Statewide Opioid Stewardship

Kentucky Hospital Association

CHFS
KENTUCKY
Cabinet for Health and Family Services

UK HealthCare

cps

Treating Mental Health and Substance Use Disorder

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THE BROOK | Hospitals
MAKING A DIFFERENCE IN MIND, BODY, SPIRIT

Disclosures

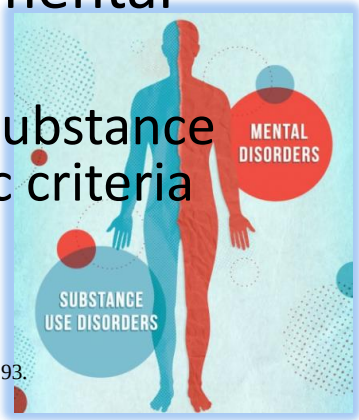
- The speakers have no actual or potential conflict of interest in relation to this program/presentation.

Objectives

Identify	Recall	Discuss	Understand	Review	Evaluate
Identify the link between mental health and substance use disorders.	Recall risk factors for mental health and substance use disorders.	Discuss treatment options both pharmacological and non-pharmacological for opioid use disorder.	Understand buprenorphine prescribing standards in Kentucky.	Review pipeline treatments.	Evaluate areas of need in mental health and substance use treatment.

Comorbidities and SUD

- Many individuals who develop substance use disorders (SUD) are also diagnosed with mental disorders, and vice versa.
- Multiple national population surveys have found that about half of those who experience a mental illness during their lives will also experience a substance use disorder and vice versa.
- Although there are fewer studies on comorbidity among youth, research suggests that adolescents with substance use disorders also have high rates of co-occurring mental illness.
  - Over 60 percent of adolescents in community-based substance use disorder treatment programs also meet diagnostic criteria for another mental illness.



Ross S, Peselow E. Co-occurring psychotic and addictive disorders: neurobiology and diagnosis. Clin Neuropharmacol. 2012;35(5):235-243. doi:10.1097/WNF.0b013e318261e193.
Kelly TM, Daley DC. Integrated Treatment of Substance Use and Psychiatric Disorders. Soc Work Public Health. 2013;28(0):388-406. doi:10.1080/19371918.2013.774673.
Hser YI, Grella CE, Hubbard RL, et al. An evaluation of drug treatments for adolescents in 4 US cities. Arch Gen Psychiatry. 2001;58(7):689-695.

Comorbidities and SUD

Han B, Compton WM, Blanco C, Colpe LJ. Prevalence, Treatment, And Unmet Treatment Needs Of US Adults With Mental Health And Substance Use Disorders. Health Aff (Millwood). 2017 Oct 1;36(10):1739-1747. doi: 10.1377/hlthaff.2017.0584. PMID: 28971918.

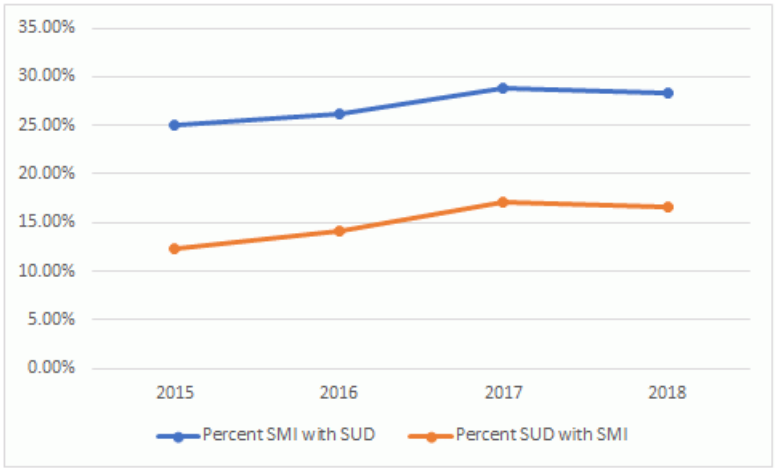
Comorbidities and SUD

- It is estimated that 40–60 percent of an individual's vulnerability to substance use disorders is attributable to **genetics**.
- An active area of comorbidity research involves the **search for that might predispose** individuals to develop both a substance use disorder and other mental illnesses, or to have a greater risk of a second disorder occurring after the first appears.
  - Most of this vulnerability arises from complex interactions among multiple genes and **genetic interactions with environmental influences.**
  - For example, frequent **marijuana use during adolescence is associated with increased risk of psychosis** in adulthood, specifically among individuals who carry a particular gene variant.
- Environmental factors such as **chronic stress, trauma, or drug exposure can induce stable changes in gene expression**, which can alter functioning in neural circuits and ultimately impact behavior.

Wang J-C, Kapoor M, Goate AM. The genetics of substance dependence. Annu Rev Genomics Hum Genet. 2012;13:241-261. doi:10.1146/annurev-genom-090711-163844.

Comorbidities and SUD

- April 2020: NIDA Research Report
  - Common Comorbidities with SUD
    - Generalize Anxiety Disorder
    - Panic Disorder
    - Post-Traumatic Stress Disorder
    - Depression
    - Bipolar
    - ADHD
    - Psychotic illness
    - Borderline personality disorder
    - Antisocial personality disorder

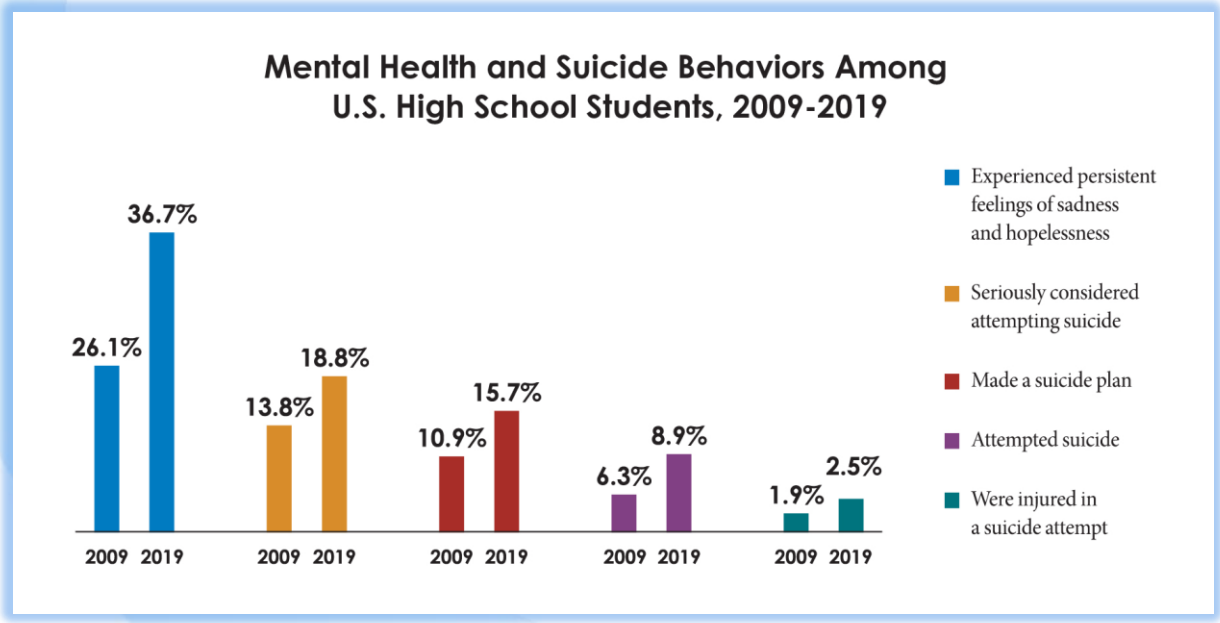


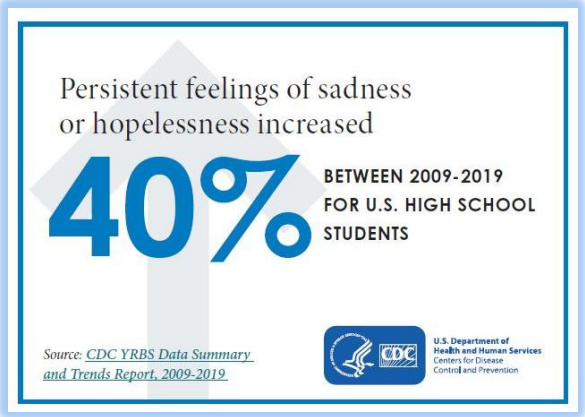
Source: SAMHSA, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, Mental Health, Detailed Tables available at: https://www.samhsa.gov/data/population-data-nsduh

NIDA. 2021, August 3. Introduction. Retrieved from https://nida.nih.gov/publications/research-reports/common-comorbidities-substance-use-disorders/introduction on 2023, June 19.

Adolescent Impact

- Mental illness may precede SUD.
- In 2021, 37% of high school students reported they experienced poor mental health during COVID, and 44% persistently felt sad/hopeless.





Centers for Disease Control and Prevention. [2009-2019] Youth Risk Behavior Survey Data. Available at: www.cdc.gov/yrbs.

Monitoring the Future Panel

- Notable changes from 2020 to 2021 included:
  - Increases in vaping (both marijuana and nicotine) in the last 30 days; decreases in cigarette smoking.
  - Decreases in daily drinking and increases in binge drinking.
  - Decreases in non-medical use of opioids and stimulants.

	Past 12 months	Past 30 days
Alcohol	81.8%	66.3%
Marijuana (any mode)	42.6%	28.5%
Vaping Nicotine	21.8%	16.1%
Vaping Marijuana	18.7%	12.4%
Cigarettes	18.6%	9.0%
Other Drugs[1]	18.3%	7.5 %

Patrick, M. E., Schulenberg, J. E., Miech, R. A., Johnston, L. D., O'Malley, P. M., & Bachman, J. G. (2022). Monitoring the Future Panel Study annual report: National data on substance use among adults ages 19 to 60, 1976-2021. Monitoring the Future Monograph Series. University of Michigan Institute for Social Research: Ann Arbor, MI. doi:10.7826/ISRUM.06.585140.002.07.0001.2022

Common Risk Factors

Genetics

- 40-60% of an individual's vulnerability
- Ability to alter responses to:
  - Alcohol
  - Tobacco
  - Cocaine
  - Opioid use
  - Marijuana
  - Response to stress

Environmental Influences: Stress/ Trauma Exposure

- 2013 Study: Veterans:
  - 16% untreated SUD and 8% needed mental health treatment
- 1 in 5 veterans with PTSD also have SUD

Both genetics and environment can influence neurotransmitters: dopamine, serotonin, glutamate, GABA, and norepinephrine.

Golub A, Vazan P, Bennett AS, Liberty HJ. Unmet need for treatment of substance use disorders and serious psychological distress among veterans: a nationwide analysis using the NSDUH. Mil Med. 2013;178(1):107-114.

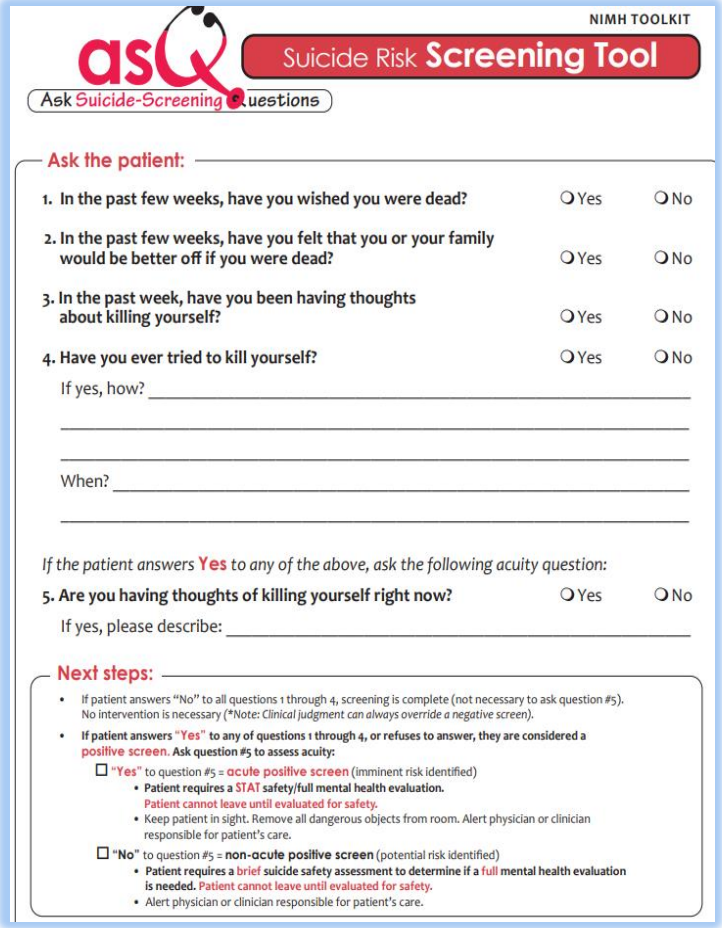
Diagnosis & Treatment

- Screening- for both SUD and mental health

Choose evidence-based screening tools and assessment resource materials

Tool	Substance type		Patient age		How tool is administered	
	Alcohol	Drugs	Adults	Adolescents	Self-administered	Clinician-administered
Screens						
Screening to Brief Intervention (S2BI)	X	X		X	X	X
Brief Screener for Alcohol, Tobacco, and other Drugs (BSTAD)	X	X		X	X	X
Tobacco, Alcohol, Prescription medication, and other Substance use (TAPS)	X	X	X		X	X
Alcohol Screening and Brief Intervention for Youth: A Practitioner's Guide (NIAAA)	X			X		X
Opioid Risk Tool – OUD (ORT-OUD) Chart		X	X		X	
Assessments						
Tobacco, Alcohol, Prescription medication, and other Substance use (TAPS)	X	X	X		X	X
CRAFFT	X	X		X	X	X
Drug Abuse Screen Test (DAST-10)* *For use of this tool - please contact Dr. Harvey Skinner*		X	X		X	X
Drug Abuse Screen Test (DAST-20: Adolescent version)* *For use of this tool - please contact Dr. Harvey Skinner*		X		X	X	X
NIDA Drug Use Screening Tool (NMASSIST) *(discontinued in favor of TAPS screening above)*	X	X	X			X
Alcohol Screening and Brief Intervention for Youth: A Practitioner's Guide (NIAAA)	X			X		X

Screening and Assessment Tools Chart | National Institute on Drug Abuse (NIDA) (nih.gov)



NIMH TOOLKIT

asQ Suicide Risk Screening Tool

Ask Suicide-Screening Questions

Ask the patient:

1. **In the past few weeks, have you wished you were dead?** ❍ Yes ❍ No
2. **In the past few weeks, have you felt that you or your family would be better off if you were dead?** ❍ Yes ❍ No
3. **In the past week, have you been having thoughts about killing yourself?** ❍ Yes ❍ No
4. **Have you ever tried to kill yourself?** ❍ Yes ❍ No

If yes, how? _____

When? _____

*If the patient answers **Yes** to any of the above, ask the following acuity question:*

5. **Are you having thoughts of killing yourself right now?** ❍ Yes ❍ No

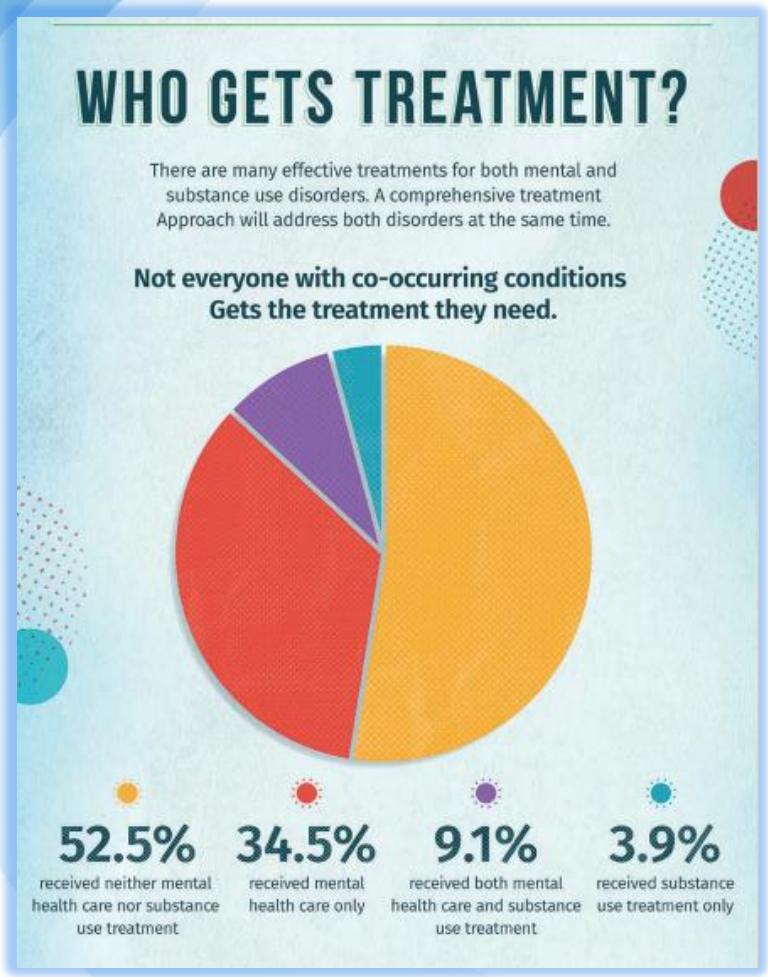
If yes, please describe: _____

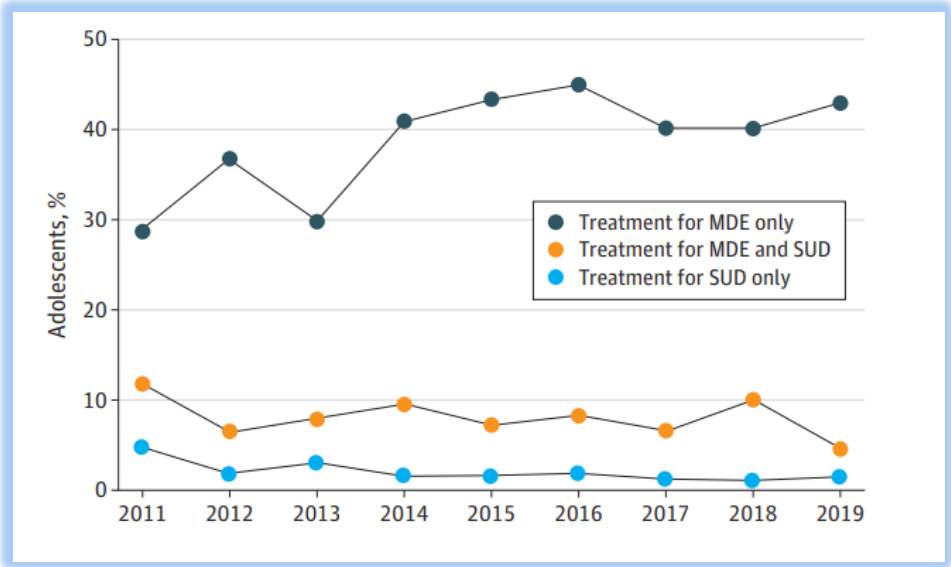
Next steps:

- If patient answers "No" to all questions 1 through 4, screening is complete (not necessary to ask question #5). No intervention is necessary (*Note: Clinical judgment can always override a negative screen).
- **If patient answers "Yes" to any of questions 1 through 4, or refuses to answer, they are considered a positive screen. Ask question #5 to assess acuity:**
  - ☐ **"Yes"** to question #5 = **acute positive screen** (imminent risk identified)
    - **Patient requires a STAT safety/full mental health evaluation.** Patient cannot leave until evaluated for safety.
    - Keep patient in sight. Remove all dangerous objects from room. Alert physician or clinician responsible for patient's care.
  - ☐ **"No"** to question #5 = **non-acute positive screen** (potential risk identified)
    - **Patient requires a brief suicide safety assessment to determine if a full mental health evaluation is needed.** Patient cannot leave until evaluated for safety.
    - Alert physician or clinician responsible for patient's care.

screening_tool_asq_nimh_toolkit.pdf (nih.gov)

Treatment

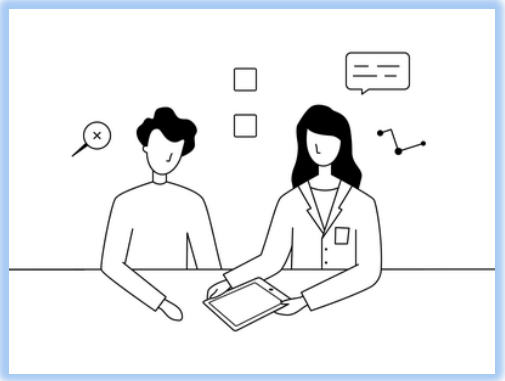




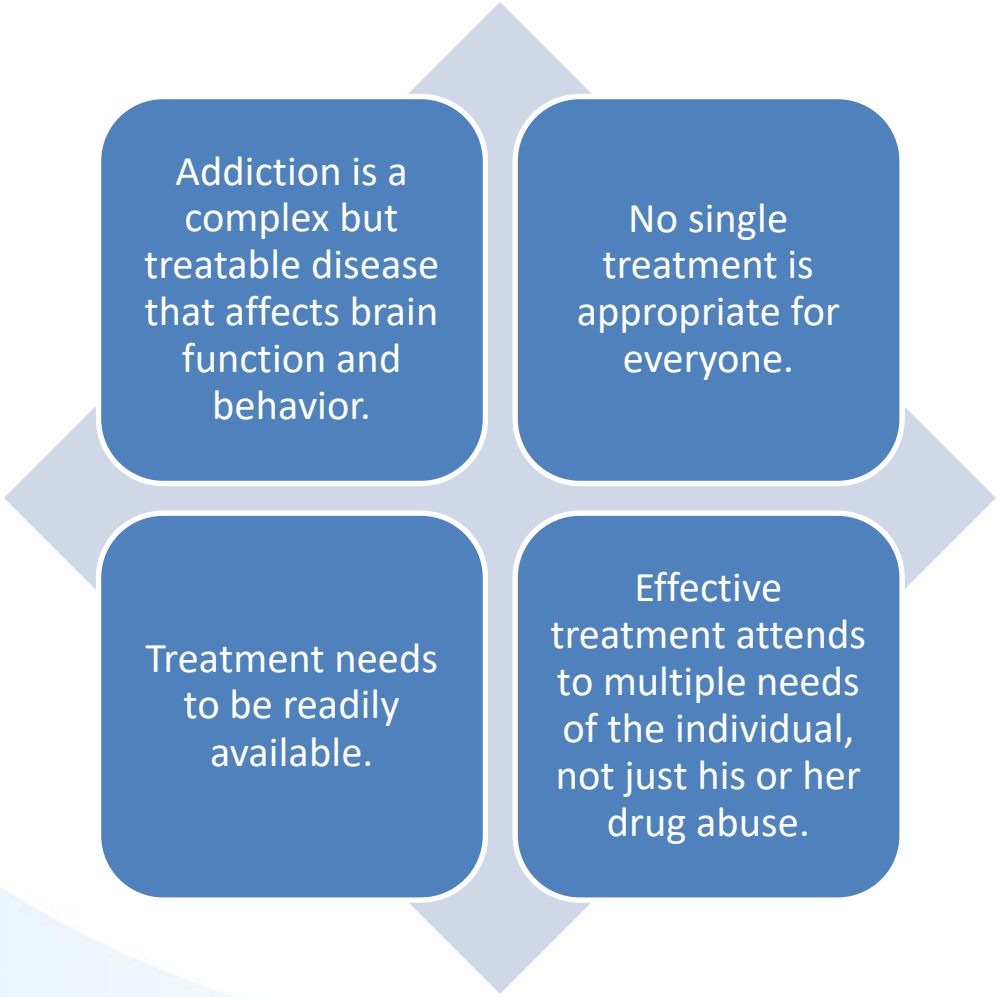
Lu W, Muñoz-Laboy M, Sohler N, Goodwin RD. Trends and Disparities in Treatment for Co-occurring Major Depression and Substance Use Disorders Among US Adolescents From 2011 to 2019. JAMA Netw Open. 2021;4(10):e2130280. doi:10.1001/jamanetworkopen.2021.30280.

Treatment

- Non-Pharmacological Treatment
  - Cognitive behavioral therapy
  - Motivational interviewing
  - 12-step facilitation
  - Community reinforcement approach
- Pharmacological Treatment
  - Treat the underlying disease



Pharmacological Treatment Principles



Marlatt, G. A., Larimer, M. E., & Witkiewitz, K. (2011). Harm reduction: Pragmatic strategies for managing high-risk behaviors. New York, NY: Guilford Press.

Alcohol Use Disorder

U.S. FDA-Approved Medications for Treating Alcohol Use Disorder		
Medication	**Typical Dose**	**Comment**
Acamprosate	666 mg three times daily	Dose reduction required with renal impairment
Disulfiram	500 mg once daily for 1-2 weeks, then decrease to maintenance dose (range 125-500 once daily)	Not for use in persons actively drinking alcohol; avoid alcohol in other products
Oral Naltrexone	50 mg once daily	Cannot be given to patients taking opioids
Extended-Release Naltrexone	380 mg IM every 4 weeks; administer in gluteal area with 1.5 inch 20-gauge needle	Cannot be given to patients taking opioids

US Preventive Services Task Force; Curry SJ, Krist AH, Owens DK, Barry MJ, Caughey AB, Davidson KW, Doubeni CA, Epling JW Jr, Kemper AR, Kubik M, Landefeld CS, Mangione CM, Silverstein M, Simon MA, Tseng CW, Wong JB. Screening and Behavioral Counseling Interventions to Reduce Unhealthy Alcohol Use in Adolescents and Adults: US Preventive Services Task Force Recommendation Statement. JAMA. 2018 Nov 13;320(18):1899-1909. doi: 10.1001/jama.2018.16789. PMID: 30422199.

Amphetamine Use Disorder

- On the basis of low- to moderate-strength evidence, most medications evaluated for methamphetamine/amphetamine use disorder have not shown a statistically significant benefit. However, there is low-strength evidence that methylphenidate may reduce use.
- Agents that have been used off-label:
  - Topiramate
  - Naltrexone
  - Mirtazapine
  - Bupropion

Karila L., Weinstein A., Aubin H.-J., Benyamina A., Reynaud M., Batki S. L. Pharmacological approaches to methamphetamine dependence: a focused review. Br J Clin Pharmacol 2010; 69: 578– 592.

Opioid Use Disorder

	Action	Precautions	Adverse Reactions and Common Side Effects	Adult Dosage
Methadone	Full opioid agonist. Long half-life allow for daily dosing which reduces need to seek illicit opioids.	Can be lethal in overdose. Has been linked with QTc interval prolongation.	Constipation and sweating.	Starting dose no more than 30 mg depending on patient tolerance to opioids. Maintenance doses of ≥ 60 mg daily more effective.
Buprenorphine	Partial opioid agonist which reduces need to seek illicit opioids. Most common formulation includes naloxone which discourages injection.	Should be opioid-free 12-24 hours prior to induction, maybe longer if using long-acting opioids. Monitor liver function.	Constipation, dizziness, nausea and vomiting	Start 4mg/1mg of sublingual buprenorphine/naloxone, total of 8 mg/2 mg in first day. Typical maintenance dose between 16-24 mg daily.
Naltrexone depot injection	Blocks opioid receptors and effects of opioids.	Must be opioid-free 7 to 10 days. If opioid analgesia needed, larger doses required and respiratory depression deeper and prolonged. Monitor liver function.	Precipitates severe withdrawal if concurrently taking opioids; hepatotoxicity at suprathera-peutic doses. Nausea, vomiting, and somnolence, site reaction.	380 mg gluteal IM injection monthly.

Park, Tae Woo & Friedmann, Peter. (2014). Medications for Addiction Treatment: An Opportunity for Prescribing Clinicians to Facilitate Remission from Alcohol and Opioid Use Disorders. Rhode Island medical journal (2013). 97. 20-24.

Buprenorphine Update

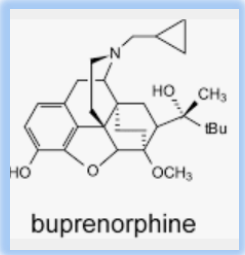
DEA Administrator's Statement
on
New Requirements on the Treatment of Substance Use Disorders

"As the United States continues to suffer 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. A new law mandated by Congress requires all medical practitioners, except veterinarians, to attest to completing training on treating patients with substance use disorders. This expands the number of practitioners eligible to treat opioid use disorder across this country to nearly two million. We want to ensure access to medication for opioid use disorder is readily and safely available to all patients who need it – and ultimately save lives."

--DEA Administrator Anne Milgram

Buprenorphine Update

- Consolidated Appropriations Act of 2023 requires new or renewing DEA registrants, starting June 27, 2023, upon submission of their application, to have at least one of the following:
  - A total of eight hours from certain organizations on opioid or other substance use disorders for practitioners renewing or newly applying for a registration from the DEA to prescribe any schedule II-V controlled medications.
  - Board certification in addiction medicine or addiction psychiatry from the ABMS, ABAM, or ASA.
  - Graduation within 5 years and status in good standing from medical, APRN, or PA school in the US that included successful completion of an opioid or other substance use disorder curriculum of at least eight hours.



buprenorphine

United States. Drug Enforcement Administration. (2003). Drug Enforcement Administration : a tradition of excellence, 1973-2003. [Washington, D.C.] :U.S. Dept. of Justice, Drug Enforcement Administration, Medication Assisted Treatment: https://www.deadiversion.usdoj.gov/pubs/docs/MATE_training.html.

Kentucky Specific

- KBML: Reminds providers: "Prior to procuring, dispensing or prescribing controlled substances to patients in KY, a physician must have the following:
  1) Active KY Medical License
  2) DEA registration number specific for Ky.
  3) An ACTIVE KASPER account
- KBN: Reminds APRNs that all nurses are "responsible and accountable for making decisions that are based upon the individuals' educational preparation and experience and shall practice with reasonable skill and safety" (KRS 314.021(2).

KBML.ky.gov KBN.ky.gov

201 KAR 9:270

- Section 1 : Qualifications
- Section 2: Standards for Prescribing, Dispensing, or Administering Bup Mono/Combo
  - Not for pain, unless delivered in a FDA approved form and for an FDA approved purpose (Butrans)
  - Mono only: pregnancy, hypersensitivity to naloxone, administered under supervision (ie. hospitals, correctional facilities, surgery centers), a patient transitioning from methadone to buprenorphine, limited to a period of no longer than one week.
  - Not for patients on benzodiazepines, other sedative hypnotics, stimulants or other opioids, w/o consult of a physician who is certified by the ABAM, ABPM, ABMS in psych, or AOA certifying board in addiction medicine or psychiatry.
    - In order to address an extraordinary and acute medical need not to exceed a combine period of thirty days.

Title 201 Chapter 9 Regulation 270 • Kentucky Administrative Regulations • Legislative Research Commission

KY SOS Statewide Opioid Stewardship

201 KAR 9:270

201 KAR 9:270. Professional standards for prescribing, dispensing, or administering Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone.

RELATES TO: KRS 218A.205, 311.530-311.620, 311.840-311.862, 311.990
STATUTORY AUTHORITY: KRS 311.565(1)(a)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 311.565(1)(a) authorizes the board to promulgate administrative regulations to regulate the conduct of its licensees. KRS 218A.205(3)(a) and (b) require the board to establish mandatory prescribing and dispensing standards related to controlled substances. KRS 311.842(1)(b) requires that the board promulgate administrative regulations establishing professional standards for prescribing and administering controlled substances by physician assistants. This administrative regulation establishes the professional standards for any board licensee who prescribes, dispenses, or administers Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone in the Commonwealth of Kentucky. Nothing within this administrative regulation shall be interpreted to grant physician assistants authority to dispense Buprenorphine-Mono-Product or Buprenorphine-Combined-With-Naloxone, unless otherwise authorized by KRS 311.842.

Section 1. Minimum Qualifications for Prescribing, Dispensing, or Administering Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone. Except as provided in Section 3 of this administrative regulation, a licensee shall not prescribe, dispense, or administer Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone unless that licensee possesses the minimum qualifications established in this section.

(1) The licensee shall obtain and maintain in good standing a waiver and license as issued by the Drug Enforcement Administration (DEA) to prescribe Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone for the treatment of opioid use disorder in the Commonwealth of Kentucky.

(2) The licensee shall successfully complete the approved educational programs required by this subsection.

(a) The prescribing licensee shall be a DEA-licensed prescriber of Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone and shall have obtained Buprenorphine certification through completion of a Substance Abuse and Mental Health Services Administration ("SAMHSA") certified course.

(b) For each three (3) year continuing education cycle, each DEA-licensed prescriber of Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone shall complete at least twelve (12) hours of continuing medical education certified in Category I specific to addiction medicine as part of the required continuing medical education hours set forth in 201 KAR 9:310 and 201 KAR 9:360.

(3) The licensee shall enroll in the Kentucky Health Information Exchange to the extent necessary to query and pull information from the Kentucky Health Information Exchange. The licensee shall not report the prescribing, dispensing, or administering Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone for medically-supervised withdrawal or as maintenance treatment for a patient diagnosed with opioid use disorder into the Kentucky Health Information Exchange unless otherwise required by law.

Section 2. Professional Standards for Prescribing, Dispensing, or Administering Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone for Medically-Supervised Withdrawal or the Treatment of Opioid Use Disorder.

(1)

(a) Except as provided in paragraph (b) of this subsection, transmucosal Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone shall only be prescribed, dispensed, or administered for medically-supervised withdrawal or as a maintenance treatment for a patient diagnosed with opioid use disorder.

(b) Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone shall not be used for the treatment of pain or any other condition, unless delivered in a Federal Drug Administration (FDA) approved form and for an FDA approved purpose.

(2) Buprenorphine-Mono-Product shall not be prescribed, dispensed, or administered for medically-supervised withdrawal or as a maintenance treatment for a patient diagnosed with opioid use disorder, except:

(a) To a pregnant patient;

(b) To a patient with demonstrated hypersensitivity to naloxone;

(c) As administered under supervision in a physician's office or other healthcare facility, including hospitals, urgent care settings, surgical care centers, residential treatment facilities, and correctional facilities; or

(d) To a patient transitioning from methadone to buprenorphine, limited to a period of no longer than one week.

(3)

(a) Except as provided in paragraph (b) of this section, Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone shall not be prescribed, dispensed, or administered to a patient who is also being prescribed benzodiazepines, other sedative hypnotics, stimulants or other opioids, without consultation of a physician who is certified by the American Board of Addiction Medicine, the American Board of Preventive Medicine, the American Board of Medical Specialties (ABMS) in psychiatry, or an American Osteopathic Association (AOA) certifying board in addiction medicine or psychiatry.

(b) A licensee may prescribe, dispense, or administer Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone to a patient who is also being prescribed benzodiazepines, other sedative hypnotics, stimulants, or other opioids, without consultation in order to address an extraordinary and acute medical need not to exceed a combined period of thirty (30) days.

(4) Except as provided in Section 3 of this administrative regulation, each licensee who prescribes, dispenses, or administers Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone for medically-supervised withdrawal or for the treatment of opioid use disorder shall fully comply with the professional standards established in this subsection.

(a) Prior to or at least within two (2) weeks of initiating treatment, the prescribing, dispensing, or administering licensee shall:

1. Obtain and record a complete and appropriate evaluation of the patient which shall at a minimum include:

a. The patient's history of present illness;

b. The patient's history of substance use;

c. The patient's social and family history;

d. The patient's past medical and psychiatric histories;

e. A focused physical examination of the patient;

f. Screening for HIV and hepatitis serology; and

g. Arranging appropriate laboratory tests, which shall include a CBC, a drug screen, and a CMP;

2. Obtain the patient's consent and authorizations in order to obtain the patient's prior medical records.

a. Upon receipt of the medical records, the prescribing, dispensing, or administering licensee shall review and incorporate the information from the records into the evaluation and treatment of the patient.

b. If the prescribing, dispensing, or administering licensee is unable, despite best efforts, to obtain the patient's prior medical records, the licensee shall document those efforts in the patient's chart;

3. Obtain and review a KASPER report for that patient for the twelve (12) month period immediately preceding the initial patient encounter and appropriately utilize that information in the evaluation and treatment of the patient;

4. Explain treatment alternatives and the risks and the benefits of treatment with Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone to the patient;

5. Obtain written informed consent from the patient in a manner that meets professional standards; and

6. If the patient is a female of child-bearing age and ability, meet the requirements of paragraph (b) of this subsection.

(b) Except as provided in Section 3 of this administrative regulation, the requirements of this paragraph shall apply to the treatment of a female of child-bearing age and ability.

1. Prior to initiating treatment, the licensee shall require that the patient submit to a pregnancy test and, if pregnant, the licensee shall provide counseling as to the risk of neonatal abstinence syndrome which shall be consistent with current SAMHSA guidance.

2.

a. Unless the licensee is certified by the American Board of Addiction Medicine, the American Board of Preventive Medicine, the American Board of Medical Specialties (ABMS) in psychiatry, or an American Osteopathic Association (AOA) certifying board in addiction medicine or psychiatry or an obstetrician or maternal-fetal medicine specialist, a licensee who prescribes, dispenses, or administers Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone to a patient who is pregnant or breastfeeding shall first obtain and document consultation with another independent physician that the potential benefit of Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone use outweighs the potential risk of use.

b. The consultation shall be obtained from a physician who is certified by the American Board of Addiction Medicine, the American Board of Preventive Medicine, the American Board of Medical Specialties (ABMS) in psychiatry, or an American Osteopathic Association (AOA) certifying board in addiction medicine or psychiatry or from an obstetrician or maternal-fetal medicine specialist.

(c) Except as provided by paragraph (d) of this subsection, while initiating treatment with Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone, the licensee shall comply with the requirements of this paragraph.

1. The licensee shall recommend to the patient an in-office observed induction protocol.

a. Except as provided in clause b. of this subparagraph, the licensee shall supervise the in-office observed induction protocol.

b. If an in-office observed induction does not occur, the licensee shall appropriately record the circumstances in the patient chart.

2. The licensee shall document the presence of opioid withdrawal before the first dose is given by using a standardized instrument, such as the clinic opioid withdrawal scale (COWS) or other similarly recognized instrument.

3. The licensee shall initiate treatment with a dose not to exceed the dose equivalency of four (4) milligrams buprenorphine generic tablet, which:

a. May be followed by subsequent doses if withdrawal persists; and

KY Buprenorphine Prescribing

- Obtain proper workup, to include:
  - Complete history and physical (including labs and pregnancy test if appropriate)
    - Drug screening will need to take place at each visit
  - Complete medical records history (including medications dispensed)
  - Review KASPER report
- Explain risks and benefits of buprenorphine.
- Utilize an in-office induction protocol documenting COWS score.
- Do not exceed 4 mg of buprenorphine with initiation.
- Office visits to occur no later than every 10 days after initiation for first month, and then every 14 days for month 2, then every month.
- Documentation once patient is in maintenance as to plan should occur every 3 month.s
- If dose is > 16 mg, a board-certified addiction medicine physician must be consulted.

Title 201 Chapter 9 Regulation 270 • Kentucky Administrative Regulations • Legislative Research Commission

KY Buprenorphine Prescribing

- Emergency Department and Acute Inpatient Setting
  - In an emergency, including in a hospital emergency department or similar outpatient urgent care setting, or in an inpatient setting, licensees may **offer and initiate buprenorphine treatment**.
  - The licensee shall initiate buprenorphine treatment under an observed induction protocol with **an initial dose not to exceed the dose equivalency of four (4) milligrams buprenorphine generic tablet**, which may be followed by subsequent doses, up to a **maximum of twenty-four (24) milligrams buprenorphine** generic tablet, if withdrawal persists and is not improving.

Title 201 Chapter 9 Regulation 270 • Kentucky Administrative Regulations • Legislative Research Commission

Non-Pharmacological

- **Brief Opportunistic Interventions** help patient understand that their substance use is putting them at risk and to encourage them to reduce or give up their substance use. 5-30 min counseling
- **Motivational Interviewing** helps people explore and resolve their ambivalence about their substance use and begin to make positive behavioral and psychological changes.
- **Cognitive-Behavioral Therapy** helps identify and modify irrational thoughts, managing negative mood and intervening after a lapse to prevent a full-blown relapse.
  - Coping with cravings
  - Cue exposure
  - Promotion of non-drug activities
  - Relaxation training
  - Preparing for and coping with relapses
  - Problem solving and effective communication

- **Therapeutic Communities**: residual programs/ sober-living houses
- **12-step approaches**
- **Family Therapy** found most helpful in adolescents

Jhanjee S. Evidence based psychosocial interventions in substance use. Indian J Psychol Med. 2014 Apr;36(2):112-8. doi: 10.4103/0253-7176.130960. PMID: 24860208; PMCID: PMC4031575.

Pipeline Treatments

- Promising opioid dependence pipeline therapies in various stages of development include **SJP 006, SJP 007, Zolunicant, Naloxone multidose nasal spray, Cannabidiol, Intranasal nalmefene, Morphine extended release, KUR 101, C4X 3256, APH-1501, IVL3004, TRV734, DMX-1002, FP-004, DMX-NB1, DMX-IB1, LYN-014, LYN-013, AZD4041, OX124, OX125, ALA-1000, ALA-1300, ALA-2000, GM-300X, SBS-226, CVL-354, BICX104, KNX100, NYX-783, and others**.
- In December 2022, the US Food and Drug Administration (FDA) accepted the resubmitted New Drug Application (NDA) for **Brixadi** (buprenorphine) extended-release weekly and monthly subcutaneous injection for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine.

Townsend EA, Negus SS, Banks ML. Medications Development for Treatment of Opioid Use Disorder. Cold Spring Harb Perspect Med. 2021 Jan 4;11(1):a039263. doi: 10.1101/cshperspect.a039263. PMID: 31932466; PMCID: PMC7778216.

Pipeline Treatments

- Through a collaboration with the National Institute on Drug Abuse (NIDA), Trevena is developing **TRV734** for use in medication-assisted therapy for the treatment of opioid use disorder.
  - Similar to current standard treatment options, it targets the mu receptor, but with an optimized mechanism of action that preferentially engages the signaling pathway responsible for therapeutic effect, with reduced activation of the signaling pathway responsible for mu receptor-mediated adverse effects.
- LYN-014, Lyndra's investigational oral, **ultra-long-acting extended-release weekly levomethadone capsule**, is being developed for the treatment of people living with opioid use disorder (OUD).
  - The capsule is expected to achieve this through a novel design that will provide extended gastric residence, controlled, steady drug release and timely passage into the gastrointestinal tract. In July 2021, LYN-014 received Fast Track designation (FTD) from the US Food and Drug Administration (FDA).

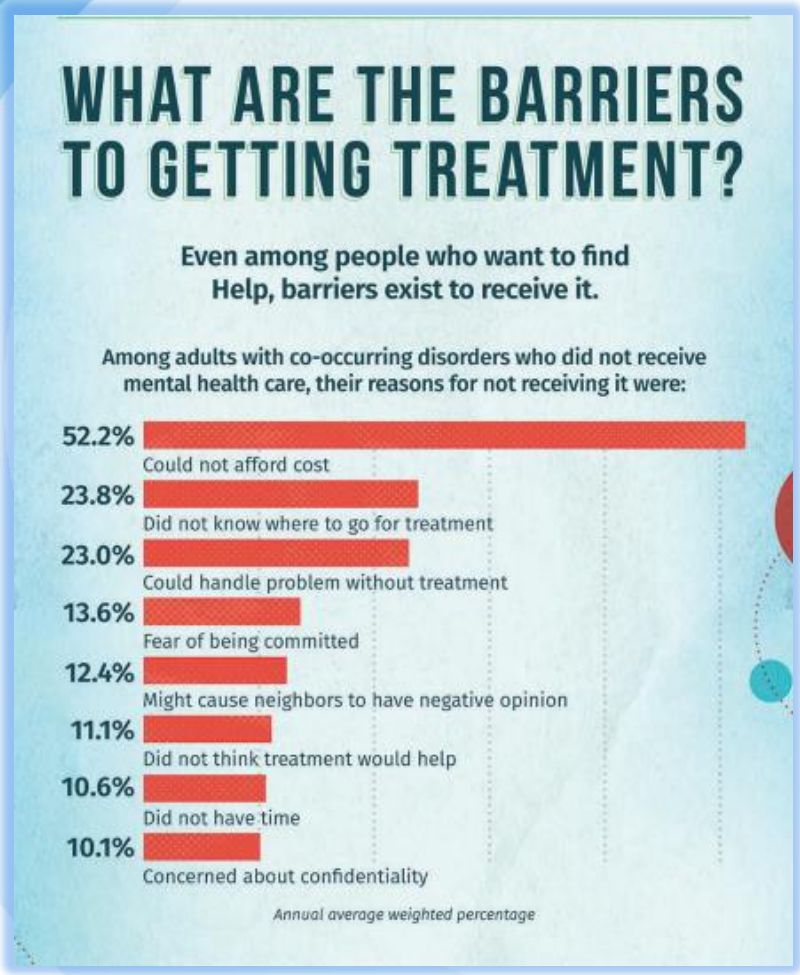
Townsend EA, Negus SS, Banks ML. Medications Development for Treatment of Opioid Use Disorder. Cold Spring Harb Perspect Med. 2021 Jan 4;11(1):a039263. doi: 10.1101/cshperspect.a039263. PMID: 31932466; PMCID: PMC7778216.

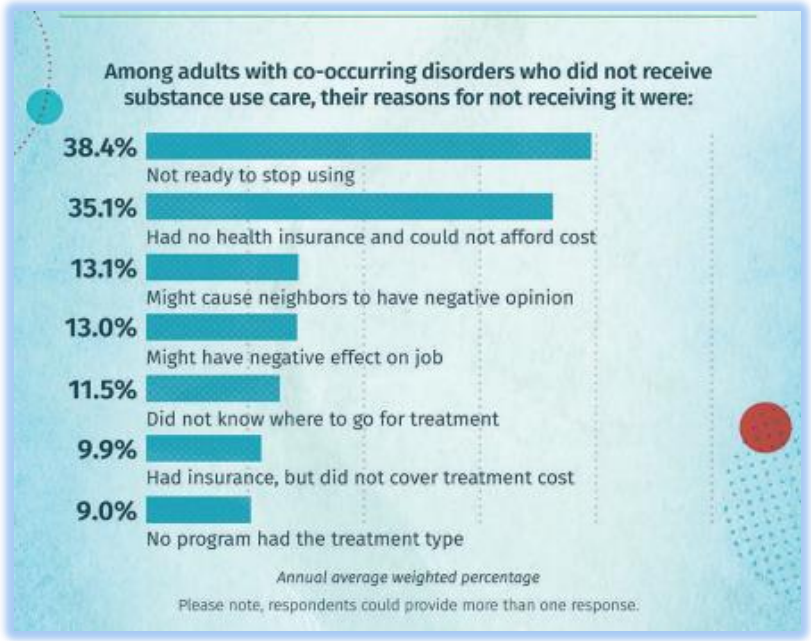
Pipeline Treatments

- In November 2022, Aptinyx Inc. announced the finalization of a grant, issued to researchers at Yale University School of Medicine, funding the research and development of **NYX-783** for the treatment of OUD.
  - NYX-783 is a small molecule that modulates the N-methyl-D-aspartate receptor (NMDAR)
- The $5.6 million grant was awarded under the National Institutes of Health (NIH) Helping to End Addiction Long-term (HEAL) Initiative, administered by the National Institute on Drug Abuse (NIDA).
- The first clinical study funded by the grant will be a randomized, double-blind, placebo-controlled, Phase I drug-drug interaction study to assess the safety, tolerability, and pharmacokinetics of **NYX-783 in combination with oxycodone** in individuals who use opioids.

Townsend EA, Negus SS, Banks ML. Medications Development for Treatment of Opioid Use Disorder. Cold Spring Harb Perspect Med. 2021 Jan 4;11(1):a039263. doi: 10.1101/cshperspect.a039263. PMID: 31932466; PMCID: PMC7778216.

Barriers to Treatment





https://nida.nih.gov/sites/default/files/infographic-comorbidity.pdf

KY SOS
Statewide Opioid Stewardship

THE BROOK
HOSPITALS
8521 LaGrange Road
Louisville, KY 40242

Confidential assessments are available 24 hours a day, 7 days a week. Call **502-426-6380** or **800-866-8876** or visit **thebrookhospitals.com.**

RIVENDELL
BEHAVIORAL HEALTH HOSPITAL

Call 270-843-1199

STAR Program

Adolescent Inpatient Substance Use Rehabilitation

The Substance Treatment and Recovery (STAR) Program, residential substance use treatment, utilizes the Seven Challenges® model for treating adolescents ages 13 to 17.

Teens may struggle with complex issues along with substance use and need treatment tailored to their unique needs. The professionals at The Brook Hospital can help patients evaluate their lives, consider desired changes and succeed in long-term recovery.

Our program includes:

- Evaluation and oversight by a psychiatrist
- Thorough assessment and oversight by a qualified mental health professional
- 24-hour skilled nursing care
- Daily educational and therapeutic groups using an evidence-based curriculum
- Individual and family therapy as needed
- Staff are certified in the Seven Challenges program

A multidisciplinary team provides each adolescent with an individualized treatment plan with a focus on problem-solving, measurable objectives and meeting criteria for discharge. Our goal is for each patient to create a healthy balance between the mental, physical and spiritual aspects of their lives.

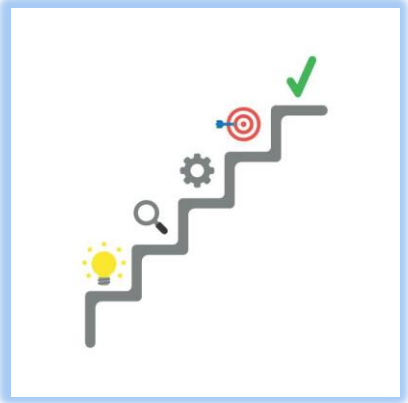
Continued treatment
Upon completion of the program, a referral is made for the patient to continue treatment in the least restrictive level of care possible (partial hospitalization, intensive outpatient or aftercare program). The level of care recommended is determined by the individual needs of the patient.

Referrals
Self-referrals are accepted as well as referrals from local and regional healthcare professionals.

Insurance
Services are covered by most insurance and managed care companies, including Kentucky Medicaid and TRICARE®.

Where do we go from here?

- Increasing **access** to BOTH pharmacological and non-pharmacological strategies to treat both mental illness and substance use disorders.
  - Payer source improvement in reimbursement and covered therapies.
- **More trained providers** and teams (therapists, counselors, peer support specialists, nurses, and pharmacists).
- **Programs for adolescents** that incorporate buprenorphine/naloxone therapy.



King C, Beetham T, Smith N, et al. Treatments Used Among Adolescent Residential Addiction Treatment Facilities in the US, 2022. *JAMA.* 2023;329(22):1983–1985. doi:10.1001/jama.2023.6266

Questions

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Statewide Opioid Stewardship

Kentucky Hospital Association

CHFS
KENTUCKY
Cabinet for Health and Family Services

UK HealthCare

cps

Treating Mental Health and Substance Use Disorder

Presented By:
Lisa Deal, PharmD, FASHP, BCACP, BSN &
Nicole Brummett, PharmD

THE BROOK | Hospitals
MAKING A DIFFERENCE IN MIND, BODY, SPIRIT