729-22-04: Prior to selling medical oxygen to a patient, the retail seller must have an order issued by a prescriber. Allows for the electronic transmission of an order for medical oxygen
- 4729-13-01: Provides the definitional section for the OAC Chapter for laboratory licensure. This rule is amended to update an incorrect cross-reference to the ORC.
- 4729-13-02: Provides the procedure for Board approval as a laboratory, including licensure as a terminal distributor of dangerous drugs.
- 4729-14-01: Provides the definitional section for the OAC chapter for animal shelter licensure. This rule is amended to update an incorrect cross-reference to the ORC.
- 4729-14-02: Provides the procedure for an animal shelter to obtain a terminal distributor of dangerous drugs.

You can view the proposed rules by visiting:
http://www.pharmacy.ohio.gov/LawsRules/ProposedRules.aspx

Comments on the proposed rules will be accepted until close of business on October 24, 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: Continuing Education/ Pharmacists-Administrative Provisions/ Approved Laboratories/ Animal Shelters / Nuclear Pharmacies / Compressed Medical Gases

Rule Number(s): New: 4729-7-10

Amended: 4729-5-12; 4729-5-21; 4729-5-27; 4729-5-30; 4729-13-01; 4729-13-02; 4729-14-01; 4729-14-02; 4729-15-03; 4729-21-03; 4729-21-06; 4729-22-04;

Date: 10/9/2014

Rule Type:

- ✓ New
- ✓ Amended
- ✓ 5-Year Review
- 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.

New Rule

- 4729-7-10: Outlines Board of Pharmacy provisions relating to the licensure of veterans and military families. Includes all Board policies regarding fee waivers, continuing education and license renewal extensions for veterans and military families.

Amended Rules

- 4729-5-12: Requires pharmacists and pharmacy interns to submit to a criminal records check prior to initial licensure. Also requires an applicant who lets their license lapse for more than three years to submit to a criminal background check if requesting a pharmacist or pharmacy intern license.
- 4729-5-21: Provides the manner in which a prescription must be processed in a pharmacy. Allows a pharmacy to document the administration of an immunization on a prescription form in order to allow the pharmacy to bill an individual's health insurance.

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- 4729-13-01: Provides the definitional section for the OAC Chapter for laboratory licensure. This rule is amended to update an incorrect cross-reference to the ORC.
- 4729-13-02: Provides the procedure for Board approval as a laboratory, including licensure as a terminal distributor of dangerous drugs.

- 4729-14-01: Provides the definitional section for the OAC chapter for animal shelter licensure. This rule is amended to update an incorrect cross-reference to the ORC.
- 4729-14-02: Provides the procedure for an animal shelter to obtain a terminal distributor of dangerous drugs.

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

The proposed rules are authorized by sections 4776.03, 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: 4729.071, 4776.01, 4776.02, 4776.04, 4729.28, 4729.37, 4729.38, 4729.381, 4729.39, 3719.05, 4729.51, 4729.54, 4729.55, 3719.05, 3719.07, 3719.13, 3719.27, 4729.27, 3719.06, 4729.01, 4729.281, 4729.52, 4729.53, 4729.57, 4729.531 and 4729.532.

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.

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:

- licensure of pharmacists and pharmacy interns;
- background checks for licensees;
- processing and dispensing of prescriptions at a pharmacy;
- oversight of radiopharmaceuticals at nuclear pharmacies;
- regulation of medical gases; and
- licensure of laboratories and animal shelters.

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 pharmacists and pharmacy interns and locations that store dangerous drugs on-site such as laboratories, pharmacies, animal shelters and sellers of medical gasses.

Section 4776.03 of the Ohio Revised Code requires the state board of pharmacy to adopt rules establishing administrative and procedural requirements for criminal records checks.

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 5903.04 of the Ohio Revised Code requires the state board of pharmacy to adopt rules to establish and implement all of the following:

- A process to obtain from each applicant documentation and additional information necessary to determine if the applicant is a service member or veteran, or the spouse or surviving spouse of a service member or veteran;
- A process to record, track, and monitor applications that have been received from a service member, veteran, or the spouse or surviving spouse of a service member or veteran; and
- A process to prioritize and expedite certification or licensing for each applicant who is a service member, veteran, or the spouse or a surviving spouse of a service member or veteran.

The public purpose of proposed rule 4729-7-10 is to recognize a veteran's education and experience obtained in the military that is substantially equivalent to or exceeds training and education required for professional licensure so that it would meet certain requirements of the profession's standard licensing process. The proposed rule is intended to lead to increased employment opportunities among Ohioans who have served in the military by considering relevant military education, skills training, and service in the professional licensure process to establish the applicant's competency and sufficiency of education and training needed for safe practice.

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:

- Ensure that pharmacists and pharmacy interns are subject to background checks.
- Ensure that pharmacists process prescriptions and maintain proper records to deter diversion of controlled substance and dangerous drugs.
- Meet the requirements mandated in the ORC to establish licensing processes for veterans, service members and their spouses.
- Ensure proper storage of dangerous drugs and controlled substances at animal shelters and laboratories.
- Provide proper record keeping requirements for medical gasses (including oxygen).
- Establish minimum standards for nuclear pharmacies.
- Ensure that only properly trained individuals and those with a valid order from a prescriber have access to medical oxygen.

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.

In addition, military veterans should be able to have their military education, skills training, and experience more efficiently reviewed by the Board when it considers the education and other requirements required for licensure and certification in applicable professions. The Board will track the number of veterans and their spouses who apply for licensure and will determine the expediency to which licensure is received in comparison with non-veteran applicants. The expectation for success of this regulation is a reduced processing time for veteran applicants as well as an increased ease for veterans to have their military service and education credited towards civilian licensure.

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

Rule 4729-21-06 was also reviewed and approved by the Oxygen Committee of the Ohio Council of Skin and Scuba Divers.

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?

4729-21-06: The Ohio Council of Skin and Scuba Divers Oxygen Committee recommended the addition of several courses from the National Association of Underwater Instructors.

4729-5-21: The Ohio Pharmacists Association recommended the addition of paragraph (K), which was approved by the Board's rules review committee.

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.

The Board also created a specific military licensing web site to assist in the implementation of the regulations. The site contains detailed information about Board policies for military veterans and their spouses. The Board also created internal policies for licensing staff to assist in the implementation of the rules.

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:

- Laboratories
- Animal Shelters
- Pharmacists
- Pharmacy Interns
- Nuclear Pharmacies
- Retail Pharmacies
- Retail Sellers of Compressed Gasses and Medical Oxygen
- **Ohio military veterans and their spouses who are potential licensees**

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, pharmacy intern, or location licensed as a terminal distributor of dangerous drugs (lab, animal shelter, nuclear pharmacy, retail pharmacy, and retail seller of compressed gasses and medical oxygen). Discipline might include reprimand, suspension of a license, required course work, monetary penalty and/or revocation of a license.

For military veterans and their spouses, the nature of the adverse impact would include the time and effort required to complete an application, and any application fees. In addition, the time and cost required to comply with any initial and/or continuing education requirements and licensure renewal expenses. The purpose of this proposed rule filing is to reduce these adverse impacts by recognizing equivalent education and experience gained in the military which would offset some of the requirements of the standard licensing process.

c. Quantify the expected adverse impact from the regulation.

4729-7-10: Outlines Board of Pharmacy provisions relating to the licensure of veterans and military families. Includes all Board policies regarding fee waivers, continuing education and license renewal extensions for veterans and military families. This will have no adverse impact on veterans and military families and will actually result in cost savings due to fee waivers and no-cost extensions for continuing education and license renewal. The specific changes being proposed in this rule filing are intended to reduce the impacts of normal licensure by recognizing equivalent education and experience gained through a potential licensee's military experiences.

4729-5-12: Requires pharmacists and pharmacy interns to submit to a criminal records check prior to initial licensure. Also requires an applicant who lets their license lapse for more than three years to submit to a criminal background check if requesting a pharmacist or pharmacy intern license. Fees for a criminal background check include: BCI/$22, plus FBI/$24, and some agencies may charge a processing fee (e.g. $5-$40).

4729-5-21: Provides the manner in which a prescription must be processed in a pharmacy. Allows a pharmacy to document the administration of an immunization on a prescription form in order to allow the pharmacy to bill an individual's health insurance. While the overall rule results in compliance costs for pharmacies and pharmacists to adhere to the requirements for processing a prescription at a pharmacy, the amendment to the rule will allow pharmacies to bill a patient's insurance for the cost of an immunization which will result in savings for both the pharmacy and the patient.

4729-21-06: Provides the approved courses that divers must complete before they are allowed to purchase and utilize medical oxygen. Authorizes individuals who have completed courses from the National Association of Underwater Instructors to purchase and possess medical oxygen for the purpose of emergency care or treatment at the scene of a diving emergency. This rule results in increased compliance costs because it requires retail sellers to ensure that a SCUBA diver has one of the required courses prior to the sale of medical oxygen.

4729-15-03: Sets the minimum standards for a nuclear pharmacy. Updates a cross-reference to a new drug compounding chapter (Chapter 16). This chapter will be in effect prior to the effective date of this rule. This rule results in increased compliance costs for nuclear pharmacies to meet all of the minimum standards outlined in the rule.

4729-5-27: Provides the required record keeping for the practice of pharmacy in an outpatient setting. Updates the rule to reflect current technology. This rule increases overall compliance costs for the pharmacy and pharmacists to ensure that all prescriptions dispensed in an outpatient setting adhere to record keeping requirements. This includes requirements to ensure the positive identification of the pharmacist dispensing the medication as well as the requirement to keep all records for three years for auditing purposes.

4729-5-30: Provides the manner in which a valid prescription must be issued by a prescriber in order to be dispensed by a pharmacy. Updates a cross-reference to a new compounding chapter (Chapter 16). This chapter will be in effect prior to the effective date of this rule. This results in increased administrative costs to prescribers and pharmacists. Prescribers are required to adhere to prescription requirements in order for their prescriptions to be considered valid by the pharmacy. Failure to comply with the rule may require to the prescriber and the pharmacist to take additional time to verify the information required in order to validate the prescription.

4729-21-03: Requires sellers of compressed medical gas to keep records for three years. Updates current terminology to match other record keeping sections of the Administrative Code. This will result in increased administrative costs on the part of the sellers of compressed medical gas to maintain these records for the required time period.

4729-22-04: Prior to selling medical oxygen to a patient, the retail seller must have an order issued by a prescriber. Allows for the electronic transmission of an order for medical oxygen. This rule was amended to allow for electronic transmission of orders, which may reduce overall costs associated with providing medical oxygen to patients.

4729-13-01: Provides the definitional section for the OAC chapter for laboratory licensure. This rule is amended to update an incorrect cross-reference to the ORC. This is a definitional section and does not have any adverse impact.

4729-13-02: Provides the procedure for Board approval as a laboratory, including licensure as a terminal distributor of dangerous drugs. The license fee, depending on the type of drugs stored by each laboratory, 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.

4729-14-01: Provides the definitional section for the OAC chapter for animal shelter licensure. This rule is amended to update an incorrect cross-reference to the ORC. This is a definitional section and does not have any adverse impact.

4729-14-02: Provides the procedure for an animal shelter to obtain a terminal distributor of dangerous drugs from the Board. The license fee, depending on the type of drugs stored by each animal shelter, 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.

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

Executive Order 2013-05K and recently-enacted House Bills 98 and 488 both recognize the contributions and qualifications of Ohio veterans and encourage streamlining of the certification and licensing process to take into account relevant military education, skills training, and service. The regulatory intent is further justified because the Board recognizes that the experiences of our military are valuable, translatable in certain circumstances, and should be considered in the licensing process wherever possible to facilitate economic opportunities for veterans returning to civilian service in a professional field.

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:

- All pharmacists and pharmacy interns are subject to background checks;
- Standards for valid prescriptions and record keeping are in place to prevent the diversion of dangerous drugs and controlled substances;
- The Board has standardized processes for veterans, service members and their spouses to receive fee waivers and licensing extensions as a result of their service;
- Dangerous drugs and controlled substances at animal shelters and laboratories are stored properly to prevent diversion.
- Sellers of medical gasses keep proper records to detect and deter diversion;
- Nuclear pharmacies keep uniform minimum standards so Ohio patients can be certain that all radiopharmaceuticals dispensed from these locations are safe; and

- Access to medical oxygen is reserved for qualified individuals that have an order from a prescriber or meet certain training standards.

- **Recognize veterans and military families experience and support their transition into gainful employment in the state of Ohio.**

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 regulation is 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 RULE

4729-7-10 VETERAN AND MILITARY FAMILY PROVISIONS RELATED TO LICENSURE AS A PHARMACIST OR PHARMACY INTERN.

(A) "Veteran" means anyone who is serving or has served under honorable conditions in any component of the Armed Forces, including the National Guard and Reserve.

(B) Substantially equivalent education.

In accordance with section 5903.03 of the Revised Code, there are no military programs of training or military primary specialties which are substantially equivalent to the education requirements for licensure as a pharmacist.

(C) Continuing education.

(1) In accordance with section 5903.12 of the Revised Code, the state board of pharmacy shall grant extension periods and waivers for the completion of license renewal and continuing education requirements for active duty veteran members and their spouses. If a current pharmacist or their spouse is called to active duty for military service, the time period allowed for completion of any continuing education requirements or license renewal will be extended by the amount of time that the pharmacist or the pharmacist's spouse was on active duty.

(2) Upon receiving the application and proper documentation, the board's director of licensing shall extend the current reporting period by an amount of time equal to the total number of months that the licensee or their spouse spent on active duty during the current reporting period. For purposes of this division, any portion of a month served on active duty shall be considered one full month.

(3) The licensee shall submit proper documentation certifying the active duty service and the length of that active duty service. Documentation required to obtain an extension or waiver pursuant to paragraph (C)(1) of this rule will be published on the state board of pharmacy's web site: www.pharmacy.ohio.gov.

(D) Determining fulfillment of continuing education.

(1) If a pharmacist is a veteran, the state board of pharmacy shall consider relevant military education, training or service that has been completed by the license holder when determining the fulfillment of any continuing education requirements.

(2) In order for the board to consider relevant education, training, or service completed by a pharmacist, the licensee shall submit a request for consideration and evidence or documentation of the education, training, or service to the director of licensing at least thirty days prior to the required continuing education reporting period pursuant to rule 4729-7-02 of the Ohio Administrative Code.

(E) Renewal of an expired license.

(1) In accordance with section 5903.10 of the Revised Code, a holder of an expired license shall be granted a renewal of the license or certificate by the state board of pharmacy at the usual cost without penalty and without re-examination if not otherwise disqualified because of mental or physical disability and if either of the following applies:

(a) The license or certificate was not renewed because of the holder's service in the armed forces.

(b) The license or certificate was not renewed because the holder's spouse served in the armed forces of the United States or a reserve component of the armed forces and the service resulted in the holder's absence from this state.

(2) A pharmacist shall submit proper documentation certifying the active duty service and the length of that active duty service. Documentation required to obtain a renewal pursuant to paragraph (E)(1) of this rule will be published on the state board of pharmacy's web site: www.pharmacy.ohio.gov.

(F) Upon receipt of all required documentation and when applicable, a pharmacist or pharmacy intern license shall be issued no later than three business days of the applicant's eligibility for licensure, to each applicant who is a veteran, spouse or surviving spouse of a veteran.

(G) The director of licensing shall maintain a system to record, track and monitor applications that have been received from a veteran, spouse or surviving spouse of a veteran.

(H) The state board of pharmacy may implement fee waivers for licensure. If implemented, the waivers will be published on the state board of pharmacy's web site: www.pharmacy.ohio.gov.

AMENDED RULES

4729-5-12 CRIMINAL RECORDS CHECK FOR PHARMACISTS AND PHARMACY INTERNS.

(A) Pursuant to section 4729.071 of the Revised Code, an applicant seeking an initial license as a pharmacist by examination or reciprocity, and an applicant seeking an initial license as a pharmacy intern must first submit fingerprint impressions to the Ohio bureau of criminal identification and investigation (BCI&I) for a criminal records check.

(B) Pursuant to section 4776.02 of the Revised Code, the criminal records check performed by BCI&I shall consist of both a BCI&I criminal records check and a federal bureau of investigation (FBI) criminal records check. BCI&I shall send the results of the BCI&I and FBI criminal records checks directly to the state board of pharmacy.

(C) The state board of pharmacy requires that the criminal records check:

(1) Be based on electronic fingerprint impressions that are submitted directly to BCI&I from a "WebCheck" provider agency located in Ohio. The state board of pharmacy may accept the results of a

criminal records check based on ink impressions from a "WebCheck" provider agency only in the event that readable electronic fingerprint impressions cannot be obtained.

(2) Results will only be considered valid if the fingerprint impressions were obtained within the previous twelve months.

(D) An applicant may submit electronic fingerprint impressions for a criminal records check anytime after he/she has submitted a licensure application to the state board of pharmacy.

(E) After the state board of pharmacy receives the results from both of the required criminal records checks the licensing process will proceed.

(F) If a pharmacist or pharmacy intern's identification card has lapsed for more than three years after the expiration of the card, the applicant shall submit to a criminal records check that meets the criteria prescribed in this rule.

4729-21-06 SALES OF MEDICAL OXYGEN TO S.C.U.B.A. DIVERS.

(A) 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 divisions (B)(1)(i) and (C)(4) of section 4729.51 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.

4729-5-21 MANNER OF PROCESSING A PRESCRIPTION.

(A) A prescription, to be valid, must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of his/her professional practice. The responsibility for the proper prescribing is upon the prescriber, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of law.

(B) A pharmacist when dispensing a prescription must:

(1) Ensure that patient information is profiled pursuant to rule 4729-5-18 of the Administrative Code;

(2) Perform prospective drug utilization review pursuant to rule 4729-5-20 of the Administrative Code;

(3) Ensure that the drug is labeled pursuant to rule 4729-5-16 of the Administrative Code;

(4) Ensure that a patient is given an offer to counsel pursuant to rule 4729-5-22 of the Administrative Code;

(5) Ensure that a prescription is filed pursuant to rule 4729-5-09 of the Administrative Code.

(C) Prescriptions:

(1) A pharmacist may receive a signed hard copy prescription, an oral prescription, a facsimile of a signed prescription, or a prescription sent using a board approved electronic prescription transmission system. The pharmacist shall follow the prescription record keeping processes noted in paragraphs (C), (D), (E), and (F) of this rule for each of these types of prescriptions received unless utilizing an alternate record keeping system pursuant to rule 4729-5-27 of the Administrative Code that has been approved by the board.

(2) When a pharmacist dispenses a drug pursuant to an original prescription, he/she must record the date of such dispensing and either manually record his/her name or initials on the original prescription or, if approved by the state board of pharmacy, enter his/her positive identification into the computerized

record keeping system pursuant to rule 4729-5-27 of the Administrative Code. If an alternate record keeping system is being used pursuant to rule 4729-5-27 of the Administrative Code, the record of dispensing must also be recorded in the alternate record keeping system.

(3) When a pharmacist dispenses a drug pursuant to an authorized refill of a prescription, he/she must record the date of such dispensing and either manually record his/her name or initials on the original prescription or enter such information in an alternate record keeping system or, if approved by the state board of pharmacy, enter his/her positive identification into a computerized record keeping system pursuant to rule 4729-5-27 of the Administrative Code.

(D) Oral prescriptions:

(1) The pharmacist shall make a record of the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent, on the original prescription and, if used, on the alternate system of record keeping. The pharmacist is responsible for assuring the validity of the source of the oral prescription.

(2) Upon receiving a prescription from a recording device, the pharmacist must remove the prescription from the recorder and reduce it to writing. The pharmacist must document on the original prescription the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent. The pharmacist is responsible for assuring the validity of the prescription removed from the recorder.

(3) A licensed pharmacy intern may receive telephone prescriptions and remove prescriptions from a recording device if the pharmacist on duty who is supervising the activity of the intern determines that the intern is competent to perform this function.

(a) The intern shall immediately reduce the prescription to writing, document the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent, and shall review the prescription with the supervising pharmacist. Prior to dispensing, positive identification of the intern and the supervising pharmacist shall be made on the prescription to identify the responsibility for the receipt of the oral order.

(b) The supervising pharmacist on duty is responsible for the accuracy of the prescription.

(c) The supervising pharmacist on duty must be immediately available to answer questions or discuss the prescription with the caller.

(E) Facsimile prescriptions:

(1) A facsimile shall only be valid as a prescription if a system is in place that will allow the pharmacist to maintain the facsimile as a part of the prescription record including the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent as well as identification of the origin of the facsimile.

(2) The pharmacist must record the prescription in writing pursuant to section 4729.37 of the Revised Code or store the facsimile copy in such a manner that will allow retention of the prescription record for three years from the date of the last transaction.

(F) Electronic prescriptions:

(1) Electronic prescriptions may be received by a pharmacy if the electronic prescription transmission system has been approved by the state board of pharmacy.

(2) A pharmacy desiring to receive electronic prescriptions directly into its computer system must obtain approval from the state board of pharmacy. The original prescription information received from the prescriber must be saved and a hardcopy prescription must be printed to document the dispensing. The hardcopy prescription must be filed in the prescription file pursuant to rule 4729-5-09 of the Administrative Code.

(3) A pharmacy computer system meeting the requirements of 21 C.F.R. 1311(04/01/13) shall be considered approved by the state board of pharmacy.

(G) A pharmacist may not dispense a dangerous drug for the first time beyond six months from the date of issuance of a prescription.

(H) The quantity dispensed shall be considered the quantity prescribed unless the quantity dispensed on a:

(1) New prescription is less than the quantity prescribed, the pharmacist shall note the quantity dispensed on the original prescription. If the quantity dispensed on a new prescription is greater than the quantity prescribed, the pharmacist shall also record on the original prescription the name of the authorizing prescriber, the full name of the agent of the prescriber if applicable, the quantity authorized to be dispensed, and the date that the authorization was obtained.

(2) Refill prescription is less than the quantity prescribed, the pharmacist shall note the quantity dispensed on the original prescription or enter the quantity dispensed on an alternate record pursuant to paragraph (F) of rule 4729-5-27 of the Administrative Code. If the quantity dispensed on a refill prescription is greater than the quantity prescribed, the pharmacist shall also record the name of the authorizing prescriber, the full name of the agent of the prescriber if applicable, the quantity authorized to be dispensed, and the date that the authorization was obtained.

(I) Where a prescription is written using a generic name, or where the pharmacist dispenses an equivalent drug product pursuant to the provisions of sections 4729.38 and 4729.381 of the Revised Code, the brand name or drug name and name of the manufacturer or distributor of the drug or the national drug code (NDC) number of the drug dispensed must be recorded on the record of dispensing by the pharmacist.

(J) A pharmacist who modifies a patient's drug therapy pursuant to a consult agreement and is:

(1) Also responsible for the dispensing of the drug to the patient must include on the drug order the name of the physician who originally prescribed the drug, sign the pharmacist's full name, and be in compliance with this rule in the same manner as the prescriber.

(2) Not responsible for the dispensing of the drug to the patient may transmit the order to a pharmacy by acting as an agent of the physician. Such pharmacist must personally transmit the order verbally or by facsimile to another pharmacist and be in compliance with this rule.

(K) A pharmacist may document their own administration of an immunization, or an immunization administered by a pharmacy intern they are supervising, on a prescription form, which may be assigned a number for record keeping purposes. This documentation is in addition to the record keeping requirements noted in rule 4729-5-27 of the Administrative Code.

4729-15-03 MINIMUM STANDARDS FOR A NUCLEAR PHARMACY.

(A) A nuclear pharmacy shall comply with all applicable local, state, and federal requirements. If a nuclear pharmacy compounds parenteral or sterile product prescriptions other than radiopharmaceuticals or biohazardous materials, the pharmacy shall also comply with rule ~~4729-19-04~~ 4729-16-03 of the Administrative Code.

(B) A policy and procedure manual shall be prepared and maintained regarding the compounding, dispensing, and delivery of sterile radiopharmaceutical prescriptions. The policy and procedure manual shall include at a minimum:

(1) A quality assurance program for the purpose of monitoring personnel qualifications, training and performance, product integrity, equipment, facilities, and guidelines regarding patient education;

(2) Justification for the chosen beyond use dates of compounded products;

(3) Proper handling, storage, and disposal of drugs, radiopharmaceuticals, and radioactive waste;

(4) Proper handling, storage, and disposal of biohazardous materials, if applicable;

(5) Handling of spills and exposure to radioactive and biohazardous materials;

(6) Proper documentation and reporting of adverse events;

(7) Procedures to resolve conflicts when sterile product preparation may interfere with radiation safety practices and equipment. These procedures should use the principle of as clean as reasonably achievable.

The policy and procedure manual shall be current and available for inspection and copying by a state board of pharmacy agent.

(C) Physical requirements

(1) The facility shall have a designated area with access limited to authorized personnel for preparing sterile radiopharmaceutical products. This area shall be isolated from other areas and must be designed to

avoid unnecessary traffic and airflow disturbances from activity within the controlled area. It shall be used only for the preparations of these specialty products. It shall be of sufficient size to accommodate a laminar airflow hood or other primary engineering control devices that provide a class 100 environment and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.

(2) The facility compounding radiopharmaceutical prescriptions shall have appropriate:

(a) Primary engineering control devices capable of maintaining at least class 100 conditions in the work place where critical objects are exposed and critical activities are performed; at a minimum, there shall be a physical barrier separating the area where biohazardous products such as human blood are prepared; furthermore, these devices are to be capable of maintaining class 100 conditions during normal activity. Examples of appropriate devices include laminar airflow hoods and zonal laminar flow of high efficiency particulate air (HEPA) filtered air.

(b) Shielding of radioactive materials;

(c) Compounding devices and equipment;

(d) Storage conditions for drugs, radiopharmaceuticals, and biohazardous materials;

(e) Appropriate disposal containers for used needles, syringes, etc.

(3) The facility shall maintain supplies adequate to maintain an environment suitable for the aseptic preparation of sterile products.

(4) The compounding of sterile products shall be done within a class 100 environment except in an emergency situation when the product is required to meet the immediate needs of a patient whose health would otherwise be jeopardized.

(D) Delivery service

The responsible nuclear pharmacist shall ensure that all employees comply with all applicable local, state, and federal requirements to assure the proper labeling, environmental controls, integrity, and safety of all products transported.

(E) Disposal of radioactive and/or biohazardous waste

The responsible nuclear pharmacist shall ensure that all employees comply with all applicable local, state, and federal requirements to assure that there is a system for the disposal of radioactive and/or biohazardous waste in a manner so as not to endanger the public health.

(F) Health care professional counseling

When appropriate, a nuclear pharmacist shall be involved in discussing with each health care professional responsible for receiving, storing, and administering a radiopharmaceutical product, the following matters:

(1) Dosage form, dosage, calibrated activity, route of administration, and duration of therapy;

(2) Special directions and precautions for preparation and administration;

(3) Proper storage; and

(4) Stability or incompatibilities of the medication.

(G) Quality assurance

(1) There shall be a documented, ongoing quality assurance control program that monitors personnel performance, equipment, finished compounded drug products, and facilities.

(2) At a minimum, there shall be written quality assurance programs developed that address:

(a) Adequate training and continuing competency monitoring of all personnel in personal cleansing, proper attire, aseptic technique, proper clean room conduct, and clean room disinfecting procedures. Instructors shall have the appropriate knowledge and experience necessary to conduct the training;

(b) Continued verification of compounding accuracy and including when possible physical inspection of end products;

(c) Continued verification of automated compounding devices;

(d) Continued verification that appropriate beyond use dates are being assigned to compounded products;

(e) End product testing including, but not limited to, the appropriate sampling of products if microbial contamination is suspected. If bulk compounding of sterile products is being performed using nonsterile chemicals, extensive end product testing must be documented prior to the release of the product from quarantine;

(f) All clean rooms and laminar flow hoods shall have environmental monitoring performed at least every six months to certify operational efficiency. There shall be a plan in place for immediate corrective action if operational efficiency is not certified. Records certifying operation efficiency shall be maintained for at least three years.

4729-5-27 RECORD KEEPING.

The following record keeping requirements do not apply to records relating to the practice of pharmacy for an inpatient as defined in rule 4729-17-01 of the Administrative Code.

(A) There must be positive identification of the pharmacist or pharmacists responsible for performing all activities relating to the practice of pharmacy including, but not limited to:

(1) Prescription information entered into the record keeping system;

(2) Prospective drug utilization review;

(3) Dispensing;

(4) Patient counseling;

(5) Administering adult immunizations;

(6) Prescription information reduced to writing from an order received by telephone, facsimile, or recording device.

(B) Records of dispensing must provide accountability and ensure that patients do not receive more drugs than intended by the prescriber.

(C) All records relating to the practice of pharmacy shall be uniformly maintained for a period of three years, be readily available, and promptly produced upon request for inspection by a state board of pharmacy officer, agent, and/or inspector during regular business hours.

(D) All prescriptions or other records relating to the practice of pharmacy, which are required to be kept for three years according to section 4729.37 of the Revised Code, may be microfilmed or placed on electronic, magnetic media. The microfilm or electronic, magnetic media used for this purpose must comply with the "International Standards Organization" standards of quality approved for permanent records. Such records are subject to all other paragraphs of this rule.

(E) Any pharmacy intending to maintain records relating to the practice of pharmacy at a location other than the place licensed with the state board of pharmacy must first send written notification to the state board of pharmacy. The request shall contain the terminal distributor of dangerous drug name and license number of the requestor and the name and address of the alternate location. The state board of pharmacy office will send written notification of the approval or denial of the request. A copy of the board's approval shall be maintained with other records relating to the practice of pharmacy. Any such alternate location shall be secured and accessible only to representatives of the terminal distributor of dangerous drugs.

(F) Alternate record keeping systems include, but are not limited to, the following:

(1) A system that utilizes the original hard copy prescription to document the initial dispensing of a prescription, but utilizes a computerized system to dispense refills that does not document the positive identification of the pharmacist responsible for the practice of pharmacy. In order to document positive identification, this system would require the manual signature or initials of a pharmacist on a hard copy record as indicated in paragraph (I) of this rule.

(2) A computerized system that documents the positive identification of the pharmacist responsible for the practice of pharmacy. If this method is used, it must be approved by the board and provide a daily backup.

(3) Any record keeping system approved by the board.

(G) All computerized record keeping systems must be capable of providing immediate retrieval (via ~~CRT~~ digital display and hard copy printout or other mutually agreeable transfer medium) of patient profile information for all prescriptions filled within the previous twelve months and retrieval within three working days, excluding weekends and holidays, of all prescriptions dispensed within the previous three years. This information shall include at least, but is not limited to, the following data:

(1) The original prescription number;

(2) Date of issuance of the original prescription order by the prescriber;

(3) Date of dispensing by the pharmacist;

(4) Full name and address of the patient;

(5) Full name and address of the prescriber;

(6) Directions for use;

(7) The name, strength, dosage form, and quantity of the drug prescribed;

(8) The quantity dispensed if different from the quantity prescribed;

(9) If utilizing a board approved system pursuant to paragraph (F)(2) of this rule, there must be positive identification documented within the system of the pharmacist responsible for prescription information entered into the computer system, the pharmacist responsible for prospective drug utilization review as defined in rule 4729-5-20 of the Administrative Code, and the pharmacist responsible for dispensing;

(10) The total number of refills authorized by the prescriber;

(11) The refill history of the prescription as defined in paragraph (H) of this rule.

(H) The refill history of the prescription must include, but is not limited to:

(1) The prescription number;

(2) The name and strength of the drug dispensed;

(3) The date of refill;

(4) The quantity dispensed;

(5) If utilizing a board approved system pursuant to paragraph (F)(2) of this rule, there must be positive identification documented within the system of the pharmacist responsible for prospective drug utilization review as defined in rule 4729-5-20 of the Administrative Code and the pharmacist responsible for dispensing for each refill;

(6) The total number of refills dispensed to date for that prescription order.

(I) Hard copy documentation as required pursuant to paragraph (F)(1) of this rule must be provided by each individual pharmacist who makes use of such system by one of the following methods:

(1) A hard copy printout of each day's prescription refill data that shall include, at a minimum, the following data:

(a) Date of dispensing;

(b) Prescription number;

(c) Patient name;

(d) Name, strength (if applicable), and quantity of drug;

(e) Identification of pharmacy and pharmacist;

(f) Identification of controlled substances.

This printout must be verified, dated, and signed by each individual pharmacist who dispensed a prescription that day. The pharmacist must verify that the data on the printout is complete and correct and sign a statement to that effect on the document as he/she would sign a check or legal document (e.g., J. H. Smith or Jane H. Smith). These documents must be maintained in chronological order in a separate file at the licensed location where the drug was dispensed for a period of three years from the date of dispensing. If the printout is prepared at a location other than that where the drug was dispensed, the printout must be provided to the licensed location within three working days, excluding holidays and weekends, of the date on which the drugs were dispensed. Such printouts must be verified and signed by each pharmacist who dispensed drugs within twenty-four hours of the date the printout is received;

(2) A tamper evident log book in which shall be entered, at a minimum, the date of dispensing and prescription number. The dispensing pharmacist must manually record his/her name or initials on each log book entry at the time of dispensing each refill; or

(3) Each individual pharmacist involved in dispensing drugs must enter into a tamper evident log book, at a minimum, the following data for each prescription refilled:

(a) Date of dispensing;

(b) Prescription number;

(c) Patient name;

(d) Name, strength (if applicable), and quantity of drug;

(e) Identification of the pharmacist;

(f) Identification of controlled substances.

Each individual pharmacist involved in dispensing drugs must review this information at the end of each day and then must sign a statement in the log book attesting to the fact that the prescription information entered into the computer that day and recorded in the log book has been reviewed by him/her and is correct as shown.

(J) In addition to the immediate retrieval and production of patient profile information required by paragraph (G) of this rule, a pharmacy that utilizes a computerized record keeping system must be able to:

(1) Produce:

(a) An electronic record in a character-delimited or fixed-width ASCII text file or other mutually acceptable format that contains any requested data fields the user pharmacy is responsible for maintaining pursuant to all federal and state laws, rules and regulations; and

(b) A hardcopy printout sorted by any requested data fields that the user pharmacy is responsible for maintaining pursuant to all federal and state laws, rules, and regulations.

(2) Provide, within three working days of a request by an individual authorized by law to access such records, any requested:

(a) Printout; or

(b) Electronic record and a definition file describing the file layout and column width, if applicable.

(K) In the event that the computerized record keeping system experiences down time, a record of all refills dispensed during such time must be recorded on the back of the original prescription. The refill information must be entered into the computerized record keeping system as soon as it is available for use. During the time the computerized record keeping system is not available, prescriptions may be refilled only if, in the professional judgment of the pharmacist, the number of refills authorized by the prescriber has not been exceeded.

(L) A pharmacy purging a computerized record keeping system of prescription records must develop a method of record keeping capable of providing retrieval (via ~~CRT~~ digital display, hard copy printout, or other mutually agreeable transfer medium) within three working days, excluding holidays and weekends, of prescription order information for all prescriptions filled or refilled within the previous three years. This information shall include, at a minimum, the following data:

(1) Pharmacy name and address;

(2) Original prescription number;

(3) Date of issuance of the original prescription order by the prescriber;

(4) Date of original dispensing by the pharmacist;

(5) Full name and address of the patient;

(6) Full name and address of the prescriber;

(7) Directions for use;

(8) Name, strength, dosage form, and quantity of the drug prescribed;

(9) Quantity dispensed if different from the quantity prescribed;

(10) Total number of refills authorized by the prescriber;

(11) Total number of refills dispensed to date for that prescription order;

(12) Date of each refill;

(13) Name or initials of each individual dispensing pharmacist.

(M) A log must be maintained of all changes made to a prescription record after the prescription has been dispensed. Such log may be accessible to the pharmacist for review, but shall be protected from being altered in any way. The log must contain at least, but is not limited to, the following:

(1) Date and time of change;

(2) Changes made;

(3) Pharmacist making the change.

(N) Prescriptions entered into a computer system but not dispensed must meet all of the following conditions:

(1) The complete prescription information must be entered in the computer system;

(2) The information must appear in the patient's profile;

(3) There is positive identification, in the computer system or on the hard copy prescription, of the pharmacist who is responsible for entering the prescription information into the system; and

(4) The original prescription is filed according to rule 4729-5-09 of the Administrative Code.

(O) Records shall be maintained for three years on all immunizations administered pursuant to section 4729.41 of the Revised Code and rule 4729-5-38 of the Administrative Code and must include at least the following information:

(1) Full name and address of the patient;

(2) Patient's date of birth or age;

(3) Patient's gender;

(4) Patient's applicable allergy information;

(5) Date of administration;

(6) Name, strength, and dose of the immunization administered;

(7) Lot number and expiration date of the immunization;

(8) Route of administration;

(9) Location of the injection site;

(10) Positive identification of the administering pharmacist or the administering pharmacy intern and supervising pharmacist;

(11) Positive identification of the patient, parent, or legal guardian of the patient who gives informed consent to administer an immunization.

(P) A pharmacist or pharmacy intern under the direct supervision of a pharmacist who administers an immunization pursuant to section 4729.41 of the Revised Code and rule 4729-5-38 of the Administrative Code shall maintain and immediately make available, upon the request of the state board of pharmacy, the following records:

(1) Documentation of the successful completion of a board approved course in the administration of immunizations;

(2) Documentation of current certification to perform basic life support procedures pursuant to division (B)(2) of section 4729.41 of the Revised Code.

4729-5-30 MANNER OF ISSUANCE OF A PRESCRIPTION.

(A) A prescription, to be valid, must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of his/her professional practice. The responsibility for the proper prescribing is upon the prescriber, but a corresponding responsibility rests with the pharmacist who

dispenses the prescription. An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of law.

(B) All prescriptions issued by a prescriber shall:

(1) Be dated as of and on the day when issued.

(2) Contain the manually printed, typewritten, or preprinted full name, professional title, and address of the prescriber.

(3) Indicate a telephone number where the prescriber can be personally contacted during normal business hours.

(4) Indicate the full name and residential address of the patient.

(5) Indicate the drug name and strength.

(6) Indicate the quantity to dispense.

(7) Indicate the appropriate and explicit directions for use.

(8) Specify the number of times or the period of time for which the prescription may be refilled. If no such authorization is given, the prescription may not be refilled except in accordance with section 4729.281 of the Revised Code. A prescription marked "Refill P.R.N." or some similar designation is not considered a valid refill authorization.

(9) Not authorize any refills for schedule II controlled substances.

(10) Authorize refills for schedules III and IV controlled substances only as permitted by section 3719.05 of the Revised Code.

(11) Not authorize a refill beyond one year from the date of issuance for schedule V controlled substances and for dangerous drugs that are not controlled substances.

(12) Identify the trade name or generic name of the drug(s) in a compounded prescription.

(13) Not be coded in such a manner that it cannot be dispensed by any pharmacy of the patient's choice.

(14) For prescriptions issued to a patient by a prescriber, be:

(a) Manually signed on the day issued by the prescriber in the same manner as he/she would sign a check or legal document.

(b) Issued in compliance with rule 4729-5-13 of the Administrative Code.

(15) For a controlled substance, indicate the drug enforcement administration registration number of the prescriber pursuant to Title 21 CFR 1306.05 (enacted on June 23, 2005).

(16) If issued by a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner with prescriptive authority, contain the nurse's prescriber number found on the certificate to prescribe issued by the state board of nursing pursuant to rule 4723-9-09 of the Administrative Code.

(17) If issued by a physician assistant with prescriptive authority, contain the certificate number of the physician assistant's certificate to prescribe pursuant to rule 4730-2-07 of the Administrative Code.

(18) Be issued in compliance with all applicable federal and state laws, rules, and regulations.

(C) When forms are used that create multiple copies of a prescription issued to a patient by a prescriber, the original prescription that bears the actual signature of the prescriber must be issued to the patient for dispensing by a pharmacist.

(D) Oral transmission by the prescriber or the prescriber's agent of original prescriptions and refills authorized by a prescriber, pursuant to the requirements of this rule, may be transmitted by telephone only to:

(1) A pharmacist.

(2) A recording device within the pharmacy if the pharmacist is unavailable. The pharmacist must remove the prescription from the recorder and reduce it to writing. The pharmacist is responsible for assuring the validity of the prescription removed from the recorder.

(3) A licensed pharmacy intern if the pharmacist on duty who is supervising the activity of the intern determines that the intern is competent to receive telephone prescriptions.

The prescriber's agent must provide his/her full name when transmitting an oral prescription.

(E) Original written prescriptions authorized and signed by a prescriber may be transmitted by the prescriber or the prescriber's agent by facsimile machine to a pharmacy pursuant to the following:

(1) The facsimile of the prescription must include the full name of the prescriber and if applicable the full name of the prescriber's agent transmitting the prescription to the pharmacy.

(2) The original prescription signed by the prescriber from which the facsimile is produced shall not be issued to the patient. The original prescription signed by the prescriber must remain with the patient's records at the prescriber's office or the institutional facility where it was issued.

(3) Prescriptions for schedule II controlled substances may not be transmitted by facsimile except for:

(a) A resident of a long term care facility pursuant to rule 4729-17-09 of the Administrative Code.

(b) A narcotic substance issued for a patient enrolled in a hospice. The original prescription must indicate that the patient is a hospice patient. The facsimile transmission must also meet the other requirements of this rule.

(c) A compounded sterile product prescription for a narcotic substance pursuant to rule ~~4729-19-02~~ 4729-16-03 of the Administrative Code.

(4) A facsimile of a prescription received by a pharmacy in any manner other than transmission directly from the prescriber or the prescriber's agent shall not be considered a valid prescription.

(5) The facsimile of the prescription must include header information identifying the origin of the facsimile.

(F) A prescription may be transmitted by means of a board approved electronic prescription transmission system provided that:

(1) The system requires positive identification of the prescriber as defined in rule 4729-5-01 of the Administrative Code and the full name of any authorized agent of the prescriber who transmits the prescription.

(2) The computer data is retained for a period of three years at the prescriber's office.

(3) An electronic prescription transmission system meeting the requirements of 21 C.F.R. 1311 for both controlled substance and non-controlled substance prescriptions shall be considered approved by the state board of pharmacy.

(G) Pursuant to section 4729.38 of the Revised Code if a prescriber does not want a pharmacist to select a generically equivalent drug the prescriber must handwrite "dispense as written" or "DAW" on the prescription, or if ordering electronically or orally the prescriber specifies that the prescribed drug is medically necessary.

4729-21-03 RECORDS.

Records required by state and federal laws and 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 and copying by board of pharmacy agents.

4729-22-04 PRESCRIBER'S ORDER.

Before making an initial sale of medical oxygen to a patient, the retail seller must have an order issued by a prescriber in the course of the prescriber's professional practice. The order must include the full name

and address of the patient, the positive identification 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, and documentation of need. The prescriber's order may be transmitted electronically to the retail seller. This order must be renewed at least annually.

4729-13-01 DEFINITIONS.

As used in Chapter 4729-13 of the Administrative Code:

(A) "Controlled substance" has the same meaning as in section ~~4729.01~~ 3719.01 of the Revised Code.

(B) "Dangerous drug" has the same meaning as in section 4729.01 of the Revised Code and in rule 4729-9-01 of the Administrative Code.

(C) "D.E.A." means the federal drug enforcement administration.

(D) "Laboratory" means any establishment or place where dangerous drugs are possessed for scientific and clinical purposes and for purposes of instruction that has been approved by the state board of pharmacy.

(E) "Registration numbers" means the numbers assigned to each person registered under the federal drug abuse control laws, sections 4729.52 and/or 4729.54 of the Revised Code.

(F) "Responsible person" means the individual designated by the licensee as the person who will maintain supervision and control over the possession and custody of such dangerous drugs that may be acquired and utilized by the licensee.

Rationale: Technical update as JCARR discovered that there wasn't actually a definition of controlled substance in 4729.01.

4729-13-02 PROCEDURE FOR STATE BOARD OF PHARMACY APPROVAL AS A LABORATORY.

(A) A person, as defined in division (S) of section 4729.01 of the Revised Code, desiring to be approved by the state board of pharmacy as a laboratory shall file with the state board of pharmacy a completed application containing information relative to the qualifications for approval as set forth in rule 4729-13-03 of the Administrative Code.

(B) The state board of pharmacy shall issue a terminal distributor of dangerous drugs license to purchase, possess, and utilize dangerous drugs for scientific and clinical purposes and for purposes of instruction at the establishment or place described in the application to each person who has submitted an application

and has paid the required license fee if the board determines that such applicant meets the requirements set forth in this chapter.

(C) All licenses issued pursuant to this rule shall be effective for a period of twelve months from the first day of ~~January~~ April of each year. A license shall be renewed by the state board of pharmacy for a like period, annually, according to the provisions of this rule, and the standard renewal procedure of sections 4745.01 to 4745.03 of the Revised Code.

(D) The fee required for issuance of the license shall be the same as that required in section 4729.54 of the Revised Code.

(E) A person desiring to renew the license shall submit a completed application for such renewal and pay the required fee on or before the thirty-first day of December each year.

(F) The state board of pharmacy, within thirty days after receipt of an application filed in the form and manner set forth in this rule for the issuance of a new or renewal license, shall notify the applicant whether or not such license will be issued or renewed. If the board determines that such license will not be issued or renewed, such notice to the applicant shall set forth the reason or reasons that such license will not be issued or renewed.

Rationale: Updates the change in the TDDD renewal date from January 1 to April 1.

4729-14-01 DEFINITIONS.

As used in Chapter 4729-14 of the Administrative Code:

(A) "Animal shelter" means a facility operated by a humane society or any society organized under Chapter 1717. of the Revised Code or a dog pound operated pursuant to Chapter 955. of the Revised Code.

(B) "Controlled substance" has the same meaning as in section ~~4729.01~~ 3719.01 of the Revised Code.

(C) "Dangerous drug" has the same meaning as in section 4729.01 of the Revised Code and in rule 4729-9-01 of the Administrative Code.

(D) "D.E.A." means the federal drug enforcement administration.

(E) "Euthanasia technician" is an individual that has successfully completed a euthanasia certification course, the curriculum of which has been approved by the veterinary medical licensing board pursuant to section 4729.532 of the Revised Code, and is in possession of a certificate which documents the successful completion of the certification course.

(F) "Registered veterinary technician" has the same meaning as given that term in section 4741.01 of the Revised Code.

(G) "Registration numbers" means the numbers assigned to each person registered under the federal drug abuse control laws and/or Chapter 4729. of the Revised Code.

(H) "Responsible person" means the individual designated by the licensee as the person who will maintain supervision and control over the possession and custody of the dangerous drugs that may be acquired and utilized by the licensee.

Rationale: Technical update as JCARR discovered that there wasn't actually a definition of controlled substance in 4729.01.

4729-14-02 PROCEDURE FOR LICENSURE AS AN ANIMAL SHELTER.

(A) A person, as defined in division (S) of section 4729.01 of the Revised Code, desiring to be licensed by the state board of pharmacy as an animal shelter shall file with the state board of pharmacy a completed application containing information relative to the qualifications for approval as set forth in rule 4729-14-03 of the Administrative Code.

(B) The state board of pharmacy shall issue a limited terminal distributor of dangerous drugs license, pursuant to sections 4729.531 and 4729.532 of the Revised Code, at the establishment or place described in the application to each person who has submitted an application and has paid the required license fee if the board determines that such applicant meets the requirements set forth in Chapter 4729-14 of the Administrative Code.

(C) All licenses issued pursuant to this rule shall be effective for a period of twelve months from the first day of ~~January~~ April of each year. A license shall be renewed by the state board of pharmacy for a like period, annually, according to the provisions of this rule, and the standard renewal procedure of sections 4745.01 to 4745.03 of the Revised Code.

(D) The fee required for issuance of the license shall be the same as that required in section 4729.54 of the Revised Code.

(E) A person desiring to renew the license shall submit a completed application for such renewal and pay the required fee on or before the thirty-first day of December each year.

(F) The state board of pharmacy, within thirty days after receipt of a complete application filed in the form and manner set forth in this rule for the issuance of a new or renewal license, shall notify the applicant whether or not such license will be issued or renewed. If the board determines that such license will not be issued or renewed, such notice to the applicant shall set forth the reason or reasons that such license will not be issued or renewed.

Rationale: Updates the change in the TDDD renewal date from January 1 to April 1.