Ohio | 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:

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

Opioid Treatment Program Rules

Rule Number(s): 5122-40-01, 5122-40-03, 5122-40-04, 5122-40-05, 5122-40-06, 5122-40-07, 5122-40-08, 5122-40-12, 5122-40-15

Date of Submission for CSI Review: January 29, 2021

Public Comment Period End Date: February 19, 2021

Rule Type/Number of Rules:

New/___ rules **No Change/____ rules (FYR? ___)**

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 _X__) **Rescinded/____ rules (FYR?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

   The Department is updating the Opioid Treatment Program (OTP) licensure rules to be more effective and reduce some administrative requirements.

   Date references that are no longer applicable are being removed in 5122-40-01, 03, 04, 08.

   5122-40-03 also adds a loss of other regulatory required certifications to the list of reasons why licensure may be revoked.

   5122-40-05 adds a new certification to those that can be used to satisfy Medical Director requirements, a new formula for Medical Director time at each location is introduced which allows for more flexibility in how the time on-site requirements are met, the

personnel on-site requirement is being updated to allow more types of clinician to meet requirements and allow for flexibility in how time on-site requirements are met.

5122-40-06 is being revised to add buprenorphine which was left off previous versions.

5122-40-07 is having a section removed that is duplicative of material in 5122-40-05.

5122-40-08 is being revised to update monitoring requirements, including requiring providers check central registry in a specific time frame.

5122-40-12 adds buprenorphine as a required supply for disaster scenarios.

5122-40-15 adds a new location for medication units, a revision to provide for medication administration and personally furnishing of medications and adds provisions for telehealth in line with other telehealth requirements.

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.

   Yes, OTP licensure is done in conjunction with Unites States Drug Enforcement Agency (DEA) and Substance Abuse and Mental Health Services Administration (SAMHSA) requirements. Ohio licensure requirements are within the requirements set forth by federal law and the regulations of those agencies.

5. **If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

   Ohio OTP licensure requirements implement some provisions that left to state level control. This includes the medical director and other personnel on-site time requirements that are the subject of the primary rule changes in this package. Ohio rules are tailored to meet Ohio needs and history with OTPs.

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)?**

   OhioMHAS is required by ORC 5119.37 to create the OTP licensure program, and these rules are in keeping with federal requirement and standards.

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

OhioMHAS will monitor OTPs and communicate with stakeholders to assess that changes in the rules will allow for broadening of the OTP availability.

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 Department has met or communicated with the following stakeholders at various times of the past six months:

   DEA
   SAMHSA
   Nursing Board of Ohio
   Baymark
   Brightview
   CAAA
   Central Community Health Board
   CHC Addiction Services
   Crossroads
   Community Medical Services
   CompDrug
   DeCoach
   Maryhaven
   New Seasons
   Pinnacle
   Sunrise
   Ohio Council of Behavioral Health & Family Services Providers

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

    The stakeholders listed above had provided a great deal of feedback and input on the rules in this package. The work with stakeholders was primarily concerned with rule

5122-40-05. The additional certification for medical director qualifications in paragraph (B)(1) was added due to stakeholder requests. The Department has worked with stakeholders to alleviate concerns over the time on-site requirements for Medical Directors and other personnel in this rule. Due to stakeholder conversations the requirements for medical directors in paragraph (B) and the other changes in paragraph (D) have been changed to allow for more flexibility in the time on-site and physician-patient meeting requirements.

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?**

    N/A

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?**

    The Department has worked with stakeholders in finding alternative methods of resolving health and safety concerns. The time on-site changes are the reflection of those discussions.

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.***

    Due to health and safety concerns for patients, many areas of OTP practice must be proscribed by rule.

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

    The Department coordinates with other agencies to avoid regulatory overlap.

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 Department will communicate changes to OTPs and work to assure that they are aware of the rule changes; in particular to the areas that allow for more flexibility in personnel matters.

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**

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

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.

The rule package will impact all OTPs

Changes in the package are to allow more flexibility. OTPs will need to be aware of the need to have adequate medication supplies as required by 5122-40-15, and there will be an initial cost to the business if medication supplies must be increased. The increase should be reasonable and not a long-term increase as OTPs should only need to increase shelf stock.

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

The Department is required by statute to create a licensure program for OTPs.

Regulatory Flexibility

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

No, business size is not applicable to these types of regulations.

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 will work with OTPs on minor first offenses and paperwork related issues. The enforcement preference is technical assistance in order to have this service provided.

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

The Department has staff dedicated to OTPs and works closely with them to assist with any issues.