NEW YORK STATE | Office of Alcoholism and Substance Abuse Services | Department of Health

Arlene González-Sánchez, M.S., L.M.S.W
Commissioner

Howard A. Zucker, M.D, J.D.
Commissioner

February 2019

Dear Colleague:

Opioid Use Disorder and opioid related overdose morbidity and mortality continue to be a public health crisis. In 2016, there were more than 3,200 deaths associated with opioids statewide. That's nearly 9 deaths per day. The New York State Department of Health (NYSDOH) and the New York State Office of Alcoholism and Substance Abuse Services (OASAS) are working together to increase access to the three medications used to treat Opioid Use Disorder: methadone, buprenorphine and long acting naltrexone.

This communication focuses on buprenorphine. Research and experience have led to changes in the standard of care in prescribing buprenorphine. In addition to these changes, there are misconceptions about the prescribers' responsibilities that impede referral to and initiation of treatment with buprenorphine.

The attached document, Implementing Transmucosal Buprenorphine for Treatment of Opioid Use Disorder, was developed to assist those caring for individuals with Opioid Use Disorder to integrate buprenorphine into their practices with the understanding that it will save lives. There are many resources in New York State to assist prescribers including free buprenorphine waiver training, mentoring and consultation.

If you have any questions, please contact Sharon Stancliff, MD, Associate Director for Harm Reduction in Health Care, NYSDOH AIDS Institute at buprenorphine@health.ny.gov or Robert Kent, OASAS General Counsel at legal@oasas.ny.gov.

Sincerely,

Howard Zucker M.D.

Howard A. Zucker, M.D., J.D.
Commissioner
New York State Department of Health

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New York State Office of Alcoholism and Substance Abuse Services

Implementing Transmucosal Buprenorphine for Treatment of Opioid Use Disorder

Best Practices from New York State Department of Health and Office of Alcoholism and Substance Abuse Services

Introduction

Opioid overdose mortality continues to ravage New York State (NYS). In 2016, there were more than 3,200 deaths associated with opioids statewide. That's nearly 9 deaths per day. Improved access to pharmacotherapy is essential for combatting this epidemic as well as for improving the lives of persons struggling with addiction. Buprenorphine prescribers have an important role in bringing greater access to life-saving medication to patients and to do so in a way that promotes enduring, positive outcomes.

Buprenorphine and methadone are the first-line treatments for Opioid Use Disorder (OUD) and are associated with significant decreases in both fatal and non-fatal opioid overdoses. Long-acting naltrexone also shows some promise and may be considered as a treatment option. NYS is committed to making these medications available to all who need them. The NYS Office of Alcoholism and Substance Abuse Services (OASAS) has worked diligently to improve access to all three medications within the drug treatment system. The NYS Department of Health (DOH) is augmenting these efforts by focusing on increased access to buprenorphine in clinical and non-clinical community settings.

NYS encourages outpatient healthcare providers to complete available training (Contact: buprenorphine@health.ny.us) to obtain a waiver to prescribe buprenorphine. NYS encourages waived buprenorphine prescribers to start prescribing buprenorphine and, if already prescribing to increase the number of patients under care. It is critical to initiate and retain patients with OUD in routine care.

Purpose

This best practice document is designed to fill information gaps and provide guidance in response to misconceptions regarding buprenorphine implementation; particularly regarding counseling, polysubstance use, assessment, and diversion.

This document is focused on buprenorphine because the standards of care are evolving rapidly in response to the opioid epidemic and research defining evidence-based practices. [i]

Counseling

Key Points:

- Federal law requires that waiver applicants attest to their capacity to refer patients for appropriate counseling and other appropriate ancillary services. [ii] This is a relatively low-threshold requirement and does not obligate prescribers to ensure that their patients attend or participate in counseling for which referrals are made.

- Guidance from the Substance Abuse and Mental Health Services Administration (SAMHSA)[iii] acknowledges that there is an intrinsic psychosocial component within the medical management buprenorphine prescribers provide which benefits patients. Many patients are likely to benefit from counseling at some point in their treatment for OUD. SAMHSA's guidance regarding counseling notes that prescribers should "offer referrals for adjunctive counseling and recovery support services as needed." The guidance further states that "patients who were not interested in adjunctive addiction or mental health counseling during induction may become receptive to it when they are feeling more stable."

NYS Best Practices:

- Prescribers should ensure continued access to buprenorphine even in the absence of counseling. [i, iii]
- Prescribers should ensure immediate and continued access to buprenorphine for patients who, at the time, may be unwilling or unable to participate in counseling or other formal psychosocial services.

Polysubstance Use

Key Points:

- Some providers erroneously believe that prescribing buprenorphine is contrary to a standard of care when patients continue to use other opioids or other classes of drugs. Buprenorphine helps patients reduce or cease use of other opioids. Reduced opioid use is not only an acceptable outcome, it is a desirable one. There have been concerns about prescribing buprenorphine to patients who use or misuse benzodiazepines or alcohol, as the risk of adverse reactions may be higher when either of these is 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." [iv] Concomitant use of other opioids, cocaine, cannabis and amphetamines does not pose elevated risk in the patients taking buprenorphine and should not be a basis for terminating care.
- Maintenance with buprenorphine can reduce morbidity and mortality even when drugs other than opioids are being used and in the presence of relapse to opioid use.

NYS Best Practice:

- Prescribers should not discharge patients solely based on the use of prescribed or unprescribed substances including, but not limited to, cannabis, and benzodiazepines.
- Prescribers should ensure continued access to buprenorphine even in the presence of other drug use. [i, iii]

Initial Assessment for Transmucosal Buprenorphine

Key Point:

- An extensive assessment is not necessary.

NYS Best Practices[1]:

- Conduct a focused assessment:

    1) Assess the patient's history to establish presence of OUD, other drug use, history of drug treatment and significant medical and psychiatric history.
    2) Conduct a focused physical examination, refer for a physical exam, or get a record of a recent one.
        - Assess for signs and symptoms of intoxication. Do not give a first dose to a patient who is sedated or intoxicated. Assess and treat him or her appropriately.
    3) Order relevant laboratory tests.
        - Conduct drug testing as needed to confirm history.
        - Conduct a pregnancy test. Pregnancy is not a contraindication to treatment but requires further counseling on options.
        - Order liver function tests if possible, but do not wait for results before starting transmucosal buprenorphine treatment as continued misuse of illicit opioids is far riskier than the risk of mild toxicity in those with undiagnosed moderate liver impairment.
    4) 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 do not wait for results before starting buprenorphine treatment.
    Check the state prescription drug monitoring program database for other controlled substances.
    5) Initiate prescribing.
        - SAMHSA guidance now supports both in-office and unsupervised induction.

Diversion of Buprenorphine

Key Point:

- Buprenorphine, like many medications, can be given or sold to people who are not prescribed the medicine. The literature shows that most diverted buprenorphine is used to alleviate withdrawal or maintain abstinence rather than to become intoxicated. Lack of access to prescribed buprenorphine is believed to be a prime factor in diversion of the medication. [v, vi]

NYS Best Practices:

- Prescribers should strive to minimize diversion and avoid allowing concerns about diversion to prevent them from treating OUD Disorder.
- Strategies for addressing medication nonadherence and diversion include carefully assessing the patient to understand underlying causes of the behavior. For example, medication may be shared with a person unable to access their own treatment. While there is no way to definitively determine if a patient is fully adherent to any medication: [iii]
    - Asking patients to bring their unused medication into the office for counting.
    - Talking with family members or significant others (with appropriate consent).

[1] Based on: 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.

- Writing prescriptions for shorter duration.
- Checking urine for buprenorphine and its metabolites.
- Avoiding doses over 24 mg (save in rare cases).

Duration of Treatment

Key Point

- Treatment with buprenorphine should continue for as long as the patient is benefiting. Risk of return to illicit opioid use is high when treatment is discontinued.

NYS Best Practices

- If care is to be terminated for any reason, the prescriber should offer the patient a transfer to an alternative prescriber allowing the patient to continue medication without interruption.
- Patients, particularly those opting to stop medication, should also be referred to harm reduction, peer, or other supportive services.

Key Resources for Implementation of Buprenorphine

- Federal guidance https://www.samhsa.gov/medication-assisted-treatment/buprenorphine-waiver-management/qualify-for-physician-waiver
- Annals of Internal Medicine: "The Next Stage of Buprenorphine Care for Opioid Use Disorder" by Martin et al (http://dx.doi.org/10.7326/M18-1652).
- Substance Abuse and Mental Health Services Administration Treatment Improvement Protocol (TIP) 63 https://store.samhsa.gov/system/files/sma18-5063fulldoc.pdf
- U.S. Department of Health and Human Services (HHS), Office of the Surgeon General, Facing Addiction in America: The Surgeon General's Spotlight on Opioids. Washington, DC: HHS, September 2018.
- Wakeman S, Barnett M. Primary care and the opioid-overdose crisis—buprenorphine myths and realities. N Engl J Med. 2018;379:1–4.

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

[ii] Drug Addiction Treatment Act of 2000 (DATA), as amended, 21 USC §823(g)(2); see also 42 CFR Part 8; Medication Assisted Treatment for Opioid Use Disorders, SAMHSA Final Rule, 81 Fed. Reg. 44712 (July 8, 2016)

[iii] 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.

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

[v] Carroll JJ1, Rich JD, Green TC. The More Things Change: Buprenorphine/naloxone Diversion Continues While Treatment Remains Inaccessible. J Addict Med. 2018 Nov/Dec;12(6):459-465

[vi] Lofwall MR, Walsh SL: A review of buprenorphine diversion and misuse: the current evidence base and experiences from around the world. J Addict Med 8(5):315–326,