February 2024

Best Practice for the Implementation of Buprenorphine for the Treatment of Opioid Use Disorder (OUD) from the New York State Department of Health (DOH) and the Office of Addiction Services and Supports (OASAS)

Introduction

Opioid overdose mortality continues to impact the U.S. with more than 107,000 drug overdose deaths in 2021 (CDC). New York State (NYS), like the rest of the country, has seen a rise in overdose deaths. The number of overdose deaths involving any opioid increased each year between 2010 and 2017, with an overall increase of 200.2 percent from 1,074 in 2010 to 3,224 in 2017. In 2019, 2,939 overdose deaths involving any opioid occurred among NYS residents. In 2021, 30 New Yorkers per 100,000 died from drug overdoses. New York's opioid overdose death rates exceeded national rates in both 2020 and 2021.[i] Two thousand six hundred and sixty-eight individuals died of a drug overdose in New York City in 2021, an increase of 78 percent since 2019 and 27 percent since 2020, with evident disparities by age, race, poverty level, and neighborhood of residence.[ii]

Data from the 2021 National Survey on Drug Use and Health found that among the 2.5 million people aged 12 or older with a past year opioid use disorder due to their use of heroin or misuse of prescription pain relievers, only 22.1 percent (or 533,000 people) received MAT in the past year for opioid misuse.[iii] Improved access to pharmacotherapy is essential for addressing this epidemic as well as for improving the lives of persons living with OUD. Buprenorphine prescribers have an important role in bringing greater access to life-saving medication to patients, within a low threshold approach, removing as many barriers as possible.

Buprenorphine and methadone are the first-line treatments for OUD and are associated with decreased opioid-related (overdose) mortality as well as all-cause mortality. Long-acting naltrexone is a second-line treatment option that is not associated with decreased opioid-related (overdose) mortality or all-cause mortality but may be a viable treatment option for some patients.
NYS is committed to making these medications available to all who need them. OASAS has worked diligently to improve access to all three medications within the substance use disorder treatment system, and the DOH is augmenting these efforts by focusing on increased access to buprenorphine in clinical and non-clinical community settings, including non-traditional settings, such as emergency departments, syringe services programs, and mobile treatment sites.

The Mainstreaming Addiction Treatment (MAT) Act, included in the Omnibus Bill, recently was signed into law on 12/29/22 by President Biden. The MAT act eliminates the DEA X-Waiver which previously was required to prescribe buprenorphine, removes the associated patient limits for buprenorphine prescribers, and makes it easier for providers to treat patients with opioid use disorder.
Increasing access to buprenorphine is the most effective way to reverse the overdose death rate. Increased treatment access will be achieved best by integrating buprenorphine initiation, stabilization, long-term use, and referral throughout specialty substance use disorder treatment programs as well as primary care clinics and other medical settings throughout the healthcare system. Federal regulations do not obligate prescribers to ensure that their patients attend or participate in counseling for which referrals are made.

NYS encourages medical professionals to increase the number of patients prescribed buprenorphine under their care. It is critical to initiate and retain patients with OUD in routine care. For further training and resources, please visit https://ceitraining.org/resources/drug_user_health/.

Purpose

This best practice document is designed to provide further guidance in addition to the NYS AI Clinical Guidelines on Substance Use. It provides information regarding buprenorphine implementation; particularly regarding counseling, continuum of care, urine toxicology testing assessment, initiating treatment, duration of care, and adherence to buprenorphine.

Medication First, Low Threshold Approach

Key Points:

- A medication-first, low-threshold approach reduces the risk of overdose. The more quickly someone is started on buprenorphine, the more quickly they reduce their risk for overdose[1].

NYS Best Practice:

- **Same-day treatment entry and medication access.** Given the ongoing risk of overdose, any treatment delay, whether due to waiting lists or clinical protocols, could be deadly for patients.
- **Harm reduction approach.** Harm reduction principles acknowledge the primacy and urgency of the goal of reducing the potential harm from substance use, rather than achieving abstinence. For some patients, achieving abstinence takes time, and other patients may not have abstinence as a goal. Prescribers should examine their assumptions and decisions for any personal biases that may affect their ability to provide effective care for persons who use drugs. Acknowledge that different patients have different priorities and goals for treatment. A harm reduction approach can improve the provider-patient relationship and reduce stigma, a barrier to engaging in treatment.[iv]
- **Flexibility.** Rigid protocols for in-person appointments, psychosocial counseling, meeting attendance, or urine toxicology testing all serve to reduce the likelihood that a person can initiate and maintain medication successfully.

[1] Winograd, R. P., Presnall, N., Stringfellow, E., Wood, C., Horn, P., Duello, A., Green, L., & Rudder, T. (2019). The case for a medication first approach to the treatment of opioid use disorder. *The American journal of drug and alcohol abuse*, *45*(4), 333–340.

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Counseling

Key Points:

- Guidance from the Substance Abuse and Mental Health Services Administration (SAMHSA)[v] acknowledges that there is an intrinsic psychosocial component within the medical care buprenorphine prescribers provide which benefits patients.
- Patients are not required to participate in counseling to commence or continue buprenorphine. Some patients may find psychosocial treatments to be helpful and patients should be offered the choice of a referral to counseling, but it should not be a requirement or accessing buprenorphine.

NYS Best Practice:

- Prescribers should ensure continued access to buprenorphine with or without counseling.
- It is of benefit for providers to be aware of evidence-based psychosocial and other ancillary services that may be beneficial referrals for patients on MOUD, such as Motivational Interviewing, CBT, peer support services, other recovery supports, etc.[vi]

Ham Reduction Informed Continuum of Care

Key Points:

- Past trauma and ongoing trauma are common among people with OUD. Traumatic experiences put people at higher risk for the development of health conditions, including substance use disorders. More than 80% of people with OUD seeking treatment have experienced at least one adverse childhood experience (ACE), significant traumatic events, adversity, and toxic stress in their lives.[vii]
- Ongoing engagement in care is crucial for patients with substance use disorders. This engagement is more likely if the provider and support staff engage with the patient utilizing a harm reduction grounded and trauma-informed approach as part of the continuum of care.

NYS Best Practice:

- When creating a care plan with a patient, engage the patient in shared decision making, applying a harm reduction grounded, trauma-informed approach and with an understanding of their social determinants of health and their hierarchy of needs.
- Care should be responsive to the needs of the patient; this includes referring for/offering methadone if that is the patient's preferred treatment option.
- Prescribers should co-prescribe naloxone and inform patients regarding and/or provide patients with fentanyl test strips.
- Prescribers should ensure access to needles/syringes through prescription and/or by referral to a syringe services program and ESAP (Expanded Syringe Access Program).

Substance Use While on Treatment

Key Points:

- Buprenorphine helps patients reduce or cease the use of other opioids. Reduced opioid use is not only an acceptable outcome but also a desirable one. There have been concerns about prescribing buprenorphine to patients who use or misuse benzodiazepines or alcohol amongst other substances, as the risk of adverse reactions may be higher when these are combined with buprenorphine. In 2017, however, the Food and Drug Administration issued a Drug Safety Communication stating that buprenorphine should not be withheld from these patients as "the harm caused by untreated opioid addiction can outweigh these risks." [viii]
- Maintenance with buprenorphine reduces morbidity and mortality. Buprenorphine can be prescribed safely independent of co-use with stimulants[ix,] alcohol, or benzodiazepines.[x] Clinicians should not deny or discontinue SUD treatment if a patient continues to use or resumes use. Treatment cessation can carry great risks for the patient. Abruptly stopping buprenorphine leads to acute opioid withdrawal and reduced tolerance, leaving patients vulnerable to overdose with subsequent opioid use. Treatment cessation on account of non-opioid substance use, such as cocaine or methamphetamine use, does not make clinical sense, as buprenorphine treatment should be expected only to treat opioid use disorder.[xi]

NYS Best Practice:

- Prescribers should not stop prescribing buprenorphine for patients based on the use of licit or illicit substances whether prescribed to the patient or acquired by other means. [xii]
- Assess changes in clinical appearance and social integration, which may improve despite continued use.
- Routinely ask patients if they wish to address other substance use, including tobacco and alcohol use, and recognize that patient goals may not include decreasing or stopping use; offer strategies, and appropriate medications as needed.
- If the patient is using other substances, including other opioids, reassess the patient's dose of and adherence to buprenorphine The buprenorphine dose should be adequate to address the urge or desire (craving) to use opioids.

Toxicology Testing

Key Point:

- Toxicology testing, primarily using urine, is ubiquitous in settings treating substance use disorders, however, no universal standards exist today in clinical toxicology testing for identification, treatment, and medication monitoring for OUD. There is very limited empirical evidence about whether the use of toxicology testing in OUD treatment settings leads to improved clinical outcomes.[xiii] This guidance is intended to assist primary care and other providers outside formal substance use disorder treatment programs with respect to some considerations in ordering, interpreting, and acting on toxicology testing.[2]
- Use caution when utilizing toxicology testing to ascertain a patient's adherence with buprenorphine and the use of other substances. Toxicology testing can be detrimental to the relationship between the provider and patient. Patients are typically more forthcoming with a complete report of substance use, when there are no punitive responses and no threat of discontinuation of care with an unexpected toxicology test result.[xiv]
- Targeted toxicology testing is helpful when evaluating a patient who is exhibiting potentially toxic effects of an unknown substance, to help guide treatment initiation for opioid agonist or antagonist therapy, or for those patients who want or would benefit from the positive reinforcement of toxicology testing.
- To address concerns if a patient is not taking buprenorphine, testing for the norbuprenorphine metabolite can be an indicator. The risk of overdose is high refer to adherence to buprenorphine best practices section of this document.
- Increased toxicology testing of patients on buprenorphine does not increase adherence to medication.[xv] It is important to consider the potential harms associated with toxicology testing when the results are used to determine whether an individual is given access to buprenorphine. Research has recognized that a medication-first strategy for OUD treatment where buprenorphine is not contingent on active substance use improves outcomes of patients with OUD.[xvi]
- Clinicians also should be aware of the limitations of point-of-care toxicology testing (e.g., false negative and false positive results, detection of only some substances). This can reduce or prevent misinterpretation of toxicology test results, conflicts with patients, and loss of trust (e.g., false positive test results). The main goal is to retain patients in care.[xvii]

NYS Best Practices:

- Clinicians should ensure open communication with patients and work to ensure patients feel comfortable disclosing ongoing use or a return to use.
- Ongoing engagement in care as an overdose prevention strategy should be the strongest consideration when acting on toxicology test results. Patients should not be discharged from treatment for use of other substances.

[2] Guidance on Toxicology Use in OASAS Certified Programs
https://oasas.ny.gov/system/files/documents/2021/11/oasas-toxicology-guidance_0.pdf

- When ordering toxicology tests, it is quite standard to order tests for commonly used substances such as cocaine, amphetamines, benzodiazepines, and cannabis. The prescriber should be considering what if any, action or discussion will take place with the results.

Initial Assessment for and Initiation of Buprenorphine

Key Point:

- An extensive assessment is not necessary.
- If buprenorphine is determined to be an appropriate treatment, the medication should be made available for the patient immediately.

NYS Best Practice:

- Conduct a focused assessment:
  While not wanting to delay the initiation of buprenorphine; assess the patient's history to establish a diagnosis of OUD, other substance use, a history of substance use disorder treatment, and other significant medical and mental health history. This includes assessment and treatment/referral for physical health, mental health, and other conditions.
  1) Conduct a focused assessment (via telehealth audio only or audio/video or in person), as per patient preference.

- Conduct a pregnancy test if possible. Pregnancy is not a contraindication to treatment and additional education for the patient should be provided.[3]
  2) Conduct hepatitis and HIV tests if possible and refer to treatment as appropriate. Hepatitis, HIV, and other co-morbidities are not a contraindication to buprenorphine treatment and you should not wait for results before starting buprenorphine treatment. It is best practice to assess for other conditions, but this does not need to occur before buprenorphine is prescribed.

Check the state prescription monitoring program (PMP) database for other controlled medications. Use of other controlled medications is not a contraindication for buprenorphine use. Clinical judgment should play a role in assessing the patient.

- Initiate prescribing:
  1) SAMHSA guidance supports both in office and unsupervised (home) initiation.
  2) In order to avoid precipitated opioid withdrawal, buprenorphine needs to be initiated when the patient is in opioid withdrawal. The Clinical Opiate Withdrawal Scale, or COWS, is a numbered scale designed to help clinicians tailor opioid withdrawal management to the individual. The initial dose of buprenorphine may need to be adjusted due to illicitly manufactured fentanyl (IMF) and its analogues Although conventional buprenorphine initiation strategies typically are successful for most individuals, treatment providers increasingly are noting that alternative initiation approaches (such as low dose or high dose initiation) may be necessary for those needing or choosing to transition from methadone to buprenorphine, and for those

[3] https://www.hivguidelines.org/substance-use/su-screening/#tab_3

knowingly or unknowingly using fentanyl regularly.[4] There is not yet a current standard however there are examples of protocols.

3) Adjunctive medications for opioid withdrawal symptoms may be of benefit for the patient when initiating buprenorphine.[5]
4) Refer to guidelines if the patient is transitioning from methadone or naltrexone to buprenorphine.
5) When patients are starting treatment, it is common to continue or return to use with other opioids and should not be interpreted as unsuccessful treatment. If the patient is no longer engaged in care, rapid access to resume buprenorphine care should be facilitated at the patient's request.
6) Frequency of medical consultations and supportive services appointments, either in person or through telehealth with the patient, should be determined in consideration of the patient's schedule and other responsibilities.

Supporting Adherence to Buprenorphine

Key Point:

- Buprenorphine, like many medications, may be shared with people who are not prescribed the medication. The literature shows that most diverted buprenorphine is used to alleviate opioid withdrawal symptoms or to maintain abstinence from opioids rather than seeking other intended effects and most individuals take the medication as intended (with respect to route of administration and frequency of administration). Most individuals take buprenorphine as prescribed and lack of access to prescribed buprenorphine has been shown to be a primary factor in diversion of the medication.[xviii]

NYS Best Practice:

- Employ a person-centered approach to ensuring continued access to buprenorphine if the patient runs out (i.e., due to loss or theft, etc.).
- Patients having adherence issues with buprenorphine may ask for early refills of medication or have inconsistent refills of prescriptions. Carefully assess the patient utilizing a harm reduction grounded, trauma-informed approach and an understanding of their social determinants of health which may contribute to the underlying causes of the behaviors. For example, assess if the patient is having difficulty starting or taking the medication consistently due to precipitated opioid withdrawal or safe and secure medication storage issues.
- While there is no way to determine definitively if a patient is fully adherent with any medication, these strategies may address medication adherence and diversion[xix]:
    - Writing prescriptions for a shorter duration so that if lost the individual can get more soon. One can increase visits or allow refills at shorter intervals
    - Checking urine for buprenorphine and its metabolite (norbuprenorphine).
    - Offer additional visits and other supportive services.
    - Some patients may benefit from in-patient stabilization.

[4] https://oasas.ny.gov/system/files/documents/2022/07/low-high-dose-buprenorphine-initiation.pdf
[5] The ASAM National Practice Guideline for the Treatment of Opioid Use Disorder

- Prescribing doses greater than 24 mg may be needed for individualized cases. For example, in patients who: have co-existing pain management issues, are pregnant (particularly in the second and third trimesters).

Duration of Treatment

Key Point:

- Treatment with buprenorphine should continue for as long as the patient is benefiting from treatment and that treatment is aligned with the patient's goals.
- Risk of return to illicit opioid use is significant when treatment is discontinued. There is an elevated risk for a fatal or nonfatal opioid overdose.
- Patients experience better outcomes with a longer duration of treatment[xx].
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NYS Best Practice:

- If a provider cannot continue treatment for the patient, the prescriber should offer the patient a transfer to an alternative prescriber, allowing the patient to continue medication without interruption.
- If the patient wishes to reduce or stop buprenorphine treatment, the prescriber should explore the patient's rationale and support the patient to make the best-informed decision for the duration of treatment. The discussion should address internalized stigma and present the risks for return to use and fatal overdose with medication cessation. A patient's desire to stop treatment with buprenorphine can be influenced by:
  - Stigma and implicit bias from previous providers,
  - Family expectations, and
  - The patient's internalized stigma regarding medication for opioid use disorder (MOUD).
- The tapering of medication needs to be individualized to the patient's needs and responsive to a return to the previous buprenorphine dose as needed.[xxi]
- Patients, particularly those with special considerations to risk of overdose should be maintained on buprenorphine. This includes:
  - The patient experiencing acute pain either from injury, surgery, or another cause; buprenorphine treatment should continue and additional analgesics, including short-acting opioids utilized as clinically indicated, and therapies should be provided additionally as appropriate.
  - The pregnant patient, treatment should continue while pregnant and post-partum. The post-partum period is a particularly vulnerable time for a return to use and an increased risk of fatal overdose.
  - Re-entry into the community post-incarceration. People leaving an incarcerated setting without continued access to MOUD have up to 40 times increased risk of dying from overdose in the first 2 weeks following their discharge than the general population.[xxii]

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[i] *Opioid-related Data in New York State. New York State Department of Health website. https://health.ny.gov/statistics/opioid/*

[ii] *NYC Office of the Chief Medical Examiner and NYC DOHMH Bureau of Vital Statistics, 2000–2021; 2021 data are provisional and subject to change.*

[iii] *Substance Abuse and Mental Health Services Administration. (2022). Key substance use and mental health indicators in the United States: Results from the 2021 National Survey on Drug Use and Health (HHS Publication No. PEP22-07-01-005, NSDUH Series H-57). Center for Behavioral Health Statistics and Quality, Substance*

Abuse and Mental Health Services Administration.

[iv] *Krawczyk N, Negron T, Nieto M, Agus D, FIngerhood M. Overcoming medication stigma in peer recovery: A new paradigm. Substance Abuse. 2018;39(4):404–4019.*

[v] *i Substance Abuse and Mental Health Services Administration. Medications To Treat Opioid Use Disorder. Treatment Improvement Protocol (TIP) Series 63, Full Document. HHS Publication No. (SMA) 18- 5063FULLDOC. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2018*

[vi] *Substance Abuse and Mental Health Services Administration. Enhancing Motivation for Change in Substance Use Disorder Treatment. Treatment Improvement Protocol (TIP) Series No. 35. SAMHSA Publication No. PEP19-02-01-003. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2019*

[vii] *Derefinko KJ, García FIS, Talley KM, et al. Adverse childhood experiences predict opioid relapse during treatment among rural adults. Addictive Behaviors. 2019;96: 171-174.*

[viii] *FDA https://www.fda.gov/Drugs/DrugSafety/ucm575307.htm.*

[ix] *Comer S, Cunningham C, Fishman MJ, et al. National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use.*

[x] *Ford, Becky R. PhD; Bart, Gavin MD, PhD; Grahan, Brian MD, PhD; Shearer, Riley D. BS; Winkelman, Tyler N.A. MD, MSc. Associations Between Polysubstance Use Patterns and Receipt of Medications for Opioid Use Disorder Among Adults in Treatment for Opioid Use Disorder. Journal of Addiction Medicine: March/April 2021 - Volume 15 - Issue 2 - p 159-162.*

[xi] *Martin SA, Chiodo LM, Bosse JD, Wilson A. The Next Stage of Buprenorphine Care for Opioid Use Disorder. Ann Intern Med. 2018;169(9):628.*

[x i] *Martin SA, Chiodo LM, Bosse JD, Wilson A. The Next Stage of Buprenorphine Care for Opioid Use Disorder. Ann Intern Med.2018; 169:628–635. doi: 10.7326/M18-1652.*

[xiii] *Jarvis, M., Williams, J., Hurford, M., Lindsay, D., Lincoln, P., Giles, L., Luongo, P., & Safarian, T. (2017). Appropriate Use of Drug Testing in Clinical Addiction Medicine. Journal of addiction medicine, 11(3), 163–173.*

[xiv] *Pytell, J. D., & Rastegar, D. A. (2021). Down the drain: Reconsidering routine urine drug testing during the COVID-19 pandemic. Journal of substance abuse treatment, 120, 108155.*

[xv] *Jarvis, M., Williams, J., Hurford, M., Lindsay, D., Lincoln, P., Giles, L., Luongo, P., & Safarian, T. (2017). Appropriate Use of Drug Testing in Clinical Addiction Medicine. Journal of addiction medicine, 11(3), 163–173.*

[xvi] *Winograd, R. P., Presnall, N., Stringfellow, E., Wood, C., Horn, P., Duello, A., ... Rudder, T. (2019). The case for a medication first approach to the treatment of opioid use disorder. The American Journal of Drug and Alcohol Abuse, 1–8.*

[xvii] *American Society of Addiction Medicine. Appropriate Use of Drug Testing in Clinical Addiction Medicine. 2017. Available at: https://www.asam.org/Quality-Science/quality/drug-testing*

[xviii] *Lofwall, M. R., & Havens, J. R. (2012). Inability to access buprenorphine treatment as a risk factor for using diverted buprenorphine. Drug and alcohol dependence, 126(3), 379–383. https://doi.org/10.1016/j.drugalcdep.2012.05.025*

[xix] *Substance Abuse and Mental Health Services Administration. Medications To Treat Opioid Use Disorder. Treatment Improvement Protocol (TIP) Series 63, Full Document. HHS Publication No. (SMA) 18- 5063FULLDOC. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2018*

[xx] *Md Mahmudul Hasan, Md. Noor-E-Alam, Jiesheng Shi, Leonard D. Young & Gary J. Young (2022) Long-term patient outcomes following buprenorphine/naloxone treatment for opioid use disorder: a retrospective analysis in a commercially insured population, The American Journal of Drug and Alcohol Abuse, 48:4, 481-491*

[xxi] *NYSDOH AIDS Institute Clinical Guidelines Program. Treatment of Opioid Use Disorder. 2021. Available at: https://cdn.hivguidelines.org/wp-content/uploads/20220801144904/NYSDOH-AI-Treatment-of-Opioid-Use-Disorder_8-1-2022_HG.pdf*

[xxii] *Merrall, E. L. C., Kariminia, A., Binswanger, I. A., Hobbs, M. S., Farrell, M., Marsden, J., Hutchinson, S. J., & Bird, S. M. (2010). Meta-analysis of drug-related deaths soon after release from prison.* Addiction, 105, *1545-1554.*