

NH DEPARTMENT OF CORRECTIONS POLICY AND PROCEDURE DIRECTIVE	CHAPTER <u>Health Services</u> STATEMENT NUMBER <u>6.08</u>
SUBJECT: Medication Assisted Treatment – Substance Use Disorders PROPONENT: <u>Paula Mattis, Administrative Dir.</u> <i>Name/Title</i> <u>Medical/Forensic Services 271-3707</u> <i>Office Phone #</i>	EFFECTIVE DATE <u>12/4/2015</u> REVIEW DATE <u>1/1/2018</u> SUPERSEDES PPD# <u>NEW</u> DATED _____
ISSUING OFFICER: _____ <i>William Wrenn, Commissioner</i>	DIRECTOR'S INITIALS _____ DATE _____ APPENDIX ATTACHED: YES _____ NO _____
REFERENCE NO: See reference section on last page of PPD.	

I. **PURPOSE:**

The purpose of Medication Assisted Treatment (MAT) is to provide pre-release treatment and post-release referral for opioid-addicted and alcohol-addicted offenders under the control and custody of the NH Department of Correction (DOC).

II. **APPLICABILITY:**

To all offenders receiving MAT and correctional staff involved in substance use treatment services within the Department of Corrections.

III. **POLICY:**

This program involves prison-based residential and non-residential substance abuse treatment and collaboration with community based clinics to provide aftercare treatment. The goal of this initiative is to increase and improve substance abuse treatment response among people under the control and custody of Department of Corrections.

IV. **DEFINITIONS:**

- A. **Medication-Assisted Treatment (MAT)** is an evidence-based substance use treatment approach made possible through prescribing and monitoring medications, along with other recovery supports, e.g., counseling and peer support.
- B. **Non-residential Substance Use Treatment Program** is defined as substance use treatment provided in our general prison housing setting 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).

V. PROCEDURES:

A. Medication Assisted Treatment Training

All Substance Use Treatment Staff, participating in MAT shall receive training on the methods to educate offenders on the following:

- Eligibility Criteria;
- Opioid Epidemic;
- Overview of Opioid and Alcohol Dependence;
- Understanding Types of Medications used in MAT;
- Overview of MAT PPD; and
- Orientation to approved MAT Clinical Treatment Guidelines.

B. Participant Screening

1. The Ohio Risk Assessment System (ORAS) is administered on all new admissions at the DOC's reception and diagnostic units. Offenders who score moderate/high in the Substance Use Domain will be referred by the counselor/case manager to behavioral health for further screening of need. In addition, referrals may be generated by any clinical staff throughout the offender's incarceration.
2. Referrals will be entered into the offender management system (CORIS) and cleared by the Administrator of Forensic Services or designee.
3. Candidates who are referred by a clinician and who are interested in participating in medication-assisted treatment (MAT) will be assessed by a licensed alcohol and drug counselor to determine the offender's motivation to change as part of the screening process to determine eligibility.
4. All referrals will be administered the Drug Abuse Screening Test (DAST). Any offender who scores 11 or greater shall be recommended to the Department's residential and/or non-residential substance use treatment program after the completion of an Addictions Severity Index (ASI) affirming the DAST results.
5. After treatment plan development and implementation, offenders who remain engaged in treatment will be assessed for participation in MAT.
6. Eligibility for inclusion at the screening stage will include:
 - a. Meets current Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria for a substance use disorder
 - b. Willingness and demonstrated ability for the prior 6 months to engage productively in psychosocial interventions for substance use treatment
 - c. Demonstrated inability of psychosocial interventions alone to control addictive behaviors
 - d. Assessed as possessing a commitment to achieving total abstinence from illegal substances and the desire to misuse prescribed medications and alcohol as clinically indicated
7. After review of all available information on the offender meeting the requirements, Substance Use Treatment Staff shall document in a progress note their recommendations. The substance use treatment staff will consult with the Administrator of Forensic Services and/or the Psychiatric Medical Director regarding the recommendations. The reviewing administrator will then make the referral to mental health for an evaluation, as recommended.
8. No offender will be coerced or pressured into receiving treatment in the MAT.

C. Mental Health Evaluation

1. The referral will be assigned by the reviewing Administrator to a mental health professional who will conduct a formal evaluation of the offender to determine whether there are acute mental health contraindications before proceeding to a medical evaluation for MAT.
2. Mental health contraindications may include, but shall not be limited to:
 - a. acute psychiatric distress (such as psychosis, mania, depression, etc.);

- b. suicidal thoughts or plans; or
 - c. significant cognitive limitations resulting in an inability to provide consent (guardians should be consulted in these cases)
3. If any clinical contraindications are identified, the mental health professional shall treat or make treatment recommendations for the offender such as a referral to psychiatry, psychological testing, or placement under observation per PPD 6.10 Suicide Prevention and Intervention. The mental health professional shall notify the Administrator of Forensic Services and/or the Psychiatric Medical Director of these outcomes. The offender may be reassessed when psychiatrically stable.
 4. Offenders having no mental health contraindications shall be referred by the mental health professional to medical staff for a comprehensive medical evaluation. This referral will be performed by contacting the Chief Medical Officer directly.
- D. Medical Evaluation
1. The Chief Medical Officer (CMO) or designee shall meet with the offender and review risks and benefits of proposed MAT.
 2. Informed consent will be obtained, and any MAT will be prescribed according to clinical guidelines approved by the CMO and Director of Medical and Forensic Services.
 3. The CMO will establish clinical guidelines for use of specific MAT therapies.
 4. The medical provider assigned by the CMO will follow the established guidelines and seek consultation with the CMO as necessary.
 5. When the treating medical provider begins the medication assisted treatment through initiating a prescription, they will notify the Administrator of Forensic Services that MAT has been initiated so additional treatments can be administered (e.g. group therapy, individual counseling, etc.).
- E. Concurrent Psychosocial Treatment and Drug Screens
1. The offender shall be required to attend all scheduled substance use counseling sessions during the course of MAT which shall be no less than one clinical encounter per month.
 2. The offender will acknowledge this requirement by signing the MAT Counseling Attendance Agreement (Attachment A).
 3. These counseling sessions shall focus on assessment of motivational state, commitment to treatment and supportive/reinforcing counseling to strengthen commitment to recovery.
 4. Substance Use Treatment Staff may discharge an offender 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.
 5. Urine or saliva scan drug screens will be performed in accordance with approved MAT clinical guidelines, the offender's treatment plans, and as clinically indicated.
 6. The nursing staff shall coordinate the collection of the urine drug screen. Licensed Drug and Alcohol counselors will collect saliva scans.
 7. An updated treatment plan will be developed when the medical provider notifies the Administrator of Forensic Services that a prescription for MAT has been written.
 8. The treatment plan will include goals and objectives to address treatment needs by clinical staff, case management, psychiatry, and any other collaborating services.
 9. The treatment team for this population may include counselor/case managers, clinicians, medical staff, and other disciplines as indicated by the individual case.
 10. Security staff will be consulted as to behavior and unit observations.
 11. All plans will be updated every three (3) months.
 12. Discharge planning and/or release planning will include monitoring of compliance with MAT and psychosocial substance treatment. The offender's counselor/case manager shall make arrangements for insurance coverage and community prescribers for MAT as appropriate.

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
<http://store.samhsa.gov/shin/content//SMA14-4854/SMA14-4854.pdf>

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

<http://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/national-practice-guideline.pdf?sfvrsn=22>

MATTIS/jc

 New Hampshire Department of Corrections Division of Medical & Forensic Services	MEDICATION ASSISTED TREATMENT COUNSELING ATTENDANCE AGREEMENT	
	Patient Name:	Click here to enter text.
	ID Number:	Click here to enter text.
	Date of Birth:	Click here to enter text.
<input type="checkbox"/> NHSPM <input type="checkbox"/> NHSPW <input type="checkbox"/> NCF <input type="checkbox"/> SPU/RTU <input type="checkbox"/> COMMUNITY CORRECTIONS SITE: _____		

Individual sessions and group counseling are equally important and you must attend both during your treatment. It is a program requirement.

- I agree to attend weekly group counseling as scheduled according to my treatment plan.
- 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 MAT program.

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

Offender Signature	Date
Print Offender's Name	Date
Substance Use Treatment Staff Signature and Title	Date



New Hampshire
Department of Corrections
Division of Medical & Forensic Services

Naltrexone Oral Medication Treatment Consent Form

Patient Name: [Click here to enter text.](#)

ID Number: [Click here to enter text.](#)

Date of Birth: [Click here to enter text.](#)

Location:

- NHSPM**
 NHSPW
 NCF
 SPU/RTU
 COMMUNITY CORRECTIONS

I, _____, do hereby voluntarily apply and consent to participate in the Naltrexone Oral Augmentation Program. I am requesting Naltrexone Therapy as a treatment for alcohol and/or 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 Provider/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 Naltrexone 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. I agree to participate in the treatment program offered by the substance use clinicians.
2. I understand that naltrexone 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 with the substance use clinicians. If I cannot keep the appointment, I will notify in advance to cancel and reschedule.
4. I agree to have a blood specimen taken for assessment of liver function prior to beginning naltrexone therapy.
5. I agree to submit to urine and/or blood draw drug screenings as required. I understand that this toxicology screen shall be conducted by the Department of Corrections and that any positive results could result in disciplinary or criminal action.
6. I agree to actively participate in individual counseling sessions prior to beginning naltrexone therapy.
7. I understand that naltrexone 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 naltrexone immediately and see my medical provider and report to sick call as soon as possible.
8. I agree to take naltrexone only as directed by the prescriber.
9. I understand that I must inform any medical provider treating me that I am receiving naltrexone therapy.
10. 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.
11. I understand that I should not take naltrexone if I am pregnant or if I am contemplating pregnancy.
12. I understand that a positive drug screen for alcohol and/or opiates, such as heroin, Methadone or Suboxone, may result in discontinuation of naltrexone therapy, because these drugs may be lethal if taken while on naltrexone.

13. I understand and agree that violating any of these conditions is grounds for dismissal from participation in the NOA program.
20. I have received verbal/written information and understand the indications, contraindications, warnings, precautions and adverse reactions pertaining to the use of naltrexone. The indications, contraindications, warnings, precautions, and adverse reactions to be reviewed by the medical provider with the patient are listed below:

Indications for Naltrexone reviewed with my provider include:

- 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 naltrexone. Patients should not be actively drinking at the time of initial naltrexone 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 naltrexone 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 had a positive urine screen for opioids within 10 days.
- Any individual who has had hypersensitivity to naltrexone

WARNINGS AND PRECAUTIONS

- Vulnerability to Opioid Overdose: Following naltrexone treatment opioid tolerance is reduced from pre-treatment baseline, and patients are vulnerable to potentially fatal overdose at the end of a dosing interval, after missing a dose, or after discontinuing naltrexone treatment. Attempts to overcome blockade may also lead to fatal overdose (death).
- Precipitation of Opioid Withdrawal: Opioid-dependent and opioid-using patients, including those being treated for alcohol dependence, should be opioid-free before starting naltrexone 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 naltrexone treatment during the clinical development program and in the post marketing period. The provider will discontinue use of naltrexone 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 naltrexone Blockade Is Required for Pain Management: In an emergency situation in patients receiving naltrexone, suggestions for pain management include regional analgesia or use of non-opioid analgesics.

ADVERSE REACTIONS

The adverse events seen most frequently in association with Naltrexone therapy for alcohol dependence (i.e., those occurring in $\geq 5\%$ and at least twice as frequently with naltrexone than placebo) include nausea, vomiting, 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 NALTREXONE, 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



NH Department of Corrections: Division of Medical & Forensic Services

Subject: Naltrexone Oral Augmentation Clinical Guidelines		
Site: All	Date Issued: 9/1/2015	Date Review: 9/1/2016
Issued By: Dr. Jeff Fetter, CMO & Director Paula Mattis		

Purpose

The purpose of the Naltrexone Oral Augmentation (NOA) is to provide pre-release treatment for opioid-addicted and alcohol-addicted inmates under the care and custody of the Department of Corrections (DOC). This program involves prison-based substance use treatment on specialized substance abuse units, mental health units, close custody, and general population. The goal is to improve the efficacy of intensive outpatient substance use treatment among incarcerated patients.

Goal

The goal of this initiative is to increase and improve substance use treatment response among incarcerated patients.

Definitions

Medication-Assisted Treatment (MAT): A substance use treatment approach made possible by provider-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.

Substance Use Treatment Staff: Staff employed by DOC to provide substance use treatment.

Target Population

The target population consists of NH DOC inmates incarcerated within NHSP/M, NCF, SPU/RTU or NHSP/W who are enrolled in substance use treatment who meet the inclusion criteria and have a documented opioid or alcohol dependence.

Participant Screening

Inmates who are identified will be referred according to PPD 6.08 (Medication Assisted Treatment) 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

The Administrator of Forensic Services and/or the Chief Psychiatric Medical Director will refer an offender to a mental health professional who shall conduct a formal evaluation of the inmate to determine whether there are acute mental health contraindications before 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

- significant cognitive limitations resulting in an inability to provide consent, in which case guardianship may be considered

If any clinical contraindications are identified, the 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 physician or nurse practitioner shall meet with the inmate and provide additional educational and orientation information about the NOA program. After discussing the NOA program with the inmate, the medical provider shall determine whether naltrexone treatment is appropriate, obtain informed consent, and write appropriate orders.

Medical providers evaluating patients for naltrexone 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.

Naltrexone Medication Guidelines:

The following represent indications for use of Naltrexone 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 naltrexone. Patients should not be actively drinking at the time of initial naltrexone 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 Naltrexone 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 a positive urine screen for opioids within 10 days.
- Patients who have previously exhibited hypersensitivity to naltrexone

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

WARNINGS AND PRECAUTIONS

- **Vulnerability to Opioid Overdose:** Following naltrexone 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 naltrexone treatment. Attempts to overcome blockade may also lead to fatal overdose.
- **Precipitation of Opioid Withdrawal:** Opioid-dependent and opioid-using patients, including those being treated for alcohol dependence, should be opioid-free before starting naltrexone 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 naltrexone treatment during the clinical development program and in the post marketing period. Providers are to discontinue use of naltrexone 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 naltrexone blockade is required for Pain Management:** In an emergency situation in patients receiving naltrexone, suggestions for pain management include regional analgesia or use of non-opioid analgesics.

ADVERSE REACTIONS

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

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

To report SUSPECTED ADVERSE REACTIONS, contact 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

- Naltrexone pharmacokinetics has not been evaluated in subjects with severe hepatic impairment.
- Caution is recommended in administering naltrexone to patients with moderate to severe renal impairment. Dose adjustment may be needed.

The medical evaluation/testing shall include an assessment of overall health and liver function tests. Screening shall be completed within 1 week of target start date.

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

The Chief Medical Officer or designee shall notify the Substance Use Treatment Staff as well as the pharmacy if the inmate has been determined to be eligible for the program and has executed all required consent forms. Also, the provider will write for the naltrexone prescription to start on the target date, as a Nurse Administered Medication.

Evaluation

After receiving the first dose of naltrexone, the patient will be given monthly urine or blood toxicology screens administered and supervised by mental health staff or nursing staff for a period of six months. The results of these tests and their medication administration records (MARs) shall be kept in the patient's medical record and copies will be forwarded to the Administrator of Forensic Services.

Record Keeping

The Administrator of Forensic Services and Chief Psychiatric Medical Director will maintain a list of each patient entered into the NOA program. The records of their urine or blood toxicology screens and naltrexone compliance as documented in MAR copies shall also be kept.

Naltrexone Medication Protocol

Patients will be prescribed Naltrexone 50 mg daily for the duration of the program. Dose may be adjusted to 25mg per day if hepatotoxicity is present.


Termination

At the end of six months, the patient will meet with the on-site medical provider, who will order liver function tests to review with the patient. The medical provider will also communicate with

the Substance Use Treatment clinician working with the patient. If the patient has experienced significant benefit from naltrexone, it may be continued.

Medication Administration

Medications shall be administered by licensed nursing staff.

 <p>New Hampshire Department of Corrections Division of Medical & Forensic Services</p>	Naltrexone Oral Medication Treatment Consent Form	
	Patient Name:	Click here to enter text.
	ID Number:	Click here to enter text.
	Date of Birth:	Click here to enter text.
<input type="checkbox"/> NHSPM <input type="checkbox"/> NHSPW <input type="checkbox"/> NCF <input type="checkbox"/> SPU/RTU <input type="checkbox"/> COMMUNITY CORRECTIONS SITE: <input type="checkbox"/> North End <input type="checkbox"/> TWC <input type="checkbox"/> Calumet <input type="checkbox"/> Shea Farm		

I, _____, do hereby voluntarily apply and consent to participate in the Naltrexone Oral Augmentation Program. I am requesting Naltrexone Therapy as a treatment for alcohol and/or 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 Provider/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 Naltrexone 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. I agree to participate in the treatment program offered by the substance use clinicians.
2. I understand that naltrexone 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 with the substance use clinicians. If I cannot keep the appointment, I will notify in advance to cancel and reschedule.
4. I agree to have a blood specimen taken for assessment of liver function prior to beginning naltrexone therapy.
5. I agree to submit to urine and/or blood draw drug screenings as required. I understand that this toxicology screen shall be conducted by the Department of Corrections and that any positive results could result in disciplinary or criminal action.
6. I agree to actively participate in individual counseling sessions prior to beginning naltrexone therapy.

Attachment A

7. I understand that naltrexone 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 naltrexone immediately and see my medical provider and report to sick call as soon as possible.
8. I agree to take naltrexone only as directed by the prescriber.
9. I understand that I must inform any medical provider treating me that I am receiving naltrexone therapy.
10. 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.
11. I understand that I should not take naltrexone if I am pregnant or if I am contemplating pregnancy.
12. I understand that a positive drug screen for alcohol and/or opiates, such as heroin, Methadone or Suboxone, may result in discontinuation of naltrexone therapy, because these drugs may be lethal if taken while on naltrexone.
13. I understand and agree that violating any of these conditions is grounds for dismissal from participation in the NOA program.
20. I have received verbal/written information and understand the indications, contraindications, warnings, precautions and adverse reactions pertaining to the use of naltrexone. The indications, contraindications, warnings, precautions, and adverse reactions to be reviewed by the medical provider with the patient are listed below:

Indications for Naltrexone reviewed with my provider include:

- 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 naltrexone. Patients should not be actively drinking at the time of initial naltrexone 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 naltrexone 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 had a positive urine screen for opioids within 10 days.
- Any individual who has had hypersensitivity to naltrexone

WARNINGS AND PRECAUTIONS

- **Vulnerability to Opioid Overdose:** Following naltrexone treatment opioid tolerance is reduced from pre-treatment baseline, and patients are vulnerable to potentially fatal overdose at the end of a dosing interval, after missing a dose, or after discontinuing naltrexone treatment. Attempts to overcome blockade may also lead to fatal overdose (death).
- **Precipitation of Opioid Withdrawal:** Opioid-dependent and opioid-using patients, including those being treated for alcohol dependence, should be opioid-free before starting naltrexone 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 naltrexone treatment during the clinical development program and in the post marketing period. The provider will discontinue use of naltrexone 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 naltrexone Blockade Is Required for Pain Management:** In an emergency situation in patients receiving naltrexone, suggestions for pain management include regional analgesia or use of non-opioid analgesics.

ADVERSE REACTIONS

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

