CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Mental Health and Addiction Services

Regulation/Package Title: Methadone Medication Licensure Program

Rule Number(s): 5122-40-01 to 5122-40-14, 5122-26-13, and Replaces 5122-29-35.

Date: February 17, 2017, Revised March 07, 2017

Rule Type:

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- **X Rescinded**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

   Senate Bill 319, of the 131st General Assembly, amended sections 5119.391 and 5119.392 of the Revised Code. Those sections are Ohio's methadone medication licensure

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117
CSIOhio@governor.ohio.gov

program as administered by the Department of Mental Health and Addiction Services (Department). SB319 changed the requirements for becoming a licensed methadone provider by eliminating the requirement to be a private, nonprofit entity; and removing the requirement to be certified as service provider by the Department for two years prior to licensure as a methadone provider. Section 5 of the Bill also requires the Department to adopt rules revising the requirement of methadone licensure by June 1, 2017 or cease issuing licenses until the rules have been adopted and are in effect. The Department is required to include in the revised rules that the licensed programs are in good standing with several governmental bodies, is in good standing in any other jurisdiction in which the provider is providing similar methadone treatment services, and is able to meet nationally recognized standards of treatment.

The Department has an existing rule, 5122-29-35, which has not been revised since 2010. The Department is taking this opportunity to update the licensure program with current practice. The single rule has been broken into separate rules for ease of use. Rule 5122-29-35 will be rescinded and replaced with Chapter 5122-40.

The rules and relevant major points are:

5122-40-01: Definitions and applicability. This rule sets the definitions to be used in the Chapter and the how the licensure program applies to providers.

5122-40-02: SOTA authority. The Federal Substance Abuse and Mental Health Services Administration

5122-40-03: Issuance of licenses. This rule sets forth the general procedures under which the Department may issue licenses, and non-treatment related items for providers. Included in this rule is the requirement that the license must be displayed, that it is site specific and cannot be transferred, and that the Department may conduct surveys and have access to records. The rule also lists the conditions for which the Department may revoke or refuse to issue a license, and the procedures to be followed when that occurs.

5122-40-04: General licensure requirements. This rule lists the actual requirements for a provider to obtain a license. The provider must meet certain prerequisite certifications from the Department and other agencies prior to licensure to work with methadone; and the provider must be in compliance with statutory distance requirements.

5122-40-05: Personnel. This rule sets the minimum management and clinical personnel needed by each program. This will include a program sponsor, medical director, and program administrator. The duties and continuing education requirements are specified, along with allowances for physician extenders and requirements for background checks for staff who have access to methadone.

5122-40-06: Methadone Administration. This rule sets the conditions under which methadone can be administered or dispensed to individuals. The authorized staff for each type of distribution is listed, as well as requirements for labeling, hours of distribution, and take home dose procedures.

5122-40-07: Program polices and patient records. This rule lists the required policies or procedures that each methadone program must have in place. These policies cover admission of patients, physical security requirements, hours of operation, and staffing and other items directly related to the clinical use of methadone. The rule also sets forth the required records for each patient.

5122-40-08: Monitoring program. The monitoring program refers to both the state's prescription drug monitoring program maintained by the state board of pharmacy and a newly implemented central registry system used only for methadone. The prescription drug monitoring program is used by the methadone program as source to review where patients have been seeking prescription medication. The central registry will be used by programs to enter information about patients, and to check for multiple methadone program enrollments. The central registry is allowed under 42 C.F.R. part 2, and will eliminate a time and resource intensive system of faxing between programs.

5122-40-09: Non-medication services. This rule describes the services to be provided to program patients which are not methadone related. This includes counseling, medical services, and assessments.

5122-40-10: Diversion. This rule sets requirements for each program with regards to diversion of controlled substances. There are requirements for recordkeeping, secure storage, handling, and staff access to methadone.

5122-40-11: Urinalysis. This rule sets forth the procedural requirements for testing patients for drug usage.

5122-40-12: Disaster plan. This rule requires programs to have disaster plans in place for the provision and continuity of service to patients.

5122-40-13: Evaluation activities. This rule sets forth requirements for each program to measure progress and submit evaluation data to the Department.

5122-40-14: Withdrawal. This rule describes the two types of withdrawal from programs: administrative or medical. Administrative withdrawal is an involuntary removal stemming from misconduct or incarceration. Medical withdrawal is voluntary and is an agreed upon procedure by patient and staff. In both cases there are procedures in the rule to follow in order to protect the health and safety of the patient.

5122-26-13: Incident notification and risk management. As part of an effort to make the methadone program rules as efficient and compact as possible, any duplication of the

certified service provider rules was eliminated. As a result, the appendix for incident notifications needs to be updated with two types of incidents that are more common in methadone settings. The incidents are medication diversion and selling drugs on the premises of the provider. No other change is being made to this rule.

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

   ORC 5119.391 and SB 319, Section 5.

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. Several of the changes stated in the draft regulation bring the states regulation in compliance with 42 CFR part 8.

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

   Technically, the central registry used for that checks for multiple program enrollments exceeds federal requirements. Although checking for dual enrollment is mandatory, the federal government only specifies faxing. Stakeholders across the state have recommended this change because of the labor intensive nature of faxing new client information every day to all OTP programs within 100 miles.

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 wanted to update this regulation to 1) bring it in compliance with current federal standards and 2) clarify standards for all Opioid Treatment Programs (OTP) across the state. The DEA, SAMHSA, the State of Ohio Board of Pharmacy, and the Department are all part of initial and annual licensure of OTPs. Unfortunately, four licensing authorities creates a complicated network of regulation, which causes confusion among OTPs. These organizations along with the State of Ohio Medical Board and OTPs were all involved in a process to revisit old regulation, update it, and give clarity to issues of concern for all parties involved. All stakeholders that were part of the process have responded favorably to the update process.

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

The Department's licensure and certification division along with the SOTA will be responsible for monitoring the success and outcomes of the proposed regulation. For example, the licensure and certification division will ensure that urinalysis and incident reporting policies are adhered to in practice, and the SOTA will ensure the evaluation activities are used in quality improvement processes for patients.

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.

   The following stakeholders reviewed drafts of regulation on December 1, 2016 and January 5th 2017 in live 2-hour meetings. Communication also frequently occurred via email and phone calls.

   - **Drug Enforcement Administration (Cleveland and Cincinnati Divisions)**
   - **Substance Abuse and Mental Health Services Administration**
   - **State of Ohio Board of Pharmacy**
   - **State of Ohio Medical Board**
   - **Central Community Health Board, a methadone OTP**
   - **CompDrug, a methadone and buprenorphine OTP**
   - **Health Recovery Services, a methadone and buprenorphine OTP**
   - **Sunrise Inc., a buprenorphine OTP**

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

   The Department received verbal and written input into the draft regulation. The Department incorporated most of the changes recommended by the community as long as they did not conflict with existing federal or state regulation.

   Changes made due to stakeholder meetings include:

   - **Clarified role of state authority and made language in 5122-40-02 more explicit regarding the position's duties.**
   - **Stakeholder's expressed concerns at meetings regarding the amount of time a medical director would be required to be onsite at a program. Finding qualified**

doctors to act as medical directors can be difficult, especially considering rural locations. Various ideas regarding site versus regional director schemes were discussed. The compromise position is in the rule, requiring medical directors to be on site for fifty percent of the time the program is open. This would allow rural programs to use doctors at more than one site, and still balance out the required duties at each location.

- **The time for medical directors to complete a plan to attain competence in opioid treatment was extended to twenty-four months, and inserted waiver authority for the Department if a medical director is unable to schedule examinations.**
- **Removed the statement of need from the license application. While this is information that it is helpful for programs to have and work through, it is not part of the statutory requirements for a methadone license.**
- **The language regarding the coordination between the Department and this license and SAMHSA accreditation in 5122-40-04 was revised to be clear that accreditation is first.**
- **The original draft of 5122-40-05 had unrealistic standards for the experience of program administrators. The requirement has been revised from a master's degree in a relevant field and four years' experience, to just the degree requirement.**
- **The requirement in 5122-40-05 for a background check for all staff has been revised to require checks of only those with access to medication. This is in keeping with standards at the Federal level.**
- **In 5122-40-08, positive drug test was changed to a positive drug test inconsistent with the patient's treatment plan.**

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?**

   No data was used in the development of these rules. OTPs provided anecdotal reports of having to fax their sister agencies inside and outside of the state for 1.5 hours a day, six days per week.

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 did review OTP and methadone regulations from a number of states and has incorporated alternatives where appropriate.

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's legal and licensure and certification teams reviewed existing regulations to assure there was no duplication.

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 Department has already notified OTPs that regulation changes are in process. The Department also will hold trainings on regulation changes at OTP quarterly meetings. Legal and licensure and certification teams along with the SOTA will be available to discuss changes with OTPs outside of quarterly meetings. The vendor of the central registry will be meeting with each agency individually to hold trainings.

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;**
    b. **Identify the nature of the adverse impact (e.g., license 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 scope of the impacted business community is any community addiction services provider who wishes to employ methadone treatment or prescribe, administer, or dispense methadone. While community addiction services provider is a defined term under ORC 5119.01 that limits the term, the effect of Federal regulation of methadone means that any business that wishes to engage in methadone medication in Ohio will be required to adhere to this licensing program.

    The Ohio MHAS licensed methadone providers are concurrently regulated by SAMHSA and the US DEA. The Department has worked to eliminate duplicative requirements or requirements that are better suited to be inspected

and enforced by another agency. Some items are repeated in order to give the Department enforcement authority if necessary.

- **Provider programs are required to adhere to set policies and procedures regarding personnel, the administration of methadone, and the record-keeping for patients. This includes minimum hours of operation, requirements for take-home dosing, minimum qualifications for staff, and tracking patients through their methadone treatment. These requirements have an initial cost but are part of the cost of doing business as a methadone provider; as without these safeguards methadone providers become unsafe businesses.**
- **The most direct and immediate impact for all methadone programs will be the annual fee. The fee is intended exclusively to support the dual enrollment monitoring system implemented in rule 5122-40-08. The fee shall be no more than the cost of the system passed on to each provider. The Department will contract with a vendor to provide the system. By utilizing a single computerized system to track enrollments, providers will no longer be required to use the time consuming and inefficient fax method. Currently, providers must send individual faxes to any other provider within a fifty mile radius to confirm that a new patient is not enrolled at one of those programs. This is a time-consuming and resource intensive process. The computerized system is anticipated to cost $100 a month per program. The Department will pass this cost on to each program as an annual license fee, which will be set and announced at the time the vendor is contracted.**
- **The background check in 5122-40-05 will be an expense for programs. Typically background checks can be obtained from third-party providers for between $35-50. These checks are limited to those employees who have access to methadone medication and are required by other regulating entities.**
- **The rules requiring monitoring of diversion, evaluation of the program outcomes, and drug testing of patients are all impacts to the programs but are also considered a cost of doing business as these activities help to keep the both the program and the patients safe from illegal drug activity centered on the program site.**

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

    The Department is trying to balance the health and safety of patients at methadone programs with the programs business interests in the face of multiple regulatory

schemes. Impacts to the business such as record-keeping, personnel requirements and the statutorily required annual inspections are intended to set minimum standards for patient care. Whereas the requirements around the administering, dispensing, and storage of methadone are intended to not only address patient care but safety of patients, staff, and the community.

The Department is aware that background checks are tangible cost but are not only a federal requirement for providers; they are sensible precaution to insure that those staff with access to the methadone are meeting a minimum level for access.

The most direct cost to providers, the central registry system, is a long-term cost reduction for methadone providers. The current system is a time and money consuming system of faxing for each patient to each program within a fifty mile radius. The central registry will for a minimal cost eliminate the faxing and allow providers to enter patient information once. The Department is taking the lead and acting as the hub of the system, which is why the costs are being passed on in the form of an annual license fee.

Regulatory Flexibility

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

    No, the licensing requirements most be applied equally across all providers.

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, and the central registry vendor will be providing individualized training to bring that system into production.