5/4/2018

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

New

- 4729:1-3-01: Allows a pharmacist to administer certain laboratory tests. (Rescinds 4729-5-25)
- 4729:1-3-02: Establishes the training requirements for a pharmacist to administer immunizations, allows a pharmacist to administer specific immunizations under a physician approved protocol, and outlines informed consent requirements (Rescinds 4729-5-36, 4729-5-37, 4729-5-38).
- 4729:1-3-03: Establishes requirements of a physician-established protocol and training requirements for a pharmacist to administer dangerous drugs by injection (Rescinds 4729-5-40).
- 4729:1-3-04: Specifies the protocols and other requirements under which a pharmacist may dispense naloxone without a prescription.

Amended:

- 4729:1-5-02: Establishes the continuing education requirements for pharmacists, amended to align with the transition to a two-year licensing cycle.

Rescinded:

- 4729-5-25: Requirements to allow for a pharmacist, pharmacy intern under the direct supervision of a pharmacist or a qualified pharmacy technician under the direct supervision of a pharmacist to administer certain laboratory tests. Content of the rule is moving to new divisions of (4729:1-3, 4729:2-3, 4729:3-3) of the Administrative Code.
- 4729-5-36: Establishes the physician adopted protocols for immunization administration. Content of the rule is moving to new divisions (4729:1-3 and 4729:2-3) of the Administrative Code.
- 4729-5-37: Establishes the training requirements for pharmacist and pharmacy interns to administer immunizations. Content of the rule is moving to new divisions (4729:1-3 and 4729:2-3) of the Administrative Code.

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- 4729-5-38: Establishes the list of vaccinations/immunizations that may be provided by pharmacists and pharmacy interns. Content of the rule is moving to new divisions (4729:1-3 and 4729:2-3) of the Administrative Code.
- 4729-5-39: Allows a pharmacist or pharmacy intern to dispense naloxone without a prescription. Content of the rule is moving to new divisions (4729:1-3 and 4729:2-3) of the Administrative Code.
- 4729-5-40: Establishes requirements of a physician-established protocol and training requirements for a pharmacist to administer dangerous drugs by injection. The content of the rule is moving to a new division (4729:1-3) of the Administrative Code.

Comments on the proposed rules will be accepted until close of business on **May 21, 2018**. Please send all comments to the following email address: **Ali.Simon@pharmacy.ohio.gov**

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

CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: State of Ohio Board of Pharmacy

Regulation/Package Title: Pharmacists

Rule Number(s):

New:

- **4729:1-3-01**
- **4729:1-3-02**
- **4729:1-3-03**
- **4729:1-3-04**

Amended:

- **4729:1-5-02**

Rescinded:

- **4729-5-25**
- **4729-5-36**
- **4729-5-37**
- **4729-5-38**
- **4729-5-39**
- **4729-5-40**

Date: 5/4/2018

Rule Type:

New 5-Year Review

Amended **Rescinded**

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should

balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

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

New

- 4729:1-3-01: Allows a pharmacist to administer certain laboratory tests. (Rescinds 4729-5-25)
- 4729:1-3-02: Establishes the training requirements for a pharmacist to administer immunizations, allows a pharmacist to administer specific immunizations under a physician approved protocol, and outlines informed consent requirements (Rescinds 4729-5-36, 4729-5-37, 4729-5-38).
- 4729:1-3-03: Establishes requirements of a physician-established protocol and training requirements for a pharmacist to administer dangerous drugs by injection (Rescinds 4729-5-40).
- 4729:1-3-04: Specifies the protocols and other requirements under which a pharmacist may dispense naloxone without a prescription.

Amended:

- 4729:1-5-02: Establishes the continuing education requirements for pharmacists, amended to align with the transition to a two-year licensing cycle.

Rescinded:

- 4729-5-25: Requirements to allow for a pharmacist, pharmacy intern under the direct supervision of a pharmacist or a qualified pharmacy technician under the direct supervision of a pharmacist to administer certain laboratory tests. Content of the rule is moving to new divisions of (4729:1-3, 4729:2-3, 4729:3-3) of the Administrative Code.
- 4729-5-36: Establishes the physician adopted protocols for immunization administration. Content of the rule is moving to new divisions (4729:1-3 and 4729:2-3) of the Administrative Code.
- 4729-5-37: Establishes the training requirements for pharmacist and pharmacy interns to administer immunizations. Content of the rule is moving to new divisions (4729:1-3 and 4729:2-3) of the Administrative Code.
- 4729-5-38: Establishes the list of vaccinations/immunizations that may be provided by pharmacists and pharmacy interns. Content of the rule is moving to new divisions (4729:1-3 and 4729:2-3) of the Administrative Code.

- 4729-5-39: Allows a pharmacist or pharmacy intern to dispense naloxone without a prescription. Content of the rule is moving to new divisions (4729:1-3 and 4729:2-3) of the Administrative Code.
- 4729-5-40: Establishes requirements of a physician-established protocol and training requirements for a pharmacist to administer dangerous drugs by injection. The content of the rule is moving to a new division (4729:1-3) of the Administrative Code.

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

The proposed rule is authorized by sections 4729.26, 4729.44, 4729.45 and 4729.41 of the Ohio Revised Code.

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

These rules do not implement a federal requirement. However, the testing approved for administration pursuant to 4729:1-3-01 are approved by the US Food and Drug Administration.

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

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

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

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

Section 4729.41 of the Ohio Revised Code requires the Board of Pharmacy to adopt rules pertaining to the administration of immunizations by pharmacy professionals.

Section 4729.44 of the Ohio Revised Code requires the Board of Pharmacy to adopt rules pertaining to the dispensing of naloxone by pharmacists and pharmacy interns pursuant to a physician-approved protocol.

Section 4729.45 of the Ohio Revised Code requires the Board of Pharmacy to adopt rules pertaining to the administration of certain injectable medications by pharmacists pursuant to a physician-approved protocol.

Without these regulations, the Board of Pharmacy would not be able to ensure uniform standards for:

- The administration of immunizations and other dangerous drugs by pharmacists;
- Pharmacist continuing education;
- The administration of tests by a pharmacist; and
- The dispensing of naloxone without a prescription.

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

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

Development of the Regulation

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

This rule package was reviewed by the Board's Rules Review Committee. The Committee, composed of pharmacists from a number of practice settings, is responsible for reviewing and approving all rules prior to their legislatively mandated five-year date.

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

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

For the proposed rules, the Board of Pharmacy Rules Review Committee reviewed the proposed changes. The Committee recommended and the Board approved waiving the required naloxone patient training if someone had received training within the previous 12-months.

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

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

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

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

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

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

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

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

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

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

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

Adverse Impact to Business

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

a. Identify the scope of the impacted business community;

The rule package impacts the following:

- Pharmacists;
- Pharmacies.

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

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

c. Quantify the expected adverse impact from the regulation.

New

- 4729:1-3-01: Allows a pharmacist to administer certain laboratory tests. These requirements are set forth currently in rule 4729-5-25. The pharmacy or facility licensed as a terminal distributor of dangerous drugs must be certified as a clinical laboratory under the Clinical Laboratory Improvement Amendments (CLIA) if it wishes to administer certain testing. CLIA waived certification fees are $150 biennially. Laboratories up for certification must also meet CLIA standards to become certified. The responsible person of the terminal distributor of dangerous drugs and the terminal distributor of dangerous drugs must take the time to ensure all staff conducting CLIA waived tests receive appropriate training to conduct safe testing.
- 4729:1-3-02 Establishes the required training for pharmacist to administer immunizations, allows a pharmacist to administer specific immunizations under a physician approved protocol, and outlines informed consent requirements. Currently, these requirements are set forth in 4729-5-36, 4729-5-37, and 4729-5-38. Pharmacists will have to complete an ACPE-accredited course meeting the requirements specified in the rule. A course for vaccine administration costs up to $390 (*https://www.ohiopharmacists.org/aws/OPA/pt/sp/education_immunization*).
- 4729:1-3-03 Establishes requirements of a physician-established protocol and training requirements for a pharmacist to administer dangerous drugs by injection. Currently, these requirements are set forth in 4729-5-40. Allows for a pharmacist to administer any additional dangerous drugs authorized in section 4729.45 of the Revised Code. Pharmacists will have to complete an ACPE-accredited course meeting the requirements specified in the rule. As this is implementing a new law the coursework is not yet available, but a similar course for vaccine administration costs up to $390.

- 4729:1-3-04: Specifies the protocols and other requirements under which pharmacists may dispense naloxone without a prescription. The rules require pharmacies to conduct initial and annual training of all staff that interact with the public if the pharmacy is offering naloxone without a prescription. This may result in increased training costs to the pharmacies. However, the training is intended to be brief as it is intended to remind employees of a service offered by the pharmacy and can incorporated into existing annual training provided by the pharmacy to its employees.
- 4729:1-5-02 Establishes the continuing education requirements for pharmacists, amended to reflect the transition to the two-year licensing cycle. The cost of this rule will be the cost incurred by the pharmacist to obtain the required continuing education (CE). While CE cost varies, the Board and other providers do offer no-cost CEs to licensees.

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

The Board believes that the regulatory intent of the proposed rules is necessary to protect the health and safety of all Ohioans by providing uniform regulations for drug administration, continuing education for pharmacists and naloxone dispensing by pharmacists.

Regulatory Flexibility

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

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

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

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

NOTE: All rule text listed (except for 4729:1-5-02) are new rules. The yellow highlights in the rule text serve to indicate the major changes from the rule language that current exists in the OAC.

4729:1-3-01 – Pharmacist administration of diagnostic tests. (RESCIND 4729-5-25)

(A) A pharmacist may administer CLIA waived diagnostic laboratory testing provided the following conditions are met:

(1) The pharmacy or facility licensed as a terminal distributor of dangerous drugs is certified by the United States department of health and human services (HHS), as a clinical laboratory through the clinical laboratory improvement amendments (CLIA);

(2) The pharmacy or facility licensed as a terminal distributor of dangerous drugs has obtained a CLIA certificate of waiver from HHS; and

(3) The responsible person of the terminal distributor of dangerous drugs and the terminal distributor of dangerous drugs shall ensure and document that all pharmacists conducting CLIA waived tests pursuant to this rule receive appropriate training to conduct testing in a safe and effective manner.

(B) A pharmacist may evaluate the results of a test administered under this rule when advising a patient or a health care professional treating a patient if the test relates to the patient's drug therapy.

(C) This rule does not restrict a pharmacist's ability to order and evaluate tests under a consult agreement pursuant to section 4729.39 of the Revised Code.

(D) This rule applies only to the administration and evaluation of laboratory testing by individuals licensed or registered in accordance with Chapter 4729. of the Revised Code.

4729:1-3-04 – Dispensing of naloxone by pharmacists.

(A) A pharmacist may dispense naloxone without a prescription to either of the following in accordance with an approved protocol specified in paragraph (B) of this rule:

(1) An individual who there is reason to believe is experiencing or at risk of experiencing an opioid-related overdose;

(2) A family member, friend, or other person in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.

(B) To be considered an approved protocol pursuant to section 4729.44 of the Revised Code, the physician-established protocol for the dispensing of naloxone by a pharmacist or pharmacy intern under the direct supervision of a pharmacist shall include, but is not limited to, the following:

(1) A description of the clinical pharmacology of naloxone.

(2) Indications for use of naloxone as rescue therapy, including criteria for identifying persons eligible to receive naloxone under the protocol.

(3) Precautions and contraindications concerning dispensing naloxone.

~~(4) Assessment and follow-up actions by the pharmacist or pharmacy intern.~~

(4) Naloxone products authorized to be dispensed, including all of the following information:

(a) Name of product;

(b) Dose;

(c) Route of administration and required delivery device; and

(d) Directions for use.

(5) Any patient instructions in addition to the counseling specified in paragraphs (C) and (D) of this rule.

(C) A pharmacist who dispenses naloxone pursuant to this rule shall instruct the individual to whom naloxone is dispensed verbally or in writing to summon emergency services as soon as practicable either before or after administering naloxone.

(D) Except as provided in paragraph (E) this rule, a pharmacist or a pharmacist's designee that is appropriately trained shall personally provide in-person training and written educational materials, unless otherwise approved by the board, to the individual to whom naloxone is dispensed, appropriate to the dosage form of naloxone dispensed, including, but not limited to, all the following:

(1) Risk factors of opioid overdose;

(2) Strategies to prevent opioid overdose;

(3) Signs of opioid overdose;

(4) Steps in responding to an overdose;

(5) Information on naloxone;

(6) Procedures for administering naloxone;

(7) Proper storage and expiration of naloxone product dispensed; and

(8) Information on where to obtain a referral for substance abuse treatment.

(E) Patient training as required by paragraph (D) of this rule is not required if the patient has previously received training and all the following apply:

(1) The patient is offered training and refuses; and

(2) The pharmacist or pharmacist designee has documentation confirming training pursuant to this rule has been provided within the previous twelve months.

(3) A pharmacist who dispenses naloxone pursuant to this rule shall still instruct the individual to whom naloxone is dispensed verbally or in writing to summon emergency services as soon as practicable either before or after administering naloxone.

(F) If training conducted pursuant to paragraph (D) of this rule is offered by a pharmacist's designee, the pharmacist shall not be required to counsel a patient or caregiver pursuant to rule 4729:5-5-09 of the Administrative Code if the patient or caregiver refuses the offer of counseling or does not respond to the written offer to counsel.

(G) A terminal distributor of dangerous drugs shall ensure that all pharmacists that dispense naloxone pursuant to this rule are appropriately trained on the use of naloxone and can meet the training requirements listed in paragraphs (C) and (D) of this rule.

(H) The terminal distributor and the pharmacy's responsible person shall ensure that all pharmacist designees are appropriately trained on the use of naloxone and can meet the training requirements listed in paragraph (D) of this rule.

(I) A pharmacist may document the dispensing of naloxone by the pharmacist on a prescription form. The form may be assigned a number for record-keeping purposes.

(J) Paragraph (L) of this rule does not apply to institutional pharmacies that provide naloxone to inpatients or patients upon discharge.

(K) All physician-established protocols shall be signed and dated by the physician prior to implementation and maintained by the pharmacy's responsible person. The protocol shall be made immediately available to the dispensing pharmacist.

(L) Any pharmacy that dispenses naloxone pursuant to this rule, shall notify the board, in a manner prescribed by the board, within thirty days of establishing an approved protocol. A pharmacy that no longer dispenses naloxone pursuant to this rule shall notify the board, in a manner prescribed by the board, within thirty days of discontinuation.

(1) Except for a product shortage, a pharmacy submitting notification of naloxone dispensing pursuant to paragraph (L) of this rule shall ensure naloxone is made available in accordance with this rule.

(2) A pharmacy that has submitted notification of naloxone dispensing pursuant to paragraph (L) of this rule shall provide initial training to all new employees and annual training to existing employees on the availability of naloxone dispensing pursuant to a protocol. Employees requiring training in accordance with this paragraph shall include: pharmacists, pharmacy interns, certified pharmacy technicians, registered pharmacy technicians, pharmacy technician trainees and support personnel, as defined in rule 4729:3-1-01 of the Administrative Code, that have direct contact with the public. Training documentation records shall be maintained for a period of three years and shall be made readily retrievable.

4729:1-3-02 – Immunization administration. (Rescind 4729-5-36, 37, 38)

(A) A course in the administration of immunizations developed pursuant to division (B)(1) of section 4729.41 of the Revised Code shall meet at least the following requirements:

(1) The instructor shall be a licensed health care professional and have the appropriate education and experience to teach a course in the administration of immunizations.

(2) The content must meet the standards established for such courses by the centers for disease control and prevention in the public health service of the United States department of health and human services.

(3) The course shall be conducted by an accreditation council for pharmacy education (ACPE) accredited provider.

(4) The course must be a minimum of five hours in length and include at least the following:

(a) A review of immunology that includes a discussion of the body's immune system reaction to immunizations.

(b) A review of each immunization authorized pursuant to paragraph (G) of this rule that includes the following:

(i) Disease states associated with the immunization;

(ii) Type or nature of activity of the immunization;

(iii) Appropriate administration schedules;

(iv) Appropriate routes of administration;

(v) Appropriate injection sites;

(vi) Appropriate dosages;

(vii) Appropriate monitoring and treatment of the patient for adverse reactions, including the use of diphenhydramine and epinephrine;

(viii) Appropriate patient populations;

(ix) Precautions and contraindications; and

(x) Proper storage requirements for the immunization.

(c) A review of sterile technique in injectable dosage preparation and administration.

(d) A minimum of one hour of instruction and physical participation in administration techniques.

(e) A review of the proper disposal procedures for contaminated needles and immunizations.

(f) A review of the proper procedures for accidental needle sticks.

(5) The course must provide a method to evaluate the successful mastery of the content.

(B) The board hereby approves all immunization coursework that meets the requirements set forth in paragraph (A) of this rule. The board reserves the right to revoke this approval status for failing to comply with the requirements of this rule. Any coursework requested for review by the board must be submitted with ten days of the receipt of a written request. Failure to do so, will result in the immediate revocation the course's approval status.

(C)

(1) Pharmacists seeking to administer any immunization listed in paragraph (G) of this rule that was added after the completion of an initial immunization course shall, at a minimum, conduct a review of appropriate clinical resources to familiarize themselves with all the following prior to the administration of the immunization:

(a) Disease states associated with the immunization;

(b) Type or nature of activity of the immunization;

(c) Appropriate administration schedules;

(d) Appropriate routes of administration;

(e) Appropriate injection sites;

(f) Appropriate dosages;

(g) Appropriate monitoring and treatment of the patient for adverse reactions;

(h) Appropriate patient populations;

(i) Precautions and contraindications; and

(j) Proper storage requirements for the immunization.

(2) Failure to adhere to the appropriate standard of care for administration of an immunization shall be consider a violation of this rule and may subject a pharmacist to discipline in accordance with rule 4729:1-4-01 of the Administrative Code.

(D) To be considered an approved protocol pursuant to division (B)(3) of section 4729.41 of the Revised Code, the physician-established protocol for the administration of immunizations must include at least the following:

(1) For each dangerous drug listed in paragraph (F) of this rule:

(a) Name and strength;

(b) Precautions and contraindications;

(c) Intended audience or patient population;

(d) Appropriate dosage;

(e) Appropriate administration schedules;

(f) Appropriate routes of administration; and

(g) Appropriate injection sites.

(2) The length of time the pharmacist or pharmacy intern under the direct supervision of a pharmacist must observe an individual for adverse effects, which shall be based on appropriate standards of care established by the physician. The location of the observation shall be in the general vicinity of the administering pharmacist or pharmacy intern to allow for on-going evaluation.

(3) A method to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks.

(4) A method to notify an individual's physician or the applicable board of health within thirty days after administering an immunization, except for influenza immunizations administered to individuals eighteen years of age and older.

(5) The locations that a pharmacist or pharmacy intern under the direct supervision of a pharmacist may engage in the administration of immunizations.

(E) All physician-established protocols must be signed and dated by the physician prior to implementation and maintained by the terminal distributor of dangerous drugs. The protocols shall be renewed on a biennial basis with the physician.

(1) A physician may sign one protocol for multiple locations licensed as terminal distributors of dangerous drugs.

(2) Each location licensed as a terminal distributor of dangerous drugs shall maintain a copy of the protocol on-site for inspection by an agent of the state board of pharmacy.

(F) Upon the request of the state board of pharmacy, a pharmacist or terminal distributor of dangerous drugs shall immediately provide the protocols for immunizations. The state board of pharmacy, after review, may approve the protocol or return it to the pharmacist or terminal distributor for revision without approval. If a protocol has been returned for revision without approval, it may not be implemented until the board has approved it.

(G) A pharmacist may administer the following immunizations in accordance with section 4729.41 of the Revised Code and this rule:

(1) Any immunization or vaccine that is included in either of the following schedules and is administered according to those schedules:

(a) The immunization schedule for persons aged zero through eighteen years recommended by the advisory committee on immunization practices of the centers for disease control and prevention in the United States department of health and human services (4/2/2018).

(b) Except as listed in paragraph (G)(2) of this rule, the adult immunization schedule recommended by the advisory committee on immunization practices of the centers for disease control and prevention in the United States department of health and human services (4/2/2018).

(2) The herpes zoster vaccine according to the age criteria specified in the F.D.A. approved labeling.

(3) Except as provided in paragraphs (G)(4) and (G)(5) of this rule, any other immunization or vaccine recommended by the advisory committee on immunization practices of the centers for disease control and prevention in the United States department of health and human services if administered in accordance with the recommendations adopted by the committee.

(4) The rabies vaccine for post exposure if all the following are met:

(a) A pharmacist does not provide the initial dose of the rabies post exposure vaccine;

(b) Follow-up doses are administered pursuant to a prescription issued by a prescriber; and

(c) The follow-up doses are administered in accordance with recommendations adopted by the advisory committee on immunization practices of the centers for disease control and prevention in the United States department of health and human services (4/2/2018).

(5) The requirements listed in paragraph (F)(4) of this rule do not apply to the rabies vaccine for preexposure if administered in accordance with recommendations adopted by the advisory committee on immunization practices of the centers for disease control and prevention in the United States department of health and human services (4/2/2018).

(6) Any immunization to an individual eighteen years of age or older pursuant to a prescription if all the following apply:

(a) The pharmacist is authorized to administer the immunization pursuant to a physician-approved protocol established in paragraph (D) of this rule; and

(b) The pharmacist has the required training in accordance with this rule to administer the immunization.

(H) A pharmacist shall obtain informed consent pursuant to rule 4729:5-5-04 of the Administrative Code to administer an immunization.

(I) A pharmacist shall comply with the vaccine information statement requirements of the National Vaccine Childhood Injury Act, 42 U.S.C. Section 300aa-26 (12/14/1993).

(J) An immunization or vaccine specified in this rule shall not be administered to any individual who is less than thirteen years of age, except in the following situations:

(1) The immunization for influenza is administered to individuals who are seven years of age or older; or

(2) Pursuant to a prescription from a licensed prescriber, an immunization or vaccine is administered to individuals who are seven years of age or older but not more than thirteen years of age.

(K) For each immunization administered to an individual by a pharmacist, other than an immunization for influenza administered to an individual eighteen years of age or older, the pharmacist shall notify the individual's family physician or, if the individual has no family physician, the board of health of the health district in which the individual resides or the authority having the duties of a board of health for that district under section 3709.05 of the Revised Code. The notice shall be given not later than thirty days after the immunization is administered. Notification of may be conducted using one of the following methods that is capable of confirming delivery of the required notification:

(1) Electronic mail;

(2) Interoperable electronic medical records system;

(3) Facsimile;

(4) Electronic prescribing system;

(5) Electronic pharmacy record system;

(6) Documented verbal communication;

(7) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.

(L) A pharmacist administering immunizations in accordance with this rule shall receive and maintain certification to perform basic life-support procedures by successfully completing a basic life-support training course certified by the American red cross, American heart association or other training course approved by the board. Certification shall be obtained and maintained through courses that are conducted in-person or, at a minimum, offer an in-person training component.

4729:1-3-03 – Administration of dangerous drugs by injection. (Rescind 4729-5-40)

(A) A pharmacist licensed under Chapter 4729. of the Revised Code may administer, by injection, any of the following dangerous drugs if the dangerous drug that is to be administered has been prescribed by a physician and the individual to whom the dangerous drug was prescribed has an ongoing relationship with the physician, an advanced practice registered nurse practicing who has entered into a standard care arrangement with the physician or a physician assistant who has entered into a supervision agreement with the physician:

(1) An opioid antagonist used for treatment of drug addiction and administered in a long-acting or extended-release form. An opioid antagonist may also be administered for the treatment of alcohol dependence in accordance with approved labeling by the United States food and drug administration.

(2) An antipsychotic drug administered in a long-acting or extended-release form.

(3) Hydroxyprogesterone caproate for pregnant women.

(4) Medroxyprogesterone acetate for non-pregnant women.

(5) Cobalamin, to include: cyanocobalamin, hydroxocobalamin or any other vitamin B12 injection approved by the United States food and drug administration.

(6) Any other dangerous drugs authorized for pharmacist administration pursuant to section 4729.45 of the Revised Code.

(B) To be authorized to administer drugs pursuant to this rule, a pharmacist shall comply with all the following:

(1) Successfully complete a course in the administration of drugs that satisfies the requirements pursuant to paragraph (L) of this rule.

(2) Receive and maintain certification to perform basic life-support procedures by successfully completing a basic life-support training course certified by the American red cross, American heart association or other training course approved by the board. Certification shall be obtained and maintained through courses that are conducted in-person or, at a minimum, offer an in-person training component.

(3) Practice in accordance with a protocol that meets the requirements of paragraphs (F) and (G) of this rule.

(C) Each time a pharmacist administers a drug pursuant to this rule, the pharmacist shall comply with all the following:

(1) For each drug administered by a pharmacist to an individual who is eighteen years of age or older, the pharmacist shall obtain written permission from the individual.

(2) For each drug administered by a pharmacist to an individual who is under eighteen years of age, the pharmacist shall obtain written permission from the individual's parent or other person having care or charge of the individual.

(3) For each drug administered by a pharmacist to an individual who lacks the capacity to make informed health care decisions, the pharmacist shall obtain written permission from the person authorized to make such decisions on the individual's behalf.

(4) Permission obtained in accordance with this paragraph shall also include notification of the patient's right to request a private area in accordance with paragraph (J) of this rule.

(5) In the case of an opioid antagonist, obtain, in accordance with paragraph (D) of this rule, test results indicating that it is appropriate to administer the drug to the individual if either of the following is to be administered:

(a) The initial dose of the drug;

(b) Any subsequent dose, if the administration occurs more than thirty days after the previous dose of the drug was administered.

(6) Observe the individual to whom the drug is administered to determine whether the individual has an adverse reaction to the drug.

(7) Notify the physician who prescribed the drug within seven days that the drug has been administered to the individual. Notification of the physician may be conducted using one of the following methods that is capable of confirming delivery of the required notification:

(a) Electronic mail;

(b) Interoperable electronic medical records system;

(c) Facsimile;

(d) Electronic prescribing system;

(e) Electronic pharmacy record system;

(f) Documented verbal communication;

(g) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.

(D) A pharmacist may obtain the test results described in paragraph (C)(5) of this rule:

(1) From the physician or the physician's agent; or

(2) By ordering blood and urine tests for the individual to whom the opioid antagonist is to be administered.

(E) If a pharmacist orders blood and urine tests pursuant to paragraph (D) of this rule, the pharmacist shall evaluate the results of the tests to determine whether they indicate that it is appropriate to administer the opioid antagonist. A pharmacist's authority to evaluate test results pursuant to this rule does not authorize the pharmacist to make a diagnosis.

(F) A physician-established protocol for the administration of dangerous drugs in accordance with section 4729.45 of the Revised Code must include the following:

(1) For the dangerous drugs included in the categories listed in paragraph (A) of this rule:

(a) Name and strength;

(b) Precautions and contraindications;

(c) Intended audience or patient population;

(d) Appropriate dosage;

(e) Appropriate administration schedules;

(f) Appropriate routes of administration;

(g) Appropriate injection sites; and

(h) The type of tests that may be conducted in accordance with paragraph (E) of this rule.

(2) The length of time the pharmacist must observe an individual for adverse effects, which shall be based on appropriate standards of care established by the physician. The location of the observation shall be in the general vicinity of the administering pharmacist to allow for on-going evaluation.

(3) A method to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks.

(4) The locations that a pharmacist shall engage in the administration of dangerous drugs in accordance with paragraph (J) of this rule.

(5) Specify procedures to be followed by a pharmacist when administering epinephrine, diphenhydramine, or both, to an individual who has an adverse reaction to a drug administered by the pharmacist.

(G) All physician-established protocols pursuant to this rule and section 4729.45 of the Revised Code shall comply with the following:

(1) The protocol shall be signed and dated by the physician prior to implementation and shall be readily available to the administering pharmacist. The protocol shall be renewed by the physician on a biennial basis.

(2) A physician may sign one protocol for multiple locations licensed as terminal distributors of dangerous drugs.

(3) Each location licensed as a terminal distributor of dangerous drugs shall maintain a copy of the protocol on-site for inspection by an agent of the state board of pharmacy.

(4) The protocol must be established by a physician who has a scope of practice that includes treatment of the condition for which the individual has been prescribed the drug to be administered.

(H) Upon the request of the state board of pharmacy, a pharmacist or terminal distributor of dangerous drugs shall immediately provide the protocols for administration of drugs in accordance with this rule. The state board of pharmacy, after review, may approve the protocol or return it to the pharmacist or terminal distributor for revision without approval. If a protocol has been returned for revision without approval, it may not be implemented until the board has approved it.

(I) A pharmacist may administer epinephrine or diphenhydramine, or both, to an individual in an emergency situation resulting from an adverse reaction to a drug administered by the pharmacist.

(J) Dangerous drugs administered in accordance with this rule shall be administered in a location that ensures the privacy and dignity of the patient and is consistent with state and federal privacy laws and regulations. When necessary to protect patient privacy, or if requested by the patient, this shall include a private area located outside of the pharmacy's prescription department.

(K) Records shall be maintained for three years for all dangerous drugs administered in accordance with this rule and shall include 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 drug administered;

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

(8) Route of administration;

(9) Location of the injection site;

(10) Positive identification of the administering pharmacist;

(11) Identification of the person who provides permission to administer the dangerous drug pursuant to paragraph (C) of this rule.

(L) A course in the administration of dangerous drugs developed pursuant to section 4729.45 of the Revised Code shall meet the following requirements:

(1) The course shall be conducted by an accreditation council for pharmacy education (ACPE) accredited provider.

(2) The course must include the following components:

(a) A minimum of an hour and a half (0.15 C.E.U.s) of live or home study coursework for each category of dangerous drug listed in paragraph (A) of this rule that is covered by the course and shall include:

(i) A review of the conditions treated or prevented;

(ii) Mechanisms of action;

(iii) Appropriate routes of administration;

(iv) Appropriate injection sites and ensuring patient privacy;

(v) Appropriate dosages and administration schedules;

(vi) Appropriate monitoring and treatment of the patient for adverse reactions, including the use of diphenhydramine and epinephrine;

(vii) Appropriate patient populations;

(viii) Precautions and contraindications;

(ix) Proper storage requirements;

(b) A minimum of thirty minutes (0.05 C.E.U.s) of live or home study coursework that includes:

(i) A review of sterile technique in injectable dosage preparation and administration;

(ii) A review of the proper disposal procedures for contaminated needles and dangerous drugs;

(iii) A review of the proper procedures for accidental needle sticks.

(c) A minimum of one hour (0.1 C.E.U.s) of live and supervised physical participation in administration techniques for the categories of drugs covered by the course.

(d) If the course includes instruction on administration of an opioid antagonist, a minimum of one hour (0.1 C.E.U.s) of live or home study coursework that includes a review of the tests necessary to comply with paragraph (C)(5) of this rule and the evaluation of such tests.

(3) A pharmacist is not required to meet the training requirements of paragraph (L)(2)(b) of this rule if the pharmacist has met the training requirements in paragraphs (A)(4)(c), (A)(4)(e) and (A)(4)(f) of rule 4729:1-3-02 of the Administrative Code;

(4) A pharmacist is not required to meet the training requirements of paragraph (L)(2)(c) of this rule if all of the following apply:

(a) The pharmacist has met the training requirements in paragraph (A)(4)(d) of rule 4729:1-3-02 of the Administrative Code; and

(b) The instruction on administration techniques provided in accordance with rule 4729:1-3-02 of the Administrative Code includes the same techniques necessary to administer each category of dangerous drug covered by the training.

(5) Each course must provide a method to evaluate the successful comprehension of the content.

(6) The course must provide a method to demonstrate the pharmacist has successfully completed the course.

(7) All live coursework shall be taught by an instructor that is a licensed health care professional who has the appropriate education and experience to teach a course in the administration of the dangerous drugs included in the categories listed in paragraph (A) of this rule.

(L) Courses may be reviewed by the state board of pharmacy. The board reserves the right to disapprove a course that fails to meet the requirements set forth in this rule.

(M) A pharmacist who has not successfully completed a course in drug administration that meets the requirements set forth in this rule must complete a course that meets the requirements

specified in this rule prior to the administration of a dangerous drug listed in paragraph (A) of this rule.

(N) A pharmacist shall maintain proof of successful completion of a training course pursuant to this rule on file at the location where the pharmacist administers medications in accordance with this rule.

4729:1-5-02 - Continuing Education Requirements.

(A)

(1) Except as provided in paragraphs (A)(2), (A)(3) and (F) of this rule, four C.E.U.s (40 contact hours) of approved continuing education shall be completed by a pharmacist licensed in accordance with Chapter 4729. of the Revised Code prior to the renewal of the pharmacist's license. At least 0.2 C.E.U.s of the total required C.E.U.s must be obtained in pharmacy jurisprudence and at least 0.2 C.E.U.s of the total required C.E.U.s must be obtained in patient or medication safety.

(2) A pharmacist who obtains an initial license by reciprocity or examination ~~after September fifteenth in an odd-numbered year or~~ during an even-numbered year shall complete two C.E.U.s (20 contact hours) of approved continuing education to be completed prior to the renewal of the pharmacist's license. At least 0.1 C.E.U. of the total required C.E.U.s must be obtained in pharmacy jurisprudence and at least 0.1 C.E.U of the total required C.E.U.s must be obtained in patient or medication safety.

(3) A pharmacist who obtains an initial license by reciprocity or examination prior to May first in an odd-numbered year shall complete two C.E.U.s (20 contact hours) of approved continuing education to be completed prior to the renewal of the pharmacist's license. At least 0.1 C.E.U. of the total required C.E.U.s must be obtained in pharmacy jurisprudence and at least 0.1 C.E.U of the total required C.E.U.s must be obtained in patient or medication safety.

(B)

(1) A pharmacist may satisfy the continuing pharmacy education requirements in accordance with paragraph (A) of this rule by providing evidence at the time of renewal that the pharmacist has met the requirements of and is currently certified by a board approved pharmacy practice-specific specialty certification program.

(2) Pharmacists who meet the requirements pursuant to paragraph (B)(1) of this rule shall be required to complete either of the following prior to renewal:

(a) At least 0.2 C.E.U.s in pharmacy jurisprudence and 0.2 C.E.U.s in patient or medication safety. The C.E.U.s must be obtained within a period that is no more than two years prior to September fifteenth of the year in which a pharmacist's license must be renewed.

(b) If the pharmacist obtains initial licensure in accordance with paragraphs (A)(2) and (A)(3) of this rule, at least 0.1 C.E.U. in pharmacy jurisprudence and 0.1 C.E.U. in patient or medication safety. The C.E.U.s must be obtained within a period that is no more than two years prior to September fifteenth of the year in which a pharmacist's license must be renewed.

(C)

(1) Except as provided in paragraph (C)(2) of this rule, C.E.U.s must be obtained within a period that is no more than two years prior to September fifteenth of the year in which a pharmacist's license must be renewed.

(2) A pharmacist obtaining initial licensure by reciprocity or examination may apply C.E.U.s obtained during the pharmacist's initial period of licensure to meet the continuing education requirements set forth in this rule.

(D) If continuing pharmacy education is required after a pharmacist's license has lapsed or where the license is being renewed after board action, continuing education must be obtained during the three-year period immediately preceding the date the renewal application is filed with the board office. A pharmacist shall obtain two C.E.U.s for each year the pharmacist's license has lapsed or is subject to board action.

(E) C.E.U.s obtained that exceed the required C.E.U.s at the time continuing education is required for licensure renewal may not be transferred and applied to future requirements.

(F) For the 2019 pharmacist license renewal cycle only, all pharmacists seeking renewal of a pharmacist license shall comply with the following:

(1) For a pharmacist with a license number that begins with "03-1", either:

(a) Complete six C.E.U.s. The C.E.U.s shall be obtained within a period that is no more than three years prior to September 15, 2019. The C.E.U.s shall include at least 0.3 C.E.U.s in pharmacy jurisprudence and at least 0.2 C.E.U.s in patient or medication safety.

(b) Comply with the requirements of paragraph (B)(1) of this rule and complete at least 0.3 C.E.U.s in pharmacy jurisprudence and at least 0.2 C.E.U.s in patient or medication safety. The required C.E.U.s must be obtained within a period that is no more than three years prior to September 15, 2019.

(2) For a pharmacist with a license number that begins with "03-2", either:

(a) Complete four C.E.U.s. The C.E.U.s shall be obtained within a period that is no more than two years prior to September 15, 2019. The C.E.U.s shall include at least 0.2 C.E.U.s in pharmacy jurisprudence and at least 0.1 C.E.U. in patient or medication safety.

(b) Comply with the requirements of paragraph (B)(1) of this rule and complete at least 0.2 C.E.U.s in pharmacy jurisprudence and at least 0.1 C.E.U. in patient or medication safety. The required C.E.U.s must be obtained within a period that is no more than two years prior to September 15, 2019.

(3) For a pharmacist with a license number that begins with "03-3", either:

(a) Complete two C.E.U.s. The C.E.U.s shall be obtained within a period that is no more than one year prior to September 15, 2019. The C.E.U.s shall include at least 0.1 C.E.U. in pharmacy jurisprudence and at least 0.1 C.E.U. in patient or medication safety.

(b) Comply with the requirements of paragraph (B)(1) of this rule and complete at least 0.1 C.E.U. in pharmacy jurisprudence and at least 0.1 C.E.U. in patient or medication safety. The required C.E.U.s must be obtained within a period that is no more than one year prior to September 15, 2019.

(4) All pharmacist license renewals after September 15, 2019, regardless of license number, shall comply with the continuing education requirements set forth in paragraph (A) or paragraph (B) of this this rule.

(G) Ohio-licensed pharmacists who hold a current license in states where continuing education is mandatory, have met the continuing pharmacy education requirements of that state, and who have not practiced pharmacy in Ohio at any time during the two years prior to the renewal date in which a pharmacist's license must be renewed, may renew their license in accordance with the provisions of Chapter 4729. of the Revised Code without having to comply with the requirements of this rule.

(H) A pharmacist may satisfy up to one-third of the pharmacist's continuing education requirements by providing health care services as a volunteer in accordance with section 4745.04 of the Revised Code. The location where health care services are provided shall be an approved in-state provider of volunteer healthcare services in accordance with rule 4729-6-03 of the Administrative Code.

(I) Pharmacists shall keep all certificates and other documented evidence of participation that have been issued by a non-A.C.P.E. accredited provider for approved C.E.U.s for which the pharmacist has claimed continuing education units towards licensure renewal for a period of one year following the year in which continuing education was required for renewal.

(1) Documentation, as determined by the state board of pharmacy, shall be submitted only when requested by the board.

(2) The board shall monitor compliance by conducting an audit of licensees.

(3) The board shall require the reporting of continuing education units to a national or state register.