TEXAS Health and Human Services | Texas Department of State Health Services

Tuberculosis and Refugee Health Services Branch

Texas Tuberculosis Work Plan

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Texas Tuberculosis Work Plan

I. Introduction

The *Texas Tuberculosis Work Plan* sets forth procedures established by the Texas Department of State Health Services (DSHS) Tuberculosis (TB) and Refugee Health Services Branch (TB Branch) and the TB/HIV/STD Epidemiology and Surveillance Branch (Surveillance Branch) to ensure performance standards are achieved by all TB programs receiving state funding or in-kind support from DSHS Health Service Regions (HSRs).

A. DSHS Central Office Responsibilities
The TB Branch will:

- Distribute funds to maximize the delivery of authorized services to eligible clients;
- Monitor TB programs' budget expenditures on a quarterly basis; and if expenditures are below the projected amounts, the jurisdictional budget may be subjected to a decrease;
- Develop standards to prevent and control TB in Texas;
- Monitor and evaluate TB programs on the performance of program functions and objectives to determine effectiveness, efficacy, and compliance with TB essential components of prevention and control guidelines and standards;
- Provide technical assistance on any aspect of TB prevention and control;
- Work with DSHS Pharmacy Branch to ensure availability of medications and supplies to treat TB disease and infections;
- Provide Texas-specific TB training directly and in collaboration with Heartland National TB Center and other partners;
- Oversee molecular epidemiology practices to determine and provide technical assistance to investigate transmission patterns and cluster events;
- Oversee TB prevention and control in high risk populations including, correctional facilities, community corrections and other congregate settings;
- Oversee targeted testing initiatives;
- Develop and revise policies and regulations;
- Serve as the point of contact for international activities involving the prevention and control of TB; and
- Conduct quality assurance activities.

The Surveillance Branch will:

- Serve as the repository for TB data reported to DSHS;
- Collect and analyze reports from TB programs to satisfy TB grant requirements
- Serve as the point of contact for inter-jurisdictional transfers;
- Promotes security and confidentiality standards for TB data exchanges;
- Prepare and report aggregate data to the CDC;

- Prepare TB epidemiologic reports; and
- Provide technical assistance to HSRs and LHDs for accurate submittal of TB data.

DSHS Central Office branches, HSRs and LHDs shall comply with the following regarding TB prevention and control activities:

- All TB Branch standards and policies on http://www.texasTB.org;
- *DSHS Standing Delegation Orders and Standing Medical Orders for Tuberculosis Prevention and Control*, http://www.texastb.org
- *Texas Tuberculosis Work Plan*, http://www.dshs.state.tx.us/idcu/disease/tb/policies/;
- DSHS Standards for Public Health Clinic Services, 2004, http:// www.dshs.state.tx.us/qmb/dshsstndrds4clinicservs.pdf;
- American Thoracic Society (ATS) and Centers for Disease Control and Prevention (CDC) joint statements on diagnosis, treatment and control of TB, *MMWR*, RR-11, Vol. 52, 2003, 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, http://atsjournals.org/doi/abs.10.1164/ajrccm.161.4.16141#.vrm6roko4dy;
- Targeted Tuberculin Testing and Treatment of Latent TB Infection (LTBI), *Morbidity and Mortality Weekly Report* (*MMWR*), Vol. 49, No. RR-6, 2000, http://www.cdc.gov/mmwr/PDF/rr/rr4906.pdf;
- 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;
- Controlling Tuberculosis in the United States, *MMWR*, Vol. 54, No. RR-12, 2005, 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, http://www.cdc.gov/mmwr/pdf/rr/rr58e0826.pdf;
- CDC, *Tuberculosis Surveillance Data Training Report of Verified Case of Tuberculosis (RVCT) Instruction Manual*, http://www.cdc.gov/tb/programs/rvct/InstructionManual.pdf.

TB programs shall comply with all applicable federal and state regulations and statutes, including but not limited to, the following:

- *Tuberculosis Code*, Texas Statutes, Health and Safety Code, Chapter 13, Subchapter B;

- *Communicable Disease Prevention and Control Act*, Texas Statutes, Health and Safety Code, Chapter 81;
- *Screening and Treatment for Tuberculosis in Jails and Other Correctional Facilities*, Texas Statutes, Health and Safety Code, Chapter 89;
- *Control of Communicable Diseases*, Texas Administrative Code TAC, Title 25, Part 1, Chapter 97, Subchapter A;
- *Tuberculosis Screening for Jails and Other Correctional Facilities*, Texas Administrative Code (TAC), Title 25, Part 1, Chapter 97, Subchapter H; and
- *Retention of Medical Records*, General Provisions Article VIII "Records Retention" and by Texas Administrative Code Title 22, Part 9, Chapter 165, §165.1.

II. Purpose

The purpose of the *Texas Tuberculosis Work Plan* is to describe the framework of a regional and local TB program and outlines activities to meet standards set forth by DSHS. This work plan:

- Serves as a prescriptive document to design and maintain a TB program;
- Outlines the expectations and responsibilities of all funded programs;
- Assures consistent TB prevention and control practices are applied throughout Texas; and
- Provides a blueprint to assess performance outcomes based on quality indicators.

Funded TB programs shall provide services to persons with suspected or confirmed TB disease, contacts to a known source case and targeted groups including but not limited to Class B immigrants and refugees without consideration of a client's ability to pay.

III. Program Stewardship and Accountability

<u>General Requirement</u>: Implement a comprehensive TB prevention and control program and manage resources in an effective manner that focuses on stewardship and accountability.

The framework of an effective TB program includes the following components:

1. Program stewardship and accountability;
2. Conducting overall planning and develop policies;
3. Managing tuberculosis cases and suspects;
4. Managing contacts to confirmed or suspected TB cases;
5. Managing clients on treatment for TB infection;
6. Conducting surveillance to identify unreported individuals with suspected or confirmed TB;
7. Submitting designated reports;
8. Implementing infection control procedures;
9. Maintaining a competent workforce;
10. Monitoring budget requirements;
11. Maintaining confidentiality and security standards;
12. Monitoring surveillance, reporting and case management activities in correctional facilities;
13. Initiating and maintaining self-auditing practices; and
14. Conducting continuing quality improvement activities to maintain a robust TB program infrastructure.

IV. Conduct Overall Planning and Develop Policies

General Requirement: Develop and Maintain Policies and Procedures

Develop and maintain policies and procedures that align with *Texas Tuberculosis Work Plan* and *Tuberculosis Program Manual* and have them available to program staff. Policies and procedures shall not contradict DSHS' expectations and requirements.

Activities:

A. Develop written policies and procedures covering the following topics:

- program administration;
- training;
- reporting;
- surveillance;
- high risk population screening and evaluation;
- discharge planning;
- cohort reviews;
- program evaluation;
- laboratory testing for TB;
- case management;
- contact investigations;
- client confidentiality;
- security;
- outbreak and incident reporting; and
- cluster investigations.

Policies and procedures shall be written and available to staff responsible for TB prevention and control activities and easily accessible to all staff responsible for TB prevention and control activities.

B. Review written policies and procedures at least once every three years and revise as appropriate to conform to DSHS recommendations and best practices.

C. Maintain a written list of local community resources that can assist TB clients with food, shelter, social services, and other medical services.

V. Manage Tuberculosis Cases and Suspects

General Requirement: Provide services to evaluate, treat, and monitor clients with suspected or confirmed tuberculosis disease regardless of ability to pay.

Adhere to procedures outlined in the *Standing Delegation Orders and Standing Medical Orders for Tuberculosis Prevention and Control (SDOs)*.

Activities:

1. Create a medical record for each person with suspected or confirmed TB disease.

   The medical record should include specific documentation relating to clinical tests i.e. nucleic acid amplification tests (NAAT), drug susceptibility testing, HIV and hepatitis screening results, chest x-rays (CXRs), etc., observations by DSHS clinical staff, client education, contact investigations, initial and follow-up interviews, and directly observed therapy.

2. Perform a medical evaluation and assessment on all clients suspected of having TB disease as outlined in the SDOs.

3. Place signed consent forms in the client's medical record. If client consents to treatment in one health jurisdiction and moves to a second health jurisdiction, the receiving health jurisdiction must obtain the client's consent to continue providing TB services and treatment.

4. Evaluate and disposition (reclassify) clients with suspected TB within 90 days of initial report to the health department.

5. Describe in a written agreement, the shared roles and responsibilities between a private medical provider and the TB program regarding the client's treatment care plan. This plan should be presented in writing to the private medical provider and the client.

   If the client does not have a medical home, the TB program should facilitate establishment of a medical home as appropriate.

6. Collect specimen for mycobacteriology testing (see Table 1). Educate clients about collecting sputum including packaging specimen for mailing. If the client is expected to mail in specimen, provide instructions about collecting, packaging and mailing specimen. These instructions should be thoroughly explained and provided in writing before the client is asked to produce and package sputum unobserved.

Observe collection of the initial sputum and document observation of this collection in the client's medical record.

At least one sputum sample should be collected early in the morning. Ship sputum per laboratory guidelines.

The clinical process for sputum collection is described in the SDOs.

Table 1. Types of Specimen Collected to Diagnose Tuberculosis

Suspected Diagnosis	Specimen Needed
Pulmonary or laryngeal tuberculosis (TB)	Sputum (phlegm from deep in the lungs) samples for smear and culture examination. If a diagnosis of pulmonary TB cannot be established from sputum smear, other procedures may be necessary, including nucleic acid amplification (NAA), bronchoscopy, and gastric aspiration in children.
Extrapulmonary TB	Depending on the anatomical site, other clinical specimens are necessary, such as: ▪ Urine ▪ Cerebrospinal fluid ▪ Pleural fluid ▪ Pus or other aspirated fluid ▪ Biopsy specimens ▪ Blood (heparinized)

7. Provide initial and ongoing education to clients regarding transmission and pathogenesis of TB; means to decrease transmission; importance of completing treatment; rationale for DOT and contact investigation; confidentiality of client information; education about adverse drug reactions and drug interactions of TB medications; responsibility of client to discuss symptoms of adverse drug reactions with nurse case manager or physician when they occur; signs and symptoms associated with disease relapse; consequences of non-compliance, etc.

Document initial and ongoing education in the client's medical record's progress notes and also on the appropriate i.e. Form TB-203 and TB-204.

8. Place surgical mask on clients that arrive to the TB Program for services. Place client

in an airborne infection isolation (AII) area at each clinic visit until client has met the following three (3) criteria for non-infectiousness:

1) Received the standard multi-drug TB treatment by DOT for two weeks;
2) Demonstrated clinical or radiographic improvement; and
3) Three (3) consecutive negative sputum smear results collected 8 to 24 hours apart with at least one specimen collected early in morning. If sputum culture results become negative before smear results, then three (3) consecutive negative culture results satisfy criteria for non-infectiousness.

The client must also have negligible likelihood of multidrug-resistant TB, meaning: no known exposure to multidrug-resistant TB and no history of prior episodes of TB with poor compliance during treatment. Earlier treatment records will need to be reviewed and assessed.

9. Place infectious clients in home isolation, if the following criteria are met:

a. A specific plan exists for follow-up care with a local TB-control program;
b. Client has been started on a standard multi-drug TB treatment regimen, and DOT has been arranged;
c. No infants or children (less than 5 years) or immune-compromised persons are present in the household; and
d. All other household members with previous exposure to client are immune-competent

Clients should refrain from travel outside of home, except for healthcare-associated visits, until client has three consecutive negative-sputum AFB smear results.

10. Develop and initiate a complete treatment and case management plan in accordance with DSHS SDOs.

a. Order a complete bacteriologic work up (including drug susceptibility tests for isoniazid, rifampin, pyrazinamide and ethambutol on initial isolates). Extended drug susceptibility testing shall be performed on all isolates with resistance to any first line agent. Send the initial isolate to DSHS Austin laboratory for genotyping.

b. Develop an initial treatment plan within one week of diagnosis (i.e. within one week of initiation of therapy for a person suspected to have TB or the identification of a positive culture).

c. Maintain appropriate clinical forms for case management in the clients' medical record.

1) Organize clients' medical records according to locally determined chart order with clear section divisions. All forms, reports, progress notes, etc. should be

securely attached in the medical record.

2) Date and sign all entries in the progress notes.
3) Document in chronological order leaving no open spaces in the medical record progress notes. Draw a line through any blank area.
4) Document all client services in the medical record and on Form TB-201 or equivalent.
5) Document assignment of nurse case manager and all other case management team members in the medical record.
6) Place a copy of any referral in the client's medical record; or document in the progress notes, the source and date of initial report to the health department TB program.
7) Submit Form TB-400A to the Surveillance Branch no later than 14 business days after the client reports to or is referred to the health department for evaluation and/or treatment. Keep form in the client's medical record.
8) Submit Form TB-400B to the Surveillance Branch within 90 days of the initial visit or referral to the clinic when client transitions from a suspect classification (class V) to a case (class III). Provide additional updates to the TB Surveillance Branch every 90 days or when medication changes occur.
9) Ensure reporting forms, such as the Report of Verified Cases of TB (RVCT), Forms TB-400A/B, Case Verification Form, etc., contain accurate information as reflected in the client's medical record.
10) Complete the medical and social history (Form TB-202).

d. Submit all required case management and case surveillance documentation to the Surveillance Branch, and when requested, to the TB Branch (including those forms that must be signed by the private provider, such as TB Forms 400A, 400B, 340/341, EF12-12062, 208, etc.).

1) Document in the medical record and on appropriately signed TB forms (Form TB-400B, etc.), the date client was started on an appropriate four-drug regimen, including client's weight and drug dosages.
2) Document in the progress notes and on the appropriate reporting forms all reasons a drug is withheld, when initiating medical treatment (physician's order), or when resuming medications (physician's order).
3) Document in the medical record—if initially culture negative, that client's regimen will be adjusted appropriately when evidence of clinical or radiographic improvement exists.
4) Document in the medical record—if initially culture positive, that client's regimen will be adjusted appropriately when drug susceptibility results are known.
5) Document consultation(s) in the medical record, if drug resistance is identified.
6) Document in the medical record a physician's evaluation, if after two months of therapy, client is not responding clinically or remains culture positive.

e. Prepare and present a written control order ("Order to implement and carry out measures) at the beginning of treatment to all persons with suspected or confirmed

TB disease, using Form TB-410.

The control order must either be in the client's preferred language, or the medical record must document that an interpreter read the order to the client (or guardian) before the client signs the control order.

f. **Provide DOT to all clients with suspected or confirmed TB disease** until the client is no longer listed as a suspect and classified as a non-count or until completion of a recommended course of therapy for persons with TB disease. DOT is the standard of care in Texas; therefore, if DOT is not provided, a clear reason must be documented in the clinical record.

- Complete all appropriate fields on Form TB-206 (DOT log) or equivalent.
- Write clearly which medications were given on each day on the DOT log. Any medication change must be noted on the log and appropriately signed.
- Pursue appropriate actions if DOT or clinic appointment is missed, up to and including court-ordered management.

11. Close record if client is no longer on treatment, as "completion of adequate therapy", "non-TB", deceased, moved out of country or lost to follow-up (LTFU). If client was closed as "completion of adequate therapy" this means that treatment was completed within 12 months, unless: 1) client's isolates shows resistance to rifampin; 2) client has meningeal disease; or 3) client is younger than 15 years with miliary disease.

Lost to Follow Up: The TB program must make at least 3 documented attempts to contact a TB client before considering a client as LTFU.

Attempts shall be documented in the progress notes of client's medical record. The three (3) attempts include: 1) calling the client, 2) visiting the client's residence, and 3) sending by certified mail a notification of the client's need to follow-up with clinic. The certified mail notification receipt should be secured in the client's medical chart.

12. Order TB medications and reconcile inventory through DSHS' Inventory Tracking Electronic Asset Management System (ITEAMS).

a. Ensure that medications and supplies purchased with TB Branch funds shall only be used in a prudent manner and shall not be distributed to entities for which that local or regional TB program does not provide treatment oversight.

b. Monitor and manage usage of medications and testing supplies furnished by DSHS in accordance with first-expiring-first-out (FEFO) principles of inventory control and set maximum stock levels at a limit no higher than a two-month average usage.

c. Count DSHS-purchased medications and supplies and reconcile inventory according to the product and lot number listed in ITEAMS.

   Coordinate with ITEAMS' inventory staff to ensure their TB orders comply with best practices.

   Perform these tasks no later than the seventh working day of the month.

d. Return to DSHS Pharmacy Branch or transfer to another TB program, (where the demand may be greater) products that have not been used in 6 months, or will not be used in 6 months, and record transfers in ITEAMs

   All DSHS-purchased medications shall be stored properly and securely, in accordance with the manufacturer's instructions.

e. To order second-line TB medications for clients with drug-resistant TB, the requesting TB program must send to the TB Branch via the PHIN, a:

   1) DSHS Pharmacy order;
   2) Forms TB-400A and TB-400B; and
   3) TB expert medical consult letter/email recommending second-line medications.

f. To order second-line TB medications for clients NOT diagnosed with drug-resistant TB, the requesting TB program must send to the TB Branch via the PHIN, a:

   1) Physician's note indicating the medical necessity for the second-line medication;
   2) DSHS Pharmacy order;
   3) Form TB-400B or equivalent; and
   4) TB expert medical consult letter/email recommending second-line medications.

   Second-line medications include but are not limited to the following groups:

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

13. Perform TB screenings using DSHS-supplied interferon gamma release assays specifically T-SPOT®.TB test or QuantiFERON®–TB Gold in-tube test for the following populations in accordance with DSHS-approved age requirements:

   a. Clients diagnosed with suspected TB disease;

b. Clients with confirmed TB disease;
c. Contacts to clients with suspected or confirmed TB disease – 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 the TB Branch' reporting schedule;
e. Employees providing TB services;
f. Class B immigrants; and
g. Refugees and other clients supported by the Refugee Health Program

Note: IGRA tests supported by DSHS funds shall not be offered and provided to any organization or establishment without prior documented approval from the TB Branch.

VI. Initiate a TB Contact Investigation

B. General Requirement: Initiate a contact investigation (CI) for all persons with possible or confirmed pulmonary, pleural or laryngeal TB disease.

The goal of a contact investigation is to find exposed persons who are more likely to be infected or progress to TB disease. Increased duration or frequency of exposure, as well as infectiousness of the presenting TB case increase probability of contacts developing TB infection and possibly progressing to TB disease.

A CI may be halted or not initiated if a NAAT (performed using CDC-recommended protocols) or another rapid laboratory test is negative for *Mycobacterium tuberculosis*.

Activities:

1. Begin the **initial interview within three (3) days of a client reporting to the TB program with possible or confirmed TB diagnosis.**

2. **Visit the primary residence** of the client **within three (3) days of report or notification**. The investigator should visit the primary location where the client sleeps and also visit other relevant sites of potentially significant transmission as appropriate.

3. Interview the TB client diagnosed with suspected or confirmed disease or a parent or guardian for younger children or the next of kin for the TB client diagnosed at death. Where possible, the interview should take place in the primary language of the client or their representative.

    a. Explain TB transmission patterns, including TB infection and disease.
    b. Establish the time period (infectious period) when disease transmission could have occurred.
    c. Gather locating information about potential contacts and hours of exposure per week over the infectious time period. This includes identifying environments that exposure is likely to occur based on client's residence, place(s) of employment, social activities and travel history.
    d. Determine the date contact was broken for each contact. A break in contact is defined as physical separation from the presenting case or suspect or when the presenting case or suspect is no longer considered infectious due to response to treatment.
    e. Document results of the interview in the client record and on forms TB-EF12-12062 and TB-208 (or equivalent)

4. Use the Contact Investigation (CI) Worksheet (Form TB-EF12-12062) and Form TB-

208 (or equivalent) during client's interview(s) to assign priority status to contacts identified.

5. **Assign priority status <u>prior to</u> initiating a CI** based on the infectiousness of the presenting suspect or case and data obtained from the CI Worksheet. ***Identify and test all high and medium priority*** contacts (see Table 2).

Table 2. Contact Evaluation Prioritization

Assignment of Contact Evaluation Priority Based on Case Characteristics			
Case Characteristics	**Investigation and Evaluation Priority**		
Pulmonary, pleural or laryngeal	**High Priority**	**Medium Priority**	**Low Priority**
Any of the following scenarios: • AFB smear positive • Cavitary CXR • Smear neg./culture pos. • ABN CXR consistent with TB/non-cavitary • Rapid test pos. or neg., culture pos.	• All household contacts • Anyone under 5 yrs old • Contacts with Medical Risk Factors: HIV, TNF alpha blockers, ESRD, long-term steroid use, cancer treatments or other immune compromising condition • Contacts exposed during a medical procedure: Bronchoscopy, sputum induction or autopsy • Contacts in a congregate setting (LTC, Detention facility) **<u>OR</u>** • Contacts exceeding environmental exposure limits for high priority contacts (See Table 2)	• Anyone 5-15 yrs old who does not meet one of the high priority criteria **<u>OR</u>** • Contacts exceeding environment exposure limits for medium priority contacts (See Table 2)	Anyone other than those listed; only considered if expansion is warranted
Any of the following scenarios: • Suspected TB with Abn CXR, not consistent with TB • AFB neg., rapid test neg., culture neg.	None	• All household contacts • Anyone under 5 years old • Contacts with Medical Risk Factors: see above **<u>OR</u>** • Contacts exposed during a medical procedure: see above	Anyone other than those listed; only considered if expansion is warranted
Extra-pulmonary	**High Priority**	**Medium Priority**	**Low Priority**
• Non-pulmonary TB with pulmonary disease ruled out	None	None	None

Source: MMWR 2005;54 (No. RR-15)

6. **Initiate screening for high priority contacts within seven days** from listing the person as a contact.

7. **Initiate screening for medium priority contacts within 14 days** from listing the person as a contact.

8. Interview all contacts to obtain their relevant medical history. Include specific questions about the symptoms of active TB disease, person-hours of exposure (per week/per month) to case (without divulging the name of the client) based on the environment in which exposure occurred.

   Assess for previous positive Interferon-Gamma Release Assays (IGRA) or tuberculin reaction and/or previous treatment for TB. Contacts having a documented history of a previous positive IGRA or TST should not be retested; however, they should be assessed for signs and symptoms and receive further clinical evaluation i.e. CXR including treatment based on physician's orders. Determine if contact was previously reported as a contact or case by reviewing the TB Surveillance Branch case registry i.e. TB PAM or the most current data application system.

9. **Complete the initial evaluation within three (3) weeks of contact identification**. An evaluation consists of interviewing all contacts to obtain their relevant medical history (including specific questions about symptoms of TB disease, previous positive tuberculin reaction and/or previous treatment for TB) and may include administration and reading of a tuberculin skin test (TST) or an interferon-gamma release assay (IGRA); a chest radiograph; and collection of sputum or another specimen for examination.

10. **Initiate and complete second round testing 8-10 weeks after break in contact with the index case.** All contacts whose initial IGRA or TST results were negative should be rescreened 8-10 weeks after break in contact with the index case. Contacts who remain negative at the second-round testing and are asymptomatic have completed a full evaluation.

11. Continue to identify contacts throughout the client's treatment. Document the date when each new contact is identified and include the date contact was broken with the index. The initial evaluation should be completed within three weeks of identification and second round testing performed (8-10 weeks after break in contact with the index case) where appropriate.

12. Expand the CI when evidence of recent transmission exists. The following are indicators of recent transmission:
    1. Infection rates of high and medium priority contacts exceed background prevalence of LTBI in the community;

2. Positive TSTs in contacts less than 5 years of age;
3. A change in TST status from negative to positive among contacts during second-round testing; or
4. Contacts diagnosed with TB disease

Expand CI in the environment (home, work, social) where recent transmission is indicated.

A. Responsibility resides with the affected health department to communicate with the TB Branch about CIs in congregate settings (correctional facilities, long-term care facilities, hospitals, and other residential facilities that provide medical services to residents), schools, and other academic and work institutions.

B. Responsibility resides with the affected health department to coordinate CI activities with the medical staff and administrators at any congregate settings in their service area.

   Coordinating activities include, collecting names and evaluation results of contacts in the congregate facility, collecting names and locating information for community contacts, reporting the outcome of the evaluations weekly to the TB Branch, assessing infection rates, sharing the percentage of infected contacts with the TB Branch, and advising the facility when an expansion of contact investigation activities is necessary.

VII. Manage Contacts to Confirmed or Suspected TB Cases

General Requirement: 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 TB disease.

Activities:

C. Provide window prophylaxis, if no contraindications to treatment exist for the following high risk contacts even if they are asymptomatic, have an initial negative IGRA / TST result and have a normal CXR to persons:

- Age 4 and under;
- With documented HIV infection; or
- With immunosuppressive conditions.

D. Refer for a CXR if the initial IGRA or TST result is positive and there is no history of a previously positive TB test **within 14 calendar days**. TB programs with on-site radiograph equipment should obtain a CXR **within ten (10) calendar days**. If the CXR is not suggestive of TB disease, and the contact is asymptomatic, offer treatment for TB infection unless there are contraindications to treatment.

E. If a contact has symptoms of TB disease, manage according to Section Five (Manage Tuberculosis Cases and Suspects).

F. **Administer within 8-10 weeks of initial testing, a second TB screening test on contacts whose initial screening results were negative** including contacts started on window prophylaxis.

1. Even if a screening result is negative, consider treatment for an infant less than six months old, HIV-infected individuals with advanced immunodeficiency and other high-risk contacts should be evaluated for continuation and completion of treatment for TB infection based on evidence of transmission of infection in other high priority contacts.

2. The decision to treat, however, is based on a physician's assessment and diagnosis. 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 TB infection and active TB disease.

3. If the repeat TST remains negative for children four years of age and under, HIV-infected individuals, and other immunosuppressed persons placed on treatment for potential TB infection and contact with the index case has been broken, treatment for TB infection may be discontinued.

4. If a repeat IGRA or TST is positive for any contact, follow instructions noted in Section B above.

G. Reassess and re-evaluate available clinical data on presenting case, to determine if the presenting case remains infectious and to review laboratory data related to drug susceptibility. The contact investigator should re-interview the presenting case one to two weeks after the initial interview to clarify data or obtain missing data. Additional interviews may also be required. For example, a client should be re-interviewed when susceptibility results indicate drug resistance or genotyping results indicate that the client is part of a cluster in the community.

   Most contact investigations are initiated before the resistance pattern of the case is known; however, if drug resistance is strongly suspected or when drug resistance to at least INH and RIF is known, the presenting case should be interviewed for contacts more frequently and by different interviewers.

   1. If an infected contact has not previously completed treatment for LTBI, evaluate for TB disease, which includes a symptom review and a chest radiograph.
   2. If there is no indication of disease, consider for treatment for LTBI.
   3. If contact has previously completed treatment for LTBI, no further treatment is required unless recommended by the treating physician.
   4. Counsel client about signs and symptoms of TB disease.

H. Use genotyping information from TB GIMS to confirm and assess suspected, and possibly unknown, epidemiological links among TB clients identified through routine contact investigations (see State TB GIMS Program Standard User Guide, https://sams.cdc.gov). To obtain this file, a user account for TB GIMs must be active.

   - For contacts who are exposed to more than one epidemiologically linked case, repeat the IGRA or TST or any necessary follow-up evaluation as many times as necessary until 8-10 weeks has passed from the last date contact was broken with any related cases.

   - Conduct monthly reviews of genotyping information and examination of concerning clusters.

VIII. Manage Clients on Treatment for TB Infection

General Requirement: Provide treatment services for at-risk persons diagnosed with TB infection.

Adhere to procedures outlined in the most current SDOs**.**

Activities:

A. Evaluate at-risk candidates (contacts, refugees, class-B immigrants, discharged inmates or other high-risk TB populations) for TB.

B. Complete the "TB Worksheet" in Electronic Disease Notification System (EDN) for all Class-B immigrants within one work week of an event (e.g., date skin test was placed, date chest x-ray (CXR) given, etc.)

C. Re-evaluate client, if treatment for TB infection is not started within three (3) months of the chest x-ray showing no abnormalities indicative of TB or the client begins to exhibit symptoms suggestive of TB.

   A new chest x-ray or other diagnostic procedures should be performed and evaluated prior to start of therapy for TB infection.

   Re-evaluate client, if treatment for TB infection is not started within one (1) month for the following persons at high risk of progressing to TB disease:

   - Persons less than one year of age;
   - Persons co-infected with HIV; or
   - Persons receiving immunosuppressive therapy.

   A repeat chest radiograph should be done prior to taking the first dose of medication if therapy for TB infection is not started within one month to ensure that TB disease has not developed in the interim.

D. Provide DOT to clients diagnosed with TB infection who are placed on a DSHS-approved short course regimen.

E. Provide DOT to all contacts, diagnosed with TB infection, having any of the following characteristics:
   - less than five years of age;
   - HIV-positive;
   - reside in the same residence as the index case receiving DOT; or

F. Provide DOT to other high-risk persons with TB infection as resources allow.

G. Document on appropriate DSHS reporting form when client has completed treatment or stopped medication. Document reason medication was stopped, if treatment was not completed.

H. Provide initial and ongoing education to client regarding TB epidemiology, transmission, and pathogenesis; the importance of completing treatment; confidentiality of client information; rationale for DOT; common adverse drug reactions and drug interactions of TB medications; responsibility of client to discuss symptoms of adverse drug reactions with their clinic nurse, physician, or DOT provider; and signs and symptoms associated with progression to TB disease. Instruct client to contact the TB clinic staff for follow-up diagnostic evaluation, if symptoms of TB disease occur at any time in the future.

   1. Document in the medical record the source and date of the initial referral to the TB program, including placing a copy of the referral in the medical record.
   2. Face-to-face physician review of medical evaluation at diagnosis is preferable for initiation of treatment or resumption of medications.
   3. Place signed informed consents (Form TB-415) in the medical record with evidence that consent was presented in client's preferred language or an interpreter was used.

IX. Conduct Surveillance to Identify Unreported Individuals with Suspected or Confirmed Tuberculosis

A. General Requirement: Develop and maintain surveillance mechanisms for early identification and reporting of TB

Activities:

1. At least monthly, contact providers that deliver TB care to at-risk populations within the TB program's service area to obtain data of unreported cases.

2. Provide education and training about TB reporting and surveillance to at least four of the following annually:
   - Hospitals;
   - HIV clinics;
   - shelters;
   - drug rehabilitation facilities;
   - indigent care facilities;
   - kidney dialysis facilities;
   - schools.

   a. Training shall include but not limited to the following elements: TB case definition, when to report, how to report, and Texas legal reporting requirements (see http://www.dshs.state. tx.us/idcu/ investigation/conditions/).
   b. These surveillance activities are to be reported on the Annual Progress Report.

3. At least monthly, communicate with the health department HIV, STD or general surveillance staff in your jurisdiction to identify unreported cases.

   a. Maintain documentation of these activities, then complete and submit the Surveillance Quality Assurance Template (SQA Template) via the PHIN to the Surveillance Branch **within ten (10) days after the end of each quarter.**
   b. The SQA Template is available at TexasTB.org.
   c. Report these activities on the Annual Progress Report.

4. Report suspicion of TB to the Surveillance Branch when any one of the following is identified through surveillance activities:

   1) A smear (from any anatomic site) positive for acid-fast bacilli (AFB);
   2) A result from a rapid laboratory analysis method, such as NAAT or high performance liquid chromatography, that is positive for *Mycobacterium tuberculosis;*

3) Biopsy, pathology, or autopsy findings consistent with active TB disease; or
4) A death certificate listing TB as the immediate or underlying cause of death.

OR at least two of the following:
1) Productive cough lasting more than 3 weeks;
2) Positive TST or positive blood assay for *Mycobacterium tuberculosis;*
3) Other signs or symptoms suggestive of TB disease;
4) Radiographic findings suggestive of TB disease;
5) Clinical suspicion of pulmonary or extrapulmonary TB disease such that the physician or other health care provider has initiated or intends to initiate isolation or treatment for TB disease.

5. Report a case of TB when the following occurs:
   a. Laboratory confirmed (one of the following):

      1) Isolation of *Mycobacterium tuberculosis* complex from a clinical specimen. (Rapid identification techniques for *Mycobacterium tuberculosis* [e.g., DNA probes and mycolic acids high-pressure liquid chromatography performed on a culture from a clinical specimen] are acceptable under this criterion.)

      2) Detection of *Mycobacterium tuberculosis* from a clinical specimen by NAAT. Nucleic acid amplification tests must be accompanied by AFB culture for mycobacteria species. However, for surveillance purposes, CDC will accept results obtained from NAA tests approved by the Food and Drug Administration [FDA] and used according to the approved product labeling on the package insert. Current FDA-approved NAA tests are only approved for smear-positive respiratory specimens.

      3) Identification of AFB smears, granulomas or other findings indicative of TB in a clinical specimen when a culture has not been or cannot be obtained.

   b. Clinical diagnosis includes all of the following:
      1) A positive tuberculin skin test;
      2) Other signs and symptoms compatible with tuberculosis (e.g., an abnormal, unstable [i.e., worsening or improving] chest radiographs, or clinical evidence of current disease);
      3) Treatment with two or more anti-tuberculosis medications; and
      4) Completed diagnostic evaluation.

   c. Clinical diagnosis based on provider decision requires documentation that includes the provider's rationale or findings on which the diagnosis was based. The following examples may be used as a rationale or finding for TB diagnosis:

1) Significant improvement on abnormal chest radiograph;
2) Significant improvement based on symptoms from onset;
3) Child who is a recent contact to an active case;
4) Autopsy report; or
5) Consultation by DSHS recommended TB expert physician.

6. **Investigate daily all open suspect records** received from the Surveillance Branch in the following priority order:

   a. jurisdictional assignment
   b. culture confirmation for *M.TB complex, M.TB, or M.Bovis*
   c. missing required data elements to assign a state case number
   d. HIV status
   e. identification by vital statistics or medical examiner's report
   f. initiation of a contact investigation but no submittal of the RVCT
   g. receipt of an out of state referral
   h. transfer of a suspected case(s) to another state or out of US

   A suspect record is created by the Surveillance Branch when either a laboratory-confirmed culture result, a positive NAAT or notification from a reporting entity has been received by the Surveillance Branch but a Report of Verified Counted Cases of Tuberculosis (RVCT) form has not been submitted by the TB Program.

   The Surveillance Branch then notifies case registrars of the reportable case.

7. **Submit the RVCT within 15 business days of receipt of laboratory-confirmed culture or NAAT** result to the Surveillance Branch.

8. **Investigate all laboratory reports of AFB smear and culture results received locally within seven (7) working days**.

9. **Resolve**:

   a) At least half of all suspect records within seven working days of receipt of laboratory–confirmed culture result in the above stated priority order; and
   b) All suspect records within 15 working days of notification by the Surveillance Branch.

   Open cases pending verification that are not received by the Surveillance Branch after 15 business days of TB programs receiving laboratory-confirmed culture or NAAT results, are delinquent.

B. <u>General Requirement</u>: Targeted testing

Identify high risk groups and congregate settings for which testing for TB infection and disease are justified. The goal for target testing is to identify, evaluate, and treat persons who are at high risk for tuberculosis infection or at high risk for progressing to TB disease.

Activities

1. Assess local epidemiologic data for high-risk populations and congregate settings to determine the need for target testing

    a. Target testing initiatives are recommended in settings where TB prevalence is high or the consequences of an undiagnosed case of TB are severe (e.g. homeless shelters, nursing homes, dialysis centers, residential facilities and social service programs for persons with HIV, drug and alcohol rehabilitation centers and methadone centers, correctional facilities and migrant farm worker camps).

    b. A genotyped cluster involving these settings indicates a high risk setting.

    c. Unfocused population-based testing is not cost-effective and drains limited resources.

2. Ensure resources are available for evaluation and treatment of persons who test positive for TB infection or disease.

    Decisions to conduct targeted testing should be based on the ability to provide preventive treatment services.

    A decision to test is a decision to treat.

3. Provide guidance to high risk facilities (e.g. health care and correctional facilities) operating or starting a TB screening program.

4. Assess the effectiveness of target testing projects based on:

    a. The TB infection yield;

    b. The likelihood of identifying infected individuals that will progress from TB infection to disease (risk classification), and

    c. TB treatment completion rates.

5. **Submit Target Testing Monthly Report to the TB Branch no later than the 2nd Friday of each month** for testing that occurred the previous month.

X. Reporting

<u>General Requirement:</u> TB programs shall submit designated reports by established deadlines and schedules using DSHS-approved mechanisms.

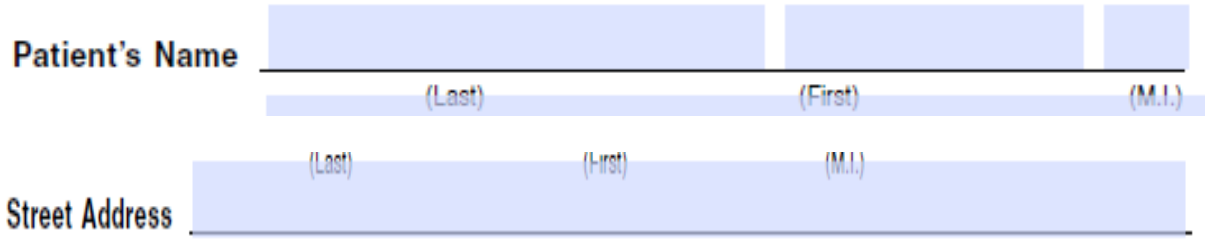
Activities:

A. Report all TB cases (ATS classification 3) using the current DSHS/CDC-approved form, RVCT, and the CDC TB case definition within 15 working days of identification of confirmed TB case to the Surveillance Branch via the PHIN.

B. Include the following required data elements on the RVCT at the time of the initial report (See Table 3).

- Name
- Date of birth
- Race and ethnicity
- Country of origin, if not US
- Date of entry into US
- Address, city, county, ZIP code with 4-digit code (and if in or outside city limits)
- If diagnosed while in a facility or shelter, facility or shelter name.

Table 3. Data elements as represented on the RVCT.



4. Reporting Address for Case Counting

City

Within City Limits *(select one)* ☐ Yes ☐ No

County

ZIP CODE —

5. Count Status *(select one)*

Countable TB Case

☐ Count as a TB case in your jurisdiction

Noncountable TB Case

☐ Verified Case: Counted by another U.S. area (state)

☐ Verified Case: TB treatment initiated in another country *Specify*_____

☐ Verified Case: Recurrent TB within 12 months after completion of therapy

6. Date Counted

Month Day Year

7. Previous Diagnosis of TB Disease *(select one)*

☐ Yes ☐ No

If YES, enter year of previous TB disease diagnosis:

8. Date of Birth

Month Day Year

9. Sex at Birth *(select one)*

☐ Male ☐ Female

10. Ethnicity *(select one)*

☐ Hispanic or Latino

☐ Not Hispanic or Latino

11. Race *(select one or more)*

☐ American Indian or Alaska Native

☐ Asian: *Specify*_____

☐ Black or African American

☐ Native Hawaiian or Other Pacific Islander: *Specify*_____

☐ White

12. Country of Birth

"U.S.-born" (or born abroad to a parent who was a U.S. citizen) *(select one)* ☐ Yes ☐ No

Country of birth: *Specify*_____

13. Month-Year Arrived in U.S.

Month Year

C. **Report remaining RVCT data elements as required**.

See *Report of Verified Case of Tuberculosis, CDC Tuberculosis Surveillance Data Training*. US Dept. of Health and Human Services, CDC, National Center for HIV/AIDS, Viral Hepatitis, STD, and Tuberculosis, p 203, CDC 2009.

1. **Each registry must maintain a digital or electronic log** of all cases in their jurisdiction, by county and year counted, of the following information:

   - Name
   - Date of birth
   - Complete address
   - Contact information

- RVCT (also referred to as the state case number)

2. **Submit reports of contacts on forms TB-340 and TB-341** via the PHIN **within 14 days** of the initial case report to the Surveillance Branch.

3. The initial contacts' report requires the following:

   a. Part A. Case/Suspect Information
   b. Part B. Interview and Exposure Site Information
   c. Part C. Contact information including:

      1) Exposure length and setting
      2) HIV test results
      3) Priority status
      4) TST/IGRA test results
      5) CXR date and interpretation
      6) Verification that a complete evaluation was performed. A complete evaluation for purposes of the contact aggregate report consists of a TST or IGRA result. If positive, a CXR date, and the ATS classification.
      7) If evaluation was not performed, provide a reason

D. Submit a completed Initial Susceptibility Report (Follow-up I) on all culture-confirmed cases to the Surveillance Branch **within 30 days** after laboratory notification.

E. Submit a completed Case Completion Report (Follow-up II) on all culture-confirmed cases to the Surveillance Branch **within 12 months** of the initial treatment start date.

   Provide a justification for any Follow-Up II reports **submitted 12 months after the initial medication start date.**

F. Provide the last date medication was given when treatment of the client stopped due to completion of adequate therapy, death or failure to locate (LTFU, definition p.11) and/or 90 days have passed since the last medication dose.

   a) For a case to be "recurrent", the drug stop and start dates must be less than 365 days apart. A "new investigation" means the drug stop and start dates are greater than 365 days apart.

   b) Submit the Case Completion Report (Follow-up II) to the TB Surveillance via the PHIN.

   Note: Any cases closed as false positive, due to laboratory contamination or other misdiagnosis, must be reported to the Surveillance Branch with documentation to justify change in case status (e.g., amended lab report, doctor's note, consult, etc.) within 10 days of closure.

- Review all other specimens associated with a false positive case to ensure they are culture negative and the positivity rate remains below the community level.

- This information must be reported to the Genotyping folder on the PHIN to facilitate investigation.

- The TB and Surveillance Branches will investigate all false positives - laboratory contamination or other misdiagnosis.

G. Submit reports of contacts on forms TB-340 and TB-341 via the PHIN **within 14 days** of the initial case report to the Surveillance Branch. The initial contacts' report requires the following:

1. Part A. Case/Suspect Information;
2. Part B. Interview and Exposure Site Information;
3. Part C. Contact information including:
   a) exposure length and setting
   b) HIV test results
   c) Priority status
   d) TST/IGRA test results
   e) CXR date and interpretation
   f) Verification that a complete evaluation was performed. A complete evaluation for purposes of the contact aggregate report consists of a TST or IGRA result, if positive, a CXR date, and the ATS classification.
   g) If evaluation was not performed, provide a reason.

H. **Identify at least three (3) contacts for sputum smear positive cases**. All missing data must be submitted to the Surveillance Branch, in accordance with CDC requirements, via PHIN.

I. Submit a follow-up report for contacts not placed on preventive treatment using form TB-341 via the PHIN. Include all updated contact information and submit to the Surveillance Branch within 90 days of the initial case report.

J. Submit a follow-up report for contacts placed on treatment. A report of contacts should be submitted via the PHIN no later than one year from the date contact started on treatment and must include treatment outcome.

K. Report contacts that develop active TB disease before submitting those cases' contacts.

L. Prepare appropriate referral Inter-Jurisdictional Notification (IJN) forms and submit to the Surveillance Branch when a suspect, case, contact or persons with latent TB infection moves to another jurisdiction, whether in-state, out-of-state, or out of the US, to ensure follow-up and continuity of care.

M. Submit all closed TB suspects and their contact investigation documentation to the Surveillance Branch using current DSHS-approved forms via the PHIN **within 90 days** of initial report. This documentation must include:

1. The RVCT
2. Form TB-340/341
3. Form TB-400B

N. Update all surveillance missing data reports via the PHIN by DSHS deadline to meet CDC objectives.

O. **Submit monthly correctional TB screening reports within 15 working days** of the following month to the TB Branch.

Collect the Monthly Correctional TB Report (Form EF12-11462) and Positive Reactor Suspect/Case Report (Form EF12-11461) from those jails and community corrections that meet Texas Health and Safety Code Chapter 89 requirements **within five (5) working days of the following month.**

Review reports for accuracy and completion. Provide guidance to jails and community corrections as needed to complete the Monthly Correctional TB Report.

P. **Complete and submit Form TB-400 on all newly diagnosed drug resistant cases within five (5) days** of notification to the TB Branch via the PHIN.

Complete and submit an updated Form TB-400B every ninety (90) days for all drug-resistant cases until treatment completion to the TB Branch.

Submit within 72 hours of notification, any **changes in case management, drug resistance patterns, or change of residence of all drug- resistant TB cases to the TB Branch.**

Q. Submit the Annual Progress Report using the template provided by the TB Branch to TBContractReporting@dshs.state.tx.us by the date stipulated in the contract.

Health service regions shall submit their Annual Progress Report to TBContractReporting@dshs.state.tx.us by the date provided by the TB Branch.

Submit to the TB Branch, a line listing of annual cases for the Annual Progress Report in a format prepared by the TB Branch via the PHIN.

R. Submit the completed cohort review reports for the appropriate cohort year and quarter to the TB Branch through the PHIN:

a. A completed Cohort Review Summary Report
b. A list of all counted cases for each quarter using Attachment 1
c. A completed presentation form for each case presented at each quarterly cohort review.

Perform required cohort review presentations in accordance with the Cohort Review Submission Schedule (see Table 4).

Submit completed cohort review forms in accordance to the Cohort Review Submission Schedule (see Table 4).

Table 4. Cohort Review Submission Schedule

Cohort Period & Submission Schedule	
Cohort Period Cases Counted In:	**Are reviewed and reported by:**
1st quarter (Jan 1 to Mar 31) current year	**March 31** of following year
2nd quarter (Apr 1 to June 30) current year	**June 30** of following year
3rd quarter (July 1 to Sep 30) current year	**September 30** of following year
4th quarter (Oct 1 to Dec 31) current year	**December 31** of following year

S. **Notify the TB Branch within 48 hours of any CI involving:**

- congregate settings;
- situations in which media attention is likely;
- >50 contacts;
- any school setting involving the exposure of 25 or more students and/or teachers;
- any location of interest (as listed below); or
- any unusual circumstance the TB Program believes DSHS should be notified.

Locations of interest include but are not limited to: academic institutions, day care centers, nursing homes, hospitals, correctional facilities including community corrections, airline exposures, other work settings, etc.

1. **Send a completed TB Incident Form (Form EF12-12104) within 48 hours** of the event to TBEpiEvaluation@dshs.state.tx.us.

The Incident Report Form can be found at http://www.texasTB.org

2. Convene a conference call with the TB Branch to discuss but not limited to the following:

   a. Clinical presentation of the client;
   b. Medical and social history of the client;
   c. Screening method and results including test dates (initial round of testing);
   d. Second round testing dates (planned);
   e. Radiologic and bacteriologic status including NAAT results;
   f. Infectious period;
   g. Contact investigation forms;
   h. Description of environmental assessment or planned environmental assessment;
   i. Incident command response plan; and
   j. Results of epidemiologic assessment and next steps.

3. Provide weekly written updates to the TB Branch that may include but not limited to the following:

   a. NAAT results;
   b. Environmental assessment to determine specific areas in which exposure; occurred and the exposure period;
   c. Stratification of contacts by risk;
   d. Scheduled and actual dates of screening;
   e. Screening methods (i.e. IGRA/TST); and
   f. Evaluation results based on risk stratification. High risk contacts should be tested first to determine the need for expansion.

   Note: **Mass screenings using DSHS-purchased supplies should not be performed without prior consultation with the TB Branch.** Every effort must be made to educate and inform the “worried well” regarding the TB screening process which should adhere to epidemiologic principles.

   Sound epidemiologic principles shall always be applied to contact investigations to ensure appropriate persons are identified for screening and to determine specific environments in which transmission may have occurred.

   Mass screenings that are not epidemiologically guided drains limited resources and yields minimal results.

   A final epidemiologic assessment report shall be submitted to the TB Branch in a format prepared by the TB Branch.

T. Perform airline exposure screening based on notifications received from the TB Branch through the Division of Global Migration and Quarantine (DGMQ).

   1. The TB Branch will contact TB programs and provide the name and phone number of the individual(s) exposed during flight.
   2. TB programs shall notify airline contacts and instruct them to report to their health department for TB screening;
   3. Contacts are to be screened; and
   4. The TB program completes the DGMQ TB Contact Investigation Form and submits it via the PHIN to the TB Branch' **TBEpiEvaluation team within ten (10) business days of notification.**

U. Submit a Report of Adverse Drug Reaction to the TB Branch' Nurse Consultant via the PHIN and posted to the "Adverse Drug Reaction" folder when a client with confirmed or suspected TB dies or is hospitalized due to an adverse drug reaction **within three (3) working days of notification.**

XI. Implement Infection Control Procedures

General Requirement: Apply appropriate administrative, environmental, and respiratory controls to prevent exposure to and transmission of *Mycobacterium tuberculosis*

Activities:

A. Develop a written infection control plan, which includes sections on administrative measures, environmental controls, personal respiratory protection, and procedures.

   See "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005."

B. 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.

XII. Maintain a Competent Workforce

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

Activities:

A. 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.

B. **Within 90 days of employment, all new employees shall receive 40 hours of TB training specific to their duties and responsibilities**.

   Each year following, 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. See http://www.cdc.gov/tb/education/ssmodules/default.htm.

   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 TB Branch.

C. Demonstrate that all persons providing services under the TB SDOs or equivalent policies and procedures have the requisite experience and/or training to deliver appropriate services.

   Demonstration of this requirement include:

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

      Track trainings through an onsite digital log to include the:
      a) date training occurred;
      b) name of person receiving the training;
      c) job title;
      d) name of the training or course; and
      e) number of hours received for successful completion of each course.

2. The digital log and scanned certificates must be readily available and obtainable for review, audit, or to allow each Medical Director and/or Health Authority to verify that those operating under their medical license have the requisite experience and training to deliver services.

3. The above requirements also apply to contracted service providers when there is limited or no documented information of contractor's requisite experience and/or training.

D. **Case registry staff shall attend the annual medical records conferences and workshops** to obtain current records management procedures.

E. **At least one case registry staff shall participate in the monthly Surveillance Branch conference calls**

F. **Core training topics for personnel providing TB services include:**

- Transmission and Pathogenesis of Tuberculosis;
- Epidemiology of Tuberculosis;
- Diagnosis of Tuberculosis Infection and Disease;
- Treatment of Tuberculosis Infection and Disease;
- TB Reporting/TB Notifiable Conditions;
- Cultural Awareness; and
- Interpreter Utilization.

G. **Specialized training topics based on duties and responsibilities include:**

- Drug Interactions and Toxicity;
- Contact Investigation for Tuberculosis;
- Tuberculosis Surveillance and Case Management in Hospitals and Institutions;
- Infectiousness and Infection Control;
- Client Adherence to Tuberculosis Control;
- Interviewing, Investigating and Influencing Techniques;
- Directly Observed Therapy;
- TB Nurse Case Management Training;
- TB Program Management; and/or
- CDC Tuberculosis Surveillance Data Training (RVCT).

H. As needed, attend trainings offered by Heartland National TB Center including webinars provided by all Regional Training Medical and Consultation Centers.

I. Participate in trainings provided by the TB and Surveillance Branches.

J. **Notify the TB Branch of newly hired TB program managers, nurses, contact investigators and case registry staff within 30 days of hire**.

Submit "Notice of Changes in TB Personnel" Form monthly. See TexasTB.org.

K. Newly hired TB program managers, nurses, contact investigators and case registry staff shall participate in the TB Branch New Employee Orientation after three months of hire.

L. 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.

M. Document all community-provider TB trainings (including the hours, topics, dates and numbers of participants) and make available upon request to the TB Branch.

Community trainings and education are to be reported on the Annual Progress Report.

XIII. Monitor Budget Expenditures

<u>General Requirement:</u> Monitor budget expenditures, and maintain accurate and concise records.

Activities:

A. TB programs may shift funds between direct cost categories by 25% except equipment

- Local health departments shall notify the Contract Management Unit (CMU) of any requests in excess of 25%, including any equipment requests.
- Health service regions shall notify the TB Branch of any requests in excess of 25%, including any equipment requests.

B. The equipment threshold is currently $5,000. Equipment requests requires TB Branch approval.

C. Notify the TB Branch of any changes in personnel, including new hires, vacancies, and changes in salary, job titles or job descriptions by **monthly submittal of the "**Notice of Changes in TB Personnel" **Form via PHIN** (see TexasTB.org).

   If a personnel change requires a contract amendment, contractor shall notify both CMU and the TB Branch.

D. Encumbrances and budget actions should be conducted on a timely basis as directed by the General Provisions, DSHS policy.

E. LHDs should adhere to all General Provisions and HSRs to all DSHS policies.

XIV. Confidentiality and Security Standards

General Requirements: All TB programs shall perform activities outlined in this plan in accordance with applicable state and federal security and confidentiality standards, policies and guidelines including but not limited to:

- DSHS Program Policy "Release of TB/HIV/AIDS and STD Data" at, http://www.dshs.state.tx.us/hivstd/policy/security.shtm;
- Federal HIV/AIDS Security and Confidentiality guidelines at, http://www.cdc.gov/hiv/resources/guidelines/security_confidentiality_hiv.htm;
- DSHS Program Policy No. 2011.01 "TB/HIV/STD and Viral Hepatitis Unit" at, http://www.dshs.state.tx.us/hivstd/policy/security.shtm; and
- DSHS Program TB/HIV/STD and Viral Hepatitis Unit Breach of Confidentiality Response Policy at, http://www.dshs.state.tx.us/hivstd/policy/security.shtm

Activities:

A. Submit documentation to DSHS Security Officer that all staff and subcontractors working on activities outlined in this work plan have received annual training on:

   - Employee's standard of conduct; and
   - DSHS security and confidentiality training course.

   1. Contact the DSHS Security Officer at Stanley.see@dshs.state.tx.us for information on security training offered at: https://tx.train.org.

      Note: All newly hired staff must successfully complete confidentiality and security training provided by DSHS within thirty (30) days of being hired.

   2. **Complete an annual refresher training course on confidentiality requirements/confidential information security** (i.e., within one year of having taken the previous confidentiality and security course).

   3. Submit all appropriate documentation to DSHS **within ten (10) days of completing each course.**

B. Designate and identify a HIPAA Privacy Officer who is authorized to act on behalf of the TB program and is responsible for the development and implementation of privacy and security requirements of federal and state privacy laws.

C. **Designate a TB program staff (i.e. manager) to serve as the Local Responsible Party (LRP)** having the responsibility to ensure the security of TB/HIV/STD confidential information maintained by the program.

The LRP must:

- Ensure that appropriate policies/procedures are in place for handling confidential information, releasing confidential TB/HIV/STD data, and for the rapid response to suspected breaches of protocol and/or confidentiality. These policies and procedures must comply with DSHS policies and procedures (LHDs may choose to adopt these DSHS policies and procedures as their own).

- Approve any program staff requiring access to TB/HIV/STD confidential information. The LRP will grant authorization to program staff who have a work-related need (i.e. work under this Program Attachment) to view TB/HIV/STD confidential information.

- Maintain a current list of authorized program staff persons who have been granted permission to view and work with TB/HIV/STD confidential information.

    - The LRP will routinely review the authorized user list throughout the fiscal year beginning ten (10) days from September 1 of each year.

    - All program staff with access to confidential information will have a signed copy of a confidentiality agreement on file and it be updated once during the term of this Program Attachment.

- Ensure that all program staff with access to confidential information are trained on TB/HIV/STD security policies and procedures including federal and state privacy laws and policies before access to confidential information is granted.

- Thoroughly and quickly investigate all suspected breaches of confidentiality in consultation with the DSHS LRP, all in compliance with the DSHS Program Policy TB/HIV/STD and Viral Hepatitis Breach of Confidentiality Response Policy" http://www.dshs.state.tx.us /hivstd/policy/security.shtm.

- Ensure that all required quarterly reports are submitted on time.

D. Incorporate the following security procedures:

- Ensure computers and networks meet DSHS security standards, as certified by DSHS information technology

- Maintain and provide a current list to DSHS of all personnel with access to secured areas and of all identified personnel who have received security training

- Maintain and provide a current list to DSHS of personnel with access to all network drives where confidential information is stored and all identified personnel received security training

- Submit to DSHS requests for TB/HIV/STD systems user account terminations within one (1) business day of the identification of need for account termination.

    - State who should be notified to disable/delete the access to secure data, secure networks and the areas in which they reside, and confirmation should be provided to the submitter when the action is completed.

- Transfer secure data electronically using PHIN.

- Maintain a visitors log for individuals entering secured areas with a quarterly review by LRP.

- Verify user passwords changes are done at least every 90 days.

- Ensure confidential data are:

    - Maintained in a secured area
    - Locked when not in use
    - Not left in plain sight
    - Shredded before disposal

Portable devices that are used to store confidential data must be approved by the LRP and encrypted.

XV. Monitor Surveillance, Reporting and Case Management Activities In Correctional Facilities (Texas Health and Safety Code Chapter 89)

General Requirement: Monitor and participate in correctional TB control activities
The goals of correctional TB control activities are early detection (case-finding), containment, treatment and prevention. Program activities outlined below are required only for jails and community corrections that meet Texas Health and Safety Code, Chapter 89 criteria.

Activities:

A. **TB Screening and Treatment**
1. Offer resources and guidance to promote correct and timely screening practices (symptom screening, TST).
2. Provide medical oversight for TB cases, suspects and contacts.
3. Provide consultation for treatment of high-risk groups with TB infection. Initiation of treatment for TB infection should include consideration and planning for likelihood of client continuing and completing treatment under supervision, if released from the facility before treatment regimen is completed.

4. **Submit Form TB-400A and Form TB-400B on all newly diagnosed cases in correctional facilities** to DSHS Correctional TB Program **within five days of notification**

B. **Discharge Planning and Continuity of Care**

1. Facilitate discharge planning for inmates with confirmed or suspected TB who are scheduled to be released or transferred to other correctional facilities or jurisdictions.
2. Follow-up to ensure that TB cases and suspects continue TB treatment at the TB clinic nearest their residence or at a receiving correctional facility.
3. Provide continuity of care for employees and any inmates released to the local community who are undergoing treatment for TB disease or infection.
4. Provide technical consultation to ensure adequate precautions are taken while transporting clients between correctional facilities or detention centers.

C. **Contact Investigation**

1. Coordinate, plan and actively participate in TB CIs

   a. Conduct interview to identify contacts and determine inmate's infectious period.
   b. Assess TB transmission risk based on client's infectiousness, person-hours per week of exposure to a contact, and environmental factors.

c. Provide TB education and counseling to client.
d. Establish an evaluation plan of identified contacts based on priority classification.

See CDC, 2005. 2005. MMWR: December 16, 2005 / 54 (RR15);1-37; http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5415a1.htm

2. **Ensure all contacts are thoroughly evaluated and that infected contacts start and complete treatment for TB infection**.
   TB testing may be conducted by the health department or the jail medical staff under the strict guidance of the health department.

3. **Submit an incident report to TB Branch within 48 hours** of identification of a suspected or confirmed TB case.

D. **TB Correctional Liaison**

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

Designate a TB Correctional Liaison to supply testing materials to jails (if needed), and conduct quality assurance of Monthly Correctional TB Reports to be submitted to DSHS Correctional TB Program.

1. Receive the *Monthly Correctional TB Reports* from correctional facilities within five (5) working days following the reporting month.
2. Review *Monthly Correctional TB Reports* for accuracy and provide technical assistance as needed.
3. **Submit *Monthly Correctional TB R*eports to TB Branch no later than 15th day of each month.**
4. Monitor quantity of testing supplies provided to jails to prevent overstocking by correctional facilities.

E. **Training and Education**
Provide training and education to jail staff on a routine basis given high employee turnover.

XVI. Initiate and Maintain Self-Auditing Practices

General Requirement: TB programs must ensure that appropriate clinical and reporting standards are adequately maintained

The goals of auditing are to ensure that quality standards are maintained by TB programs and to assure the appropriate use of state and federal funds. TB programs shall designate a staff or team to assess program practices to ensure services are delivered in accordance with DSHS program standards as outlined in the *Texas Tuberculosis Work Plan*.

Activities:

A. Reviewers shall:

1. At a minimum, ensure medical record documentation will include and follow current Texas Administrative Code requirements, Title 22, Part 9, Chapter 165, Rule §165.1.

2. Develop a check list to identify missing information in the medical record.

3. Ensure the most current SDOs are reviewed and signed annually by the Regional Medical Director and signed or acknowledged in writing by all regional staff serving under those orders, as required by clinical practice.

   Regional medical directors must be able to verify that those operating under their medical license, meet the requisite experience and training to provide TB services.

   In the event of a vacancy, the Division of Regional and Local Health Services shall appoint a designee to serve as an interim regional medical director. The designee will serve as signatory for the SDOs until a new regional medical director is appointed.

4. Retain a signed acknowledgement form for each employee that performs clinical duties as affirmation of their understanding of the SDOs, policies and procedures under which activities are performed.

   - DSHS TB Policy 5003 and 22 TAC § 193.2 requires the “physician responsible for TB services” to review and sign SDOs at least annually.

   - TB Policy 5003 also assigns TB managers the responsibility to ensure that the SDOs and procedures are reviewed and signed at least annually by employees delivering TB Services.

- The relationship between the TB program and a private provider should be clear and documented should any complications arise with a client receiving treatment.

B. By **October 14th of each year**, compile appropriate signature forms demonstrating acknowledgment of jurisdictional TB policies and procedures. Orders and procedures are to be reviewed and signed **at least annually** by all employees delivering TB clinical (registered nurses, licensed vocational nurses, and non-licensed staff) or data services (epidemiologists, case registrars, etc.):

1. All health services regions shall submit the "Attestation of Authorized Licensed Nurses" (Attachment 1) from the TB Standing Delegation Orders (FY2014-15) to the TB Branch via the PHIN to NurseAdmin folder.

2. Each local health department (LHD) shall send the following documents to the TB Branch via the PHIN to NurseAdmin folder:

   a. Copy of fully signed TB Policies and Procedures signature page, and
   b. Copy of table of contents listing all enacted TB policies and procedures with the following information to be included:
      a. period of time policies are valid; and
      b. interval time for the review of all TB policies and procedures.

3. Policies and procedures are subject to DSHS audits and TB-Surveillance Branch reviews and audits.

C. Regions shall provide technical support as needed to LHDs that provide TB services.

XVII. Conduct Continuing Quality Improvement Activities to Maintain a Robust TB Infrastructure

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

Activities:

A. Conduct quarterly cohort reviews in accordance with DSHS TB Branch policy and procedures.

- Compare treatment completion and contact evaluation rates by cohort periods and years to assess program progress.
- Identify trends that support or create barriers to effective TB prevention and control activities.
- Prepare, complete and submit the Cohort Review Summary and each individual Presentation Form to DSHS Tuberculosis in accordance with DSHS submission schedule documented in Cohort Review Policy.

B. Perform routine case management reviews and document findings. Conduct follow-up reviews to ensure recommendations are addressed. See the TB Branch's Audit Tool on texas.tb.org

C. Update and develop policies and procedures to support continuing quality improvement efforts.

D. Review CDC's National Tuberculosis Indicators Project (NTIP) to assess TB program's progress in achieving performance outcomes.

E. Texas Performance Measures - FY16

1. Newly-reported TB cases shall have an HIV test performed (unless they are known HIV-positive, or if the client refuses) and shall have positive or negative HIV test results reported to DSHS according to the reporting schedule.

For FY16 reporting, data will be drawn from calendar year 2015 (1/1/2015 - 12/31/2015). 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 to improve that percentage, on a timeline set by DSHS;

2. Cases, and suspected cases, of TB under treatment shall be placed on timely and appropriate Directly Observed Therapy (DOT).

For FY16 reporting, data will cover all cases from calendar year 2015 (1/1/2015 - 12/31/2015). 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 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 FY16 reporting, data will be drawn from calendar year 2015 (1/1/2015 - 12/31/2015). 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 to improve that percentage, on a timeline set by DSHS;

4. Newly-reported TB clients 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.

For FY16 reporting, data will be drawn from calendar year 2015 (1/1/2015 - 12/31/2015). 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 to improve that percentage, on a timeline set by DSHS;

5. 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.

For FY16 reporting, data will be drawn from calendar year 2014 (1/1/2014-12/31/2014). A compliance percentage of not less than 47% is required.

If data indicates a compliance percentage for this Performance Measure of less than 47%, then DSHS may (at its sole discretion) require additional measures be taken 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 FY16 reporting, data will cover all cases from calendar year 2014 (1/1/2014 - 12/31/2014). 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 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 FY16 reporting, data will be drawn from calendar year 2015 (1/1/2015 - 12/31/2015). 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 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 FY16 reporting, data will be drawn from calendar year 2014 (1/1/2014 - 12/31/2014). 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%, then DSHS may (at its sole discretion) require additional measures be taken to improve that percentage, on a timeline set by DSHS;

9. Newly-reported TB clients 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 FY16 reporting, data will be drawn from calendar year 2015 (1/1/2015 - 12/31/2015). 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 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 TB infection and disease.

For FY16 reporting, data will be drawn from calendar year 2014 (1/1/2014 - 12/31/2014). 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 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 TB infection (TBI) shall be started on timely and appropriate treatment.

For FY16 reporting, data will be drawn from calendar year 2014 (1/1/2014 - 12/31/2014). 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 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 LTBI and that were started on treatment shall complete treatment for TB infection

For FY16 reporting, data will be drawn from calendar year 2014 (1/1/2014 - 12/31/2014). 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 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 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 FY16 reporting, data will be drawn from calendar year 2015 (1/1/2015 - 12/31/2015). 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 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 evaluation within 90 days of arrival.

For FY16 reporting data will be drawn from calendar year 2015 (1/1/2015-12/31/2015). A compliance percentage of not less than 45% is required.

If data indicates a compliance percentage for this Performance Measure of less than 45%, then DSHS may (at its sole discretion) require additional measures be taken 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 TB infection (TBI during evaluation in the US, increase the proportion who start treatment.

For FY16 reporting, data will be drawn from calendar year 2015 (1/1/2015 - 12/31/2015). A compliance 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 to improve that percentage, on a timeline set by DSHS; and

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 (TBI during evaluation in the US and started on treatment, increase the proportion who complete TBI treatment.

For FY16 reporting, data will be drawn from calendar year 2014 (1/1/2014 - 12/31/2014). 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 to improve that percentage, on a timeline set by DSHS.

Maintain documentation used to calculate performance measures as required by General Provisions Article VIII “Records Retention” and by Texas Administrative Code Title 22, Part 9 Chapter 165, §165.1 regarding retention of medical records.

APPENDIX 1: Glossary

AII – Airborne infection isolation is a negative pressure room that is an isolation technique used in hospitals or clinics to **isolate** clients with **airborne** contagious **diseases.**

ATS – American Thoracic Society

TB Branch – DSHS Tuberculosis and Refugee Health Services Branch

CDC – The Centers for Disease Control and Prevention

CI – Contact Investigation

Class B Immigrants –Class B conditions are defined as physical or mental abnormalities, diseases, or disabilities serious enough or permanent in nature as to amount to a substantial departure from normal well-being. Follow-up evaluation soon after US arrival is recommended for immigrants or refugees with class B conditions.

Congregate settings – an environment where a number of people meet or gather and share the same space for a period of time. Examples include: day cares, nursing homes, hospitals, correctional facilities, airplanes, public transportation, schools, etc.

CXR – (also referred to as Chest x-ray). A posterior-anterior (PA) chest X-ray is the standard view used; other views (lateral or lordotic) or CT scans may be necessary. In active pulmonary TB, infiltrates or consolidations and/or cavities are often seen in the upper lungs with or without mediastinal or hilar lymphadenopathy. However, lesions may appear anywhere in the lungs. In HIV and other immunosuppressed persons, any abnormality may indicate TB or the chest X-ray may even appear entirely normal. Old healed tuberculosis usually presents as pulmonary nodules in the hilar area or upper lobes, with or without fibrotic scars and volume loss. Nodules and fibrotic scars may contain slowly multiplying tubercle bacilli with the potential for future progression to active tuberculosis. Persons with these findings, if they have a positive tuberculin skin test reaction, should be considered high-priority candidates for treatment of latent infection regardless of age. Conversely, calcified nodular lesions (calcified granuloma) pose a very low risk for future progression to active tuberculosis.

DGMQ – Division of Global Migration and Quarantine, a division within CDC

DSHS – Department of State Health Services

DOT – directly observed therapy.

EDN – Electronic Disease Notification system

ELR – Electronic Lab Reporting

FEFO – first-expiring-first-out principle of inventory control

Genotyping – a laboratory approach using specific elements of bacterial DNA that serve as markers for *M.tuberculosis* strains.

Genotyping clusters – When an isolate genotype matches at least one other person's isolate genotype**.**

HSR – Health Service Region

HIV Infection – **Human immunodeficiency virus infection** and **acquired immune deficiency syndrome** (**HIV/AIDS**) is a spectrum of conditions caused by infection with the human immunodeficiency virus (HIV). Following initial infection, a person may experience a brief period of influenza-like illness. This is typically followed by a prolonged period without symptoms. As the infection progresses, it interferes more and more with the immune system, making the person much more susceptible to common infections like tuberculosis, as well as opportunistic infections and tumors that do not usually affect people who have working immune systems. The late symptoms of the infection are referred to as **AIDS**. This stage is often complicated by an infection of the lung known as pneumocystis pneumonia, severe weight loss, a type of cancer known as Kaposi's sarcoma, or other AIDS-defining conditions.

IDSA – Infectious Diseases Society of America

IGRA – Interferon-Gamma Release Assay, a blood test for TB infection

IJN – inter-jurisdictional notification

ITEAM – The DSHS Inventory Tracking Electronic Asset Management System (ITEAMS) facilitates ordering and delivery of medications and supplies to TB programs.

LHD – Local Health Department

LRP – Local Responsible Party, the person having overall responsibility for ensuring security of confidential information.

MDR – multi-drug resistant TB; MDR TB is a form of drug-resistant TB in which the TB bacteria can no longer be killed by at least the two best antibiotics, isoniazid (INH) and rifampin (RIF), commonly used to cure TB. As a result, this form of the disease is more difficult to treat and requires up to two years of treatment.

NAAT – Nucleic Acid Amplification Test, a rapid molecular technique used to identify a virus or bacteria.

NTIP -- National Tuberculosis Indicators Project

NTSS – National Tuberculosis Surveillance System, Centers for Disease Control and Prevention (CDC)'s National Tuberculosis Surveillance System (NTSS) is the national repository of tuberculosis (TB) data in the United States. Jurisdictions report to NTSS through the Report of Verified Case of Tuberculosis (RVCT) form that transitioned to a web-based system in 2009.

PCR – The polymerase chain reaction (**PCR**) is a technology in molecular biology used to amplify a single copy or a few copies of a piece of DNA across several orders of magnitude, generating thousands to millions of copies of a particular DNA sequence

PHIN (or TXPHIN) -- Texas Public Health Information Network

RVCT – Report of Verified Cases of TB, The Report of Verified Case of Tuberculosis is the national TB surveillance data reporting form. All jurisdictions report these data to CDC on each newly reported case of TB. The results are used for determining the TB morbidity case rates for the United States, U.S. Territories, and U.S.-Affiliated Pacific Islands.

SDO – Standard Delegation Orders, Physician's orders or instructions for the care of an individual in a HSR clinic when a physician is not actively working in that clinic and nurses must abide and work under a physician's orders to legally provide clinical services. In Texas the SDOs written for HSR clinics serve as another tool to aid local health departments on their policies and procedures in TB.

TAC – Texas Administrative Code, The Texas Administrative Code (TAC) is a compilation of all state agency rules in Texas. There are 16 titles in the TAC. Each title represents a category and related agencies are assigned to the appropriate title.

TB (tuberculosis) – A bacteria that is spread from person to person through the air.

TB Disease – a contagious and an often severe airborne disease caused by a bacterial infection. TB typically affects the lungs, but it also may affect any other organ in the body. It is usually treated with a regimen of drugs taken for 6 months to 9 months.

TBGIMS – The TB Genotyping Information Management System (TB GIMS) is a secure web-based system designed to improve access and dissemination of genotyping information nationwide.

TB Infection – When a person has been exposed to someone with TB disease and has breathed in the TB germs, that person may become infected with TB. In most cases, people with healthy immune systems can contain the infection and do not become ill with

TB disease. A person with TB infection only (positive TB skin test but normal chest x-ray) is not sick and is not contagious to others.

TST – the Mantoux *tuberculin skin test* (*TST*) is the standard method of determining whether a person is infected with Mycobacterium tuberculosis

TXPHIN (or PHIN) – Texas Public Health Information Network is the secure method for distributing public health information

Appendix 2: NTIP Reporting Requirements

For TB cases, registries are required to ensure at least 99.2% valid responses for all NTIP reporting variables, by the end of the current reporting year and 99.4% by the TB surveillance deadline, in mid-March of the following year.

Minimum NTIP variables required at the time of initial report:

1. date of initial report
2. date case was confirmed as a class 3
3. criteria for the published case definition for a lab confirmed diagnosis or clinical case of TB or a clinical case of TB by provider diagnosis
4. a valid and verified address
5. race and ethnicity
6. date of birth
7. country of birth; if not U.S., date of arrival into the U.S.
8. for culture confirmed cases, initial susceptibilities including MDR and XDR cases
9. HIV status
10. site of disease (select all that apply); if miliary, must provide at least two sites of disease where one site is pulmonary
11. vital status at diagnosis
12. history of prior disease

The remaining variables are required to be reported within the current year:

13. additional information for pediatric client
14. sputum smear
15. sputum culture
16. smear/ pathology/cytology of tissue and other body fluids
17. culture of tissue and other body fluids
18. NAA test result
19. initial chest radiograph and other chest imaging study
20. tuberculin skin test
21. IGRA test result
22. occupation
23. primary reason evaluated for TB
24. homeless within past year
25. primary occupation within the past year
26. injecting drug use within past year
27. non-injecting drug use within past year
28. excess alcohol use within past year
29. additional TB risk factors
30. immigration status

31. date therapy started
32. initial drug regimen

Upon case closure, registries must also provide valid responses for the following NTIP variables if the case was alive at diagnosis

33. sputum culture conversion date, (collection date must be at least 7 days from last known positive sputum culture)
34. moved, if yes specify if in-state and use TB-220 form to submit to corresponding jurisdiction; if out of state, use IJT form; if out of the U.S., use CDC notification form or Cure-TB form
35. date therapy stopped
36. type of outpatient provider (all that apply)
37. DOT
38. final drug susceptibility testing
39. final drug susceptibility test results; collection date must be at least 30 days from date of collection of initial susceptibility results

Appendix 3: State Funding Formula Variables

The minimum criteria required to meet the definition and variables required for state funding formula are as follows:

a) Complete name and date of birth;
b) Sex, race and ethnicity;
c) Country of origin; if foreign born-date of arrival;
d) Client's verified residential address when initially suspected;
e) Name of correctional or long term care facility or homeless shelter and physical address from master lists of addresses;
f) Tuberculin skin test or IGRA test result;
g) Chest x-ray;
h) Smear results;
i) HIV test result;
j) Diabetes status;
k) Substance abuse (alcohol, injecting and non-injecting drugs)
l) All laboratory or clinically confirmed cases
m) MDR-TB cases
n) TB cases completing treatment
o) TB suspects
p) HIV/TB Co-infected Cases and Suspects
q) TB Cases and Suspects from Special Populations (*member of a special population (child less than 5 at diagnosis, U.S. born minority, homeless, foreign born, substance abuse, Border resident-La Paz counties and diabetes) or a client of a DSHS-funded refugee resettlement program.)
r) Total Population in Funded Area
s) Total Square Miles in Funded Area
t) TB Infection (TB infection using a DSHS Branch approved treatment regimen that were identified as: 1) contacts to a counted case in Texas; 2) member of a special population, or 3) client of a DSHS-funded refugee health clinic)

Any closed non-TB suspects that are submitted after the established TB surveillance deadline may not be counted in the funding formula.