

**Department of Correction
Medication Assisted Treatment Re-Entry Initiative (MATRI)
Clinical Guidelines**

Purpose

The purpose of the Medication Assisted Treatment Re-Entry Initiative (MATRI) is to provide pre-release treatment and post-release referral for opioid-addicted and alcohol-addicted inmates at participating sites in the Department of Correction (DOC). This program involves prison-based residential and non-residential substance abuse treatment and collaboration with community based clinics to provide aftercare treatment. The goal is to facilitate transition into an outpatient substance abuse treatment program which employs a multi-faceted approach to treatment including the use of the medication Vivitrol/Naltrexone, counseling, and aftercare referral to community based providers.

Goal

The goal of this initiative is to increase and improve substance abuse treatment post release, and decrease recidivism rates.

The goal is also to conduct a program evaluation that examines the criminal justice and treatment outcomes related to Medication-Assisted Treatment (i.e., Vivitrol), administered to inmates prior to release from Massachusetts state correctional facilities.

Definitions

Correctional Offender Management Profiling for Alternative Sanctions (COMPAS): A validated, evidence-based risk/needs assessment tool that assesses an offender's level of risk to recidivate, risk of general violence and several criminogenic need areas that contribute to criminal behavior according to research

Medication-Assisted Treatment (MAT): A substance abuse treatment approach made possible by physician-prescribed and monitored medications, along with other recovery supports, e.g., counseling and peer support.

Naltrexone: (Revia): An oral tablet used for opioid and alcohol dependence.

Non-residential Substance Abuse Treatment Programs: Substance abuse programs facilitated by the department's contracted vendor.

Residential Substance Abuse Treatment Program: Correctional Recovery Academy – the DOC's six month intensive residential substance abuse treatment program for male offenders: Health Living Community – the DOC's intensive residential substance abuse program for female offenders.

Recovery Support Navigator: Staff who provide non-clinical services that engage, educate and support individuals seeking treatment, and their families, in order to motivate them in culturally relevant behavioral health services in the community.

Substance Abuse Graduate Maintenance Program: A non-residential substance abuse treatment program designed to keep inmates who have graduated from the CRA or completed other non-residential programs engaged in treatment up to their releases.

Substance Abuse Treatment Staff: Staff employed by DOC's vendor who provide substance abuse treatment.

Vivitrol:(Naltrexone for extended-release injectable suspension) is the injectable form of Naltrexone. The medication is indicated for the prevention of relapse to opioid dependence, following opioid detoxification. It is also indicated for the treatment of alcohol dependence in patients who are able to abstain from alcohol in an outpatient setting prior to initiation of treatment with Vivitrol. Vivitrol is prescribed to reduce the cravings for and blocks the effects of ingested opioids and alcohol.

Target Population

Eligibility is determined by those inmates who have completed or are enrolled in residential or non-residential substance abuse treatment who meet the inclusion criteria and have a documented opioid or alcohol dependence. (Attachment F – Outpatient Treatment Centers and Catchment Areas).

Assessment and Process

All new admissions will be administered the Texas Christian University Drug Screen II (TCUDSII). Any inmate who scores high on this assessment shall be recommended to the Department's residential and/or non-residential substance abuse treatment program. Inmates who remain engaged in treatment will be assessed for participation in MATRI.

Medication Assisted Treatment Training

All Substance Abuse Treatment staff, facilitating MATRI shall receive training on the methods to educate inmates on the following:

- Opioid Epidemic;
- Overview of Opioid and Alcohol Dependence
- Understanding Vivitrol; and
- Overview of MATRI

In addition, all Substance Abuse Treatment Staff, vendor Medical and Mental Health staff, DOC Re-entry staff and Recovery Support Navigators shall receive training on educational resources for both professionals and patients (Attachment A). All training shall be documented. The Substance Abuse Treatment vendor shall keep track of all training. This information will be made available to DOC upon request.

Medication Assisted Treatment Education for Inmates

A medication-assisted recovery lesson plan shall be included in the curriculum of the CRA, all non-residential substance abuse programs and Reentry and Employment Readiness Workshop. In addition, informational sessions on medication-assisted recovery shall be offered monthly

targeting inmates engaged in substance abuse treatment. Informational sessions shall be facilitated by Substance Abuse Treatment Staff. The lesson plan shall include objective information pertaining to various medications used to treat addiction. It shall also focus on the importance of non-medicinal treatment methods, such as counseling and addiction meetings as an essential component of medication assisted recovery. The lesson plan shall be approved by the Director of Program Services. All inmate medication assisted recovery education shall be documented. This information is documented in IMS, case plan – substance abuse treatment need area – medication assisted treatment reentry initiative.

Participant Screening

Substance Abuse Treatment Staff shall review identified inmate's TCUDS assessment for initial screening. Inmates who are identified as being eligible and who are interested in participating in medication-assisted recovery shall submit an Inmate Request Form/Questionnaire (Attachment B) to Substance Abuse Treatment staff or Reentry Planner. Substance Abuse Treatment Staff shall administer the MATRI Inmate Questionnaire and assess the inmate's motivation to change as the final screening process to determine eligibility. Substance Abuse Treatment Staff shall review the inmate's TCUDS assessment for initial screening. Substance Abuse Treatment Staff shall issue the MATRI Counseling Attendance Agreement (Attachment D) and obtain the inmate's signature.

Based upon review of all available information in cases in which the inmate meets all requirements, Substance Abuse Treatment staff shall enter a recommendation of Medication Assisted Treatment Reentry Initiative (MATRI) into the Substance Abuse Need area of the case plan, documenting the inmate's eligibility for the program.

The disposition of "ineligible" shall be utilized for inmates without a documented opioid or alcohol dependence.. The disposition of "accepted" shall be utilized for inmates with a documented opioid or alcohol dependence.. Substance Abuse Treatment Staff shall refer eligible inmates to Program Services who will then forward the request to the medical vendor's Statewide Medical Director and Chief Nursing Officer via e-mail. The Statewide Medical Director and Chief Nursing Officer shall notify the Health Service Administrators at the applicable sites. This shall facilitate the clinical screening process for potential contraindications and appropriateness for medication-assisted treatment within 30 to 60 days of a defined release date. No inmate will be coerced or pressured into receiving treatment in the MATRI.

Parole Eligibility Process

The institutional parole officer (IPO) shall be responsible for notifying the Institutional designee and the Program Services Division designee anytime an inmate receives a parole vote recommending screen for MATRI.

Program Services shall notify Spectrum who will assign a Counselor/Recovery Support Navigator within one (1) business day to meet with the inmate to discuss the program and determine the inmate's willingness and eligibility to participate in MATRI.

- Inmates who agree to participate shall complete the application and be added to the MATRI tracker.

- The Program Services Division shall notify the Health Services Unit designee to begin the medical/mental health screening process.
- The IPO shall provide the Program Services Division a 14 day notification from the parolee's approved release date to ensure the parolee receives both the three (3) days of Naltrexone and Vivitrol injection prior to release.

The Program Services Division designee shall notify the IPO if at any point throughout the process an inmate declined to participate, is determined to be ineligible or is incomplete.

Mental Health Evaluation

A designated qualified mental health professional shall conduct a formal evaluation of the inmate to determine whether there are acute mental health contraindications to proceeding to the medical screening.

Mental health contraindications may include, but shall not be limited to:

- acute psychiatric distress (such as psychosis, mania, depression, etc);
- suicidal thoughts or plans; and
- significant cognitive limitations resulting in an inability to provide consent; etc.

If any clinical contraindications are identified, the qualified mental health professional shall refer the inmate to a psychiatrist for a formal evaluation. The psychiatric evaluation shall be completed within 30 to 45 days prior to a defined release date.

Inmates having no mental health contraindications shall be referred to medical staff for a comprehensive medical evaluation.

Medical Evaluation

The Health Services Unit medical director, physician, nurse practitioner or physician's assistant shall meet with the inmate approximately thirty (30) days prior to a defined release date. At this time, the inmate shall receive additional information about the MATRI program. The medical provider and inmate shall discuss whether Vivitrol treatment is appropriate.

Vivitrol Medication Guidelines:

The following represent indications for use of Vivitrol to be reviewed by the medical provider with the patient:

- For the treatment of alcohol dependence in patients who are able to abstain from alcohol in an outpatient setting prior to initiation of treatment with VIVITROL. Patients should not be actively drinking at the time of initial VIVITROL administration.
- For the prevention of relapse to opioid dependence, following opioid detoxification.
- As part of a comprehensive management program that includes psychosocial support.

Contraindications for the use of Vivitrol to be reviewed by the medical provider with the patient are:

- Patients receiving opioid analgesics.
- Patients with current physiologic opioid dependence.
- Patients in acute opioid withdrawal.
- Any individual who has failed the naloxone challenge test or has a positive urine screen for opioids.
- Patients who have previously exhibited hypersensitivity to naltrexone, polylactide-co-glycolide (PLG), carboxymethylcellulose, or any other components of the diluent.

The following must be reviewed by the medical provider with the patient:

WARNINGS AND PRECAUTIONS

- **Vulnerability to Opioid Overdose:** Following VIVITROL treatment opioid tolerance is reduced from pretreatment baseline, and patients are vulnerable to potentially fatal overdose at the end of a dosing interval, after missing a dose, or after discontinuing VIVITROL treatment. Attempts to overcome blockade may also lead to fatal overdose.
- **Injection Site Reactions:** In some cases, injection site reactions may be very severe. Some cases of injection site reactions required surgical intervention.
- **Precipitation of Opioid Withdrawal:** Opioid-dependent and opioid-using patients, including those being treated for alcohol dependence, should be opioid-free before starting VIVITROL treatment, and should notify healthcare providers of any recent opioid use. An opioid-free duration of a minimum of 7-10 days is recommended for patients to avoid precipitation of opioid withdrawal that may be severe enough to require hospitalization.
- **Hepatotoxicity:** Cases of hepatitis and clinically significant liver dysfunction were observed in association with VIVITROL treatment during the clinical development program and in the post marketing period. Discontinue use of VIVITROL in the event of symptoms or signs of acute hepatitis.
- **Depression and Suicidality:** Monitor patients for the development of depression or suicidal thinking.
- **When Reversal of VIVITROL Blockade Is Required for Pain Management:** In an emergency situation in patients receiving VIVITROL, suggestions for pain management include regional analgesia or use of non-opioid analgesics.

ADVERSE REACTIONS

The adverse events seen most frequently in association with VIVITROL therapy for alcohol dependence (i.e., those occurring in $\geq 5\%$ and at least twice as frequently with VIVITROL than placebo) include nausea, vomiting, injection site reactions (including induration, pruritus, nodules and swelling), muscle cramps, dizziness or syncope, somnolence or sedation, anorexia, decreased appetite or other appetite disorders.

The adverse events seen most frequently in association with VIVITROL therapy in opioid-dependent patients (i.e., those occurring in $\geq 2\%$ of patients treated with VIVITROL and at least twice as frequently with VIVITROL than placebo) were hepatic enzyme abnormalities, injection site pain, nasopharyngitis, insomnia, and toothache.

To report SUSPECTED ADVERSE REACTIONS, contact Alkermes, Inc. at 1-800-VIVITROL (1-800-848-4876) and/or email: usmedinfo@alkermes.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

Naltrexone antagonizes the effects of opioid-containing medicines, such as cough and cold remedies, antidiarrheal preparations, and opioid analgesics.

USE IN SPECIFIC POPULATIONS

- VIVITROL pharmacokinetics have not been evaluated in subjects with severe hepatic impairment.
- Caution is recommended in administering VIVITROL to patients with moderate to severe renal impairment.

The medical evaluation/testing shall include an assessment of overall health and Liver Function Tests (Blood Lab). All forms must be properly executed in order for the inmate to participate in the program. Screening shall be completed within thirty (30) to sixty (60) days of release.

At the conclusion of the meeting, the inmate shall be given the opportunity to sign the MATRI Consent form (Attachment D), consenting to participate in the medical screen/testing and acknowledging the requirements of the medication-assisted treatment.

The Health Services designee shall notify Substance Abuse Treatment Staff if the inmate has been determined to be eligible for the program and has executed all required consent forms.

Participant Enrollment

Substance Abuse Treatment Staff shall enter the disposition of “enrolled” into the substance abuse need area of the case plan for inmates referred by the medical vendor. A disposition of “ineligible” shall be entered into the substance abuse need area of the case plan outcome section by substance abuse treatment staff for inmates deemed as not appropriate due to medical or mental health contraindications. Substance Abuse Treatment Staff shall enter a “provider note” in the case plan stating that the inmate was deemed as not appropriate.

Inmates accepted to MATRI shall be required to attend monthly individual counseling sessions and any other recommended programming. The inmate shall be required to meet with a Recovery Support Navigator a minimum of two (2) times 90 days prior to release. These sessions shall focus on assessment of motivational state, commitment to treatment and supportive/reinforcing counseling to strengthen commitment to recovery

Substance Abuse Treatment Staff shall enter a monthly case note in the substance abuse need area of the inmate's case plan documenting participation and motivation in substance abuse programming. Substance Abuse Treatment staff may terminate an inmate from the program if he/she fails to attend recommended programming.

Substance Abuse Treatment staff should update the case plan to "completed" when an inmate has received his/her pre-release injection or if the enrolled inmate refuses the injection the outcome should be updated to "incomplete".

Inmates who are housed at a non-participating MATRI facility who have submitted an application to participate in MATRI, shall be referred to a reclassification hearing to a host site. Program Services will notify Central Classification via email when a potential MATRI candidate residing at a non host site has submitted an application. Central Classification will notify the the Deputy Superintendent that a reclassification hearing should be scheduled within one week for transfer to a host site.

Urine Drug Screen

Prior to the initiation of medication administration, a urine drug screen shall be conducted pursuant to 103 DOC 525. Inmates shall agree to consent to a urinalysis screen to ensure they have not consumed opiates or alcohol ten (10) days prior to release which is the same day as the first oral dose of Naltrexone being administered. Inmates who are found guilty based upon a positive urinalysis screen shall be subject to the provisions of 103 DOC 525, Inmate Substance Abuse Monitoring and Testing and 103 CMR 430, Inmate Discipline.

The Health Service Administrator (H.S.A.) or designee shall coordinate the collection of the urine drug screen with the facility's Substance Abuse Monitor and/or Superintendent's designee, who shall be responsible for the collection and testing of urine specimens. The H.S.A. or designee shall provide the Substance Abuse Monitor or designee with a 30-day notice of those inmates who will require urine drug screens prior to the administration of Naltrexone. The Substance Abuse Monitor or designee shall collect the urine specimen and immediately test pursuant to procedures outlined in 103 DOC 525. Results of the urine drug screen shall be immediately communicated with the H.S.A. or designee. Once the urine drug screen is completed and results are determined to be negative, the inmate shall be escorted to the Health Services Unit to receive the oral first dose of Naltrexone.

Post Release Treatment

Medical vendor staff shall submit all required documents and the intake form to the Recovery Support Navigator Supervisor who will coordinate the post-release substance abuse counseling component of medication assisted recovery with one of the Outpatient Treatment Centers listed on Attachment E that have agreed to collaborate with the DOC on MATRI. Recovery Support

Navigator supervisor shall forward all required documents to the Outpatient Treatment Centers. The RSN Supervisor shall communicate this information to the assigned RSN and the Discharge Planner of the outpatient appointment.

Attachment E includes a list of the catchment areas for Outpatient Treatment Centers. The goal is to provide as much information as needed for continuity of care post release, consistent with the requirements of 103 DOC 153, CORI Regulations, and subject to the execution of a signed consent form by the inmate.

Naltrexone Tolerance Trial

In order to evaluate for possible adverse side effects, it is recommended that inmates participating in the Vivitrol Pre-Release Program be prescribed Naltrexone 50 mg daily for 1-3 days prior to beginning Vivitrol therapy.

Once the first dose of Naltrexone is administered, the nurse shall provide the inmate with a Vivitrol ID bracelet (Attachment F) and instruct the inmate on the importance of wearing the bracelet at all times. This is important information needed for emergency pain management that needs to be shared with medical personnel treating the inmate in the event of an emergency.

Initiation of Vivitrol Treatment

Inmates participating in the Vivitrol Pre-Release Program shall receive the first injection of Vivitrol approximately seven (7) days prior to their release. The facility Medical Director, Physician, Nurse Practitioner or Physician's Assistant shall prescribe the medication for inmates who are screened, approved and voluntarily consent to participate in the MATRI. Vivitrol medication shall be stored according to manufacturers' instructions and per DOC Policy in the participating facilities' health services units. Vivitrol shall be maintained on count within the Sharps Log Book (as each dosing kit contains a hypodermic needle).

Medication Administration

Medications shall be administered by licensed healthcare staff who have been trained and deemed competent to administer Vivitrol. Upon second review of the previously signed MATRI Consent Form (Attachment D), the administering nurse shall sign the Consent Form, and the medication shall then be administered. Administration of medication shall be documented in the inmate's medical record in the Medication Administration Record (MAR).

The medication shall be supplied by the State Office of Pharmacy Services (SOPS) in accordance with established policy and procedures. The medical vendor provider shall complete the Certification and Requests for Vivitrol (380mg/vial carton) (Attachment H) The provider shall complete the section noted, "Licensed/Dispensing Healthcare Practitioner" and shall then forward the form to the facility Deputy Superintendent, who shall complete the section noted, "Correctional Facility Name" and once completed, the Deputy Superintendent shall forward the Attachment to the Health Services Administrator or designee who shall fax the form to the Vivitrol pharmaceutical supply company (Alkermes) at 781-207-1057.

Discharge Planning

For inmates who have been determined to be enrolled in the MATRI, the medical vendor's discharge planners will initiate discharge planning which includes the following:

- Ensuring Insurance Eligibility in collaboration with DOC.
- Obtaining the inmate's signature authorizing the Medical Vendor to release Sensitive Medical / Substance Abuse Treatment information to the designated Outpatient Treatment Center. This shall facilitate the continuation of post release treatment in the community. The form shall be co-signed by the Medical Vendor's designee.
- Complete the MATRI Referral Request Form (Attachment I) and forward information to RSN Supervisor to coordinate initial intake meeting.
- Discharge Planners shall document discharge plans in IMS.

At the time of the Vivitrol injection, nursing staff shall prepare a discharge planning packet and submit, via e-mail to the Regional Director for Spectrum. The discharge planning package will include:

- Copies of the MAR documenting medication administration of oral doses of Naltrexone and IM injection of Vivitrol.
- Copies of recent lab results including LFTs.
- Routine Discharge Summary.

**Department of Correction
Medication Assisted Treatment Re-Entry Initiative (MATRI)
Medication Assistant Therapy Facilitator Guide**

- I.** Welcome and Introductions 8:30 AM – 8:45 AM
- II.** The Opioid Epidemic 8:45 AM – 10:45 AM
- III.** Overview of Opioid and Alcohol Dependence
- IV.** Understanding VIVITROL
 - a. FDA-approved uses for VIVITROL
 - b. How VIVITROL Works
 - c. Efficacy in Opioid and Alcohol Dependence
 - d. Important Safety Information
- V.** Questions and Answers
- BREAK – 15 Minutes 10:45 AM – 11:00 AM
- IV.** Overview of the MATRI Program 11:00 AM – 12:00 PM
 - a. MATRI Participant Screening
 - b. MH and Medical Screening
 - c. Participant Enrollment
 - d. Urine Drug Screening
 - e. Post Release Treatment and Outpatient Treatment Centers
 - f. Naltrexone and Vivitrol Administration, Discharge Planning
- V.** Questions and Answers
- LUNCH – 1 Hour 12:00 PM – 1:00 PM
- VI.** Breakout Sessions 1:00 PM – 3:00 PM
 - a. Substance Abuse Treatment Staff, Reentry Staff, Mental Health Professionals and Discharge Planners – (Break out group 1 in Cafetorium). Review of educational resources for both professionals and patients. Overcoming inmate obstacles.
 - b. Medical Vendor Staff - (Break out group 2 – Classroom 1) Medication Administration and Storage.

**Department of Correction
Medication Assisted Treatment Re-Entry Initiative (MATRI)
Inmate Request Form/Inmate Questionnaire**

Inmate Name: _____ Comm. # _____

DOB: _____ Age: _____

Release Date: _____ Release Phone Number: _____

Release Address: _____

I am requesting to be included in the Medication Assisted Treatment Re-Entry Initiative. I understand that eligibility for the program will be determined through medical screening and testing. I also understand that I will be required to attend multiple meetings with the CRA Program Director and Clinicians to complete the screening and admission process.

I acknowledge that I must remain engaged in my recovery and demonstrate pro-social behavior. I will continue to attend AA/NA meetings and comply with any program requirements.

Following my release, I will attend all counseling sessions as directed by the community outpatient clinic and follow all rules and regulations of the clinic. I agree to work toward all treatment goals outlined in my treatment plan.

Drug Use History

Substance	Check ones you have used in your lifetime	Check ones you were currently using at time of incarceration	Route of use (IV, snort, smoke, etc.)	Frequency of use at time of incarceration (Daily, Weekly, Monthly, etc.)	How long have you abused this substance?
Alcohol					
Cocaine/Crack					
Marijuana					
Hallucinogens (acid, mushrooms)					

Attachment B

Designer Drugs (Ecstasy, Liquid G, Bath Salts, etc.)					
CAmphetamines (Crystal Meth, Adderall, etc.)					
Benzodiazepines (Xanax, Klonopin, Ativan, Valium, etc.)					
Opiates (heroin, OC's, Percocet, Vicodin, methadone, etc.)					
Suboxone (NOT prescribed)					

Overdose

Have you ever overdosed? YES NO

If yes, what substance did you overdose on? _____

Have you ever been hospitalized because of an overdose? YES NO

Substance Abuse Treatment History

Have you had any substance abuse treatment? YES NO

How many times have you been to detox? _____

Have you ever been prescribed Suboxone or Methadone? YES NO

If yes, was it helpful? YES NO If no, Why or why not?

Clean Time History

How many serious attempts have you made to get clean? _____

How long was the longest period of time that you have been clean? _____

When was this? _____

Mental Health

Have you ever received mental health counseling? YES NO

If yes, was it helpful? Why or why not?

Have you ever attempted to hurt yourself? YES NO If yes, when?

Attachment B

Have you been diagnosed with a mental illness? YES NO If yes, what is your diagnosis? _____

Have you ever been hospitalized for mental health issues? YES NO If yes, when? _____

Social Support

What is your current relationship status (single, married, in a relationship, etc.)?

Do you plan to live with your partner/significant other? YES NO

Does your partner have an active substance use/abuse problem? YES NO

Is your partner/significant other currently in treatment? YES NO

Planning for Treatment

What are your goals for treatment? _____

Is your goal to stop using all substances, or just some of them?

Are you interested in participating in individual counseling, group counseling and/or substance abuse meetings as part of your treatment after release?

Inmate Signature

Date

Print Inmate's Name

Date

Substance Abuse Treatment Staff Signature

Title



Attachment C

**Department of Correction
Medication Assisted Re-Entry Treatment Initiative (MATRI) Counseling Attendance
Agreement**

Inmate Name: _____ ID#: _____ Date of Admission: __/__/____

The following is an agreement for counseling services as part of the Spectrum Health Systems treatment program.

Individual sessions and group counseling are equally important and you must attend both during your treatment. There are no exceptions. It is a program requirement.

- I agree to attend weekly group counseling sessions. Groups are 90 minutes in length.
- I agree to attend individual counseling as scheduled by my counselor according to my treatment plan.
- I understand that failure to participate in the required counseling services may result in discharge from the program.

By signing below I acknowledge that I understand the Counseling Attendance Agreement and that my lack of participation may result in my discharge.

Inmate Signature

Date

Print Inmate's Name

Date

Substance Abuse Treatment Staff Signature and Title

Date

Attachment D

Department of Correction
Medication-Assisted Treatment Re-Entry Initiative (MATRI)
Consent Form

I, _____, do hereby voluntarily apply and consent to participate in the Medication Assisted Treatment Re-Entry Initiative. I am requesting Vivitrol (Naltrexone extended release injection) Therapy as a treatment for alcohol and opioid dependence. I understand that, as far as possible, precautions will be taken to prevent any complications or ill effects on my health. I further understand that it is my responsibility to tell the Physician/Nurse in the program as much as I can about my health. It is my responsibility to seek medical attention immediately if any reaction occurs to Vivitrol or if any changes occur in my health status. As a participant, I freely and voluntarily agree to adhere to the treatment protocol as follows:

1. I understand that medication alone is not sufficient treatment for managing my substance dependence. After I am released, I agree to participate in the outpatient treatment program offered by the designated community clinic.
2. I understand that Vivitrol (naltrexone extended release injection) is being prescribed as part of a comprehensive treatment plan for my alcohol and/or opiate dependence.
3. I agree to keep, and be on time, for my scheduled appointment at the community clinic. If I cannot keep the appointment, I will call in advance to cancel and reschedule.
4. I agree to have a blood specimen taken for assessment of liver function prior to beginning Vivitrol therapy.
5. I agree to submit to urine drug screenings as required. I understand that this urine toxicology screen shall be conducted by the Department of Correction and that any positive results could result in disciplinary or criminal action.
6. I agree to participate in two (2) verbal assessments measuring my level of motivation and level of risk relating to my substance dependence.
7. I agree to actively participate in individual counseling sessions prior to beginning Vivitrol therapy.
8. I understand that I will be prescribed Naltrexone (the pill form of Vivitrol) for up to three (3) days prior to beginning Vivitrol therapy. The purpose of this trial is to assess for any adverse effects from the medication. I understand that I am to inform the medical staff if I experience any side effects during this time.
9. I understand that I will receive the first injection of Vivitrol therapy approximately one (1) week prior to my release.

Attachment D

10. I understand that Vivitrol is well-tolerated in the recommended doses, but it may cause liver injury when taken in excess or in people who develop liver disease from other causes. If I experience excessive tiredness, unusual bleeding or bruising, pain in upper right part of my stomach that lasts more than a few days, light-colored bowel movements, dark urine, or yellowing of the skin or eyes, I will stop taking Vivitrol immediately and see my medical provider as soon as possible.
11. I agree to take Vivitrol only as directed by the prescriber.
12. I understand that I must inform any medical provider treating me that I am receiving Vivitrol therapy.
13. I attest that I am not using opiates at this time and understand that I cannot use opiates within 10 days of the administration of Naltrexone and Vivitrol.
14. I understand that I should not take Vivitrol if I am pregnant or if I am contemplating pregnancy.
15. I understand that the community clinic offering follow-up treatment can terminate my treatment at any time if I do not comply with treatment guidelines.
16. I understand it is my responsibility to maintain active health insurance coverage, so that I do not have difficulty receiving my Vivitrol injections.
17. I understand that a positive urine drug screen for alcohol and/or opiates, such as heroin, Methadone or Suboxone, may result in discontinuation of Vivitrol therapy, because these drugs may be lethal if taken while on Vivitrol.
18. I agree to sign the Release of Medical Records pursuant to 103 DOC 607 Inmate Medical Records authorizing the release of relevant medical/treatment information to the designated Outpatient Treatment Centers to facilitate in the continuation of my post-release treatment in the community.
19. I understand and agree that violating any of these conditions is grounds for dismissal from participation in the Vivitrol Pre-Release Program.
20. I have received verbal/written information and understand the indications, contraindications, warnings, precautions and adverse reactions pertaining to the Vivitrol injections. The Vivitrol indications, contraindications, warnings, precautions, and adverse reactions to be reviewed by the medical provider with the patient are listed below:

Attachment D

- For the treatment of alcohol dependence in patients who are able to abstain from alcohol in an outpatient setting prior to initiation of treatment with VIVITROL. Patients should not be actively drinking at the time of initial VIVITROL administration.
- For the prevention of relapse to opioid dependence, following opioid detoxification.
- As part of a comprehensive management program that includes psychosocial support.

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WARNINGS AND PRECAUTIONS

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- **Injection Site Reactions:** In some cases, injection site reactions may be very severe. Some cases of injection site reactions required surgical intervention.
- **Precipitation of Opioid Withdrawal:** Opioid-dependent and opioid-using patients, including those being treated for alcohol dependence, should be opioid-free before starting VIVITROL treatment, and should notify healthcare providers of any recent opioid use. An opioid-free duration of a minimum of 7-10 days is recommended for patients to avoid precipitation of opioid withdrawal that may be severe enough to require hospitalization.
- **Hepatotoxicity:** Cases of hepatitis and clinically significant liver dysfunction were observed in association with VIVITROL treatment during the clinical development program and in the post marketing period. Discontinue use of VIVITROL in the event of symptoms or signs of acute hepatitis.
- **Depression and Suicidality:** Monitor patients for the development of depression or suicidal thinking.
- **When Reversal of VIVITROL Blockade Is Required for Pain Management:** In an emergency situation in patients receiving VIVITROL, suggestions for pain management include regional analgesia or use of non-opioid analgesics.

ADVERSE REACTIONS

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WARNING: IF I ATTEMPT TO SELF-ADMINISTER LARGE DOSES OF ALCOHOL, HEROIN OR ANY OTHER NARCOTIC WHILE ON VIVITROL, I MAY DIE OR SUSTAIN SERIOUS INJURY, INCLUDING COMA.

Inmate Signature

Date

I, the undersigned, have defined and fully explained the above information to this individual.

Medical Provider Signature

Date

Nursing staff to review this informed consent again prior to administering the first dose.

Medication Administration Nurse

Date

**Department of Correction
Outpatient Treatment Centers and Catchment Areas**

Intake	Address	Phone Number
Intake Center	Spectrum Health Systems 585 Lincoln Street Worcester, MA	Fax: 508-853-1264
	176 Main Street Southbridge, MA	
	42 Summer Street Pittsfield, MA	
	210 Bear Hill Road Waltham, MA	
	100 Plastow Street Haverhill, MA	
	105 Merrick Street Worcester, MA	
	200 East Main Street Milford, MA	
	68 Franklin Street Framingham, MA	
	40 Spruce Street Leominster, MA	
	1274 Curran Highway North Adams, MA	
	184 Broadway Saugus, MA	
Clinics and Servicing Areas		
Worcester (2 clinics)		
Boylston, W. Boylston, Holden, Paxton, Leicester, Spencer, Auburn, Millbury, Sutton, Grafton, Shrewsbury	Spectrum Health Systems 585 Lincoln Street Worcester, MA	508-854-3320
	Spectrum Health Systems 105 Merrick Street Worcester, MA	508-797-6100
Framingham		
Marlboro, Hudson, Sudbury, Southborough, Westborough, Ashland, Hopkinton, Sherborn, Natick, Wayland, Westin, Stow, Berlin	Spectrum Health Systems 68 Franklin Street Framingham, MA	508-875-5801
Southbridge		

Sturbridge, Holland, Brimfield, Charlton, Oxford, Brookfield, E. Brookfield, Dudley, Webster, Holland, Wales	Spectrum Health Systems 176 Main Street Southbridge, MA	508-765-5940
Milford		
Hopkinton, Holliston, Medway, Millis, Bellingham, Mendon, Hopedale, Upton, Northbridge, Uxbridge, Franklin, Medfield	Spectrum Health Systems 200 East Main Street Milford, MA	508-634-1877
Waltham		
Bedford, Concord, Lincoln, Wayland, Westin, Wellesley, Needham, Newton, Brookline, Watertown, Belmont, Cambridge, Arlington, Lexington, Woburn, Medford	Spectrum Health Systems 210 Bear Hill Road Suite 2203 Waltham, MA	781-290-4970
Pittsfield		
Adams, N. Adams, New Ashford, Savoy, Cheshire, Lanesborough, Hancock, Windsor, Dalton, Hinsdale, Peru, Richmond, Lenox, Washington, W. Stockbridge, Lee, Becket, Middleford	Spectrum Health Systems 42 Summer Street Pittsfield, MA	413-442-0402, Ext. 6300
Haverhill (March 2014)		
Andover, Methuen, Lawrence, Boxford, Topsfield, Danvers, Newbury, W. Newbury, Amesbury, Salisbury, Georgetown, Dracut, Lowell, Tewksbury	Spectrum Health Systems 100 Plaistow Road, Suite B Haverhill, MA	978-373-4985
New Bedford (Non Spectrum)		
Fairhaven, Westport, Dartmouth, Fall River, Taunton, Acushnet, Freetown, Dighton, Berkley, Rehoboth, Swansea, Somerset	Seven Hills Behavioral Health 34 Gifford Street New Bedford, MA	Lee Dalphonse (508-450-2724) ldalphonse@sevenhills.org Referrals: Contact Bonnie Almeida at 774-634-3827
	All Care Wellness Institute 2343 Purchase Street New Bedford, MA	781-436-3352
Boston		
	Boston Medical Center 725 Albany Street Shapiro Building, Suite 5-C Boston, MA 02118	Director: Colleen Labelle P – 617-414-7459 C – 617-797-6712 Referrals: Lexie Bergeron Lexie.pierson@bmc.org P – 617-414-4123

		F – 617-414-4231
	Gavin Foundation 210 Old Colony Avenue S. Boston, MA	O – 617-268-5000 Referrals: Barbara Samick (Fax: 617-268-5008)
Springfield		
	Experience Wellness 80 Congress Street Springfield, MA	P – 413-732-0040 (George. Collins) F – 508-890-0993 (Attn: James Collins)
Hyannis		
	Duffy Health Center	P – 508-771-9599, Ext. 207 Referrals: Contact John Barboza jbarbosa@duffyhealthcenter.org
Brockton		
	Highpoint Treatment Center (Suboxone, Methadone, and Vivাত্রol)	Referrals: Craig Gaspard P – 508-742-4421 F – 508-742-4430
	South Bay Mental Health Clinic 103 Commercial St., 2 nd Fl. Brockton, MA	P – 508-580-4691 All referrals go through Intake Dept – 508-427-5362
Plymouth		
	Highpoint Treatment Center (Suboxone and vivitrol) 2 School Street Plymouth, MA	Contact: Shannon Elliot P – 508-830-1234 Referrals to Maria: 508-830- 1234 F – 508-830-1191
Gloucester		
	North Shore Community, Inc.	978-282-8899
Fall River		
	SSTAR Family Health Care Center 400 Stanley Street Fall River, MA	Cynthia Kenney ckenny@SSTAR.org 508-324-3521
Centerville		
	Gosnold Vivitrol Program 1185 Falmouth Road Centerville, MA	Brittany Fortin P - 508-862-9929 F – 508-862-2499 bfortin@gosnold.org
Buzzards Bay		
	Community Health Center of Cape Cod 123 Waterhouse Road Buzzards Bay, MA	508-759-7920 Angela accepts applications. Applicant <u>must</u> be signed by the inmate. They have a strict

		zero tolerance policy.
Taunton	Highpoint 4 Post Office Square Crocker Building Taunton, MA 02780	Mariene Jaochim or Jennifer Scherer 508-823-5291 Fax: 508-823-5906
Lynn		
	Lynn Community Health Center 280 Union Street Lynn, MA	Vivatrol Nurse: Aubrey 781-586-5601 Main Desk: 781-780-4984
Salem		
	North Shore Community Health 47 Congress Street Salem, MA	978-744-8388
Quincy		
	Nova Psychiatric 1261 Furnace Brook Pkway Quincy, MA	P – 617-479-4545 F – 617-479-4555 Dan Morris, Director
Allston		
	Arbour Counseling Services 14 Fordham Road Allston, MA 02134	617-782-6460
Roxbury		
	Casa Esperanza 245 Eustis Street Roxbury, MA	617-445-1123
Lowell		
	HKD Treatment Options 21 George Street Lowell, MA 01852	978-710-9877
Lawrence		
	34 Haverhill Street Lawrence, MA	978-686-0090
Beverly		
	Lahey Vivitrol Program 800 Cummings Center, Suite 226-T Beverly, MA	P – 978-927-3724
Attleboro		
	South Bay Mental Health 607 Pleasant Street, Suite 115 Attleboro, MA	P – 508-223-4691 F – 508-223-3386

Weymouth		
	South Shore Wellness and Renewal	Daniel – 781-812-2701 C – 781-534-0431
	Weymouth Primary Care and Counseling 884 Washington Street Weymouth, MA	781-812-1643, extension 20
W. Springfield, Springfield, Holyoke, Pittsfield, Greenfield, Athol, Ware, Worcester, New Bedford and Tewksbury	Clean Slate P.O. Box 32 Northampton, MA	Jess Norman P - 413-341-1771 F – 413-584-2427





**Department of Correction
Certification and Request for VIVITROL (380mg/vial Carton)**

Certification

By signing this Certification and Request for Product, the correctional facility* listed below hereby certifies that it is conducting a comprehensive re-entry program that includes the following components:

- The treatment of medically appropriate adults, ages 18 and older, with a diagnosis of opioid dependence and/or alcohol dependence;
- The medication is provided as a voluntary component of the re-entry program and, in all instances, in combination with psychosocial support, such as counseling;
- Education is provided with respect to the risks and benefits of the medication;
- A continuity of care plan is developed for post-release services to promote lasting recovery;
- Inmates/clients participate in pre-and post-release programming;
- Program assessments are conducted in order to evaluate the program’s overall effectiveness;
- Limited to one dose of medication per inmate;
- Product will be handled and stored in accordance with the package labeling for the product;
- The correctional facility may not receive more than 50 samples per calendar year.

The correctional facility and the licensed healthcare practitioner listed below certify that (i) the samples of VIVITROL (manufactured by Alkermes) received under the terms of this program are for the medical needs of patients; (ii) they will not sell, resell, trade, barter, return for credit or seek third party reimbursement for the samples of VIVITROL received under this program; and (iii) the healthcare practitioner is validly licensed and eligible to request product samples received hereunder. Alkermes, in its sole discretion, may discontinue or alter this program at any time.

Request for Product

The licensed healthcare practitioner listed below hereby requests ___ units** of VIVITROL (NDC# 65757-301-01) under the terms of this program, and requests that such samples be sent to the Massachusetts State Office of Pharmacy Services at the “shipping address” below.

IN WITNESS WHEREOF, the correctional facility and the licensed healthcare practitioner have executed and delivered this Certification by its duly authorized representative as of the date listed below.

Correctional Facility Name: _____

Print Full Name: _____

Professional Title: _____

Signature: _____ Date: _____

LICENSED/DISPENSING HEALTHCARE PRACTITIONER: (Print Full Name) _____

Address: _____

State License Number: _____ Professional Designation: _____

Practitioner's Signature: _____ Date: _____

Shipping Address:

STATE OFFICE OF PHARMACY SERVICES

Attention: Donald Rogers, Chief of Pharmacy Phone: (978) 858-2114

Address, City, State, Zip: 365 East Street, Tewksbury, Massachusetts 01876

* The Massachusetts Department of Corrections facilities, taken together, shall constitute one facility for purposes of this per facility annual limit.

** Please order in multiples of 4 units, where possible.



**Department of Correction
Request for Shipment of VIVITROL**

From: Correctional Facility
To: Alkermes, Inc.
Facsimile #: (781) 207-1057
In Re: Alkermes, Inc. Correctional Facility Sampling Program
Massachusetts Department of Correction
Attention: Trade and Corporate Accounts

The Massachusetts Department of Correction facility and the licensed healthcare practitioner identified on the attached Certification and Request for Product (the "Certification Form") hereby request shipment of samples of VIVITROL in the amount, and to the address, listed on the attached Certification Form.

Upon receipt of this document and the attached Certification Form, please proceed to ship product to the shipping address specified thereon.

Attachment: Certification and Request for Product



Department of Correction
Alkermes, Inc. Correctional Facility Sampling Program

Alkermes will offer samples of VIVITROL, free of charge, to the Massachusetts Department of Correction facilities* conducting comprehensive re-entry programs that include the following components:

- The treatment of medically appropriate adults, ages 18 and older, with a diagnosis of opioid dependence and/or alcohol dependence.
- The medication is provided as a voluntary component of the re-entry program and, in all instances, in combination with psychosocial support, such as counseling.
- Education is provided with respect to the risks and benefits of the medication.
- A continuity of care plan is developed for post-release services to promote lasting recovery.
- Inmates/clients participate in pre-and post-release programming.
- Program assessments are conducted in order to evaluate the program's overall effectiveness.
- Limited to one dose per inmate.
- Alkermes will make available up to 50 samples per correctional facility* per calendar year as part of this program. Alkermes, in its sole discretion, may increase this annual limit.
- The correctional facility, the pharmacy receiving the samples, and any other person using the samples will agree not to sell, resell, trade, barter, return for credit or seek third-party reimbursement for such samples.
- Product will be handled and stored in accordance with the package labeling for the product.
- Alkermes, in its sole discretion, may discontinue or alter this program at any time. Alkermes will provide reasonable advance notice in the event of any such alteration or discontinuation.

* All Massachusetts Department of Corrections facilities, taken together, shall constitute one facility for purposes of this per facility annual limit.

Logistics:

- Any correctional facility conducting a comprehensive re-entry program that meets the above criteria and that wishes to request a sample under this program must complete and sign a Certification and Request Form, a copy of which is set forth in Exhibit A, and fax such form to Alkermes using the fax cover page set forth as Exhibit B.



- Upon receipt of these documents in a form satisfactory to Alkermes, Alkermes will ship product to the licensed pharmacy listed in the correctional facility request form. Please allow 3 to 5 business days for delivery of product.

**Department of Correction
Medication Assisted Treatment Re-Entry Initiative (MATRI)
Referral Request Form**

To be completed by Medical Vendor's Discharge Planner

Site/Location: _____ Discharge Planner: _____

Date Submitted: _____

Inmate Name: _____ DOB: ___/___/___

Address: _____

Home Phone: _____ Work/other Phone: _____

Release Date: _____

Parole/Probation Officer (if applicable): _____

Phone: _____

Has inmate received first injection? _____ Date of injection: _____

Type of Insurance: _____

The following documentation will be provided:

- MATRI discharge packet to include lab results, copies of MAR documenting PO and IM doses of Naltrexone / Vivitrol and discharge summary
- Signed Release of Information Form
- Signed counseling agreement

Appointment Scheduled for: _____ @ _____

With: _____

Additional Information: _____

Medical Vendor / Discharge Planner's Signature: _____