CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Mental Health and Addiction Services

Regulation/Package Title: Opioid Treatment Program License

Rule Number(s): Chapter 5122-40, inclusive of all rules including new rule 5122-40-15

Date: May 25, 2018

Rule Type:

- **X New**
- **X Amended**
- ☐ **5-Year Review**
- ☐ **Rescinded**

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. **Please briefly describe the draft regulation in plain language.**
   Please include the key provisions of the regulation as well as any proposed amendments.

   The current methadone licensure rules in OAC Chapter 5122-40 were updated in June of 2017, concurrent with a change in statutory authority. The statutory authority in

ORC 5119.391 expanded the scope of the methadone licensure program and the rules were updated to reflect that change. The Department has worked with providers to review rules in the time since the rules were adopted and is proposing the following changes to enhance the ability of licensees to provide this service.

Additionally, HB 111 will expand the scope of the license program from methadone to an opioid treatment program license. Many of the proposed changes in this rule package reflect are the result of the change in that statutory authority and are being put out for public comment now to bring updated rules online as close as possible to the effective date of the statutory change.

The proposed rule changes are:

All rules in Chapter 5122-40 are being updated to modify the methadone license to an OTP license, and language changes are made throughout.

5122-40-01 – Definitions are added for the change to OTPs and for the medication unit addition.

5122-40-03- A clarification has been added that a renewal application must be received ninety days prior to the end of the current license.

5122-40-04 – A provisions regarding "good standing" documentation have been added, as "good standing" is now a statutory requirement. A clarification to the geographic restriction has been added due to statutory change.

5122-40-05 An additional certification for the medical director was added, as well as a provision for a co-medical director. A clarification on how often a physician should meet with patients has been added.

5122-40-06 Nurse practioners are added to the list of personnel who can dispense. Clarifications around take-home doses and closing days are added, in line with federal regulations.

5122-40-07- Providers are required to have policies and procedures regarding patient transfer, and two new tests are added to the medical tests.

5122-40-08 – The reporting time for the central registry is changed to 24 hours to assist with patient transfers. Requirements for new patients who state they are receiving treatment elsewhere are changed to require educational material and request transfer of records.

5122-40-09 – Incentives has been removed from the list of services and activities.

5122-40-13 – New information is required for central registry data, and the time for entry is set at the sixth working day to facilitate patient records and transfers.

5122-40-15 – This is a new rule that creates medication units that providers may use away from their main location in certain underserved areas. The units must still meet all requirements and remain under the authority of the main provider location.

2. **Please list the Ohio statute authorizing the Agency to adopt this regulation.**

   ORC 5119.37 and 5119.371

3. **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.

   No, although the regulation, and its authorizing statute, work in conjunction with federal requirements regarding the use of controlled substances such as methadone.

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

   The changes to the rules in OAC 5122-40 are not intended to exceed the federal requirements, they work within the parameters set by federal and state statutory authority.

5. **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)?**

   The Department is required to license opioid treatment programs, per ORC 5119.37, to assure the safety and effectiveness of these programs.

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

   The rules have reporting requirements that will be monitored for effectiveness of the programs and regulatory requirements are adjusted as necessary.

Development of the Regulation

7. **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.

   Ohio's OTPs were consulted through regularly scheduled provider meetings. The material changes in this package were initial presented in February 2018.

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

Stakeholders provided information on medication units and a proposed transfer policy. The medication units rule that is being proposed is the result of stakeholder input regarding the locations of medications units; both in the how the description of the urban units is phrased and the definition of the rural units was arrived at. Stakeholders also provided input on how telehealth services should be included in the rule.

9. **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?**

   Not applicable.

10. **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 initial proposed a transfer rule to address issues relating to patient transfers and the availability of records. After consultation with stakeholders the Department dropped the proposed rule and is clarifying existing rules regarding records.

11. **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.***

    Not applicable.

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

    The Department consults with the Ohio Pharmacy Board to prevent overlapping regulations regarding these types of programs.

13. **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 changes in the licensing program will be communicated through the Department's scheduled quarterly open meetings with all OTPs and provided to all OTP license applicants.

Adverse Impact to Business

14. 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;
Any provider of opioid treatment as defined by ORC 5119.37

b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and
The impact will primarily be in employer time.

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.

Most changes in the rule package are either to accommodate the change from methadone to OTP or are expanding the scope of allowable activities. New providers will be able to obtain licenses or existing providers will no longer be hindered by some unintended consequences of last year's initial rules. The medication units do not impose a burden, but rather allow for expanded operations.

Providers will need to spend some time reviewing and overseeing the implementation of their records policies regarding transfers. This is not expected to be a major source of time.

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

The changes in this rule package that are not the result of a statutory change are the result of requests from stakeholders for improvements to the OTP license requirements. Changes will allow for an increase of scope of operations.

Regulatory Flexibility

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

Not applicable.

17. 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?

Violations that do not impact patient health and safety will be addressed with education; other issues will be addressed on a case-by-case basis. The goal of the licensing program is to make treatment available but in a safe manner, and enforcement will be focused on operational violations that are reoccurring or serious in nature.

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

    Providers will be able to take advantage of both the SOTA and the Department's licensure and certification office for education on new requirements.