Common Sense Initiative

Mike DeWine, *Governor*
Jon Husted, *Lt. Governor*
Joseph Baker, *Director*

MEMORANDUM

TO: Lisa Musielewicz, Ohio Department of Mental Health and Addiction Services

FROM: Caleb White, Business Advocate

DATE: October 30, 2024

RE: **CSI Review – OTP 2024 Update (OAC 5122-40-01, 5122-40-02, 5122-40-03, 5122-40-04, 5122-40-05, 5122-40-06, 5122-40-07, 5122-40-08, 5122-40-09, 5122-40-10, 5122-40-11, 5122-40-12, 5122-40-13, 5122-40-14, and 5122-40-15)**

On behalf of Lt. Governor Jon Husted, 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 nine amended rules and six no-change proposed by the Ohio Department of Mental Health and Addiction Services (OMHAS) as a part of the statutory five-year review process. This rule package was submitted to the CSI Office on May 3, 2024, and the public comment period was held open through May 17, 2024. After the initial comment period, OMHAS further amended the rules and reopened the rules for a second comment period beginning on August 16, 2024, and ending on August 30, 2024. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI Office on August 16, 2024.

Ohio Administrative Code (OAC) 5122-40-01 establishes the definitions and applicability of the chapter. This rule is amended to add, remove and update definitions. OAC 5122-40-02 requires OMHAS to designate an individual within the department to serve as the state opioid treatment authority and lists the powers and duties of this position. OAC 5122-40-03 establishes the process for obtaining an opioid treatment program (OTP) license as well as the duration, requirements, stipulations, and reasons for the denial or revocation of a license. OAC 5122-40-04 establishes the requirements an applicant for an OTP license must meet to obtain or renew a license and outlines

certain geographical restrictions for the location of the OTP. OAC 5122-40-05 establishes personnel requirements for OTPs. This rule is amended to align the requirements for medical directors, program administrators, and mid-level practitioners with federal requirements. These changes include removing certification requirements for medical directors, reducing the onsite requirements for medical directors, allowing medical directors to serve more OTPs, adjusting the duties of program directors and administrators, updating terminology, removing outdated, redundant or unnecessary language, and correcting typographical errors. OAC 5122-40-06 establishes the requirements for the administration of medication by OTPs. This rule is amended to increase flexibility surrounding the administration of medication by adjusting the requirements surrounding take-home supplies of medication and emergency dosing and expanding who may supervise medication administration, aligning language with both federal regulations and that of the Ohio Board of Pharmacy, as well as to reformat, correct update, and streamline language. OAC 5122-40-07 establishes requirements surrounding the program policies of OTPs and the maintenance of their patient records. This rule is amended to update terminology and admission criteria, clarify language related to counselor to patient ratios, update references, as well as to update and streamline language. OAC 5122-40-08 establishes the requirements related to information to be reviewed in the state's drug database, information to be reported to the central registry, and how patient information is to be obtained and handled. This rule is amended to add a requirement related to contact information, update terminology, as well as to reformat, update, and streamline language. OAC 5122-40-09 establishes the non-medication services OTP providers are required to offer. This rule is amended to update a reference, update and clarify the requirements regarding counseling sessions, as well as to reformat, update, and streamline language and more closely align it with federal regulations. OAC 5122-40-10 establishes requirements surrounding diversion control plans and pharmacy procedures. This rule is amended to add additional signature options for medical directors regarding the list of employees authorized to receive medication deliveries, and update references, as well as to update and streamline language. OAC 5122-40-11 establishes requirements related to toxicology screenings. This rule is amended to align the rule with federal toxicology requirements in addition to updating and streamlining language. OAC 5122-40-12 establishes requirements related to disaster plans. OAC 5122-40-13 establishes the information that is required to be submitted to the central registry system and requires the central registry system to make this information available to OMHAS. OAC 5122-40-14 establishes the process and requirements surrounding withdrawal from an OTP. OAC 5122-40-15 establishes requirements for medication units. This rule is amended to remove geographic restrictions for medication units, require mobile medication units to be located at least five miles from the nearest OTP, add clarification around tele-counseling requirements align medication unit personal requirements and responsibilities with those in OAC 5122-40-05, as well as to update and streamline language.

During early stakeholder outreach, OMHAS shared the proposed rules with the OTP stakeholder group and with several state entities. The OTP stakeholder group consists of 326 members that are

directly involved with an active OTP. Based on the feedback received during the early stakeholder outreach period, OMHAS amended the rules to remove medical director certification requirements, reduce onsite requirements for medical directors, remove the upper limit on the amount of OTPs that can be served by a single medical director, remove a requirement for certain counseling sessions, and remove requirements surrounding the geographical location of both mobile and non-mobile medication units.

During the first CSI public comment period, OMHAS received five comments regarding the rules. In response to these comments, OMHAS amended the rules to add definitions for "mobile and non-mobile medication units," "correctional facility," "personally furnish," "prescriber," and "program prescriber," eliminate the requirement for a medical director to be present two times a month, update position titles and duties, update terms, eliminate certain patient visit restriction differences between certified nurse practitioners and physicians, align language for dispensation of medication with that of the Board of Pharmacy, align language with federal requirements, add clarifying language, regarding contact information, telecounseling, OTP locations, and counseling sessions, align staff responsibilities between OTPs and medication units, as well as to correct references, typographical errors, and reorganize, update and streamline language.

During the second CSI public comment period, OMHAS amended the rules to remove unnecessary use of the term "licensed" in the rules, remove a provision to eliminate confusion, remove an outdated reference, clarify that a program director may delegate certain duties, clarify training timelines, remove a reference to a requirement that has been removed, align toxicology testing requirements with federal regulations, and eliminate duplicative language. Other changes were not made in response to comments related to delegation of duties, a requirement for medical directors to be present at OTPs two times a month, the telephone availability of a program prescriber, follow-up appointment frequency, prior authorization requirements, methadone serum testing on pregnant women, detoxification, primary care counselor ratio requirements, information reported by the OTP, records requirements, telehealth references, eliminating counseling provisions, and theft reporting requirements. These changes were not made as MHAS determined they would create confusion, make the rules stricter than federal requirements, violate federal regulations, be better left to the discretion of the prescriber, were unnecessary, not evidence-based practices, or only required clarification. After the CSI public comment periods, OMHAS also amended OAC 5122-40-09 to change a reference.

The business community impacted by the rules includes all OTP operators in Ohio which currently consists of 125 licensed OTPs. The adverse impacts created by the rules include reporting requirements, notification requirements, certain staff supervision requirements, policy requirements, procedural requirements, records maintenance requirements, staffing requirements, counseling requirements, signature requirements, and the requirement and associated fee to participate in the

central registry. Currently the central registration fee is $1,800. OMHAS notes that the changes to these rules will reduce the adverse impacts to business by more closely aligning with the federal minimal standards which will increase flexibility in operational and personnel areas. OMHAS states that the adverse impacts created by the rules are justified to ensure the health and safety of OTP patients, staff, and the communities in which they are located.

Recommendations

Based on the information above, the CSI Office has no recommendations on this rule package.

Conclusion

The CSI Office concludes that OMHAS should proceed in filing the proposed rules with the Joint Committee on Agency Rule Review.