

**HEALTH AND HUMAN SERVICES COMMISSION
CONTRACT NO. 2017-050004 -002
AMENDMENT NO. 2**

The **HEALTH AND HUMAN SERVICES COMMISSION** (“HHSC” OR “SYSTEM AGENCY”) and **METHADONE CLINIC OF EAST TEXAS, LLC.** (“Contractor”), who are collectively referred to herein as the “Parties,” to that certain Treatment - Adult Opioid Treatment Services (TRA-OTS) Contract effective January 1, 2017, and denominated HHSC Contract No. 2017-050004 (“Contract”), as amended, now desire to further amend the Contract.

WHEREAS, the Parties desire to revise the Contract’s attachments to add Texas Targeted Opioid Response (TTOR) funds; revise related language to allow for the expansion of services; and add System Agency “Guidelines for the Use of Extended-Release Injectable Naltrexone”; and

WHEREAS, the revision will result in an increase in the funding amount; revised number served and capacity; and an increase in the Total Contract Value.

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

1. The estimated Total Contract Value for the five-year term of the contract will increase to **\$3,822,439.00**.
2. **ATTACHMENT B – PROGRAM SERVICES AND UNIT RATES** of the Contract, is hereby supplemented and replaced with **ATTACHMENT B – PROGRAM SERVICES AND UNIT RATES – REVISED JANUARY 2018**, which includes the following:
 - a. The FY18 funding amount was revised to reflect the FY 2018 TTOR funding increase in the amount of **\$129,428.00**, no additional match is required.

System Agency Share:	\$885,944.00
Contractor Share (Match):	\$0.00
Total:	\$885,944.00
 - b. The TTOR funding increase breakdown and dates by which services must be provided and funds must be expended.
 - c. The annual funding amounts, required match, totals, and CFDA numbers associated with the funding sources for this contract.
 - d. Applicable items from Sections V.H. through V.N. of **ATTACHMENT A--STATEMENT OF WORK** were moved to **ATTACHMENT B**.
3. The **ATTACHMENT A--STATEMENT OF WORK – REVISED JANUARY 2018**, will supplement the existing **ATTACHMENT A – STATEMENT OF WORK**, and includes revisions as follows:
 - a. Updated the Substance Abuse mailbox address to SubstanceAbuse.Contracts@dshs.texas.gov.

- b. **SECTION I. STATEMENT OF WORK** was changed to **I. PURPOSE**. Language was added to more clearly define the medications dispensed, and how it is used in treatment.
 - c. **SECTION II. CONTRACTOR RESPONSIBILITIES** was updated to include the following additions and revisions:
 - i. Section II.A. added language to clarify the approved medications, treatment population, and to include the types of counseling and behavior therapy.
 - ii. Section II.C. regarding rule compliance, added Chapter 140, Subchapter I- Counseling Licensure, and removed Chapter 441 General Provisions.
 - 1. The title for 42 CFR, part 8 was specified.
 - 2. The most current version of the Drug Formulary requirements was added.
 - 3. In Section II.C.4., the System Agency “Guidelines for the use of Extended-Release Injectable Naltrexone” was added.
 - Section II.I. “Other Support Services (One-time funds-Refer to Attachment B) was added.
 - Section II.K. (formerly II.J.) added language to clarify the types of medications that the Contractor may deliver to a client.
 - Section II.L. (formerly II.K.) 10 was added regarding administration of medication prior to discharge.
 - Section II.L. (formerly II.K.) 12 was added regarding the training and expertise of clinical staff providing direct services.
 - Section II.N. (formerly II.M.) revised language on staff that participate in monthly conference calls.
 - Section II.O. (formerly II.N.) added item #3 regarding collecting data and outcomes.
 - d. An Outcome Measures table was added to **SECTION III. PERFORMANCE**.
 - e. **SECTION IV. PROGRAM SERVICE AREA** was moved to **ATTACHMENT A-1**.
 - f. **SECTION V. INVOICE AND PAYMENT** was changed to **SECTION IV.**, and was updated to include the following changes:
 - Added the following language to IV.B. (formerly V.B.), “Reimbursement from System Agency will be considered payment in full. Additional charges may not be collected from state-funded clients.”
4. **ATTACHMENT A-1 – STATEMENT OF WORK SUPPLEMENTAL** is being added, with duplicate information being removed in the **ATTACHMENT A--STATEMENT OF WORK – REVISED JANUARY 2018**.
5. Added SYSTEM AGENCY “**GUIDELINES FOR THE USE OF EXTENDED-RELEASE INJECTABLE NALTREXONE.**”
6. This Amendment No. 2 shall be effective as of January 1, 2018.


7. Except as amended and modified by this Amendment No. 2, all terms and conditions of the Contract, as amended, shall remain in full force and effect.
8. Any further revisions to the Contract shall be by written agreement of the Parties.

SIGNATURE PAGE FOLLOWS

**SIGNATURE PAGE FOR AMENDMENT NO. 2
HHSC CONTRACT NO. 2017-050004-002**

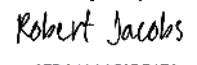
**TEXAS HEALTH AND HUMAN SERVICES
COMMISSION**

METHADONE CLINIC OF EAST TEXAS, LLC.

DocuSigned by:

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Charles Smith

Executive Commissioner

DocuSigned by:

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BY:

NAME: Robert Jacobs

TITLE: Program Director

DATE OF EXECUTION: May 14, 2018

DATE OF EXECUTION: May 3, 2018

**THE FOLLOWING ATTACHMENTS ARE ATTACHED AND INCORPORATED AS
PART OF THE CONTRACT:**

ATTACHMENT A – STATEMENT OF WORK – REVISED JANUARY 2018

ATTACHMENT A-1 – STATEMENT OF WORK SUPPLEMENTAL

ATTACHMENT B – PROGRAM SERVICES AND UNIT RATES – REVISED JANUARY 2018

“GUIDELINES FOR THE USE OF EXTENDED-RELEASE INJECTABLE NALTREXONE”

**ATTACHMENT A
STATEMENT OF WORK
REVISED JANUARY 2018**

I. PURPOSE

To provide opioid treatment services to adults (TRA-OTS) 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 administer and dispense medications for the treatment of moderate or severe opioid use disorder along with providing counseling and behavioral therapy. Funds will also be utilized to expand and integrate communicable disease testing, immunizations, and chronic disease prevention, and treatment for comorbid conditions such as abscesses due to injection drug use, Hepatitis C, and/or co-occurring psychiatric disorders within the context of OTS in order to provide clients with an opportunity to improve their health and the quality of their overall lives while also obtaining help for their substance use disorder.

TARGET POPULATION

Adult Texas residents who meet financial criteria for System Agency-funded substance use disorder 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. Expend funds under the Contract to administer and dispense medications approved for the treatment of moderate or severe opioid use disorders in combination with providing counseling and behavioral therapy to include other supportive services to sustain recovery, change potential self-destructive behaviors and employ techniques to address motivation and engagement.
- B. Maintain, throughout the term of the Contract, the organization's certification and licensure compliance with applicable statutes, guidelines, and regulations related to opioid treatment services 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. Maintain the organization's compliance with rules adopted by System Agency related to providing OTS to the target population as stated in Title 25 of the Texas Administrative Code (TAC) and Code of Federal Regulations (CFR) throughout the term of the contract.
 - 1. Title 25 of the Texas Administrative Code (TAC)
 - a. Chapter 140, Subchapter I – Counseling Licensure;
 - b. Chapter 229, Subchapter J – Minimum Standards for Narcotic Treatment Programs; and
 - c. Chapter 442 - Investigations and Hearings.

2. Federal Guidelines for Opioid Treatment Programs; 42 CFR, part 8, Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction; Final Rule.
 3. Contractor will 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 (DADS) 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>.
 4. Contractor will utilize the System Agency “Guidelines for the Use of Extended-Release injectable naltrexone” as applicable.
- D. Ensure that Contractor’s staff providing direct OTS maintain their professional license and compliance with the rules adopted by the 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.
- E. 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:
1. System Agency-funded treatment, prevention, intervention, mental health, co-occurring psychiatric, and substance use disorders (COPSD) providers.
 2. Local Mental Health Authorities (LMHAs) and Local Behavioral Health Authorities (LBHAs) within Contractor’s Health & Human Services (HHS) Region and service area including System Agency-funded Outreach, Screening, Assessment, and Referral (OSAR) providers.
 3. Local and regional health departments, local Federally Qualified Health Centers (FQHC’s), and other primary care centers.
- F. Coordinate with local OSAR for conducting screening and determining financial eligibility functions prior to service delivery.
- G. Establish Memorandum of Understanding (MOU) with the regional OSAR to provide screening and financial eligibility services. Contractor will maintain copies of the required MOUs and make them available to the System Agency for review upon request. The MOU must include and describe, but is not limited to, the following:
1. Coordinate with the regional OSAR to conduct screening and financial eligibility functions in the System Agency Clinical Management for Behavioral Health Services (CMBHS) system before the potential System Agency-funded client can receive authorization for OTS; and
 2. Ensure the MOU states that client financial eligibility on each System Agency funded client is conducted every 180 days.
- H. Medication-Assisted Treatment (MAT) and Counseling

Provide System Agency licensed Medication-Assisted Treatment that includes individual and group counseling services and behavioral therapies to adults in conjunction with medications approved for the treatment of moderate or severe opioid use disorders

I. Other Support Services

1. Contractor will ensure that the majority of clients achieve sustained remission for the symptoms of their substance abuse disorder through the provision of other supportive services to sustain recovery, change of potential self-destructive behaviors, and employ techniques to address motivation and engagement.
2. Contractor may provide Other Support Services to Medicaid clients in Medication Assisted Recovery that meet the eight point criteria to receive take home medication. The Contractor will document Other Support Services specified activities in the CMBHS System as required and instructed through the System Agency training to bill for services.

J. Overdose Prevention and Reversal Education

1. Provide overdose prevention education to clients on the Contractor's waiting list. Contractor will also provide overdose prevention education to all clients prior to discharge, including those that received it prior to admission.
2. General overdose prevention and reversal education will be provided to all clients as a part of treatment education requirements that include education on how to access and administer naloxone. Specific activities will be conducted 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, refer to the SAMHSA's Opioid Overdose Prevention Tool Kit found at: <http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit/SMA13-4742>.

K. Contractor shall admit priority populations in the following order:

1. Based on Federal and State guidelines, pregnant injecting individuals must be admitted immediately;
2. Based on Federal and State guidelines, pregnant individuals must be admitted immediately;
3. Based on Federal guidelines, injecting drug users must be admitted within 14 days;
4. Based on State guidelines, High Risk for overdose, individuals must be admitted immediately; and
5. Based on State guidelines, DFPS referred individuals must be admitted within 72 hours.

6. If unable to provide immediate admission to these populations, the Contractor must 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).
 7. Contractor will have policies and procedures that conform with System Agency's definition for wait list and interim services.
 8. The Contractor will report available capacity and waiting list information Monday through Friday through CMBHS and comply with procedures specified by System Agency.
- L. Contractor may deliver medications approved to treat moderate or severe opioid use disorder to adult clients in a residential treatment facility, a jail or correction facility, or when medically necessary and approved by a physician. According to 42 CFR § 8.12 an Exception Request and Record of Justification Form is required prior to deviation of 8-point criteria due to transportation hardships. <https://www.samhsa.gov/medication-assisted-treatment/opioid-treatment-programs/submit-exception-request>

Contractor will submit notification form to the System Agency within 72 hours to the designated Substance Abuse email mailbox (SubstanceAbuse.Contracts@dshs.texas.gov) of transport of medication and counseling services offsite to individuals that are restricted to the home for medical reasons or are in a restricted environment including jails and residential treatment centers. <https://www.samhsa.gov/medication-assisted-treatment/opioid-treatment-programs/submit-exception-request>

M. Documentation and Testing

1. Document opioid treatment-related activities including MAT and counseling, treatment services, and testing in CMBHS within seven business days of service delivery. This information collected in CMBHS will assist the System Agency in determining the number of clients served, the opioid treatment-related services, and activities provided by the Contractor.
2. Ensure that staff providing MAT and/or counseling services maintain privacy and security controls related to client confidential information.
3. Document information from the informed-consent form in an administrative note and record clinical documentation into the client's CMBHS record; e.g. diagnostic tests such as the Clinical Institute Withdrawal Assessment or Beck Depression Inventory, physician orders, etc.
4. Provide or arrange for interim services including screening for tuberculosis, hepatitis B and C, sexually transmitted diseases (STD), and Human Immunodeficiency Virus (HIV) and document in CMBHS.
5. Provide and document in CMBHS, health screenings, testing, and prevention education. Contractor will use the funds and associated billing codes provided through this Contract to directly provide the services listed in item 6, while only subcontracting laboratory services and hepatitis C virus (HCV) treatment components.
6. Document, upon admission, on the standard consent to treat form, the client's choice on testing and immunization services and upload the form in CMBHS. Ensure the client is informed of the following testing choices:
 - a. Tuberculosis,

- b. Hepatitis B,
 - c. Hepatitis C,
 - d. Gonorrhea,
 - e. Chlamydia,
 - f. Human Immunodeficiency Virus (HIV) (Initial and, if necessary Confirmatory),
and
 - g. Diabetes (using A1c testing).
7. Physician may choose to consult with the client on comorbid conditions and provide services upon admission or as indicated for the following:
 - a. First-line wound care therapy which could include wound cleansing, use of systemic or topical antibiotics, use of pressure loading devices, perform compression, and apply dressing;
 - b. Co-occurring psychiatric disorders; and
 - c. HCV treatment.
 8. Document the needs of the client using the CMBHS assessment tool.
 9. Document the treatment plan and include courtesy dosing/temporary transfer, discharge criteria, and discharge plan.
 10. If the discharge plan includes the use of extended-release injectable naltrexone, the medical director or qualified designee shall either administer the medication prior to discharge or contractor shall ensure that the client has immediate access to such medication services upon discharge.
 11. Ensure that clinical staff providing direct services have the training and expertise in:
 - a. Motivational Enhancement Therapy (MET) or Motivational Interviewing (MI) techniques;
 - b. Overdose prevention;
 - c. Certified Methadone Advocate Training;
 - d. Co-Occurring Psychiatric and Substance Use Disorders (COPSD); and
 - e. Trauma, abuse and neglect, violence, Post-Traumatic Stress Disorder (PTSD), and related conditions.
 12. If a client is discharged, Contractor must identify a specific physician or authorized healthcare professional, as appropriate, to whom the client is being discharged and will ensure that an appointment has been made with that provider to occur within 72 hours in order to maximize the client's chances for success. The name, address, and telephone number of the provider caring for the client after discharge will be recorded in the patient's record and given to the client in writing.

N. Annual Survey

1. Collect the OTS Annual Survey.
2. Use the System Agency approved client satisfaction OTS Annual survey template for collecting information from clients who have received OTS.
3. Have a process and procedure for collecting client satisfaction survey data.
4. Submit results of client surveys in an annual report to the System Agency.

O. Conference Calls

Ensure Contractor's medical director and/or sponsor participate in monthly conference calls as scheduled by the System Agency to address programmatic, documentation, or testing issues.

P. Reporting and CMBHS Requirements

1. Contractor will use the CMBHS components and/or functionality as specified in accordance with System Agency instructions.
2. Contractor will use the updated components and/or functionality as directed by System Agency.
3. Contractor will collect data on the use of and outcomes related to extended-release injectable naltrexone as directed by System Agency.

Q. Submission Schedule, Reporting, and CMBHS Requirements.

Contractor shall:

1. Use the System Agency CMBHS system to document OTS-related activities and 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.
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. The CMBHS Security Attestation Form will be submitted electronically biannually as designated by System Agency to the designated Substance Abuse mailbox (SubstanceAbuse.Contracts@dshs.texas.gov).
7. Use the CMBHS components and/or functionality specified below, in accordance with System Agency instructions. Contractor shall use the updated components and/or functionality as directed by System Agency. Required CMBHS components include:
 - a. Add/Update Staff, (including access control and Credential maintenance)
 - b. Provider Detail
 - c. Location Detail
 - d. Attachments (Financial Eligibility Screen, Progress Note screens, Detox Intake Report screens, Assessment screens)
 - e. Client Profile
 - f. Assessment (Initial, Update, Service End, and Discharge)
 - g. Admission and Discharge
 - h. Service Begin
 - i. Treatment Plan
 - j. Treatment Plan Review

- k. Discharge Plan
 - l. Discharge Summary
 - m. Discharge Follow-up
 - n. Consent/Revoke Consent
 - o. Referral and Referral Follow-up
 - p. Referral List
 - q. Progress Note
 - r. Psycho-educational Note
 - s. Administrative Note
 - t. Medication Order
 - u. Medication List
 - v. Medication Service
 - w. Provider Census Board
 - x. Wait List
 - y. Daily Capacity Report
 - z. Service End
 - aa. Lab Results (Drug Screen)
 - bb. Contracts
 - cc. Pending Claims
 - dd. Submitted Claims
 - ee. Services Offered
 - ff. Discharge Follow up Reminder List
 - gg. Consent Release Request List
 - hh. Assign/Reassign Clinician
8. Submit all documents identified in this Contract by the required due date.
 9. Contractor’s duty to submit documents survives the termination or expiration of this Contract.

III. PERFORMANCE

The System Agency will monitor the Contractor’s performance of the requirements in this Attachment and compliance with the Contract’s terms and conditions.

Opioid Treatment Services	
Number served	Formula
Percent of clients whose length of stay is at least one year	40%
Percent abstinent	65%
Percent with no arrest since admission	85%
Percent of all new clients who received at least one immunization for tetanus or hepatitis B and C	75%
Percent of all new clients who received all health screenings/testing (syphilis, gonorrhea, chlamydia, hepatitis B and C, HIV and TB)	75%
Percent of all new clients who received diabetes screening and individualized BMI information	90%

Report Name	Due Date*
CMBHS Security Attestation Form and List of Authorized Users	September 15 and March 15
CMBHS Documentation and Testing	Ongoing
Client Satisfaction Survey	Ongoing
OTS Annual Survey Report	Due August 31
Closeout documents	Due 45 days after Program Attachment end date

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

IV. INVOICE AND PAYMENT

- A. Submit monthly claims through CMBHS no later than the 15th of the following month.
- B. 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 resort which means that other applicable reimbursement resources such as Medicaid or other third-party payers must be billed first. Reimbursement from System Agency will be considered payment in full. Additional charges may not be collected from state-funded clients.
- C. Except as indicated by the CMBHS financial eligibility assessment, Contractor shall accept reimbursement or payment from the System Agency as payment in full for services or goods provided to clients, and Contractor will not seek additional reimbursement or payment from clients for services or goods, to include benefits received from federal, state, or local sources.
- D. Contractor shall operate within the funded capacity indicated in this Contract for the duration of the Contract term.
- E. Submitted claims in excess of the Contractor's stated funded capacity will be approved for payment based on availability of funds.
- F. 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 the 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>.
- G. Contractor may not apply any unexpended funds associated with a previous State Fiscal Year to expenses incurred in the performance of the requirements of this State Fiscal Year's contract.

- H. Contractor will be paid monthly in accordance with the Program Services and Unit Rates Table in **Attachment B** of this Contract.
- I. Contractor may access the Transactions List report in CMBHS to identify the amount of federal funds allocated to this award for each transaction. The CFDA number is identified in the CMBHS Transactions List report.

**Attachment A-1
Statement of Work Supplemental**

Contractor Name: Methadone Clinic of East Texas, LLC.

Attachment ID: 2017-050004-002

A. CONTRACT INFORMATION

Vendor ID:	17527633956
Contract Number: (CAPPS)	
Contract Type	Treatment
Payment Method:	Fee for Service
DUNS Number:	101753148
Federal Award Identification Number (FAIN)	T1080272, TI010051-17
Solicitation Document:	537-17-0021

B. SERVICE AREA:

Services or activities will be provided to participants and/or clients from the following counties:

Anderson, Bowie, Camp, Cass, Cherokee, Delta, Franklin, Gregg, Harrison, Henderson, Hopkins, Lamar, Marion, Morris, Panola, Rains, Red River, Rusk, Smith, Titus, Upshur, Van Zandt, Wood

C. POPULATION SERVED:

Adults – Male and Female

D. CONTACT INFORMATION

Name:	John Norton
Email:	John.Norton2@HHSC.state.tx.us
Telephone:	(512) 206-5329
Address:	909 W 45 th Street, Bldg 552 (MC 2058)
City/Zip:	Austin TX 78751

**ATTACHMENT B
PROGRAM SERVICES AND UNIT RATES
REVISED JANUARY 2018**

Contractor Name: Methadone Clinic of East Texas, LLC.

Attachment ID: 2017-050004-002

- A. System Agency-funded capacity is defined as the stated number of clients that will be concurrently served as determined by this Contract.
- B. The Assigned Contract Manager must approve clinic Numbers before billing can occur. The Clinic Change Request form is located at: <http://www.dshs.texas.gov/sa/For-Substance-Abuse-Contractors.pdf>.
- C. Funding from The United States Health and Humans Services (HHS), Substance Abuse and Mental Health Services Administration (SAMHSA).
- D. TTOR Funding:
 - 1. Texas Targeted Opioid Response (TTOR) funding in the amount of \$129,428.00 to be expended by:
 - a. FY2018, through **April 30, 2018** - \$102,540.00
 - i. \$75,652.00 –One-Time Funds for Other Support Services
 - ii. \$26,888.00 – Pro-rated funds for services
 - b. FY2018, May 1, 2018 through August 31, 2018 - \$26,888.00, funds for services
- E. Total reimbursements will not exceed \$885,944.00 for the period September 1, 2017 through August 31, 2018.

System Agency Share:	\$885,944.00
Contractor Share (Match):	\$0.00
Total:	\$885,944.00
- F. System Agency Share may contain funds from the following:
 - 1. Substance Abuse Prevention Treatment (SAPT) Grant, CFDA 93.959
 - 2. Texas Targeted Opioid Response (TTOR), CFDA 93.788
 - 3. State
- G. The following Treatment Services and Rates are approved and will be delivered through this Contract.

Service Type/Capacity/Unit Rate Chart is on the following page.

Service Type	Number Served	*Capacity	Unit Rate**	Amount** *
Opioid Treatment Services	113	113		\$753,572.00
Methadone	0	0	\$17.00	
Buprenorphine	0	0	\$24.00	
Extended-Release Injectable Naltrexone	0	0	\$978.67	
Naltrexone Support Services	0	0	\$235.00	
New Admission Health Screening Services	0	0		\$0.00
Outpatient visit - Immunization Consent	0	0	\$40.27	
Hepatitis B - Testing	0	0	\$11.84	
Hepatitis C - Testing	0	0	\$16.35	
HIV (initial) - Testing	0	0	\$27.60	
HIV (confirmatory) - Testing	0	0	\$10.18	
Gonorrhea - Testing	0	0	\$40.21	
Chlamydia - Testing	0	0	\$40.21	
Diabetes - Testing	0	0	\$11.12	
TB Testing Intradermal	0	0	\$7.07	
Outpatient visit - Follow-up (Results/Linkages)	0	0	\$33.27	
CoMorbid Services				\$56,721.00
Hepatitis C - Treatment Coordination	0	0	\$55.87	
Hepatitis C - Confirmatory Test	0	0	\$21.10	
Hepatitis C - Viral Load Quantification	0	0	\$38.65	
Initial Interview ofr diagnosis of psychiatric condition	0	0	\$113.91	
Thirty-minute physician visit for psychiatric follow-up	0	0	\$44.66	
Wound Care Management	0	0	\$60.34	
Other Support Services *****	0	0	\$15.00	\$75,651.00

*Capacity – Naltrexone is not a factor in determining the capacity number. Capacity is projected using an average of Methadone and Buprenorphine services and is subject to change depending on services utilized.

** Rates are subject to change.

***Service Types with no associated Amount will be paid from the preceding Service Type with an associated Amount.

***Other Support Services - for Medicaid clients in MAT that meet the eight-point criteria to receive take home medication.

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 SAMHSAⁱ, VAⁱⁱ, ASAMⁱⁱⁱ and Providers' Clinical Support System for Medication Assisted Treatment (PCSS-MAT)^{iv} 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 Department of State Health Services (DSHS) / Texas Health & Human Services (HHSC) Drug Formulary requirements, including *Reserve Drug Criteria* and *Audit Criteria*^v.

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^{vi} 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.

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^{vii}. SAMHSA has published a guide entitled *Decisions in Recovery: Treatment for Opioid Use Disorder Handbook*^{viii} 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.

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

ⁱ 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>

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

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

ⁱⁱⁱ 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>

^{iv} PCSS-MAT Resource Page including multiple applicable publications

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

^v Decisions in Recovery: Treatment for Opioid Use Disorder Handbook

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

^v DSHS/HHSC Drug Formulary, including criteria for the use of Reserve Drugs, along with the Medication Audit Criteria and Guidelines, can be found at:

<http://dshs.texas.gov/mhprograms/Formulary.shtm>

^{vi} PCSS-MAT CME modules <http://pcssmat.org/category/module/naltrexone/>.

^{vii} AMA Code of Ethics, Chapter 2.1: Informed Consent & Shared Decision

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