Kentucky Society of Addiction Medicine

A Chapter of American Society of Addiction Medicine

STATEMENT of
James Patrick Murphy MD, DFASAM
on behalf of
The Kentucky Society of Addiction Medicine
to
The Kentucky General Assembly's Interim Joint Committee on Health Services

RE: Repeal of 201 KAR 9:270, *Professional Standards for Prescribing, Dispensing, or Administering Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone*

October 23, 2024

Introduction

Chair Moser, Chair Meredith and esteemed Members of this committee, thank you for inviting me to participate in today's critically important hearing. My name is Dr. James Patrick Murphy. I am board-certified in Anesthesiology, Pain Management, and Addiction Medicine. I care for patients with pain, addiction and co-occurring conditions in Kentucky and surrounding regions. I have served in various roles, including President of the Greater Louisville Medical Society and President of the Kentucky Society of Addiction Medicine. I currently serve on the Board of Directors of the American Society of Addiction Medicine and the American Medical Association's Substance Use and Pain Care Task Force. I am Co-director of the Kentucky Harm Reduction Coalition. I am an Assistant Clinical Professor at the University of Louisville School of Medicine. Today, I am testifying on behalf of the Kentucky Society of Addiction Medicine and in my individual capacity as a concerned citizen.

We are asking for your help in repealing 201 KAR 9:270, Kentucky's outdated regulation that limits access to the life-saving medication buprenorphine for the treatment of opioid use disorder. There is no need for this regulation. It is harming the people it was intended to help. It should be repealed permanently and without delay.

A Public Health Emergency

Kentucky is mired in the throes of a deadly public health emergency, an opioid overdose crisis that has taken the lives of over 26,000 of our neighbors, friends, family members, and loved ones since the year 2000. Buprenorphine, a DEA schedule III controlled medication, has emerged as an essential standard of care for the treatment of opioid use disorder. However since 2015, Kentucky physicians' efforts to effectively care for patients with addiction have been hampered by a regulation, **201 KAR 9:270**, that impedes access to life-saving treatment for Kentuckians most at risk of dying from an overdose. **201 KAR 9:270** forces physicians to practice below the standard of care. This is harmful to the citizens of Kentucky and worsens our state's opioid crisis. As

scholars of addiction treatment policy have explained, no evidence supports the requirements in **201 KAR 9:270**, which by preventing access to buprenorphine, allows preventable deaths to occur. Kentuckians are needlessly dying because of this regulation.

Repeal 201 KAR 9:270

Therefore, on behalf of the Kentucky Society of Addiction Medicine, I respectfully call upon the Kentucky General Assembly to pass legislation to repeal **201 KAR 9:270**, *Professional Standards for Prescribing, Dispensing, or Administering Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone* and ensure that the Kentucky Board of Medical Licensure (KBML) cannot promulgate future regulations that impose additional restrictions on buprenorphine beyond those applicable to other Schedule III medications in the state.

201 KAR 9:270, is out of date and does not reflect the best evidence in the field of Addiction Medicine. Given the severe underuse of life-saving buprenorphine treatment, the scale of fentanyl overdose, and scholarly evidence about barriers to buprenorphine treatment, it has become clear that Kentucky's **201 KAR 9:270** is harming Kentuckians.

Buprenorphine Treats the Disease of Addiction

Research shows that buprenorphine effectively treats opioid use disorder through therapeutic neurobiological actions in diseased parts of the affected person's brain. Buprenorphine is unique among prescription opioids. It is known to be merely a partial opioid receptor agonist and is remarkably safer than other more potent opioids (e.g., methadone, morphine, oxycodone, and fentanyl) due in large part to an inherent pharmacodynamic limit on buprenorphine's respiratory effects for most patients. However, despite being so safe and effective, Kentucky regulates buprenorphine more strictly than the other more potent opioids.

Treatment with buprenorphine is not merely replacing one drug dependency with another. Far from it, buprenorphine, treats the physiologic disease process causing the addiction, promoting health and recovery and preventing overdose and death. To treat opioid use disorder, buprenorphine is usually taken orally, once a day, or by way of an injection given monthly by a clinician. Physiological dependence to buprenorphine is not the same as an active opioid use disorder. People with physiological dependence to buprenorphine can return to work, school, their lives effectively.

A Brief History of Buprenorphine

In 2000, Congress passed the Drug Abuse Treatment Act (DATA 2000), allowing physicians to prescribe Schedule III-V controlled substances for maintenance/detoxification treatment of opioid

use disorder (OUD) if the medication was approved by the FDA for those purposes. In 2002, buprenorphine, a Schedule III controlled substance, was FDA approved for the treatment of OUD. Then in 2015, the Kentucky Board of Medical Licensure created **201 KAR 9:270**, a regulation imposing restrictions far exceeding the requirements of federal law. Federal law has since changed dramatically, largely eliminating previous prescribing requirements unique to buprenorphine treatment. The intention of such change was to increase treatment of OUD with buprenorphine during a time of drastically increasing overdose deaths. The federal law changes reflected growing awareness in the addiction treatment field of the large benefits and low risk of buprenorphine treatment. For example, in response to bipartisan action, Congress eliminated the federal DEA X-waiver requirement in December 2022, and the DEA wrote in a letter to all registered prescribers:

"DEA fully supports this significant policy reform. In this moment, when the United States is suffering tens of thousands of opioid-related drug poisoning deaths every year, the DEA's top priority is doing everything in our power to save lives. Medication for opioid use disorder helps those who are fighting to overcome opioid use disorder by sustaining recovery and preventing overdoses. At DEA, our goal is simple: we want medication for opioid use disorder to be readily and safely available to anyone in the country who needs it. The elimination of the X-Waiver will increase access to buprenorphine for those in need."

Yet, Kentucky – along with a handful of other states – has ignored the legal trend of making buprenorphine treatment more flexible, person-centered, and accessible. In fact, Kentucky's current regulations now completely fail to resemble those under federal law and instead burden patients and physicians with non-evidence-based requirements, e.g., excessive mandatory drug screens, onerous in-person visit schedules, and overly conservative dose limits in a time when extremely potent illicit synthetic drugs are flooding our streets. **201 KAR 9:270** is so outdated that it even continues to explicitly require possession of a DEA X-waiver – even though the X-waiver has been eliminated for almost two years.

Removing Barriers

Given the urgency of Kentucky's opioid overdose crisis, we must work to eliminate all unnecessary barriers to buprenorphine treatment access, to include **201 KAR 9:270**. Buprenorphine will remain a DEA schedule III controlled substance and will still be regulated by Kentucky's other controlled substance laws (i.e., 201 KAR 9:260) even with repeal of **201 KAR 9:270**. In other words, repeal of **201 KAR 9:260** would not lead to a "wild west" of buprenorphine prescribing. Repeal would instead allow buprenorphine to be treated like all other Schedule III controlled substances – an approach already implemented by the vast majority of other U.S. states.

Buprenorphine is a relatively safe medication. However, the existence of a buprenorphine-specific regulation (i.e., **201 KAR 9:270**) fosters the perception that treatment with buprenorphine is somehow more dangerous and more difficult than treatment with other schedule III medications.

Unfounded beliefs such as these worsen the prejudice and stigma directed at patients suffering from the disease of addiction as well as the physicians who care for these patients. **201 KAR 9:270** unfairly targets people struggling with opioid use disorder by treating them differently from individuals with other medical conditions like hypertension or diabetes, for example, which makes seeking medical treatment more difficult for patients with addiction. Fewer people then receive effective treatment for their opioid use disorder. This can lead to higher crime rates, increased homelessness, a greater burden on social services, and greater costs to our state's economy. Furthermore, **201 KAR 9:270** exacerbates disparities in healthcare access, especially for marginalized populations like low-income individuals or minoritized populations. **201 KAR 9:270** makes it harder for these groups to receive treatment, thereby perpetuating health inequities.

201 KAR 9:270 Promotes Drug Diversion

Some proponents of buprenorphine access restrictions in excess of DEA standards do so with the unsubstantiated belief that buprenorphine is at high risk of diversion. To the contrary, increased access to legally prescribed buprenorphine treatment is likely to prevent diversion and illicit purchases. A 2019 systematic review found that lack of access to legally prescribed buprenorphine is the primary reason for buprenorphine diversion—with illicitly purchased buprenorphine primarily used by patients self-treating to manage cravings and withdrawal symptoms rather than to experience a "high." Another study from the University of Kentucky in 2012, concluded that improving access to buprenorphine treatment could be an effective public health strategy to mitigate buprenorphine diversion and abuse.

Rather than prevent drug diversion, **201 KAR 9:270** likely contributes to the demand for illicitly obtained buprenorphine, because it discourages physicians from prescribing the medication legally to those who need it. Repeal of **201 KAR 9:270** would reduce the burdensome limitations experienced by physicians who prescribe buprenorphine and reduce barriers to legal access of buprenorphine, which would decrease the demand for illicit buprenorphine.

KY Does Not Need a Buprenorphine-specific Regulation

For Kentucky to have an effective clinical response to its deadly opioid crisis, Kentucky prescribers must be allowed to treat patients in accordance with current expert guidance, uncoupled from a regulatory review process that has proven itself to be woefully inadequate. The process for revising state law is too slow to keep up with scientific advances, i.e., the Kentucky Board of Medical Licensure, by its own admission, might need years to update **201 KAR 9:270**.

In contrast, evidence-based clinical guidelines can more quickly change in response to scientific advancement. So, if Kentucky wants to specify some manner of buprenorphine prescribing requirements, Kentucky should simply require that physicians follow clinical practice guidelines

of relevant professional organizations, e.g., the American Society of Addiction Medicine. Alternatively, Kentucky can rely on physicians to follow their best clinical judgment – the legal norm for practically all other treatments and fields of medicine. With almost six Kentuckians dying every day from overdose—all of which are preventable deaths—waiting years for KBML to update **201 KAR 9:270** is unconscionable, especially since there is no longer a compelling need for the regulation to exist.

Clinical Judgment

In providing patient-centered care, physicians must be afforded latitude to exercise their clinical judgment. However, the rigid dictates in **201 KAR 9:270** force physicians to treat patients in accordance with inflexible provisions, rather than in accordance with individual patient needs. The non-evidence-based requirements in **201 KAR 9:270** can force patients and physicians into adversarial situations with punitive consequences, damaging trust—the foundation of a therapeutic patient-physician relationship.

Our Default Future is a Choice

For reasons that remain unclear, Kentucky experienced a modest decrease in overdose deaths in 2023. Any progress is welcomed, however it remains true that Kentucky's aggregate overdose death rate over the past four years represents the deadliest overdose period in Kentucky's history. And it must not be overlooked that, while overdose deaths among Kentucky's White residents decreased slightly in 2023, our state experienced another increase in overdose deaths among Black residents, continuing the disproportionate deadly impact Kentucky's overdose crisis has had on our Black and Indigenous communities. Research has repeatedly demonstrated that racially and ethnically minoritized communities are among those least likely to have access to a buprenorphine prescriber—**201 KAR 9:270** just makes this disparity worse. The ethical principle of justice requires that policies be enacted to increase buprenorphine access in underserved communities; yet **201 KAR 9:270**, which places unnecessary burdens on buprenorphine physicians and patients, does the opposite.

This does not have to be our default future. We have a choice. There is an alternative future with dramatically fewer overdose deaths for all groups of Kentuckians. Better access to buprenorphine is key to achieving this goal. In March of this year, NIDA Director Dr. Nora Volkow, our nation's premier addiction scientist, stated that if buprenorphine was made available to all patients in need, our nation's overdose death rate could be cut by half, while presenting very minimal risk to public health or patients' health.

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Summary

Buprenorphine is a safe, effective, and life-saving medication for the treatment of people with opioid use disorder. However, due to buprenorphine access barriers (e.g., **201 KAR 9:270**), buprenorphine is accessed by only approximately one out of five people who need treatment with this medication. **201 KAR 9:270** limits access to life-saving treatment with buprenorphine, worsens the societal impact of the opioid crisis, perpetuates stigma, and harms the people it was intended to help. Considering current scientific evidence, there is no plausible reason a separate buprenorphine regulation should continue to exist in Kentucky, especially considering our federal government has eliminated more restrictive national buprenorphine-specific regulations.

Therefore, the Kentucky General Assembly must take immediate action to repeal **201 KAR 9:270** and ensure that the Kentucky Board of Medical Licensure cannot promulgate future regulations that impose additional restrictions on buprenorphine beyond those applicable to other Schedule III medications in the state. In this time of unparalleled crisis, physicians must be empowered to treat patients struggling with opioid use disorder without being hampered by this flawed and unnecessary regulation. **201 KAR 9:270** is medically unsound, ethically unacceptable, harmful, and unsalvageable. It must be repealed.

Respectfully,

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