SEPTEMBER 2025

KENTUCKY BOARD OF PHARMACY

Newsletter to Promote Pharmacy and Drug Law Compliance.

KASPER Announcement From OIG

The go-live date for Narcotic Treatment Program (NTP) data transmission to the Kentucky All Schedule Prescription Electronic Reporting (KASPER) prescription drug monitoring program was scheduled for July 1, 2025.

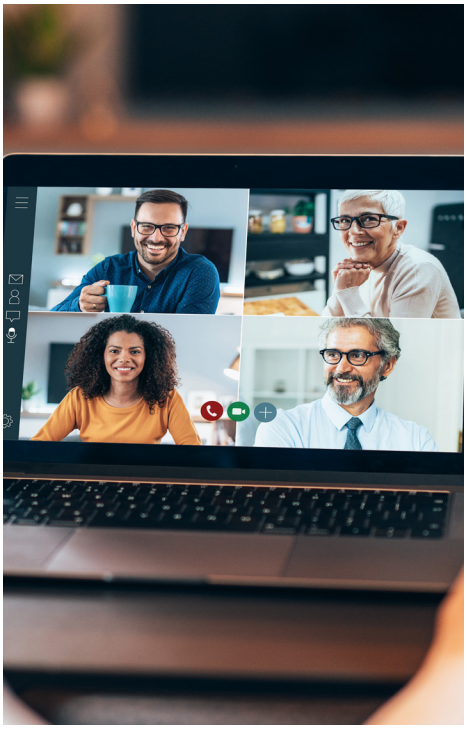
To aid providers and pharmacists in supporting patients in recovery and understanding NTP prescription data, a training, "Bridging Data and Recovery," was developed in partnership with the Kentucky Department of Behavioral Health, NTP providers, the Office of Inspector General (OIG) pharmacist consultant, and the KASPER program administrator.

This training is available now for continuing education (CE) credit. We are excited to support individuals struggling with addiction who are seeking treatment through medication for opioid use disorder (OUD). We encourage all providers to attend the following training: CECentral "Bridging Data and Recovery" Presentation.

If you have any questions or would like more information, please reach out to Misty Rose, KASPER program administrator, at mrose@ky.gov or 502/564-2815.

Access the National Pharmacy Compliance News

A Service of the National Association of Boards of Pharmacy Foundation® (NABPF®)



Resource for Kentucky Pharmacists Seeking Opioid CE Requirement

The University of Kentucky College of Pharmacy offers free on-demand webinars on OUD and substance use disorder for CE credit:

- *Red Flags in the Real World: Case-Based Scenarios for Buprenorphine Dispensing for Opioid Use Disorder*
- *Patient Perspectives: Pharmacy's Role in Supporting Opioid Use Disorder Remission and Recovery*
- *Opioid Use Disorder: The Science and Evidence for Initiating and Maintaining Remission and Recovery*
- *Buprenorphine Essentials: Q&A for Safe and Effective Dispensing*
- *Naloxone and Beyond: The Changing Landscape of Opioid Antagonists*

Board-Authorized Protocols Update

On May 28, 2025, the Kentucky Board of Pharmacy approved revisions for the following Board-authorized protocol:

Tobacco Cessation Therapy Protocol v3

The latest versions approved by the Board have been posted to its website and can be found here.

Any pharmacy that has been utilizing a previously approved version is expected to use the latest version of a Board-authorized protocol to ensure compliance with 201 Kentucky Administrative Regulations (KAR) 2:380(2)(1)(b) if the protocol was updated to align with current practice guidelines.

Pitfalls of Using AI for Legal Guidance

Written by Madeline Wix, Law Clerk, and Jessica L. Brown, Esq, General Counsel

Artificial intelligence (AI) is now deeply integrated across industries like law and pharmacy, promising instant access to legal information, simplified explanations of complex regulations, and cost savings. These advantages make AI legal tools highly appealing to the general public, especially for those seeking quick answers without the expense or wait associated with professional legal counsel. Yet, despite their convenience, AI platforms carry substantial risks and limitations that users must weigh carefully.

One major concern is the accuracy and reliability of AI-generated legal advice. While AI may deliver responses quickly and with confidence, these answers can be factually incorrect or even entirely fabricated, known as "hallucinations." For example, someone recently contacted the Board because they received AI guidance from a major internet

Pitfalls of Using AI for Legal Guidance *(cont)*

browser that said prescription drug "pick-up" lockers and kiosks were legal in Kentucky. The AI opinion referenced a prior Board Advisory Council meeting agenda where the topic of kiosks was discussed and cited 201 KAR 2:100. However, the regulatory provision referenced 201 KAR 2:100(3), which governs the after-hours drop-off of hard copy prescription orders and refill requests, **not** prescription drug lockers or kiosks. This is just one example of the risks of using AI for legal guidance. The tools often struggle with fundamental legal comprehension, apply the law incorrectly, and can misstate the significance of actual cases. All these risks pose real-world consequences, like sanctions in court.

Also, AI falls short in contextual reasoning and professional judgment. Unlike experienced attorneys, AI cannot interpret the nuances of individual cases or understand specific client needs. It often fails to differentiate between binding legal precedent and persuasive but non-binding arguments, leading to incorrect or risky recommendations. Moreover, AI lacks ethical reasoning and empathy, qualities that are critical for thoughtful, effective legal guidance.

Beyond accuracy and reasoning, ethical and privacy concerns arise when using AI for legal guidance. Users often need to input sensitive personal or business details into the AI platform to receive relevant guidance. Not all systems guarantee confidentiality or comply with data protection laws, exposing the data to unauthorized parties and potentially violating confidentiality obligations. As AI technologies evolve faster than regulations, this opacity about data use further compounds uncertainty and legal vulnerabilities.

Legal practitioners have a duty of care or professional oversight that protects them and their clients, and AI is not subjected to the same standards or regulatory frameworks as licensed attorneys. If AI mistakes cause harm, tracing responsibility or seeking redress are often impossible, since AI tools cannot be held accountable. The lack of transparency in how AI reaches decisions can make it difficult to identify errors or biases, which are easily overlooked by lay users.

While there is promise for AI's use in pharmacy, concerns include data privacy risks, opaque decision making, and the danger of overreliance on machine-generated outputs. As pharmacies adopt more AI tools, they face legal obligations regarding patient data privacy, cybersecurity, and informed consent for digital health interventions. When AI systems drive clinical or dispensing decisions, questions arise about accountability and liability if errors or harm occur. Regulatory agencies should pay close attention to AI algorithms used in health care decision making to promote evolving legal standards to validate and regulate AI use.

While AI offers benefits, enhancing efficiency, access, and decision making, it also introduces serious obstacles that cannot be ignored. From generating inaccurate legal advice to potentially harmful medication recommendations, AI tools lack the contextual understanding, ethical judgment, and accountability that are essential in professional practice.

The Expanding Use of Ketamine: Therapeutic Potential, Safety Risks, and Regulatory Gaps

Ketamine, a Schedule III controlled substance, was originally developed in the 1960s and used as a battlefield anesthetic during the Vietnam War due to its ability to provide sedation while maintaining cardiorespiratory stability. Over the following decades, it became a mainstay in surgical and emergency settings for its safety profile and effectiveness. In recent years, however, ketamine has entered a new realm of use – psychiatric treatment – most notably for patients with treatment-resistant depression. This shift has sparked growing clinical interest but also significant public health and safety concerns.

A major driver of this renewed attention is the proliferation of ketamine infusion clinics, many of which promote the drug as a "miracle" solution for a wide range of mental health conditions. While some patients report rapid symptom relief, the absence of uniform clinical standards has raised red flags. The 2023 ketamine-related overdose death of actor Matthew Perry underscored the potential dangers of unsupervised or loosely regulated ketamine use.

Beyond depression, ketamine is increasingly being used off-label to treat chronic pain, psychiatric disorders, and even autoimmune diseases. This expanded use has contributed to drug shortages and increased demand for compounded ketamine products. While compounding can provide access during shortages, these formulations are not Food and Drug Administration (FDA) approved for psychiatric indications and may pose added risks due to variability in potency, sterility, and quality control.

In contrast to compounded ketamine, FDA-approved esketamine nasal spray Spravato® provides a regulated alternative for patients with severe depression. Approved in 2019, Spravato can only be administered in health care settings certified under a risk evaluation and mitigation strategy (REMS) program. This ensures that patients are monitored for at least two hours post-dose due to the drug's known risks, which include sedation, dissociation, increased blood pressure and heart rate, and the potential for misuse or worsening psychiatric symptoms. The REMS protocol reinforces the importance of medical oversight in the administration of ketamine-related therapies.

Despite regulatory efforts, ketamine's potential for abuse remains a significant concern. Both ketamine and esketamine are misused recreationally, often referred to by the street name "Special K." At high doses, the drugs can induce hallucinations, euphoria, and out-of-body experiences. Overdose is a serious risk, particularly when ketamine is used in combination with other central nervous system depressants such as alcohol.

Adding to the complexity of the current ketamine landscape is the recent surge in direct-to-consumer marketing for at-home ketamine treatments, particularly sublingual and oral compounded forms promoted for psychiatric use. This advertising trend accelerated

The Expanding Use of Ketamine: Therapeutic Potential, Safety Risks, and Regulatory Gaps *(cont)*

during the COVID-19 pandemic, as telehealth platforms and social media made it easier for for-profit entities to reach consumers directly. Unbeknownst to most consumers, many of the advertised products, such as vitamin and supplement programs and "med spas," fall outside the scope of FDA's current regulatory authority, which is limited to companies that manufacture, distribute, or package prescription medications. Instead, the Federal Trade Commission regulates advertising of over-the-counter medications and products, and there are less stringent guidelines applied to these advertisements than for prescription drug advertisements. This regulatory gap has enabled companies to promote unapproved health and wellness products without meeting the stringent safety and efficacy standards required of FDA-regulated drugs.

The federal regulatory environment surrounding compounded ketamine products, combined with the lack of FDA approval for psychiatric indications and significant concerns regarding patient and public safety, has made it challenging for boards of pharmacy to support the "at-home" ketamine treatment model. Recently, the Board received a nonresident pharmacy application from a facility that dispenses compounded ketamine. In response to safety concerns, the Board requested documentation showing that the pharmacy had implemented a program that was substantially similar to FDA's REMS for Spravato. The applicant declined to provide the documentation and instead entered into an agreed order stating it would not dispense compounded ketamine products within Kentucky.

As ketamine continues to expand beyond its traditional inpatient medical use, there is a call for greater state and federal regulatory oversight, coupled with increased education for physicians and pharmacists to ensure that the therapeutic promise of ketamine is balanced with responsible clinical practice and public safety.

Additional information from FDA about potential risks with ketamine products:

- FDA alerts health care professionals of potential risks associated with compounded ketamine nasal spray – February 16, 2022
- FDA warns patients and health care providers about potential risks associated with compounded ketamine products, including oral formulations, for the treatment of psychiatric disorders – October 10, 2023

The Kentucky Board of Pharmacy News is published by the Kentucky Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

Christopher P. Harlow, PharmD, RPh - State News Editor
Lemrey "Al" Carter, PharmD, MS, RPh - National News Editor & Executive Editor
Megan Pellegrini - Publications and Editorial Manager

State Office Building Annex, Suite 300 | 125 Holmes Street | Frankfort, KY 40601