Kentucky Society of Addiction Medicine
A Chapter of American Society of Addiction Medicine

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December 5, 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) to Revise Sections of 201 KAR 9:270

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 timely revisions to 201 KAR § 9:270 – Professional Standards for Prescribing, Dispensing, or Administering Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone. In brief, recent federal statute changes, new clinical considerations in the age of fentanyl, and new policy guidance necessitate a fresh review of these professional standards to ensure that physicians and other clinicians trained to treat addiction are appropriately equipped to provide high quality care. KYSAM believes these changes warrant reconsideration of the existing rules in support of expanding access to care. Absent a discussion about a full-scale revision/retraction of these rules, KYSAM supports prompt revisions to several provisions of the rules in support of access to treatment of opioid use disorder (OUD). Below are highlighted areas of the current rules for which we urge immediate revision.

Specifically, KYSAM requests that KBML review and strongly consider updating regulations at 201 KAR § 9:270 regarding:

KBML licensee qualifications to prescribe buprenorphine products to treat OUD

On December 29, 2022, President Biden signed the Consolidated Appropriations Act, 2023 (the "CAA 2023") into law. Section 1262 of the CAA 2023 eliminates the requirement that a healthcare practitioner apply for a separate waiver through the Drug Enforcement Administration (DEA) to dispense controlled medications in Schedule III, IV and V of the Controlled Substances Act (e.g., buprenorphine) for substance use disorder (SUD) treatment. There are no longer any federal limits or patient caps on the number of patients a prescriber may treat for opioid use disorder with buprenorphine.[1] [2] **Accordingly, KYSAM recommends that KBML update these regulations to reflect that a separate waiver from the DEA is no longer required to prescribe buprenorphine for the treatment of OUD**

Appropriate treatment of OUD in pregnant patients

While ASAM's National Practice Guideline (NPG) recommends that care for pregnant patients with OUD should be comanaged by a clinician experienced in obstetrical care and a

clinician experienced in the treatment of OUD such as an addiction specialist physician (ASP), it is also explicitly clear that MOUD should be used to care for pregnant patients in the treatment of OUD, and should be initiated as early as possible.[3] The inability of a non-ASP to obtain a consult from an ASP should not preclude a physician from initiating a patient on MOUD. **Similarly, KBML should update its regulations at 201 KAR 9:270 § (2)(4)(b)(2)(a) and 201 KAR 9:270 § (2)(4)(b)(2)(b) such that non-ASPs would not be required to obtain an independent consultation with an ASP in the provision of MOUD for pregnant patients.**

Dosage limits on buprenorphine in the treatment of OUD

Additionally, these rules place restrictions on prescribing buprenorphine at doses greater than 16 mg. ASAM's NPG cites a typical buprenorphine dose limit of 24 mg per day, noting the potential risks of higher doses. However, ASAM recently released updated clinical considerations for Buprenorphine Treatment of OUD for Individuals Using High-Potency Synthetic Opioids (HPSOs).[4] These clinical considerations account for the increased prevalence of high potency synthetic opioids--like fentanyl-- in the drug supply. Crucially, the clinical considerations point to high quality studies showing improved treatment retention, reduced opioid use, and lack of adverse events at doses of buprenorphine 16-32 mg per day. As such, the clinical considerations conclude that some patients may benefit from high buprenorphine doses during buprenorphine stabilization (greater than 24 mg per day). **In light of this new information, KYSAM strongly recommends that KBML revise current restrictions on prescribing greater than 16 mg of buprenorphine, allowing for increased doses as appropriate, as determined at the professional discretion of the practitioner.**

Frequency of patient visits with clinicians for treatment using buprenorphine

Relatedly, 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 morethan 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 MOUD are posing challenges for practitioners and their patients. The prescriptive nature of the required number of office visits diverge from practice guidelines such as the NPG for the Treatment of Opioid Use Disorder.[5] Furthermore, the prescriptive nature of office visits mean that these regulations move in the opposite direction of Substance Abuse and Mental Health Services Administration (SAMHSA), which has recently proposed new rules[6] for opioid treatment programs (OTPs)/methadone, allowing for greater clinician discretion in the context of methadone for OUD.

Given that treatment plans should be individualized for each patient based on their needs, ASAM's 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. **Therefore, KBML should update these regulations to remove requirements regarding the frequency of patient visits. Instead, these decisions should be left to the treating practitioner in accordance with nationally recognized practice guidelines, such as those from the SAMHSA and ASAM**.

The requirement that patients receive counseling or other behavioral modification services

201 KAR 9:270 § (2)(4)(e)(1) requires that *"if the licensee prescribes, dispenses, or administers Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone medication, the licensee shall implement a treatment plan that requires objective behavioral modification by the patient. The behavioral modification shall include the patient's participation in a behavioral modification program that may include counseling or atwelve (12) step facilitation."* To be clear, KYSAM wholeheartedly supports the use of psychosocial treatment in conjunction with MOUD due to its positive contributions to treatment outcomes. ASAM's NPG states "psychosocial treatment can help patients manage cravings, reduce the likelihood of relapse, and assist them in coping with the emotional and social challenges that often accompany substance use disorders." However, the NPG goes on to explain that "psychosocial treatment is provided using a variety of approaches in various milieus, including social skills training; individual, group, and couples counseling; cognitive behavioral therapy; motivational interviewing; and family therapy. Determining the level of need and best approach to psychosocial treatment is individualized to each patient."
As you can see, individual and group psychotherapy/counseling is not just the only form of psychosocial treatment that patients with addiction can receive during their treatment. Itwouldn't be prudent or ethical for a provider to require a patient to receive a specific psychosocial treatment when they may be better off receiving contingency management, cognitive behavioral therapy, or another service. The practice of requiring behavioral modification would take away the flexibility of both the clinician and the patient in determining an individualized treatment plan. Decisions about the appropriate type, modality, and duration of treatment should remain the purview of the treatment provider and the patient, working in collaboration to achieve shared treatment goals. **At the very minimum, these regulations should be modified to *encourage*, but not require clinicians to recommend the appropriate evidence-based behavioral modification services at their discretion**

Concomitant prescribing of buprenorphine and other controlled medications

Finally, patients should not be denied evidence-based treatment for OUD due to the presence of other medications. **As such, allow non-ASPs to co-prescribe buprenorphine in addition to other medications, provided that these non-ASPs provide documentation in the patient's chart that a consultation attempt with an ASP was made, even if the attempt was not successful. KYSAM strongly encourages that individualized psychosocial interventions and/or intensity of monitoring be documented in the patient's chart when co-prescribing buprenorphine, at the professional discretion of the practitioner.**

As you can see, there are several items that are of concern to KYSAM. We look forward to working with KBML in a timely manner to address these issues. 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

Digitally signed by Tuyen T. Tran, MD, MBA
Date: 2023.11.30 16:40:08 -05'00'

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

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

Addiction specialist physicians (ASPs) include physicians from multiple different primary specialties. Four medical subspecialty certifications for ASPs demonstrate and define expertise in addiction treatment:

1. Subspecialty board certification in addiction medicine by the American Board of Preventive Medicine (ABPM);
2. Subspecialty board certification in addiction psychiatry by the American Board of Psychiatry and Neurology (ABPN);
3. Subspecialty board certification in addiction medicine by the American Osteopathic Association (AOA); or
4. Certification by the American Board of Addiction Medicine (ABAM).

[1] SAMHSA. (2023). Waiver Elimination (MAT Act). Substance Abuse and Mental Health Services Administration. https://www.samhsa.gov/medications-substance-use-disorders/waiver-elimination-mat-act

[2] Milgram, A. (2023). DEA announces important change to registration requirement. U.S. Department of Justice. https://www.deadiversion.usdoj.gov/pubs/docs/A-23-0020-Dear-Registrant-Letter-Signed.pdf

[3] 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.

[4] 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.0000000000001202

[5] 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.

[6] 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.