Drug Diversion Toolkit

Buprenorphine—A Primer for Prescribers and Pharmacists

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Content Summary

This booklet provides guidance to physicians and pharmacists on buprenorphine regulatory requirements, prescribing, dispensing, and safety recommendations, and additional information to improve decision-making and promote beneficial outcomes. Information on the history of opioid addiction and traditional treatments in comparison to buprenorphine is included. The booklet details the process of obtaining a Drug Addiction Treatment Act of 2000 waiver and describes treatment initiation and maintenance. This booklet educates pharmacists on how to verify the Drug Addiction Treatment Act of 2000 waiver status of a physician, how to validate a Drug Enforcement Administration registration number, how Federal privacy regulations pertain to opioid addiction treatment, and what key buprenorphine counseling parameters to consider. This booklet supports the use of buprenorphine as a viable alternative to traditional opioid treatment centers to address the unmet need for office-based treatment of opioid addiction, and advocates the partnership of physicians and pharmacists in the effective administration and execution of a buprenorphine-based opioid addiction treatment plan.

Patients seeking treatment for opioid use disorder, including misuse of prescription opioids, should be offered medication-assisted treatment with one of the medications approved by the U.S. Food and Drug Administration (FDA) for this indication. The FDA-approved medications include naltrexone, methadone, and buprenorphine-containing products. Prescribers and pharmacists should be familiar with the contents of this booklet to promote safe and appropriate use of this pharmacotherapy.

Naltrexone is a blocker of the mu opioid receptor and has no potential for abuse. It can be prescribed by any physician, advanced practice nurse (APN) or physician assistant (PA) and is not subject to any Federal or State regulations. It is widely covered by public and commercial insurance. Patients who choose this option must undergo detoxification from opioids prior to initiating pharmacotherapy. Methadone is available for the treatment of opioid use disorder through opioid treatment programs (OTPs) that are certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) and are often licensed or otherwise regulated by States. Buprenorphine may also be offered through OTPs. The risk of diversion of medication from OTPs is generally considered to be low because OTPs can only administer or dispense medications under specific regulations. Under specific conditions buprenorphine can also be prescribed by a physician and dispensed to the patient by a pharmacy.

Mechanisms of Action

Unlike methadone, which is a full agonist, buprenorphine is a partial agonist of the mu opioid receptor. Buprenorphine offers several advantages over full agonists: convenience, safety, and lower abuse potential.[1] As a partial agonist, there is an upper limit, or ceiling effect, to the sedating and euphoric effects of buprenorphine making it safe enough and of low enough abuse potential to be listed in Schedule III of the Controlled Substances Act (CSA).

As a therapeutic agent for the treatment of opioid use disorder, the partial agonist properties of buprenorphine have important consequences. First, while the patient still becomes physiologically dependent on the medication, the degree of dependence is thought to be lower and the withdrawal associated with discontinuation less severe than with a full agonist. Second, buprenorphine will competitively displace full opioid agonists from the mu opioid receptor and precipitate acute opioid withdrawal. Therefore, it must only be administered to a patient who is opioid dependent and who is in moderate opioid withdrawal.

Buprenorphine is currently most widely administered sublingually and transmucosally. It is available in generic and branded product combined with naloxone. The naloxone is not well absorbed sublingually or transmucosally, but is formulated with buprenorphine to function as a deterrent if someone should choose to abuse the product by administering it through injection. If injected, the naloxone produces a sudden and intense opioid withdrawal in a patient who is opioid dependent and lessens the opioid effects for patients who are not opioid dependent.[2]

Abuse and Adverse Drug Reactions

Like other opioids, buprenorphine can be abused for its euphoric effects, especially in patients who are not tolerant of opioids. Physicians and pharmacists should take appropriate precautions to protect buprenorphine from diversion. Buprenorphine can also cause many of the same adverse reactions as other opioids, such as nausea, pruritus, headache, insomnia, and moderate withdrawal upon discontinuation or taper. Serious adverse reactions may occur, including respiratory depression and overdose, especially when combining opioids with other central nervous system depressants, such as alcohol or benzodiazepines.[3]

While there are fewer drug interactions between buprenorphine and drugs used to treat common co-occurring conditions, such as human immunodeficiency virus (HIV) or hepatitis C, prescribers and dispensing pharmacists should be attentive to the possibility of sedation or cognitive dysfunction when new medications are started for patients receiving buprenorphine. Visit the FDA website at https://www.accessdata.fda.gov/scripts/cder/drugsatfda/ and search on a drug name, then check section seven (Drug Interactions) of the product label for up-to-date information about drug interactions for that medication.[4]

Prescribing Buprenorphine Products

Physicians may choose from several buprenorphine products, including generic buprenorphine or buprenorphine and naloxone sublingual tablets, and trade-name buprenorphine and naloxone buccal films, sublingual films, or sublingual tablets.[5, 6, 7, 8, 9] Physicians should remember that injectable buprenorphine and transdermal buprenorphine are not approved for the treatment of opioid use disorder.[10, 11] To minimize the risk of abuse or diversion, buprenorphine combined with naloxone should be prescribed preferentially. Buprenorphine mono-products should be reserved for pregnant or breast-feeding women or patients with documented, true allergic reactions to naloxone.[12] Care should be taken to dose the medication in accordance with FDA recommendations and only the number of doses needed until the next appointment should be provided. Refills should be reserved for stable patients with good recovery support to assure compliance. Use other clinical strategies (such as toxicology testing and having patients present their unused prescription to office or pharmacy staff to be inventoried) to reinforce compliance and minimize harm to the community that could result from undetected diversion of buprenorphine.

Treatment Initiation

Prior to induction, physicians should establish the diagnosis of opioid use disorder and screen for any co-occurring substance use disorders. Informed consent should be obtained and a treatment agreement should be in place for each patient. Individualized treatment plans should be developed for each patient and should address the management of co-occurring medical and psychiatric problems as well as the need for behavioral interventions and recovery support resources.[13, 14] SAMHSA Treatment Improvement Protocols (TIPs) provide extensive information about buprenorphine medication-assisted treatment (MAT) for opioid dependence. Pharmacology of buprenorphine products, patient assessment techniques, and practice guidelines are discussed in depth in SAMHSA TIP 40, "Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction." Visit http://store.samhsa.gov/product/TIP-40-Clinical-Guidelines-for-the-Use-of-Buprenorphine-in-the-Treatment-of-Opioid-Addiction/SMA07-3939 to access the digital version or to order print copies of SAMHSA TIP 40.

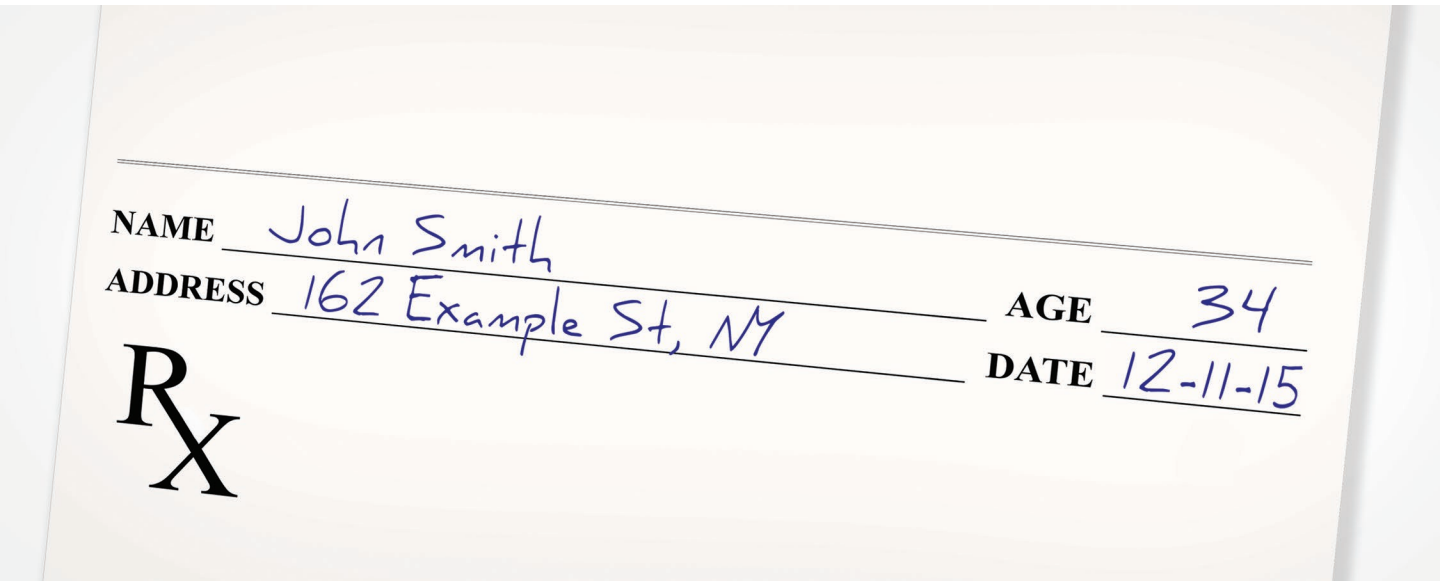
Maintenance

Individualize dosing for each patient. A buprenorphine and naloxone combination product is most often dosed once daily, as a buccal film or as a sublingual film or tablet. The approved maintenance dosage ranges of the combination products are indicated in Table 1.[15, 16, 17, 18]

Table 1. Approved Maintenance Dosage Ranges

Trade Name Product	Dosage Form	Target Dose Buprenorphine/ Naloxone	Maintenance Dosage Range Buprenorphine/ Naloxone
Bunavail®	Buccal film	8.4/1.4 mg	2.1/0.3 mg to 12.6/2.1 mg
Suboxone®	Sublingual film	16/4 mg	4/1 mg to 24/6 mg
Generic	Sublingual tablet	16/4 mg	4/1 mg to 24/6 mg
Zubsolv®	Sublingual tablet	11.4/2.9 mg	2.8/0.7 mg to 17.1/4.2 mg

Maintenance therapy should not be subject to arbitrary time or dosage limits. For some, maintenance therapy may need to continue for years. Criteria such as stability, life skills, and recovery support should be used to establish when it is appropriate to taper or discontinue pharmacotherapy.



Buprenorphine Regulation

A 2013 SAMHSA national drug use survey found that 681,000 people reported use of and 517,000 people reported addiction to heroin in the prior year. In addition, 4.5 million people reported illicit use of and 1.9 million people reported dependence on or abuse of prescription analgesics.[19] CSA special registration requirements pertain to narcotic drugs approved by the FDA for use in maintenance or detoxification treatment of opioid addiction.[20] Methadone and buprenorphine are the only two narcotic drugs currently approved by the FDA for maintenance or detoxification of opioid addiction.[21] To improve access for patients seeking treatment of opioid use disorder, the Drug Addiction Treatment Act of 2000 (DATA 2000) allows qualifying physicians to get a waiver from the CSA to prescribe buprenorphine for opioid use disorder outside of a SAMHSA-certified OTP. Specifically, DATA 2000 waivers allow physicians to dispense or prescribe any CSA Scheduled III, IV, or V medication approved by the FDA for the treatment of opioid addiction via an office-based opioid treatment (OBOT) program; currently buprenorphine-containing products are the only ones covered by DATA 2000. DATA 2000-waived physicians may not dispense or prescribe Schedule II drugs, such as methadone, to treat addiction. Buprenorphine can also be administered or dispensed for the treatment of opioid use disorder by SAMHSA-certified OTPs.[22]

Drug Addiction Treatment Act Waiver Requirements

To qualify for the Drug Enforcement Administration (DEA) waiver, physicians must be licensed and agree to treat no more than 30 patients initially. However, the 30-patient maximum may be increased to 100 patients after 1 year, if requested by the physician and approved by the Center for Substance Abuse Treatment (CSAT).[23] In addition, to qualify for the waiver, a physician must meet one of the following criteria:

- American Board of Medical Specialties (ABMS) certification in addiction psychiatry;
- American Society of Addiction Medicine (ASAM) certification in addiction;
- American Osteopathic Association (AOA) certification in addiction medicine;

- Completion of 8 hours of addiction training provided by the ASAM, the American Academy of Addiction Psychiatry (AAAP), the American Medical Association, the American Osteopathic Academy of Addiction Medicine (AOAAM), the American Psychiatric Association (APA), or other approved organization;
- Investigator status, which leads to the approval of a CSA Scheduled III, IV, or V drug for the treatment of opioid addiction maintenance or detoxification; or
- Other training deemed by the State medical licensing authority or by the Secretary of Health and Human Services to demonstrate ability to manage opioid addiction maintenance or detoxification treatment.[24]

The Providers' Clinical Support System for Medication Assisted Treatment (PCSS-MAT) is an addiction training and mentoring program that offers waiver eligibility training in collaboration with the AAAP, AOAAM, and APA. For physicians who seek DATA 2000 waivers, SAMHSA's PCSS-MAT program provides a portion of the required training online at http://pcssmat.org/education-training/waiver-eligibility-training/ on the program's website.[25] Also, PCSS-MAT offers additional review training and support for providers who provide medical treatment for patients who are opioid dependent.

DATA 2000-waived physicians must adhere to all waiver requirements and are subject to unannounced DEA inspections to verify compliance.[26] Careful recordkeeping, including the number of patients participating in the treatment program, is vital to passing an audit. For further information, review "How to Prepare for a Visit from the Drug Enforcement Administration (DEA) Regarding Buprenorphine Prescribing," available at http://pcssmat.org/wp-content/uploads/2014/02/FINAL-How-to-Prepare-for-a-DEA-Inspection.pdf on the Internet.[27]

Doctors of Medicine (DMs) or Doctors of Osteopathic Medicine (DOMs) interested in obtaining a DATA 2000 waiver must first contact SAMHSA through the CSAT. Contact SAMHSA by phone or on the Internet:

SAMHSA Buprenorphine Waiver Management:

Phone: 1-877-SAMHSA-7 (1-877-726-4727)

TTY: 1-800-487-4889

Website: http://www.samhsa.gov/medication-assisted-treatment/buprenorphine-waiver-management

CSAT's Division of Pharmacologic Therapies maintains a website devoted to buprenorphine pharmacotherapy at http://www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine on the Internet.

Applicants can access the online version of the DATA 2000 Waiver Notification Form SMA-167 at http://www.samhsa.gov/medication-assisted-treatment/buprenorphine-waiver-management/apply-for-physician-waiver on the Internet.

Addiction Treatment and Patient Confidentiality

Federal regulations regarding privacy of patients being treated for substance abuse require a higher degree of discretion than what is required of physicians and pharmacists under the security and privacy provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Title 42—The Public Health and Welfare law and the associated regulations (Title 42, Part 2 of the Code of Federal Regulations[CFR]) prohibit health care providers from revealing any identifying information of a patient being treated for substance abuse addiction, except in very specific circumstances. A pharmacist filling a buprenorphine prescription may not even disclose the patient's name when talking directly to the physician to verify the physician's DATA 2000 waiver.[28] Disclosure of specific patient identifying characteristics may be made only to qualified medical personnel in an emergency or if authorized by a court order.[29]

Filling Buprenorphine Prescriptions

When a patient presents a buprenorphine prescription to be filled, pharmacists should verify that the prescribing physician is appropriately registered with the DEA and that the physician has received a DATA 2000 waiver to prescribe buprenorphine. Keep in mind that mid-level practitioners, such as APNs or PAs, cannot obtain a DATA 2000 waiver to prescribe buprenorphine for the treatment of opioid use disorder. If a physician has obtained the DATA 2000 waiver, the physician will be assigned an additional DEA registration number (DEA number) that begins with the letter X. Physicians prescribing buprenorphine products are required to include the special X DEA number that identifies the physician as a DATA 2000-waived physician on the face of any written prescription in addition to his or her regular DEA number. The physician or representative should provide these registration numbers verbally if the buprenorphine prescription is phoned in to a pharmacy.[30] All other aspects of the DEA number remain the same.

DEA numbers consist of two letters and seven numbers. Pharmacists can perform a simple calculation to determine if both DEA numbers presented meet construction composition standards.[31] To perform this check, add the first, third, and fifth digits; then add double the sum of the second, fourth, and sixth digits. Combine the two calculated numbers. If the last digit of this sum is identical to the seventh digit of the DEA number, the number conforms to the composition model.

For example, Dr. Zahara's DEA number is AZ1234567. The sum of the first (1), third (3), and fifth (5) digits is 9. The sum of the second (2), fourth (4), and sixth (6) digits is 12; 12 multiplied by 2 equals 24. When added together, 9 plus 24 equals 33. If this were a valid DEA number, the last digit of this calculated value (3) would be identical to the last digit of the DEA number (7).

In contrast, Dr. Abraham's DEA number is BA1424326. The sum of the first (1), third (2), and fifth (3) digits is 6. The sum of the second (4), fourth (4), and sixth (2) digits is 10; 10 multiplied by 2 equals 20. When added together, 6 plus 20 equals 26. The last digit of this calculated value (6) is identical to the seventh digit of the DEA number, so this DEA number meets construction composition standards. Pharmacists can also validate DEA numbers online at https://www.deadiversion.usdoj.gov/webforms/validateLogin.jsp on the DEA Office of Diversion Control (ODC) website.[32] The pharmacist must log on with their DEA number to search the database.

Verification of DATA 2000-Waived Physician Status

Pharmacists can verify the DATA 2000-waived status of a physician using four different methods:

1. Visit the SAMHSA's Physician and Treatment Program Locator at http://www.samhsa.gov/medication-assisted-treatment/physician-program-data/treatment-physician-locator on the SAMHSA website to verify the DEA number of a physician who has agreed to be listed on the site. Not every physician with a valid waiver elects to be listed on the SAMHSA Locator;
2. Call SAMHSA at 866-BUP-CSAT (866-287-2728);
3. Email SAMHSA at info@buprenorphine.samhsa.gov; or
4. Request a faxed copy of the physician's DATA 2000 waiver.[33]

Patient Informed Consent

Physicians

Because patients have started the withdrawal phase when buprenorphine treatment is initially sought, it is important to review informed consent after the patient is stabilized on buprenorphine therapy. Valid informed consent should:

- Explain confidentiality in relation to 42 CFR § 2 and HIPAA regulations;
- Describe common adverse reactions: headache, nausea/vomiting, excessive sweating, constipation, dry or painful mouth, and insomnia;
- Describe possible drug interactions: benzodiazepines and other central nervous system depressants, as well as tramadol and other opiate agonists;
- Provide background information about addictive disorders;
- Explain the benefit of treatment, the stages of treatment, and the expected outcome;
- Talk about diversion—explain toxicology testing, refill policies, and use of State Prescription Drug Monitoring Programs;
- Advise patients to safeguard their medication at all times;
- Be clear about compliance expectations and discharge from care for noncompliance; and
- Provide referrals for therapy, community resources, counseling, and support services.[34, 35, 36, 37, 38]

Pharmacists

After the pharmacist has verified the DATA 2000-waived status of the prescribing physician and has prepared the prescription for pickup, the last step in the process is to provide appropriate counseling to the patient. Pharmacist-provided medication counseling should reinforce topics discussed with the physician and should:

- Advise the patient of the prescribed once-daily dosing regimen, including dosing during induction and switching to a buprenorphine/naloxone combination product, if applicable;
- Instruct the patient to keep all buprenorphine-containing products away from children and advise the patient to seek immediate medical intervention if ingestion by a child is suspected;
- Inform the patient of the risk of breathing difficulties, especially when combined with benzodiazepines or alcohol and advise the patient to seek immediate medical intervention if breathing becomes shallow, slowed, or labored;
- Inform the patient that if injected, naloxone-containing products may cause immediate withdrawal symptoms including pain, vomiting, diarrhea, and dysphoria;
- Remind the patient that films should not be chewed, cut, or swallowed;
- Advise the patient not to stop taking the buprenorphine product without consulting a physician because a gradual reduction in dose may be required;
- Remind the patient to take special precautions to protect the buprenorphine product from theft or loss; and
- Advise the patient that selling or giving away prescription medications is against the law.[39, 40, 41, 42, 43]

Some patients may require referral for specialty addiction management. Through establishment of long-term patient relationships that promote continuity of care and enable meaningful patient–physician communication, OBOT physicians can provide considerable and effective addiction treatment services. Given proper coordination and collaboration between pharmacists and DATA 2000-waivered physicians, patients can derive the full benefit of medication-assisted treatment in the privacy and convenience of their physician's office, allowing them to recover from opioid use disorder while the community is protected from diversion of medications leading to abuse and misuse.

To see the electronic version of this booklet and the other products included in the "Drug Diversion" Toolkit, visit the Medicaid Program Integrity Education page at https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/edmic-landing.html on the CMS website.

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