

5/25/22

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.

No Change:

- 4729:5-23-02- Provides the requirements of the responsible person on the license which includes establishing standards for security, control and storage of dangerous drugs.
- 4729:5-23-03- Provides the requirements for record keeping at limited facilities.

Comments on the proposed rules will be accepted until close of business on **April 21, 2022**. Please send all comments to the following email address: Kylynnne.Johnson@pharmacy.ohio.gov.

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

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Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

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Business Impact Analysis

Agency, Board, or Commission Name: State of Ohio Board of Pharmacy

Rule Contact Name and Contact Information: Kylynne Johnson
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Regulation/Package Title (a general description of the rules' substantive content):

First Aid Departments

Rule Number(s): 4729:5-23-02; 4729

Date of Submission for CSI Review: _____

Public Comment Period End Date: _____

Rule Type/Number of Rules:

New/___rules

No Change/_2__ rules (FYR? __)

Amended/___rules (FYR? __)

Rescinded/___ rules (FYR? __)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness,

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predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

- 1. R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

Which adverse impact(s) to businesses has the agency determined the rule(s) create?

The rule(s):

- a. ☐ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**
- b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**
 - Violation of this rule may result in administrative licensure discipline for a terminal distributor of dangerous drugs. Discipline might include reprimand, continuing education, suspension of a license, monetary fine and/or revocation of a license.
- c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.**
 - 4729:5-23-02- Provides the requirements of the responsible person on the license which includes establishing standards for security, control and storage of dangerous drugs. There may be additional costs associated with investing in a lockable cabinet or other secure storage area to store controlled substances, dangerous drugs and hypodermics, performing daily checks if drugs are refrigerated or frozen and ensuring that multiple use vials are appropriately labeled to ensure they are not expired or adulterated.
 - 4729:5-23-03- Provides the requirements for record keeping at limited facilities. There may be an overall increase in administrative costs associated with complying with the rule.
- d. ☐ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

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

Please include the key provisions of the regulation as well as any proposed amendments.

No Change:

- 4729:5-23-02- Provides the requirements of the responsible person on the license which includes establishing standards for security, control and storage of dangerous drugs.
- 4729:5-23-03- Provides the requirements for record keeping at limited facilities.

3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.

The proposed rule is authorized by sections 4729.26 and 3719.28 of the Ohio Revised Code.

4. 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?

If yes, please briefly explain the source and substance of the federal requirement.

This rule does not implement a federal requirement.

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

This rule package exceeds federal requirements because the regulation of dangerous drugs has traditionally been done at the state level by legislatively created state boards of pharmacy. The oversight of dangerous drugs is also required by Chapter 4729. of the Ohio Revised Code.

6. 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 which includes licensing requirements for locations that store dangerous drugs on-site including limited facilities.

Section 3719.28 of the Ohio Revised Code authorizes the 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, prescribe, or administer.

Without this rule package, the Board would not be able to fulfill its mission to provide safe and effective regulations to ensure the security and accountability of dangerous drugs.

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

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

8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?

If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

No.

Development of the Regulation

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

If applicable, please include the date and medium by which the stakeholders were initially contacted.

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

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

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

The Board received a request from the Ohio Council for Home Care and Hospice to add hospice care providers of in-home services to the definition of limited facilities. The Board approved the addition of this request as part of the draft rule package.

11. 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.

12. 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 distribution of dangerous drugs, the State of Ohio Board of Pharmacy did not consider any regulatory alternatives.

13. Did the Agency specifically consider a performance-based regulation? Please explain.

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Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.

The agency did put forth a performance-based regulation for this rule package, specifically as it relates to policies for responding to temperature excursions to ensure drug integrity.

14. 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 rule to ensure that the regulation does not duplicate another State of Ohio Board of Pharmacy regulation.

15. 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 rule will be posted on the Board of Pharmacy's web site, information concerning the rule 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 rule. 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, regular compliance staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, email updates, webinars from the Director of Policy and Communications and feedback from the Board's legal department for every citation submitted.

Adverse Impact to Business

16. 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; and

The rule impacts the following:

- Dog trainers affiliated with an Ohio law enforcement agency;
- Home health care providers, including those offering in-home services;
- Hospice care providers of in-home services;
- Physical therapy providers;
- Teaching institutions; and
- Any other facility as determined by the board.

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

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

c. Quantify the expected adverse impact from the regulation.

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a “representative business.” Please include the source for your information/estimated impact.

No Change:

- 4729:5-23-02- Provides the requirements of the responsible person on the license which includes establishing standards for security, control and storage of dangerous drugs. The expected adverse impact associated with this rule are the costs of investing in a lockable cabinet or other secure storage area to store controlled substances, dangerous drugs and hypodermics, performing daily checks if drugs are refrigerated or frozen and ensuring that multiple use vials are appropriately labeled to ensure they are not expired or adulterated.
- 4729:5-23-03- Provides the requirements for record keeping at limited facilities. There may be an overall increase in administrative costs associated with complying with the rule.

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

The Board believes that the regulatory intent justifies the impact on business because the regulations are intended to protect and promote public safety. The rules ensure uniform regulations protect the health and safety of patients receiving office-based opioid treatment.

Regulatory Flexibility

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

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

19. 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?

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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 office-based opioid treatment 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.

20. 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. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

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4729:5-23 – Limited Facilities

4729:5-23-02 – Security, control and storage of dangerous drugs.

(A) The security and control of dangerous drugs is the responsibility of the responsible person on the terminal distributor of dangerous drugs license and the terminal distributor of dangerous drugs.

(B) Except as provided in paragraph (G) of this rule, controlled substances, dangerous drugs, dangerous drugs containing propofol and gabapentin, and exempt narcotics shall be stored in a securely locked, substantially constructed cabinet, including a refrigerator/freezer for drugs requiring temperature control, or safe to deter and detect unauthorized access

(1) The cabinet or safe shall be placed in a designated drug storage area that is not accessible by the public, except when it is necessary for employee maintenance personnel, nonemployee maintenance personnel, patients, business guests, or visitors to be present in or pass through areas containing the cabinet or safe, a prescriber, pharmacist or licensed health care professional shall provide for adequate observation of the area.

(2) The cabinet or safe shall remain locked and secured when not in use.

(3) In the case of a combination lock or access code, the combination or access code shall be changed upon termination of employment of an employee having knowledge of the combination or access code.

(4) In the case of a key lock, all keys shall be maintained in a secure place that is inaccessible to anyone other than a prescriber or pharmacist if not being used by a prescriber, pharmacist or a licensed health care professional in accordance with paragraph (B)(6)(a), (B)(6)(b), or (B)(6)(c) of this rule. All locks shall be kept in good working order with keys removed therefrom.

(5) During non-business hours, the cabinet or safe shall be maintained in an area secured by a physical barrier with suitable locks, which may include a locked room or secure facility.

(6) Except as provided in paragraph (B)(6)(a), (B)(6)(b), or (B)(6)(c) of this rule, only a prescriber, pharmacist or responsible person shall have possession of the keys or access codes to the secure area or areas specified in paragraph (B) of this rule. Any additional keys shall be maintained in a secure place that is inaccessible to unauthorized persons.

(a) A prescriber, pharmacist or responsible person may provide a licensed health care professional, or an employee of a dog training facility, with a temporary key for the purposes of accessing controlled substances and dangerous drugs listed paragraph (B) of this rule. A licensed health care professional or employee shall return the key provided in accordance with this rule to the prescriber or pharmacist or to a secured location with restricted access (such as a

lockbox) no later than the end of the provider's shift or if there is no longer a prescriber, pharmacist or responsible person available to provide personal supervision.

(b) A prescriber, pharmacist or responsible person may provide a licensed health care professional or an employee of a dog training facility with a key, combination or access code for the purposes of accessing controlled substances and dangerous drugs listed paragraph (B) of this rule, if all the following conditions apply:

(i) The cabinet or safe is maintained in a room secured by a physical barrier with suitable locks that can only be unlocked by a prescriber, pharmacist, or responsible person;

(ii) The room is locked during non-business hours or when there is no longer a prescriber, pharmacist, or responsible person is not available to provide personal supervision.

(c) Any other method approved by the board's executive director or the director's designee that provides effective controls and procedures to guard against theft and diversion of controlled substances.

(C) Except as provided in paragraph (D) of this rule, a licensed health care professional, acting within the scope of the professional's practice may have access to controlled substances, dangerous drugs containing propofol and gabapentin, and exempt narcotics only under the personal supervision of a prescriber or pharmacist.

(D) A limited facility that is a dog trainer affiliated with an Ohio law enforcement agency shall permit access to controlled substances and dangerous drugs containing propofol and gabapentin to those engaged in the training of canines only under the personal supervision of the responsible person.

(E) Only a prescriber shall have access to uncompleted prescription blank(s) used for writing a prescription. Uncompleted prescription blank(s) shall be secured when not in use.

(F) Personnel authorized by the responsible person may have access to D.E.A. controlled substance order forms only under the personal supervision of a prescriber or pharmacist. D.E.A. controlled substance order forms shall be secured when not in use.

(G) Thiafentanil, carfentanil, etorphine hydrochloride and diprenorphine shall be stored in a separate safe or steel cabinet equivalent to a U.S. Government Class V security container from all other controlled substances.

(1) There is no minimum size or weight requirement but if the cabinet or safe weighs less than 750 pounds, it must be secured to the floor or wall in such a way that it cannot be readily removed.

(2) The cabinet or safe shall be placed in a designated drug storage area that is not accessible by the public, except when it is necessary for employee maintenance personnel, nonemployee maintenance personnel, patients, business

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guests, or visitors to be present in or pass through areas containing the safe or steel cabinet, a prescriber, pharmacist, responsible person or licensed health care professional shall provide for adequate observation of the area.

(3) The cabinet or safe shall remain locked and secured when not in use.

(4) In the case of a combination lock or access code, the combination or access code shall be changed upon termination of employment of an employee having knowledge of the combination or access codes.

(5) In the case of a key lock, all keys shall be maintained in a secure place that is inaccessible to anyone other than a prescriber, pharmacist or responsible person if not being used by a prescriber, pharmacist or responsible person. All locks shall be kept in good working order with keys removed therefrom.

(6) During non-business hours, the cabinet or safe shall be maintained in an area secured by a physical barrier with suitable locks, which may include a locked room or secure facility.

(7) Only a prescriber, pharmacist, or responsible person shall have possession of the key, combination or access code to the safe or cabinet specified in this paragraph.

(H) During non-business hours, hypodermics shall be stored in an area secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, locked room or secured facility. During normal business hours, hypodermics shall not be stored in areas where members of the public are not supervised by individuals authorized to administer injections or possess hypodermics.

(I) During non-business hours, non-controlled dangerous drugs shall be stored in an area secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, locked room, or secured facility. During normal business hours, non-controlled dangerous drugs shall not be stored in areas where members of the public are not supervised by individuals authorized to administer such drugs or employees of a dog training facility.

(J) All records relating to the administration, distribution, personal furnishing and sale of dangerous drugs shall be maintained under appropriate supervision and control to restrict unauthorized access.

(K) All areas where dangerous drugs and devices are stored shall be dry, well-lit, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures and conditions which will ensure the integrity of the drugs prior to use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling. Refrigerators and freezers used for the storage of drugs and devices shall comply with the following:

(1) Maintain temperature logs with, at a minimum, daily observations to ensure proper refrigeration and freezer temperatures are maintained.

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- (2) The terminal distributor shall develop and implement policies and procedures to respond to any out of range individual temperature readings or excursions to ensure the integrity of stored drugs.
- (3) The terminal distributor shall develop and implement a policy that no food or beverage products are permitted to be stored in refrigerators or freezers used to store dangerous drugs.
- (L) Upon the initial puncture of a multiple-dose vial containing a drug, the vial shall be labeled with a beyond-use date or date opened. The beyond-use date for an opened or entered (e.g., needle punctured) multiple-dose container with antimicrobial preservatives is twenty-eight days, unless otherwise specified by the manufacturer. A multiple-dose vial that exceeds its beyond-use date shall be deemed adulterated.
- (M) Adulterated drugs, including expired drugs, shall be stored in accordance with rule 4729:5- 3-06 of the Administrative Code.
- (N) Disposal of controlled substances shall be conducted in accordance with rule 4729:5-3-01 of the Administrative Code.
- (O) Disposal of non-controlled dangerous drugs shall be conducted in accordance with rule 4729:5-3-06 of the Administrative Code.
- (P) Disposal of controlled substances that are not dangerous drugs by a dog trainer shall be conducted as follows:
- (1) The method of disposal shall render the drug or substance non-retrievable as defined in rule 4729:5-3-01 of the Administrative Code.
- (2) Disposal shall be conducted by any of the following:
- (a) The responsible person and one other employee of the dog training facility;
- (b) A law enforcement officer; or
- (c) A contracted waste disposal company in compliance with all federal, state and local laws, rules and regulations.
- (3) Records for the disposal of the drug shall contain the actual identification of the drug or substance, form, and quantity disposed, the date disposed, the method of disposal and, if disposal is conducted on-site, the positive identification of the person or persons conducting and witnessing the disposal.

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4729:5-23-03 – Record Keeping.

(A) A limited facility shall keep a record of all drugs received, administered, personally furnished, disposed or transferred.

(B) Records of receipt shall contain the name, strength, dosage form, national drug code (if applicable), and quantity of the dangerous drugs received, the name and address of the seller, the name and address of the recipient, and the date of receipt.

(C) Temperature logs maintained in accordance with paragraph (K) of rule 4729:5-23-02 shall include either:

(1) The date and time of observation, the full name or the initials of the individual performing the check, and the temperature recorded; or

(2) For automated systems that provide temperature monitoring, a report that provides, at a minimum, the date and time of observation and the temperature recorded.

(D) Records of personally furnishing shall contain the name, strength, dosage form, lot number and quantity of the dangerous drugs personally furnished, the name, address and date of birth of the person to whom or for whose use the dangerous drug were personally furnished, the positive identification of the prescriber or delegated pharmacist personally furnishing the drug, the date the drug is personally furnished and, if applicable, the date the drug is received by the patient or patient's caregiver.

(E)

(1) Records of administration shall contain the name, strength, dosage form, and quantity of the dangerous drugs administered, the name and date of birth of the person to whom or for whose use the dangerous drugs were administered and the date of administration, and either:

(a) For non-controlled substance dangerous drugs: the identification of the health care professional administering the drug.

(b) For controlled substance dangerous drugs: the positive identification of the health care professional administering the drug.

(2) Records of dangerous drugs administered which become a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph.

(3) Records of dangerous drugs administered by a health care professional, acting within the professional's scope of practice, who is not a prescriber shall include documentation of an order issued by a prescriber or protocol

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authorizing the administration of the drug. An order that is a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph. Orders for the administration of controlled substances shall be documented using positive identification.

(F) Records of disposal of dangerous drugs from inventory, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed, the date of disposal, the method of disposal, the identification of the licensed health care professional that performed the disposal.

(G) Records of disposal of controlled substances that are not dangerous drugs shall comply with the requirements of paragraph (P) of rule 4729:5-23-02 of the Administrative Code.

(H) Records of controlled substance dangerous drug disposal shall comply with the requirements of rule 4729:5-3-01 of the Administrative Code.

(1) If the disposal of controlled substance drug inventory is performed on-site, records shall also include the positive identification of two licensed healthcare professionals conducting and witnessing the disposal, one of whom shall be the responsible person or the responsible person's designee.

(2) If conducting the disposal of an unused portion of a controlled substance resulting from administration to a patient, records shall also include the positive identification of two licensed healthcare professionals conducting and witnessing the disposal.

(I) Records of transfer conducted in accordance with rule 4729:5-3-09 of the Administrative Code shall contain the name, strength, dosage form, national drug code, lot number, expiration date and quantity of the dangerous drug transferred, the address of the location where the drugs were transferred, and the date of transfer.

(J) Controlled substance inventory records shall be maintained in accordance with rule 4729:5-3-07 of the Administrative Code.

(K) All records maintained in accordance with this rule shall be readily retrievable and shall be kept on-site for a period of three years.

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

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

(L) All records maintained pursuant to this rule may be electronically created and maintained, provided that the system that creates and maintains the electronic record does so in accordance with the following:

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- (1) All paper records shall be scanned in full color via technology designed to capture information in one form and reproduce it in an electronic medium presentable and usable to an end user;
- (2) A record or entry in a record, once created, shall be unalterable but may be added to or annotated as necessary if the identification of the individual that made the addition or annotation to the record or entry is captured by the recordkeeping system and complies with the requirements of this rule;
- (3) Contains security features, such as unique user names and passwords, to prevent unauthorized access to the records; and
- (4) Contains daily back-up functionality to protect against record loss.

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