

**DEPARTMENT OF STATE HEALTH SERVICES
CONTRACT 2014-001417-00**



This Contract is entered into by and between the Department of State Health Services (DSHS or the Department), an agency of the State of Texas, and Hidalgo County (Contractor), a Governmental, (collectively, the Parties) entity.

- 1. Purpose of the Contract:** DSHS agrees to purchase, and Contractor agrees to provide, services or goods to the eligible populations.
- 2. Total Amount:** The total amount of this Contract is \$664,963.00.
- 3. Funding Obligation:** This Contract is contingent upon the continued availability of funding. If funds become unavailable through lack of appropriations, budget cuts, transfer of funds between programs or health and human services agencies, amendment to the Appropriations Act, health and human services agency consolidation, or any other disruptions of current appropriated funding for this Contract, DSHS may restrict, reduce, or terminate funding under this Contract.
- 4. Term of the Contract:** This Contract begins on 09/01/2013 and ends on 08/31/2014. DSHS has the option, in its sole discretion, to renew the Contract. DSHS is not responsible for payment under this Contract before both parties have signed the Contract or before the start date of the Contract, whichever is later.
- 5. Authority:** DSHS enters into this Contract under the authority of Health and Safety Code, Chapter 1001.
- 6. Program Name:** TB/PC-STATE Tuberculosis Prevention and Control-State

7. Statement of Work:

A. PROVISION OF SERVICES:

Contractor shall develop and provide basic services and associated activities for tuberculosis (TB) prevention and control, and expanded outreach services to individuals of identified special populations (as directed by DSHS) who have TB and/or who are at high risk of developing TB.

Contractor shall perform the activities required under this Program Attachment in the Service Area designated in the most recent version of Section 8. "Service Area" of this contract.

Contractor shall provide these services in compliance with the following:

- DSHS' most current version of the Standards of Performance for the Prevention and Control of Tuberculosis, available at <http://www.dshs.state.tx.us/IDCU/disease/tb/publications/SOP-2008-final.doc>;
- DSHS Standards for Public Health Clinic Services, Revised August 31, 2004 available at <http://www.dshs.state.tx.us/qmb/dshsstndrds4clinciservs.pdf>;
- DSHS' TB Policy and Procedures Manual, available at <http://www.dshs.state.tx.us/idcu/disease/tb/publications/>;
- American Thoracic Society (ATS) and Centers for Disease Control and Prevention (CDC) joint statements on diagnosis, treatment and control of TB available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5211a1.htm>;
- Diagnostic Standards and Classification of Tuberculosis in Adults and Children, (American Journal of Respiratory and Critical Care Medicine, Vol. 161, pp. 1376-1395, 2000) at <http://ajrccm.atsjournals.org/cgi/content/full/161/4/1376>;
- Treatment of Tuberculosis, (ATS/CDC/IDSA), 2003 available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5211a1.htm>;
- Targeted Tuberculin Testing and Treatment of Latent TB Infection (LTBI), Morbidity and Mortality Weekly Report, Vol. 49, No. RR-6, 2000 at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4906a1.htm>;
- Updated: Adverse Event Data and Revised American Thoracic Society/CDC Recommendations Against the Use of Rifampin and Pyrazinamide for Treatment of Latent Tuberculosis Infection – United States, 2003, MMWR 52 (No. 31) at [http://www.eclipsconsult.com/eclips/article/Pulmonary%20Disease/S8756-3452\(08\)70243-3](http://www.eclipsconsult.com/eclips/article/Pulmonary%20Disease/S8756-3452(08)70243-3);
- Controlling Tuberculosis in the United States, MMWR, Vol. 54, No. RR-12, 2005 at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5412a1.htm>;
- Guidelines for the Prevention and Treatment of Opportunistic Infections Among HIV-Exposed and HIV-Infected Children at <http://www.cdc.gov/mmwr/pdf/rr/rr58e0826.pdf>;
- Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents at <http://www.cdc.gov/mmwr/pdf/rr/rr58e324.pdf>; and
- Updated Guidelines on Managing Drug Interactions in the Treatment of HIV-Related Tuberculosis at http://www.cdc.gov/tb/publications/guidelines/TB_HIV_Drugs/default.htm.

Contractor shall comply with all applicable federal and state regulations and statues, including, but not limited to, the following:

- Texas Tuberculosis Code, Health and Safety Code, Chapter 13, subchapter B;
- Communicable Disease Prevention and Control Act, Health and Safety Code, Chapter 81;
- Screening and Treatment for Tuberculosis in Jails and Other Correctional Facilities, Health and Safety Code, Chapter 89;

- Texas Administrative Code TAC, Title 25, Part 1, Chapter 97, Subchapter A, Control of Communicable Diseases; and
- Texas Administrative Code TAC, Title 25, Part 1, Chapter 97, Subchapter H, Tuberculosis Screening for Jails and Other Correctional Facilities.

All references to TB cases or suspected TB cases refer to active TB disease unless otherwise stated. All references to latent TB infection (LTBI) refer to the condition where infection has occurred but there has not been progression to active TB disease.

Contractor shall monitor and manage its usage of anti-tuberculosis 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. On a monthly basis, the Contractor shall perform a count of its inventory of anti-tuberculosis medications and tuberculosis testing supplies furnished by DSHS and reconcile the quantities by product and lot number found by this direct count with the quantities by product and lot number listed in the electronic inventory management system furnished by DSHS. All these tasks shall be performed by the Contractor using the database and procedures designated by DSHS.

Contractor shall perform all activities under this Program Attachment in accordance with Contractor's final, approved work plan (attached as Exhibit A), and detailed budget as approved by DSHS. Contractor must receive written approval from DSHS before varying from applicable policies, procedures, protocols, and the final approved work plan, and must update its implementation documentation within forty-eight (48) hours of making approved changes so that staff's working on activities under this contract are made aware of the change(s).

Use of Funds:

Contractor will be subject to adjustments in award amounts based on changes to the number of clients served, utilization of funds, or other factors, as directed by DSHS.

Contractor shall provide a match of no less than 20% of the total budget reflected in the Program Attachment. Contractor shall provide match at the required percentage or DSHS may withhold payments use administrative offsets, or request a refund from Contractor until such time as the required match ratio is met. No federal or other grant funds can be used as part of meeting the match requirement.

Contractor shall not use DSHS funds or matching funds (including in-kind contributions) for:

1. Food;
2. Incentives;
3. Entertainment; or
4. Sectarian worship, instruction, or proselytization.

DSHS reserves the right, where allowed by legal authority, to redirect funds in the event of financial shortfalls. DSHS Program will monitor Contractor's expenditures on a quarterly basis. If expenditures are below those projected in Contractor's total Program Attachment amount, Contractor's budget may be subject to a decrease for the remainder of the Program Attachment term. Vacant positions existing after ninety (90) days may result in a decrease in funds.

B. REPORTING:

Due to the inherent time to complete treatment for tuberculosis disease and latent tuberculosis infection in relation to the period of the Program Attachment, required reporting under this Program Attachment will

show results for work performed under previous Program Attachments.

Contractor shall provide a complete and accurate annual narrative report covering the period from January to December 2013 (inclusive), in the format provided by DSHS, demonstrating compliance with the requirements of the program attachments in place during that time period. The report shall include, but is not limited to, a detailed analysis of performance related to the performance measures listed in the applicable Program Attachments. The narrative report is due February 14, 2014, and shall be sent to the Department of State Health Services, Tuberculosis Services Branch, Mail Code 1873, 4110 Guadalupe, PO Box 149347, Austin, Texas 78714-9347 via regular mail, or by fax to (512)371-4675, or e-mail to TBContractReporting@dshs.state.tx.us. See Programmatic Reporting Requirements section for required reports. Contractor shall maintain the documentation used to calculate performance measures as required by the General Provisions Article VIII "Records Retention" and by the Texas Administrative Code Title 22, Part 9 Chapter 165, §165.1 regarding the retention of medical records.

Contractor shall send all initial reports of confirmed and suspected TB cases to DSHS within seven (7) working days of identification or notification.

Updates to initial DSHS Report of Cases and Patient Services Form (TB-400) (e.g., diagnosis, medication changes, x-rays, and bacteriology) and case closures shall be sent within thirty (30) calendar days from when a change in information in a required reporting field occurs to DSHS at 4110 Guadalupe, Mail Code 1873, PO Box 149347, Austin, Texas 78714-9347.

Contractor shall send an initial report of contacts on all Class 3 TB cases and smear-positive Class 5 TB suspects within thirty (30) days of identification using DSHS Report of Contacts Form (TB-340 and TB-341).

New follow-up information (not included in the initial report) related to the evaluation and treatment of contacts shall be sent to DSHS on the TB-340 and TB-341 at intervals of ninety (90) days, 120 days, and two (2) years after the day Contractor became aware of the TB case.

Electronic reporting to DSHS for Class 3 TB cases, smear positive Class 5 TB suspects, and their contacts may become available during the term of this Program Attachment. Contractor may avail itself of this option if it adheres to all the electronic reporting requirements (including system requirements) provided at that time.

Contractor will determine and report annually the number of persons which receive at least one (1) TB service including but not limited to tuberculin skin tests, chest radiographs, health care worker services, or treatment with one or more anti-tuberculosis medications.

Contractor shall evaluate and monitor Class B immigrants and when needed place them on appropriate prophylaxis for successful completion of treatment. Immigrant notifications shall be obtained through the Electronic Disease Notification (EDN) system. The TB Follow-up Worksheet in EDN shall be completed for all immigrants whose notification was obtained through EDN.

Contractor shall evaluate refugees and other at-risk clients referred by the Refugee Health Program for further clinical evaluation and when needed place those refugees on appropriate prophylaxis and monitor them for successful completion of treatment. The TB Worksheet in EDN shall be completed on refugees and other at-risk clients who are reported through EDN.

PERFORMANCE MEASURES:

The following performance measures will be used to assess, in part, Contractor's effectiveness in providing the services described in this Contract, without waiving the enforceability of any of the other terms of the Contract or any other method of determining compliance:

1. Cases, and suspected cases, of TB under treatment by Contractor shall be placed on timely and appropriate Directly Observed Therapy (DOT). If data indicates a compliance rate for this Performance Measure of less than 90%, then DSHS may (at its sole discretion) require additional measures be taken by Contractor to improve that percentage, on a timeline set by DSHS;

2. 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.

If data indicates a compliance rate for this Performance Measure of less than 85%, 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. 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. If data indicates a compliance rate for this Performance Measure of less than 97.4%, 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 cases of TB with Acid-fast Bacillis (AFB) positive sputum culture results will have documented conversion to sputum culture-negative within 60 days of initiation of treatment. If data indicates a compliance rate for this Performance Measure of less than 45%, then DSHS may (at its sole discretion) require additional measures be taken by contractor to improve the percentage, on a timeline set by DSHS;

5. Newly-reported TB cases shall have an HIV test performed (unless they are known HIV- positive, or if the patient refuses) and shall have positive or negative HIV test results reported to DSHS according to the reporting schedule provided in Section 1, B herein. If fewer than 80% 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;

6. Newly-reported suspected cases of TB disease shall be started in timely manner on the recommended initial 4-drug regimen. If fewer than 93.2% 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;

7. 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. If data indicates a compliance rate for this Performance Measure of less than 90%, 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. Newly-identified contacts, identified through the contact investigation, that are associated with a sputum AFB smear-positive TB case shall be evaluated for TB infection and disease. If data indicates a compliance rate for this Performance Measure of less than 81.5%, then DSHS may (at its sole discretion) require additional measures be taken by Contractor to improve that percentage, on a timeline set by

DSHS;

9. Contacts, identified through the contact investigation, that are associated with a sputum AFB smear-positive case and that are newly diagnosed with latent TB infection (LTBI) shall be started on timely and appropriate treatment. If data indicates a compliance rate for this Performance Measure of less than 65%, 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. Contacts, identified through the contact investigation, that are associated with a sputum AFB smear-positive case that are newly diagnosed with LTBI and that were started on treatment shall complete treatment for LTBI as described in Targeted Tuberculin Testing and Treatment of Latent TB Infection (LTBI), Morbidity and Mortality Weekly Report, Vol. 49, No. RR-6, 2000, and according to the timelines given therein. If data indicates a compliance rate for this Performance Measure of less than 45%, 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. Newly-reported TB patients that are older than 12-years-old and that have a pleural or respiratory site of disease shall have sputum AFB-culture results reported to DSHS according to the timelines for reporting initial and updated results given herein. If data indicates a compliance rate for this Performance Measure of less than 89.5%, then DSHS may (at its sole discretion) require additional measures be taken by Contractor to improve that percentage, on a timeline set by DSHS; and

12. All reporting to DSHS shall be completed as described in Section I, B-Reporting and submitted by the deadlines given.

If Contractor fails to meet any of the performance measures, Contractor shall furnish in the narrative report, due February 14, 2014, a written explanation including a plan (with schedule) to meet those measures. 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.

BILLING INSTRUCTIONS:

Contractor shall request payment electronically through the Contract Management and Procurement System (CMPS) with acceptable supporting documentation for reimbursement of the required services/deliverables. Billing will be performed according to CMPS instructions found at the following link <http://www.dshs.state.tx.us/cmeps/>. For assistance with CMPS, please email CMPS@dshs.state.tx.us or call 1-855-312-8474.

8. Service Area

Hidalgo County

This section intentionally left blank.

10. Procurement method:

Non-Competitive

Interagency/Interlocal

GST-2012-Solicitation-00061

FY14 TB State

11. Renewals:

Number of Renewals Remaining: 0 Date Renewals Expire: 08/31/2014

12. Payment Method:

Cost Reimbursement

13. Source of Funds:

STATE

14. DUNS Number:

103110834

15. Programmatic Reporting Requirements:

Report Name	Frequency	Period Begin	Period End	Due Date
Annual Report	Annually	January 1, 2013	December 31, 2013	February 14, 2014

16. Special Provisions

General Provisions, Article III. Funding, Section 3.06 Nonsupplanting, is revised to include the following:

Funding from this Contract shall not be used to supplant (i.e., used in place of funds dedicated, appropriated or expended for activities funded through this Contract) state or local funds, but Contractor shall use such funds to increase state or local funds currently available for a particular activity. Contractor shall maintain local funding at a sufficient rate to support the local program. If the total cost of the project is greater than DSHS' share set out in SECTION VII. BUDGET, Contractor shall supply funds for the remaining costs in order to accomplish the objectives set forth in this Contract.

All revenues directly generated by this Contract or earned as a result of this Contract during the term of this Contract are considered program income; including income generated through Medicaid billings for TB related clinic services. Contractor may use the program income to further the scope of work detailed in this Contract, and must keep documentation to demonstrate such to DSHS's satisfaction. This program income may not be used to take the place of existing local, state, or federal program funds.

General Provisions, Article XIII. General Terms, Section 13.15 Amendment, is amended to include the following:

Contractor must submit all amendment and revision requests in writing to the Division Contract Management Unit at least ninety (90) days prior to the end of the term of this Program Attachment.

17. Documents Forming Contract. The Contract consists of the following:

- a. Contract (this document) 2014-001417-00
- b. General Provisions Subrecipient General Provisions
- c. Attachments Budgets

- d. Declarations Certification Regarding Lobbying, Fiscal Federal Funding Accountability and Transparency Act (FFATA) Certification
- e. Exhibits

Any changes made to the Contract, whether by edit or attachment, do not form part of the Contract unless expressly agreed to in writing by DSHS and Contractor and incorporated herein.

18. Conflicting Terms. In the event of conflicting terms among the documents forming this Contract, the order of control is first the Contract, then the General Provisions, then the Solicitation Document, if any, and then Contractor's response to the Solicitation Document, if any.

19. Payee. The Parties agree that the following payee is entitled to receive payment for services rendered by Contractor or goods received under this Contract:

Name: Hidalgo County
Vendor Identification Number: 17460007176

20. Entire Agreement. The Parties acknowledge that this Contract is the entire agreement of the Parties and that there are no agreements or understandings, written or oral, between them with respect to the subject matter of this Contract, other than as set forth in this Contract.

I certify that I am authorized to sign this document and I have read and agree to all parts of the contract, including any attachments and addendums.

Department of State Health Services

Hidalgo County

By:
Signature of Authorized Official

By:
Signature of Authorized Official

Date

Date

Name and Title
1100 West 49th Street
Address
Austin, TX 787-4204
City, State, Zip

Name and Title

Address

City, State, Zip

Telephone Number

Telephone Number

E-mail Address

E-mail Address

BUDGET SUMMARY

Organization Name: Hidalgo County
 Contract Number: 2014-001417-00
 Proposal ID: DCPS-2014-Hidalgo -00019

Program ID: TB/PC-STATE
 Procurement ID: GST-2012-Solicitation-00061
 Procurement Name: FY14 TB State

Budget Categories

Budget Categories	DSHS Funds Requested	Cash Match	In Kind Match	Category Total
Personnel	\$427,954	\$129,046	\$0	\$557,000
Fringe Benefits	\$133,222	\$40,172	\$0	\$173,394
Travel	\$61,715	\$0	\$0	\$61,715
Equipment	\$0	\$0	\$0	\$0
Supplies	\$36,572	\$0	\$0	\$36,572
Contractual	\$0	\$0	\$0	\$0
Other	\$5,500	\$0	\$0	\$5,500
Total Direct Costs	\$664,963	\$169,218	\$0	\$834,181
Indirect Costs	\$0	\$0	\$0	\$0
Totals:	\$664,963	\$169,218	\$0	\$834,181

Subcontracting

Subcontracting Percentage: 0.00%

Match Contributions

Required Match Percentage: 20.00%
 Required Match Amount: \$132,993

Calculated Match Percentage: 25.45%
 Calculated Match Amount: \$169,218

Source of Cash Match Funds

Personnel & Fringe

18 of 500

Source of In Kind Match Funds

0 of 500

Program Income

Projected Earnings: \$0

Source of Earnings

0 of 500

Non DSHS Funding

Direct Federal Funds: \$0
 Other State Agency Funds: \$0
 Local Funding Sources: \$0
 Other Funds: \$0
 Total Projected Non DSHS Funding: \$0

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SAVE

CHECK GLOBAL ERRORS

CERTIFICATION REGARDING LOBBYING

Organization Name: Hidalgo County
Contract Number: 2014-001417-00

For contracts greater than \$100,000, this attachment is applicable and must be signed as part of the contract agreement.

CERTIFICATION REGARDING LOBBYING CERTIFICATION FOR CONTRACTS, GRANTS, LOANS AND COOPERATIVE AGREEMENTS

The undersigned certifies, to the best of his or her knowledge and belief that:

- (1) No federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or an employee of any agency, a member of congress, an officer or employee of congress, or an employee of a member of congress in connection with the awarding of any federal contract, the making of any federal grant, the making of any federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any federal contract, grant, loan, or cooperative agreement.
- (2) If any funds other than federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a member of congress federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit, an officer or employee of congress, or an employee of a member of congress in connection with this Standard Form-11, "Disclosure Form to Report Lobbying," in accordance with its instructions.
- (3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by Section 1352, Title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less that \$10,000 and not more than \$100,000 for each such failure.

Applicable Non-Applicable

Signature of Authorized Individual

Date:

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	Fiscal Federal Funding Accountability and Transparency Act (FFATA) Certification			
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	General Provisions			
	Contract Print			
	Exhibit A			

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FISCAL FEDERAL FUNDING ACCOUNTABILITY AND TRANSPARENCY ACT (FFATA) CERTIFICATION

The certifications enumerated below represent material facts upon which DSHS relies when reporting information to the federal government required under federal law. If the Department later determines that the Contractor knowingly rendered an erroneous certification, DSHS may pursue all available remedies in accordance with Texas and U.S. law. Signor further agrees that it will provide immediate written notice to DSHS if at any time Signor learns that any of the certifications provided for below were erroneous when submitted or have since become erroneous by reason of changed circumstances. If the Signor cannot certify all of the statements contained in this section, Signor must provide written notice to DSHS detailing which of the below statements it cannot certify and why.

Organization Name Hidalgo County
 Address 1304 S 25th St
 City Edinburg State Texas Zip Code (9 digit) 78539

Payee Name Hidalgo County
 Address Hidalgo County Treasurer
 2810 S Business 281
 City Edinburg State TX Zip Code (9 digit) 78539-6243

Vendor identification No. 17460007176 MailCode 060

Payee DUNS No. *  103110834

1. Did your organization have a gross income, from all sources, of more than \$300,000 in your previous tax year? *

Yes No

2. Certification Regarding % of Annual Gross from Federal Awards.

Did your organization receive 80% or more of its annual gross revenue from federal awards during the preceding fiscal year?

Yes No

3. Certification Regarding Amount of Annual Gross from Federal Awards.

Did your organization receive \$25 million or more in annual gross revenues from federal awards in the preceding fiscal year?

Yes No

Identify contact persons for FFATA Correspondence. *

FFATA Contact Person #1

Name* Ramon Garcia
 Email* ramon.garcia@co.hidalgo.tx.us
 Telephone* (956) 318-2600

FFATA Contact Person #2

Name* Ray Eufrazio
 Email* ray.eufrazio@auditor.co.hidalgo.tx.us
 Telephone* (956) 318-2511

As the authorized representative of the Organization, I hereby certify that the statements made by me in this certification form are true, complete and correct to the best of my knowledge.

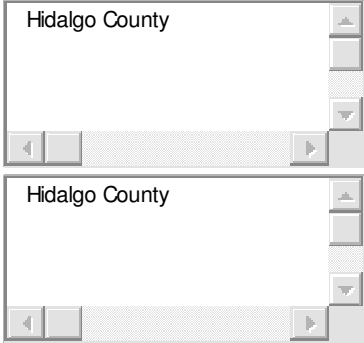
E-Signature

Date

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EXHIBIT A

Organization Name:  Hidalgo County

Contract Number:

Contract Term: -

Tuberculosis Work Plan

Program ID:
Program
Name:

UNIT A

Program Stewardship and Accountability

Contractor General Requirement A-1

Implement a comprehensive Tuberculosis (TB) Prevention and Control Program. Activities under this requirement shall be conducted in accordance with the Department of State Health Services (DSHS) Standards of Performance for the Prevention and Control of Tuberculosis.

Activities:

- Maintain current policies in compliance with the DSHS Standards of Performance for the Prevention and Control of Tuberculosis (TB) and have them available to Contractor's staff.
- Administer activities that include the following core components.
 - A. Conduct overall planning and policy
 - B. Manage TB cases and suspects
 - C. Manage contacts to known or suspected cases of tuberculosis
 - D. Manage patients on treatment for latent TB infection (LTBI)
 - E. Conduct surveillance to identify unreported individuals with suspected or confirmed TB
 - F. Reporting to DSHS
 - G. Implement infection control procedures
 - H. Maintain a competent workforce
 - I. Conduct continuing quality improvement activities to maintain a robust TB program infrastructure

Contractor General Requirement A-2

Demonstrate fiduciary responsibility in administering program funds

Activities:

- Provide a match of no less than 20% of the total budget reflected in the Program Attachment. Contractor shall provide match at the required percentage or DSHS may withhold payments, use administrative offsets, or request a refund from Contractor until such time as the required match ratio is met. No federal or other grant funds can be used as part of meeting the match requirement. Contractor shall not use DSHS funds or matching funds (including in-kind Contributions) for:
 1. Food;
 2. Incentives;
 3. Entertainment; or
 4. Sectarian worship, instruction, or proselytization.
- Provide TB services to cases, suspects, contacts, refugees and class B immigrants regardless of their ability to pay for services.
- Lapse no more than 5% of total funded amount of the contract.
 1. Maintain and adjust spending plan throughout the contract term to avoid lapsing funds.
 2. Maintain staffing levels to meet required activities of the contract and to ensure that all funds in the personnel category are expended.

UNIT B

Conduct Overall Planning and Policy

Contractor General Requirement B-1

Develop policies to cover the following topics: administration of the program; training; reporting practices and surveillance; program evaluation; laboratory testing for mycobacteria; case finding, and management; treatment of persons with TB disease and latent TB infection; contact investigations; targeted testing for latent TB infection; and standard responses to foreseeable adverse situations (e.g., uncooperative patients, outbreaks, and multidrug-resistant TB).

Activities:

- Develop written policies and procedures covering the aforementioned topics. Policies and procedures shall be written and available to staff responsible for TB prevention and control activities.
- Review written policies and procedures at least once every three years and revise as appropriate to conform to state recommendations and best practices.
- Maintain a written list of community resources that can assist TB patients with food, shelter, social services, and other medical services.
- Develop procedures to coordinate TB care with other socio/medical conditions. If the patient does not already have a primary medical provider or medical home, the program should facilitate establishment of a medical home as appropriate.

UNIT C

Manage Tuberculosis Cases and Suspects

Contractor General Requirements C-1

Provide services to evaluate, treat and monitor patients with suspected or confirmed tuberculosis disease. The goal of TB patient management is to initiate treatment promptly and ensure completion of effective therapy to cure illness, reduce transmission and prevent the development of drug resistant TB.

Activities:

- Conduct a complete medical evaluation on all patients suspected of having TB disease. A complete medical evaluation and assessment for TB includes medical history (symptoms, prior TB treatment, risk factors for TB, and history of exposure); physical examination; Mantoux tuberculin skin test (TST) or interferon-gamma release assay (IGRA) (e.g., QuantiFERON-Gold test); chest x-ray; and appropriate bacteriologic (smear, culture, drug susceptibility) and/or histologic examinations. If a patient is reported to the health department with laboratory culture results indicating the presence of Mycobacterium tuberculosis complex, a TST result would not change the diagnosis and may be waived.
- Complete the informed consent form and place in the patient's medical record.
- For patients whose TB care will be shared by both a private medical provider and a local health department, develop a written document signed by both parties that describes the specific roles and responsibilities of each provider.
- Utilize interpreter services to facilitate patient and provider communication as it relates to limited English proficient (LEP) clients.
- Sputum Collection
 1. Educate patients about collection of sputum and packaging for mailing, if the patient will mail in specimens. Education shall be given prior to collection. The health care worker shall observe the collection of at least the initial sputum obtained by the health department and document the observation of this collection in the medical record.
 2. For patients who are able to produce natural or induced sputum:
 - a. Obtain three sputum specimens, 8 to 24 hours apart, prior to or at the initiation of therapy for the determination of smear and culture. At least one of the samples should be collected early in the morning. Ship specimens according to laboratory guidelines.
 - b. Collect at least every two weeks, three sputum specimens (of which at least one should be collected early in the morning) for the determination of smears only until three consecutive smears are negative.
 - c. Collect monthly, at least one sputum specimen for the determination of culture until all specimens collected for 2 consecutive months are culture negative. Monthly sputum must be collected from patients with isolates resistant to both isoniazid and rifampin and all other MDR TB cases throughout the treatment course.
 - d. Collect at least one further sputum collection at completion of therapy, if possible.
- HIV Screening
 1. Perform HIV screening for all persons with newly diagnosed or suspected TB disease unless the patient has HIV positive documentation or has documented negative HIV test result from a specimen collected within the last 14 days.
 2. Present HIV testing to the patient in the same manner as information about other routine tests. The patient may decline to be tested for HIV, but should be educated about the importance of knowledge about their HIV status to the medical management of their TB disease.
 3. Report newly positive HIV test results to the appropriate local or health service regional public health HIV/STD program. The patient shall be informed of newly positive HIV test results in person by a health care worker who is trained in post-test counseling. For patients with TB disease who are also infected with HIV, a CD4 count should be obtained.
- Place a surgical mask on patients with symptoms of pulmonary, pleural, or laryngeal TB that arrive at the local health department for services or place patients in an airborne infection isolation area at each clinic visit until the patient has met the following three (3) criteria for non-infectiousness and the patient has negligible likelihood of multidrug-resistant TB (no known exposure to multidrug-resistant TB and no history of prior episodes of TB with poor compliance during treatment):
 1. Received standard multidrug anti-tuberculosis treatment by directly observed therapy (DOT) for two weeks;
 2. Has demonstrated clinical or radiographic improvement; and
 3. Has three consecutive negative sputum smear results collected 8 to 24 hours apart with at least one specimen being collected early in the morning. If sputum culture results become negative before the smear results, then three consecutive negative culture results satisfy the criteria for non-infectiousness.

- Place infectious patients in home isolation if the following criteria are met:
 1. A specific plan exists for follow-up care with the local TB-control program;
 2. The patient has been started on a standard multidrug antituberculosis treatment regimen, and DOT has been arranged;
 3. No infants or children aged less than 4 years or persons with immunocompromising conditions are present in the household;
 4. All immunocompetent household members have been previously exposed to the patient; and
 5. The patient is willing to refrain from travel outside of the home except for health-care-associated visits until the patient has three consecutive negative sputum smear results.
- Order a complete bacteriologic work up, including drug susceptibility tests for isoniazid, rifampin and ethambutol on initial isolates. Extended drug susceptibility testing shall be performed on all isolates with resistance to any first line agent in accordance to TB Drug Resistant policy TB 4002. Assure that at least one specimen from cases with a positive culture is sent to the DSHS Austin lab for genotyping.
- Obtain for all adult patients, baseline laboratory tests for aspartate aminotransferase (AST), alanine aminotransferase (ALT), bilirubin, alkaline phosphatase, serum creatinine, and a complete blood count including platelets must be performed prior to starting treatment. All patients with a history of liver disease, symptoms of liver disease, baseline liver function tests above the upper limit of normal, or risk factors for liver disease should receive screening for viral or other causes of hepatitis. Refer to DSHS Standards of Performance for the Prevention and Control of Tuberculosis for additional monitoring of liver function test results.
- Develop and initiate a complete treatment and case management plan according to ATS/CDC/IDSA guidelines and recommendations of DSHS. Refer to DSHS Standards of Performance for the Prevention and Control of Tuberculosis, Management of TB Suspects and Cases
- Provide DOT to all cases and suspects until the recommended course of therapy is completed. Directly observed therapy is the standard of care in Texas.
- Obtain consultation from a DSHS recognized expert physician consultant within three days of laboratory notification for all TB cases whose Mycobacterium tuberculosis organisms are resistant to isoniazid and/or rifampin or shows a resistance to any drug on the drug susceptibility panel in accordance to TB 4002 policy. Provide written documentation the consultation occurred and the consultant's recommendations were followed or a justification for deviations from the advice of the consultant shall be maintained in the patient's record and a copy of the consult must be sent to the DSHS Tuberculosis Services Branch within twenty-four hours.
- Obtain consultation from a recognized expert physician for cases with HIV infection or cases less than 15 years of age.
- Obtain consultation from a recognized expert physician to resume treatment after interruptions of more than 2 weeks in the initiation phase of therapy or more than 2 months in the continuation phase. A list of recognized expert physician consultants is available from the DSHS Tuberculosis Services Branch.
- Prepare and present a written control order (order to implement measures) at the beginning of treatment to all persons with suspected or confirmed tuberculosis disease.
- Provide treatment to all TB cases and suspects without consideration of ability to pay.
- Provide initial and ongoing education to the patient regarding the epidemiology, transmission and pathogenesis of TB; means to decrease transmission; need to complete therapy; rationale for directly observed therapy and contact investigation; confidentiality of patient information, common adverse drug reactions and drug interactions of TB medications; responsibility of patient to discuss symptoms of adverse drug reactions with the nurse case manager or physician when they occur; and signs and symptoms associated with disease relapse.

Contractor General Requirements C-2

Initiate a contact investigation on persons with possible or confirmed pulmonary, pleural or laryngeal TB disease.

Activities:

- Initiate a contact investigation for suspected or confirmed cases of pulmonary, pleural, or laryngeal TB disease within three (3) days of report or notification. Contact investigations should not be delayed pending laboratory results in congregate settings or where there is some indication that children younger than five, persons who are HIV-infected or persons who are otherwise immunocompromised may be among the contacts. A contact investigation may be halted or not initiated if a nucleic acid amplification test performed by CDC recommended protocol or another rapid laboratory test is negative for Mycobacterium tuberculosis complex.
- Use the Contact Investigation Worksheet (Form # EF12-12062) during patient's interview to assign priority status to contacts identified.
- Assign priority status prior to initiating contact investigations based on the infectiousness of the presenting suspect or case and data obtained from the Contact Investigation Worksheet:
 1. (First priority – persons with acid-fast bacilli (AFB) sputum smear positive or with cavitary TB) Identify and test all high and medium priority contacts.
 2. (Second priority – persons with suspected or confirmed pulmonary/pleural TB, AFB sputum smear negative and an abnormal chest radiograph consistent with TB disease) Identify and test all high and medium priority contacts.
 3. (Third priority – all other cases and suspects) Identify and test contacts that are living in the household, aged less than 5 years, have a medical risk factor, or were exposed during an unprotected medical procedure (such as bronchoscopy, sputum induction or autopsy).
 - a. Negative test results of contacts with the most exposure to extrapulmonary cases confirms that there has been no transmission due to pulmonary involvement.
 - b. Testing of contacts with the most exposure to cases aged less than 5 years may identify the source of the child's infection or other associates that may have been infected by that source case.

Refer to DSHS Standards of Performance for the Prevention and Control of Tuberculosis for detailed steps in a contact investigation.

UNIT D

Manage Contacts to Known or Suspected Cases of Tuberculosis

Contractor General Requirements D-1

Provide services to evaluate, treat, and monitor contacts to suspected or confirmed cases of pulmonary, pleural, or laryngeal TB disease. The goal of contact management is to evaluate promptly, initiate treatment when indicated, and ensure completion of effective therapy to prevent progression to tuberculosis disease.

Activities:

- Find exposed persons who are more likely to be infected or to become ill with TB disease. Increased length or frequency of exposure as well as the relative infectiousness of the presenting TB case increase the probability of infection.
- Complete an initial interview including education, testing and evaluation of contacts within three weeks of the report of the suspect to the local health department.
- Prioritize all contact investigations as documented in the DSHS Standards of Performance for the Prevention and Control of Tuberculosis, Section 4 and noted in C-2.
- Interview all contacts to obtain their relevant medical history (including specific questions about the symptoms of TB disease, previous positive tuberculin reaction and/or previous treatment for TB).
- Administer and read a tuberculin skin test (TST), or administer an interferon-gamma release assay (IGRA). If reactive, perform a chest radiograph. If an abnormality is noted on the chest radiograph, collect sputum or another specimen for examination.
- Provide window prophylaxis, if there are no contraindications to treatment, to the following contacts if they are asymptomatic and have a negative TB screening result on the initial IGRA or TST:
 1. Children less than five years of age;
 2. Persons with documented HIV-positive results; or
 3. Persons with other immunosuppressed conditions.
- Administer the second TB screening test on the aforementioned contacts within 8-10 weeks of the initial test. If the screening result is negative, discontinue treatment. Contacts that are HIV-infected will need a chest radiograph if the initial screening result is negative. As recommended by the treating physician, individuals who are HIV infected may need the results of the analysis of smears, cultures or other rapid diagnostic procedures on appropriate specimens to differentiate between LTBI and active TB disease.
- Refer to DSHS Standards of Performance for the Prevention and Control of Tuberculosis, Section 4 for detailed information regarding the management of contacts.

UNIT E

Manage Patients on Treatment for Latent TB Infection

Contractor General Requirements E-1

Provide treatment services for at-risk persons diagnosed with latent TB infection.

Activities:

- Evaluate at-risk candidates for TB. At-risk candidates may include contacts, refugees, class B immigrants, discharged inmates or other high risk populations in which TB is prevalent.
- Contacts to a person known or suspected to have TB should receive a chest radiograph regardless of their ability to pay. A health history containing at least as much information as the TB-202 Tuberculosis Health Assessment/History must be documented in the patient's medical record.
- Complete the informed consent form for treatment and place in the patient's medical record. The consent form should be in the patient's preferred language or the medical record must document the use of an interpreter to read the consent form to the patient before signing.
- Complete the TB Worksheet in the Electronic Disease Notification System for all class B immigrants and refugee notifications.
- If treatment for LTBI is not started within three (3) months of the chest x-ray showing no abnormalities indicative of TB or the patient begins to exhibit symptoms suggestive of TB, a new chest x-ray or other diagnostic procedures should be performed and evaluated prior to the start of therapy for LTBI.
- A repeat chest radiograph should be done prior to taking the first dose of medication if therapy for LTBI is not started within one month for persons at high risk of progressing to TB disease including those < 1 year of age, those co-infected with HIV, or those receiving immunosuppressive therapy to ensure that TB disease has not developed in the interim.
- Order baseline laboratory testing if risk factors for potential adverse drug reactions are identified.
- Provide DOT to all contacts diagnosed with LTBI who are placed on a DSHS-approved short course regimen.
- Provide DOT to all contacts diagnosed with LTBI who are less than five years of age or HIV positive or live in the same residence as a case receiving directly observed therapy. Directly observed therapy for LTBI may be provided to other high-risk persons as resources allow.
- Document on the appropriate DSHS reporting form when patient has completed treatment or stopped medication. Document the reason medication was stopped if patient did not complete treatment.
- Provide treatment for LTBI without consideration of the patient's ability to pay.
- Provide initial and ongoing education to the patient regarding the epidemiology, transmission, and pathogenesis of TB; need to complete therapy; confidentiality of patient information; rationale for directly observed therapy; common adverse drug reactions and drug interactions of TB medications; responsibility of the patient to discuss symptoms of adverse drug reactions with the nurse case manager or physician when they occur; and signs and symptoms associated with progression to TB disease. Instruct the patient to contact the TB program nurse or physician for a diagnostic evaluation if symptoms of TB disease occur at any time in the future.

UNIT F

Conduct Surveillance to Identify Unreported Individuals with Suspected or Confirmed Tuberculosis

Contractor General Requirement F-1

Develop and maintain a surveillance mechanism for early identification and reporting of TB.

Activities:

- Identify specific community and health care organizations in which at-risk populations are likely to receive services.
- Provide education and training to community based and health care organizations to increase awareness about TB to include TB transmission, disease presentation, community-specific epidemiology of TB and reporting requirements.
- Incorporate TB in existing surveillance mechanisms. If one does not exist, develop an active surveillance system that promotes routine TB reporting.
- Evaluate surveillance mechanisms to enhance TB reporting processes.
- Perform daily searches in DSHS reporting database for documents needing review for unreported laboratory confirmed cases submitted through the electronic laboratory reporting (ELR) system.
- Cross match report of verified cases of TB (RVCT) with TB GIMS data

UNIT G

Reporting

Contractor General Requirement G-1

In accordance with reporting requirements, submit all reports by established deadlines using the Public Health Information Network (PHIN).

Activities:

- Report 100% of all TB cases (ATS classification 3) using a DSHS approved form, the minimum required case criteria within seven (7) days of notification to DSHS TB/HIV/STD Epidemiology and Surveillance Branch. Refer to the Case Verification Report form for initial reporting case criteria at <http://www.texas.tb.org>. Submit an updated DSHS Tuberculosis Services Branch approved form whenever a change in information in a required reporting field occurs for all TB cases.
- Submit within fourteen (14) days of the initial case or suspect report, an initial report of contacts on forms TB-340 and TB-341 to the DSHS TB/HIV/STD Epidemiology and Surveillance Branch except Houston Department of Health and Human Services. Follow-up information shall be submitted at intervals not exceeding 90 days, 120 days and 2 years.
- Submit 100% of all initial, follow up, and last positive Mycobacterium tuberculosis culture laboratory reports and drug susceptibilities as well as the first negative culture report after the last positive within seven (7) days of notification to DSHS TB/HIV/STD Epidemiology and Surveillance Branch. (Note: for culture reports that originate from a DSHS laboratory or through the ELR, this requirement is automatically met. For culture reports not originating from a DSHS lab or ELR, a copy of the laboratory report must be submitted.)
- Document the dates of sputum and culture conversion on a DSHS approved report form to DSHS TB/HIV/STD Epidemiology and Surveillance Branch. Since sputum specimens may have culture results that fluctuate from positive to negative to positive over a period of time before true conversion occurs, the collection dates for the last positive sputum culture and the first consistently negative sputum culture must be separated by at least 7 days. The collection dates for the initial drug susceptibility test results must be no earlier than 7 days before the drug start date and no later than 7 days after the drug start date. The collection dates for the follow-up susceptibilities should be at least 30 days from the initial drug susceptibilities.
- Prepare the appropriate referral forms when a suspect, case, contact or persons with latent TB infection moves to another jurisdiction to ensure follow-up and continuity of care. Refer to <http://www.texas.tb.org> to access appropriate referral forms.
- Report 100% of all TB suspects (ATS classification 5) using a DSHS approved form within 7 days of disposition to DSHS TB/HIV/STD Epidemiology and Surveillance Branch. See Suspect Verification Report Form for definition. Note: all suspects must be dispositioned no later than 90 days of initial report.
- If treatment of a TB case or suspect has stopped due to completion of adequate therapy, death, or failure to locate the patient after three solid attempts and/or 90 days have passed since the last dose, provide acceptable closure codes and the last date medication was given and submit to the DSHS TB/HIV/STD Epidemiology and Surveillance Branch. In the event of a cross-contamination or misdiagnosis, provide documentation to justify change (e.g., amended lab report, doctor's note, consult, etc.). Note: all other cultures must be negative and positivity rate for contacts evaluated cannot be greater than 30%.
- Update all missing data reports on cases and contacts by DSHS suspense dates to meet national TB indicators (NTIP) objectives. Refer to <http://www.texas.tb.org> to download TB Suspense Date Schedule.
- Submit the monthly correctional TB screening reports within fifteen (15) working days of the following month to DSHS Tuberculosis Services Branch. Local health departments shall receive the monthly correctional TB screening reports from jails meeting Texas Health and Safety Code Chapter 89 Requirements within five (5) working days of the following month, review reports for accuracy and completion and provide guidance to jails as needed in completing the monthly reports.
- Complete and submit form TB-400 on all newly diagnosed drug resistant cases within five (5) days of notification to the DSHS Tuberculosis Services Branch. Submit an updated form TB-400 every ninety (90) days for all drug resistant cases until completion of treatment to DSHS Tuberculosis Services Branch.
- Submit within seventy-two (72) hours of notification any changes in case management, drug resistance patterns, or change of residence of all drug resistant TB cases to DSHS Tuberculosis Services Branch.
- Submit the required Annual Narrative Report, using the standardized format provided, to DSHS, Tuberculosis Services Branch at TBCContractReporting@dshs.state.tx.us by February 14, 2014.
- Submit the completed Cohort Review Summary Report Form to DSHS Tuberculosis Services Branch in accordance with the Cohort Review Policy. Refer to the Cohort Review Policy for the cohort review presentation and submission schedule.

- Submit to the Health Service Region (HSR) in your jurisdiction, verified data on the number of persons with LTBI completing treatment in the LHD service area. The above named LHD will collaborate with the DSHS Health Service Region (HSR) TB program in its area to review completion data for LTBI for calendar year 2011. Additionally, preliminary data for calendar year 2012 shall be reviewed for completion of treatment. Upon verification by the HSR and LHD, the HSR will submit on behalf of the LHD, the data to the DSHS TB/HIV/STD Epidemiology and Surveillance Branch. The following verified data reflecting the number of persons completing treatment for LTBI with a DSHS TB Services Branch approved treatment regimen will be included in the funding formula:

- contacts to a counted case in Texas, or
- high risk contact to a case counted in another state, or
- member of a special population, or as noted in the TB funding formula, or
- client of a DSHS-funded refugee resettlement program.

UNIT H

Implement Infection Control Procedures

Contractor General Requirements H-1

Utilize appropriate administrative, environmental, and respiratory controls to prevent exposure to and transmission of Mycobacterium tuberculosis

Activities:

- Develop a written infection control plan, which includes sections on administrative measures, environmental controls, personal respiratory protection, and procedures in accordance with the "Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005."
- Refer to Section 7 of DSHS Standards of Performance for the Prevention and Control of Tuberculosis for detailed instructions regarding administrative measures, environmental controls and respiratory protection.

UNIT I

Maintain a competent workforce

Contractor General Requirements I-1

Provide professional education, training and orientation for new TB program staff and continuing education for current TB program staff.

Activities:

- Provide orientation and training to all employees involved in TB activities including physicians, nurses, contact investigators, outreach workers, case registry staff, receptionists, and other support staff.
- Within 60 days of employment, all new employees shall receive 40 hours of TB training specific to their duties and responsibilities. Each year employees shall receive 16 hours of continuing education or training relevant to their position. The CDC's "Self-Study Modules on Tuberculosis" shall be used in the initial training. Documentation of all training (including the hours, topics, and dates) shall be retained for each employee who delivers TB services and made available upon request by the DSHS Tuberculosis Services Branch.
- Case registry staff shall attend annual medical records conference and workshop to obtain the latest records management procedures.
- Topics for training of personnel include:
 - a) Transmission and Pathogenesis of Tuberculosis;
 - b) Epidemiology of Tuberculosis;
 - c) Diagnosis of Tuberculosis Infection and Disease;
 - d) Treatment of Tuberculosis Infection and Disease;
 - e) Drug Interactions and Toxicity;
 - f) Contact Investigation for Tuberculosis;
 - g) Tuberculosis Surveillance and Case Management in Hospitals and Institutions;
 - h) Infectiousness and Infection Control;
 - i) Patient Adherence to Tuberculosis Control;
 - j) Interviewing, Investigating and Influencing Techniques;
 - k) Medical Record Keeping and Management;
 - l) Budgeting and Fiscal Management;
 - m) Operations Management;
 - n) Directly Observed Therapy;
 - o) TB Nurse Case Management Training;
 - p) Cultural Awareness;
 - q) Interpreter Utilization.
 - r) CDC Tuberculosis Surveillance Data Training; Report of Verified Case of Tuberculosis (RVCT)
 - s) TB Reporting; Report of Contacts TB-340 Instructions

- Notify DSHS Tuberculosis Services Branch of newly hired TB program managers, nurses and case registry staff within 30 days of hire.
- Newly hired TB program managers, nurses and case registry staff shall participate in the DSHS Tuberculosis Services Branch orientation within three months of hire.

- Provide TB education and training as resources allow to correctional facilities, community health care and social service providers who serve populations at high risk for TB.
- Document all community-provider TB training (including the hours, topics, dates and numbers of participants) make available upon request to the DSHS Tuberculosis Services Branch.

UNIT J

Conduct continuing quality improvement activities to maintain a robust TB infrastructure

Contractor General Requirements J-1

Assess program performance by determining rates of completion of therapy, contact identification and initiation and completion of treatment for latent TB infection.

Activities:

- Conduct quarterly cohort reviews in accordance with DSHS Tuberculosis Services Branch policy and procedures.
- Compare treatment completion rates and contact evaluation rates by cohort periods and years to assess program progress.
- Using the cohort review process, identify trends that support or create barriers to effective TB prevention and control activities.
- Prepare and submit the Cohort Review Summary Form to DSHS Tuberculosis Services Branch in accordance with the DSHS submission schedule documented in the Cohort Review Policy.
- Perform routine case management reviews and document findings. Conduct follow-up reviews to ensure recommendations are addressed.