Common Sense Initiative

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Business Impact Analysis

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

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

FYR Opioid Treatment Programs

Rule Number(s): 4729:5-21-01, 4729:5-21-02, 4729:5-21-03, 4729:5-21-04, 4729:5-21-05

Date of Submission for CSI Review: 4/29/2025

Public Comment Period End Date: 5/30/2025

Rule Type/Number of Rules:

New/___ rules
No Change/____ rules (FYR? __)
Amended/__5__ rules (FYR? _Y_)
Rescinded/____ rules (FYR?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.**

   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.**

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.

▪ 4729:5-21-01 - Definition section for opioid treatment programs rule chapter. Makes small grammatical changes, updates reference dates for 42 CFR 8.11, and rewords part of the "positive identification" definition.

▪ 4729:5-21-02 - Establishes the requirements for personally furnishing dangerous drugs from an opioid treatment facility. Makes small grammatical changes, updates reference dates for 21 CFR 1306.07, updates naloxone section to align with Chapter 3715. of the Revised Code, and updates the rules for when a prescriber can mail or deliver a dangerous drug that has been personally furnished.

▪ 4729:5-21-03 - Provides the requirements of the responsible person on the license which includes establishing standards for security, control, and storage of dangerous drugs. Makes small grammatical changes, updates reference dates for 21 CFR 1301.72, and changes references from registered nurses to nurses.

▪ 4729:5-21-04 - Provides the recordkeeping requirements for opioid treatment programs. Makes grammatical changes and removes expiration date from the requirements for a record of transfer or sale.

▪ 4729:5-21-05 - Establishes the process for an opioid treatment program to implement a mobile opioid treatment program. Updates reference dates for 21 CFR 1301.72 and 21 CFR 1317.

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.

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.

Yes. The Board created rule 4729:5-21-05 to authorize mobile opioid treatment programs in accordance with rules promulgated by the U.S. Drug Enforcement Administration. These rules by the DEA are intended to make maintenance or detoxification treatments more widely available, while ensuring that safeguards are in place to reduce the likelihood of diversion. For reference, a copy of the DEA Mobile OTP rules can be accessed here: https://www.federalregister.gov/documents/2021/06/28/2021-13519/registration-requirements-fornarcotic-treatment-programs-with-mobile-components

5. **If the regulation implements a federal requirement, but 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, such as the Ohio Board 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 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.

Without these regulations, 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.

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

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

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.

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 proponent comments from the Ohio Association for the Treatment of Opioid Dependence (OATOD).

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 package.

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? ***Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.***

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

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

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

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

regulated community.

The rules will be posted on the Board of Pharmacy's web site; information concerning the rules will be included in materials e-mailed to licensees; and notices will be sent to associations, individuals, and groups. Board of Pharmacy staff are also available via phone or email to answer questions regarding implementation of the rules.

In addition, the Board's compliance agents are trained to educate licensees on current and/or new regulations during on-site inspections. Board of Pharmacy staff receive regular updates on rules via a monthly internal newsletter, biannual staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, email updates and quarterly webinars from the Director of Policy, and feedback from the Board's legal department for every citation submitted.

Additionally, the Board has developed inspection guides that licensees can use to conduct self-inspections. These guides align with internal guidance used by Board inspectors and allow licensees to conduct self-inspections to maintain compliance. The guides also include links to the rules, important definitions, and reminders of when a licensee is required to submit notification or additional information to the Board.

Adverse Impact to Business

15. Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:

a. Identify the scope of the impacted business community, and

The rule package impacts the following non-limited facilities:

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

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

In general, 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.

16. Are there any proposed changes to the rules that will reduce a regulatory burden imposed on the business community? Please identify. ***(Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability,***

eliminating requirements, reducing compliance time or fees, or other related factors).

Yes. The Board eliminated the need to include the expiration date on transfer records.

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 care in an opioid treatment program.

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 regulations are 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 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 and host regional meetings to discuss changes to Ohio laws and rules. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules.

The Board has also developed inspection guides that licensees can use to conduct self-inspections. These guides align with internal guidance used by Board inspectors and allow licensees to conduct self-inspections to maintain compliance. The guides also include links to the rules, important definitions, and reminders of when a licensee is required to submit notification or additional information to the Board.

Rule 4729:5-21-01 | Opioid Treatment Programs - Definitions. (AMEND)

As used in Chapter 4729:5-21 of the Administrative Code:

(A) "Opioid Treatment Program" or "OTP" means a facility that is licensed as a terminal distributor of dangerous drugs in accordance with section 4729.54 of the Revised Code and holds, or is in the process of applying for, a valid certification from the substance abuse and mental health services administration of the United States department of health and human services pursuant to 42 CFR 8.11 (~~33~~/~~1917~~/~~2001~~2025). The facility shall comply with all requirements set forth in this chapter. An OTP does not include ~~an~~ office-based opioid treatment performed in accordance with rule 4731-33-03 of the Administrative Code.~~clinic as defined in chapter 4729:5-18 of the Administrative Code.~~

(B) "Controlled substance" has the same meaning as in section 3719.01 of the Revised Code.

(C) "Dangerous drug" has the same meaning as in section 4729.01 of the Revised Code.

(D) "Dosage unit" means any of the following:

(1) A single pill, capsule, ampule, tablet;

(2) In the case of a liquid solution, one milliliter;

(3) In the case of a cream, lotion, or gel, one gram; or

(4) Any other form of administration available as a single unit.

(E) "Licensed health professional authorized to prescribe drugs" or "prescriber" has the same meaning as in rule 4729:5-1-02 of the Administrative Code but shall be limited to a prescriber practicing within the prescriber's applicable scope of practice.

(F) "Personal supervision" means the person specified in rule shall be physically present at the licensed location to deter and detect the diversion of dangerous drugs.

(G) "Personally furnish" or "personally furnishing" means the final association of a drug with a patient by a prescriber prior to the distribution to a patient for use outside the prescriber's practice setting.

(H)

(1) "Positive identification" means a method of identifying a person that does not rely on the use of a private personal identifier such as a password, but must use a secure means of identification that includes any of the following:

(a) A manual signature on a hard copy record;

(b) A magnetic card reader;

(c) A bar code reader;

(d) A biometric method;

(e) A proximity badge reader;

(f) A board approved system of randomly generated personal questions;

(g) A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who performed the action requiring positive identification. The printout must be maintained for three years and made readily retrievable; or

(h) Other effective methods for identifying individuals that have been approved by the board.

(2) A method relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier.

~~A method relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier, such as a password, for entry into a secure mechanical or electronic system.~~

(I) "Readily retrievable" means that records maintained in accordance with this chapter shall be kept in such a manner that, upon request, they can be produced for review no later than three business days to an agent, officer, or inspector of the board.

(J) "Responsible person" has the same meaning as defined in rule 4729:5-2-01 of the Administrative Code and is responsible for the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as

required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs, and maintaining all drug records otherwise required.

(K) "Sample" means a dangerous drug or pharmaceutical preparation that would be hazardous to health or safety if used without the supervision of a licensed health professional authorized to prescribe drugs, or a drug of abuse, and that, at one time, had been placed in a container plainly marked as a sample by a manufacturer.

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 (~~68~~/~~238~~/~~20052023~~);

(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 practicing in accordance with Chapter 4723. of the Revised Code 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 patient's 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) Naloxone and other overdose reversal drugs may be personally furnished or otherwise distributed in accordance with Chapter 3715. of the Revised Code. A terminal distributor of dangerous drugs shall not be required to maintain any patient-specific records for the distribution of naloxone or other overdose reversal drug. ~~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.

(M) Except as provided in paragraph (N) of this rule, a prescriber may only mail or provide delivery of a dangerous drug that has been personally furnished if all the following apply:

(1) The prescriber does not routinely mail or deliver the drug to the patient;

(2) The drug is unavailable at a local pharmacy or the patient cannot afford the drug;

(3) Failure to mail or deliver the drug would result in harm to the patient; and

(4) The prescriber includes in the records required for personally furnishing the name of the common carrier (including the United State Postal Service), contract carrier, or employee of the terminal distributor who performed, or attempted to perform, the delivery.

(N) The restrictions listed of paragraph (M) of this rule do not apply if the drug that has been personally furnished is either:

(1) Part of a clinical trial approved by the United States food and drug administration. A prescriber that mails or delivers a drug that is part of a clinical trial shall comply with the requirements of paragraph (N)(4) of this rule; or

(2) Delivered or otherwise provided by a mobile opioid treatment program in accordance with rule 4729:5-21-05 of the Administrative Code or a mobile clinic or medication unit in accordance with rule 4729:5-3-23 of the Administrative Code.

(O) Any drug that has left the possession of the terminal distributor of dangerous drugs shall comply with the requirements of rule 4729:5-3-16 of the Administrative Code.

Rule 4729:5-21-03 | Security and control of dangerous drugs. (AMEND)

(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) All schedule II controlled substances shall be maintained in accordance with 21 CFR 1301.72 (3/17/2025~~12/5/2018~~). Only prescribers, pharmacists, and nurses licensed under Chapter 4723. of the Revised Code may have access to schedule II controlled substances maintained in accordance with this paragraph.

(C) All schedule III through V controlled substances shall be maintained in accordance with 21 CFR 1301.72 (3/17/2025~~12/5/2018~~). Only prescribers, pharmacists, and nurses licensed under Chapter 4723. of the Revised Code may have access to controlled substances maintained in accordance with this paragraph.

(D) When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests, or visitors to be present in or pass through storage areas maintained in accordance with paragraphs (B) and (C) of this rule, the opioid treatment program shall provide for adequate observation of the area by a prescriber, pharmacist, or nurse specifically authorized in writing.

(E) Controlled substances administered for the treatment of opioid dependence or addiction may be administered directly to the patient by any of the following:

(1) A licensed prescriber, in accordance with the prescriber's scope of practice and as authorized by federal or state law.

(2) A ~~registered~~ nurse licensed under Chapter 4723. of the Revised Code ~~or licensed practical nurse~~ pursuant to a valid order issued by a licensed prescriber.

(3) A pharmacist in accordance with a consult agreement pursuant to section 4729.39 of the Revised Code. The pharmacist shall only administer the drug pursuant to a valid order by the consulting physician.

(F) Persons enrolled in an opioid treatment program will be required to wait in an area physically separated from the drug storage and preparation areas. This requirement shall be enforced by the responsible person and program employees.

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

(H) 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 a person delegated power of attorney in accordance with 21 CFR 1305.05 (9/30/2019). D.E.A. controlled substance order forms shall be secured when not in use.

(I) 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.

(J) 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.

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

(L) All areas where dangerous drugs 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 shall comply with the following:

(1) Maintain either of the following to ensure proper refrigeration and/or freezer temperatures are maintained:

(a) Temperature logs with, at a minimum, daily observations; or

(b) A temperature monitoring system capable of detecting and alerting staff of a temperature excursion.

(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 drugs.

(M) 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.

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

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

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

Rule 4729:5-21-04 | Record Keeping. (AMEND)

(A) An OTP shall keep a record of all dangerous drugs received, administered, personally furnished, disposed, sold, or transferred.

(B) Records of receipt shall contain the name, strength, dosage form, 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. An invoice from a drug distributor licensed in accordance with division 4729:6 of the Administrative Code containing the required information may be used to meet this requirement.

(C) Records of temperature control monitoring described in paragraph (L)(1) of rule 4729:5-21-03 of the Administrative Code shall include any of the following:

(1) For temperature logs, either:

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

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

(2) For temperature monitoring systems capable of detecting and alerting staff of a temperature excursion, maintain reports that provide information on any temperature excursion that includes the date, time, temperature recorded, and length of each excursion.

(D) 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 drugs were personally furnished~~,~~; the positive identification of the prescriber, delegated pharmacist, or delegated nurse 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~~,~~; 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 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~~,~~; and the identification of the licensed health care professional that performed the disposal.

(G) Records of controlled substance 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.

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

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

(J) 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.

(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) Complies with the requirements of this rule;

(2) 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;

(3) Contains security features, such as unique user names and passwords, to prevent unauthorized access; and

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

Rule 4729:5-21-05 | Mobile opioid treatment programs. (AMEND)

(A) As used in this rule, "mobile opioid treatment program" has the same meaning as "mobile narcotic treatment program" as used in 21 CFR part 1301 (~~73~~/~~12~~17/~~2021~~2025).

(B) For any opioid treatment program intending to operate a mobile opioid treatment program, the licensee shall notify the local drug enforcement administration (DEA) office, in writing, its intent to do so, and the opioid treatment program must receive explicit written approval from the local DEA office prior to operating the mobile opioid treatment program. The mobile opioid treatment program may only operate in the same state in which the opioid treatment program is registered with the DEA.

(1) Licensees are not required to obtain a separate terminal distributor of dangerous drugs license for conveyances (mobile components) utilized by the licensee to transport dangerous drugs away from licensed locations for use as part of a mobile opioid treatment program. Vehicles must possess valid county/city and state information (e.g., a vehicle identification number (VIN) or license plate number) on file at the licensed location of the opioid treatment program licensed by the board.

(2) A mobile opioid treatment program is not permitted to reverse distribute, share, or transfer dangerous drugs from one mobile component to another mobile component while deployed outside of the licensed location. These mobile components of opioid treatment programs may not function as hospitals, long-term care facilities, or emergency medical service vehicles, and shall not transport patients.

(C) For any conveyance operated as a mobile opioid treatment program, a securely locked safe must be installed and used to store dangerous drugs in schedules II-V for the purpose of maintenance or detoxification treatment~~,~~ when not located at the licensee's licensed location.

(1) The safe must conform to the requirements set forth in paragraph (a)(1) of 21 CFR 1301.72 (3/17/2025~~7/12/2021~~).

(2) The mobile component shall also be equipped with an alarm system that conforms to the requirements set forth paragraph (a)(1)(iii) of 21 CFR 1301.72 (3/17/2025~~7/12/2021~~).

(3) The storage area of the mobile component must conform to the accessibility requirements in paragraph (d) of 21 CFR 1301.72 (3/17/2025~~7/12/2021~~).

(4) The storage area for controlled substances in a mobile component of an opioid treatment program must not be accessible from outside of the vehicle.

(a) Authorized personnel transporting the controlled substances on behalf of the mobile opioid treatment program are required to retain control over the controlled substances when transferring controlled substances between the licensed location and the conveyance, from the conveyance to the location where medication will be administered or personally furnished, and when administering or personally furnishing medication. At all other times during transportation, all controlled substances must be properly secured in the safe.

(b) Upon completion of the operation of the conveyance on a given day, the conveyance must be immediately returned to the licensed location, and all controlled substances must be removed from the conveyance and secured within the licensed opioid treatment program. After the conveyance has returned to the registered location and the controlled substances have been removed, the conveyance may be parked until its next use at the licensed location or any secure, fenced-in area, once the local DEA office has been notified of the location of this secure, fenced-in area.

(c) A mobile opioid treatment program may apply to the DEA for an exception to the requirements in paragraph (C)(4)(b) of this rule.

(i) The application for such an exception shall be submitted in accordance with 21 CFR 1301.72 (3/17/2025).

(ii) If an exception is granted, the licensee shall comply with the security conditions set forth in the approval granted by the DEA. Any conveyance maintained in accordance with an exception granted under this rule shall be subject to inspection by a board of pharmacy agent.

(iii) If an exception is revoked or otherwise rescinded by the DEA, the licensee shall comply with the requirements in paragraph (C)(4)(b) of this rule.

(iv) All approvals from the DEA shall be maintained at the licensed location and made immediately available for inspection by an agent of the state board of pharmacy.

(d) All opioid treatment programs with mobile components shall be required to establish a standard operating procedure to ensure, if the mobile component becomes inoperable (mechanical failure, accidents, fire, etc.), that the controlled substances on the inoperable conveyance are accounted for, removed from the inoperable conveyance, and secured at the licensed location.

(5) Only prescribers, pharmacists, and nurses licensed under Chapter 4723. of the Revised Code may have access to controlled substances maintained by the mobile opioid treatment program.

(D) Persons enrolled in any opioid treatment program, including those receiving treatment at a mobile opioid treatment program, will be required to wait in an area that is physically separated from the medication storage area and areas used for administration or personally furnishing by a physical entrance such as a door or other entryway. Patients will need to wait outside of a mobile opioid treatment program if that unit does not have seating or a reception area that is separated from the medication storage area and areas used for administration or personally furnishing. This requirement shall be enforced by the terminal distributor of dangerous drugs and the licensee's employees.

(E) Any controlled substances being transported for disposal from the location where the drugs are administered or personally furnished shall be secured and disposed of in compliance with 21 CFR 1317 (3/17/2025~~7/12/2021~~) and rule 4729:5-3-01 of the Administrative Code.

(F) A conveyance used as part of a mobile opioid treatment program may only be supplied with controlled substance dangerous drugs by the licensed opioid treatment program that operates such conveyance. Persons permitted to administer or personally furnish controlled substances from mobile opioid treatment programs shall not:

(1) Receive controlled substances from other mobile opioid treatment program or any other entity;

(2) Deliver controlled substances to other mobile opioid treatment program or any other entity; or

(3) Conduct reverse distribution of controlled substances on a mobile opioid treatment program.

(G) A mobile opioid treatment program shall maintain records with the following information for each dangerous drug:

(1) Name of drug;

(2) Strength of drug;

(3) Dosage form;

(4) Date dispensed;

(5) Adequate identification of patient (consumer);

(6) Amount consumed;

(7) Amount and dosage form taken home by patient; and

(8) Initials of the employee personally furnishing or administering a drug.

(H) The records required by paragraph (G) of this rule shall be maintained in a log at the licensed opioid treatment program.

(1) As an alternative to maintaining a paper log, an opioid treatment program may also use an automated/computerized data processing system for the storage and retrieval of the program's records, if the following conditions are met:

(a) The automated system maintains the information required in paragraph (G) if this rule;

(b) The automated system has the capability of producing a hard copy printout of the records required in paragraph (G) of this rule;

(c) The opioid treatment program or its mobile component prints a hard copy of each day's log, which is then initialed appropriately by each person who personally furnished/administered the medication to the program's patients;

(d) The automated system is approved by DEA;

(e) The opioid treatment program or its mobile component maintains an off-site back-up of all computer generated program information; and

(f) The automated system is capable of producing accurate summary reports for both the licensed site of the opioid treatment program and any mobile component, for any time-frame selected by DEA personnel during an investigation. If these summary reports are maintained in hard copy form, they must be kept in a systematically organized file located at the licensed opioid treatment program.

(2) The opioid treatment program must retain all records for any mobile component three years from the date of execution.

(I) A mobile opioid treatment program shall comply with all other applicable requirements of 21 CFR 1301 (~~7~~3/~~12~~17/~~2021~~2025).