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 Update

Rule Number(s): 5122-40-01, 5122-40-06, and 5122-40-09.

Date of Submission for CSI Review: 11/8/21

Public Comment Period End Date: 12/1/21

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 _X__) **Rescinded/____ rules (FYR?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

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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.

   5122-40-01 is being updated to include a definition of telemedicine and to update the definition of Opioid Treatment Program (OTP) to change the word "using" to "dispensing".

   5122-40-03 is being updated to implement new license terms for the amended ORC 5119.37.

   5122-40-06 is being amended to change "medication assisted treatment" to "medication administration". Providers are referred to as prescribers, a more expansive definition. The requirements for take-home dosing will include the requirement that policies and procedures are individualized to each patient. Paragraph (S) is being added to allow for medication at other locations.

   5122-40-09 is being amended to separate and update telehealth requirements for OTPs.

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.

   The OTP program, OAC Chapter 5122-40, works in coordination and partially under the authority of federal opioid regulations.

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

   Chapter 5122-40 does not exceed federal requirements.

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 in order protect 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 OTP's for issues necessitating changes in license term, and working to minimize those events. The Department will also be monitoring for improvements in the use of telehealth and take home dosing.

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 initial draft of most of the rules were reviewed at the SUD 1115 Waiver Meeting on May 3rd, 2021. This committee is composed of ADAMHS Boards opioid treatment programs, and other behavioral health providers across the state of Ohio.

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

    The stakeholders did not provide any feedback on the draft rules.

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?**

    NA

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?**

    NA.

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.***

    NA

14. **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 to assure that these rules do not overlap with Pharmacy regulations. The changes to wording in these revisions are in part a response to that work.

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

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.

These rules impact every OTP provider in Ohio, and OTP's will need to account for employee time needed to adjust to these changes. These changes will clarify some parts of the OAC that were vague, align OTP OAC with changes in other behavioral health-related OAC for the Medicaid 1115 Waiver, and clean up language.

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

The changes in these rules are meant to expand the work that OTP's conduct.

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.