

October 6, 2023

Ms. Kimberly Anderson Chief Legal Counsel State Medical Board of Ohio 30 E Broad St 3rd Floor Columbus, OH 43215

Re: OHSAM's Comments on the Proposed Changes to Medical Board's OH Physician Rules Relating to Buprenorphine Treatment

Dear Ms. Anderson.

On behalf of the Ohio Society of Addiction Medicine (OHSAM), the medical specialty society representing physicians and clinicians in Ohio who specialize in the prevention and treatment of addiction, thank you for the opportunity to comment on this important proposal. We greatly appreciate your continued efforts to ensure that the practice of medicine is safe for the patients of Ohio. Today, we write to comment on the Board's proposed changes to the Physician Rules Chapter 4731-33 regarding the provision of buprenorphine treatment in our state. In sum, while we feel that this proposal represents an improvement over the previous iteration, we urge revisions in areas such as the numerically defined frequency of urine drug screenings and continued limitations around prescribing higher dose buprenorphine in the era of high potency synthetic opioids (HPSO's). Absent a discussion about a full-scale revision/retraction of these rules, OHSAM supports a prompt review of the highlighted provisions in support of further expanding access to evidence-based treatment for opioid use disorder (OUD) at this time of great need.

First, we want to highlight the language in §4731-33-02(D)(1) (b) of the withdrawal management section of the proposal. The language states that treatment should only initiate treatment if there is 'high likelihood of treatment adherence and retention in treatment.' While OHSAM agrees that treatment adherence and retention are important goals, we feel that this language is subjective and stigmatizing. Further, we fear that in worst cases it could be used as a justification to deny withdrawal management services from vulnerable populations, such as low-income persons and the unhoused. Ultimately, we want to ensure that treatment for OUD is as accessible as possible, regardless of a person's station in life. As such, we urge you to remove this line from the final version of these rules.

Section 4731-33-03 sets the rules for practitioners operating in office-based treatment for opioid addiction (OBOT). Specifically, in §4731-33-03(G)(6), the proposal stipulates that practitioners must require at least two drug tests per quarter during the first year of treatment then one per quarter afterwards. Drug tests, including urine drug screenings, are a useful tool to evaluate patient compliance with a treatment plan. However, OHSAM opposes placing numerical

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requirements on clinicians and instead urges an approach of maximizing clinical discretion. Indeed, ASAM's 2020 National Practice Guideline acknowledges that limited research supports an exact frequency of drug screenings for patients receiving treatment for OUD. Instead, it states that frequency should be determined by a number of individual factors, including the stability of the patient, the type of treatment, and the treatment setting. The guideline also states that urine drug screenings are more likely necessary during the beginning stages of treatment. Additionally, the guideline notes federal laws requiring opioid treatment programs (OTPs) to conduct 8 drug screens per year at a minimum. However, given the inconclusive nature of research supporting an ideal frequency of drug tests and the importance of clinical flexibility in this area, we urge you to consider removing numerical defined requirements for a minimum amount of drug tests in OBOT settings. We encourage replacing these numerical requirements with language clarifying the utility of drug testing and recommending practitioners use it as a tool to address patient compliance, rather than explicitly defining a minimum number of tests per quarter.

Additionally, we seek revision to §4731-33-03(G)(7) of the OBOT rules, relating to daily dosage guidelines for buprenorphine. While we appreciate the Board proposing to revise a strict cap on more than 24mg of buprenorphine per day, OHSAM feels that the language is still too restrictive to meet the treatment challenges posed by HPSO's. ASAM recently released updated clinical considerations for Buprenorphine Treatment of OUD for Individuals Using High-Potency Synthetic Opioids (HPSOs).² These clinical considerations account for the increased prevalence of HPSO's--like fentanyl-- in the drug supply. 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.³ The clinical considerations conclude that some patients may benefit from high buprenorphine doses during buprenorphine stabilization (greater than 24 mg per day).

However, this proposed rule does not grant all practitioners the same ability to treat patients with higher dosages of buprenorphine if necessary. Instead, this rule would only allow clinicians with board certification in addiction medicine/psychiatry to prescribe dosages above 24mg/day. While OHSAM recognizes the value of addiction specialist physicians (ASPs)⁴ who are uniquely trained and qualified to treat addiction and similarly appreciates the Board's recognition, OHSAM is concerned that the Board did not consider whether there are enough ASPs to meet the demand of patients in Ohio who may need treatment with buprenorphine beyond 24mg due to HPSOs. Before the Board finalizes a requirement to mandate that only ASPs be permitted to prescribe buprenorphine beyond 24mg or require a consultation with an ASP in the case of non-ASPs, OHSAM encourages the Board to consider whether this mandate would jeopardize access to treatment due to limited numbers of board-certified addiction medicine/psychiatrist clinicians.

Relatedly, OHSAM encourages the Board to define board-certified addiction medicine specialists/addiction psychiatrists in line with ASAM's Recognition and Role of Addiction Specialist Physicians in Health Care in the United States policy statement.⁵

OHSAM greatly appreciates the opportunity to comment on this important proposal. We commend the Board for its willingness to change and improve. We hope that you will consider our suggestions and look forward to working collaboratively to produce rules that ensure expanded access to treatment for OUD. Please do not hesitate to contact me at typ@cwru.edu

or Dr. Krisanna Deppen at <u>krisanna.deppen@ohiohealth.com</u> if our organization can assist you any further.

Sincerely,

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Theodore V. Parran, MD, FACP, FASAM President, Ohio Society of Addiction Medicine

¹ American Society of Addiction Medicine - ASAM. (2020). The ASAM National Practice Guideline For the Treatment of Opioid Use Disorder: 2020 Focused Update. Journal of Addiction Medicine, 14(2S), 1–91. https://doi.org/10.1097/adm.000000000000033

² Weimer, M. B., Herring, A. A., Kawasaki, S. S., Meyer, M., Kleykamp, B. A., & Ramsey, K. S. (2023). ASAM Clinical Considerations: Buprenorphine Treatment of Opioid Use Disorder for Individuals Using High-potency Synthetic Opioids. Journal of Addiction Medicine. https://doi.org/10.1097/adm.000000000001202

³ Chambers, L. C., Hallowell, B. D., Zullo, A. R., Paiva, T. J., Berk, J., Gaither, R., Hampson, A. J., Beaudoin, F. L., & Samp; Wightman, R. S. (2023). Buprenorphine Dose and Time to Discontinuation Among Patients With Opioid Use Disorder in the Era of Fentanyl. JAMA Network Open, 6(9). https://doi.org/10.1001/jamanetworkopen.2023.34540

⁴ American Society of Addiction Medicine - ASAM. (2022). Recognition and Role of Addiction Specialist Physicians in Health Care in the United States. Public Policy Statement. https://www.asam.org/advocacy/public-policy-statements/details/public-policy-statements/2022/01/28/public-policy-statement-on-the-recognition-and-role-of-addiction-specialist-physicians-in-health-care-in-the-united-states.

⁵ Ibid.