Kentucky Society of Addiction Medicine

A Chapter of American Society of Addiction Medicine

OFFICERS
President
Tuyen T. Tran, MD, MBA, FACP, FASAM
Vice President/President Elect
Colleen Ryan, MD, FASAM
Immediate Past President
James Patrick Murphy, MD, DFASAM
Treasurer
Marvin Bishop, MD, FASAM
Secretary
Katrina Nickels, MD, FASAM

May 16, 2023

William C. Thornbury, MD
Chair
Kentucky Board of Medical Licensure
310 Whittington Parkway
Suite IB
Louisville, KY 40222

Re: KYSAM Request for Kentucky Board of Medical Licensure (KBML) Emergency Opinion Pursuant to KRS § 311.602

Dear Dr. Thornbury -

On behalf of the Kentucky Society of Addiction Medicine (KYSAM), the medical specialty society representing physicians and other clinicians in Kentucky who specialize in the prevention, treatment, and recovery from addiction, thank you for your attention to this important matter. We write today to request an emergency KBML opinion regarding 201 KAR § 9:270 - Professional standards for prescribing, dispensing, or administering Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone. Specifically, KYSAM requests an emergency KBML opinion regading 201 KAR 9:270 § (2)(4)(e)(3) as it concerns patient visits for the treatment of opioid use disorder (OUD).

201 KAR 9:270 §(2)(4)(e)(3) mandates that practitioners licensed by KBML shall ensure that a patient treated for OUD is seen no later than ten (10) days after initiation of buprenorphine and then at intervals of no more than ten (10) days for the first month after initiation; and at intervals of no more than fourteen (14) days for the second month after initiation. The regulations also mandate that "if the patient demonstrates objective signs of positive treatment progress, the licensee shall ensure that the patient is seen at least once monthly thereafter."

While KYSAM understands and appreciates KBML's responsibility to set professional standards for licensees, the regulations set forth at 201 KAR 9:270 §(2)(4)(e)(3) governing the frequency of patient visits for treatment with medications for OUD (MOUD) are posing challenges for practitioners, particularly those patients who receive their MOUD in the Fayette County Detention Center (FCDC). A recent settlement agreement between FCDC and the US Department of Justice ensures that people who take MOUD can maintain access while in the custody of FCDC. However, FCDC now faces the difficult challenge of meeting their obligations under this settlement agreement while adhering to the frequency of visits as set forth at 201 KAR 9:270 §(2)(4)(e)(3). These visit frequency requirements are difficult for FCDC to adhere to due to limited transportation service to these visits. Transportation service is limited for the following reasons: (1) every person in the custody of FCDC must be accompanied by 1-3 officers

for security purposes; (2) many people in FCDC's custody (including those with OUD) have other medical problems that require them to be transported to see various other specialists; and (3) FCDC is currently impacted by a facility staff shortage.

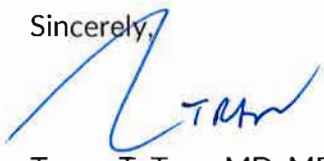
Regardless, the prescriptive nature of the required number of office visits diverge from practice guidelines such as the ASAM National Practice Guideline for the Treatment of Opioid Use Disorder.[1] Given that treatment plans should be individualized for each patient based on their needs, these guidelines recognize that treatment is not a one-sized approach and that medical-decision making about the treatment needs of patients, including the frequency of visits, should be left to the discretion of the clinician. Furthermore, the prescriptive nature of office visits mean that these regulations move in the opposite direction of the Substance Abuse and Mental Health Services Administration (SAMHSA), which has recently proposed new rules[2] for opioid treatment programs (OTPs)/methadone, allowing for greater clinician discretion in the context of methadone for OUD. These regulations also directly conflict with recent bipartisan Congressional action intended to significantly expanding access to MOUD by removing a requirement for clinicians treating OUD with buprenorphine to acquire a separate Drug Enforcement Administration (DEA) waiver. Finally, the regulations governing the frequency of visits is also more prescriptive than the federal standard at 21 U.S.C. § 829(e)(2)(A) which only require one (1) in-person visit for a prescription for a controlled substance to be considered valid.

Additionally, these regulations state that "Failure to comply with or a violation of the professional standards established in Sections 2, 3 and 4 of this administrative regulation shall constitute a "departure from, or failure to conform to the standards of acceptable and prevailing medical practice within the Commonwealth of Kentucky..."

As you can see, there are several items that are of concern to KYSAM. **Given the inconsistencies of these regulations with nationally recognized guidelines such as ASAM and SAMHSA, a more prescriptive standard than what's required federally, the possibility of enforcement actions against physicians who deviate from these misaligned rules, and the impact these potential enforcement actions on patient access to evidence-based treatment, KYSAM strongly encourages KBML to issue an emergency board opinion until the board and other stakeholders can convene to discuss a significant revision of these regulations. This opinion should recognize the extraordinary circumstances and categorically permit treatment decisions about the frequency of patient visits for MOUD to remain a clinical decision left to the treating practitioner, governed by what (1) constitutes a clinician-patient relationship under Kentucky law and (2) is within the confines of the US Controlled Substances Act (CSA).**

Thank you for your prompt attention to KYSAM's concerns. Please do not hesitate to reach out to me at tratuy7@gmail.com to discuss further if you have any questions or concerns.

Sincerely,



Tuyen T. Tran, MD, MBA, FACP, FASAM
President, Kentucky Society of Addiction Medicine

CC: Mike Rodman, Executive Director
Leanne Diakov, General Counsel

[1] The ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update. J Addict Med. 2020 Mar/Apr;14(2S Suppl 1):1-91. doi: 10.1097/ADM.0000000000000633. Erratum in: J Addict Med. 2020 May/Jun;14(3):267. PMID: 32511106.

[2] Abuse, S., & Mental Health Services Administration, H. H. S. (2022). Medications for the Treatment of Opioid Use Disorder. Proposed rule. Federal register, 87(241), 77330-77365.