11/9/21

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 rule.

Amend:

- 4729:5-21-02 – Permits a prescriber to delegate the act of personally furnishing buprenorphine to a licensed nurse employed by a licensed opioid treatment program.

Comments on the proposed rule will be accepted until close of business on **November 24, 2021**. Please send all comments to the following email address: RuleComments@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: Cameron McNamee
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Regulation/Package Title (a general description of the rules' substantive content):

Mobile Opioid Treatment Program (OTP)

Rule Number(s): 4729:5-21-02

Date of Submission for CSI Review: 11/9/21

Public Comment Period End Date: 11/24/21

Rule Type/Number of Rules:

New/ 1 rules
Amended/ 1 rules (FYR? Y)
No Change/___ 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Rescinded/____ rules (FYR?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 licensee. Discipline might include reprimand, suspension of a license, denial 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.**

   - The rule requires the use of methadone dispensing software if delegating personally furnishing of methadone to a nurse. This is already part of the existing rule. The proposed amendments do not require additional expenditures.

   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.

- 4729:5-21-02 – The rule includes the general requirements (labeling, counseling, etc.) for personally furnishing prescription medications from an opioid treatment program. Permits a prescriber to delegate the act of personally furnishing buprenorphine to a licensed nurse employed by a licensed opioid treatment program.

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, 4729.51 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.

No.

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 in relation to who is authorized to conduct the validation of prescription medications provided by the opioid treatment program. The Ohio requirements ensure that licensed healthcare professionals have oversight over the distribution and verifications of prescription medications distributed by an opioid treatment program.

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.

Without these regulations, the Board of Pharmacy would not be able to ensure the safe distribution of prescription medications used to treatment opioid use disorder.

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 amendment was discussed with the Ohio Association for the Treatment of Opioid Dependence who represent who operate 78 out of the 97 federally certified and state licensed opioid treatment programs (OTP) in Ohio. Additionally, this rule is implementing a temporary COVID-19 waiver issued by the Board. The Board received supportive comments from external stakeholders when vetting which waivers to make permanent.

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

Stakeholders were supportive of the amendments to the rules and did not have any additional feedback.

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 rule is essential to protecting the public's safety by ensuring uniform standards for the distribution of prescription medications by opioid treatment programs, 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 standards for opioid treatment programs 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 did 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 rule will be included in materials such as inspection guides 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 field staff meetings featuring a regulatory update, mandatory 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:

• Opioid treatment programs licensed as terminal distributors of dangerous drugs.

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:

- 4729:5-21-02 – Permits a prescriber to delegate the act of personally furnishing buprenorphine to a licensed nurse employed by a licensed opioid treatment program. This adjustment may reduce overall costs to opioid treatment programs because it allows a physician (or other prescriber) to delegate verification and distribution of buprenorphine to a nurse. This frees up time for the physician to conduct other activities.

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 standards for how opioid treatment programs engage in the distribution of prescription drugs.

Regulatory Flexibility

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

This rule package 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.

Rule 4729:5-21-02 - Personally furnishing dangerous drugs from an opioid treatment program. (AMEND)

(A) A prescriber who personally furnishes a dangerous drug, other than a sample drug pursuant to section 3719.81 of the Revised Code, shall affix to the container a label showing:

(1) The name and address of the prescriber;

(2) The name of the patient for whom the drug is intended;

(3) Name and strength of the dangerous drug;

(4) Directions for use;

(5) Date furnished; and

(6) If a compounded drug, the statement "Compounded Drug" or other similar statement shall also be displayed prominently on the label.

(B) A prescriber who personally furnishes a dangerous drug labeled as a sample and where the directions for use are different from the directions on or in the sample container, the prescriber shall affix a label to the sample container or provide written documentation accompanying the sample that includes the following:

(1) Name of the prescriber;

(2) The name of the patient for whom the drug is intended; and

(3) Directions for use.

(C) For controlled substances, quantities personally furnished to a patient are limited to a seventy-two-hour supply and in any thirty day period quantities personally furnished to all patients shall not exceed two thousand five hundred dosage units pursuant to section 4729.291 of the Revised Code.

(D) None of the following shall be counted in determining whether the amounts specified in paragraph (C) of this rule have been exceeded:

(1) Methadone personally furnished to patients for the purpose of treating drug dependence or addiction, if the prescriber meets the conditions specified in 21 CFR 1306.07 (6/23/2005);

(2) Buprenorphine personally furnished to patients for the purpose of treating drug dependence or addiction as part of an opioid treatment program licensed under section 5119.37 of the Revised Code.

(3) Controlled substances personally furnished to research subjects by a facility conducting clinical research in studies approved by a hospital-based institutional review board or an institutional review board accredited by the association for the accreditation of human research protection programs.

(E)

(1) A prescriber may designate a licensed health care professional acting within the scope of the professional's practice and, under the personal supervision of a prescriber or pharmacist, to prepare and package a dangerous drug that will be personally furnished by the prescriber, a pharmacist, or a nurse in accordance with paragraph (F) of this rule.

(2) The personal supervision requirement listed in paragraph (E)(1) of this rule does not apply if a licensed health care professional acting within the scope of the professional's practice is preparing and packaging either of the following:

(a) Methadone for the purpose of treating drug dependence or addiction; or

(b) Buprenorphine for the purpose of treating drug dependence or addiction.

(3) A prescriber may designate an unlicensed person, under the personal supervision of a prescriber or pharmacist, to prepare and package a dangerous drug that will be personally furnished by the prescriber or a pharmacist in accordance with paragraph (F) of this rule. An unlicensed person shall not prepare and package any of the following dangerous drugs:

(a) Anesthesia;

(b) Controlled substances; or

(c) Drugs administered intravenously.

(F) Only a prescriber shall personally furnish a drug. The act of personally furnishing shall be documented using positive identification.

A prescriber may delegate the act of personally furnishing pursuant to the following:

(1) A prescriber may delegate the act of personally furnishing to a licensed pharmacist. The delegated pharmacist shall document the act of personally furnishing using positive identification.

(2) A prescriber may delegate the act of personally furnishing methadone for the purpose of treating drug dependence or addiction to a nurse ~~licensed~~ **practicing in accordance with Chapter 4723. of the Revised Code** ~~under Chapter 4723. of the Revised Code in accordance with the~~ pursuant to the following:

(a) The opioid treatment program utilizes an automated methadone dispensing system that is routinely calibrated to ensure the accuracy of the methadone personally furnished.

(b) The nurse shall document the act of personally furnishing using positive identification.

(3) A prescriber may delegate the act of personally furnishing buprenorphine for the purpose of treating drug dependence or addiction to a nurse practicing in accordance with Chapter 4723. of the Revised Code. The nurse shall document the act of personally furnishing using positive identification.

(G) Counseling.

(1) A prescriber, pharmacist or a delegate in accordance with paragraph (H)(1) of this rule shall personally offer to provide, or may provide in writing, the service of counseling pursuant to paragraph (G)(2) of this rule to a patient or caregiver whenever any dangerous drug is personally furnished. A prescriber or pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses, either verbally or in writing, the offer of counseling or does not respond to the written offer to counsel.

(2) Prescriber or pharmacist counseling may include, but is not limited to, the following:

(a) The name and description of the drug;

(b) The dosage form, dose, route of administration, and duration of drug therapy;

(c) The intended use of the drug and the expected action;

(d) Special directions and precautions for preparation, administration, and use by the patient;

(e) Common adverse effects or interactions and therapeutic contraindications that may occur, including possible methods to avoid them, and the action required if they occur;

(f) Techniques for self-monitoring drug therapy;

(g) Proper storage and disposal;

(h) Action to be taken in the event of a missed dose; and

(i) The prescriber or pharmacist's comments relevant to the patients drug therapy, including other necessary information unique to the specific patient or drug.

(H) Provision of dangerous drugs.

(1) A prescriber may delegate a licensed healthcare professional acting within the scope of the professional's practice to distribute dangerous drugs personally furnished by a prescriber or pharmacist if all the following apply:

(a) A prescriber or pharmacist provides personal supervision;

(b) Counseling is offered in accordance with paragraph (G) of this rule; and

(c) This task may be delegated in accordance with applicable state laws and rules.

(2) Paragraph (H)(1)(a) of this rule does not apply under any of the following circumstances:

(a) The drug is provided to the patient by a licensed health care professional, acting within the scope of the professional's practice, and the drug provided is either:

(i) Methadone for the purpose of treating drug dependence or addiction and a prescriber or licensed pharmacist is available for counseling by means of electronic communication during normal hours of operation; or

(ii) Buprenorphine for the purpose of treating drug dependence or addiction as part of an opioid treatment program and a prescriber or licensed pharmacist is available for counseling by means of electronic communication during normal hours of operation.

(b) The drug is being provided to a patient by a licensed pharmacist.

(c) A non-controlled dangerous drug is provided to the patient by a licensed health care professional, acting within the scope of the professional's practice, and a prescriber or pharmacist is available for counseling by means of electronic communication during normal hours of operation.

(I) No prescriber or pharmacist may personally furnish to a patient to whom there is no valid prescriber patient relationship, pursuant to applicable state and federal laws, regulations, and rules.

(J) Personally furnishing naloxone.

(1) Except as provided in paragraph (J)(3) of this rule, an authorized individual personally furnishing naloxone on behalf of a physician pursuant to a protocol established in accordance with sections 4731.941 and 3707.561 of the Revised Code, shall do all of the following:

(a) Prepare, package, and label the naloxone in accordance with the requirements of this rule.

(b) Conduct the final association of the naloxone to the patient.

(c) Keep and maintain all records in accordance with this chapter.

(d) Conduct patient counseling, including training on the use of naloxone, as specified in the physician protocol.

(2) An authorized individual personally furnishing naloxone on behalf of a physician pursuant to a protocol established in accordance with sections 4731.941 and 3707.561 of the Revised Code may personally furnish the drug to themselves in order to assist an individual who there is reason to believe is experiencing an opioid-related overdose if all of the following conditions are met:

(a) The authorized individual complies with the protocol established by the authorizing physician, including having completed the training required by the protocol.

(b) The authorized individual has received training instructing them to summon emergency services as soon as practicable either before or after administering naloxone.

(c) Such practice is authorized in the physician approved protocol.

(3) An authorized individual personally furnishing naloxone pursuant to paragraph (J)(2) of this rule shall not be required to comply with paragraphs (J)(1)(a), (J)(1)(b) and (J)(1)(d) of this rule.

(4) A terminal distributor of dangerous drugs may also administer naloxone in accordance with section 4729.514 of the Revised Code.

(K) Any patient specific dangerous drug dispensed by a pharmacy that is provided to a patient by a prescriber pursuant to rule 4729:5-5-14 of the Administrative Code is the property of that patient and is not considered personally furnishing. No prescriber that provides a patient with a drug pursuant to rule 4729:5-5-14 of the Administrative Code shall charge any additional fees or require any additional monetary compensation for the dangerous drug.

(L) Paragraph (K) of this rule does not prohibit a prescriber from charging a patient for any of the following:

(1) The cost of an office visit or any expense related to the administration of a dangerous drug; or

(2) The cost of a dangerous drug dispensed by a pharmacy to a patient if paid for by the prescriber.