



Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Joseph Baker, Director

MEMORANDUM

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

FROM: Michael Bender, Business Advocate

DATE: March 13, 2023

RE: **CSI Review – Opioid Treatment Programs Rules Update (OAC 5122-40-05, 5122-40-07, 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 Department as provided for in ORC 107.54.

Analysis

This rule package consists of three amended rules proposed by the Ohio Department of Mental Health and Addiction Services (Department). This rule package was submitted to the CSI Office on October 18, 2022, and the public comment period was held open through November 4, 2022. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI Office on October 18, 2022.

Ohio Administrative Code (OAC) 5122-40-05 provides for the personnel that work for an opioid treatment program (OTP), particularly program sponsors, medical directors, program administrators, physicians, physician extenders, and counselors. The rule is amended to update language, specify the requirements that must be met in order for an OTP to employ mid-level nurse practitioners (MLPs), and remove certain restrictions in order to expand the use of telehealth services. OAC 5122-40-07 sets forth the requirements for OTPs to adopt written policies and procedures as well as to maintain individual client records. The rule is amended to update language, add clarifying language regarding in-office and staff supervised cheek swabs, and remove language referencing the COVID-19 state of emergency declared by the Governor of Ohio. OAC 5122-40-15 allows OTPs to establish medication

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units. The rule is amended to allow the use of mobile medication units, specify the types of services that medication units are required or allowed to provide, expand the allowable use of telehealth services, and update language.

During early stakeholder outreach, the Department provided the draft rules to stakeholders in August 2022 via its administrative rules email list. Comments were received from the Ohio Association for the Treatment of Opioid Dependence (OATOD), Brightview Health (Brightview), and a private consultant. In response to the comments, the Department adjusted the rules to remove references to “stable patients” as they were unnecessary, add language regarding the use of MLPs to allow for the use of additional qualified personnel in OTP operations, clarify where OTP services could be provided, and indicate that wholesalers are included in approved sources of controlled substances. During the CSI public comment period, the Department received comments from CompDrug, the OATOD, Brightview, Community Medical Services (CMS), the Ohio Association of Advanced Practice Nurses (OAAPN), and Pinnacle Treatment Centers (PTC). Comments primarily focused on medication unit geographic requirements, medical director requirements, the definition of “mid-level practitioner,” central registry verification, the requirement for the medical director or program physician to meet with patients, and cheek swabs.

The OATOD, CompDrug, Brightview, and CMS asked for the removal of geographic restrictions on medication units. The Department denied this request, stating that removing these restrictions would negatively impact the availability of OTP services. The OATOD, Brightview, and CMS also asked the Department to remove the minimum on-site requirements for medical directors, citing workforce shortage issues. The Department rejected this suggestion as well, asserting that the requirement was necessary to assure proper supervision of programs and noting that feedback from OTP employees revealed sentiments of disconnection from management and good practices when medical directors were not on-site. CompDrug, Brightview, and CMS expressed support for the expanded scope of MLPs in OTP settings but also had concerns about the language used with respect to this issue, particularly the definition of “mid-level nurse practitioner.” The Department replied that their definition of a “mid-level nurse practitioner” is the same one used by the federal Substance Abuse and Mental Health Services Administration. Brightview also recommended adding paramedics to the list of professionals eligible to work in an OTP. The Department acknowledged that the idea has merit but needs further review. Additionally, Brightview urged the Department to clarify that central registry verification can be performed either at the primary OTP or the medication unit but need not be done more than once per patient enrollment. The Department agreed and revised the rules accordingly. The OATOD urged the Department to remove the requirement for the medical director or program physician to meet each accepted patient within seventy-two hours of admission, stating that this goes beyond federal requirements. The Department acquiesced and aligned the rule with federal standards, changing the seventy-two-hour requirement to two weeks. Lastly, PTC suggested changing the term “cheek swab” to state “oral fluid testing” instead. The Department revised the rules

to make this change. The Department declined to make changes in other areas of concern raised by the commenters, citing conflict with either federal requirements or the intent of the program's statutory authority in protecting the health and safety of OTP patients. Further discussions took place between CSI, stakeholders, and the Department regarding requirements that were not in the rules or statute, but which were included on the Department's application forms that OTPs use for MLP exemption requests and renewals. The stakeholders advocated for the removal of these requirements, stating that they posed a barrier to hiring more MLPs in an OTP setting. The Department agreed and revised the application forms to remove these requirements. The Department added that upcoming federal changes may possibly remove eliminate the need for the application entirely and expand the scope of practice for MLPs.

The business community impacted by the rules includes operators of OTPs. The adverse impacts created by the rules include requirements for the employment of certain personnel, requirements for the adoption of certain policies and procedures, and adjustment costs for operations such as the setup of mobile medication units. According to the Department, the changes to the rules will allow for the expansion of OTP services and are more permissive than what the rules currently allow. The Department states that the adverse impacts to business are justified to implement ORC requirements to license OTPs for the protection of the health and safety of patients.

Recommendations

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

Conclusion

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