

**6/22/22**

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.

**Amend:**

- 4729:5-15-05: Chemical capture classification.

Comments on the proposed rules will be accepted until close of business on July 11, 2022. Please send all comments to the following email address: [RuleComments@pharmacy.ohio.gov](mailto:RuleComments@pharmacy.ohio.gov)

In addition, please copy your comments to: [CSIPublicComments@governor.ohio.gov](mailto:CSIPublicComments@governor.ohio.gov)

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# Common Sense Initiative

Mike DeWine, Governor  
Jon Husted, Lt. Governor

Carrie Kuruc, Director

## 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):

Chemical Capture Classification

Rule Number(s): 4729:5-15-05

Date of Submission for CSI Review: 6/22/2022

Public Comment Period End Date: 7/11/2022

**Rule Type/Number of Rules:**

New/    rules

No Change/    rules (FYR?   )

Amended/   1   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Rescinded/    rules (FYR?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

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costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, 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 licensee. Discipline might include reprimand, 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.
- d.  Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.
  - Facilities that engage in chemical capture are required to comply with the recordkeeping, storage, and security provisions of the rule. This will likely increase expenses for the facility.

**Regulatory Intent**

2. Please briefly describe the draft regulation in plain language.  
*Please include the key provisions of the regulation as well as any proposed amendments.*

**Amend:**

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4729:5-15-05: Adds three drugs that are permitted for use by a certified officer as part of the chemical capture process.

**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 4729.531 of the revised code. The proposed rule is amplified by sections 4729.01, 4729.532, 4729.533, 4729.534 and 4729.535 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.*

These rules do 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 exceeds federal requirements because licensure and regulation of terminal distributors is reserved for state authorities and is required pursuant to Chapter 4729. of the Revised Code [see HB 24 (133rd General Assembly)].

Section 4729.531 of the Ohio Revised Code requires the Board to adopt rules to implement the licensure of animal shelters.

Furthermore, sections 4729.533 and 4729.534 of the Ohio Revised Code requires the Board to adopt rules to implement the chemical capture classification for a limited terminal distributor license.

**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 such as animal shelters or county dog wardens.

Section 3719.28 of the Ohio Revised Code authorizes the Board of Pharmacy prescribing 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.

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Section 4729.531 of the Ohio Revised Code requires the Board to adopt rules to implement the licensure of animal shelters.

Sections 4729.533 and 4729.534 of the Ohio Revised Code requires the Board to adopt rules to implement the chemical capture classification for a limited terminal distributor license.

**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 was sent for initial public stakeholder comment via the Board's website. The Board also consulted with the State Veterinary Board on the amendment to the rule, as is required by ORC 4729.553.

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

The Board did not receive comments from its public stakeholder posting.

**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?**

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As the regulations are essential to protecting the public's safety by ensuring uniform security and recordkeeping standards for dangerous drugs utilized by animal shelters and dog wardens, 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.**

*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 a performance-based regulations.

**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

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The rule impacts the following:

- Veterinarians;
- County dog wardens; and
- Animal Shelters

**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 discipline for a licensee. Discipline might include reprimand, denial of a license, 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.*

**Amend:**

- 4729:5-15-05: Adds three drugs that are permitted for use by a certified officer as part of the chemical capture process. The proposed change should not have an adverse effect on the regulated entities. However, a licensee who engages in chemical capture of animals may experience increased administrative costs to comply with the recordkeeping, security, and protocol provisions of the rule.

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

The Board determined that the regulatory intent justifies the impact on business because the regulations protect and promote public safety by ensuring uniform licensing, security, and record keeping requirements for controlled substances and other dangerous drugs maintained by animal shelters and dog wardens.

**Regulatory Flexibility**

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

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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?**

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

**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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**Animal Shelters - 4729:5-15-05 - Chemical capture classification. (AMEND)**

(A) Upon application of an animal shelter or county dog warden that holds a limited license issued under section [4729.531](#) of the Revised Code, the state board of pharmacy may grant a chemical capture classification to the limited license. The classification permits the holder to purchase, possess, and administer a combination of drugs for chemical capture. Unless otherwise approved by the board, no such classification shall authorize or permit the distribution of these drugs to any person other than the originating wholesale distributor of the drugs.

(1) To qualify for a chemical capture classification under this rule, an applicant shall appoint or employ a certified officer.

(2) An animal shelter or county dog warden shall comply with the initial licensure and renewal requirements set forth in rule [4729:5-2-02](#) of the Administrative Code. As part of this licensing process, the animal shelter or county dog warden shall provide a list of drugs, signed by the responsible person, that will be used for chemical capture.

(3) A certified officer may use any of the following drugs for **use as part of the** chemical capture **process**:

(a) Ketamine;

(b) Xylazine; **and**

(c) Tiletamine and zolazepam;

(d) Yohimbine;

(e) **Tolazoline; and**

(f) **Atipamezole.**

(B) All areas where drugs and devices used for chemical capture are stored shall comply with the security and storage requirements of rule [4729:5-15-02](#) of the Administrative Code and rule [4729:5-3-13](#) of the Administrative Code.

(C) All drugs used for chemical capture shall comply with the following:

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- (1) Recordkeeping requirements of rule [4729:5-15-03](#) of the Administrative Code; and
- (2) Drug disposal requirements of rule [4729:5-15-02](#) of the Administrative Code.

(D) The animal shelter or dog warden shall develop and implement a drug dosing protocol for all drugs and equipment used in chemical capture.

- (1) The protocol shall be reviewed and signed by a veterinarian licensed under Chapter 4741. of the Revised Code.
- (2) The protocol shall include the following: drug, dose, concentration, approved uses for drug delivery, approved equipment for use, circumstances for use, contraindications, any known common complications/side effects, and weight ranges with corresponding volume of drug to be administered.
- (3) A documented review of the protocol shall be conducted by a veterinarian licensed under Chapter 4741. of the Revised Code at least once every five years.

(E) All equipment used in chemical capture shall:

- (1) Be secured to prevent unauthorized access by individuals who are not certified officers;
- (2) Maintained and used in accordance with the manufacturer's instructions and the protocol established in accordance with paragraph (D) of this rule.
- (3) Be disposed of in accordance with the manufacturer's instructions.

(F) An animal shelter or dog warden with a chemical capture classification shall develop and implement policies and procedures that incorporate the following based upon nationally recognized standards for chemical capture:

- (1) Determining when chemical capture is appropriate. Such policies and procedures shall make all reasonable efforts to ensure animal safety, certified officer safety, and the safety of the public.
- (2) The care of a companion animal immediately upon capture. Certified officers engaged in chemical capture must have a written animal handling and post capture protocol which includes:
  - (a) The procedure for removing the dart from a captured animal;

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(b) First aid for the animal, with particular reference to the dart wound and potential emergencies (including: hyperthermia, hypothermia, shock, bloat, respiratory distress, and cardiac arrest); and

(c) Appropriate location and handling for the animal during recovery from the capture event.

(G) A terminal distributor of dangerous drugs with a chemical capture classification shall maintain records for every certified officer that has completed training in accordance section [4729.534](#) of the Revised Code. Such documentation shall be made readily retrievable and shall be maintained for one year from the date the certified officer is no longer employed by or affiliated with the terminal distributor of dangerous drugs.

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