Statement

of

American Medical Association

American Academy of Family Physicians

American College of Obstetricians and Gynecologists

American Psychiatric Association

American Society of Addiction Medicine

American Academy of Addiction Psychiatry

Kentucky Academy of Family Physicians

Kentucky Psychiatric Medical Association

Kentucky Section of the American College of Obstetricians and Gynecologists

Kentucky Society of Addiction Medicine

Kentucky's Administrative Regulation Review Subcommittee

Meeting Re: Board of Medical Licensure 201 KAR 009:270. Professional standards for prescribing, dispensing, or administering Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone. (Amended After Comments)

September 4, 2025

The above-listed medical organizations, representing thousands of physicians nationwide, respectfully submit this statement to urge the Administrative Regulation Review Subcommittee (the "Subcommittee") to find the Kentucky Board of Medical Licensure ("KBML")'s proposed 201 KAR 9:270 deficient and to recommend that KBML either amend the proposed regulation to correct its deficiencies or repeal 201 KAR 9:270 entirely. Kentucky has one of the country's highest rates of opioid use disorder (OUD). We are concerned that current language in the proposed 201 KAR 9:270 would restrict access to buprenorphine in a manner that would needlessly perpetuate increased opioid overdose risks and suppress treatment retention throughout the Commonwealth.

More specifically, pursuant to KRS 13A.030(2)(a), the Subcommittee should determine that KBML's proposed 201 KAR 9:270 is deficient because:

1. Several provisions conflict with nationally recognized, evidence-based, medical guidelines/guidance on prescribing buprenorphine, as detailed in **Exhibit A**. At the same time, the proposed regulation does not provide the clinical flexibility explicitly endorsed by those same guidelines/guidance;
2. KBML's Statement of Consideration Relating to 201 KAR 9:270 contains inaccurate or outdated information; and
3. KBML's proposed 201 KAR 9:270 contains the drafting errors identified below, requiring correction.

Accordingly, under KRS 13A.030(2)(c), the Subcommittee should recommend that KBML amend the proposed 201 KAR 9:270 to address these deficiencies or repeal 201 KAR 9:270 in its entirety.

I. Provisions Conflicting with Nationally Recognized, Evidence-Based, Medical Guidelines/Guidance on Prescribing Buprenorphine and the Proposal's Insufficient Preservation of Necessary Clinical Flexibility

Exhibit A identifies several provisions that conflict with national medical guidelines and guidance. Moreover, unlike 201 KAR 9:260, which governs the prescribing of controlled substances generally, the proposed 201 KAR 9:270 does not permit a physician to document (a) circumstances beyond their control or (b) a professional determination that a specific standard is inappropriate for a patient's diagnosis and treatment, and then proceed with prescribing buprenorphine when clinically justified – that is, unless the prescribing of buprenorphine is also in accordance with SAMHSA Tip 63, ***despite Tip 63's clear statement that its guidelines "should not be considered substitutes for individualized client care and treatment decisions." (ES-12).***

II. Deficiencies in KBML's Statement of Consideration Relating to 201 KAR 9:270

KBML's Statement of Consideration Relating to 201 KAR 9:270 contains the following inaccurate or outdated information:

- **Page 19:** KBML states that 201 KAR 9:270's proposed requirement of buprenorphine prescribers to obtain prior medical records is also required of other controlled substance prescribers in 201 KAR 9:260 for the treatment of pain. This is incorrect. As shown in **Exhibit A**, 201 KAR 9:260 only requires obtaining prior medical records if the prescriber determines such review is necessary to justify long-term prescribing, dispensing, or administering of a controlled substance for the treatment of pain.
- **Pages 23-24**: KBML references guidance on post-initiation buprenorphine doses that ***predate a Food and Drug Administration (FDA)'s December 2024 notice***, in which the FDA recommended changes to the labeling of buprenorphine-containing transmucosal products for the treatment of OUD, to remove a "target dose" and clarify that neither 16 mg/day nor 24 mg/day should be construed as maximum dosages for these medications. (Read more here.)
- **Page 26:** KBML cites selective excerpts from federal guidelines to justify its proposal on objective behavioral modification. However, those same guidelines clearly state that access to buprenorphine for OUD should not be conditioned on participation in such interventions, as further detailed in **Exhibit A**.
- **Pages 30-31:** KBML states that it disagreed with recommendations to allow prescribers to exercise their discretion as long as the discretion complies with American Society of Addiction Medicine (ASAM) guidelines, because ". . . a majority of buprenorphine prescribing for OUD is undertaken by general practitioners" and "ASAM's recommendations are drafted without input from a broader and more diverse prescriber base." This is misleading and incorrect. ASAM represents addiction specialist physicians and primary care clinicians treating addiction, and ASAM guidelines are developed using a rigorous, evidence-informed process.
    - Addiction medicine is a multi-disciplinary medical subspeciality, requiring primary board certification. Addiction medicine specialists are often primary boarded in family medicine or internal medicine.
    - On page 8 of ASAM's National Practice Guideline (NPG) (2020), it states: "This Practice Guideline is primarily intended for clinicians involved in evaluating patients and providing authorization for pharmacological treatments at any level. The intended audience falls into the broad groups of physicians; other healthcare providers (especially those with prescribing authority); medical educators and faculty for other healthcare professionals in training; and clinical care managers, including those offering utilization management services."
    - On page 19 of ASAM's NPG, it states: "These guidelines were developed using the RAND/ UCLA Appropriateness Method (RAM)—a process that

combines scientific evidence and clinical knowledge to determine the appropriateness of a set of clinical procedures . . . . ASAM's Quality Improvement Council (QIC) was the oversight committee for guideline development. The QIC appointed a Guideline Committee to participate throughout the development process, rate treatment scenarios, and assist in writing. . . . The 2015 Guideline Committee was composed of 11 experts and researchers from multiple disciplines, medical specialties, and subspecialties, including academic research, internal medicine, family medicine, addiction medicine, addiction psychiatry, general psychiatry, obstetrics/gynecology, and clinical neurobiology. Physicians with both allopathic and osteopathic training were represented on the Guideline Committee."

- On page 21 of ASAM's NPG, it states: "ASAM sought input from ASAM members, patient and caregiver groups, and other stakeholders including experts from the criminal justice system, government agencies, other professional societies, and hospitals and health systems. ASAM also made the document and a qualitative review guide available to ASAM members and the general public for a 2-week period of review and comment. The final draft Practice Guideline was submitted to the ASAM Board of Directors in April 2015."

III. Drafting Errors

The proposed 201 KAR 9:270 contains the following drafting errors, requiring correction:

- **Prescribing of Buprenorphine-Mono-Product to Patients Transitioning from Full Opioid Agonists:** On page 18 of KBML's Statement of Consideration Relating to 201 KAR 9:270, KBML states that the proposed regulation reflects that physicians may prescribe Buprenorphine-Mono-Product to patients transitioning from full opioid agonists for a period of up to thirty (30) days. This is incorrect. The proposed regulation does not reflect such allowance.
- **Specialty Consultations for Patients Prescribed More Than 16mg every 12 Months:** On page 13 of the proposed regulation, physicians certified by the American Board of Preventive Medicine in addiction medicine are not listed as an acceptable specialty consult though KBML recognizes such physicians as experts in addiction medicine elsewhere in the regulation. This is a clear drafting error.

Exhibit A

201 KAR 9:270	201 KAR 9:260	VA Guidelines	ASAM NPG (2020)	SAMHSA Tip 63 (2021)	SAMHSA OTP Regulations/ Guidelines (2024)	FDA/SAMHSA	Comment
Link to Proposed 201 KAR 9:270.	Link to 201 KAR 9:260	Link to VA Guidelines (2022)	Link to ASAM NPG (2020) and Link to ASAM's Clinical Considerations (CC) (2023).	Link to Tip 63.	Link to OTP Regulations.	See below links.	
In-Office Initiation of Treatment: The licensee shall recommend to the patient an in-office observed initiation**.** (Section 3(4)(b)1.)			"Both office-based and home-based initiation are considered safe and effective when starting buprenorphine treatment. Clinical judgement should be used to determine the most appropriate setting for a given patient and may include consideration of the patient's past experience with buprenorphine and assessment of their ability to manage initiation at home." (NPG Page 12)	"Induction can occur in the office or at home. Most clinical trials were conducted with office-based induction, and extant guidance recommends this approach. However, office-based induction can be a barrier to treatment initiation. Home induction is increasingly common." (3-63) "Clinical experience indicates that patients suitable			

201 KAR 9:270	201 KAR 9:260	VA Guidelines	ASAM NPG (2020)	SAMHSA Tip 63 (2021)	SAMHSA OTP Regulations/ Guidelines (2024)	FDA/SAMHSA	Comment
				for home induction: Can describe, understand, and rate withdrawal. Can understand induction dosing instructions. Can and will contact their provider about problems." (3-64)			
With limited exceptions, prohibition on using buprenorphine for pain, unless formulation is approved by the FDA for pain. (Section 3(1)(b))		"For patients receiving daily opioids for the treatment of chronic pain, we suggest the use of buprenorphine instead of full agonist opioids due to lower risk of overdose and misuse." (Page 43)	"Some evidence suggests that patients experiencing substantial pain on high doses of full agonist opioids experience improved pain management when transitioned to buprenorphine. Overall, buprenorphine therapy carries a lower risk of adverse effects, especially overdose, compared to full agonist				

201 KAR 9:270	201 KAR 9:260	VA Guidelines	ASAM NPG (2020)	SAMHSA Tip 63 (2021)	SAMHSA OTP Regulations/ Guidelines (2024)	FDA/SAMHSA	Comment
			opioids." (NPG Page 55)				
Initiation dose requirements and limit – e.g., Day 1 max 16mg (Section 3(4)(b)3.)			Buprenorphine initiation dosing should be titrated according to withdrawal symptoms; dose should be sufficient to enable patients to discontinue illicit opioid use; doses may exceed 16 mg if clinically indicated. Clinicians using extended-release products should use them as indicated. (NPG Pages 12, 42) "Buprenorphine dose and dosing frequency should be individualized based on patients' treatment needs, the possibility of novel components in the drug supply should be considered	"The guidelines presented should not be considered substitutes for individualized client care and treatment decisions." (ES-12)			Prescriptive dosing standards may result in undertreatment and higher relapse risk. Recommended protocols in 201 KAR 9:270 also does not account for the use of extended-release buprenorphine products.

201 KAR 9:270	201 KAR 9:260	VA Guidelines	ASAM NPG (2020)	SAMHSA Tip 63 (2021)	SAMHSA OTP Regulations/ Guidelines (2024)	FDA/SAMHSA	Comment
			during OUD treatment . . .” (CC Page 1)				
Mandatory behavioral modification/ Counseling (Section 3(4)(d)1.)			“Patients’ psychosocial needs should be assessed, and patients should be offered or referred to psychosocial treatment based on their individual needs. However, a patient’s decision to decline psychosocial treatment or the absence of available psychosocial treatment should not preclude or delay pharmacotherapy, with appropriate medication	EXHIBIT 2.16. Referring Patients Who Receive OUD Medications to Behavioral Health Therapies: If the patient is unwilling to engage in additional behavioral health therapies, then Offer best advice and ongoing motivational interviewing; revisit offer for	42 CFR 8.12 (f)(5)(i): “Patient refusal of counseling shall not preclude them from receiving MOUD.”	May 2023 Dear Colleague Letter: “An often-cited barrier to prescribing buprenorphine for the treatment of OUD is the perception that patients must engage in counseling and other services in order to start or continue receiving the medication. This letter serves to clarify the importance of	Makes MOUD contingent on counseling, directly contradicting federal OTP regulations, national medical guidelines and guidance. It discriminates against underserved patients, creating non-medical barrier to lifesaving addiction medicine.

201 KAR 9:270	201 KAR 9:260	VA Guidelines	ASAM NPG (2020)	SAMHSA Tip 63 (2021)	SAMHSA OTP Regulations/ Guidelines (2024)	FDA/SAMHSA	Comment
			management." (NPG Page 10)	behavioral health therapies." (2-24)		counseling and other services as part of a comprehensive treatment plan, but to also reiterate that the provision of medication should not be made contingent upon participation in such services."	

201 KAR 9:270	201 KAR 9:260	VA Guidelines	ASAM NPG (2020)	SAMHSA Tip 63 (2021)	SAMHSA OTP Regulations/ Guidelines (2024)	FDA/SAMHSA	Comment
Rigid visit schedule (Post initiation: within 10 days; Month 2: within 14 days; Then Monthly; After 2 years & compliant: every 3 months) (Section 3(4)(d)3.,4.)			"Patients should be seen frequently at the beginning of their treatment until patients are determined to be stable. The stability of a patient is determined by an individual clinician based on several indicators which may include abstinence from illicit drugs, participation in psychosocial treatment and other recovery-based activities, and productive occupational and social functioning. Stable patients can be seen less frequently." (NPG Page 42)	"The guidelines presented should not be considered substitutes for individualized client care and treatment decisions." (ES-12)			A fixed schedule is not evidence-based, and it may discourage retention. The proposed rigid visit schedule does not appear to account for the use of extended-release buprenorphine products.

201 KAR 9:270	201 KAR 9:260	VA Guidelines	ASAM NPG (2020)	SAMHSA Tip 63 (2021)	SAMHSA OTP Regulations/ Guidelines (2024)	FDA/SAMHSA	Comment
Mandatory specialist consultation with an addiction specialist physician for certain dosing: Annually, if prescribed more than 16mg of buprenorphine daily and not an addiction specialist physician, then refer patient for a formal consultation with an addiction specialist physician. (Section 3(4)(d)5.c.)						FDA Notice (12/2024): "FDA recommends the following specific changes to the maintenance dosage recommendations in the "Dosage and Administration" section of the most recent approved BTOD labeling: After treatment induction to the recommended dose of [equivalent 16 mg buprenorphine OR equivalent 16 mg/4 mg buprenorphine/naloxone] per day, dosing should be further adjusted based on the individual patient and clinical response. The maintenance dose of [DRUG NAME] is generally in the	Proposal does not appear to account for extended-release buprenorphine products or recent label changes indicating maintenance dose range is generally up to 24mg daily. "In 2019, Kentucky had **almost 160,000** people aged 18–64 years old with OUD—nearly 6 % of the population." (See here.). Yet, based on ABMS' 2022-2023 Certification Report, there are only 113 ABPM-certified addiction medicine physicians in KY, and only 12

201 KAR 9:270	201 KAR 9:260	VA Guidelines	ASAM NPG (2020)	SAMHSA Tip 63 (2021)	SAMHSA OTP Regulations/ Guidelines (2024)	FDA/SAMHSA	Comment
						range of [equivalent 4 mg buprenorphine OR equivalent 4 mg/1 mg buprenorphine/naloxone] to [equivalent 24 mg buprenorphine OR equivalent 24 mg/6 mg buprenorphine/naloxone] per day. Dosages higher than [equivalent 24 mg buprenorphine OR equivalent 24 mg/6 mg buprenorphine/naloxone] daily have not been investigated in randomized clinical trials but may be appropriate for some patients." Suboxone Label Change (5/2025): "The maintenance dose of SUBOXONE sublingual film is generally in the	ABPN-certified addiction psychiatrists in KY.

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						range of 4 mg/1 mg to 24 mg/6 mg per day and should be based on clinical response. Dosages higher than 24 mg/6 mg daily have not been investigated in randomized clinical trials but may be appropriate for some patients."	
Mandatory comprehensive evaluation of patient and prescriber obligation to make "best efforts" to obtain prior medical records	"If the licensee determines that the patient has previously received medical treatment for the presenting medical complaint or		"If not completed before initiating treatment, assessments should be completed soon thereafter." (Page 10)		42 CFR 8.12(f)(2)(B): "A patient's refusal to undergo lab testing for co-occurring physical health conditions should not preclude them		Failure to meet rigid evaluation timelines could cause inappropriate discontinuation of buprenorphine, risking patient safety.

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before (or within 14 days of) initiation (Section 3(4)(a)1.,2.)	related symptoms **and that review of the prior treatment records is necessary to justify long-term prescribing, dispensing, or administering of a controlled substance**, the licensee shall obtain those prior medical records and incorporate the information therein into the evaluation and treatment of the patient." (Section (4)(2)(e))				from access to treatment, provided such refusal does not have potential to negatively impact treatment with medications."		

201 KAR 9:270	201 KAR 9:260	VA Guidelines	ASAM NPG (2020)	SAMHSA Tip 63 (2021)	SAMHSA OTP Regulations/ Guidelines (2024)	FDA/SAMHSA	Comment
Mandatory specialist consultation with an addiction specialist physician (which can be provider-to-provider) for certain co-prescriptions beyond a period of 3 months. (Section 3(3))			"The use of benzodiazepines and other sedative-hypnotics should not be a reason to withhold or suspend treatment with methadone or buprenorphine. While the combined use of these medications increases the risk of serious side effects, the harm caused by untreated opioid use disorder can outweigh these risks. A risk-benefit analysis should be conducted, and greater support should be provided including careful medication management to reduce risks." (NPG Page 10)	"Co-prescribing benzodiazepines or other sedatives should not preclude or delay treatment with buprenorphine." (Part 3, page 4)		FDA (9/2017): FDA is "advising that the opioid addiction medications buprenorphine and methadone should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS). The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction can outweigh these risks. Careful medication management by health care professionals can reduce these risks. We are requiring this information to be added to the	While a specialist consultation may be ideal in this scenario, it's not always practical. Discontinuation of buprenorphine could risk patient safety. "In 2019, Kentucky had **almost 160,000** people aged 18–64 years old with OUD—nearly 6 % of the population." (See here.). Yet, based on ABMS' 2022-2023 Certification Report, there are only 113 ABPM-certified addiction medicine physicians in KY, and only 12 ABPN-certified addiction psychiatrists in Kentucky.

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						buprenorphine and methadone drug labels along with detailed recommendations for minimizing the use of medication-assisted treatment (MAT) drugs and benzodiazepines together."	
Allowable Deviations from Standards: Must be " . . . in accordance with SAMHSA guidelines as set forth in: Substance Abuse and Mental Health Services Administration, Medications for Opioid Use Disorder, Treatment Improvement Protocol (TIP) Series 63, Publication No. PEP21-01-002, Rockville, MD: Substance Abuse	"If a licensee is unable to conform to professional standards for prescribing, dispensing, or administering controlled substances due to circumstances beyond the licensee's control, or the licensee makes a professional determination that it is not						More clinical flexibility is allowed by 201 KAR 9:260, which covers Schedule II medications, including full opioid agonists.

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and Mental Health Services Administration, 2021." (Section 4(2))	appropriate to comply with a specific standard, based upon the individual facts applicable to a specific patient's diagnosis and treatment, the licensee shall document those circumstances in the patient's record and only prescribe, dispense, or administer a controlled substance to the patient **if the patient record appropriately justifies the prescribing, dispensing, or administering of a controlled substance under the**						

201 KAR 9:270	201 KAR 9:260	VA Guidelines	ASAM NPG (2020)	SAMHSA Tip 63 (2021)	SAMHSA OTP Regulations/ Guidelines (2024)	FDA/SAMHSA	Comment
	circumstance." (Section 2(2))						