June 25, 2025

Ms. Leanne K. Diakov
General Counsel
Kentucky Board of Medical Licensure
310 Whittington Parkway, Suite 1B
Louisville, KY 40222

RE: Proposed amendments to 201 KAR 9:270, "Professional standards for prescribing, dispensing, or administering Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone"

Dear Ms. Diakov:

The Legal Action Center and Kentucky Equal Justice Center write to oppose the proposed 201 KAR 9:270 regulations because they would discriminate against people with opioid use disorder in violation of the Americans with Disabilities ("ADA") and potentially the Rehabilitation Act of 1973 by singling them out and limiting their access to evidence-based treatment due to stereotypes and assumptions, rather than any legitimate justification. Proposed 201 KAR 9:270 also would discriminate against licensees by interfering with their ability to aid their patients with OUD in the exercise of their rights under the ADA.

The Legal Action Center (LAC) is a law and policy organization that fights discrimination, builds health equity, and restores opportunity for people with substance use disorders (SUD), arrest and conviction records, and HIV or AIDS. We use a multi-dimensional strategy involving impact litigation, direct services, education, and policy advocacy. Through our work with clients, community groups, health care providers, and advocates in Kentucky and across the country, we have witnessed first-hand the life-changing and life-saving benefits of buprenorphine treatment for opioid use disorder. We also have witnessed the myriad barriers and discrimination people face when trying to access buprenorphine treatment – jeopardizing their lives and increasing their chance of criminal justice and child welfare system involvement. LAC has partnered with the Kentucky Equal Justice Center and Vital Strategies' Overdose Prevention Program to fight discriminatory denial of health care for Kentuckians with SUD. LAC is submitting these comments because proposed 201 KAR 9:270, if enacted, would be one more discriminatory barrier to an essential form of health care.

Kentucky Equal Justice Center (KEJC) is a nonprofit law firm and public interest advocacy organization, founded in 1976 and dedicated to ensuring equal justice for all Kentuckians. KEJC serves as an advocate for low income and other vulnerable members of society, working cooperatively with a multitude of community partners. In addition to partnering with Vital

Strategies' Overdose Prevention Program and LAC, as mentioned above, KEJC also works alongside organizations in Kentucky, like VOCAL-KY and Dream.org, to ensure Kentuckians with SUD know their rights and are treated fairly by the systems and institutions they need to achieve and sustain long-term recovery.

The ADA and the Rehabilitation Act of 1973 (RA) provide a comprehensive statutory mandate to prohibit discrimination based on disability.[1] Their overarching goal is to eliminate discrimination by requiring government-run programs, places of public accommodation, employers, and others to treat individuals with disabilities equally and fairly, based on an objective evaluation of their need for and eligibility for services, rather than stereotypes and myths.[2] The Kentucky Board of Medical Licensure ("KBML") is an instrumentality of State government, and as such, is subject to Title II of the ADA (Title II).[3] It is well settled that individuals with opioid use disorder ("OUD") typically have a "disability" under the ADA – including when they take lawfully prescribed buprenorphine to treat OUD.[4]

Title II prohibits a State government entity – like the KBML – from denying a qualified[5] individual with a disability the benefits of the government's program, activities, or services or otherwise subjecting them to discrimination by reason of their disability.[6] "Services" under Title II include medical services, such as the prescribing of medications like buprenorphine.[7]

---

[1] 42 U.S.C. § 12101.

[2] 42 U.S.C. § 12101, et. seq.; 29 U.S.C. § 794, et. seq.

[3] 42 U.S.C. § 12131(1).

[4] *Get Back Up, Inc. v. City of Detroit, Mich*., 725 Fed.Appx. 389, 392 (2018); *MX Grp. v. City of Covington*, 293 F.3d 326, 332–40 (6th Cir. 2002).

[5] An individual is not a "qualified" individual with a disability if they pose a "direct threat to the health and safety of others[]" or themselves. *See* 28 C.F.R. § 35.139(a); *Smith v. Newport Utils.*, No. 24-5502, 129 F.4th 944, 949-50 (6th Cir. 2025). A "direct threat" must be based on a "rigorous" and "individualized" inquiry, *Entine v. Lissner*, No. 2:17-cv-946, 2017 WL 5507619, at *6-8 (S.D. Ohio 2017). The court must consider three factors: (1) "The nature, duration, and severity of the risk" posed, (2) The probability such harm will actually occur, and (3) whether the risk of the harm may be mitigated by "modifications of policies, practices, or procedures or the provision of auxiliary aids or services." *See Bennett v. Hurley Med. Ctr.*, 86 F.4th 314, 327-28 (6th Cir. 2023) (citing 28 C.F.R. § 35.139(b)).

[6] 42 U.S.C. § 12132. To establish a prima facie case of intentional discrimination under Title II of the ADA, a plaintiff must discrimination under Title II, a plaintiff must show that: (1) she has a disability; (2) she is otherwise qualified; and (3) she was being excluded from participation in, denied the benefits of, or subjected to discrimination under the program because of her disability*." Bennett v. Hurley Medical Center*, 86 F.4th 314, 325 (6th Cir. 2023) (citations omitted). To show that the discrimination was "because of" disability, a plaintiff must present evidence that animus against the protected group was "a significant factor in the position taken by the ... decision-makers themselves or by those to whom the decision-makers were knowingly responsive." *Id*. (citations omitted) If a plaintiff establishes a prima facie case, the burden shifts to the defendant to proffer a "'legitimate, nondiscriminatory' reason for its actions." If the defendant does so, the burden shifts back to the plaintiff to show that the "proffered reason is merely a pretext for unlawful discrimination." *Id*. (citations omitted).

[7] *See Pesce v. Coppinger*, 355 F. Supp.3d 35, 45 (D. Mass. 2018).

The Title II regulations provide numerous illustrations of discrimination, including administering a licensing program in a way that subjects individuals with disabilities to discrimination.[8] Title II regulations also provide that discrimination includes "deny[ing] a qualified individual with a disability the opportunity to . . . benefit from [a] . . . service" and "afford[ing] a qualified individual with a disability an opportunity to … benefit from …[a] service that is not equal to that afforded others[.]"[9]

As explained below, Kentucky's adoption and implementation of 201 KAR 9:270 would constitute discrimination under all of these provisions because the regulations would deny individuals with OUD equal access to medical services because of their disability and would constitute discriminatory administration of a licensing program. Specifically, proposed 201 KAR 9:270 would impose more burdensome requirements on buprenorphine than on other controlled substances without legitimate justification and is based on stereotypes and assumptions about people with OUD, rather than legitimate considerations. It also would interfere with buprenorphine prescribers' ability to aid their patients with OUD in the exercise of their rights under the ADA.[10]

Proposed 201 KAR 9:270 would impose more burdensome restrictions on buprenorphine than on other controlled substances without legitimate justification

Proposed 201 KAR 9:270 is more restrictive and burdensome than regulations governing the prescribing of other controlled substances, without legitimate reason. This differential treatment is because of the disability of those who receive buprenorphine treatment, and therefore, is discriminatory.[11]

Kentucky has a separate regulatory scheme for the prescribing, dispensing, and administering of controlled substances generally.[12] Among the many provisions in these regulations are those specifying obligations prior to the initial prescribing, dispensing, or administering of the controlled substance (e.g., information to obtain and document from the patient and to provide to the patient, a required physical or mental health examination, instructions and agreements, and

[8] "A public entity may not administer a licensing . . . program in a manner that subjects qualified individuals with disabilities to discrimination on the basis of disability, nor may a public entity establish requirements for the programs or activities of licensees . . . that subject qualified individuals with disabilities to discrimination on the basis of disability." 28 C.F.R. § 35.130(b)(6).

[9] 28 C.F.R. §§ 35.130(b)(1)(i) and (ii).

[10] 42 USC § 12203(b); 28 C.F.R. § 35.134(b).

[11] Notably, the statute authorizing KBML to regulate the prescribing of controlled substances does not require – or even suggest the need for -- a more onerous standard for buprenorphine. *See* KRS § 218A.205(30(a)-(b).

[12] 201 KAR 9:260, Professional standards for prescribing, dispensing, and administering controlled substances.

periodic reviews of the patient's file),[13] and obligations when continuing to prescribe, dispense or administer the controlled substance.[14]

Prescribing, dispensing, or administering controlled substances for pain (and related symptoms associated with the same primary medical complaint) involves additional requirements – but even the regulations governing long-term use of pain medication are not as restrictive as those in the proposed buprenorphine regulations. For example, the pain prescribing regulations include one baseline and random drug screens for long-term use of pain medication[15] but not weekly and monthly drug screening as in proposed 201 KAR 9:270.[16] KBML's guidance on the frequency of such drug screens only recommends it three to four times per year for "high risk" patients, and only at every visit for patients exhibiting aberrant behavior.[17] The long-term pain medication prescribing regulations require obtaining a patient's prior medical records only if the prescriber has determined "that review of the prior treatment records is necessary" to justify long-term prescribing, dispensing, or administration,[18] whereas 201 KAR 9:270 requires always obtaining prior medical records (with patient consent) unless the licensee is unable to obtain them despite best efforts.[19]

Stimulants and hydrocodone are the only other controlled substances with State regulations that go beyond 201 KAR 9:260,[20] but neither imposes restrictions like those in the proposed buprenorphine regulations. For example, they lack the requirements for frequent drug testing, behavioral counseling, dosage regulation, and patient visits found in proposed 201 KAR 9:270.[21]

In short, none of Kentucky's regulations governing prescribing, dispensing, or administration of controlled substances – including opioids prescribed long term for pain – contain the types of additional requirements that proposed 201 KAR 9:270 would impose for buprenorphine to treat opioid use disorder. The latter governs everything from the medical records licensees must

---

[13] 201 KAR 9:260 § 2.

[14] 201 KAR 9:260 § 7.

[15] 201 KAR 9:260 §§ 4(2)(h)(4) and 5(2)(k)(1).

[16] 201 KAR 9:270 § 3(4)(d)(5)(f).

[17] KBML, Considerations for Drug Use Screening, https://kbml.ky.gov/hb1/Pages/Considerations-For-Urine-Drug-Screening.aspx.

[18] 201 KAR 9:260 § 4(2)(e).

[19] 201 KAR 9:270 § 3(4)(a)(2).

[20] *See 201 KAR 9:016,* Restrictions on use of amphetamine and amphetamine-like anorectic controlled substances; 201 KAR 9:220, Restriction upon dispensing of Schedule II controlled substances and Schedule III controlled substances containing Hydrocodone.

[21] It is also worth noting that Kentucky is one of only six states that regulate all practitioners that prescribe buprenorphine for OUD, one of only six states that establish visit frequency requirements for some or all buprenorphine patients, and one of only three states that apply visit frequency requirements for the duration of treatment. *See* Law Atlas, Buprenorphine Prescribing Requirements and Limitations, https://lawatlas.org/datasets/buprenorphine-prescribing-requirements-and-limitations

obtain to the increased frequency of drug testing and patient visits, as well as limits on dosing that, as noted below, are not based in evidence and are contrary to the standard of care.

The singling out of a medication to treat OUD for unnecessary, burdensome restrictions not imposed on medications to treat other health conditions would deny individuals with OUD the equal opportunity to benefit from medical services because of their disability. It also would constitute the discriminatory administration of a licensing program.

Proposed 201 KAR 9:270 is based on stereotypes and assumptions about individuals with OUD, rather than evidence-based standards

Proposed 201 KAR 9:270 is also discriminatory because it is based on stereotypes and assumptions about people with OUD, rather than objective medical evidence.[22] The United State Court of Appeals for the Sixth Circuit – which has jurisdiction over Kentucky – has held that government action based on fear and stereotypes about people with SUD constitutes discrimination. In *MX Group, Inc. v. City of Covington*, 293 F.3d 326 (2002), the Court upheld a lower court decision that the City of Covington's denial of a permit to a methadone program and subsequent enactment of a zoning ordinance banning methadone programs violated Title II of the ADA because it was "based on stereotypes and fear."[23] In taking these zoning actions, government officials had responded to unsubstantiated concerns that patients of the methadone program would engage in illegal drug use and other criminal conduct. In contrast, there was "ample evidence" that the plaintiff had operated another methadone program in the State "without incident of criminal activity, and that methadone clinics present no more problems in the way of drug trafficking and diversion than other facilities that deal with lawfully administered drugs, such as hospitals and pharmacies."[24] The government pointed to no evidence that methadone clinics attracted increased drug activity or crime.[25]

The United States Department of Justice (DOJ) similarly has found that State government agencies violate the ADA when they restrict access to health care for people with substance use disorder due to stereotypes and assumptions about them or the medication they receive to treat OUD, rather than objective medical evidence. In one case, DOJ entered into a settlement agreement with the Alabama Medicaid program for imposing "non-medically indicated sobriety

---

[22] *See Bennett v. Hurley Medical Center*, 86 F.4th 314 (6th Cir. 2023) (by showing that animus against the protected group was "'a significant factor in the position taken by the ... decision-makers themselves or by those to whom the decision-makers were knowingly responsive,'" a plaintiff can demonstrate that the denial of government services or benefits was "because of" disability. *Id*. at 325.

[23] *MX Group, Inc. v. City of Covington*, 293 F.3d 326, 341-42 (2002). The lower court had found that the permit denial and zoning ordinance Zoning action were a "panicked reaction to public hysteria based on stereotypes of MX Group's clients….This is exactly what the ADA forbids." *MX Group Inc*., 106 F. Supp.2d 914, 920 (E.D. KY 2000).

[24] *Id*. at 342.

[25] *Id.*

restrictions" for Medicaid coverage of hepatitis medication.[26] DOJ also issued a Letter of Findings that the Indiana State Board of Nursing violated the ADA by prohibiting nurses from receiving medication for OUD (buprenorphine or methadone) as a condition of participating in the Indiana State Nursing Assistance Program. The Letters of Finding reasoned that the requirements "conflict[ed] with prevailing medical guidance on OUD medication."[27]

Likewise, proposed 201 KAR 9:270 reflects unsubstantiated stereotypes and assumptions about people with OUD – namely that they generally will misuse and divert their medication, and that they will do so even more than individuals prescribed controlled substances for other health conditions, including pain. The regulations also suggest a skepticism about the value of buprenorphine as treatment when it is received for more than twelve months or at the higher end of clinically appropriate doses – even though, as explained below, longer-term treatment and doses above 16 mg. are consistent with the standard of care and improve outcomes for many, and there is no objective medical reason to restrict such practices.

KBML's President Dr. William Thornbury testified that in developing 201 KAR 9:270, KBML sought to provide "a careful balance between the access to treatment and implementing appropriate safeguards to prevent misuse and drug diversion."[28] Yet, the proposal itself reflects no such balance. Instead, it reflects assumptions, stereotypes, and misconceptions about people with OUD and the medication used to treat it. Ironically, it hinders, rather than promotes, "access to treatment."

Many addiction medicine professionals submitted comments during the regulatory process, articulating the numerous ways in which earlier and current versions of 201 KAR 9:270 were not evidence-based and would needlessly keep people out of care. Their recommendations went largely unheeded. Some of their key, salient points, in addition others, are as follows:

- **Dosage restrictions are not evidence-based and impede appropriate care**. Proposed 201 KAR 9:270 § 3(4)(b)(3) limits a patient's first dose to 4 mg., with a maximum first day dose of 16 mg. Proposed 201 KAR 9:270§ 3(4)(d)(5)(c) requires annual visits to an

[26] Settlement Agreement Between the United States of America and the State of Alabama's Medicaid Agency, Dec, 25, 2022, https://www.justice.gov/archives/opa/media/1262871/dl.

[27] *See* March 25, 2022 letter from DOJ to the Indiana Attorney General, https://www.justice.gov/archives/opa/press-release/file/1487121/dl?inline=. *See also* DOJ Letter of Findings, Dec. 17. 2004, https://www.justice.gov/crt/media/1380956/dl (Tennessee Board of Law Examiners and Tennessee Lawyers Assistance Program (TLAP) violated Title II of the ADA by prohibiting individuals from participating in the TLAP program if they received buprenorphine to treat OUD and subjecting them to additional, burdensome examinations based on their lawful use of prescribed medication for OUD).

[28] October 23, 2024 hearing before the Kentucky General Assembly's Interim Joint Committee on Health Services, available at https://www.youtube.com/live/Kn76XFxalxY?t=3572s. We know of no written justification that KBML has provided for the restrictions in proposed 201 KAR 9:270.

addiction medicine specialist[29] if an individual's dose exceeds 16 mg. per day. These requirements are not evidence-based. Studies show improved treatment retention, reduced opioid use, and lack of adverse events at doses of buprenorphine 16-32 mg per day. As a result, ASAM updated its *Clinical Considerations for Buprenorphine Treatment of OUD for Individuals Using High-Potency Synthetic Opioids*,[30] concluding that some patients may benefit from high buprenorphine doses during buprenorphine stabilization (greater than 24 mg per day). The United States Substance Abuse and Mental Health Services Administration ("SAMHSA") also has recommended not using a uniform maximum dosage because it imposes high barriers to care; instead, SAMHSA supports individualized medication dosage for low-barrier access to care.[31] For the same reason, the United States Food and Drug Administration had recommended changing the labeling for buprenorphine so that after treatment induction to the recommended dose of 16 mg per day, "dosing should be further adjusted based on the individual patient and clinical response" with a maintenance dose generally in the range of 4 to 24 mg per day, acknowledging that doses higher than 24 mg. may be appropriate for some patients even though they have not been investigated in randomized clinical trials.[32]

The requirement for an annual visit to an addiction medicine specialist – even via telehealth – is a challenging condition for some patients, given the scarcity of addiction medicine professionals and the high cost of seeing one. It also suggests a mistrust of long-term treatment with buprenorphine and contributes to a commonly stigmatized notion that buprenorphine is merely "substituting one addiction for another," when objective medical evidence shows the opposite: outcomes are better when patients remain in treatment longer.[33]

- **Patient visit requirements are inconsistent with the standard of care.** Proposed 201 KAR 9:270 § 3(4)(d)(3) requires patients to visit their prescriber within 10 days after initiation of buprenorphine and at intervals of no more than 10 days for the first month, 14 days for the second month, and at least monthly thereafter "if the patient demonstrates

---

[29] Specifically, the requirement is to visit a physician certified by the American Board of Addiction Medicine, American Board of Medical Specialties in psychiatry, American Osteopathic Association certifying board in addiction medicine, or a physician who has completed an addiction psychiatry fellowship. *Id.*

[30] Available at https://downloads.asam.org/sitefinity-production-blobs/docs/default-source/advocacy/letters-and-comments/asam_clinical_considerations__buprenorphine.212-(1).pdf.

[31] SAMHSA Advisory, *Low Barrier Models of Care for Substance Use Disorders,* Dec. 2023, https://library.samhsa.gov/sites/default/files/advisory-low-barrier-models-of-care-pep23-02-00-005.pdf. Additionally, recent recommendations from the Federation of State Medical Boards (FSMB) call for the removal of non-evidence-based barriers to treatment.

[32] Modifications to Labeling of Buprenorphine-Containing Transmucosal Products for the Treatment of Opioid Dependence, 89 Fed. Reg. 105613 (Dec. 27, 2024).

[33] *See, e.g.,* Hillary Samples et al., *Impact Of Long-Term Buprenorphine Treatment On Adverse Health Care Outcomes In Medicaid,* 39, HEALTH AFFAIRS, 747 (2020); Md. Mahmudul Hasan et al., *Long-term patient outcomes following buprenorphine/naloxone treatment for opioid use disorder: a retrospective analysis in a commercially insured population,* 48, AM. J. OF DRUG & ALCOHOL ABUSE, 481 (2022).

objective signs of treatment progress.[34] The required number of office visits diverges from practice guidelines such as ASAM's National Practice Guideline for the Treatment of Opioid Use Disorder.[35] It also moves in the opposite direction of SAMHSA, which has recently implemented new rules for opioid treatment programs (OTPs)/methadone, allowing for greater clinician discretion in the context of methadone for OUD.[36] The patient visit requirements also impose a significant financial and time burden on patients, who may not be able to pay for such visits, take the needed time off work or child-care duties, or access transportation to see their prescriber. By mandating a one-size-fits-all approach and removing clinical discretion, proposed 201 KAR 9:270 deviates from the standard of care and increases the likelihood of patients not accessing essential treatment.

- **Behavioral modification requirements are not evidence-based and could force licensees to discharge patients in violation of their ethical duties.** Proposed 201 KAR 9:270 § 3(4)(e)(1) requires the licensee to implement a treatment plan that requires the patient to obtain "objective behavioral modification," such as "counseling or a twelve (12) step facilitation." Such a rigid requirement that leaves no room for clinical discretion and is not evidence-based.[37] Further, it will result in some clinicians having to stop treating individuals who do not want, do not need, cannot afford, or are unable to access behavioral modification services – particularly in geographic areas where such services are scarce. The requirement will require some clinicians to risk violating their ethical duty to their patients or face sanctions from KBML.

- **Drug testing requirements are costly, burdensome, and not evidence-based:** Proposed 201 KAR 9:270 § 3(4)(e)(5)(f) requires buprenorphine prescribers to conduct

---

[34] 201 KAR 9:270 §3(4)(d)(3). After two years, the visits can be reduced to every three months if certain conditions are met. *Id.*

[35] *ASAM National Practice Guideline for the Treatment of Opioid Use Disorder (2020 Focused Update* (ASAM National Practice Guidelines 2020 Update), https://www.asam.org/quality-care/clinical-guidelines/national-practice-guideline.

[36] 42 C.F.R. Part 8.

[37] *See* Letter from Mirian E. Delphon Rittmon, Assistant Secretary for Mental Health and Substance Use and Patrizia Cavazzoni, Director, Center for Drug Evaluation and Research, to FDA and SAMHSA Colleagues (May 9, 2023), https://www.samhsa.gov/sites/default/files/dear-colleague-letter-fda-samhsa.pdf, clarifying that "the provision of medication should not be made contingent upon participation" in counseling, that the decision as to when counseling is provided should be made in collaboration with the individual patient, and that the evidence-base does not provide direction on the type of counseling or services that might be optimal for different patients and at different stages; ASAM National Practice Guidelines 2020 Update, supra note 35 ("A patient's decision to decline psychosocial treatment or the absence of available psychosocial treatment should not preclude or delay pharmacological treatment of opioid use disorder, with appropriate medication management."); Sarah E. Wakeman, MD, et. al., *Comparative Effectiveness of Different Treatment Pathways for Opioid Use Disorder*, JAMA NETWORK OPEN, Feb. 2020 at e192062 ("patient-centered MOUD care, which allows participants to determine the services they need rather than requirements, such as mandatory counseling, are noninferior to traditional treatment.); David A. Fiellin, et. al, *A Randomized Trial of Cognitive Behavioral Therapy in Primary Care-based Buprenorphine*, 126 AM. J MED. 74.e11 (2013) (Among patients receiving buprenorphine/naloxone in primary care for opioid dependence, the effectiveness of physician management did not differ significantly from that of physician management plus cognitive behavioral therapy).

drug testing, at minimum, weekly during the early stages of treatment, and monthly thereafter, regardless of a patient's time in treatment, though with sustained remission, can be "less frequent." Random testing upon intake and annually also is required. Testing must resume the initial schedule if the patient "returns to substance use." This requirement is not evidence-based and even exceeds the strict federal requirements for drug testing at opioid treatment programs.[38]

- **Obtaining prior medical records is unnecessarily burdensome and harmful.** Proposed 201 KAR 9:270 § 3(4)(a)(2) requires licensees to obtain authorizations for patients' "prior medical records" and to document when such records could not be obtained despite "best efforts." This requirement differs substantially from the regulations governing controlled substances for long-term pain management, where obtaining such records is suggested only in limited circumstances and left to clinician discretion.[39] More disturbingly, the regulations do not define which "prior medical records" must be sought – not the type of records (former buprenorphine prescribers only? all health care providers?), nor the time period, nor for what purpose. Given the cost, difficulty, and length of time required to obtain medical records, and the invasion of patients' privacy interests, this requirement needlessly burdens patients and licensees and reduces access to essential treatment. Notably, other provisions in the regulations already impose safeguards against patients' seeking the same medication from more than one prescriber, by requiring licensees to check the KASPER.

The burdensome restrictions in proposed 201 KAR 9:270 would not only continue to block access to essential evidence-based care, but they also would be unlikely to achieve their purported purpose of addressing misuse and diversion. As stated in the Kentucky Society of Addiction Medicine's letter to Governor Beshear, restricting access to buprenorphine may well increase illicit use of buprenorphine.[40] Studies have shown that people receiving MOUD rarely divert their medication, while conversely, inability to access treatment is a motivating factor to use diverted buprenorphine. [41] In fact, the overwhelming majority of "diverted" buprenorphine is

---

[38] 42 C.F.R. § 8.12(f)(6). *See also* Valencia Lyle et. al., *Association between high-threshold practices and buprenorphine treatment termination***,** International Journal of Drug Policy, Volume 124, February 2024, 104318, https://www.sciencedirect.com/science/article/abs/pii/S0955395924000033?via%3Dihub (finding that Michigan's higher threshold buprenorphine requirements with drug testing at every visit and mandated counseling were associated with higher rates of treatment termination, thereby reducing risk of overdose).

[39] *See* 201 KAR 9:260 § 4(2)(e) ("If the licensee determines that the patient has previously received medical treatment for the presenting medical complaint or 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.")

[40] KYSAM letter to Governor, Jan, 8, 2025, https://www.kysam.org/kysam-advocacy.

[41] Scope of, Motivations for, and Outcomes Associated with Buprenorphine Diversion in the United States: A Scoping Review. *Substance Use & Misuse*, *58*(5), 685–697. https://doi.org/10.1080/10826084.2023.2177972.

used to manage OUD-related symptoms by people who are unable to access treatment services, often due to regulatory barriers and high-threshold clinical practices.[42] In short, making buprenorphine treatment more accessible is more likely to reduce illicit use than erecting the type of barriers found in proposed 201 KAR 9:270. For this reason, national authorities like SAMHSA and the Federation of Medical Boards (FSMB) have called for the removal of non-evidence-based barriers to treatment like those in proposed 201 KAR 9:270.[43]

Proposed 201 KAR 9:270 could discriminate against licensees

Proposed 201 KAR 9:270 also could discriminate against licensees by interfering with their ability to assist their patients in the exercise of their rights under the ADA.[44] As explained above, the dosing and mandatory behavioral modification requirements are not consistent with clinical standards. Consequently, if proposed 201 KAR 9:270 is implemented, a licensee might be prohibited from prescribing a clinically appropriate dose. A licensee also might be required to discharge a patient who does not obtain the mandated behavioral modification services or annual formal consultation with an addiction medicine doctor. In any of these instances, proposed 201 KAR 9:270 would be interfering with the licensee's ability to assist patients in exercising their right to non-discriminatory health care under the ADA.

Proposed 201 KAR 9:270 also could violate 28 CFR 35.130(b)(6), which prohibits a public entity from establishing requirements for the program or activities of licensees that subject qualified individuals with disabilities to discrimination on the basis of disability. As noted above, proposed 201 KAR 9:270 would establish requirements on KBML licensees that subject their patients to discrimination on the basis of disability.

Conclusion

To continue reducing overdose deaths in Kentucky, the State needs evidence-based solutions. Unfortunately, proposed 201 KAR 9:270's restrictions on buprenorphine treatment are not evidence-based and erect unnecessary and discriminatory barriers to life-saving care. LAC and KEJC believe that adoption and implementation of proposed 201 KAR 9:270 would violate the ADA and potentially the Rehabilitation Act.

---

[42] National Academies of Sciences, Engineering, and Medicine. Medications for opioid use disorder save lives (Alan I. Leschner and Michelle Macher, eds., 2019).

[43] SAMHSA Advisory, *Low Barrier Models of Care for Substance Use Disorders*, supra at 31; Federation of State Medical Boards Position Statement on Access to Evidence-Based Treatment for Opioid Use Disorder, Apr. 2024, https://www.fsmb.org/siteassets/advocacy/policies/position-statement-on-access-to-evidence-based-treatment.pdf.

[44] "It shall be unlawful to . . . interfere with any individual in the exercise or enjoyment of . . . or on the account of his or her having aided or encouraged any other individual in the exercise or enjoyment of, any right granted or protected by this chapter." 42 U.S.C. § 12203(b); 28 C.F.R. § 35.134(b).

Thank you for considering these comments.

Sally Friedman
Senior Vice President of Legal Advocacy
Legal Action Center
225 Varick St., 4th Fl.
New York, NY 10014
(212) 243-1313
sfriedman@lac.org

Chloe Atwater
Staff Attorney
Health Justice Project Lead
Kentucky Equal Justice Center
P.O. Box 12253
Lexington, KY 40582
(859)233-3057 ext. 109
chloe@kyequaljustice.org