MEMORANDUM

TO: Howard Henry, Ohio Department of Mental Health and Addiction Services

FROM: Tess Eckstein, Regulatory Policy Advocate

DATE: March 17, 2017

RE: **CSI Review – Methadone Licensure Program (OAC 5122-26-13, 5122-29-35, 5122-40-01 through 5122-40-14)**

On behalf of Lt. Governor Mary Taylor, and pursuant to the authority granted to the Common Sense Initiative (CSI) Office under Ohio Revised Code (ORC) section 107.54, the CSI Office has reviewed the abovementioned administrative rule package and associated Business Impact Analysis (BIA). This memo represents the CSI Office's comments to the Agency as provided for in ORC 107.54.

Analysis

This rule package consists of 16 rules—14 new, one amended, and one rescinded—being proposed by the Ohio Department of Mental Health and Addiction Services. The rule package was submitted to the CSI Office on February 21, 2017, and the public comment period remained open through March 13, 2017. A revised BIA was submitted to the CSI Office on March 7, 2017. The rules have been proposed in response to recently-enacted Senate Bill 319, which mandates that the Department revise the methadone licensure program to meet new statutory requirements for licensure by June 1, 2017, including requiring that licensed programs are in good standing in any other jurisdiction in which the provider provides similar methadone treatment services, and that programs meet nationally recognized standards of treatment.

The proposed rules address topics such as general licensure requirements, personnel, medication administration, monitoring, diversion, evaluations, and withdrawal. Currently, all program requirements are contained in rule 5122-29-35. This rule is being rescinded and divided into 14 new rules (Chapter 5122-40) to improve ease of use. The new rules preserve much of the language from rule 5122-29-35 but also incorporate revisions that update the rules to be aligned with current practice. Another important revision being proposed requires Opioid Treatment Programs (OTPs) to participate in the central registry for dual enrollment, guest dosing, disaster planning, and administrative efforts. While checking for dual enrollment is mandatory by federal standards, no

system currently exists that can compile necessary information that must be shared among OTPs. Finally, rule 5122-26-13, the sole amended rule, has been revised to update incident reporting appendices to make the methadone program as efficient and compact as possible.

The rules impact all OTPs that employ methadone treatments, or that prescribe, dispense, or administer methadone for the treatment of opioid addiction. Potential adverse impacts of the rules include submitting licensing applications; providing quarterly evaluation data that allows the State Opioid Treatment Authority (SOTA) to measure aggregate patient progress; developing or approving policies and procedures for important program details, such as take-home doses, patient admission, and dispensing and storing medications; maintaining continued education; employing required personnel; obtaining criminal records checks of all staff with access to methadone; retaining required records; participating in the central registry, and paying a monthly fee for it of approximately $100; submitting written patient evaluations; developing a quality improvement plan, disaster plan, diversion control plan, and relapse prevention plan; and providing patients with required information, counseling, training, and a naloxone kit (or a prescription for one). Finally, failure to comply with the rules could lead to having a license revoked, denied, or withdrawn, or the Department has the ability to permit an OTP to develop a plan of correction with monitored implementation.

The Department indicated in the BIA that these adverse impacts are justified because the rules ensure the health and safety of patients of OTPs, as well as the safety of staff and the community. In addition, the proposed amendments bring this regulation into compliance with current federal standards and clarify standards for all OTPs across the state. Finally, the rules relieve OTPs of the labor and time-intensive nature of faxing new client information daily. For a minimal fee, the central registry eliminates faxing and allows providers to enter patient information once.

The Department sought comment on the drafted rules from multiple stakeholders in December 2016 and January 2017: the Drug Enforcement Administration (Cleveland and Cincinnati Divisions), the Substance Abuse and Mental Health Services Administration, the State of Ohio Board of Pharmacy, the State of Ohio Medical Board, and several OTPs throughout Ohio. From these distributions, the Department received verbal and written input. Most stakeholder recommendations were incorporated into the rules, as long as they did not conflict with existing federal or state regulations, before the rules were submitted to the CSI Office. Some of these revisions include reducing the amount of time that a medical director is required to be on-site at an OTP, clarifying the role of the SOTA, extending the time that medical directors are allowed to complete a plan to attain competence in opioid treatment, and limiting required background checks to those with access to methadone.

During the CSI public comment period, 10 comments were submitted. The Department subsequently provided the CSI Office with responses to each comment, detailing revisions it had made to the rules to implement many stakeholder recommendations, as well as its rationale for not implementing others. While the Department made revisions to many rules, some key revisions include modifying a requirement for a medical director to be on-site at the OTP for 50 percent of the time that the facility is open to 50 percent of the time that the program is administering or dispensing methadone; eliminating the requirement for a program administrator to have a Master’s degree, but adding that

those with only a Bachelor's degree must also have two years of work experience in a related field; adding an exception for a requirement to provide each patient with a naloxone kit to allow OTPs to instead provide patients with a prescription for the naloxone kit; changing the required ratio of counselors to patients from 1:50 to 1:65, while clarifying that the ratio applies to full-time equivalent individual counselors, not an average across a program; and eliminating a required frequency of counseling sessions after a patient's first 90 days of treatment. It also implemented all suggestions for grammatical changes, and revised language to enhance clarity where requested.

As for instances in which rationale was offered for other recommendations not being implemented, the Department explained that it did not require specific courses or development plan components because it expects competency plans to vary and wants doctors to personalize them to best meet program and patient needs. The Department also defended its inclusion of a recommendation (not a requirement) to monitor blood serum levels in pregnant patients because of new research presented by the American Association for the Treatment of Opioid Dependence, which found that the amount of methadone taken by a patient may need to be decreased after pregnancy, when pre-pregnancy metabolism levels return, so blood serum levels remain clinically appropriate. Furthermore, the Department is not willing to remove a requirement that patients be monitored while toxicology screening specimens are collected, since temperature checks and other methods for detecting fraudulent samples may not be fully adequate to prevent falsification.

Following its review of the Department's response to comments, the CSI Office recommended further revisions to six rules, all of which the Department implemented. Many of these suggested revisions were based on a reconsideration of recommendations submitted by stakeholders that had not already been implemented. For example, the Department added a formal definition for "program administrator;" revised vague language (e.g. a requirement for "supervision on a regular basis" was changed to "direct supervision at least once a week"); removed several sections mirroring take-home dosing language in 42 CFR 8.12 and replaced them with a reference to the federal regulations; added a paragraph in the rule pertaining to program evaluation that explicitly states that publically available reports will be presented in aggregate form, so that no patient or OTP can be identified. Having reviewed each of the Department's proposed revisions, the CSI Office considers all concerns to have been satisfactorily addressed and determines the purpose of the rules to be justified.

Recommendations

For the reasons discussed above, the CSI Office does not have any recommendations for this rule package.

Conclusion

Based on the above comments, the CSI Office concludes that the Ohio Department of Mental Health and Addiction Services should proceed with the formal filing of this rule package with the Joint Committee on Agency Rule Review.

cc: Mark Hamlin, Lt. Governor's Office