

❖ UNIT A

Program Stewardship and Accountability

Contractor General Requirement A-1

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

Activities:

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

Contractor General Requirement A-2

Demonstrate fiduciary responsibility in administering program funds

Activities:

- Provide a match of no less than 20% of the total budget reflected in the Program Attachment. Contractor shall provide match at the required percentage or DSHS may withhold payments, use administrative offsets, or request a refund from Contractor until such time as the required match ratio is met. No federal or other grant funds can be used as part of meeting the match requirement. Contractor shall not use DSHS funds or matching funds (including in-kind Contributions) for:
 - 1. Food;
 - 2. Incentives;
 - 3. Entertainment; or

4. Sectarian worship, instruction, or proselytization.
- Provide TB services to cases, suspects, contacts, refugees and class B immigrants regardless of their ability to pay for services.
- Lapse no more than 5% of total funded amount of the contract.
 1. Maintain and adjust spending plan throughout the contract term to avoid lapsing funds.
 2. Maintain staffing levels to meet required activities of the contract and to ensure that all funds in the personnel category are expended.

❖ **Unit B**

Conduct Overall Planning and Policy

Contractor General Requirement B-1

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

Activities:

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

❖ **Unit C**

Manage Tuberculosis Cases and Suspects

Contractor General Requirements C-1

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

Activities:

- Conduct a complete medical evaluation on all patients suspected of having TB disease. A complete medical evaluation and assessment for TB includes medical history (symptoms, prior TB treatment, risk factors for TB, and history of exposure); physical examination; Mantoux tuberculin skin test (TST) or interferon-gamma release assay (IGRA) (e.g., QuantiFERON-Gold test); chest x-ray; and appropriate bacteriologic (smear, culture, drug susceptibility) and/or histologic examinations. If a patient is reported to the health department with laboratory culture results indicating the presence of *Mycobacterium tuberculosis* complex, a TST result would not change the diagnosis and may be waived.
- Complete the informed consent form and place in the patient's medical record.
- For patients whose TB care will be shared by both a private medical provider and a local health department, develop a written document signed by both parties that describes the specific roles and responsibilities of each provider.
- Utilize interpreter services to facilitate patient and provider communication as it relates to limited English proficient (LEP) clients.
- Sputum Collection
 1. Educate patients about collection of sputum and packaging for mailing, if the patient will mail in specimens. Education shall be given prior to collection. The health care worker shall observe the collection of at least the initial sputum obtained by the health department and document the observation of this collection in the medical record.
 2. For patients who are able to produce natural or induced sputum:
 - a. Obtain three sputum specimens, 8 to 24 hours apart, prior to or at the initiation of therapy for the determination of smear and culture. At least one of the samples should be collected early in the morning. Ship specimens according to laboratory guidelines.
 - b. Collect at least every two weeks, three sputum specimens (of which at least one should be collected early in the morning) for the determination of smears only until three consecutive smears are negative.
 - c. Collect monthly, at least one sputum specimen for the determination of culture until all specimens collected for 2 consecutive months are culture negative. Monthly sputum must be collected from patients with isolates resistant to both isoniazid and rifampin and all other MDR TB cases throughout the treatment course.
 - d. Collect at least one further sputum collection at completion of therapy, if possible.
- HIV Screening
 1. Perform HIV screening for all persons with newly diagnosed or suspected TB disease unless the patient has HIV positive documentation or has documented

- negative HIV test result from a specimen collected within the last 14 days.
2. Present HIV testing to the patient in the same manner as information about other routine tests. The patient may decline to be tested for HIV, but should be educated about the importance of knowledge about their HIV status to the medical management of their TB disease.
 3. Report newly positive HIV test results to the appropriate local or health service regional public health HIV/STD program. The patient shall be informed of newly positive HIV test results in person by a health care worker who is trained in post-test counseling. For patients with TB disease who are also infected with HIV, a CD4 count should be obtained.
- Place a surgical mask on patients with symptoms of pulmonary, pleural, or laryngeal TB that arrive at the local health department for services or place patients in an airborne infection isolation area at each clinic visit until the patient has met the following three (3) criteria for non-infectiousness and the patient has negligible likelihood of multidrug-resistant TB (no known exposure to multidrug-resistant TB and no history of prior episodes of TB with poor compliance during treatment):
 1. Received standard multidrug anti-tuberculosis treatment by directly observed therapy (DOT) for two weeks;
 2. Has demonstrated clinical or radiographic improvement; and
 3. Has three consecutive negative sputum smear results collected 8 to 24 hours apart with at least one specimen being collected early in the morning. If sputum culture results become negative before the smear results, then three consecutive negative culture results satisfy the criteria for non-infectiousness.
 - Place infectious patients in home isolation if the following criteria are met:
 1. A specific plan exists for follow-up care with the local TB-control program;
 2. The patient has been started on a standard multidrug antituberculosis treatment regimen, and DOT has been arranged;
 3. No infants or children aged less than 4 years or persons with immunocompromising conditions are present in the household;
 4. All immunocompetent household members have been previously exposed to the patient; and
 5. The patient is willing to refrain from travel outside of the home except for health-care-associated visits until the patient has three consecutive negative sputum smear results.
 - Order a complete bacteriologic work up, including drug susceptibility tests for isoniazid, rifampin and ethambutol on initial isolates. Extended drug susceptibility testing shall be performed on all isolates with resistance to any first line agent in accordance to *TB Drug Resistant policy TB 4002*. Assure that at least one specimen from cases with a positive culture is sent to the DSHS Austin lab for genotyping.
 - Obtain for all adult patients, baseline laboratory tests for aspartate aminotransferase (AST), alanine aminotransferase (ALT), bilirubin, alkaline phosphatase, serum creatinine, and a complete blood count including platelets must be performed prior to starting treatment. All patients with a history of liver disease, symptoms of liver disease, baseline liver function tests above the upper limit of normal, or risk factors for liver disease should receive screening for viral or other causes of hepatitis. Refer

to *DSHS Standards of Performance for the Prevention and Control of Tuberculosis* for additional monitoring of liver function test results.

- Develop and initiate a complete treatment and case management plan according to ATS/CDC/IDSA guidelines and recommendations of DSHS. Refer to *DSHS Standards of Performance for the Prevention and Control of Tuberculosis, Management of TB Suspects and Cases*
- Provide DOT to all cases and suspects until the recommended course of therapy is completed. Directly observed therapy is the standard of care in Texas.
- Obtain consultation from a DSHS recognized expert physician consultant within three days of laboratory notification for all TB cases whose *Mycobacterium tuberculosis* organisms are resistant to isoniazid and/or rifampin or shows a resistance to any drug on the drug susceptibility panel in accordance to TB 4002 policy. Provide written documentation the consultation occurred and the consultant's recommendations were followed or a justification for deviations from the advice of the consultant shall be maintained in the patient's record and a copy of the consult must be sent to the DSHS Tuberculosis Services Branch within twenty-four hours.
- Obtain consultation from a recognized expert physician for cases with HIV infection or cases less than 15 years of age.
- Obtain consultation from a recognized expert physician to resume treatment after interruptions of more than 2 weeks in the initiation phase of therapy or more than 2 months in the continuation phase. A list of recognized expert physician consultants is available from the DSHS Tuberculosis Services Branch.
- Prepare and present a written control order (order to implement measures) at the beginning of treatment to all persons with suspected or confirmed tuberculosis disease.
- Provide treatment to all TB cases and suspects without consideration of ability to pay.
- Provide initial and ongoing education to the patient regarding the epidemiology, transmission and pathogenesis of TB; means to decrease transmission; need to complete therapy; rationale for directly observed therapy and contact investigation; confidentiality of patient information, common adverse drug reactions and drug interactions of TB medications; responsibility of patient to discuss symptoms of adverse drug reactions with the nurse case manager or physician when they occur; and signs and symptoms associated with disease relapse.

Contractor General Requirements C-2

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

Activities:

- Initiate a contact investigation for suspected or confirmed cases of pulmonary, pleural, or laryngeal TB disease within three (3) days of report or notification. Contact investigations should not be delayed pending laboratory results in congregate settings or where there is some indication that children younger than five, persons

who are HIV-infected or persons who are otherwise immunocompromised may be among the contacts. A contact investigation may be halted or not initiated if a nucleic acid amplification test performed by CDC recommended protocol or another rapid laboratory test is negative for *Mycobacterium tuberculosis* complex.

- Assign priority status prior to initiating contact investigations based on the infectiousness of the presenting suspect or case:
 1. (First priority – persons with acid-fast bacilli (AFB) sputum smear positive or with cavitary TB) Identify and test all high and medium priority contacts.
 2. (Second priority – persons with suspected or confirmed pulmonary/pleural TB, AFB sputum smear negative and an abnormal chest radiograph consistent with TB disease) Identify and test all high and medium priority contacts.
 3. (Third priority – all other cases and suspects) Identify and test contacts that are living in the household, aged less than 5 years, have a medical risk factor, or were exposed during an unprotected medical procedure (such as bronchoscopy, sputum induction or autopsy).
 - a. Negative test results of contacts with the most exposure to extrapulmonary cases confirms that there has been no transmission due to pulmonary involvement.
 - b. Testing of contacts with the most exposure to cases aged less than 5 years may identify the source of the child’s infection or other associates that may have been infected by that source case.

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

❖ Unit D

Manage Contacts to Known or Suspected Cases of Tuberculosis

Contractor General Requirements D-1

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

Activities:

- Find exposed persons who are more likely to be infected or to become ill with TB disease. Increased length or frequency of exposure as well as the relative infectiousness of the presenting TB case increase the probability of infection.
- Complete an initial interview including education, testing and evaluation of contacts within three weeks of the report of the suspect to the local health department.

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

❖ Unit E

Manage Patients on Treatment for Latent TB Infection

Contractor General Requirements E-1

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

Activities:

- Evaluate at-risk candidates for TB. At-risk candidates may include contacts, refugees, class B immigrants, discharged inmates or other high risk populations in which TB is prevalent.
- Contacts to a person known or suspected to have TB should receive a chest radiograph regardless of their ability to pay. A health history containing at least

as much information as the TB-202 Tuberculosis Health Assessment/History must be documented in the patient's medical record.

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

❖ Unit F

Conduct Active Surveillance to Identify Unreported Individuals with Suspected or Confirmed Tuberculosis

Contractor General Requirement F-1

Develop an active surveillance mechanism for early identification and reporting of TB.

Activities:

- Identify specific community and health care organizations in which at-risk populations are likely to receive services.
- Provide education and training to community based and health care organizations to increase awareness about TB to include TB transmission, disease presentation, community-specific epidemiology of TB and reporting requirements.
- Incorporate TB in existing surveillance mechanisms. If one does not exist, develop an active surveillance system that promotes routine TB reporting.
- Evaluate surveillance mechanisms to enhance TB reporting processes.

❖ Unit G

Reporting

Contractor General Requirement G-1

In accordance with reporting requirements, submit all reports by established deadlines.

Activities:

- Report 100% of all TB cases (ATS classification 3) using a DSHS approved form, with all the required reporting fields complete within seven (7) days of notification to DSHS TB/HIV/STD Epidemiology and Surveillance Branch. Submit an updated DSHS Tuberculosis Services Branch approved form whenever a change in information in a required reporting field occurs for all TB cases.
- Submit 100% of all initial, follow up, and last positive *Mycobacterium tuberculosis* culture laboratory reports and drug susceptibilities as well as the first negative culture report after the last positive within seven (7) days of notification to DSHS TB/HIV/STD Epidemiology and Surveillance Branch. (Note: for culture reports that originate from a DSHS laboratory, this requirement is automatically met. For culture reports not originating from a DSHS lab, a copy of the laboratory report must be submitted.)

- Document the dates of sputum and culture conversion on a DSHS approved report form to DSHS TB/HIV/STD Epidemiology and Surveillance Branch. Since sputum specimens may have culture results that fluctuate from positive to negative to positive over a period of time before true conversion occurs, the collection dates for the last positive sputum culture and the first consistently negative sputum culture must be separated by at least 7 days. The collection dates for the initial drug susceptibility test results must be no earlier than 7 days before the drug start date and no later than 7 days after the drug start date. The collection dates for the follow-up susceptibilities should be at least 30 days from the initial drug susceptibilities.
- If treatment of a TB case or suspect has stopped due to completion of adequate therapy, death, or failure to locate the patient after three solid attempts and/or 90 days have passed since the last dose, provide acceptable closure codes and the last date medication was given and submit to the DSHS TB/HIV/STD Epidemiology and Surveillance Branch. In the event of a cross-contamination or misdiagnosis, provide documentation to justify deletion of the class 3 record (e.g., amended lab report, doctor's note, consult, etc.) and a request to delete the record from the state case registry.
- Submit the monthly correctional TB reports within fifteen (15) working days of the following month to DSHS Tuberculosis Services Branch. Local health departments shall receive the monthly correctional TB reports from jails meeting Texas Health and Safety Code Chapter 89 Requirements within five (5) working days of the following month, review reports for accuracy and completion and provide guidance to jails as needed in completing the monthly reports.
- Complete and submit form TB-400 on all newly diagnosed drug resistant cases within five (5) days of notification to the DSHS Tuberculosis Services Branch. Submit an updated form TB-400 every ninety (90) days for all drug resistant cases until completion of treatment to DSHS Tuberculosis Services Branch.
- Submit within seventy-two (72) hours of notification any changes in case management, drug resistance patterns, or change of residence of all drug resistant TB cases to DSHS Tuberculosis Services Branch.
- Submit within fourteen (14) days of the initial case or suspect report, an initial report of contacts on forms TB-340 and TB-341 to the DSHS TB/HIV/STD Epidemiology and Surveillance Branch. Follow-up information shall be submitted at intervals not exceeding 90 days, 120 days and 2 years;
- Submit the required Annual Narrative Report, using the standardized format provided, to DSHS, Tuberculosis Services Branch at TBContractReporting@dshs.state.tx.us by February 14, 2014.
- Submit the completed Cohort Review Summary Report Form to DSHS Tuberculosis Services Branch in accordance with the Cohort Review Policy. Refer to the Cohort Review Policy for the cohort review presentation and submission schedule.
- Submit to the Health Service Region (HSR) in your jurisdiction, verified data on the number of persons with LTBI completing treatment in the LHD service area. The above named LHD will collaborate with the DSHS Health Service Region

(HSR) TB program in its area to review completion data for LTBI for calendar year 2010. Upon verification by the HSR and LHD, the HSR will submit on behalf of the LHD, the data to the DSHS TB/HIV/STD Epidemiology and Surveillance Branch. The following verified data reflecting the number of persons completing treatment for LTBI with a DSHS TB Services Branch approved treatment regimen¹ will be included in the funding formula:

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

❖ Unit H

Implement Infection Control Procedures

Contractor General Requirements H-1

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

Activities:

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

❖ Unit I

Maintain a competent workforce

Contractor General Requirements I-1

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

Activities:

- Provide orientation and training to all employees involved in TB activities including physicians, nurses, contact investigators, outreach workers, medical records clerks, receptionists, and other support staff.
- Within 60 days of employment, all new employees shall receive 40 hours of TB training specific to their duties and responsibilities. Each year employees shall receive 16 hours of continuing education or training relevant to their position. The CDC's "Self-Study Modules on Tuberculosis" shall be used in the initial training. Documentation of all training (including the hours, topics, and dates) shall be retained for each employee who delivers TB services and made available upon request by the DSHS Tuberculosis Services Branch.
- Topics for training of personnel include:
 - a Transmission and Pathogenesis of Tuberculosis;
 - b Epidemiology of Tuberculosis;
 - c Diagnosis of Tuberculosis Infection and Disease;
 - d Treatment of Tuberculosis Infection and Disease;
 - e Drug Interactions and Toxicity;
 - f Contact Investigation for Tuberculosis;
 - g Tuberculosis Surveillance and Case Management in Hospitals and Institutions;
 - h Infectiousness and Infection Control;
 - i Patient Adherence to Tuberculosis Control;
 - j Interviewing, Investigating and Influencing Techniques;
 - k Medical Record Keeping and Management;
 - l Budgeting and Fiscal Management;
 - m Operations Management;
 - n Directly Observed Therapy;
 - o TB Nurse Case Management Training;
 - p Cultural Awareness;
 - q Interpreter Utilization.
- Notify DSHS Tuberculosis Services Branch of newly hired TB program managers and nurses within 30 days of hire.
- Newly hired TB program managers and nurses shall participate in the DSHS Tuberculosis Services Branch orientation within three months of hire.
- Provide TB education and training as resources allow to correctional facilities, community health care and social service providers who serve populations at high risk for TB.
- Document all community-provider TB training (including the hours, topics, dates and numbers of participants) make available upon request to the DSHS Tuberculosis Services Branch.

❖ Unit J

Conduct continuing quality improvement activities to maintain a robust TB infrastructure

Contractor General Requirements J-1

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

Activities:

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