

Rule Summary and Fiscal Analysis

Part A - General Questions

Rule Number: 5122-40-06

Rule Type: Amendment

Rule Title/Tagline: Medication administration.

Agency Name: Department of Mental Health and Addiction Services

Division:

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I. Rule Summary

1. **Is this a five year rule review?** Yes
 - A. **What is the rule's five year review date?** 10/31/2024
2. **Is this rule the result of recent legislation?** No
3. **What statute is this rule being promulgated under?** 119.03
4. **What statute(s) grant rule writing authority?** R.C. 5119.37
5. **What statute(s) does the rule implement or amplify?** R.C. 5119.37
6. **Does the rule implement a federal law or rule in a manner that is more stringent or burdensome than the federal law or regulation requires?** Yes
 - A. **If so, what is the citation to the federal law or rule?** 42 C.F.R. part 8.12
7. **What are the reasons for proposing the rule?**

R.C. 5119.37(F) requires the Department to establish procedures and adopt rules for licensing, inspection, and supervision of community addiction services providers that operate an opioid treatment program. The rules must establish standards for the control, storage, furnishing, use, dispensing, and administering of medications used in medication-assisted treatment; prescribe minimum standards for the operation of

the opioid treatment program component of the provider's operations; and comply with federal laws and regulations.

8. Summarize the rule's content, and if this is an amended rule, also summarize the rule's changes.

OAC 5122-40-06 establishes rules and procedures around medication administration. These rule changes would clarify who in the OTP can dispense medication in accordance with Ohio law. The rule also clarifies the requirements for staff administering medication to receive supervision. This would align Ohio OTP rules with those of the State of Ohio Board of Pharmacy specific to medication dosing. The rule also clarifies the supervision requirements in response to the scope of practice expansion. These changes also add language requiring an OTP to establish agreements with neighboring providers to cover any patient cost associated with an emergency closure. This recognizes the need to ensure patient continuity during emergency situations and requiring structured preparations for provider communication. The rule also increases collaboration among OTPs to provide back-up patient care for emergency situations. These changes also remove language specifying state-level take home phasing for methadone and state-level stability criteria. Also, the rule removes the 14-day restriction on partial-opioid agonist medication in the first 90 days of treatment. This increases engagement in care and adherence to medication treatments. The rule also reduces stigma for addiction as a chronic medical condition and expands access to care. The rule also finalizes the OTP use of the federal methadone take-home schedule and reinforces the provider/patient individualization of medications for opioid use disorder (MOUD) treatment. The rule also standardizes the criteria that a program prescriber must use when determining if a patient can safely receive unsupervised doses of medication. These changes also add language allowing for the use of a trusted third party consistent with DEA regulations. Also, the rule allows for appropriate law enforcement pickup of medication for patients in structured environments consistent with rule. This increases adherence with medication treatments. The rule also reduces the burden on controlled environments (nursing facilities, jails, and prisons) to manage patients who otherwise would not have access to their medications. The rule recognizes the need for flexibility in dispensing and delivering medications. The rule allows for expanded options by the OTP when a patient is in a controlled environment or unable to be transported to the OTP to receive their medication. The rule aligns treatment with other chronic medical conditions. Lastly, these changes clarify that the OTP may dispense medication to a patient residing in a correctional facility or other inpatient or residential facility. This increases adherence with medication treatments. It also reduces the burden on controlled environments (nursing facilities, jails, and prisons) to manage patients who otherwise would not have access to their medications. The rule recognizes the need for inpatient facilities to allow the admission of patients who are active with an OTP

and receiving MOUD, especially methadone. The rule also clarifies that OTPs are able to deliver medication to a patient residing in one of these settings.

9. **Does the rule incorporate material by reference? No**
10. **If the rule incorporates material by reference and the agency claims the material is exempt pursuant to R.C. 121.75, please explain the basis for the exemption and how an individual can find the referenced material.**

Not Applicable

11. **If revising or re-filing the rule, please indicate the changes made in the revised or re-filed version of the rule.**

Not Applicable

II. Fiscal Analysis

12. **Please estimate the increase / decrease in the agency's revenues or expenditures in the current biennium due to this rule.**

This will have no impact on revenues or expenditures.

0

Not applicable

13. **What are the estimated costs of compliance for all persons and/or organizations directly affected by the rule?**

There are no additional costs of compliance.

14. **Does the rule increase local government costs? (If yes, you must complete an RSFA Part B). No**

15. **Does the rule regulate environmental protection? (If yes, you must complete an RSFA Part C). No**

16. **If the rule imposes a regulation fee, explain how the fee directly relates to your agency's cost in regulating the individual or business.**

Not applicable

III. Common Sense Initiative (CSI) Questions

17. Was this rule filed with the Common Sense Initiative Office? Yes

18. Does this rule have an adverse impact on business? No

A. Does this rule require a license, permit, or any other prior authorization to engage in or operate a line of business? No

This particular rule does not, however another rule in O.A.C. chapter 5122-40, O.A.C. 5122-40-04, specifies the licenses or other authorizations needed to operate an OTP. A person or government entity seeking to operate an OTP must be licensed as an OTP under R.C. 5119.37; be certified as a community addiction services provider to provide general services described in O.A.C. 5122-29-03, SUD case management services in O.A.C. 5122-29-13, and crisis intervention in accordance with O.A.C. 5122-29-10; be certified by SAMHSA pursuant to 42 C.F.R. Part 8.11; and have a category III terminal distributor of dangerous drugs license from the Ohio State Board of Pharmacy under R.C. Chapter 4729. OTPs are also required to use a centralized registry system pursuant to O.A.C. 5122-40-08.

B. Does this rule impose a criminal penalty, a civil penalty, or another sanction, or create a cause of action, for failure to comply with its terms? No

The rules in O.A.C. chapter 5122-40 do not impose a penalty or sanction. However, R.C. 5119.99 specifies that a person or government entity that operates an OTP without a license or operates an OTP in a manner inconsistent with R.C. 5119.37 or the rules in O.A.C. chapter 5122-40 is guilty of a felony of the fifth degree.

C. Does this rule require specific expenditures or the report of information as a condition of compliance? No

D. Is it likely that the rule will directly reduce the revenue or increase the expenses of the lines of business of which it will apply or applies? No

IV. Regulatory Restriction Requirements under S.B. 9. Note: This section only applies to agencies described in R.C. 121.95(A).

19. Are you adding a new or removing an existing regulatory restriction as defined in R.C. 121.95? Yes

A. How many new regulatory restrictions do you propose adding to this rule? 0

B. How many existing regulatory restrictions do you propose removing from this rule? 43

(A) Medication administration shall....

methadone medication shall only....

(B) Medication administration shall....

(C) Methadone medication shall only....

(E) Medication shall....

(F) Dispensing or personally furnishing medication shall....

(G) Providers of medication administration services shall....

(H) A written, signed, and dated prescriber's order shall....

The prescriber must....

(I) Labels for dispensing or personally furnishing medication shall....

(J) Medication orders shall....

The following procedures shall....

(1) A prescriber's order for medication shall....

(2) A prescriber's order for medication shall....

(K) Opioid treatment programs shall....

(K) Closure dates may not....

The patient shall ingest....

(N) Take-home doses of medication shall not....

(P) The opioid treatment program shall....

(1) Statement that the opioid treatment program decisions on dispensing take-home doses of medication shall....

(3) A requirement that take-home doses of medication shall....

the medical director or other authorized prescriber shall....

(5) Statement that prescriber order for take-home doses of medication shall....

the opioid treatment program shall....

the medication bottles shall....

(g) The label shall contain....

(h) Any other requirements....

(Q) An individual must....

The approval shall....

(T) The provision of interim maintenance with medication is prohibited....

(3) To receive interim maintenance, a patient must....

(6) Programs offering interim maintenance must....

(U) Each opioid treatment program shall....

the medical director or treating prescriber must....

health care provider shall....

the clinical record shall....

to whom they have been referred shall....

other authorized prescriber shall....

the program shall....

patients who are parents or shall....

(a) The medical director or other authorized prescriber shall....

the medical director or other authorized prescriber shall....

medication administration shall....

- C. If you are not removing existing regulatory restrictions from this rule, please list the rule number(s) from which you are removing restrictions.**
- D. Please justify the adoption of the new regulatory restriction(s).**

Not Applicable