I. PURPOSE:
The purpose of Medication Assisted Treatment (MAT) Program is to provide treatment for Persons Under Departmental Control (PUDC) of the NH Department of Correction (NHDOC) diagnosed with opioid use disorders and alcohol use disorders. This is to include treatment while a person under departmental control is housed in a NHDOC Facility, as well as specific pre-release treatment and post-release successful transition to community resources.

II. APPLICABILITY:
To all PUDCs receiving MAT and correctional staff involved in substance use disorder treatment services within the Department of Corrections.

III. POLICY:
This program involves prison-based residential and non-residential substance disorder treatment models in NHDOC Facilities, as well as collaboration and successful transition to community-based treatment resources. The goal of this program is to promote abstinence, harm reduction, and continuity of care, for opioid- and alcohol-addicted persons under departmental control.

IV. DEFINITIONS:
A. Medication Assisted Treatment (MAT) is an evidence-based treatment that uses FDA-approved medications, in combination with counseling and other behavioral therapies, to provide a whole person approach in the treatment of substance use disorders. It is designed to increase adherence, improve outcomes, and assist with long term abstinence and harm reduction.

B. Outpatient Substance Use Treatment Programs are defined as substance use treatment provided in the general prison housing settings, in the outpatient mental health clinic and other transitional housing units.
C. **Modified Residential Substance Use Treatment** is defined as substance use treatment provided in specifically identified treatment units in our prison housing settings (e.g. Focus Unit, Wellness, and Residential Treatment Unit).

D. **Naltrexone** is a non-addictive opioid antagonist that blocks the effects of opioid medications. It also reduces alcohol craving in alcohol dependence.

E. **Vivitrol** is an extended release injectable form of naltrexone.

F. **Buprenorphine** is an oral combination opioid and opioid blocker that largely blocks the euphoria from other narcotics if these are ingested.

G. **Sublocade** is an extended release injectable form of Buprenorphine.

H. **Disulfiram** is an oral medication that inhibits the body from metabolizing alcohol normally, usually causing a toxic reaction when alcohol is consumed, with vomiting, sweating, headache, palpitations and other physical distress resulting almost immediately.

I. **Acamprosate** is an oral medication designed to maintain the chemical balances in the brain that are disrupted by alcoholism, improving recovery.

V. **PROCEDURES:**

A. **Medication Assisted Treatment Training**
   All Substance Use Treatment staff, participating in MAT shall receive training on methods to educate persons under departmental control on the following:
   a. Eligibility Criteria;
   b. Motivational Interviewing
   c. Opioid Epidemic;
   d. Overview of Opioid and Alcohol Dependence;
   e. MAT Treatment foundation, philosophy, and types of Medications used in MAT;
   f. Overview of MAT PPD;
   g. Orientation to approved MAT Clinical Treatment Guidelines, as established in the References Section of this policy.
   h. Tracking of individuals throughout entry, active participation, follow up care in the MAT Program and referral to Re-entry Program Coordinator’s for continuity of care.

B. **Participant Screening/Assessment**
   1. The Ohio Risk Assessment System (ORAS) is administered on all new admissions at the DOC’s reception and diagnostic units. PUDCs who score moderate/high in the Substance Use Domain will be referred by the counselor/case manager to a LADC clinician for further screening of need for both substance use disorder programming as well as MAT Program referral. In addition, referrals for these services may be generated by any clinical staff throughout the PUDC’s incarceration.
   2. All referrals will include a urinalysis facilitated by nursing staff and results documented in the PUDCs electronic health record with triage to the referring LADC. Any positive results identified by nursing will be triaged according to PPD 6.86 Detoxification.
   3. Candidates who are referred and are interested in participating in the Medication-Assisted Treatment Program will be assessed by a licensed alcohol and drug counselor to determine the PUDC’s stage of change, as per the Prochaska Stage of Change Model.
   4. Appropriate referrals will be administered the Drug Abuse Screening Test (DAST), Texas Christian University Drug Screen 11 (TCU5), or others diagnostic/screening tools to assess need. Any PUDC who scores in the moderate or severe range will be recommended to the Department’s residential and/or outpatient substance use treatment program after the completion of the Addictions Severity Index (ASI) affirming the results. A clear diagnosis will be determined and documented in the electronic health record. A multidisciplinary approach will be taken for treatment of any identified coexisting mental health disorders.
5. After review of all available information on the PUDC meeting the assessed level of need, substance use treatment staff shall add a Special Needs code of SUD-MAT in the electronic health records, document in a progress note their recommendations and send an alert in the electronic medical record to the Administrator of Forensic Services and/or the Psychiatric Medical Director regarding the recommendations. The reviewing administrator will then determine final recommendations for treatment. Participation for inclusion will include:
   a. Meets current Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria for a substance use disorder
   c. Assessed as possessing a commitment to achieving demonstrable harm reduction, with a goal of total abstinence from illegal substances as well as misuse of prescribed medications and alcohol.

6. A treatment plan will be developed by the LADAC in coordination with the psychiatric or medical provider assigned and documented into the electronic health record for all PUDCs who enter the MAT Program. This will include documentation on: substance use disorder diagnosis, current stage of change, motivational strategies to be utilized appropriate for identified stage of change, integration into current psycho-social substance use treatment services, as well as identification and treatment plan integration for treatment of other identified mental health diagnoses. If there is an existing treatment plan, substance use treatment and MAT will have separate identifiable goals as part of the plan. Eligibility for inclusion at the screening stage will include:

7. Medical Evaluation
   a. Medical Provider Staff will meet with the PUDC to identify and diagnose any medical contraindications to MAT. If there are medical contraindications, these will be addressed and continued referral, when appropriate, will be made to the Administrator of Forensic Services or Psychiatric Medical Director. A psychiatric or medical provider will be assigned by the Chief Medical Officer (CMO) or Psychiatric Medical Director (PMD) to provide the medication interventions of the MAT, and will follow the established guidelines and seek consultation with the CMO or PMD. The assigned psychiatric or medical provider will also coordinate treatment with the assigned clinical staff for treatment integration as necessary.
   b. Informed consent will be obtained, and any MAT will be prescribed according to clinical guidelines approved by the CMO, psychiatric medical director and Director of Medical and Forensic Services, in accordance with established National MAT guidelines concerning oral naltrexone, injectable naltrexone, oral buprenorphine, injectable buprenorphine. (Attachments A through D). Informed consent for additional or other MAT medication interventions will be done with the medication informed consent process in the EHR.
   c. When the treating psychiatric or medical provider begins the medication assisted treatment through initiating a prescription, they will notify the Administrator of Forensic Services and the psychiatric medical director that MAT has been initiated.
   d. The CMO and/or PMD will quarterly review a random sample of MAT patients to ensure adherence to the clinical guidelines as referenced in the reference section, as appropriate to the medication intervention section, and report findings in the Quality Review (QI) meeting on a quarterly basis.
8. Concurrent Psychosocial Treatment and Drug Screens

1. The PUDC shall be required to attend all scheduled substance use counseling sessions/groups during the course of MAT which shall be no less than one clinical encounter every two weeks.

2. The PUDC will be required to attend all MAT provider appointments, which shall be no less than quarterly.

3. The PUDC will acknowledge these requirements in 1 and 2 above by signing the MAT Counseling Attendance Agreement (Attachment A).

4. The counseling/group sessions with LADC Professional staff shall focus on continued assessment of motivational state, commitment to treatment and supportive/reinforcing counseling to strengthen commitment to recovery.

5. The MAT provider appointments shall focus on assessment of general and mental health status, side effects, review of abstinence through review of CORIS drug screens, review of medically ordered drug screens, assessment of physiologic responses to treatment (cravings, triggers), as well as documentation of stage of change.

6. Substance use treatment staff may discharge a PUDC from the program if he/she fails to meaningfully participate in recommended programming after consultation with the Administrator of Forensic Services and/or the Psychiatric Medical Director and through documentation of justification.

7. Urine or saliva scan drug screens will be performed in accordance with approved MAT clinical guidelines, the PUDC’s treatment plans, and as clinically or behaviorally indicated.

8. The nursing staff shall coordinate the collection of the urine drug screen. LADC staff will collect saliva scans. Both nursing and LADC staff will document in progress notes the action of doing the screens and outcome of the screen in the EHR.

9. Any missed medication nursing staff will notify the LADC so an intervention can be scheduled at the next possible time.

10. The treatment team for this population may include counselor/case managers, LADC staff, mental health clinicians, psychiatric and medical staff, and other disciplines as indicated by the individual case.

11. Security staff will be consulted as to behavior and unit observations.

12. All treatment plans will be updated every three (6) months.

13. A substance use disorder (SUD) alert will be added in the EHR to ensure continuity of care when leaving departmental custody.

14. Discharge planning and/or release planning will focus on a continuum of care with outside resources. The person under departmental control counselor/case manager shall make arrangements as indicated below. This will include, but not limited to the following referrals and interventions:
   a. Referral to the State Targeted Response (STR) Program Coordinator
   b. Referral for continued MAT services, as clinically appropriate and recommended by the current MAT provider
   c. Referral to mental health treatment resources as clinically appropriate and recommended by mental health treatment staff for the purpose of integrated care with above treatment modalities

REFERENCES:

Standards for the Administration of Correctional Agencies
Second Edition Standards
Standards for Adult Correctional Institutions
Fourth Edition Standards

Standards for Adult Probation and Parole Field Services
Third Edition Standards

Standards for Adult Community Residential Services
Fourth Edition Standards

National Commission on Correctional Healthcare
STANDARDS FOR HEALTH SERVICES IN PRISONS: 2008

P-D-02: MEDICATION SERVICES (essential)
P-G-08: OFFENDERS WITH ALCOHOL AND OTHER DRUG PROBLEMS (important)

Other

Medicaid Coverage and Financing of Medications to Treat Alcohol and Opioid Use Disorders

Medication-Assisted Treatment, Substance Abuse and Mental Health Services Administration (SAMHSA)
https://www.samhsa.gov/medication-assisted-treatment

Guidance Document on Best Practices: Key Components for delivering Community Based Medication Assisted Treatment Services for Opioid Use Disorders in New Hampshire, second edition

ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use

MATTIS/lb
I, ______________, do hereby voluntarily apply and consent to participate in the Naltrexone Injection at Discharge 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 clinical staff 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.
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 Information 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 NIDI 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:

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 include:**

○ Patients receiving opioid analgesics.
○ Patients with current physiologic opioid dependence.
○ Patients in acute opioid withdrawal.

Revised: 8/12/2016
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 ≥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.

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.

<table>
<thead>
<tr>
<th>PUDC Signature</th>
<th>Date</th>
</tr>
</thead>
</table>
I, the undersigned, have defined and fully explained the above information to this individual.

<table>
<thead>
<tr>
<th>Medical Provider Signature</th>
<th>Date</th>
</tr>
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</table>
Revised: 8/12/2016

7
Nursing staff to review this informed consent again prior to administering the first dose.

Medication Administration Nurse ___________________________ Date ___________________________

Naltrexone Bracelet Provided- □ Yes □ No, Why? ________________________________

Revised: 8/12/2016
Department of Correction (Sample)

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: ________________________________ Phone: ________________________________

Address, City, State, Zip: ________________________________

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* The New Hampshire 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.

Revised: 8/12/2016
Department of Correction (Sample)
Request for Shipment of VIVITROL

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

The New Hampshire Department of Corrections 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

Revised: 8/12/2016
Vivitrol Treatment Release and Referral Request Form

PUDC Name: Click here to enter text.
ID Number: Click here to enter text.
Date of Birth: Click here to enter text.

☐ NHSPM  ☐ NHCFW  ☐ NCF  ☐ SPU  ☐ RTU
☐ COMMUNITY CORRECTIONS SITE:
☐ North End  ☐ TWC  ☐ Calumet  ☐ Shea Farm

To be completed by Counselor Case Manager, and then submitted to Administrator of Forensic Services or Psychiatric Medical Director

Date Submitted: ____________________________

Patient Discharge Contact/Address Information:

<table>
<thead>
<tr>
<th>Phone</th>
<th>Address</th>
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<tbody>
<tr>
<td>☐ Home:</td>
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<td>☐ Cell:</td>
<td>☐</td>
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<tr>
<td>☐ Work:</td>
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</tbody>
</table>

Parole/Probation Officer (if applicable): ____________________________ Phone: ____________________________

Has the PUDC received first injection? ☐ Yes, Date of injection: ___ / ___ / _______ ☐ No

Insurance Company

☐ Medicaid
☐ NI Health Protection Program
☐ Private Insurer:
Insurance ID #: ____________________________

The following documentation will be provided to Community Provider:

- NIDI 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

Established Community Provider Follow-Up:

Appointment Scheduled for: ___ / ___ / _______ @ _______ AM/PM

With: ____________________________

Additional Information: ____________________________

Counselor Case Manager’s Signature: ____________________________

Revised: 8/12/2016
Participant Screening

Persons Under Departmental Control (PUDC) who are identified will be referred according to PPD 6.08 (Medication Assisted Treatment – Substance Use Disorders) and approved by the Administrator for Forensic Services or Psychiatric Medical Director who will arrange a mental health evaluation. A Licensed Drug and Alcohol Counselor will ask them to sign the MAT Counseling Attendance Agreement (See PPD 6.08 Attachment A).

Mental Health Evaluation

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

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

- acute psychiatric distress (such as psychosis, mania, depression, etc.)
- suicidal thoughts or plans
- significant cognitive limitations resulting in an inability to provide consent, in which case guardianship may be considered

If any clinical contraindications are identified, the qualified mental health professional shall treat the patient as clinically indicated and notify the Administrator of Forensic Services or the Psychiatric Medical Director.

If the patient has no mental health contraindications, the mental health professional will notify the Chief Medical Officer who will arrange a medical evaluation.

Medical Evaluation

The Health Services Unit medical director, physician, nurse practitioner or physician’s assistant shall meet with the PUDC approximately thirty (30) to sixty (60) days prior to a defined release date. At this time, the PUDC shall receive additional information about the NIDI program. The medical provider and PUDC shall discuss whether Vivitrol treatment is appropriate, obtain informed consent, and write appropriate orders.

Medical providers evaluation patients for Vivitrol treatment will review the medical record, take a focused history and physical exam, and ensure that liver function tests have been performed within the past six (6) months. They will determine the expected release date in order to time the initiation of the oral naltrexone challenge and the first Vivitrol injection. They will insure the patient has given informed consent and signed the NIDI Informed Consent Form (Attachment A).

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

PUDCs receiving Vivtrol shall receive the injection of 380mg IM one time, approximately seven (7) days prior to their release.
Vivitrol Medication Guidelines:

The following represent indications as identified by the manufacturer 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 as identified by the manufacturer 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, polyactide-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 (as identified by the manufacturer)

- 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 ≥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 ≥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 PUDC to participate in the program. Evaluation shall be completed within sixty (60) days of release.

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

Monitoring and Pre-Release Treatment
The licensed mental health counselor will coordinate care amongst the counselor/care manager, medical provider, nursing staff, mental health clinicians and other staff as needed, to ensure the patient’s treatment plan goals are completed.

The patient will meet with the substance abuse counselor at least once after receiving the Vivitrol and prior to release, in order to review the release plan.

Post Release Treatment
The Counselor Case manager is responsible for post release treatment coordination. Tasks will include at a minimum completing Attachment C (Referral Form) and:

• Complete all forms for insurance coverage after release

Revised: 8/12/2016
• Scheduling a primary care visit within 28 days of the scheduled Vivitrol injection

• Release of Information for medical and mental health records to a receiving Outpatient Treatment Center which has agreed to collaborate with NH DOC

Nursing Procedure

Once the first dose of Naltrexone is administered, the nurse shall provide the PUDC with a Vivitrol ID bracelet and instruct the PUDC 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 PUDC in the event of an emergency. Administration of medication shall be documented in the PUDC’s medical record in the Medication Administration Record (MAR).

Pharmacy Procedure

Vivitrol medication shall be stored according to manufacturers’ instructions and per DOC Policy in the DOC Pharmacy. Vivitrol shall be maintained on count within the Sharps Log Book (as each dosing kit contains a hypodermic needle). Upon receiving an order for Vivitrol, the Pharmacy will ensure adequate stock is available for the planned date of injection, and if it is not, request a supply from the manufacturer using both the Certification and Request for Vivitrol form and the Request for Shipment form stored in the Pharmacy (Sample Attached as Attachment B ).