

## DEPARTMENT OF STATE HEALTH SERVICES



### Amendment No. 04

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**THE DEPARTMENT OF STATE HEALTH SERVICES ("DSHS") and SAN ANTONIO METROPOLITAN HEALTH DISTRICT ("Contractor")** agree to amend Contract No. 2014-045668-001C (Contract), which was effective on July 1, 2014. This Contract has been amended prior to this Amendment. This Amendment shall be denominated as 2014-045668-001D.

- I. The Parties agree to amend Section 4 of the Contract and the term of the Program Attachment to renew the Contract for the term beginning October 1, 2016 through September 30, 2017.
- II. The Parties agree to delete in its entirety Section 1. STATEMENT OF WORK and replace it with the following:

#### **SECTION I: STATEMENT OF WORK:**

- A. Contractor, with guidance from DSHS and in collaboration with other project contractors or partners, will focus on the development and execution activities to support achievement of goals and metrics to implement Delivery System Reform Incentive Payment ("DSRIP") 1115 Medicaid Waiver Project 133257904.2.1 (the "Project"). The Project's long-term goal is to reduce TB disease by increasing regional capacity to identify TB through targeted screening of high-risk populations using interferon gamma release assay ("IGRA") and engaging those with identified tuberculosis infection ("TBI") into treatment..
- B. Contractor will implement the following activities:
  1. Work with the DSHS, SAMHD, other project subcontractors or partners in the systematic identification, outreach to and enrollment of project sub-contractors to provide TBI testing for populations at high risk and treatment to persons with confirmed TBI. Examples of providers that should be targeted for participating in the Project include: Federally Qualified Health Centers ("FQHCs"), rural health centers, rural hospitals, clinics, dialysis centers, drug rehabilitation facilities, mental health and substance abuse centers, and other facilities that serve persons at high-risk of developing tuberculosis.

2. Educate potential and existing subcontractors and partners about the benefits of IGRA tests to minimize false positives in the Bacillus Calmette-Guérin (BCG) vaccinated as well as the benefits of the new shortened TBI regimens such as the 12 week doses of isoniazid and rifapentine (3HP) and the continued use of traditional for those not eligible for 3HP. Tuberculin skin testing may be used for patients not eligible for IGRA testing.
  3. Contractor and its sub-contractors or partners will target their TB testing activities on those at high risk for TB disease. Generally, persons at high risk for developing TB disease fall into two categories: 1) persons who have been recently infected with TB bacteria; and, 2) persons with medical conditions that weaken the immune system. The following sites describe these populations: <http://www.cdc.gov/tb/topic/basics/risk.htm>; <http://www.cdc.gov/tb/topic/populations/>; <https://www.cdc.gov/mmwr/preview/mmwrhtml/00001642.htm>.
  4. Increase targeted testing for tuberculosis infection (TBI) in high-risk populations. Targeted population will include populations residing in congregate settings such as homeless shelters or drug rehabilitation centers, individuals living with HIV and diabetes, the homeless, and refugees.
  5. Focus on working with providers who serve persons who are covered by Medicaid or are low-income or are uninsured.
- C. To support successful implementation of IGRA testing, treatment for TBI, and reporting by sub-contractors and partners, Contractor will implement the following training and technical assistance activities:
1. Educate and train sub-contractors or partners and their staffs on the following topics: TBI and TB disease and its management, available regimens, benefits of IGRA tests, project logistics, referral processes for treatment of those with TBI, and Project data reporting processes. Educational and training needs of sub-contractors should be systematically identified and documents.
  2. Assist with development of processes necessary for successful implementation of IGRA testing.
  3. Provide follow-up training or assistance as requested by sub-contractors or partners or as identified by Contractor.
  4. Encourage sub-contractors to participate in project Learning Collaborative activities.

5. Monitor, document and report sub-contractor or partner performance with a specific focus on establishment of screening processes that systematically identify persons at risk for TBI with IGRA tests as well as work with sub-contractors/partners to correct identified performance issues.
  6. Provide testing supplies for collecting blood for IGRAs and for placing TB skin tests (TST). The cost to run the test and medications will be covered by DSHS. Contractor or Sub-Contractor may charge a fee for performing phlebotomy.
  7. Encourage sub-contractors to participate in project Learning Collaborative activities.
  8. Contractor may use incentives (“tangible reinforcement”) to encourage patient participation and retention in treatment.
- D. Contractor will ensure that TBI in patients identified through screening activities is appropriately treated and managed. Contractor will:
1. Ensure that patients with a positive IGRA receive a chest x-ray that is read by a radiologist. DSHS will reimburse x-ray and reading costs.
  2. Ensure that patients with an abnormal chest x-ray are referred to San Antonio Metropolitan Health District’s Chest Clinic or the DSHS Region 8 TB Program based on patient residency.
  3. Perform clinical evaluation to determine TB infection (TBI) or active TB disease among persons screened and found to have a positive IGRA result.
  4. Refer patients with active TB that cannot be successfully treated as an outpatient to DSHS for hospitalization.
  5. Ensure that for patients diagnosed with LTBI (positive IGRA and normal CXR), blood is drawn for baseline labs including a) a complete metabolic panel (CMP) and b) a complete blood count (CBC). These samples should be sent to the South Texas Lab. DSHS will provide reimbursement associated supplies and lab fees.
  6. Ensure that patient’s being treated for TBI receive monthly toxicity screening.

7. Provide routine treatment for TBI through a 12 dose, 12 week regimen administered by directly observed therapy (DOT) to improve patient adherence and completion of treatment.
  8. Alternate recognized treatment regimens for treating TBI may be used if the 12 dose, 12 week regimen is not appropriate.
- E. Contractor will collect, data-enter, quality assure and manage data collected during Contractor project activities. Data collected may be from Contractor testing activities or from partner organizations activities. Contractor will:
1. Collect and submit monthly data sets to the Project contractor responsible for aggregating and reporting Project level data.  
  
DSHS will provide direction and guidance on report structure, content/data elements and format/s. Contractor understands that report structure, content, and data elements are subject to change based on evolving project needs.
  2. Manage project data in a manner that assures protection of protected health and personal participant information.
  3. Provide quality and timely reports on schedules and in formats specified by DSHS and/or Project contractor responsible for data management. These reports may include but are not limited to: Monthly data reports used to plan and assess project performance; Special or ad hoc reports needed to address emerging Project questions or to support dissemination activities; or, reports needed for DSRIP related reporting.
- F. Contractor agrees to participate in and support the following project activities:
1. Meetings;
  2. Annual work plan development;
  3. Evaluation;
  4. Sustainability planning;
  5. Continuous Quality Improvement (CQI);
  6. Learning Collaborative(s); and
  7. Dissemination.

- G. Contractor agrees that the knowledge and information gathered through the activities of this Contract are the exclusive intellectual property of the DSHS.
- H. Contractor agrees that Contractor dissemination activities associated with this Project should be reviewed and approved by the DSHS. All disseminated products should cite the DSHS as the funding source.
- I. Contractor will not exceed the total amount of this Contract without DSHS prior approval and the Parties executing a written amendment.
- J. Contractor will comply with all applicable federal and state laws, rules, and regulations including, but not limited to, the following:
  - 1. Texas Tuberculosis Code, Health and Safety Code, Chapter 13, Subchapter B;
  - 2. Communicable Disease Prevention and Control Act, Texas Health and Safety Code, Chapter 81; and,
  - 3. Texas Administrative Code TAC, Title 25, Part 1, Chapter 97, Subchapter A, Control of Communicable Diseases.
- K. Contractor will comply with all applicable regulations, standards and guidelines in effect on the beginning date of the Term of this Contract. Contractor will provide the services outlined above in compliance with the following:
  - 1. DSHS Standards of Performance for the Prevention and Control of Tuberculosis,  
<http://www.dshs.state.tx.us/IDCU/disease/tb/publications/SOP-2008-final.doc>;
  - 2. DSHS Standards for Public Health Clinic Services,  
<http://www.dshs.state.tx.us/qmb/dshsstndrds4clincservs.pdf>;
  - 3. DSHS TB Policy and Procedures Manual,  
<http://www.dshs.state.tx.us/idcu/disease/tb/publications/>;
  - 4. American Thoracic Society (ATS) and Centers for Disease Control and Prevention (CDC) joint statements on diagnosis, treatment and control of TB, <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5211a1.htm>;

5. Diagnostic Standards and Classification of Tuberculosis in Adults and Children, (American Journal of Respiratory and Critical Care Medicine), Vol. 161, pp. 1376-1395, 2000)  
<http://ajrccm.atsjournals.org/cgi/reprint/161/4/1376>;
  6. Treatment of Tuberculosis, (ATS/CDC/IDSA), 2003,  
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5211a1.htm> ;
  7. Targeted Tuberculin Testing and Treatment of Latent TB Infection (LTBI), Morbidity and Mortality Weekly Report, Vol. 49, No. RR-6, 2000,  
<http://www.cdc.gov/mmwr/PDF/rr/rr4906.pdf> ;
  8. Updated: Adverse Event Data and Revised ATS/CDC Recommendations Against the Use of Rifampin and Pyrazinamide for Treatment of Latent Tuberculosis Infection – United States, 2003, MMWR 52 (No. 31),  
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5231a4.htm> ;
  9. Controlling Tuberculosis in the United States, MMWR, Vol. 54, No. RR-12, 2005 <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5412a1.htm> ;  
and
  10. Guidelines for the Prevention and Treatment of Opportunistic Infections Among HIV-Exposed and HIV-Infected Children,  
<http://www.cdc.gov/mmwr/pdf/rr/rr58e0826.pdf> .
- L. Contractor must receive written approval from DSHS before varying from the procedures outlined in Section L and must update its implementation documentation within forty-eight (48) hours of making approved changes so that staff working on activities under this contract knows of the change(s).
- M. Contractor will adhere to reporting requirements documented in the CDC Tuberculosis Surveillance Data Training Report of Verified Case of Tuberculosis (RVCT) Instruction Manual available at,  
<http://www.cdc.gov/tb/programs/rvct/InstructionManual.pdf>.
- N. Contractor will inform DSHS in writing if Contractor will not continue performance under this Program Attachment within thirty days of receipt of an amended standard(s) or guideline(s). DSHS may terminate this Contract immediately or within a reasonable period of time as determined by DSHS.

O. Contractor will develop, implement and maintain a timekeeping system for accurately documenting staff time and salary expenditures for all staff funded through this Contract, including partial full-time employees and temporary staff.

P. Contractor will not use DSHS funds for:

1. Entertainment; or
2. Sectarian worship, instruction, or proselytization.

DSHS reserves the right, where allowed by legal authority, to redirect funds in the event of financial shortfalls. DSHS will monitor Contractor's expenditures on a quarterly basis. If expenditures are below that projected in Contractor's total Contract amount, Contractor's budget may be subject to a decrease for the remainder of the Term of the Contract. If applicable, vacant positions existing after ninety days may result in a decrease in funds.

Q. Contractor activities will take place in Bexar County which is one of 20 1115 Waiver Regional Healthcare Partnership 6 (RHP 6) counties. RHP 6 boundaries can be found at: <https://www.hhsc.state.tx.us/1115-docs/Regions-Map-Aug12.pdf>.

R. Contractor will submit financial and any other reports that DSHS determines necessary to accomplish the objectives of this contract and to monitor compliance. If Contractor is legally prohibited from providing such reports, Contractor will immediately notify DSHS in writing.

S. Contractor will provide services in the following county: Bexar

III. The Parties agree to delete in its entirety Section II PERFORMANCE MEASURES and replace it with the following:

**SECTION II. PERFORMANCE MEASURES:**

A. Contractor activities will support achievement of the following DSRIP Project level measures and metrics specified in the most current approved HHSC project plan:

1. Contractor and its sub-contractors or partners will conduct a minimum of 2,700 IGRA tests required for the Project to meet its quantifiable patient impact (QPI) target for the project demonstration year.
2. 15% of providers trained will adopt the new IGRA TBI testing technology.

3. 73.53% of patients initiating TBI treatment will complete treatment.
4. 30% of Contractor's QPI target will be on Medicaid or be low-income or uninsured.

B. Contractor will submit a monthly report to the DSHS HSR 8 Project Manager and the assigned DSHS Contract manager by the 10th of every month. Format and content will be specified by DSHS.

IV. Except as provided in this Amendment, all other terms and conditions in the Contract will remain and be in full effect.

V. This Amendment is effective on October 1, 2016.

By signing this Amendment, the undersigned certify that they have the authority to bind their respective party to this Amendment's terms and conditions.

**Department of State Health Services**

By: \_\_\_\_\_  
David Gruber  
Assistant Commissioner  
Division for Regional and Local Health  
Services

Date: \_\_\_\_\_

**Contractor**

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_