Tennessee Society of Addiction Medicine
A Chapter of American Society of Addiction Medicine

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December 18, 2023

Krysten Velloff
Assistant Director
Division of Planning, Policy, and Legislation
Department of Mental Health and Substance Abuse Services
500 Deaderick St, 5th Floor, Andrew Jackson Building
Nashville, TN 37243

Re: Feedback on Chapter 0940-05-35 Minimum Program Requirements for Nonresidential Office-Based Opiate Treatment Facilities Amendments and Chapter 0940-05-42 Minimum Program Requirements for Non-Residential Opiate Treatment Program Facilities Amendments

Dear Ms. Velloff,

On behalf of the Tennessee Society of Addiction Medicine (TNSAM), the leading medical specialty society representing physicians and clinicians in Tennessee who specialize in the prevention and treatment of addiction, thank you for your work to provide standardized guidance for the treatment of opioid use disorder (OUD) throughout our state. Today, we write to provide feedback on the Department of Mental Health and Substance Abuse Services (TDMHSAS)'s recently proposed amendments to the Minimum Program Requirements for Nonresidential Office-Based Opiate Treatment Facilities (OBOT) and Minimum Program Requirements for Non-Residential Opiate Treatment Program Facilities (OTP). Overall, we feel that these revisions are an improvement over previous iterations. However, upon our review, we identified several areas for suggested revision, Ultimately, we hope our feedback will improve upon these rules and help strengthen the addiction treatment system in Tennessee at a time of great need.

1. **Specifically, we seek the following revisions to Chapter 0940-05-35 Minimum Program Requirements for Nonresidential Office-Based Opiate Treatment Facilities Amendments regarding:**

Revise the seven-day timeline for a drug screen and screening tests for communicable diseases

Rule 0940-05-35-.06 sets the standards for admissions and discharge from a non-residential OBOT facility. Within the components for an initial assessment, this rule requires a drug screen as well as other communicable disease tests to be completed within seven days of admission. We are concerned that the seven-day timeline for these tests to be completed may be unrealistic for OBOTs to satisfy. Specifically, we are concerned that this requirement may serve as a barrier to treatment for patients from underserved communities and those receiving treatment by telehealth. Further, many OBOT facilities do not have communicable disease tests on-site, presenting further difficulties for meeting this seven-day requirement. **As such, we urge**

TDMHSAS to consider adding flexibility to this requirement by removing the requirement for a seven-day timeline and instead replacing it with the phrase 'as soon as practicable.'

Revise requirement for adolescents' verified failure of medically supervised withdrawal

Further, Rule 0940-05-35-.06 (k) states that recipients under 18 years of age must verify two documented unsuccessful attempts at short-term withdrawal management within a twelve-month period to initiate treatment. We feel that this requirement is arbitrarily restrictive and may serve as a barrier to initiating medically necessary treatment. **As such, we urge that you revise the language in the final rule to strengthen a provider's ability to act quickly if necessary. We urge for the insertion of the following language:** 'If a prospective service recipient is under 18 years of age, a parent, legal guardian and/or representative, or in the case of an emancipated minor the minor themself, shall consent in writing to such treatment. Such consent shall be documented in the patient chart. This requirement shall not serve as an impediment to stabilization services if the certified provider, in their best clinical judgment deem it medically necessary."

Remove strict requirements that patients receive in-person examinations annually for Individualized Patient Plans

In rule 0940-05-35-.09, the components of individualized treatment plans are set forward. Specifically, this section requires that patients receive in-person physical examinations on an annual basis for the purpose of informing the individualized patient plan. While we agree that annual in-person examinations are beneficial under ideal circumstances, we are concerned that this requirement could inadvertently cause the discontinuation of treatment should patients decline to arrange primary care appointments. Specifically, we fear that patients receiving treatment through telehealth may find themselves non-compliant with the proposed rule, even as telehealth may be the only option for some patients who live long distances from an available clinician for in-person care. Further, many patients with addiction face destabilizing and unpredictable life circumstances. As such, we must prioritize maintaining access to life-saving treatment for OUD, even if a person is unable to obtain an in-person physical examination annually. **We urge TDMHSAS to amend the language of this rule to read:** "All patients should be strongly encouraged to receive a physical exam on at least an annual basis. If the patient declines, they must be informed of the risks associated declining to receive a physical exam."

Revise requirement for OBOT Facilities to transfer individuals with polysubstance misuse to more intensive care settings

Rule 0940-05-35-.11 puts forth requirements for treating patients in special population categories. One of the special populations cited is patients encountering polysubstance misuse. In our experience, most patients face challenges relating to polysubstance misuse, primarily related to alcohol, tobacco, and cannabis use. Indeed, this anecdotal experience is supported by research as estimates indicate that a substantial percentage of individuals with OUD also have a co-occurring substance use disorder. [1, 2] While patients with polysubstance misuse may benefit from receiving treatment at more intensive care settings, OBOT clinicians and patients often share their decision-making. In our experience, many patients with polysubstance use disorder may be comfortable within the OBOT setting and hesitant to pursue a higher level of care. While addiction treatment providers at OBOTs may recommend that these patients consider seeking a

higher level of care (in alignment with nationally accredited standards like the ASAM Criteria), it should not be a requirement to continue treatment. **As such, we urge for the language to be changed to read as follows:** "Ongoing polysubstance use is not necessarily a reason for discharge; however, the Facility shall consider the merits of a referral of the patient, with documentation of referral in the patient record, to more intensive levels of care. However, if the patient refuses this referral, the refusal shall be documented, and the current level of care maintained."

Revise dosing requirements within Rule 0940-05-35-.13

Rule 0940-05-35-.13 sets forth guidelines for medication dosages in the treatment of OUD, particularly for the use of buprenorphine in the treatment of OUD. Similar to previous iterations of this rule, 16 mg per day and above is considered high dosage and subject to heightened restriction. While 16 mg may once have been considered high dosage,[3] facts on the ground have changed primarily due to the proliferation of high potency synthetic opioids—specifically fentanyl—within the drug supply. In response to mounting evidence supporting the enhanced access of higher dosage buprenorphine, ASAM released updated clinical considerations for Buprenorphine Treatment of OUD for Individuals Using High-Potency Synthetic Opioids (HPSOs).[4] Crucially, the clinical considerations reference high quality studies showing improved treatment retention, reduced opioid use, and lack of adverse events at 16-32 mg doses of buprenorphine. The clinical considerations conclude that some patients may benefit from high buprenorphine doses during buprenorphine stabilization (greater than 24 mg per day). These conclusions are echoed by other recent studies of higher dose buprenorphine.[5] As such, we urge that the dosing guidance to be revised to reflect this reality. **Specifically, we urge you to adopt the language below within the final rule:**

- "A patient dose greater than 24 milligrams or its equivalent, per day, for more than thirty (30) consecutive days, shall be considered a high dose and shall clearly document in the patient's medical record why the patient needs the high dosage amounts.
- A patient dose of 32 milligrams or its equivalent, per day shall be considered a maximum dose. Doses greater than the maximum dose may only be used with prior written approval from the State Opioid Treatment Authority. Documentation of this approval shall be kept in the patient's medical chart or otherwise be readily retrievable upon request or facility inspection."

Finally, remove Community Relations Requirement within Rule 0940-05-35-.19 and any miscellaneous references to the Data 2000 waiver

Rule 0940-05-35-.19 sets forth Community Relations requirements for OBOTs to follow. While we support OBOTs having strong relationships with the surrounding community, we do not feel that enumerating these requirements formally is the correct approach. Specifically, we believe that language relating to 'community disruption' is inherently stigmatizing towards patients with addiction. **As such, we urge you to reconsider including this Community Relations section within the final rule. Additionally, we urge you to remove all references to the Data 2000 waiver in the final rule as it is now obsolete due to Congressional action that removed the requirement.**

2. Additionally, we seek the following revisions to Chapter 0940-05-42 Minimum Program Requirements for Non-Residential Opiate Treatment Program Facilities Amendments:

Remove the 120 mg methadone dose cap

Rule 0940-05-42-.15 sets forth the provisions for medication management provided within OTPs. Specifically, this rule maintains a dosage cap of 120 mg without prior approval. We believe that this dosage cap is too low and out of step with medical best practice. For example, Tennessee is one of only three states restricting the upper dosing of methadone at OTPs.[6] Dosage caps inhibit the ability of OTPs to address the individual needs of patients. In turn, there is a risk that methadone dosage caps at OTPs may cause patients to discontinue treatment in worst cases. **As such, we urge TDMHSAS to remove the 120 mg dosage cap on methadone provided by OTPs.**

Align OTP take-home rules with most recent SAMHSA Guidelines

Rule 0940-05-42-.15(c) set the take-home rules for patients admitted to OTPs. According to the take-home schedule proposed in this rule, daily dosing is required for days 1-30. Then, attendance at the location would be required every two weeks from days 31-365. From days 366 and onwards 'clinical stability' determines the frequency that patients must attend on location at OTPs. These standards for take-home medications differ somewhat from the most recent guidelines advanced by the Substance Abuse and Mental Health Services Administration (SAMSHA).[7] Further, the section details a number of factors that addiction treatment providers must weigh to determine clinical stability. While we agree that many of these factors are important to consider, we are concerned that this manner of determining clinical stability may be too rigid to make individualized patient decisions. **Instead, we urge that the rule be amended to fully align with SAMHSA's updated guidelines for take-home dosing within the first month and enhance provider discretion in determining clinical stability for take-home dosing.**

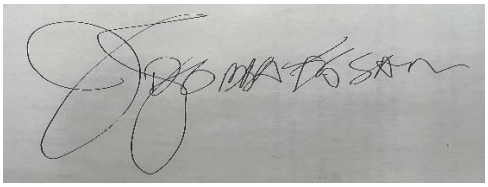
Finally, revise the requirement for observed drug screens

Rule 0940-05-35-.10 outlines the phases of treatment for patients receiving treatment in OTPs. Specifically, sections (d), (e), and (f) include requirements for observed drug screens to meet specific phases of treatment. While we understand that randomized drug screens are important tool to determine patient adherence to a treatment plan, many patients may feel uncomfortable submitting to a high number of observed drug screens-- especially within their first twelve months of treatment. As such, these experiences may prove traumatic and impact their retention in treatment long-term. Further, federal rules set forth a minimum number of drugs screens for all OTPs to adhere.[8] However, these proposed rules unnecessarily exceed the federal standard of eight randomized drug screens per year in maintenance therapy. **We urge you to align all drug testing requirements with the federal minimum standard and remove requirements for removed drug screens from the final rule.**

We greatly appreciate the opportunity to share our suggestions about how to improve the state's guidelines for OBOT and OTPs. We are both working towards the same goal of providing safe, effective, and accessible treatment to all Tennesseans with OUD. As such, we look forward to collaborating with your department to accomplish these goals. Please do not hesitate to contact our President-Elect, Dr. Chad Elkin, directly at

chadelkin@nationaladdictionspecialists.com with any follow-up that you have. We look forward to working with you and your team.

Sincerely,



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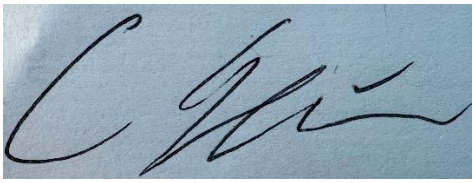

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CC: Wesley Geminn, PharmD

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