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.

No Change (Office-Based Opioid Treatment):

- 4729:5-18-04- Provides the requirements of the responsible person on the license which includes establishing standards for security, control and storage of dangerous drugs

- 4729:5-18-05- Provides the requirements for record keeping for an office-based opioid treatment clinic.

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: Kylynne.Johnson@pharmacy.ohio.gov

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

Business Impact Analysis

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

Rule Contact Name and Contact Information: Kylynne Johnson
Kylynne.Johnson@pharmacy.ohio.gov

Regulation/Package Title (a general description of the rules' substantive content):

Office-Based Opioid Treatment

Rule Number(s): 4729:5-18-04; 4729:5-18-05

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

Public Comment Period End Date: 7/11/22

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Rescinded/____ rules (FYR?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,

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, 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.**

   - 4729:5-18-04- Provides the requirements of the responsible person on the license which includes establishing standards for security and control 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 dangerous drugs and hypodermics, performing monthly checks if drugs are refrigerated or frozen and ensuring that multiple use vials are appropriately labeled to ensure they are not expired or adulterated.

   - 4729:5-18-05- Provides the requirements for record keeping for an office-based opioid treatment clinic. There may be an overall increase in administrative costs associated with complying with the rule. The rule also requires notification of the Board if maintaining records off-site.

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

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:

- 4729:5-18-04- Provides the requirements of the responsible person on the license which includes establishing standards for security, control and storage of dangerous drugs

- 4729:5-18-05- Provides the requirements for record keeping for an office-based opioid treatment clinic.

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 rules are authorized by sections 4729.26 and 3719.28 of the Ohio Revised Code. The following sections of the Ohio Revised Code are also considered authorizing statutes for this rule package: 4729.55 and 4729.553.

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 locations providing office-based opioid treatment is the purview of the State of Ohio Board of Pharmacy pursuant to recent legislation adopted by the General Assembly (SB 319, 131st General Assembly).

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 distribution of dangerous drugs.

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 controlled substances.

Section 4729.553 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules necessary to implement the licensure of terminal distributors of dangerous drugs with an office-based opioid treatment classification.

Without these regulations, the Board of Pharmacy would not be able to ensure the licensure and safe operation of office-based opioid treatment facilities.

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 package 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 did not receive any feedback from stakeholders on the contents of the 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 safe operation of office-based opioid treatment facilities, 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 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, 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 package impacts the following:

- Terminal distributors of dangerous drugs with an office-based opioid treatment classification;

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:

- 4729:5-18-04- Provides the requirements of the responsible person on the license which includes establishing standards for security and control 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 dangerous drugs and hypodermics, performing monthly checks if drugs are refrigerated or frozen and ensuring that multiple use vials are appropriately labeled to ensure they are not expired or adulterated.
- 4729:5-18-05 - Provides the requirements for record keeping for an office-based opioid treatment clinic. 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 rules do not provide any exemptions or alternative means of compliance for small businesses. The law does not differentiate on the size of the business and therefore the regulation is uniform across Ohio.

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 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.

4729:5-18 – Office-Based Opioid Treatment Clinics.

4729:5-18-04 – 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.

(B) Controlled substance dangerous drugs, dangerous drugs containing propofol and gabapentin, uncompleted prescription blank(s) used for writing a prescription, D.E.A. controlled substance order forms, and poisons must be stored in an area or areas secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, to deter and detect unauthorized access.

(1) Only a prescriber 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.

(2) 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 poisons only under the direct supervision of a prescriber.

(3) Only a prescriber shall have access to uncompleted prescription blank(s) used for writing a prescription.

(4) Personnel authorized by the responsible person may have access to D.E.A. controlled substance order forms only under the direct supervision of a prescriber.

(5) Only prescribers may have unsupervised access to controlled substance dangerous drugs.

(C) Non-controlled dangerous drugs shall be secured in a tamper-evident manner to deter and detect unauthorized access.

(D) 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, and/or an electronic barrier to deter and detect unauthorized access. 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.

(E) 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.

(F) All areas where dangerous drugs and devices are stored shall be dry, well-lighted, well ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures 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 monthly temperature logs to ensure proper refrigeration temperatures at 36º to 46ºF (2º to 8ºC) and freezer temperatures at 14º to -13ºF (-25º to -10ºC) are maintained at all times;

(2) If a temperature excursion occurs, all affected inventory must be temporarily removed from active inventory and not administered or personally furnished until a documented evaluation of product integrity is completed; and

(3) The responsible person shall develop and monitor a policy that no food or beverage products are permitted to be stored in the refrigerators or freezers.

(G) Upon the initial puncture of a multiple-dose vial containing a drug, the vial shall be labeled with a beyond-use date or the beyond-use date shall be maintained in a separate record. 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.

(H) Adulterated drugs, including expired drugs, shall be stored in accordance with rule 4729:5-3- 06 of the Administrative Code.

(I) Disposal of controlled substances shall be conducted in accordance with rule 4729:5-3-01 of the Administrative Code.

(J) Disposal of non-controlled dangerous drugs shall be conducted in accordance with rule 4729:5-3-06 of the Administrative Code.

4729:5-18-05 – Record Keeping.

(A) A clinic or prescriber office shall keep a record of all dangerous drugs received, administered, personally furnished, disposed or transferred.

(B) The acts of prescribing, administering, and disposal of controlled substance dangerous drugs shall be documented with positive identification.

(C) Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received, the name and address of the persons from whom received and the date of receipt.

(D) Temperature logs maintained in accordance with paragraph (F) of rule 4729:5-19-03 shall include the date of observation, the full name or the initials of the individual performing the check, and the temperature recorded.

(E) Records of personally furnishing shall contain the name, strength, dosage form, 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 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.

(F) Records of administration shall contain the name, strength, dosage form, and quantity of the dangerous drugs administered, the identification of the health care professional administering the drug, 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.

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

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

(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 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.

(G) Records of dangerous drug disposal, 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.

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

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

(J) All records maintained in accordance with this rule shall be readily retrievable and shall be kept for a period of three years at the place where the dangerous drugs are located.

(1) A terminal distributor intending to maintain records, described in this rule, at a location other than the place 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 representatives or contractors of the terminal distributor of dangerous drugs.

(K) 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:

(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 image once created shall be unalterable but may be annotated as necessary so long as the original record or image is still available for review and the individual that made the annotation is noted.

(3) Contains security features to prevent unauthorized access to the records; and

(4) Contains daily back-up functionality to protect against record loss.