

**HEALTH AND HUMAN SERVICES COMMISSION  
CONTRACT NO. 2018-050035  
AMENDMENT NO. 1**

The **HEALTH AND HUMAN SERVICES COMMISSION** (“HHSC” or “System Agency”) and **NORTH TEXAS BEHAVIORAL HEALTH AUTHORITY** (“Contractor”), who are collectively referred to herein as the “Parties,” to that certain Office Based Opioid Treatment (OBOT) contract effective September 1, 2017, and denominated HHSC Contract No. 2018-050035 (“Contract”), now desire to amend the Contract.

**WHEREAS**, the parties desire to revise the Contract’s attachments, to add Texas Targeted Opioid Response (TTOR) funds and related language to allow for the expansion of services; and

**WHEREAS**, this revision will result in an increase to the Total Contract Value.

**NOW, THEREFORE**, the Parties hereby amend and modify the Contract as follows:

1. **INTERLOCAL COOPERATION CONTRACT, SECTION V. CONTRACT AMOUNT AND PAYMENT FOR SERVICES**, is hereby amended to add \$189,070.00 to the Contract for a total not to exceed \$278,130.00.
2. **ATTACHMENT A, STATEMENT OF WORK REVISED DECEMBER 2017**, will supplement the existing **ATTACHMENT A, STATEMENT OF WORK**. The revised **ATTACHMENT A, STATEMENT OF WORK** includes revisions as follows:
  - a. The term “Local Government” has been replaced with “Contractor” throughout the contract document.
  - b. The term “office based opioid treatment” (OBOT) has been replaced with “office based treatment” (OBT) in the following sections:
    - I. **PURPOSE**
    - II. **LOCAL GOVERNMENT RESPONSIBILITIES**
      - Section E - previously referred to as Section C
      - Section G - previously referred to as Section E
      - Section J.1. - previously referred to as Section H.1.
      - Section J.2. - previously referred to as Section H.2.
      - Section K.1. - previously referred to as Section I.2.
      - Section O.1. - previously referred to as Section M.1.
      - Section P - previously referred to as Section N
      - Section S - previously referred to as Section Q
  - c. **SECTION I. PURPOSE**, to add the following language:

“Office-based treatment (OBT) services consist of office-based opioid treatment (OBOT) through the provision of buprenorphine and/or office-based addiction

treatment (OBAT) through the provision of extended-release injectable Naltrexone.”

d. Section II. CONTRACTOR RESPONSIBILITIES (previously Local Government Responsibilities), language revisions and additions are as follows:

1. Letter A, regarding contractor’s medication, counseling and behavioral therapy.
2. Letter C, regarding the utilization and adherence to Texas HHSC Department of State Health Services (DSHS) / Department of Aging and Disability (DADS) Drug Formulary requirements.
3. Letter D, regarding the utilization of Attachment C “Guidelines for the use of the Extended-Release Injectable Naltrexone.”
4. Letter E (previously Letter C), regarding medical professional licensing and certifications and DATA 2000 Waiver.
5. Letter I (previously Letter G), regarding medical professionals that may notify Contractor of ineffective services for the purpose of alternative referrals.
6. Letter J.2. regarding MOU requirement with the Department of Family and Protective Services local regional offices
7. Letter J.4. regarding clarification of applicable medical staff to ensure OBT approved clients receive evaluations and extended-release injectable Naltrexone and the contents of the MOU.
8. Letter J.4.b.i., regarding Admission Notes clarification for OBT;
9. Letter K.2. (previously Letter I.2.), regarding the expansion of services to include buprenorphine and/or extended-release injectable Naltrexone to treat moderate to severe opioid use disorder.
10. Letter S.8. (previously Letter Q.8.), regarding the list all the required CMBHS components.

e. SECTION VI. INVOICE AND PAYMENT is hereby revised as follows:

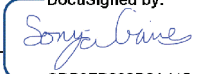
1. Letter K. **SYSTEM AGENCY SHARE: \$278,130.00**
3. **ATTACHMENT B, PROGRAM SERVICES AND UNIT RATES** is hereby deleted in its entirety and replaced with the addition of **ATTACHMENT B, PROGRAM SERVICES AND UNIT RATES - REVISED DECEMBER 2017**.
4. This Amendment No. 1 shall be effective as of the last date signed below.
5. Except as amended and modified by this Amendment No. 1, all terms and conditions of the Contract, as amended, shall remain in full force and effect.
6. Any further revisions to the Contract shall be by written agreement of the Parties.

**SIGNATURE PAGE FOLLOWS**

**SIGNATURE PAGE FOR AMENDMENT NO. 1  
HHSC CONTRACT NO. 2018-050035**

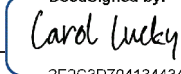
**HEALTH AND HUMAN SERVICES COMMISSION**

**NORTH TEXAS BEHAVIORAL HEALTH  
AUTHORITY**

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Sonja Gaines

Assoc. Commissioner IDD/BH

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**BY:**

**NAME:** Carol Lucky

**TITLE:** CEO

**DATE OF EXECUTION:** March 7, 2018

**DATE OF EXECUTION:** March 6, 2018

The following attachments to System Agency Contract No. 2018-050035 are hereby incorporated as follows:

- ATTACHMENT A: STATEMENT OF WORK – Revised December 2017**
- ATTACHMENT B: PROGRAM SERVICES AND UNIT RATES – Revised December 2017**
- ATTACHMENT C: GUIDELINES FOR THE USE OF EXTENDED-RELEASE  
INJECTABLE NALTREXONE**

## **ATTACHMENT A STATEMENT OF WORK**

### **I. PURPOSE**

To provide office-based treatment (OBT) services to alleviate the adverse physiological effects of withdrawal from the use of opioids as required to meet the individualized needs of the client. Contractor will expend funds to provide opioid treatment for opioid use disorders in combination with providing counseling and behavioral therapies. Office-based treatment (OBT) services consist of office-based opioid treatment (OBOT) through the provision of buprenorphine and/or office-based addiction treatment (OBAT) through the provision of extended-release injectable naltrexone.

### **TARGET POPULATION**

Adult Texas residents who meet financial criteria for Health and Human Services Commission (HHSC or System Agency)-funded substance use disorder (SUD) services and have met the Diagnostic and Statistical Manual of Mental Disorders criteria for a moderate or severe opioid use disorder.

### **II. CONTRACTOR RESPONSIBILITIES**

Contractor will:

- A. Provide medications approved for office based treatment of opioid use disorders along with providing counseling and behavioral therapy.
- B. Maintain, throughout the term of the Contract, the organization's certification and licensure compliance with applicable statutes, guidelines, and regulations related to outpatient treatment services and office-based treatment as adopted by System Agency, the Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Treatment (CSAT), and the Drug Enforcement Agency (DEA).
- C. Utilize and adhere to the most current Texas Health and Human Services Commission Department of State Health Services (DSHS) / Department of Aging and Disability Services Drug Formulary requirements, which includes the *Reserve Drug Criteria* and *Audit Criteria* also referenced in the *Interim Formulary Updates* and located at <http://dshs.texas.gov/mhprograms/Formulary.shtm>.
- D. Utilize the System Agency Attachment C "Guidelines for the use of the Extended-Release Injectable Naltrexone" as applicable.
- E. Ensure Physician(s), Physician's Assistant(s) and Nurse Practitioner(s) providing OBOT services maintain their license to practice medicine and ensure the license remains in good standing for the duration of the Contract. Contractor will ensure the Physician(s), Physician's Assistant(s), and Nurse Practitioner(s) achieve the following:
  - 1. Obtain the Drug Addiction Treatment Act (DATA) of 2000 Waiver registration for dispensing buprenorphine as defined in the Controlled Substances Act.
  - 2. Ensure the Physician(s), Physician's Assistant(s), and Nurse Practitioner(s) DATA 2000 Waiver remains in good standing throughout the duration of this Contract.

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- F. Ensure that medical and clinical staff providing OBT services maintain compliance with rules adopted by System Agency related to medication and counseling treatment, and records management as required by SAMHSA and the Code of Federal Regulations (CFR).
- G. Ensure that clinical staff providing direct OBT services maintain their professional license and are in compliance with professional rules adopted by System Agency as stated in Title 25 of the Texas Administrative Code (TAC), Chapter 140 Health Professions Regulation, Subchapter I. Licensed Chemical Dependency Counselors (LCDCs) throughout the term of the Contract.
- H. Establish a comprehensive resource network made up of community, health, and social service agencies serving or having interest in the target population. Contractor will engage and collaborate with community resources through written agreements defining the collaborative relationships, including:
  - 1. System Agency-funded treatment, prevention, intervention, mental health and co-occurring psychiatric and substance use disorders (COPSD) providers;
  - 2. Local Mental Health Authorities (LMHAs), and/or Local Behavioral Health Authorities (LBHAs) within Contractor's Health & Human Services (HHS) Region and service area including System Agency-funded providers or System Agency-funded Outreach, Screening, Assessment, and Referral (OSR) providers; and
  - 3. Local and regional health departments, local Federally Qualified Health Centers (FQHCs) and other primary care centers.
- I. Coordinate with local OSR for conducting screening and determining financial eligibility functions for medication and counseling services prior to service delivery. Contractor will continue to collaborate with the OSR to ensure that services are appropriate and effective. If the Physician, Physician Assistant, or Nurse Practitioner notifies the Contractor that services are not effective, the client(s) is referred to OSR for referral to another Medication Assisted Therapy provider, via agreement, for appropriate services.
- J. Maintain Memoranda of Understanding (MOU), during the term of this contract, with the following:
  - 1. Regional OSR to provide screening and financial eligibility services, including:
    - a. Coordinating with the regional OSR to conduct screening and financial eligibility in the Clinical Management for Behavioral Health Services (CMBHS) system before the potential System Agency-funded client is able to receive authorization for OBT;
    - b. Maintain copies of the required MOUs; and
    - c. Provide recurring client financial eligibility on each System Agency-funded client every 180 days.
  - 2. Department of Family and Protective Services (DFPS) local regional offices;

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3. A DATA 2000 Waived physician, physician assistant, or nurse practitioner to provide patient evaluation and prescribing of buprenorphine. The agreement will include the following:
    - a. Referral process to and from LMHAs/LBHAs and prescribing physician;
    - b. Communication and transfer of records to and from the physician to the licensed outpatient staff. Records may include, but are not limited to, the following:
      - i. Admission notes from the physician with criteria met for office-based treatment (OBT);
      - ii. Urinalysis test/results;
      - iii. Medication orders to include milligrams, frequency, and duration; and
      - iv. Level of care determinations and frequency of outpatient counseling services.
    - c. Clinical data entry in CMBHS electronic medical record; and
    - d. Diversion control.
  4. Physician, Physician Assistant, and Nurse Practitioner ensures OBT approved client(s) receive evaluations, and prescribes and administers extended-release injectable Naltrexone. The MOU will include the following:
    - a. Referral process to and from LMHAs/LBHAs and administering physician;
    - b. Communication and transfer of records to and from the physician to the licensed outpatient staff. Records may include, but are not limited to, the following:
      - i. Admission notes from the physician with criteria met for office-based treatment (OBT);
      - ii. Urinalysis test/results;
      - iii. Medication orders;
      - iv. Level of care determinations and frequency of outpatient counseling services.
    - c. Clinical data entry in CMBHS electronic medical record; and
  5. A pharmacy that details the process of reimbursement for Buprenorphine provision;
- K. Provide Medication and Counseling Treatment:
1. Provide OBT through System Agency licensed SUD outpatient treatment provider including Adult Treatment (TRA) outpatient and/or Adult Specialized Female treatment (TRF) outpatient services.
  2. Services will include individual and group counseling services, specialized female services when applicable, and behavioral therapies as well as medication, to include buprenorphine and/or extended-release injectable Naltrexone, to treat moderate to severe opioid use disorder. Contractor will refer all OBT clients to the prescribing and administrating physician and if applicable, referrals to the contracted pharmacy for the provision of buprenorphine.
- L. Provide Overdose Prevention and Reversal Education:
1. Provide overdose prevention education to clients on Contractor's waiting list.
  2. Provide overdose prevention education to all clients prior to discharge, including clients who received the overdose prevention education prior to admission;

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3. Provide general overdose prevention and reversal education will be provided to all clients as a part of treatment education requirements to include education on how to access and administer naloxone;
  4. Conduct overdose prevention activities with clients with opioid use disorders and those clients that use drugs intravenously to include:
    - a. Education on overdose prevention and risk reduction strategies;
    - b. Education about and referral to System Agency-funded HIV Outreach services for clients with IV drug use history;
    - c. Education about and referral to System Agency-funded Pregnant Postpartum Intervention (PPI) services for pregnant clients, postpartum clients, and clients involved with Child Protective Services (CPS);
    - d. Referral to local community resources that work to reduce harm associated with high risk behaviors associated with drug use; and
    - e. For detailed guidance please refer to SAMHSA's Opioid Overdose Prevention Tool Kit found at:  
<http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit/SMA13-4742>.
- M. Immediately admit pregnant women, injecting drug users, individuals at high risk for overdose, and individuals referred by the DFPS presenting for treatment.
1. If unable to provide immediate admission to these populations, the Contractor will notify System Agency program services staff so that assistance can be provided that ensures referral to an alternate provider for immediate admission (within 72 hours).
  2. Contractor will have policies and procedures that conform with System Agency's definition for wait list and interim services.
  3. The Contractor will report available capacity and waiting list information Monday through Friday through CMBHS and comply with procedures specified by System Agency.
- N. Provide or arrange for interim services including screening for tuberculosis, hepatitis B and C, sexually transmitted diseases (STDs), and Human Immunodeficiency Virus (HIV) and document in CMBHS.
- O. Document medication and counseling services, including, but not limited to:
1. OBT-related activities and services in CMBHS. This information will assist System Agency in determining the number of clients served and the OBT-related services and activities provided by the Contractor;
  2. The informed consent form and upload the informed consent form to an administrative note and record clinical documentation in the client's CMBHS record, e.g. diagnostic tests such as the Clinical Institute Withdrawal Assessment or Beck Depression Inventory, physician orders, etc.;
  3. In CMBHS counseling services, medication provision, and overdose prevention education within seven business days of service delivery. Contractor will use the funds and associated billing codes provided through this Contract to directly provide the adult outpatient services, while only subcontracting physician and pharmacy services;



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4. Physician orders and medication provision;
  5. Outpatient SUD counseling services including individual, group, and psychoeducation;
  6. The needs of the client using the CMBHS assessment tool;
  7. The treatment plan including discharge criteria, and discharge plan; and
  8. If a client is discharged, Contractor will identify a specific physician or authorized healthcare professional, as appropriate, to whom the client is being discharged. The name, address, and telephone number of the provider caring for the client after discharge are to be recorded in the client's CMBHS record.
- P. Ensure staff providing OBT and/or counseling services maintain privacy and security controls related to client confidential information.
- Q. Ensure that clinical staff providing direct services have the training and expertise in:
1. Motivational Enhancement Therapy (MET) or Motivational Interviewing (MI) techniques;
  2. Overdose prevention;
  3. Medication Assisted Treatment (MAT) Advocacy;
  4. Co-Occurring Psychiatric & Substance Use Disorders (COPSD);
  5. Trauma, abuse and neglect, violence, Post-Traumatic Stress Disorder (PTSD), and related conditions;
  6. Medicaid, Temporary Aid to Needy Families (TANF), and Children's Health Insurance Plan (CHIP) eligibility;
  7. Seeking Safety curriculum;
  8. Fetal Alcohol Spectrum Disorders (FASD);
  9. Cultural Competency, specifically including but not limited to gender and sexual identity and orientation; and
  10. Substance Use and Child Welfare by the National Center for Substance Abuse and Child Welfare, Tutorial 1: Understanding Child Welfare and the Dependency Court: A Guide for Substance Abuse Treatment Professionals.
- R. Conference Calls:  
Ensure Contractor's program directors and/or medical directors participate in monthly conference calls as scheduled by System Agency to address programmatic, documentation, or testing issues.
- S. Submission Schedule, Reporting, and CMBHS Requirements  
Contractor will:
1. Use the System Agency CMBHS system for documenting OBT-related activities, services, and testing;
  2. Designate a Security Administrator and a back-up Security Administrator. The Security Administrator is required to implement and maintain a system for management of user accounts/user roles to ensure that all the CMBHS user accounts are current;
  3. Establish and maintain a security policy that ensures adequate system security and protection of confidential information;

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4. Notify the CMBHS Help-desk within ten (10) business days of any change to the designated Security Administrator or the back-up Security Administrator;
5. Ensure that access to CMBHS is restricted to only authorized users. Contractor will, within 24 hours, remove access to users who are no longer authorized to have access to secure data;
6. In addition to CMBHS Helpdesk notification, Contractor will submit a signed CMBHS Security Attestation Form and a list of Contractor's employees, contracted labor and subcontractors authorized to have access to secure data;
7. Submit the CMBHS Security Attestation Form electronically biannually as designated by System Agency to the designated Substance Abuse mailbox;
8. Use the CMBHS components and/or functionality, in accordance with System Agency instructions. Contractor will use the updated components and/or functionality as directed by System Agency. Contractor's duty to submit documents survives the termination or expiration of this Contract;
9. Contractor will meet required number of clients served per year based on funded amount; and
10. Contractor will submit all documents identified in this Contract to the designated System Agency Substance Abuse mailbox (SubstanceAbuse.Contracts@dshs.texas.gov) by the required due date.

Document Name	Due Date
CMBHS Security Attestation Form and List of Authorized Users	15 <sup>th</sup> day after Contract start date
Executed MOU with Physician(s)	By 60th day after Contract Start date
Executed MOU with Pharmacy	By 60th day after Contract Start date
Closeout documents	Due 45 days after state fiscal year end date

\*If the Due Date is on a weekend or holiday, submission is due on the next business day.

**III. PERFORMANCE MEASURES**

System Agency will monitor the Contractor's performance of the requirements in Attachment A and compliance with the Contract's terms and conditions.

Deliverables	Delivery Date
CMBHS documentation	Ongoing
Client Satisfaction Survey	Ongoing

**OUTCOME MEASURES:**

Contractor will ensure that the majority of clients achieve sustained remission from the symptoms of their substance abuse disorder as indicated in the table below.

OBT - Adult Treatment (Male/Female)	
Number served	Formula
Percent of clients whose length of stay is at least one year	42%

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Percent abstinent (includes individuals taking medication as prescribed) at discharge	45%
Percent discharging to stable housing	55%
Percent admitted to/involved in ongoing treatment/recovery episode (supportive residential, outpatient, 12-step groups, and other recovery support services)	55%
Percent with no arrest since admission	90%
Percent employed at discharge	60%
<b>OBT – Adult Treatment (Specialized Female)</b>	
Number served	Formula
Percent whose length of stay is at least one year	42%
Percent abstinent (includes individuals taking medication as prescribed) at discharge	40%
Percent discharging to stable housing	50%
Percent admitted to/involved in ongoing treatment/recovery episode (supportive residential, outpatient, 12-step groups, and other recovery support services)	90%
Percent with no arrest since admission	90%
Percent employed at discharge	45%

**IV. PROGRAM SERVICE AREA**

Contractor will deliver services or activities to clients from the following counties:

Dallas County, Ellis County, Hunt County, Kaufman County, Navarro County, Rockwall County

**V. ELIGIBLE POPULATION**

Male & Female

**VI. INVOICE AND PAYMENT**

- A. Contractor will submit billings to the System Agency through CMBHS monthly. Contractor will be reimbursed for services provided under this Contract utilizing the established unit rates.
- B. Upon receipt of Notice to Proceed from System Agency, Contractor will receive Texas Targeted Opioid Response (TTOR) funds to provide the office-based dispensing opioid and counseling services detailed in this Statement of Work. Contractor will be responsible for tracking the TTOR expenditures from other sources of funding.
- C. Contractor will demonstrate their capacity to bill insurance and Medicaid for those clients with insurance coverage. Funds under the Contract can only be used as payment of last

**ATTACHMENT A  
STATEMENT OF WORK**

resort which means that other applicable reimbursement resources such as Medicaid or other third-party payers will be billed first.

- D. Contractor will operate within the funded capacity indicated in this Contract for the duration of the Contract term. Submitted claims in excess of the Contractor's stated funded capacity will be approved for payment based on availability of funds, and contingent upon approval of a subsequent amendment.
- E. System Agency, at its sole discretion, will adjust the funded capacity of this Contract based on Contractor's performance and/or other criteria determined by System Agency, and contingent on availability of funds. Treatment Capacity Worksheet can be found on the Substance Abuse website: <http://www.dshs.texas.gov/sa/For-Substance-Abuse-Contractors.aspx>.
- F. Except as indicated by the CMBHS financial eligibility assessment, Contractor will accept reimbursement or payment from the System Agency as payment in full for services or goods provided to clients or participants, and Contractor will not seek additional reimbursement or payment for services or goods, to include benefits received from federal, state, or local sources, from clients or participants.
- G. Contractor will be paid monthly in accordance with the Program Services and Unit Rates Table in **Attachment B** of this Contract.
- H. PAYMENT METHOD: Fee-For-Service
- I. SOURCE OF FUNDING: State; 93.788
- J. DUNS NUMBER: 078377909
- K. SYSTEM AGENCY SHARE: \$278,130.00
- L. Contractor may access the Transactions List report in CMBHS to identify the amount of federal funds allocated to this award for each transaction. The Catalog of Federal Domestic Assistance (CFDA) number for the Texas Targeted Opioid Treatment (TTOR) Grant is 93.788. The CFDA number is identified in the CMBHS Transactions List report.
- M. SOLICITATION DOCUMENT: Exempt - Governmental Entity
- N. All invoices will reference the Purchase Order Number.

**ATTACHMENT B - PROGRAM SERVICES AND UNIT RATES REVISED****Program Attachment: 2018-050035-001****Contractor: North Texas Behavioral Health Authority**

- A. System Agency-funded capacity is defined as the stated number of clients that will be concurrently served as determined by this Contract.
- B. Service Types with no associated amount will be paid from the preceding Service Type with an associated Amount.
- C. Total reimbursements will not exceed \$278,130.00 for the period from September 1, 2017, through August 31, 2018.
- D. Clinic Numbers must be approved by the Assigned Contract Manager before billing can occur. Clinic Change Request form is located at: <http://www.dshs.texas.gov/sa/For-Substance-Abuse-Contractors.aspx>.
- E. The following treatment services and rates are approved and shall be delivered through this contract:

Service Type	Number Served	Capacity	Unit Rate	Amount
<b>Office-Based Opioid Treatment</b>				<b>\$278,130.00</b>
Adult OBOT Services	22	22	\$24.00	
Specialized Female OBOT Services	9	9	\$26.00	
<b>Office-Based Addiction Treatment</b>				
Extended-release Injectable Naltrexone	0	0	\$978.67	
Monthly supportive services, Per injection	0	0	\$235.00	

## ATTACHMENT C GUIDELINES FOR THE USE OF EXTENDED-RELEASE INJECTABLE NALTREXONE

### A. TREATMENT CONSIDERATIONS

The medical literature supports the use of opioid substitution therapy as first-line treatment for patients with opioid use disorders. Substance Abuse and Mental Health Services Administration (SAMHSA), American Society of Addiction Medicine (ASAM) and the Veterans Administration (VA) indicate that extended-release injectable naltrexone may be an acceptable alternative to opioid substitution therapy in selected patients.

Careful patient selection is essential in order to maximize the chance of long-term treatment success and to minimize the risk of adverse outcomes including relapse and overdose. Several organizations, including SAMHSA<sup>i</sup>, VA<sup>ii</sup>, ASAM<sup>iii</sup> and Providers' Clinical Support System for Medication Assisted Treatment (PCSS-MAT)<sup>iv</sup> have published guidance on which patients may be the best candidates for treatment with extended-release injectable naltrexone. Patient selection criteria based on that guidance and on a review of the other available literature are included below. These criteria are intended as guidelines and should not be considered a substitute for the clinical judgment of the treating physician.

The optimal duration of treatment with extended-release injectable naltrexone has not been determined. Most studies have been based on 6 months of medication, but data on long-term outcomes is lacking. The decision to discontinue medication must be determined on a case-by-case basis and in conjunction with patient preference, taking into account the relative risks and benefits.

As with other forms of medication-assisted treatment (MAT), extended-release injectable naltrexone must only be used as part of a comprehensive program of treatment that includes counseling and behavioral therapy. Patients should be encouraged to participate in recovery-related activities in addition to formal counseling.

### B. PHYSICIAN EDUCATION REQUIREMENTS

Prior to initiation of treatment with extended-release injectable naltrexone, the ordering physician must gain a thorough understanding of the use of this medication in the treatment of patients with opioid use disorder. The treating physician must:

1. Become familiar with the published guidelines for the use of this medication, such as those by SAMHSA, ASAM and the VA;
2. Become familiar with and follow the Food & Drug Administration (FDA) prescribing information, REMS and manufacturer's recommendations regarding the appropriate use and administration of the medication;
3. Become familiar with and follow the Texas Health and Human Services Commission Texas Department of State Health Services (DSHS) / Department of Aging and Disability Services Drug Formulary<sup>v</sup>, which includes the *Reserve Drug Criteria* and *Audit Criteria* also referenced in the *Interim Formulary Updates* and located at <http://dshs.texas.gov/mhprograms/Formulary.shtm>.<sup>vi</sup>

**ATTACHMENT C**  
**GUIDELINES FOR THE USE OF EXTENDED-RELEASE INJECTABLE**  
**NALTREXONE**

4. In addition to the resources previously mentioned, the physician may wish to access continuing medical education (CME) such as that offered by PCSS-MAT<sup>vii</sup> at <http://pcssmat.org/category/module/naltrexone/>.

**C. PATIENT SELECTION**

To be considered a candidate for treatment with extended-release injectable naltrexone, a patient must meet all of the following screening requirements:

1. Have an FDA indication;
2. Not have a contraindication;
3. Be fully detoxified and verified abstinent from all opioids;
4. Be at significant risk for relapse;
5. Be willing and able to participate in ongoing care and follow-up;
6. Be non-pregnant, not intending to become pregnant and using a reliable form of contraception.

Those patients meeting the following additional criteria may then be considered appropriate candidates for the use of extended-release injectable naltrexone:

1. Have considered and rejected agonist treatment due to one or more of the following reasons:
  - a. Treatment failure with prior agonist maintenance;
  - b. Not interested in agonist maintenance;
  - c. Not able to access agonist maintenance.
2. Be highly motivated and committed to maintaining abstinence in the opinion of the patient's treatment providers and as evidenced by:
  - a. regular attendance at and participation in group and/or individual counseling;
  - b. appropriate behaviors in the treatment setting;
  - c. no positive drug screens.
3. Be actively engaged in recovery-related activities, e.g. peer supported groups such as 12-step, SMART, etc.
4. Have a less severe form of opioid use disorder based on route of administration and/or duration, level and pattern of use
5. Have no history of relapse or have a history of long periods of abstinence between relapses.
6. Have good social supports and a stable home environment.
7. Be psychiatrically stable.

Patients that meet any of the following criteria are likely better served by treatment with agonist maintenance:

1. Advanced liver disease;
2. History of opioid overdose(s);
3. Limited social supports (e.g. homeless, unstable lives);
4. History of psychiatric illness that worsened after previous detoxifications;
5. Heavy marijuana use (due to increased risk of psychosis);
6. Chronic pain requiring opioid medications.

## ATTACHMENT C GUIDELINES FOR THE USE OF EXTENDED-RELEASE INJECTABLE NALTREXONE

### D. INFORMED CONSENT & INITIATION OF TREATMENT

It is the responsibility of the ordering physician to ensure that the patient is fully informed about all available treatment alternatives, along with the risks and potential benefits associated with each alternative<sup>viii</sup>. SAMHSA has published a guide entitled *Decisions in Recovery: Treatment for Opioid Use Disorder Handbook*<sup>ix</sup> that may be of assistance to patients in making treatment choices, but such materials are intended to supplement rather than replace the discussion between physician and patient.

Out of respect for the patient's autonomy, counseling must be given in a non-directive fashion, occur face-to-face and provide an opportunity for the patient to ask questions prior to initiation of treatment.

Prior to initiation of treatment with extended-release injectable naltrexone, the physician must:

1. Inform the patient of all options for medical treatment of opioid use disorder, including:
  - a. methadone and buprenorphine for long-term maintenance;
  - b. medication-assisted detoxification; and
  - c. post-detoxification control of craving and other symptoms.
2. Ensure that the patient is an appropriate candidate for the use of the medication, in accordance with the selection criteria above, national guidelines and best practices;
3. Inform the patient of all risks associated with use of the medication as outlined in the FDA prescribing information, including:
  - a. Vulnerability to opioid overdose
    - i. following discontinuation of the medication
    - ii. during attempts to overcome the medication's blockade effect
  - b. Precipitation of opioid withdrawal
  - c. Injection site reactions
  - d. Hepatotoxicity
  - e. Depression & Suicidality
  - f. Potential issues with acute pain management
  - g. Eosinophilic pneumonia
  - h. Hypersensitivity reactions
4. Ensure that the patient is opioid free for a sufficient period of time to avoid precipitation of acute withdrawal, as evidenced by patient self-report, drug screening and a naloxone challenge test.

### E. Ongoing Treatment and Follow-up

Patients must be followed no less than weekly for the first 4 weeks, then no less than monthly until 1 month after last injection. Post-treatment surveillance must include patient contacts every month for 3 months, then every 3 months for an additional 12 months.

Face-to-face counseling must occur at a minimum of once monthly to coincide with injections, with additional visits and / or telephone contacts as deemed appropriate by the provider.



**ATTACHMENT C**  
**GUIDELINES FOR THE USE OF EXTENDED-RELEASE INJECTABLE**  
**NALTREXONE**

F. Data Collection Requirements

In order to assess safety and long-term outcomes, HHSC requires certain data to be collected for patients undergoing treatment with extended-release injectable naltrexone. Details of data collection requirements will be at the discretion of HHSC and a data collection form will be provided.

G. REFERENCES

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<sup>i</sup> Clinical Use of Extended-Release Naltrexone in the Treatment of Opioid Use Disorder: A Brief Guide

<https://store.samhsa.gov/shin/content//SMA14-4892R/SMA14-4892R.pdf>

<sup>ii</sup> VA/DoD Clinical Practice Guidelines: Management of Substance Use Disorder (SUD) (2015)

<https://www.healthquality.va.gov/guidelines/MH/sud/>

<sup>iii</sup> The ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction involving Opioid Use <https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf>

<sup>iv</sup> PCSS-MAT Training Resource Page including multiple applicable publications

<http://pcssmat.org/opioid-resources/medication-assisted-treatment-for-opioid-addiction/>

<sup>v</sup> Texas Health and Human Services Commission Texas Department of State Health Services (DSHS) / Department of Aging and Disability Services Drug Formulary which includes the *Reserve Drug Criteria* and *Audit Criteria* and Guidelines also referenced in the *Interim Formulary Updates*, can be found at: <http://dshs.texas.gov/mhprograms/Formulary.shtm>

<sup>vi</sup> PCSS-MAT Training CME modules <http://pcssmat.org/category/module/naltrexone/>

<sup>vii</sup> AMA Code of Medical Ethics, Chapter 2.1: Informed Consent & Shared Decision Making

<https://www.ama-assn.org/delivering-care/ama-code-medical-ethics>

<sup>viii</sup> Decisions in Recovery: Treatment for Opioid Use Disorder Handbook

<https://store.samhsa.gov/shin/content/SMA16-4993/SMA16-4993.pdf>