2005 Market Street, Suite 2800
Philadelphia, PA 19103-7077
P 215.575.9050
F 215.575.4939

901 E Street NW, 10th Floor
Washington, DC 20004
pewtrusts.org
P 202.552.2000
F 202.552.2299

October 4, 2022

Submitted to the Office of Regulatory Affairs at CHFSregs@ky.gov

Wendy Morris
Commissioner
Department of Behavioral Health, Developmental and Intellectual Disabilities
Cabinet for Health and Family Services
275 E. Main St. 4W-F
Frankfort, KY 40621

RE: 908 KAR 1:374. Licensure of nonhospital-based outpatient alcohol and other drug treatment entities

Dear Commissioner Morris,

Thank you for soliciting feedback on 908 KAR 1:374. The proposed regulations will make evidence-based treatment for opioid use disorder more widely available, and better aligned with federal regulations.

The Pew Charitable Trusts (Pew) is an independent, nonpartisan research and policy organization. Pew's Substance Use Prevention and Treatment Initiative works with states and at the federal level to address the nation's opioid overdose crisis by developing solutions that improve access to evidence-based treatment for opioid use disorder (OUD), including medications for OUD (MOUD) – methadone, buprenorphine, and naltrexone – the most effective therapy for people with OUD.

In March 2021, Pew was invited to provide the Commonwealth of Kentucky with technical assistance on its substance use disorder (SUD) programs and policies, resulting in a set of policy recommendations.[i] The full set of policy recommendations was released in March 2022 by Governor Beshear. One element of Pew's work in the Commonwealth was collaboration with the Department of Behavioral Health, Developmental, and Intellectual Disabilities (DBHDID) to revise regulations for opioid treatment programs (OTPs), also known as narcotic treatment programs in the Commonwealth.

OTPs are the only care setting authorized to offer methadone, in addition to other medications for opioid use disorder that are available in other settings. These essential health care facilities are highly regulated at both the federal and state level. Like in many states, current regulations in Kentucky contain elements that are not evidence-based or go beyond federal rules. These regulations can create significant barriers to care for people with OUD and negatively impact the lives of OTP patients.

The proposed regulations address these barriers and advance evidence-based recommendations for improving care by making the following changes to 908 KAR:

1. Prohibiting involuntary administrative discharge for positive drug screens (the practice of ending treatment for a patient who continues to use illicit substances);
2. Removing burdensome drug screening requirements;
3. Removing the set counseling schedule;
4. Creating flexibility for people to receive take-home medications;
5. Removing discontinuation of medications as the goal of treatment.

Additionally, the DBHDID has made much needed changes to stigmatizing language, including adopting the use of person-first language.

Administrative discharge: Pew supports DBHDID's decision to prohibit involuntary administrative discharge based on a positive drug screen in proposed regulations. As it currently stands, 908 KAR allows OTPs to involuntarily discharge patients for illicit drug use.[ii] However, involuntary termination from medication treatment puts individuals with OUD at high risk for overdose.[iii] Evidence shows that it is common for individuals to return to use during their recovery given that OUD is a chronic condition. Positive drug screens may indicate that a patient's treatment dose is not high enough, and warrant a discussion between a provider and patient, rather than disciplinary action. Kentucky's proposed regulations enhance patient care by downgrading a positive screen from a program infraction to program non-compliance and allowing patients to retain or increase their number of take-home medications. The proposed regulations also remove the requirement to move people back a phase if they have a positive screen.

By making these changes, DBHDID will allow OTP clinicians to provide individualized care based on the specific needs and treatment goals of patients, rather than requiring all cases of positive screens to be treated in the same way.

Drug screens: The proposed regulations reduce the number of required drug screens for clients to monthly drug screens after the first phase treatment and remove the observation requirement from those drug screens. Currently, Kentucky's OTP regulations require up to 26 observed drug screens per year in contrast to federal regulations that mandate eight without any observation requirement.[iv] While drug screens can provide valuable insight into patients' ongoing substance use and clinical needs, frequent drug screens, especially if they are observed, can be demeaning to patients.[v] Only 10 states total have requirements for observed collection of urinalysis samples.[vi] Although the proposed regulations lower the number of required drug screens, it is still higher than the number of federally required drug screens. Kentucky should reduce the number of drug screens, particularly in the first phase of treatment, to better align with federal regulations.

Set counseling schedule: The new regulations remove counseling requirements from clients in order to receive medication treatment, implementing one of Pew's recommendations to the Commonwealth. This is in line with federal regulations, which require OTPs to provide counseling to patients as clinically necessary.[vii] Strict counseling requirements have been shown to reduce retention in treatment, while medication alone has been proven effective.[viii] OTPs should offer counseling based on individual patient needs and desire. While some patients may desire counseling as part of their treatment, removing the counseling requirement will make it easier for all potential OTP clients to access care. With these revisions, DBHDID would only require counseling "as clinically indicated," which aligns with Pew's recommendations to the Commonwealth.

Take-homes: Kentucky's current OTP regulations go beyond federal requirements by prohibiting patients from receiving take-home medications in the first 90 days of treatment and reducing patient access to take-home medications through heightened educational or employment requirements.[ix] The proposed regulations implement Pew's recommendation that clients be allowed take-homes in the first 90 days of treatment. This aligns Kentucky's regulations with federal regulations and most states' regulations (only 12 states totally prohibit take-home medications in the first 30 days of treatment, and just seven others prohibit it throughout the first 90 days).[x] However, the additional employment and educational requirements remain, which reduces flexibility for patients, for whom recovery can be a full-time endeavor.

Without the ability to receive take-home medication, patients must travel to their OTP near-daily to receive care. This poses a barrier to treatment for people in Kentucky, where there are only 26 OTPs.[xi] Traveling to treatment every day can be burdensome for OTP patients, especially since most individuals residing in Kentucky's rural areas live further than a 30 minute drive to an OTP.[xii] Kentucky's lack of flexibility and additional criteria on take-home medications can interfere with clients' ability to remain in treatment, given time spent on travelling to and experiencing daily appointments. In order for an OTP client to reach treatment phases 3-6, and be granted increased access to take-home medications, they must be pursuing or engaged in gainful employment; pursuing vocational training; attending school; engaged in volunteer work; attending parenting classes; or be experiencing disabilities or other circumstances that make compliance unattainable.

Federal regulations allow patients to take home a single dose per week during the first 90 days of treatment.[xiii] Additionally, they outline the following take-home medication criteria for clients:[xiv] absence of recent abuse of drugs, including alcohol; regularity of clinic attendance; absence of serious behavioral problems at the clinic; absence of known recent criminal activity; stability of the patient's home environment and social relationships; length of time in comprehensive maintenance treatment; assurance that the take-home medication can be safely stored within the patient's home; and whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion. The federal government loosened those requirements as a result of the COVID-19 pandemic, and early research shows that these increased flexibilities have not led to greater rates of medication diversion.[xv]

Already, take-home criteria are rigorous; by imposing additional requirements, Kentucky is making it more difficult for individuals to attain treatment.

Goal of treatment: DBHDID removes discontinuation as the goal of treatment from this iteration of 908 KAR, which aligns with Pew's recommendations to the Commonwealth. There is no scientific consensus that long-term use of MOUD is harmful. In fact, long-term treatment can lead to better outcomes in employment, health, and criminal justice involvement, while the period immediately after discontinuing treatment poses a high overdose risk.[xvi]

Language changes

In addition to implementing Pew's recommendations, DBHDID makes much-needed changes to language in 908 KAR. DBHDID changes "medication assisted treatment" to "medications for addiction treatment" and "medications for opioid use disorder". The term 'medication assisted treatment' suggests that medicines are not integral to therapy. Medication is the most effective treatment available

without requiring other interventions. The change to MOUD aligns with recommendations from the American Society of Addiction Medicine, the American Medical Association, and other experts.

The proposed regulations will make OTP care more patient-centered and accessible. These changes are essential in light of Kentucky's rising overdose death rate, which is the second highest in the country.[xvii]

Sincerely,

Kamren Gilbard

Associate I

Substance Use Prevention and Treatment Initiative

The Pew Charitable Trusts

Sheri Doyle

Senior Manager

Substance Use Prevention and Treatment Initiative

The Pew Charitable Trusts

---

[i] The Pew Charitable Trusts, "Improving Access to Opioid Use Disorder Treatment in Kentucky" (2021). https://odcp.ky.gov/Resources/Documents/Pew%20Kentucky%20Memo%20FINAL.pdf

[ii] Kentucky Administrative Regulations 908 KAR 1:374 (2021) https://apps.legislature.ky.gov/law/kar/titles/908/001/374/

[iii] The National Academies of Sciences, Engineering, and Medicine, "Medications for Opioid Use Disorder Save Lives" (2019), https://doi.org/10.17226/25310.

[iv] 908 Kentucky Administrative Regulations 1:374; 42 Code of Federal Regulations, Part 8.12

[v] C. Strike and C. Rufo, "Embarrassing, Degrading, or Beneficial: Patient and Staff Perspectives on Urine Drug Testing in Methadone Maintenance Treatment," *Journal of Substance Use* 15, no. 5 (2010): 303-12, https://doi.org/10.3109/14659890903431603.

[vi] The Pew Charitable Trusts, "Overview of Opioid Treatment Program Regulations by State" (2022), https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2022/09/overview-of-opioid-treatment-program-regulations-by-state.

[vii] Federal Opioid Treatment Program Standards, 42 C.F.R Part 8, (2001).

[viii] M. Hochheimer and G.J. Unick, "Systematic Review and Meta-Analysis of Retention in Treatment Using Medications for Opioid Use Disorder by Medication, Race/Ethnicity, and Gender in the United States," Addictive Behaviors 124 (2022): 107113, https://www.sciencedirect.com/science/article/pii/S0306460321002987; National Academies of Sciences, Engineering, and Medicine, "Medications for Opioid Use Disorder Save Lives" (2019), https://doi.org/10.17226/25310.

[ix]Kentucky Administrative Regulations 908 KAR 1:374 (2021) https://apps.legislature.ky.gov/law/kar/titles/908/001/374/

[x] Joanna Jackson, "Characterizing variability in state-level regulations governing opioid treatment programs," *Journal of Substance Abuse Treatment,* vol. 115 (2020): https://www.sciencedirect.com/science/article/abs/pii/S0740547219307081.

[xi] Substance Abuse and Mental Health Services Administration (SAMHSA), Behavioral Health Treatment Services Locator, Accessed August 2022, https://findtreatment.samhsa.gov/locator

[xii] Unpublished Pew Analysis of Substance Abuse and Mental Health Services Administration (SAMHSA), Behavioral Health Treatment Services Locator, Accessed April 2021, https://findtreatment.samhsa.gov/locator.

[xiii] Federal Opioid Treatment Program Standards, 42 C.F.R Part 8, (2001).

[xiv] Federal Opioid Treatment Program Standards, 42 C.F.R Part 8, (2001).

[xv] Substance Abuse and Mental Health Services Administration Opioid Treatment Program (OTP) Guidance, March 16, 2020, https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf.
Figgatt et.al, "Take-home dosing experiences among persons receiving methadone maintenance treatment during COVID-19," *Journal of Substance Abuse Treatment* vol. 123 (2021) https://doi.org/10.1016/j.jsat.2021.108276.

[xvi] The National Academies of Sciences, Engineering, and Medicine," Medications for Opioid Use Disorder Save Lives" (2019), https://www.ncbi.nlm.nih.gov/books/NBK538936/.

[xvii] Centers for Disease Control and Prevention, National Center for Health Statistics Drug Overdose Mortality by States, March 2022, https://www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm.