Michigan Society of Addiction Medicine

A Chapter of American Society of Addiction Medicine

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September 1st, 2021

Orlene Hawks
Director, Michigan Department of Licensing and Regulatory Affairs
611 W. Ottawa St
P.O. Box 30004
Lansing, MI 48933

Re: LARA Rules Governing Medication for Addiction Treatment

Dear Director Hawks,

On behalf of the Michigan Society of Addiction Medicine (MISAM), the medical specialty society representing physicians and other clinicians in Michigan who specialize in the prevention, treatment, and recovery from addiction, thank you for the Department of Licensing and Regulatory Affairs' (LARA) efforts to ensure there are appropriate guardrails in the provision of addiction treatment. Given the nature of the opioid overdose epidemic in Michigan, we appreciate the opportunity to flag the concerns below for LARA so that we may begin a conversation about how to continue to ensure access to high-quality, evidence-based, comprehensive addiction treatment.

MISAM is committed to ensuring access to and improving the quality of addiction treatment in Michigan. To that end, we are concerned about LARA's rules that mandate compliance with scheduled drug testing prior to and during treatment. LARA Rule 325.1383, sections 12-14 set forth the state's drug testing requirements for medication for addiction treatment (MAT). The drug testing rules compel physicians to obtain test results before initial prescription dosage. Biweekly tests are required for six-months afterwards, regardless of the patient's unique disposition. These rules conflict with best practice guidelines for addiction treatment.

Drug-testing is a useful tool to supplement self-report surveys and ensure patient compliance with a treatment plan. However, LARA's stringent testing rules run counter to medical best-practice, as outlined by the American Society of Addiction Medicine's National Practice Guideline. According to the guideline, while requirements ensuring a minimum amount of drug testing are commonplace (specifically, eight tests per year based on federal law), the specific characteristics of testing are best determined on an individual basis. Several complex factors shape drug-testing regimen, including the stability of the patient, type of treatment, and treatment setting. Additionally, the American Society of Addiction Medicine's Drug Testing Guidelines add that "drug testing should not face undue restrictions" and "decisions about the type and frequency of testing should be made by the ordering physician."

The provision within LARA's rule as described above limits the discretion of addiction specialist physicians (ASPs) to exercise their best professional judgement and creates barriers for patients to access regular treatment. Ultimately, LARA drug-testing rules that impose an exact schedule on physicians and their patients constitute an "undue restriction" as this schedule removes discretionary authority from ASPs. Additionally, LARA's restrictions on physician's ability to prescribe buprenorphine and naltrexone (both FDA approved medications) to over 100 patients present unnecessary hurdles for ASPs to prescribe patients with life-saving cures. While some regulatory requirements for drug-testing are reasonable, LARA's current regulations are burdensome for both physicians and patients in Michigan. **Therefore, we strongly urge that you reconsider these onerous rules for the benefit of patients across the state.**

Rule 325.1303, section 3, subsection c places numerical limits on ASPs' authority to treat patients with buprenorphine and naltrexone. This rule adds additional restrictions to the federal standard set by the Substance Abuse and Mental Health Service Administration's (SAMHSA) guidance on the matter. SAMSHA guidance authorizes physicians to treat more than 100 patients with buprenorphine if "the physician holds a board certification in addiction medicine or addiction psychiatry by the American Board of Preventative Medicine or the American Board of Psychiatry" or if "the practitioner provides medication assisted treatment in a qualified practice setting." Current LARA rules impose additional restrictions on top of federal mandates which may inadvertently limit access to life-saving treatment. LARA's rules on buprenorphine administration are reminiscent of standard practice for the regulation of methadone. However, buprenorphine has different characteristics than methadone—as described in ASAM's official statement on the Regulation of Office-Based Opioid Treatment. Therefore, buprenorphine warrants a different set of rules for use. We understand that LARA's priority is to curb improper administration of buprenorphine. However, LARA must ensure that regulations on the use of buprenorphine are consistent with federal guidance and clinal guidance such as ASAM's National Practice Guideline for the Treatment of Opioid Use Disorder. Current LARA rules also restrict the usage of naltrexone, despite it not being a controlled substance. Both buprenorphine and naltrexone are proven to be life-saving treatments for those with addiction. Restricting patients' use of these medications unnecessarily complicates the process of attaining treatment, especially given that federal guidance already exists on the topic.

Additionally, the Covid-19 pandemic has shown that growing numbers of patients have shifted to telemedicine to continue their treatment plans. In light of these developments, LARA's strict drug-testing and patient limit requirements are even more prohibitive for both patients and their doctors. Recognizing the need to grant ASPs increased flexibility during the pandemic, SAMHSA and the DEA relaxed restrictions on MAT by telemedicine. However, LARA's current rules on MAT are antithetical to this guidance, intended to expand access to medications during the pandemic. **Therefore, due to the challenges of providing care during this unprecedented public health emergency, we urge LARA to reconsider its policies on MAT as set forth above.**

While we believe that LARA's rules are well-intentioned, both its drug-testing and patient limit requirements place undue constraints on ASPs and limit access to care, especially during an

unprecedented global pandemic. We would like to offer suggestions on how to best streamline the process for access to MAT, while also guaranteeing that only qualified practitioners can provide treatment. **As such, MISAM would greatly appreciate the opportunity to meet with you to discuss these issues in greater detail.** Thank you for considering our perspective and we hope to work with you further. Please contact me if you have any questions or concerns. We look forward to the opportunity for additional dialogue.

Sincerely,

Timothy Gammons, DO, FASAM
President, Michigan Society of Addiction Medicine

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