Common Sense Initiative

Mike DeWine, *Governor*
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Business Impact Analysis

Agency, Board, or Commission Name: Ohio Department of Mental Health and Addiction Services

Rule Contact Name and Contact Information: Original BIA completed by Emily Henry. Lisa Musielewicz, (614) 995-1958, Lisa.Musielewicz@mha.ohio.gov, is the contact for this package as of 5/6/2024.

Regulation/Package Title (a general description of the rules' substantive content):
OTP 2024 Update

Rule Number(s): O.A.C. Chapter 5122-40

Date of Submission for CSI Review: 5/3/2024 by Emily Henry; updated BIA submitted by Lisa Musielewicz on 5/29/2024. Second updated BIA submitted by Lisa Musielewicz on 8/16/2024. Third updated BIA submitted by Lisa Musielewicz on 10/18/2024.

Public Comment Period End Date: First comment period: 5/17/2024; second comment period: 8/30/2024

Rule Type/Number of Rules:

New/___ rules **No Change/__X_(6 rules) (FYR? _X__)**

Amended/__X (9 rules) rules (FYR? _X__) **Rescinded/____ rules (FYR?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.

   MHAS is proposing to amend 5122-40-01, 05, 06, 07, 08, 09, 10, 11 and 15. The proposed changes are in response to recent federal regulation changes and will align Ohio's opioid treatment program (OTP) rules with those changes. All other rules in Chapter 5122-40 are being proposed as no change rules to comply with the five-year review requirement.

   5122-40-01 is the definition rule and updates are being made to be consistent with other changes.

   UPDATED 10/18/2024: 5122-40-05 is being updated to align the requirements for medical directors, program administrators, and mid-level practitioners with federal requirements. This change will allow for expansion of services and will not compromise patient safety. This section defines the duties of the program director.

   5122-40-06 is being updated to make take—home supply and emergency dosing requirements consistent with federal regulation. These changes will allow for more flexible medication administration with patients.

   5122-40-07 is being updated to reflect the change in withdrawal management terminology and updated admission criteria. Counselor to patient ratio language is being clarified.

5122-40-08 is being clarified that OTPs will provide direct contact info central registry purposes rather a call center.

5122-40-09 is being updated to change language regarding counselors. The requirements for counseling sessions are being changed to match best practices.

5122-40-10 is being updated to fix statutory references.

UPDATED 10/18/2024: 5122-40-11 is being updated to align OAC with federal toxicology requirements and remove duplicative language.

5122-40-15 is being updated to remove geographic restrictions on mobile and non-mobile medication units.

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.**

   ORC 5119.37

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.

   According to the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA), oversight of OTPs is a multilateral system involving states, SAMHSA, the U.S. Department of Health and Human Services, and the U.S. Drug Enforcement Administration (DEA) (see SAMHSA, Certification of Opioid Treatment Programs (OTPs), available at https://www.samhsa.gov/medications-substance-use-disorders/become-accredited-opioid-treatment-program#:~:text=OTPs%20must%20be%20both%20certified,through%20their%20local%20DEA%20office.

   The federal regulations governing OTPs are codified in Title 42 of the Code of Federal Regulations Part 8. Under those regulations, OTPs must possess current valid accreditation status, be certified by SAMHSA, be registered with the U.S. Drug Enforcement Administration (DEA), and be licensed in the state in which they operate.

   The rules in OAC Chapter 5122-40 work in coordination with the federal regulations described above to implement state licensure.

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.**

   The primary goal for this rule package was to align rules for OTPs more closely with new federal regulations. However, there are a few areas in which OhioMHAS is exercising its discretion to protect patients; in those few areas, the rules remain unaligned with federal regulations. Rules 5122-40-05, 06, 09, and 15 have provisions that have no federal counterpart. These provisions are in response to observed conditions in Ohio OTPs and the need to have OTPs maintain proper supervision of their sites.

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)?**

   ORC 5119.37 requires the Department to license OTPs for the purpose of protecting the health and safety of patients.

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

   The Department will be monitoring OTPs for issues necessitating changes in license term and working to minimize those events.

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.

   The draft rules were shared directly with the OTP Stakeholder group. This group consists of 326 members with direct involvement with an active OTP in either direct service, medical provider, administration, etc. In addition, the rules were shared with the Chronic Pain and MAT Policy Committee. This group consists of 23 individuals from OhioMHAS, the State Medical Board, the Board of Pharmacy, the Board of Nursing, Ohio Department of Medicaid, Recovery Ohio, and the Governor's Office.

   Meetings scheduled with the OTP stakeholder group to discuss the draft rules were held on: 6/23/23, 7/3/23, 9/26/23, 3/13/24, 3/22/24, 4/4/24, 4/26/24

Meetings scheduled with the MAT Policy Group to discuss the draft rules were held on: 2/29/24, 3/27/24, 4/5/24

UPDATED 8/15/2024: OhioMHAS posted the rules for public comment on 5/3/2024. Following the review of comments received, OhioMHAS made changes to the proposed rules as summarized below under question 10.

UPDATED 10/17/2024: OhioMHAS posted the rules for additional public comment on 8/16/2024. Following the review of comments received, OhioMHAS made changes to the proposed rules as summarized below under question 10.

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

Based on feedback from these meetings changes were made to the draft rules in the following key areas:

- 40-05(B)(1) - removal of MD certification requirements.
- 40-05(B)(3) - relaxation of the onsite requirements for the MD
- 40-05(D)(6) - removal of specific maximum OTPs assigned to a single MD.
- 40-09(H) - removal of language requiring specific counseling sessions.
- 40-15(B) - removal of language defining geographic restrictions to mobile and non-mobile medication units.

UPDATED 8/15/2024: After the first round of comments was received in May 2024, OhioMHAS made some changes suggested by stakeholders. A summary of key changes appears below. Please note that rule number paragraphs refer to the paragraph numbers of the *revised rules*.

- 40-01(A) – Added definitions, including mobile and non-mobile medication units, correctional facility, personally furnish, prescriber, and program prescriber.
- 40-05(B)(3) – Eliminated the requirement that the medical director be present a minimum of two times per month.
- 40-05(C) – Replaced “program administrator” with “program director” and specified responsibilities for this position, which are intended to ensure program quality
- 40-05(D) – Eliminated the references to “physician extender”; replaced with references to “program prescribers other than physicians.” The term, “program prescriber” is also now defined in -01 as specified above.
- 40-05(D)(5) – Corrected a typographical error to specify “more than six weeks.”
- 40-05(D)(6) and (7) – Eliminated the differences between frequency of patient visits by certified nurse practitioners and physicians.

- 40-06(C) – Eliminated this paragraph regarding methadone only being able to be administered orally because it is duplicative of content in paragraph (A).
- 40-06(E) – After consulting with Pharmacy Board staff, modified this paragraph to make the language used consistent with the language used by that Board. Only pharmacists dispense. Physicians and others personally furnish.
- 40-06(G) – Corrected this provision (now in paragraph (F)) regarding who may supervise medication administration.
- 40-06(H) – Corrected a cross-reference to Pharmacy Board rules.
- 40-06(N)(7) – Removed the list of requirements for packaging of take-home medication and instead, cross-referenced applicable drug statute and Pharmacy Board rule.
- 40-06(Q) – Corrected a grammatical mistake in the paragraph and added that correctional facilities are another place that a patient may receive medication from an OTP.
- 40-06(R) – Modified the provision on admission of patients for interim treatment to align with the applicable federal regulation.
- 40-07(A)(1) and (2) – Paragraph (A)(2) was eliminated because it duplicates content in paragraph (A)(1). Paragraph (A)(1) was modified to cross-reference the applicable federal regulation.
- 40-07(A)(23) – Eliminated an incorrect cross-reference to a Pharmacy Board statute.
- 40-08(B)(3) – Clarified that the purpose of the requirement on OTPs to ensure that contact information of program staff is available is to facilitate timely access to information in the central registry *for dual enrollment verification purposes*.
- 40-09(A) and (B) – These paragraphs regarding the non-medication services OTPs must provide were reorganized and rewritten to reduce the redundancy in language between the two paragraphs and to more closely align with the applicable federal regulation.
- 40-09(H)(3) – This paragraph was modified to clarify that there is an exception to the requirement of counseling sessions being available to the patient at least weekly during the first 90 days of treatment, for at least 15 minutes in duration.
- 40-10(B)(5) – This paragraph was modified to cite to the correct Pharmacy Board rule and to require that, when an OTP discovers a loss or theft of any controlled substance, that local law enforcement authorities must be notified in accordance with R.C. 2921.22.
- 40-15(B) – This paragraph was modified to specify that mobile medication units may *only* be located in areas that are greater than five miles from the nearest opioid treatment program.

- 40-15(E) – This paragraph was modified to cross-reference the applicable federal regulation, to clarify that medication units that choose to provide telecounseling must ensure that each patient has a designated *program* counselor as described in that federal regulation.
- 40-15(H) – Added a requirement, consistent with 5122-40-05, that each mobile and non-mobile medication unit have a program director who, with respect to operation of the medication unit, is to exercise the same responsibilities as a program director at the primary opioid treatment program.

UPDATED 10/17/2024 After the second round of comments was received in August 2024, OhioMHAS made some changes suggested by stakeholders. A summary of key changes appears below. Please note that rule number paragraphs refer to the paragraph numbers of the *revised rules*.

- 40-05(A)(3) – Removed the term "licensed" from "licensed physician" as this term is already defined in 40-01.
- 40-05(B)(4) – Removed this section entirely as not to cause unnecessary confusion related to the medical director role due to existing edits to 40-05(B).
- 40-05(B)(4) – Removed the reference to the DEA waiver that was eliminated by the DEA in 2022.
- 40-05(C) – Modified language to sections 3, 4, and 5 to clarify the program director may delegate certain duties to appropriate program staff.
- 40-05(D)(1)(b) – Clarified that initial training should be completed within six months of the initial hire date.
- 40-05(D)(5) – Removed the reference to an hours on site requirement as this was removed in 40-05(B).
- 40-11(B) – Removed specific toxicology completion requirements and aligned OAC with 42 CFR 8.12(f)(6).
- 40-11(I) – Removed this section to eliminate duplicity as this is already addressed in 40-14.

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?

The proposed rule changes are based on changes to federal regulations and feedback from Ohio providers.

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.

NA

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

The Department works with the Board of Pharmacy, the State Medical Board, and the Board of Nursing to ensure that these rules do not overlap with other regulations.

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 Department will communicate the proposed changes to the OTP providers and work with them in implementing changes in response to these rule amendments.

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

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.

The rule changes impact all OTP operators in Ohio (currently, there are 125 licensed OTPs). Generally, the rule changes are permissive in nature, in that operators will be able to do more than current rules allow. OTPs will be able to operate closer to the federal minimum guidelines and will experience a reduction in operating expenses due to the increased flexibility in operational and personnel areas.

There is no licensure fee to operate an OTP in Ohio and the new proposed rules are not adding a fee. There is, however, a fee for each OTP to participate in the central registry which is referenced in rule 5122-40-08. Every state has a central registry, which is intended to keep patients from enrolling in more than one OTP (more information on central registries is in the *Federal Guidelines for Opioid Treatment Programs*, available here: https://store.samhsa.gov/product/Federal-Guidelines-for-Opioid-Treatment-Programs/PEP15-FEDGUIDEOTP. Ohio, like 16 other states, contracts with Lighthouse Software Systems, LLC, to participate in the central registry they operate. Currently each OTP pays a central registry fee of $1,800; the fee may be increased each year to account

for inflation and cloud expenses incurred by Lighthouse.

16. **Are there any proposed changes to the rules that will <u>reduce</u> 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, these rule changes reduce burdens on OTPs by providing greater flexibility with personnel, allowing for increased usage of medication units, and through new dosing and counseling parameters.

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

    The adverse impacts are justified because the rules ensure the health and safety of OTP patients, as well as the safety of OTP staff and the communities in which they are located. Moreover, federal regulations require OTPs to be licensed by the state in which they operate (see U.S. Substance Abuse and Mental Health Services Administration, *Certification of OTP Programs (OTPs)*, available at https://www.samhsa.gov/medications-substance-use-disorders/become-accredited-opioid-treatment-program; 42 C.F.R. part 8).

    As stated above, under the proposed amended rules, OTPs will be able to operate closer to the federal minimum guidelines and will experience a reduction in operating expenses due to the increased flexibility in operational and personnel areas. The Department believes that these changes will allow for expansion of the availability of OTP services.

Regulatory Flexibility

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

    NA

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 Department prefers to work with licensees wherever possible in order to prevent disruption of services.

20. **What resources are available to assist small businesses with compliance of the regulation?**

The Department has dedicated OTP staff who are available to work with any OTP regarding these rules.