

DEPARTMENT OF STATE HEALTH SERVICES



AMENDMENT #: 01

The Department of State Health Services (DSHS) and Collin County (Contractor) agree to amend Contract No. 2016-001394-00 (Contract), which was effective on September 1, 2015. This Contract has been not been amended prior to this Amendment.

I. The Parties agree to amend Section II of this Contract to add ONE HUNDRED FIFTY-TWO THOUSAND EIGHT HUNDRED TWENTY-EIGHT DOLLARS (\$152,828.00) to increase the total amount that the Contract will not exceed to THREE HUNDRED FIVE THOUSAND SIX HUNDRED FIFTY-SIX DOLLARS (\$305,656.00).

II. The Parties agree to amend Section IV this Contract to extend the end of the Contract term to August 31, 2017.

III. The Parties agree that the amended Contract will be denominated Contract No. 2016-001394-01 for administrative purposes.

IV. The Parties agree to amend Section 7-A PROVISION OF SERVICES of this Contract by adding the following:

The Contractor may, at its discretion, elect to provide directly observed therapy (DOT) using a video platform. To the extent Contractor elects to utilize DOT using a video platform, it comply with the requirements outlined in the Requirement and Recommendation Guidance Document for Video DOT located at <http://www.texas.tb.org>.

V. The Parties agree to delete in its entirety Section 7-C MEDICATIONS AND SUPPLY INVENTORY MANAGEMENT of this Contract and replace it with the following:

Contractor shall order TB medications through DSHS-enabled pharmacy ordering system. Contractor shall ensure that TB medications purchased with DSHS TB Branch funds are used in a prudent manner that contributes to disease control in their service area and shall not be distributed to other entities.

Contractor shall monitor and manage its usage of medications and testing supplies furnished by DSHS in accordance with first-expiring-first-out (FEFO) principles of inventory control to minimize waste for those products with expiration dates and set maximum stock levels at a 1-month supply and based on the number of patients receiving treatment.

Between the first and the seventh working day of every month, the Contractor shall perform a physical count of its inventory of medications and supplies furnished by DSHS and appropriately reconcile the quantities by product and lot number in the Inventory Tracking Electronic and Asset Management System (ITEAMS). Failure to reconcile in ITEAMS may prohibit release of medications. All DSHS-purchased medications shall be stored properly and securely, in accordance with manufacturer's instructions (refer to TB Work Plan, Section V).

Products that have not been used in nine (9) months, or will not be used in nine (9) months shall be returned to DSHS Pharmacy or transferred to another TB program where the demand may be greater and recorded in ITEAMS.

Contractor shall obtain a TB expert physician consultation and approval from the TB Branch prior to

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ordering the following second-line medications:

- Injectable Agents: capreomycin, kanamycin, amikacin, streptomycin;
- Fluoroquinolones: levofloxacin (Levoquin), ciprofloxacin, moxifloxacin, ofloxacin;
- Bacteriostatic Agents: ethionamide, para-aminosalicylic acid, cycloserine; and
- Other Agents: clofazamine, linezolid, bedaquiline, clarithromycin, amoxicillin.

Contractor may distribute Purified Protein Derivative (PPD) and syringes for TB skin testing to correctional facilities that meet Texas Health and Safety Code, Chapter 89 requirements. Contractor shall monitor distribution of these items in accordance with screening activities submitted on the correctional monthly report.

VI. The Parties agree to delete in its entirety Section 7-D

USE OF INTERFERON GAMMA RELEASE ASSAY TESTS of this Contract and replace it with the following:

1. Perform tuberculosis screenings using DSHS-supplied interferon gamma release assays (IGRA). DSHS reserves the right to select either T-SPOT®.TB and/or QuantiFERON®-TB Gold in-tube tests for the following populations in accordance with DSHS-approved age requirements:

- a. TB suspects;
- b. TB cases;
- c. Contacts to TB suspects and cases – Consultation with the TB Branch is required for contact investigations in which 50 or more persons are targeted for screening;
- d. Targeted testing except screening in correctional facilities – Monthly screening reports shall be submitted in accordance with reporting schedule; and
- e. Routine screening of employees providing TB services.

2. IGRA testing products/supplies supported by DSHS funds shall not be provided to any organization or establishment without documented approval from the TB Branch.

VII. The Parties agree to amend Section 7-F REPORTING of this Contract by adding the following:

1. Provide a complete and accurate Annual Progress Report covering the period from January to December 2016, in the format provided by DSHS, demonstrating compliance with requirements of the contract during that time period. The report shall include, but is not limited to, a detailed analysis of performance related to the performance measures (see Section II FY16 Performance Measures).

2. The Contractor's Annual Progress Report shall not be combined with another Contractor's or health service region's Annual Progress Report. The report is due March 15, 2017, and shall be sent to the TB Reporting Mailbox at TBContractReporting@dshs.state.tx.us (refer to TB Work Plan, Section IX, O). Any individual-level patient data must be sent via the PHIN. Contractors can mail the Annual Progress Report to their DSHS Health Service Region (HSR) thereby authorizing them to submit the report on their behalf. If the Contractor sends the report to a DSHS HSR, the deadline for submission to the TB Branch remains unchanged.

VIII. The Parties agree to amend Section 7- Performance Measures of this Contract by adding the following:

1. For FY17 reporting, data will be drawn from calendar year 2016 (1/1/2016 -12/31/2016). A compliance percentage of not less than 82.9% is required. If fewer than 82.9% of newly reported TB cases have a result of an HIV test reported, then DSHS may (at its sole discretion) require additional measures be taken by Contractor to improve that percentage, on a timeline set by DSHS.

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2. Cases, and suspected cases, of TB under treatment by Contractor shall be placed on timely and appropriate Directly Observed Therapy (DOT).
For FY17 reporting, data will cover all cases from calendar year 2016 (1/1/2016 -12/31/2016). A compliance percentage of not less than 91.6% is required.
If data indicates a compliance percentage for this Performance Measure of less than 91.6%, then DSHS may (at its sole discretion) require additional measures be taken by Contractor to improve that percentage, on a timeline set by DSHS.
3. Newly-reported suspected cases of TB disease shall be started in timely manner on the recommended initial 4-drug regimen. For FY17 reporting, data will be drawn from calendar year 2016 (1/1/2016 -12/31/2016). A compliance percentage of not less than 93.4% is required. If fewer than 93.4% of newly-reported TB cases are started on an initial 4-drug regimen in accordance with this requirement, then DSHS may (at its sole discretion) require additional measures be taken by Contractor to improve that percentage, on a timeline set by DSHS.
4. Newly-reported TB patients that are older than 12-years-old and that have a pleural or respiratory site of disease shall have sputum acid-fast bacilli (AFB)-culture results reported to DSHS according to the timelines for reporting initial and updated results given herein.
For FY17 reporting, data will be drawn from calendar year 2016 (1/1/2016 -12/31/2016). A compliance percentage of not less than 91.5% is required.
If data indicates a compliance percentage for this Performance Measure of less than 91.5%, then DSHS may (at its sole discretion) require additional measures be taken by Contractor to improve that percentage, on a timeline set by DSHS.
5. Newly-reported cases of TB with AFB positive sputum culture results will have documented conversion to sputum culture-negative within 60 days of initiation of treatment. For FY17 reporting, data will be drawn from calendar year 2015 (1/1/2015-12/31/2015). A compliance percentage of not less than 95% is required. If data indicates a compliance percentage for this Performance Measure of less than 95%, then DSHS may (at its sole discretion) require additional measures be taken by contractor to improve the percentage, on a timeline set by DSHS.
6. Newly diagnosed TB cases that are eligible* to complete treatment within 12 months shall complete therapy within 365 days or less.*Exclude TB cases 1) diagnosed at death, 2) who die during therapy, 3) who are resistant to Rifampin, 4) who have meningeal disease, and/or 5) who are younger than 15 years with either miliary disease or a positive blood culture for TB. For FY17 reporting, data will cover all cases from calendar year 2016 (1/1/2016 -12/31/2016). A compliance percentage of not less than 87% is required. If data indicates a compliance percentage for this Performance Measure of less than 87%, then DSHS may (at its sole discretion) require additional measures be taken by Contractor to improve that percentage, on a timeline set by DSHS.
7. Increase the proportion of culture-confirmed TB cases with a genotyping result reported. For FY17 reporting, data will be drawn from calendar year 2016 (1/1/2016 -12/31/2016). A compliance percentage of not less than 94.2% is required. If data indicates a compliance percentage for this Performance Measure of less than 94.2%, then DSHS may (at its sole discretion) require additional measures be taken by Contractor to improve that percentage, on a timeline set by DSHS.
8. TB cases with initial cultures positive for Mycobacterium tuberculosis complex shall be tested for drug susceptibility and have those results documented in their medical record. For FY17 reporting, data will be drawn from calendar year 2015 (1/1/2015 -12/31/2015). A compliance percentage of not less than 97.8% is required. If data indicates a compliance percentage for this Performance Measure of less than 97.8%,

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then DSHS may (at its sole discretion) require additional measures be taken by Contractor to improve that percentage, on a timeline set by DSHS.

9. Newly-reported TB patients with a positive AFB sputum-smear result shall have at least three contacts identified as part of the contact investigation that must be pursued for each case. For FY17 reporting, data will be drawn from calendar year 2016 (1/1/2016 -12/31/2016). A compliance percentage of not less than 92% is required. If data indicates a compliance percentage for this Performance Measure of less than 92%, then DSHS may (at its sole discretion) require additional measures be taken by Contractor to improve that percentage, on a timeline set by DSHS.

10. Newly-identified contacts, identified through the contact investigation, that are associated with a sputum AFB smear-positive TB case shall be evaluated for TBI and disease. For FY17 reporting, data will be drawn from calendar year 2015 (1/1/2015 -12/31/2015). A compliance percentage of not less than 82.5% is required. If data indicates a compliance percentage for this Performance Measure of less than 82.5%, then DSHS may (at its sole discretion) require additional measures be taken by Contractor to improve that percentage, on a timeline set by DSHS.

11. Contacts, identified through the contact investigation, that are associated with a sputum AFB smear-positive case and that are newly diagnosed with TBI shall be started on timely and appropriate treatment. For FY17 reporting, data will be drawn from calendar year 2015 (1/1/2015 -12/31/2015). A compliance percentage of not less than 70% is required. If data indicates a compliance percentage for this Performance Measure of less than 70%, then DSHS may (at its sole discretion) require additional measures be taken by Contractor to improve that percentage, on a timeline set by DSHS.

12. Contacts, identified through the contact investigation, that are associated with a sputum AFB smear-positive case that are newly diagnosed with TBI and that were started on treatment shall complete treatment for TBI as described in Targeted Tuberculin Testing and Treatment of Latent TB Infection (LTBI), Morbidity and Mortality Weekly Report, Vol. 49, No. RR-6, 2000; according to timelines given, therein. For FY17 reporting, data will be drawn from calendar year 2016 (1/1/2016 -12/31/2016). A compliance percentage of not less than 50% is required. If data indicates a compliance percentage for this Performance Measure of less than 50%, then DSHS may (at its sole discretion) require additional measures be taken by Contractor to improve that percentage, on a timeline set by DSHS.

13. For Class B immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB, increase the proportion who initiate a medical evaluation within 30 days of arrival. Arrival is defined as the first notice or report; whether that is by fax, phone call, visit to the health department or EDN notification. For FY17 reporting, data will be drawn from calendar year 2016 (1/1/2016 -12/31/2016). A compliance percentage of not less than 62% is required. If data indicates a compliance percentage for this Performance Measure of less than 62%, then DSHS may (at its sole discretion) require additional measures be taken by Contractor to improve that percentage, on a timeline set by DSHS.

14. For Class B immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB, increase the proportion who initiate and complete a medical evaluation within 90 days of arrival. For FY17 reporting data will be drawn from calendar year 2016 (1/1/2016-12/31/2016). A compliance percentage of not less than 60% is required. If data indicates a compliance percentage for this Performance Measure of less than 60%, then DSHS may (at its sole discretion) require additional measures be taken by Contractor to improve that percentage, on a timeline set by DSHS.

15. For Class B immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB and who are diagnosed with TBI during evaluation in the US, increase the proportion who start treatment. For FY17 reporting, data will be drawn from calendar year 2016 (1/1/2016 -12/31/2016). A compliance

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percentage of not less than 64% is required. If data indicates a compliance percentage for this Performance Measure of less than 64%, then DSHS may (at its sole discretion) require additional measures be taken by Contractor to improve that percentage, on a timeline set by DSHS.

16. For Class B immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB and who are diagnosed with TB infection during evaluation in the US and started on treatment, increase the proportion who complete treatment for TB infection. For FY17 reporting, data will be drawn from calendar year 2015 (1/1/2015 -12/31/2015). A compliance percentage of not less than 70% is required. If data indicates a compliance percentage for this Performance Measure of less than 70%, then DSHS may (at its sole discretion) require additional measures be taken by Contractor to improve that percentage, on a timeline set by DSHS

If Contractor fails to meet any of the performance measures, Contractor shall furnish in the Annual Progress Report, due March 15, 2017, a written narrative explaining the barriers and the plan to address those barriers. This requirement does not excuse any violation of this Contract, nor does it limit DSHS as to any options available under the contract regarding breach

IX. The Parties agree to amend Section 16 of this Contract to add the following:
General Provisions, ARTICLE XXI. PROGRAM OPERATIONS, Section 21.05, Contractor's Notification of Change to Certain Contract Provisions to replace it with the following:
Subject to the following restrictions, without prior approval, Contractor may transfer money between budget categories and must provide the System Agency Contract Manager with prior notification of this transfer. No budget category transfer or cumulative transfers may exceed 25% of the total contract value or \$100,00, whichever is less. If the budget transfer(s) exceeds \$100,000, alone or cumulatively, prior written approval from the System Agency is required. If the budget transfer(s) exceeds 25% of the total contract value, alone or cumulatively, a formal contract amendment is required.

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

XI. This Amendment is effective on September 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: Janna Zumbrun
Title: Assistant Commissioner
Date: August 10, 2016

Contractor

By: Keith Self
Title: County Judge
Date: August 08, 2016

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Department Of State Health Services

By:
Title:
Date:

Contractor

By: *Keith A. Bell*
Title: *County Judge*
Date: *8/19/16*