

Treatment of Opioid Use Disorder with

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NAME.....AGE.....

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DATE.....

PRESCRIPTION

● Buprenorphine and Buprenorphine/Naloxone



EXECUTIVE SUMMARY

In 2017, over five North Carolina (NC) residents died each day from an unintentional opioid overdoseⁱ. Improved access to evidence-based treatment is essential to improve the lives of people struggling with opioid use disorder (OUD) and reduce unintended consequences including opioid overdose, death, and the transmission of infectious diseases.

The North Carolina Department of Health and Human Services (NCDHHS) is committed to improving workforce capacity and subsequent access to buprenorphine and buprenorphine/naloxone, FDA-approved medications indicated for the treatment of OUD.

The purpose of this document is to provide brief guidance for providers on prescribing buprenorphine products for the treatment of opioid use disorder in both outpatient and inpatient settings. This also serves to address common concerns surrounding buprenorphine treatment that often limit access to effective care among underserved populations.

● WHO CAN PRESCRIBE BUPRENORPHINE?

The Drug Addiction Treatment Act of 2000 (DATA 2000) reduced the regulatory burden on providers to treat OUD by allowing them to obtain a waiver to dispense or prescribe Schedule III-V narcotic medications in settings other than an opioid treatment program, such as in a provider's office. Currently, specific buprenorphine formulations are the only controlled medications meeting this criteria. To qualify for a waiver, MD/DO physicians must complete eight hours of training. Physician assistants, nurse practitioners, certified nurse specialists, certified registered nurse anesthetists, and certified nurse midwives must complete 24 hours of training. Upon approval for a waiver, the practitioner is assigned an identification number by the Drug Enforcement Agency (DEA), which must be included on all buprenorphine prescriptions for OUD treatment.ⁱⁱ

A few exceptions allow for providers without a DATA 2000 waiver to administer buprenorphine products to patients with OUD. Any provider can administer buprenorphine or buprenorphine/naloxone to patients with OUD that are admitted to the hospital with a primary diagnosis other than OUD. **(SEE BELOW: initiating and maintaining buprenorphine in the hospital.)**

NCDHHS is encouraging providers to complete waiver training, which is available online or in-person. A list of upcoming waiver trainings is at: <https://opioid.governorsinstitute.org/upcoming-trainings/> or <https://pcssnow.org/medication-assisted-treatment/>

If you hold a waiver, but are not currently prescribing buprenorphine products, please visit <https://pcssnow.org/resources/clinical-tools/> or mahec.net/safer for technical assistance on how to begin utilizing your waiver. For waived providers that are prescribing buprenorphine products, there are a variety of technical assistance resources through Project ECHO®, Provider Clinical Support Systems (PCSS), and other professional organizations.

INITIAL ASSESSMENT AND INITIATION

KEY POINTS:

- The patient needs an adequate assessment to determine a diagnosis of OUD and that no contraindications to the initiation of treatment exist.
- If possible, patients requesting treatment should be seen on the same day or as soon as possible.

ACCEPTED PRACTICES:

1. Assess the patient's history to establish presence of an OUD as defined by the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) or International Classification of Diseases, 10th edition, Clinical Modification (ICD-10-CM) criteria.
2. Conduct a focused physical examination.
3. Obtain relevant laboratory tests.
 - a. Urinary drug test.
 - b. Pregnancy test for women of childbearing age.
 - c. Hepatitis B and C screens and HIV antibody test, if available.
4. Review the NC Controlled Substances Reporting System (CSRS) to determine prescription history.
5. Administer the Clinical Opiate Withdrawal Scale (COWS) to determine level of withdrawal if conducting observed induction. This assessment may be found at: <https://www.drugabuse.gov/sites/default/files/files/ClinicalOpiateWithdrawalScale.pdf>
6. If appropriate, initiate prescribing or administration of buprenorphine or buprenorphine/naloxone and provide relevant education regarding the induction, stabilization, and maintenance phases.
 - a. Substance Abuse and Mental Health Services Administration (SAMHSA) guidance for unsupervised inductions as well as in-office inductions. <https://store.samhsa.gov/system/files/sma18-5063fulldoc.pdf>
 - b. Pregnant women with OUD should receive early initiation of treatment to decrease the risk of fetal withdrawal. Consult with the obstetrics provider as needed. <https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf>
 - c. Patients receiving buprenorphine products should be offered a naloxone kit or prescription for naloxone.
7. Refer patients for appropriate counseling and other appropriate services such as family planning.

COUNSELING

KEY POINTS:

- Upon applying for a waiver, qualifying providers must attest to their capacity to refer patients for appropriate counseling and other non-pharmacological treatments.
- Guidance from SAMHSA acknowledges that patients treated with medications for OUD are likely to benefit from individualized psychosocial supports, including counseling. Prescribers should “offer referrals for adjunctive counseling and recovery support services as needed.” The guidance further states, “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.”ⁱⁱⁱ

ACCEPTED PRACTICES:

1. Prescribers should ensure immediate and continued access to MAT for patients who, at the time of initiation, may be unwilling or unable to participate in counseling or other formal psychosocial services.
2. Prescribers should continue to ensure that adequate counseling and other recovery support services are available to their patients, particularly if they need motivational enhancement for positive changes in their lifestyle.

DURATION OF TREATMENT

KEY POINTS:

- Treatment with buprenorphine, buprenorphine/naloxone, and other forms of MAT should continue for as long as the patient is benefiting and not experiencing any significant adverse events.
- OUD is a chronic relapsing and remitting disease that may require prolonged treatment. Research has shown a patients' all-cause mortality more than doubles when buprenorphine maintenance therapy is discontinued.^{iv}

ACCEPTED PRACTICES:

1. While treatment should continue for as long as the patient is benefiting, if the buprenorphine product is to be discontinued for any reason:
 - a. Taper dose gradually as tolerated and discuss management of withdrawal symptoms.
 - b. Educate patient on the increased risk of overdose should the patient decide to resume opioid use due to a decrease in tolerance.
 - c. Ensure the patient has access to naloxone.
2. Patients who discontinue MAT should be referred to other treatment, recovery, or harm reduction services (e.g. syringe exchange programs, peer support.)

POLYSUBSTANCE USE

KEY POINTS:

- Due to the potential risk of serious adverse effects, there is concern regarding prescribing buprenorphine products when patients concurrently use or misuse other opioids, illicit substances (e.g. cocaine, methamphetamines, THC), benzodiazepines, alcohol, or other sedatives.
- The United States Food and Drug Administration (FDA) issued a Drug Safety Communication in 2017 noting that buprenorphine products should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS) as the "harm caused by untreated opioid addiction can outweigh these risks."^v

ACCEPTED PRACTICES:

1. Prescribers should not discharge patients or discontinue buprenorphine products solely based on the use of polysubstances, including benzodiazepines or other CNS depressants. However, education should be provided to all patients regarding the serious risk of combined use.
2. Prescribers should coordinate care to ensure that other prescribers are aware of the patient's buprenorphine treatment. Medication management may include tapering down benzodiazepines and other high-risk medications, if appropriate. If these medications are being utilized in the treatment of anxiety or insomnia, consider alternative medications.
3. Prescribers should monitor for illicit drug use through urine or blood screening. People using multiple substances should be offered higher level or emergent treatment services as needed. Higher level services may include a Substance Abuse Intensive Outpatient Program, opioid treatment program, or inpatient detoxification from illicit substances while maintaining the patient on the prescribed medication for OUD.

INITIATING AND MAINTAINING BUPRENORPHINE IN THE HOSPITAL^{vi}

KEY POINTS:

- If a patient is admitted to the hospital with a primary medical diagnosis other than OUD (i.e. endocarditis, sepsis, abscess, fracture, etc.) and secondarily found to have OUD, an inpatient hospital provider without a waiver may maintain or initiate buprenorphine or buprenorphine/naloxone throughout the length of the hospital stay in order to prevent withdrawal symptoms that may complicate the primary medical condition. The provider may adjust dosages of this medication as per the provision of good medical care or pain management. Discharge planning should include arranging for the continuation of MAT by an external or internal provider.^{vi}
- If a patient presents with a primary diagnosis of OUD, providers without a waiver must adhere to the “three-day rule” (Title 21, Code of Federal Regulations, Part 1306.07(b)), which allows a provider who is not separately registered as a narcotic treatment program or certified as a waived DATA 2000 provider, to **administer (but not prescribe)** narcotic drugs to a patient for the “purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment”, under the following conditions:^{vi}
 - a. Not more than one day’s medication is administered or given to a patient at one time.
 - b. Treatment does not exceed 72 hours.
 - c. The 72-hour period cannot be renewed or extended.

ACCEPTED PRACTICES:

1. At discharge from a hospital or emergency department, a provider without a waiver cannot write a buprenorphine or buprenorphine/naloxone prescription for the patient, but may administer medication and have the patient to return for onsite administration of the medication for a maximum of 72 hours.
2. Inpatient providers should obtain a waiver in order to prescribe buprenorphine or buprenorphine/naloxone at discharge for transition of care into the outpatient setting.
3. Every effort should be made to provide a warm hand-off to an outpatient MAT provider or opioid treatment program (OTP) that may also offer buprenorphine products within 24-72 hours of discharge in order to improve engagement into long-term treatment. Hospitals should work toward fostering relationships with OTPs, community-based behavioral health providers, pharmacies, and other community resources to improve continuity of care. If a patient is initiated on buprenorphine or buprenorphine/naloxone and refuses referral for continuation of treatment, they should be provided with information on available treatment options, local providers, and other community resources.
4. Patients receiving a buprenorphine product should be offered a naloxone kit or prescription.

REFERENCES

ⁱ NC Opioid Action Plan Data Dashboard. Retrieved from <https://injuryfreenc.shinyapps.io/OpioidActionPlan/>

ⁱⁱ Substance Abuse and Mental Health Services Administration. Buprenorphine Waiver Management. 2019. Retrieved from <https://www.samhsa.gov/medication-assisted-treatment/training-materials-resources/buprenorphine-waiver>

ⁱⁱⁱ Substance Abuse and Mental Health Services Administration. Treatment Improvement Protocol (TIP) 63: Medications for Opioid Use Disorder. 2018. Retrieved from <https://store.samhsa.gov/system/files/sma18-5063fulldoc.pdf>

^{iv} Sordo L, et al. Mortality risk during and after opioid substitution treatment: systematic review and meta-analysis of cohort studies. *BMJ*. 2017; 357:j1550.

^v United States Food and Drug Administration. Drug Safety Communication. 2017. Retrieved from <https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-urges-caution-about-withholding-opioid-addiction-medications>

^{vi} Substance Abuse and Mental Health Services Administration. Special Circumstances for Providing Buprenorphine. 2019. Retrieved from <https://www.samhsa.gov/medication-assisted-treatment/legislation-regulations-guidelines/special>

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