

# Guidelines for Medication for Addiction Treatment for Opioid Use Disorder within the Emergency Department

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**January 2019**



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## Introduction

The Massachusetts Health and Hospital Association (MHA) worked in collaboration with the Massachusetts College of Emergency Physicians (MACEP) and through a member workgroup composed of practitioners from member hospitals, including specialists in emergency medicine, addiction medicine, behavioral health, and nursing, to develop guidelines to assist with a specific provision within Chapter 208 of the Acts of 2018. (Please see Appendix VI for a full list of MHA’s MAT for OUD Workgroup members.) Chapter 208 requires acute care hospitals that provide emergency services within an emergency department and satellite emergency facilities to have the capacity to initiate opioid agonist therapy to patients that present after an opioid-related overdose. The patient must also be directly connected to continuing treatment prior to discharge.

The goal of these materials is to provide hospitals with clinical and operational recommendations for developing policies and procedures for administering and/or prescribing medication for addiction treatment (MAT) in hospital emergency departments or satellite emergency facilities. The three medications approved by the federal Food and Drug Administration (FDA) to treat opioid use disorder (OUD) are buprenorphine, methadone, and naltrexone. These guidelines focus primarily on buprenorphine, which has the most well-developed evidence base for feasibility and efficacy in the emergency department setting. Specifically, these guidelines contain considerations for prescribing buprenorphine in the emergency department setting for the treatment of OUD, which requires practitioners to obtain a federal waiver. The federal regulations also authorize emergency practitioners to administer buprenorphine for the treatment of opioid withdrawal for up to three days while referral for treatment is being arranged without a federal waiver. In certain clinical situations, practitioners may also consider the development of policies and clinical practices to administer methadone or naltrexone as appropriate alternatives.

Please note that these guidelines provide general recommendations for the development of an MAT program within a hospital. Due to a variety of factors, including different patient populations, varying operational and clinical practices, availability of various staffing and laboratory services, and availability of resources, hospitals should consider which relevant recommendations can be adopted as part of its overall policies and procedures. This document was developed using best practices from several hospitals within Massachusetts as well as other states that have or are considering the adoption of MAT.

In addition to the clinical and operational recommendation section, we also encourage providers to review the “MAT Practitioner Prescribing Guidelines” section. This section assists hospitals with understanding the requirements for obtaining an X-waiver needed to prescribe buprenorphine as well as applicable state laws and regulations allowing facilities to discharge patients with a take-home kit of buprenorphine.

Should you have any questions about the guidelines, please do not hesitate to contact Leigh Simons Youmans, MHA’s Director of Behavioral Health & Healthcare Policy, at [lyoumans@mhalink.org](mailto:lyoumans@mhalink.org).

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## Clinical and Operational Guidelines

### Key Operational Criteria

- Emergency departments (EDs) and satellite emergency facilities (SEFs) must have institutional protocols and capacity to possess, dispense, administer, and prescribe opioid agonist treatment (i.e., buprenorphine and/or methadone), including partial agonist treatment (buprenorphine), and offer such treatment to patients who present in an acute-care hospital ED or SEF for care and treatment of an opioid-related overdose.
- Hospitals should coordinate with appropriate practitioners within the facility to obtain a Drug Enforcement Agency (DEA) Category X waiver to prescribe opioid partial agonist medications under schedules III-V (namely buprenorphine) for the treatment of opioid use disorder prior to a patient's discharge from the ED.
  - Practitioners (MD, DO, NP, PA) without a waiver can administer buprenorphine to treat opioid withdrawal for up to 72 hours while the patient is in the ED, but these practitioners cannot prescribe buprenorphine to patients upon discharge or transfer.
  - Certified Nurse Specialists, Certified Nurse Midwives, and Certified Registered Nurses Anesthetists were recently added as practitioner types able to prescribe MAT by the federal SUPPORT for Patients and Communities Act.
  - See the "MAT Practitioner Prescribing Guidelines" section, which provides greater detail on the rules and requirements for practitioners regarding category X-waivers.
  - Please note that if hospitals do not have x-waivered practitioners, they should consider a telemedicine option that would allow the treating site to coordinate with an x-waivered practitioner to provide a patient with a prescription upon discharge from the ED. Under current Massachusetts requirements, providers who are providing services through telemedicine should note that they will need to be fully credentialed at both locations under state licensure requirements. MHA is working with various groups to seek applicable coverage and payment for telemedicine, which is not currently available in Massachusetts. Facilities interested in using telemedicine to prescribe buprenorphine should reference the Board of Registration in Medicine policy requiring that any prescription made via telemedicine must be issued by a practitioner in the usual course of his professional practice, that there must be a physician-patient relationship for the purpose of maintaining the patient's well-being, and the physician must conform to certain minimum norms and standards for the care of patients, such as taking an adequate medical history and conducting an appropriate physical and/or mental status examination and recording the results. The policy is available here: <https://www.mass.gov/doc/policy-03-06-policy-on-internet-prescribing-december-17-2003/download>. Facilities should also reference this September 2018 guidance from the U.S. Department of Health and Human Services that stipulates that DEA-registered practitioners, which include DATA 2000-waivered practitioners, are exempt from the in-person medical evaluation requirement as a prerequisite to prescribing or otherwise dispensing controlled substances via the internet if the practitioner is engaged in the "practice of telemedicine" as defined under 21 U.S.C. § 802(54): <https://www.hhs.gov/opioids/sites/default/files/2018-09/hhs-telemedicine-hhs-statement-final-508compliant.pdf>

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- In the absence of x-waivered clinicians, facilities can also develop a next-day, treatment-on-demand relationship with a cooperating organization for the treatment. With this relationship, a practitioner can use the 72-hour exemption (see MAT Practitioner Prescribing section) to administer buprenorphine to a patient in acute opioid withdrawal in an emergency setting and arrange for the patient to see the cooperating organization the following day.
  - Hospitals should develop a process for continuity of care (e.g., through community resources, partnerships, or internal facility clinics) for referral of patients for MAT continuation following discharge from the ED.
    - External partners may include opioid treatment programs (OTPs), community health centers (CHCs), primary care providers and psychiatrists that prescribe MAT, and other community based behavioral health providers.
      - Note that as of the issuance of these guidelines, OTPs in Massachusetts are working toward the ability to administer buprenorphine and naltrexone, and will be able to do so in the near future. Hospitals should contact local OTPs to create formal linkages prior to implementing an MAT policy. See page 12 of these guidelines for more details.
      - See Appendix IV for a memo from the Association for Behavioral Healthcare (ABH) to its member MAT providers, particularly OTPs, encouraging them to reach out to the emergency departments in their catchment areas to proactively develop connections to continuing treatment.
      - Note that most CHCs will request information regarding the patient’s ACO enrollment; some CHCs may prefer that the patient enrolls as a primary care patient when accessing MAT services.
    - Hospitals should be aware that federal and state privacy requirements may preclude the ability to share certain clinical information without express patient consent; however, many community MAT providers have specific processes and consent forms that a hospital should use to ensure that the sharing of information meets federal and state requirements as well as the community based provider’s needs to provide care.
  - Coordinate with local pharmacies (preferably those that are open 24 hours a day/7 days a week) that are willing to accept short-term “bridge” prescriptions that a patient can fill as needed following the ED level services.
  - Hospitals should consider using Recovery Coaches (RC) and Recovery Support Navigators (RSN) as part of the overall ED or hospital clinical team to engage patients and assist them in navigating services.
    - Both Recovery Coach and Recovery Support Navigator services are a covered benefit for MassHealth Managed Care Organization and Primary Care Clinician Plan members if the RCs and RSNs are employed by a Licensed Behavioral Health Outpatient Clinic or Opioid Treatment Center. Similar benefits will be extended to MassHealth Fee for Service members in January 2019. Licensed Behavioral Health Outpatient Clinics and Opioid Treatment Centers providing these services are required to have affiliation agreements with various service settings, including EDs, and hospitals should consider partnering with Licensed Behavioral Health Providers and Opioid Treatment Centers to provide these services in their ED.

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## Criteria and Clinical Information to Obtain Prior to Induction of MAT

- Patient demographic information
- Demonstration of signs of opioid withdrawal (using clinician gestalt and Clinical Opiate Withdrawal Scale [COWS] or other score)
- Confirmed history of opioid use disorder
- Ability to follow up with outpatient services
- Example criteria from a MAT induction protocol:
  - The procedure applies to patients who have an opioid use disorder based on meeting at least three of the following criteria:
    - Craving;
    - Tolerance;
    - Withdrawal;
    - Using larger amounts or over longer period than intended;
    - Persistent desire or unsuccessful efforts to cut down/control use;
    - Great deal of time spent obtaining, using, recovering from use;
    - Recurrent use resulting in a failure to fulfill major role obligations;
    - Recurrent use in situations in which it is physically hazardous;
    - Continued use despite persistent or recurrent social or interpersonal problems caused or exacerbated by substance;
    - Continued use despite knowledge of having a persistent or recurrent physical or psychological problem caused or exacerbated by use;
    - Important activities given up because of use.

## Suggested Patient Assessment Options in ED

### After a Patient is Triageed:

- Medical screening exam performed
- Patient screened for a substance use disorder (SUD)
  - The practitioner, including MD/DO, NP, or PA, should interview the patient about his/her opioid use and examine him/her for signs/symptoms of withdrawal. If the patient is interested in assistance with his/her opioid use disorder and does not meet the exclusion criteria, the practitioner may consider initiating MAT.
  - Alternatively, once the patient is screened, they may consult a qualified practitioner who uses a SUD screening tool and will discuss with the patient the option for buprenorphine and ability to follow up with outpatient resources. If the practitioner

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believes the patient may be a candidate for buprenorphine induction, a consult may be placed for psychiatry (or other relevant MAT provider).

- Practitioners should use their clinical judgment in balancing the need for timely administration of buprenorphine to treat withdrawal with the need to conduct a thorough substance use disorder evaluation (SUDE). Patients in acute withdrawal may be extremely uncomfortable and find it difficult to engage in extended interviews or discussions about treatment options until their withdrawal is treated. These patients are also at high risk of leaving against medical advice to use opioids from another source if their withdrawal is not adequately treated.
- Practitioners should use an appropriate screening and diagnostic tool for conducting the SUDE in the ED. There are multiple tools that are available and practitioners may want to use a combination or modification of screening tools listed below that is tailored to the setting where the screen is being conducted:
  - NIDA -1
  - DAST-10
  - ASSIST
  - Short Inventory of Problems (SIP-AD)
  - RODS
  - TAPS
  - DSM-5 Opioid Use Disorder Checklist
- Screening tools for risk of opioid misuse prior to prescribing an opioid for pain:
  - ORT
  - SOAPP-R
- Screening for opioid misuse among people on chronic opioids for pain:
  - COMM
- Appropriately trained and licensed medical professional who may screen, in various settings as approved by the hospital's medical staff policies:
  - MD/DO (psychiatrist, emergency physician)
  - Psychologist
  - NP
  - PA
  - Licensed Psychiatric Clinical Nurse Specialist
  - Certified Addictions Registered Nurse
  - LICSW
  - LCSW

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- LMHC
  - LADC
  - Labs/urine test ordered if appropriate, including pregnancy test on females of childbearing age.
    - A lab/urine test should not be a prerequisite for initiating MAT. At the discretion of the practitioner, self-reporting of opioid misuse by the patient may be sufficient for a practitioner to decide it is appropriate to initiate MAT.
    - Practitioners should also note that not all facilities may have urine assays to detect fentanyl, and so a negative urine test may inappropriately rule out patients that have used fentanyl.
  - Practitioners may perform the COWS to assess for opioid withdrawal.
  - Check the Massachusetts Prescription Monitoring Program (PMP – which is also called the MassPAT) and medical records before dispensing or writing a prescription for buprenorphine.
    - Consider working with IT to develop an internal trigger or flag within the electronic medical record (EMR) to alert the treating practitioners if a patient has been referred to or connected with MAT in the past, including methadone.
    - Note that methadone dispensed from an OTP will not show up in the PMP.
    - Providers should also be aware that buprenorphine administered or dispensed as take home in the ED will also not show up in the PMP.
  - Work with the patient (and if available, the family, caregiver, and/or legal guardian) to develop a treatment plan or MAT option. Note in the medical record if the patient refuses to participate in a plan.

### Other Situations:

- Buprenorphine is recommended for the treatment of OUD in patients 16 and above and the American Academy of Pediatrics has recommended medication treatment for youth with OUD. For adolescents with a history of use of 6 months or more, consider offering a buprenorphine induction. For patients with a shorter history, consider admission to an Acute Residential Treatment program for supportive treatment of withdrawal and, once safe, if the patient and family are interested, naltrexone can be started as a maintenance medication.
  - Please note, that for adolescent populations, it is not advisable to offer home induction.
  - We recommend observed inductions for all adolescent patients. To maintain youth on the lowest effective dose, we recommend inductions that begin with 2-4 mg (depending on severity of withdrawal), that patients be reassessed every 45 minutes, and the dose be increased by 1-2 mg at a time until withdrawal symptoms

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are suppressed. A review of guidance on buprenorphine treatment for youth in the Journal of Addiction Medicine is available here:

[https://journals.lww.com/journaladdictionmedicine/Fulltext/2018/06000/Buprenorphine\\_Treatment\\_for\\_Adolescents\\_and\\_Young.2.aspx](https://journals.lww.com/journaladdictionmedicine/Fulltext/2018/06000/Buprenorphine_Treatment_for_Adolescents_and_Young.2.aspx)

- After the initial induction, youth should be reassessed every 3-5 days and the dose titrated to suppress cravings and minimize side effects. As such, facilitating care continuity is particularly critical for youth.
- For patients who are pregnant, obtain an obstetrical assessment and work with the obstetrical practitioner to develop a treatment plan.
  - For women of child-bearing age, the risks/benefits of treating withdrawal with an opioid agonist should be explained. A pregnancy test should be ordered, but at the clinical discretion of the provider, treatment of withdrawal should not be delayed for women who agree to treatment with MAT.
- For patients with chronic pain requiring opioid therapy, consider addiction medicine or psychiatry consult prior to induction.
  - Note that a remote consult for addiction and pain management, the Massachusetts Consultation Services for Treatment of Addiction and Pain (MCSTAP), is currently under development, as required by Sections 3 and 95 of Chapter 208.
- As you would for full opioid agonists, use caution when combining buprenorphine with other central nervous system depressants, especially benzodiazepines, as severe respiratory depression can occur.
- Patients with severe cirrhosis may not be able to metabolize buprenorphine well and are at increased risk of over-sedation. For these patients, initiate MAT at half the dose, or less, than you would otherwise administer or prescribe.
- Patients should not have been treated with naloxone in the last hour. If a patient has been treated with naloxone in the previous hour, practitioners should first treat the patient's withdrawal symptoms. Once withdrawal is managed, practitioners should continue with the framework with these guidelines, including engaging the patient in overdose prevention and treatment.
- Note that these guidelines are designed for initiation on buprenorphine. For some patients, particularly patients with previous history of methadone treatment, methadone may be appropriate for long-term chronic treatment. Methadone can be initiated upon cessation of buprenorphine treatment. In instances where methadone is a better treatment option for a patient, the practitioner should coordinate with an OTP in the community upon initiating treatment in the ED to arrange for a "direct admission" to the OTP and ensure that the patient can receive methadone at the OTP the next day.

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## Clinical Protocol if Patient Meets Criteria for MAT Induction:

### ED Induction for Active Withdrawal (Medication Administered in ED):

- Buprenorphine is initiated in ED by appropriate practitioner (MD/DO, NP, PA).
- Monitor patient for 1 hour.

### If Patient to Receive Take Home Kit:

- Practitioner with DEA Category X waiver will order buprenorphine/naloxone sublingual film 8mg-2mg outpatient kit. While current Massachusetts regulations allow facilities to fill prescriptions for emergency room patients and discharge patients in an amount not to exceed a 14-day supply (see “MAT Practitioner Prescribing Guidelines” section), best practice indicates that as short a course as possible be dispensed or prescribed. While the clinician has the discretion as to the appropriate amount, the MHA MAT Workgroup recommends 3 days or less of medication. If the take home kit is to be provided by a hospital pharmacy, see appropriate regulations that hospitals must follow in Appendix II. If the pharmacy is not available when the patient is being discharged, or if the hospital prefers, the take home kit can be provided in the ED following the requirements detailed in Appendix III.
- If Kit is Provided in ED:
  - Kit containing adequate doses to reach a follow-up appointment will be provided onsite rather than by prescription.
  - Kit must conform with the requirements in Appendix II or III.
  - Please note that the ED, depending on patient volume, may want to work with the hospital pharmacy to meet the individual practitioner requirements by having pre-packaged kits available for an ED practitioner that only require the practitioner to write in the patient name, practitioner name, and date.
- If Kit is to be Obtained in Pharmacy:
  - Indicate on the prescription that the pharmacy can substitute the tablet formulation and a pill cutter if the patient’s insurance does not cover the film.
  - Indicate on the prescription the prescriber’s DEA X-waiver number.
- An example of discharge instructions could include:
  - **Day 1:** After experiencing withdrawal signs and symptoms, patient to take ½ of film or 4mg of buprenorphine tablet.
    - Followed by ½ of film or 4mg of buprenorphine tablet every 6 hours as needed for withdrawal symptoms.
    - Do not exceed 16mg (two full films if in film form) in first 24 hours.
  - **Day 2:** Dosage that was required on day 1 to prevent withdrawal symptoms would be dose for second day or up to 16mg.
  - Alternative dosing instructions are available here: <https://ed-bridge.org/guide>.

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## Discharge

- Ensure patient is stable and educated on MAT.
  - Address that recovery encompasses other biopsychosocial factors and make appropriate referrals, including psychiatry, social work, support groups, social determinants of health, etc.
- Coordinate continuity of care.
  - Determine appropriate provider:
    - Health system internal provider: Waivered primary care provider, clinic, psychiatrist, etc.
    - External provider: External partners may include opioid treatment programs (OTPs), community health centers, primary care providers and psychiatrists that prescribe MAT, and other community-based behavioral health providers.
      - Please note that as of the issuance of these guidelines, OTPs in Massachusetts are working toward the ability to administer buprenorphine and naltrexone, and will be able to do so in the near future. Hospitals should contact local OTPs to create formal linkages prior to implementing an MAT policy.
      - Please note that most CHCs will request information regarding the patient's ACO enrollment; some CHCs may prefer that the patient enrolls as a primary care patient when accessing MAT services.
      - The Massachusetts Substance Use Helpline has a provider-directed site to search for MAT services:  
[https://mahelplineonline.custhelp.com/app/account/opa\\_result](https://mahelplineonline.custhelp.com/app/account/opa_result)  
and is available at: 800-327-5050
      - Additionally, SAMHSA maintains a database of individual providers that are able to provide buprenorphine here:  
[https://www.samhsa.gov/medication-assisted-treatment/physician-program-data/treatment-physician-locator?field\\_bup\\_physician\\_us\\_state\\_value=MA](https://www.samhsa.gov/medication-assisted-treatment/physician-program-data/treatment-physician-locator?field_bup_physician_us_state_value=MA)
  - Obtain required consent and facilitate external referrals. Hospitals should be aware that federal and state privacy requirements may preclude the ability to share certain clinical information without express patient consent; however, many community MAT providers do have specific processes and consent forms that a hospital should use to ensure that the sharing of information meets federal and state requirements as well as the community based provider's needs to provide care. In developing care coordination with external parties, hospitals should work with the external provider to obtain their consent form and processes used for that provider, including what type of clinical information will be needed for follow up care in the consent document and the specific clinical information (e.g., a continuum of care

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agreement) that should be shared post-discharge from the ED. Please see Appendix V for the standardized form used when a patient is admitted directly from detox to an OTP for an example of the type of information that is needed by continuing providers.

- Hospitals should aim to connect patients with an appointment for the next day, either using an internal provider or through relationships with external providers.
  - If an appointment cannot be confirmed for the next day, hospitals should consider:
    - Providing patients with a take home kit with sufficient medication to bridge until the appointment. (Please note that the practitioner should determine the appropriate dosage given the number of days until the appointment following the ED discharge.);
    - Instructing the patient to return to the ED to either be administered additional MAT, receive an additional prescription, or be provided a take home kit to bridge until the appointment. (Note that if administration is needed to occur for longer than 72 hours, or if the additional prescription or take home process is used, the practitioner would require an X-waiver.); or
    - Other alternative arrangements.
- Release to community provider.
  - Hospitals should coordinate with the providers with whom they have developed a continuity of care relationship (clinic, community-based providers, others) to develop a common set of clinical and other demographic information that are included as part of the discharge paperwork. These items may include: clinical treatment, medication information, prescription information, applicable lab tests, contact information for the patient should they not attend the next scheduled appointment, any available information on whether the patient has been connected with MAT in the past, including methadone, and information for family or caregivers, if applicable.
- Confirm patient is able and willing to follow up at pre-designated outpatient clinic, and provide appropriate referral. Hospitals should consider as part of the referral that an appointment is made prior to the patient being discharged.
- Give patient necessary documents.
  - Work with the community provider to use the standard release of information that is used in their practices to share discharge documentation with the appropriate continuing care provider, if possible.
  - Discharge paperwork should include community follow-up instructions, in-home induction fact sheet (if applicable), clinic information, etc. Please see Appendix I for two sample patient fact sheets.

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- If a facility has an internal clinic that is open and able to take the patient when they are discharged from the ED, walk the patient to the clinic.
  - Connect the patient with available family supports as well as Recovery Coaches (RCs) or Recovery Support Navigators (RSNs), if appropriate and available.
    - Both Recovery Coach and Recovery Support Navigator services are a covered benefit for MassHealth Managed Care Organization and Primary Care Clinician Plan members if the RCs and RSNs are employed by a Licensed Behavioral Health Outpatient Clinic or Opioid Treatment Center. Similar benefits will be extended to MassHealth Fee for Service members in January 2019. Licensed Behavioral Health Outpatient Clinics and Opioid Treatment Centers providing these services are required to have affiliation agreements with various service settings, including EDs, and hospitals should consider partnering with Licensed Behavioral Health Providers and Opioid Treatment Centers to provide these services in their ED.
  - Provide the patient with a naloxone rescue kit.
  - If patient refuses MAT and/or connection to continuing treatment:
    - If a patient refuses MAT and is otherwise medically stable pursuant to the treating practitioner determination, the treating practitioner should continue the general discharge plan that includes existing care coordination policy/procedures of the ED and provide the patient with information on the availability and importance of MAT, including local and statewide treatment options, providers, and other relevant information as deemed appropriate.
    - Document patient's overdose and treatment recommendations within the patient's hospital record and notify patient's primary care physician (if known) about opioid overdose and recommendations.
    - Document in the medical record the patient's reasons for refusal of MAT.

### Coverage/Coding

- Please note that MHA is currently working with public and private payers to determine the appropriate coding and medical necessity documentation requirements to ensure coverage for these services within the ED, in an outpatient setting, and other appropriate levels of care. Bulletins from the Division of Insurance and MassHealth are forthcoming.

## MAT Practitioner Prescribing Guidelines

### Practitioner Prescribing Requirements and Exceptions

This section assists hospitals with understanding the requirements for obtaining an X-waiver needed to prescribe buprenorphine as well as laws and regulations allowing facilities to discharge patients with a take-home kit of buprenorphine.

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## MD/DO

### *Qualifications for an “X-Waiver”:*

A “qualifying physician” is specifically defined in the Drug Addiction Treatment Act of 2000 (DATA 2000) as one who is:

- Licensed under state law;
- Registered with the Drug Enforcement Administration (DEA) to dispense controlled substances;
- Limited to treat no more than 30 patients at a time within the first year; and
- Qualified by training and/or certification.

Please note that in order to maintain a waiver, a physician must be capable of referring patients to counseling and other services.

### *X-Waiver Training for MD/DO:*

- This involves at least eight hours of training through classroom situations, seminars at professional society meetings, electronic communications, or training otherwise provided by ASAM and other organizations.
- Once SAMHSA verifies that the background of a physician is correct and valid, DEA assigns the qualified physician a special identification number (the “x number”). DEA regulations require this identification number and the physician’s regular DEA registration number on all buprenorphine prescriptions for opioid dependence treatment. If approved, physicians receive a letter via email that confirms their waiver and includes their prescribing identification number. This can take up to 45 days.
- Under DATA 2000, individual physicians may have a maximum of 30 concurrent patients in opioid dependence treatment at a time for the first year. One year after the initial notification is submitted, the physician may submit a second notification of the need and intent to treat up to 100 concurrent patients. The physician must complete this [Online Notification Form to Increase Patient Limit](#) at least one year after initial waiver was approved. Physicians who have prescribed buprenorphine to 100 patients for at least one year can apply to increase their patient limits to 275 under new federal regulations. Practitioners must keep records and inventories of all controlled substances dispensed, including approved buprenorphine products.
- For more information pertaining to Documentation for DEA inspections please click here: <https://30qkon2g8eif8wrj03zeh041-wpengine.netdna-ssl.com/wp-content/uploads/2015/03/DEA-Inspection-References.pdf>

### *MAT Administration Exception:*

72-hour/3-day rule exception for practitioners who have not obtained an x-waiver:

- Federal regulations (21 CFR 1306.07(b)) allow a practitioner who is not separately registered as a narcotic treatment program or a “waivered DATA 2000 physician” to administer (but

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not prescribe) narcotic drugs to a patient for the purpose of relieving acute withdrawal symptoms while arranging for the patient’s referral for treatment.

- The intent of this exception is to provide practitioners flexibility in emergency situations where s/he may be confronted with a patient undergoing withdrawal. In such emergencies, it is impractical to require practitioners to obtain a separate registration.
- In order to use the “Three Day Rule,” the following conditions must be met:
  - The practitioner cannot administer more than one day’s medication at one time;
  - The practitioner must also limit the administration of the treatment to a three-day (72-hour) period, provided that they are continuously being treated during that three-day period; and
  - The practitioner is precluded from renewing or extending the three-day (72-hour) period once the treatment begins.

### **NP/PA**

The Comprehensive Addiction and Recovery Act of 2016 extended the privilege of prescribing buprenorphine in office-based settings to qualifying nurse practitioners (NPs) and physician assistants (PAs) until Oct. 1, 2021. The sunseting of NP and PA ability to prescribe buprenorphine was lifted by the SUPPORT for Patients and Communities Act of 2018 so that PAs and NPs are now allowed to prescribe buprenorphine in perpetuity.

### **NP/PA Training**

- NPs and PAs are required to obtain no fewer than 24 hours of initial training addressing each of the eight topics outlined in 21 USC 823(g)(2)(G)(ii)(IV):
  - **Opioid** maintenance and detoxification;
  - Appropriate clinical use of all **drugs** approved by the Food and **Drug** Administration for the treatment of **opioid** use disorder;
  - Initial and periodic patient assessments (including substance use monitoring);
  - Individualized treatment planning, overdose reversal, and relapse prevention;
  - Counseling and recovery support services;
  - Staffing roles and considerations;
  - Diversion **control**; and
  - Other best practices, as identified by the **Secretary**.
- The NP/PA training is currently offered by the following groups: the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, and the American Psychiatric Association.
- Please note that alternatively, NPs and PAs may take the eight-hour DATA-waiver course for treatment of opioid use disorder that physicians currently take, as well as the additional 16 hours course offered for free by SAMHSA through the **Providers Clinical Support System**.

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- NPs and PAs who have completed the 24 hours of required training may seek to obtain a DATA 2000 waiver for up to 30 patients by completing the [Waiver Notification Form](#).
  - Waiver applications are forwarded to the Drug Enforcement Administration (DEA), which will assign the NP or PA a special identification number. DEA regulations require this number to be included on all buprenorphine prescriptions for opioid dependency treatment, along with the NP's or PA's regular DEA registration number.
  - SAMHSA shall review waiver applications within 45 days of receipt. If approved, NPs and PAs will receive a letter via email that confirms their waiver and includes their prescribing identification number.

***MAT Administration Exception (similar to physician exception and dependent on hospital medical staff policies and bylaws):***

72-hour/3-day rule exception for practitioners who have not obtained an x-waiver:

- Federal regulations (21 CFR 1306.07(b)) allow a practitioner who is not separately registered as a narcotic treatment program to administer (but not prescribe) narcotic drugs to a patient for the purpose of relieving acute withdrawal symptoms while arranging for the patient's referral for treatment.
- The intent of this exception is to provide practitioners flexibility in emergency situations where s/he may be confronted with a patient undergoing withdrawal. In such emergencies, it is impractical to require practitioners to obtain a separate registration.
- In order to use the "Three Day Rule," the following conditions must be met:
  - The practitioner cannot administer more than one day's medication at one time;
  - The practitioner must also limit the administration of the treatment to a three-day (72-hour) period, provided that the patient is continuously being treated during that three-day period; and
  - The practitioner is precluded from renewing or extending the three-day (72-hour) period once the treatment begins.

**MAT Waiver Trainings**

Hospitals are strongly encouraged to work with appropriate practitioners to obtain an X-Waiver. There are a number of additional options available for practitioners seeking the x-waiver training, including those listed below. Please note that there are pediatric-specific x-waiver training courses available through these resources.

1. BMC OBOT

About: <https://www.bmcobat.org/>

How to register: <https://www.bmcobat.org/training/register/>

2. Providers' Clinical Support System

About & Registration Link: <https://pcssnow.org/education-training/mat-training/>

3. ASAM

About & Registration Link:

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<https://www.asam.org/education/live-online-cme/waiver-training>

4. SAMHSA

Online Resources for Trainings: <https://www.samhsa.gov/medication-assisted-treatment/training-resources/buprenorphine-physician-training>

5. Visual Steps for Physicians and NPs/PAs on how to obtain your X-waiver

<https://indd.adobe.com/view/bc7271a7-b477-45ca-87e8-5bef726a9446>  
<https://indd.adobe.com/view/c9a9fe5b-18c1-4bbb-af84-4ef052124c98>

This information was obtained from the federal Substance Abuse and Mental Health Services Agency and is subject to change. We encourage practitioners to check the SAMHSA website for updates to any of the information provided above (<https://www.samhsa.gov/medication-assisted-treatment/training-resources/buprenorphine-physician-training>).

## Laws and Regulations Governing Take Home Buprenorphine

If a hospital intends to discharge a patient with take-home buprenorphine in order to bridge the patient to the patient's appointment with continuing treatment, please note that the take-home buprenorphine must conform to the following federal and state laws and regulations. While current Massachusetts regulations allow facilities to fill prescriptions for emergency room patients and discharge patients in an amount not to exceed a 14-day supply, best practice indicates that as short a course of buprenorphine as possible be dispensed or prescribed – ideally 3 days or less of medication. If the take home kit is to be provided by a hospital pharmacy, see appropriate regulations that hospitals must follow in Appendix II. If the pharmacy is not available or if the hospital prefers, the take home kit can be provided in the ED and must meet the requirements detailed in Appendix III. A summary of these requirements is available immediately below, but full information is included in the referenced Appendices.

*Information obtained from: (1) the Massachusetts Board of Registration in Medicine (BORIM) Prescribing Practices and Policy Guidelines (Policy 15-05) and (2) DPH regulations.*

### Specific Massachusetts Regulatory Allowances for Hospital Pharmacies Filling Prescriptions for ED Patients:

DPH's regulation governing *Dispensing Procedures for Clinic and Hospital Pharmacies*, 105 CMR 722.000, allows hospital pharmacies and their satellites or branches to fill prescriptions for emergency room patients and discharge patients in an amount not to exceed a 14-day supply of the prescribed medication.

Additionally, requirements include that:

1. Prescriptions for emergency room patients and discharge patients may not be refilled by the hospital pharmacy.

- 
2. Drug products which are only available from the manufacturer in greater than 14-day supplies may be dispensed in larger quantities for emergency room and discharge patients. The quantity dispensed, however, may not exceed the smallest quantity supplied by the manufacturer.

In the case of drugs which are not available in a retail pharmacy, a hospital pharmacist may fill prescriptions for emergency room patients and discharge patients in the amount prescribed by the practitioner. Please note that DPH may establish a list of those drugs which may be obtained from a hospital pharmacy.

Please see Appendix II for applicable regulations.

### **Limitations on Opioid Prescriptions**

Chapter 94C § 19D of the Massachusetts General Laws limits new adult outpatient opiate prescriptions to a 7-day supply, but there is a specific exception for medications designed for the treatment of substance abuse or opioid dependence, so this limitation would not apply for MAT.

Please see Appendix II for applicable regulations.

### ***Registered Individual Practitioner Dispensing Requirements***

In the event that a hospital pharmacy is not available – and is therefore unable to fill prescriptions for buprenorphine – or if the hospital prefers, federal and state law allows registered individual practitioners to dispense in limited circumstances. Please note that the hospital may want to work with its pharmacy and have prepackaged take home kits available to the practitioner that only require the patient name, practitioner name, and date to be written in at bedside.

Please see Appendix III for applicable regulations.

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## General Q & A Developed by the MHA MAT for OUD in EDs Workgroup:

- How should we describe or outline the process for treatment of opioid use disorder in conjunction with buprenorphine?
  - According to SAMHSA’s TIP 63: “Patients treated with medications for OUD can benefit from individualized psychosocial supports. These can be offered by patients’ healthcare providers in the form of medication management and supportive counseling and/or by other providers offering adjunctive addiction counseling, recovery coaching, mental health services, and other services that may be needed by particular patients.” The data on buprenorphine does indicate that “medical management” is sufficient, and that the absence of counseling support should not stop us from prescribing buprenorphine. Medical management simply means that a non-specialist can provide basic medical treatment, such as primary care doctor or even a nurse. While buprenorphine is not a magic pill, we don’t need to provide highly specialized treatment.
- How should we discuss the use of support staff in the ED – such as an interdisciplinary team comprised of (but not limited to) Recovery Coaches, nurse care managers, or social workers – to take the burden off of ED physicians regarding identification, screening, evaluation for services?
  - Hospitals should discuss within the medical staff the ability to use additional staff, including Recovery Coaches and Recovery Support Navigators, as part of the ED team that provides services and/or care coordination for the patient. This should be based on applicable licensure, scope of practice, hospital policies and by-laws, and available staff in various regions of the state. Hospitals should also consider coordinating with local provider groups that provide these services under contract to the hospital.
- Do the guidelines include those who won’t be in withdrawal because they’ve had a period of abstinence recently?
  - If someone is not in withdrawal because of a period of abstinence, it is important to confirm history of OUD. The practitioner could initiate buprenorphine for risk of relapse even if not actively using. (An example might be patients recently incarcerated or in an abstinence-based program.)
- If the patient returns frequently for continued MAT, is the patient eligible?
  - Yes, provided that the hospital should consult with the medical staff and others to determine the applicable policy that would be used in the hospital to determine when a patient will be eligible for continued MAT within the ED.
- What findings from the PMP report would disqualify a patient from receiving treatment—any opioid prescription, undisclosed benzodiazepines, remote prescription for buprenorphine?
  - These PMP findings would not necessarily be exclusionary. The most concerning would be multiple recent prescription opioids, benzodiazepines as well as

- 
- buprenorphine that seem suspicious. Even in that case, the need for treatment may still be legitimate. Providing 1-2 days' worth of medications seems quite reasonable.
- If the patient is currently prescribed buprenorphine, it would be important to try to reach out to that prescriber to connect the person back to care rather than connecting to a new community-based MAT program or bridge clinic unless the patient prefers otherwise.
  - What findings from the urine screen disqualify patients with multiple substance use disorders? Will recreational THC or alcohol disqualify from buprenorphine treatment? What about cocaine/amphetamines?
    - None of these are exclusions. Someone who has a severe active alcohol use disorder would need more treatment and caution given risk of sedation with alcohol and buprenorphine. That would be a case to consider involving addiction medicine/psychiatry. Research shows buprenorphine treatment works even if the patient uses cocaine, smokes marijuana, has depression, has chronic pain, etc.
  - Some hospitals do not have the resources to discharge with a buprenorphine kit, what are options for such facilities?
    - Give a prescription for the patient to fill at a pharmacy with a way for the pharmacy to call if there is a prior authorization (PA) issue. Following Massachusetts regulatory allowances, the MHA Workgroup suggests a very short dose (up to 48 or 72 hours) to help the patient get to next appointment.
    - MHA is working to determine existing resources where hospitals can develop linkages between the EDs and clinics, community health centers, opioid treatment programs, and other community-based providers that are able to see patients urgently, either as a temporary placement or for long-term treatment.
    - Hospitals should also consider the use of Recovery Coaches and Recovery Support Navigators to engage patients and assist with care coordination to same day appointments with local community providers.
  - Doctors may feel uncomfortable giving 16mg of buprenorphine as take home (or more depending on the amount of days provided in the take home kit) due to threat of poisoning if children get hold of it.
    - This is an important fear but we discharge patients home with lots of medications that would pose a safety risk if a child ingested them. While this is understandable in light of a recent study/publicity, in fact buprenorphine is usually dispensed in childproof envelopes, and it is no more risky to children than the more common practice of dispensing 20 mg of oxycodone, for example. The risk is greater to children at home if the parent continues to use heroin/fentanyl than if s/he is discharged with buprenorphine.
    - The education when buprenorphine is initiated must include the risk of fatal overdose if taken by anyone other than the patient, with an emphasis on keeping this medication out of the reach of children and the legal consequences of diversion. Instructions about proper storage are also critical, and the film is therefore preferred because it is harder for small kids to accidentally ingest.

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- There is a cost issue if take home kits are given to patients with no compensation/reimbursement policies.
    - Hospitals should discuss their MAT policy with appropriate staff (finance, managed care, case management, and others) to determine the best approach for ensuring internal coverage on the cost of providing take home kits. While MHA is working with public and private payers to clarify the coding and coverage requirements, as there is currently no applicable payment mechanism for these services, hospitals should ensure a process to provide internal coverage for these services as part of the overall ED service.

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## **Appendix I – Patient Resources**

The MHA MAT Workgroup encourages providers to consider the use of a patient fact sheet to give to patients upon discharge explaining how to begin buprenorphine treatment at home. The first fact sheet was developed by two Massachusetts hospitals, Massachusetts General Hospital and Brigham and Women’s Hospital, which your hospital is free to tailor to your specific hospital process, including directions on how to navigate continuing treatment, contact information, and general appointment details. The second fact sheet is based on a National Institute on Drug Abuse (NIDA) document.

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## Buprenorphine Resources for Patients

### *Your Guide to Safely Taking buprenorphine at Home*

#### **1. Your brain prefers buprenorphine to any other opioid (like heroin or oxycodone).**

**What does this mean?** You must wait until you feel like you are withdrawing to start the medication - which typically happens 12 hours after taking heroin/fentanyl or prescription pills or 36-72 hours after taking methadone. The reason why you must wait is because if you take buprenorphine after recent use of an opioid you will go into withdrawal within 30 minutes of taking the medication. The worse you feel when you begin the medication, the better it will make you feel after you take it. There are medications that contain both buprenorphine and naloxone, including the brand name Suboxone. The naloxone in Suboxone and similar medications is inactive if taken as directed but if the Suboxone is smoked, snorted, or injected, the naloxone is activated and will cause instant and intense withdrawal.

#### **2. Buprenorphine is taken as a film or tablet placed under the tongue.**

**What does this mean?** It only works and is effective if you allow it to sit UNDER your tongue until it FULLY dissolves. If you swallow, chew, or take with water, it will not work at all (the medication will not help you). You should avoid drinking, eating, or smoking 15 minutes before and after the dose and until it dissolves. \*NOTE: You can take a sip of water to moisten your mouth before you take your dose.

### **Buprenorphine Beginning Treatment**

#### **Day 1**

Before taking a buprenorphine dose you want to feel lousy from your withdrawal symptoms. It should be at least 12 hours since you used heroin or pain pills (OxyContin, Vicodin, etc.) and at least 24 hours since you used methadone. The worse you feel when you begin the medication the better it will make you feel and the more satisfied you will be with the experience.

#### **Symptoms**

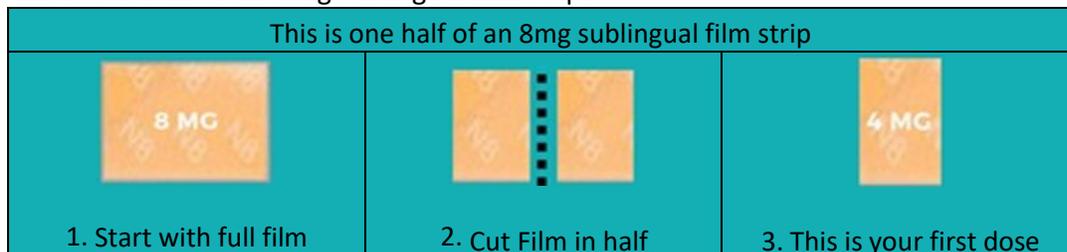
You should have at least 3 of the following feelings:

- Twitching, tremors, shaking
- Joint and bone aches
- Bad chills or sweating
- Anxious or irritable
- Goose pimples
- Restlessness
- Heavy yawning
- Enlarged pupils
- Stomach cramps, nausea, vomiting or diarrhea

#### **Administration of 1<sup>st</sup> Dose**

4 MG of buprenorphine in film or tablet form.

This is one half of an 8 mg sublingual film strip.



## Administration: Hour 1

 <p><b>1. Place the strip or tablet under your tongue</b> Put the 4mg strip or tablet under your tongue and do not swallow it.</p>	 <p><b>2. Keep it there for 15 minutes</b> The medicine is absorbed through the skin at the bottom of your tongue and will work over the course of 15 minutes. Do not eat food, or drink liquids at this time.</p>	 <p><b>3. Check in at one hour</b> Feel better? Good, the medicine is working. Don't take any more.  Still feel lousy after one hour? Don't worry you will just need more medication. If you still have feelings of withdrawal, put the remaining 4mg strip or tablet under your tongue.</p>
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## Administration of 2<sup>nd</sup> Dose

Administration: Hours 6 - 12		
 <p><b>1) Check in at Hour 6</b> Later in the day (6-12 hours after the first dose), see how you feel again. If you feel fine, don't take any more. If you have withdrawal feelings, take another 4 mg dose under your tongue</p>	 <p><b>2) 12 MG limit and withdrawal</b> Do not take more than 12 mg on the first day. Most people feel better after 4-12 mg on their first day but if you still feel really bad, like you are having a bad withdrawal, return to the emergency department.</p>	<p><b>3) Create a plan for your clinic visit.</b> It is crucial that you follow up at the clinic to start your follow up care. Take a moment to answer these questions to create a plan:</p> <ol style="list-style-type: none"> <li>1. What time will you go to the clinic tomorrow</li> <li>2. What will you be doing immediately before this?</li> <li>3. How will you get to the clinic?</li> </ol>

## Day 2

The right dose depends on how you felt on day 1. Getting to the clinic on Day 2 is absolutely critical. On the morning before your appointment, it will be important to take another one time dose of buprenorphine. The dose you take is based on your experience on Day 1.

4 MG	8 MG		8 MG		8 MG + 4 MG	
If you took a 4 mg on Day 1 and felt fine this morning, take 4mg as your Day 2 dose.	If you took 8 mg on Day 1 and felt fine this morning, take 8 mg as your Day 2 dose.	OR	If you took 4 mg on Day 1 and woke up feeling withdrawal symptoms, take 8 mg as your Day 2 dose.	If you took 12 mg on Day 1 and felt fine this morning, take 12 mg as your Day 2 dose.	OR	If you took 8 mg on Day 1 and woke up feeling withdrawal symptoms, take 12 mg as your day 2 dose.

\*Note, based on clinical determination, the maximum amount for day 2 should not exceed 16mg.

# A Guide for Patients Beginning Buprenorphine Treatment at Home

Before you begin you want to feel very sick from your withdrawal symptoms

It should be at least . . .

- **12 hours** since you used heroin/fentanyl
- **12 hours** since snorted pain pills (Oxycontin)
- **16 hours** since you swallowed pain pills
- **48-72 hours** since you used methadone

You should feel at least three of these symptoms . . .

- Restlessness
- Heavy yawning
- Enlarged pupils
- Runny nose
- Body aches
- Tremors/twitching
- Chills or sweating
- Anxious or irritable
- Goose pimples
- Stomach cramps, nausea, vomiting or diarrhea

Once you are ready, follow these instructions to start the medication

## DAY 1:

**8-12mg of buprenorphine**

Most people feel better the first day after 8-12mg. (Dosing depends on how early on the first day you started)

### Step 1.

Take the first dose

Wait 45 minutes

4mg



- Put the tablet or strip under your tongue
- Keep it there until fully dissolved (about 15 min.)
- Do NOT eat or drink at this time
- Do NOT swallow the medicine

### Step 2.

Still feel sick?  
Take next dose

Wait 6 hours

4mg



Most people feel better after two doses = 8mg

### Step 3.

Still uncomfortable?  
Take last dose

Stop

4mg



- Stop after this dose
- Do not exceed 12mg on Day 1

## DAY 2:

**up to 16mg of buprenorphine**

### Take up to a 16mg dose

Most people feel better with up to a 16mg dose

16mg

Repeat this dose until your next follow-up appointment

If you develop worsening symptoms while starting buprenorphine before your scheduled outpatient appointment return to the emergency department

## Appendix II - Relevant Massachusetts Regulatory Allowances for Hospital Pharmacies Filling Prescriptions for ED Patients

### Dispensing procedures for clinic and hospital pharmacies (105 CMR 722.090)

#### Hospital Pharmacies

(A) Hospital pharmacies may fill medication orders for hospital inpatients, prescriptions for hospital outpatients and employees, and medication orders or prescriptions for inpatients of a hospital-based skilled nursing facility or a long-term care facility that is solely owned by a hospital that meets the Federal criteria for a sole community hospital contained at 42 CFR § 412.92 and is located on the hospital premises. Patients of such a hospital-based skilled nursing facility or long-term care facility shall be considered hospital patients for the purposes of receiving pharmacy services.

***(B) Notwithstanding the provisions of 105 CMR 722.090(A), hospital pharmacies and their satellites or branches may fill prescriptions for emergency room patients and discharge patients in an amount not to exceed a 14 day supply of the prescribed medication.***

***(1) Prescriptions for emergency room patients and discharge patients may not be refilled by the hospital pharmacy.***

***(2) Drug products which are only available from the manufacturer in greater than 14 day supplies may be dispensed in larger quantities for emergency room and discharge patients. The quantity dispensed, however, may not exceed the smallest quantity supplied by the manufacturer.***

(C) Notwithstanding 105 CMR 722.090(B), in the case of drugs which are not available in a retail pharmacy, a hospital pharmacist may fill prescriptions for emergency room patients and discharge patients in the amount prescribed by the practitioner. The Department may establish a list of those drugs which may be obtained from a hospital pharmacy under 105 CMR 722.090(B).

### Limitations on Opioid Prescriptions (M.G.L. Chapter 94C § 19D)

*Chapter 94C § 19D of the Massachusetts General Laws limits new adult outpatient opiate prescriptions to a 7-day supply, but there is a specific exception for medications designed for the treatment of substance abuse or opiate dependence, so this limitation would not apply for MAT.*

### Supply limitations for opiate prescriptions; exception for palliative care (M.G.L. Chapter 94C § 19D)

Section 19D. (a) When issuing a prescription for an opiate to an adult patient for outpatient use for the first time, a practitioner shall not issue a prescription for more than a 7-day supply. A practitioner shall not issue an opiate prescription to a minor for more than a 7-day supply at any time and shall discuss with the parent or guardian of the minor the risks associated with opiate use and the reasons why the prescription is necessary.

(b) Notwithstanding subsection (a), if, in the professional medical judgment of a practitioner, more than a 7-day supply of an opiate is required to treat the adult or minor patient's acute medical condition or is necessary for the treatment of chronic pain management, pain associated with a cancer diagnoses or for palliative care, then the practitioner may issue a prescription for the quantity needed to treat such acute medical condition, chronic pain, pain associated with a cancer diagnosis or pain experienced while the patient is in palliative care. The condition triggering the prescription of an opiate for more than a 7-day supply shall be documented in the patient's medical record and the practitioner shall indicate that a non-opiate alternative was not appropriate to address the medical condition.

**(c) Notwithstanding subsections (a) and subsection (b), this section shall not apply to medications designed for the treatment of substance abuse or opioid dependence.**

## **Appendix III - Relevant Massachusetts Regulatory Allowances for Registered Individual Practitioners Dispensing Medications**

In the event that a hospital pharmacy is unable to fill prescriptions for buprenorphine, or if the hospital prefers, federal and state law allow registered individual practitioners to dispense in limited circumstances. Registered individual practitioners would need to conform with the requirements detailed in this Appendix. Many of these requirements may already be met by existing hospital practices, which should be tailored to ensure operability when an individual practitioner is dispensing the buprenorphine take home kit. Hospitals should note this is a similar process to the one they may already have in place to provide starter packs of prophylactic medications for patients following treatment for a sexual assault.

### **General Requirements**

Federal law permits physicians to dispense Schedule II controlled substances without a prescription only in emergency situations. Under both federal and Massachusetts law, physicians and other practitioners, including physician assistants, nurse practitioners, psychiatric nurse mental health clinical specialists, and nurse anesthetists, may dispense controlled substances in Schedules III - V without a prescription, as long as the drug is being delivered or administered directly to the patient for legitimate medical purposes, but in Massachusetts, the practitioner must be dispensing the medication for immediate treatment, which is defined as “that quantity of a controlled substance which is necessary for the proper treatment of the patient until it is possible for him to have a prescription filled by a pharmacy.”<sup>1,2</sup>

### **Technical Requirements for Dispensing under Regulatory Requirements Listed Above (Board of Registration in Medicine Policy 15-05)**

#### **Labeling**

When a practitioner does dispense a controlled substance to a patient (and the substance is not administered by the physician or ingested in the practitioner’s presence) the practitioner must package the controlled substance in a container and affix a label to the container that includes the following information:

- The practitioner’s name and address;
- The date of dispensing;
- The name of the patient;
- The name, dosage and strength of the drug;
- Directions for use; and

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<sup>1</sup> 21 U.S.C. § 829; M.G.L. c. 94C, § 9(b) and 105 CMR 700.010(A)(2).

<sup>2</sup> M.G.L. c. 94C, § 9(b).

- Any necessary cautionary statements.<sup>3</sup>

### Recordkeeping Requirements

There are strict record-keeping requirements for practitioners who stock controlled substances.<sup>4</sup> Practitioners who stock controlled substances in Schedules II and III must maintain records of:

- Their receipt and/or administration, including the names and quantities of the controlled substances,
- The name and address of the patient to whom it is administered or dispensed;
- The name, dosage and strength per dosage unit of each controlled substance; and
- The date of the administration or dispensing.<sup>5</sup>

Inventories and records of Schedules II controlled substances that are dispensed to patients must be maintained in records separate from the inventories and records of other controlled substances dispensed.<sup>6</sup> Inventories and records of controlled substances in Schedules III, IV, and V must be maintained separately, as well.<sup>7</sup> All drug records and inventories must be readily retrievable from the practitioner's ordinary business records.<sup>8</sup>

Practitioners must take a detailed, initial inventory of all controlled substances on hand for each location at which they dispense, with subsequent inventories done at least every two years.<sup>9</sup> All records related to controlled substances must be maintained at the registered location for at least two years and be available for inspection for a minimum of two years.<sup>10</sup>

### Security Requirements

All practitioners who dispense controlled substances must have effective controls and procedures to guard against theft and diversion.<sup>11</sup>

Schedule II through V controlled substances must be in a securely locked, substantially constructed cabinet. Practitioners are required to screen all employees or agents who will be working in areas where controlled substances are handled, and are prohibited from knowingly employing anyone who:

- Has been convicted of a felony offense related to controlled substances;
- Has been denied a DEA registration;

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<sup>3</sup> M.G.L. c. 94C, §22(b) and 105 CMR 700.010

<sup>4</sup> 21 U.S.C. §§ 331(t), 333(b), and 353(c)-(d); 21 U.S.C. §§ 824, 827; 21 C.F.R. § 1304.21; M.G.L. c. 94C, § 9(d) and 105 CMR 700.006.

<sup>5</sup> 21 C.F.R. § 1304.03(b); 21 C.F.R. § 1304.22 and M.G.L. c. 94C, § 9(d).

<sup>6</sup> 21 U.S.C. § 827(b) and 21 C.F.R. § 1304.04(g).

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

<sup>9</sup> 21 C.F.R. § 1304.11(b); 21 C.F.R. § 1304.11(c) and 105 CMR 700.006.

<sup>10</sup> 21 U.S.C. § 827(c); 21 U.S.C. § 880; 21 C.F.R. § 1304.21 and 105 CMR 700.007.

<sup>11</sup> 21 C.F.R. §§ 1301.71(a), 1301.75 and 105 CMR 700.005(A).

- Has had a DEA registration revoked; or
- Has surrendered a DEA registration for cause.<sup>12</sup>

Practitioners should notify the DEA when they discover any thefts or significant losses of controlled substances from stock and complete the necessary DEA forms regarding the theft or loss.<sup>13</sup> Practitioners must also report drug theft, loss or any drug discrepancy to the Massachusetts Drug Control Program (DCP) within 24 hours of discovery by:

- Telephoning DCP within 24 hours, then mailing a Drug Incident Report (DIR) to the DCP within 7 days; or
- By visiting the DCP website, downloading a DIR form and faxing that form to DCP with 24 hours.<sup>14</sup>

The submission of the DIR form will satisfy DCP's requirements for both a telephonic and written report. Practitioners should submit all subsequent relevant information they discover to the DCP. Practitioners may dispose of out-of-date, damaged, or otherwise unusable or unwanted controlled substances, including samples, by transferring them to a registrant who is authorized to receive such materials. Schedule I and II controlled substances should be transferred via the DEA Form 222, while Schedule III–V compounds may be transferred via invoice. In Massachusetts, the DCP is responsible for drug destruction. Practitioners should maintain copies of the records documenting the transfer and disposal of controlled substances for a period of two years.

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<sup>12</sup> 21 C.F.R. § 1301.76(a) and 105 CMR 700.005(B).

<sup>13</sup> 21 C.F.R. § 1301.76(b).

<sup>14</sup> 105 CMR 700.005(D).

## **Appendix IV - Association for Behavioral Healthcare Memo to Members**

*(See next Page)*



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**Vicker V. DiGravio III** PRESIDENT / CEO  
**Diane E. Gould, LICSW** CHAIR

ASSOCIATION  
FOR BEHAVIORAL  
HEALTHCARE

October 18, 2018

To: ABH MAT Providers  
From: Vic DiGravio, President/CEO  
Mandy Gilman, Senior Director of Public Policy & Research  
Re: MAT Requirement for Emergency Departments included in CARE Act

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Governor Baker signed into law a new, expansive addiction treatment bill in August, named the CARE Act ([Chapter 2018 of the Acts of 2018](#)). An ABH summary of the legislation is available [here](#). This new law continues to promote the importance of expanding access to medication assisted treatment (MAT) for opioid addiction. The Legislature and Governor have continued to support this type of treatment as a best practice in the field.

In particular, the law requires acute care hospitals that provide emergency services and satellite emergency facilities to maintain the ability to induce MAT for patients when it's appropriate before discharge while also connecting these individuals with treatment in the community.

ABH has engaged with the Massachusetts Health and Hospital Association (MHA) as they work to support their members through the implementation of this new requirement. MHA and ABH believe there are many opportunities for hospitals to partner with community behavioral health providers in order to make the connections necessary to offer clients the best and most appropriate care.

**ABH strongly encourages our members with MAT programs, particularly Opioid Treatment Programs (OTPs), to reach out the emergency departments in your catchment areas to proactively develop these relationships.**

As we continue to work with MassHealth to expand the capacity of OTPs to administer all three FDA approved medications for opioid addiction, we believe OTPs are uniquely positioned to evaluate clients to address their individual needs and fill this gap in the treatment system.

If you have any questions about this requirement, please do not hesitate to contact Vic DiGravio ([vdigravio@abhmass.org](mailto:vdigravio@abhmass.org)) or Mandy Gilman ([agilman@abhmass.org](mailto:agilman@abhmass.org)).

## **Appendix V – ATS Patient Direct Admit to OTP Form**

*(See next Page)*

**ATS Patient Direct Admit to OTP Form**

**Patient Name:** \_\_\_\_\_ **D.O.B:** \_\_\_\_/\_\_\_\_/\_\_\_\_

Patient Contact Phone: \_\_\_\_\_ Cell Phone: \_\_\_\_\_

Payer or Insurance: \_\_\_\_\_

**ATS Program Name:** \_\_\_\_\_

ATS Address: \_\_\_\_\_

ATS Contact Name: \_\_\_\_\_

Phone Number: \_\_\_\_\_ ext: \_\_\_\_\_ Fax number: \_\_\_\_\_

**OTP Program Name:** \_\_\_\_\_

Program Address: \_\_\_\_\_

Contact Name: \_\_\_\_\_

Phone Number: \_\_\_\_\_ ext: \_\_\_\_\_ Fax number: \_\_\_\_\_

**Please attach the following materials to this form prior to sending to OTP** (check all that are attached)

- OTP Application (if needed)
- Nursing assessment including history & physical, tox screens & any lab work
- Bio-Psych-Social assessment including current list of patient's medications
- TB risk assessment form
- Patient photo ID, if available
- Signed Release of Information form
- Patient's insurance information

**Patient's current methadone dose at ATS:** \_\_\_\_\_

**Is the patient pregnant?** Yes \_\_\_\_\_ No \_\_\_\_\_

**Estimated Last Day at ATS Program** \_\_\_\_\_

**Estimated First Day at OTP Program** \_\_\_\_\_

**Other relevant information:** (please specify medical and/or mental health issues, allergies, legal or illicit medications of concern, other substance use, etc.)

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**Staff Signature:** \_\_\_\_\_

**Title:** \_\_\_\_\_ **Date** \_\_\_\_/\_\_\_\_/\_\_\_\_

## Appendix VI - MHA MAT for OUD Workgroup Members

Name	Affiliation	Title
Ali Raja, MD, MBA, MPH – Workgroup Chair	Massachusetts General Hospital	Executive Vice Chair, Department of Emergency Medicine
Leigh Simons Youmans, MPH – MHA Staff Workgroup Contact	Massachusetts Health & Hospital Association	Director, Behavioral Health & Healthcare Policy
Susan Hillis, LICSW, CADC-II, LADC-I	AdCare Hospital	Vice President Clinical Services
Peter Friedmann, MD, MPH, DFASAM, FACP	Baystate Health	Chief Research Officer and Endowed Chair for Clinical Research
William DeMarco, DO FACOI SFHM	Berkshire Medical Center	Division Chief, Hospital Medicine  Vice Chair, Department of Internal Medicine
Michael McHugh, MD	Berkshire Medical Center	Chairman, Emergency Medicine
Sarah Cloud, MBA, MSW, LICSW	Beth Israel Deaconess Hospital- Plymouth	Director of Social Work
Alejandro Mendoza, MD	Beth Israel Deaconess Medical Center Beth Israel Deaconess Hospital- Plymouth Beth Israel Deaconess Hospital – Milton Beth Israel Deaconess Hospital - Needham South Shore Hospital	Director of Network Integration, Department of Psychiatry, BIDMC  Chairman, Department of Psychiatry, BIDPlymouth  Medical Director, Consultation- Liaison Psychiatry, BIDMilton  Director, Division of Psychiatry, South Shore Hospital
Stephen Nicolson, MD	Beth Israel Deaconess Hospital - Plymouth	
Michael Ganetsky, MD, FACEP, FACMT	Beth Israel Deaconess Medical Center	Director, Division of Medical Toxicology  Department of Emergency Medicine
Katherine Boyle, MD	Beth Israel Deaconess Medical Center	Associate Director of Research, Department of Emergency Medicine Division of Medical Toxicology
Kate Ginnis, MSW, MPH	Boston Children’s Hospital	Director of Behavioral Health Advocacy and Policy
Evan Berg, M.D.	Boston Medical Center	Vice Chair of Clinical Operations,  Department of Emergency Medicine

Alexander Y. Walley, MD, MSc	Boston Medical Center Boston University School of Medicine	Associate Professor of Medicine Director, Addiction Medicine Fellowship Clinical Addiction Research and Education Unit
Jennifer Michaels, MD, FASAM	Brien Center	Medical Director
Joji Suzuki, MD	Brigham and Women's Hospital	Director, Division of Addiction Psychiatry
Scott G. Weiner, MD, MPH	Brigham and Women's Hospital	Attending Emergency Physician  Director, Brigham Comprehensive Opioid Response and Education (B- CORE) Program  Director, Fellowship in EM Health Policy Research Translation
Melisa Lai-Becker MD FACEP FAAEM	CHA Everett Hospital Cambridge Health Alliance	Chief, CHA Everett Hospital Emergency Department Director, Division of Medical Toxicology , Cambridge Health Alliance (CHA)
Benjamin Milligan, MD, FACEP	Cambridge Health Alliance	Chief of Emergency Medicine
James J. Sullivan, Jr., M.D.	Harrington Memorial Hospital	Chief of Emergency Medicine
Kelly F. Marcroft, RN, MSN, CEN	Holyoke Medical Center	Director, Emergency Services
Barry Ginsberg, M.D.	Lahey Health Behavioral Services	Chief Medical Officer
Nathan R. MacDonald, MD, FACEP	Lowell General Hospital	Chief, Emergency Medicine
Lisa Brown, PMHNP	Lowell General Hospital	Psychiatric Nurse Practitioner, Circle Care Behavioral Health
Sarah E. Wakeman, MD	Massachusetts General Hospital RIZE Massachusetts	Medical Director, MGH Substance Use Disorder Initiative Chief Medical Officer, RIZE Massachusetts Director, Addiction Medicine Fellowship Program
Erin Daley, RN, BSN, MBA	Mercy Medical Center	Director of Emergency Services
Steven M. Defossez, MD, EMHL, CPE	Massachusetts Health & Hospital Association	Vice President, Clinical Integration
Anuj K. Goel, Esq.	Massachusetts Health & Hospital Association	Vice President, Legal and Regulatory Affairs
Alexandra Levie	Massachusetts Health & Hospital Association	MAT Workgroup Intern
Janice Peters, MPH	Massachusetts Health & Hospital Association	Manager, Healthcare Policy
Kevin Kent, MD FACEP	Milford Regional Medical Center	Emergency Physician and Medical Toxicologist
Jane Clarke, MSN, MRA, RN	North Shore Medical Center	Executive Director, Emergency Department

Jennifer Pope, MD	Southcoast Health	Chair, St. Luke's Emergency Department
Michele Azevedo MSN, MM, RN, CEN, NEA-BC	Southcoast Health	Director of Emergency Services, St. Luke's Hospital
Robert Roose, MD, MPH, FASAM	Trinity Health Of New England	Chief, Addiction Medicine & Recovery Services
Kavita Babu, MD	UMass Memorial Health Care	Professor of Emergency Medicine Director, Division of Toxicology
Rachel Davis-Martin, PhD	University of Massachusetts Medical School	Assistant Professor, Emergency Medicine