The Commonwealth of Massachusetts Executive Office of Health and Human Services Department of Public Health

250 Washington Street, Boston, MA 02108-4619

CHARLES D. BAKER

Governor

KARYN E. POLITO

Lieutenant Governor

**Protocol for**

MARYLOU SUDDERS

Secretary

MONICA BHAREL, MD, MPH

Commissioner

**Tel: 617-624-6000**

[**www.mass.gov/dph**](http://www.mass.gov/dph)

**Consent to Treatment with Medications for Opioid Use Disorder In Correctional Facilities**



# Purpose

Pursuant to Chapter 208 of the Acts of 2018, certain County Houses of Corrections[1](#_bookmark0) (HOCs) and facilities within the Massachusetts Department of Corrections are required to offer Medication Assisted Treatment (MAT) for opioid use disorder in coordination with the Department of Public Health (DPH). Correctional facilities must obtain voluntary consent to treatment from any person in custody as a pre-requisite to beginning MAT for opioid use disorder.

This document outlines requirements to be met regarding consent, offers links to additional related resources, and provides sample consent forms.

# Requirements

The following provisions must be met regarding consent to treatment for MAT from any person in custody[2](#_bookmark1):

* A program physician shall ensure that each patient voluntarily chooses MAT, all relevant facts concerning the use of the opioid drug are clearly and adequately explained to the patient, and each patient provides informed consent to treatment.
* A consent form must be signed by the patient prior to the administration of the medication.
* The patient shall receive a copy of the signed form which shall become part of the medical record.
* The following information must be provided to the patient orally and recorded in writing on the consent form.

1 The following counties are included in the pilot program: Franklin, Hampden, Hampshire, Middlesex, Norfolk Essex, Suffolk

2 St.2018 c.208;105 CMR 164.302(A)(4); 42 CFR § 8.12(e)

1. Their Opioid Use Disorder (OUD) diagnosis and the nature of the disorder.
2. The nature of FDA-approved medication used in opioid treatment, including benefits and risks, and the benefits and risks of not receiving treatment. Use language and written materials appropriate to each patient’s comprehension level to ensure they understand all of the options and can make informed decisions.
3. Alternative treatment options that may include other evidence-based treatment options.
4. The distinction between detoxification and maintenance and the availability of short-term detoxification treatment for a period not less than 30 days nor more than 180 days.
5. The approximate length of each type of treatment. This timeframe should be individualized to each patient.
6. A clear statement of the goals of each type of treatment and the tasks necessary to reach those goals.
7. The need for the client to inform the Opioid Treatment Program (OTP) or the corrections facility of current medical conditions and medications the client is currently taking. This should include any prescribed and over the counter medication.
8. An acknowledgement that the client has received information on all three forms of FDA-approved MAT.
9. An acknowledgement that the client has the option to withdraw voluntarily from treatment once initiated and discontinue the use of MAT. This determination should be made in conjunction with the treating physician to ensure education regarding potential impacts such as possible increased risk of overdose.
10. The options available to both the patient and the program as a result of either a voluntary or involuntary termination, including medically supervised withdrawal. When appropriate, ensure direct referrals are made for other treatment options.

**For women of child-bearing age**, the form must acknowledge the benefits and risks of treatment during pregnancy, and the importance of informing the provider if she is or becomes pregnant. All treatment options must be provided and explained to the patient.

**For patients younger than 18,** admission criteria includes (1) two documented unsuccessful medically supervised withdrawals or treatments without one of the three approved opioid use disorder treatment medications in a 12-month period, and (2) the parent or legal guardian must provide written informed consent.

# Protocol for Initiating Consent

* The Program must establish written criteria for identifying a patient’s prospective appropriateness for MAT for opioid use disorder.
* Staff training regarding MAT, addiction, and opioid use disorder is required.
* The Program must develop a consent form that includes the required information in compliance with state and federal requirements. Policies specific to the protocol for obtaining consent must also be in place and staff training in the policies and protocol must occur.
* The Program must establish consent forms and protocols which include information specifically for women of childbearing age, and pregnant women. These protocols should include education regarding all available treatment options.
* Once a patient has been identified as appropriate for the MAT, the Program must obtain written consent to provide MAT from the patient prior to the patient receiving MAT.
* Should a person in custody choose not to obtain MAT after being informed of their treatment options, a form should be signed by the individual indicating that MAT has been discussed and they are declining treatment and this form should be maintained in the client record.
* The process for obtaining patient consent cannot be coercive or incentive based. Program must take into consideration any environmental factors that may impact a patient’s perception of voluntary participation.
* The Program must ensure the patient and staff are educated regarding the substance use treatment confidentiality laws 42 CFR part 2. The Program must have the capacity to have the consent document translated to accommodate any patient who requires such accommodation.
* All required information that must be relayed to the patient as part of consent must be reviewed with the patient in person by a physician or designated trained staff. Any designated staff must possess the necessary knowledge/expertise in order to effectively deliver the required information and answer any related questions.
* The signed consent document must be maintained in the patient medical record.

Programs that employ any vendor staff to complete this process will have a mechanism in place to audit patient medical records to ensure compliance.

* The Program must ensure that patient consent has been provided and evidence of the signed consent document exists within the patient medical record before any MAT administered. Programs that employ a vendor staff to complete this process will have a mechanism in place to audit patient medical records to ensure compliance.

# Links to Detailed Regulatory Citations, Provisions and Authority

For detailed citations and more information see:

* Code of Federal Regulations Substance Abuse and Mental Health Services Administration Center for Substance Abuse Treatment 42 Part 8. See [https://www.gpo.gov/fdsys/pkg/CFR-2017-title42-vol1/xml/CFR-2017-title42-vol1-](https://www.gpo.gov/fdsys/pkg/CFR-2017-title42-vol1/xml/CFR-2017-title42-vol1-part8.xml) [part8.xml](https://www.gpo.gov/fdsys/pkg/CFR-2017-title42-vol1/xml/CFR-2017-title42-vol1-part8.xml)
* MA Department of Public Health Bureau of Substance Addiction Services Regulations 105 CMR 164.000. See [https://www.mass.gov/regulations/105-CMR-16400-licensure-](https://www.mass.gov/regulations/105-CMR-16400-licensure-of-substance-abuse-treatment-programs) [of-substance-abuse-treatment-programs](https://www.mass.gov/regulations/105-CMR-16400-licensure-of-substance-abuse-treatment-programs)
* MA Department of Public Health Drug Control Program. See

<https://www.mass.gov/regulations/105-CMR-70000-implementation-of-mgl-c94c>

* DEA. See <https://www.deadiversion.usdoj.gov/pubs/manuals/pract/section6.htm>
* Federal Guidelines for Opioid Treatment Programs. See [https://store.samhsa.gov/product/Federal-Guidelines-for-Opioid-Treatment-](https://store.samhsa.gov/product/Federal-Guidelines-for-Opioid-Treatment-Programs/PEP15-FEDGUIDEOTP) [Programs/PEP15-FEDGUIDEOTP](https://store.samhsa.gov/product/Federal-Guidelines-for-Opioid-Treatment-Programs/PEP15-FEDGUIDEOTP)
* SAMHSA TIP 63: Medications for Opioid Use Disorder. See

[https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-](https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document-Including-Executive-Summary-and-Parts-1-5-/SMA18-5063FULLDOC) [Document-Including-Executive-Summary-and-Parts-1-5-/SMA18-5063FULLDOC](https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document-Including-Executive-Summary-and-Parts-1-5-/SMA18-5063FULLDOC)

* American Society of Addiction Medicine. See <https://www.asam.org/>
* American Association for the Treatment Opioid Dependence, Inc. See

<http://www.aatod.org/>

* Providers Clinical Support System. See <https://pcssnow.org/>
* Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants, SAMHSA, see <https://store.samhsa.gov/system/files/sma18-5054.pdf>
* SAMHSA TIP 32: Treatment of Adolescents with Substance Use Disorders, see [http://adaiclearinghouse.org/downloads/TIP-32-Treatment-of-Adolescents-with-](http://adaiclearinghouse.org/downloads/TIP-32-Treatment-of-Adolescents-with-Substance-Use-Disorders-62.pdf) [Substance-Use-Disorders-62.pdf](http://adaiclearinghouse.org/downloads/TIP-32-Treatment-of-Adolescents-with-Substance-Use-Disorders-62.pdf)

# Sample Consent to Treatment Form - Methadone

**NOTE:** *This sample form is for educational/informational purposes only. It does not establish a legal or medical standard of care. Healthcare professionals should use their judgment in interpreting this form and applying it to the circumstances of their individual patients and practice arrangements. The information provided in this form is provided “as is” with no guarantee as to its accuracy or completeness and is based upon a sample form provided by the Substance Abuse and Mental Health Services Administration.*

SAMPLE CONSENT TO PARTICIPATE IN MEDICATION ASSISTED TREATMENT (METHADONE)

Patient’s Name: Date:

I authorize and give voluntary consent to [insert name of facility] to dispense and administer the [methadone] to treat my opioid use disorder. Treatment procedures have been explained to me, including the approximate length of each type of treatment, and I understand that I should take my medication at the scheduled time determined by the physician, or his/her designee, in accordance with federal and state regulations.

I understand that I have been diagnosed as suffering from opioid use disorder and that it has further been determined that an appropriate treatment is opioid maintenance therapy, which involves the daily use of medication (methadone), often combined with medical and rehabilitative (counseling) services, to alleviate the adverse medical, psychological, or social effects incident to opioid use disorder.

I understand that, like all other medications, methadone can be harmful if not taken as prescribed. It has been explained to me that I must safeguard these medications and not share them with anyone because they can be fatal to children and adults if taken without medical supervision. I also understand that methadone produces physical opioid dependence. I understand that it is important for me to inform a qualified addiction specialist, medical and psychiatric provider who may treat me of any medical conditions, including pregnancy, and medications that I am currently taking. In this way, the provider will be aware of any medical conditions and all the medications I am taking, can provide the best possible care, and can avoid prescribing medications that might affect my treatment or my recovery.

I understand that I will submit to medically indicated testing (blood and urine tests) to ensure I am adhering to the appropriate treatment regimen and not experiencing any adverse effects of the medication.

I understand that methadone does not cure addiction, and is itself an opioid drug, which is addictive and can have serious, even fatal, side effects. The most commonly reported side effects are:

* constipation and abdominal pain
* nausea/vomiting
* sweating/flushing
* headache
* dizziness, especially after sitting or lying down
* drowsiness
* mood changes
* vision problems
* difficulty falling or staying asleep
* missed periods
* sexual side effects
* weight gain
* swelling

Serious and sometimes fatal side effects include

* seizures;
* low blood pressure
* severe allergic reaction;
* slowed or difficult breathing;
* cardiac arrest, especially in patients with certain existing heart conditions
* liver damage

I understand and have had reviewed with me and been provided in writing a description of the patients’ rights and responsibilities. I understand that my medical record including the use of taking this medication will be kept confidential in accordance with state and federal law including but not limited to 42 CFR Part 2.

I understand that I may withdraw voluntarily from this treatment program and discontinue the use of these medications at any time. If I choose this option, I understand I will be offered medically supervised withdrawal, including short-term detoxification treatment for not less than 30 days nor more than 180 days.

For women of childbearing age:

* Pregnant women treated with methadone or buprenorphine have better outcomes than pregnant women not in treatment who continue to use opioid drugs. Newborns of mothers who are receiving methadone or buprenorphine treatment may have opioid withdrawal symptoms (i.e., neonatal abstinence syndrome). The delivery hospital may require babies who are exposed to opioids before birth to spend a number of days in the hospital for monitoring of withdrawal symptoms. Some babies may also need medication to stop withdrawal. If I am or become pregnant, I understand that I should tell medical staff right away so I can receive or be referred to prenatal care. I understand that there are ways to maximize the healthy course of my pregnancy while I am taking methadone or buprenorphine.

The information in this form has been conveyed to me in my preferred language of understanding and I understand the risks, benefits, and requirements of taking this medication. My signature below affirms my consent for the named medication and the anticipated dose range. I understand that I can discuss any questions with my medical team.

Signature of Patient: Date of Birth:

Signature of Parent/guardian (if under 18 years old): Date: \_ Witness:

Signature of Provider Date:

# Sample Consent to Treatment Form - Buprenorphine

**NOTE:** *This sample form is for educational/informational purposes only. It does not establish a legal or medical standard of care. Healthcare professionals should use their judgment in interpreting this form and applying it to the circumstances of their individual patients and practice arrangements. The information provided in this form is provided “as is” with no guarantee as to its accuracy or completeness and is based upon a sample form provided by the Substance Abuse and Mental Health Services Administration.*

SAMPLE CONSENT TO PARTICIPATE IN MEDICATION ASSISTED TREATMENT (BUPRENORPHINE)

Patient’s Name: Date:

I authorize and give voluntary consent to [insert name of facility] to dispense and administer the [Buprenorphine] to treat my opioid use disorder. Treatment procedures have been explained to me, including the approximate length of each type of treatment, and I understand that I should take my medication at the scheduled time determined by the physician, or his/her designee, in accordance with federal and state regulations.

I understand that I have been diagnosed as suffering from opioid use disorder and that it has further been determined that an appropriate treatment is opioid maintenance therapy, which involves the daily use of medication (Buprenorphine), often combined with medical and rehabilitative (counseling) services, to alleviate the adverse medical, psychological, or physical effects incident to opioid use disorder.

I understand that, like all other medications, buprenorphine can be harmful if not taken as prescribed. It has been explained to me that I must safeguard these medications and not share them with anyone because they can be fatal to children and adults if taken without medical supervision. I also understand that buprenorphine produces physical opioid dependence. I understand that it is important for me to inform a qualified addiction specialist, medical and psychiatric provider who may treat me of any medical conditions, including pregnancy, and medications that I am currently taking. In this way, the provider will be aware of any medical conditions and all the medications I am taking, can provide the best possible care, and can avoid prescribing medications that might affect my treatment or my recovery.

I understand that I will submit to medically indicated testing (blood and urine tests) to ensure I am adhering to the appropriate treatment regimen and not experiencing any adverse effects of the medication.

I understand that buprenorphine does not cure addiction, and is itself an opioid drug, which can be addictive and can have serious side effects. I understand that buprenorphine can precipitate withdrawal if I am not in at least a mild withdrawal of opioids when taking the medication. The most commonly reported side effects are:

* Opioid withdrawal
* constipation and abdominal pain
* oral numbness
* sweating/flushing
* dizziness, especially after sitting or lying down
* drowsiness
* headache
* palpitations
* mood changes
* vision problems
* difficulty falling or staying asleep
* sexual side effects
* weight gain
* swelling

Serious and sometimes fatal side effects include

* seizures;
* low blood pressure
* severe allergic reaction
* adrenal (hormonal) insufficiency
* slowed or difficult breathing
* cardiac arrest, especially in patients with certain existing heart conditions
* liver damage

I understand and have had reviewed with me and been provided in writing a description of the patients’ rights and responsibilities. I understand that my medical record including the use of taking this medication will be kept confidential in accordance with state and federal law including but not limited to 42 CFR Part 2.

I understand that I may withdraw voluntarily from this treatment program and discontinue the use of these medications at any time. If I choose this option, I understand I will be offered medically supervised withdrawal, including short-term detoxification treatment for not less than 30 days nor more than 180 days.

For women of childbearing age:

* Pregnant women treated with methadone or buprenorphine have better outcomes than pregnant women not in treatment who continue to use opioid drugs. Newborns of mothers who are receiving methadone or buprenorphine treatment may have opioid withdrawal symptoms (i.e., neonatal abstinence syndrome). The delivery hospital may require babies who are exposed to opioids before birth to spend a number of days in the hospital for monitoring of withdrawal symptoms. Some babies may also need medication to stop withdrawal. If I am or become pregnant, I understand that I should tell medical staff right away so I can receive or be referred to prenatal care. I understand that there are ways to maximize the healthy course of my pregnancy while I am taking buprenorphine.

The information in this form has been conveyed to me in my preferred language of understanding and I understand the risks, benefits, and requirements of taking this medication.

My signature below affirms my consent for the named medication and the anticipated dose range. I understand that I can discuss any questions with my medical team.

Signature of Patient: Date of Birth:

Signature of Parent/guardian (if under 18 years old): Date: \_ Witness:

Signature of Provider Date:

# Sample Consent to Treatment Form – Naltrexone Injectable Extended Release

**NOTE:** *This sample form is for educational/informational purposes only. It does not establish a legal or medical standard of care. Healthcare professionals should use their judgment in interpreting this form and applying it to the circumstances of their individual patients and practice arrangements. The information provided in this form is provided “as is” with no guarantee as to its accuracy or completeness and is based upon a sample form provided by the Substance Abuse and Mental Health Services Administration.*

SAMPLE CONSENT TO PARTICIPATE IN

MEDICATION ASSISTED TREATMENT (NALTREXONE INJECTABLE EXTENDED RELEASE)

Patient’s Name: Date:

I authorize and give voluntary consent to [insert name of facility] to dispense and administer the [Naltrexone - Injectable] to treat my opioid use disorder. Treatment procedures have been explained to me, including the approximate length of each type of treatment, and I understand that I should take my medication at the scheduled time determined by the physician, or his/her designee, in accordance with federal and state regulations.

I understand that I have been diagnosed as suffering from opioid use disorder and that it has further been determined that an appropriate treatment is opioid maintenance therapy, which involves the daily use of naltrexone, often combined with medical and rehabilitative (counseling) services, to alleviate the adverse medical, psychological, or physical effects incident to opioid use disorder.

I understand that, like all other medications, naltrexone can be harmful if not taken as prescribed. I understand that it is important for me to inform a qualified addiction specialist, medical and psychiatric provider who may treat me of any medical conditions, including pregnancy, and medications that I am currently taking. In this way, the provider will be aware of any medical conditions and all the medications I am taking, can provide the best possible care, and can avoid prescribing medications that might affect my treatment or my recovery.

I understand that I will submit to medically indicated testing (blood and urine tests) to ensure I am adhering to the appropriate treatment regimen and not experiencing any adverse effects of the medication.

I understand that naltrexone does not cure addiction. I understand that I should have abstained from opioids for 7-14 days prior to initiating naltrexone or I will be at increased risk for withdrawal symptoms.

I understand that any period of sustained abstinence from opioids, including when I am treated with naltrexone results in lower tolerance for opioid use. Naltrexone works by blocking the effect of opioids; thus, patients may not perceive any effect if they attempt to self-administer heroin/fentanyl or any other opioid drug in small doses while on naltrexone. Further.

administration of large doses of any opioid to try and bypass the blockade while on naltrexone, could lead to serious injury, coma, or death.

Therefore, I am at an increased risk of opioid overdose if I use opioids after missing a naltrexone treatment or use opioids to overcome naltrexone’s effect.

Like any medication, I understand that Naltrexone can cause side effects. The most common side effects include:

* nausea/vomiting
* runny nose
* abdominal pain
* headache
* muscle and joint pain
* mood changes
* vision problems
* difficulty falling or staying asleep
* changes in appetite

Serious and sometimes fatal side effects include

* injection site pain, swelling, blistering, and infection
* severe allergic reaction
* accidental opioid overdose
* depression and suicidality
* liver damage

I understand and have had reviewed with me and been provided in writing a description of the patients’ rights and responsibilities. I understand that my medical record including the use of taking this medication will be kept confidential in accordance with state and federal law including but not limited to 42 CFR Part 2.

I understand that I may withdraw voluntarily from this treatment program and discontinue the use of naltrexone at any time

For women of childbearing age:

* I have been educated about the increased chance of pregnancy while stopping illicit opioid use and starting Naltrexone treatment. I have been informed about methods for preventing pregnancy. I have been informed that if I become pregnant during naltrexone treatment, I should inform medical staff and have a discussion about the risks and benefits of continuing to take Naltrexone.

The information in this form has been conveyed to me in my preferred language of understanding and I understand the risks, benefits, and requirements of taking this medication. My signature below affirms my consent for the named medication and the anticipated dose range. I understand that I can discuss any questions with my medical team.

Signature of Patient:

Date of Birth:

Signature of Parent/guardian (if under 18 years old): Date: \_ Witness:

Signature of Provider Date: