Texas Department of Health

TB Elimination Division

Standards of Performance

5th Edition

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TDH

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Standards of Performance

Section One

Introduction

Conducting tuberculosis services is a key element in the control and management of tuberculosis in the State of Texas. To improve delivery of services, establish realistic goals and objectives, and generate outcomes commensurate with the investment of resources associated with each contract, standards of performance have been developed for contracts with local health departments, other contracting entities and regional health departments. Each contractor or TB program must have a distinct scope of work that will allow each contracting entity to establish a service delivery plan that addresses their strategies and approaches to control and eliminate tuberculosis. The service delivery plan also describes how each entity will accomplish the objectives described in the contract. Each contracting entity will be required to submit a service delivery plan 120 days prior to the beginning of the contract period. Service delivery plans should define new and continued effective approaches to control and eliminate tuberculosis with emphasis in the following areas:

- Management of TB cases and suspects with emphasis on provision of directly observed therapy (DOT)
- Management of contacts to known or suspected cases of tuberculosis
- Management of patients on treatment for latent TB infection (LTBI)
- Surveillance to identify unreported individuals with latent TB infection and TB disease as well as reporting of all TB cases, suspects and contacts
- Infection control procedures
- Targeted testing of high risk groups
- Professional education and training for new TB staff and continuing education for current staff
- Patient and provider communication as it relates to limited English proficient (LEP) clients
- Quality assurance

The service delivery plan must name a person responsible for TB program management and for quality assurance. This may be the same person. The TB Elimination Division (TBED) must be notified immediately with the name of a replacement or acting TB program manager.

In addition, special provisions in the general appropriations relating to all health and human services agencies mandated specific requirements for the execution of all client service contracts.

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Section Two

Management of TB Cases and Suspects

A. A complete medical evaluation must be obtained on all patients confirmed or 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; chest x-ray; and appropriate bacteriologic (smear, culture, drug susceptibility) and/or histologic examinations. A signed consent form is to be placed in the patient's medical record. Suspects must be evaluated and dispositioned (reclassified) within 90 days of the initial report.

B. HIV testing and counseling are recommended for all patients. For patients infected with HIV, a CD4 count should be obtained.

C. Patients with symptoms of pulmonary or laryngeal TB must be placed in AFB respiratory isolation until infectiousness has been ruled out as evidenced by all of the following: the patient's having received adequate treatment by DOT for two to three weeks; shown favorable clinical response to therapy; and three sputum specimens (at least two of which are collected early in the morning of consecutive days) are smear negative. Supervised sputum collection is preferred.

D. A complete bacteriologic work up, including drug susceptibility tests for isonaizid, rifampin and ethambutol on initial isolates, must be ordered. Extended drug susceptibility testing should be performed on all isolates with resistance to any first line agent. For all adult patients, baseline blood tests for aspartate aminotransferase (AST), alanine aminotransferase (ALT), bilirubin, alkaline phosphatase, serum creatinine, and a complete blood count including platelets must be completed prior to starting treatment. Generally, it is not necessary to perform these baseline blood tests for patients under 18 years of age. For patients who will take ethambutol, visual acuity using Snellen chart and red/green color discrimination using Ishihara plates must be ordered. For patients who will take amikacin, capreomycin, kanamycin or streptomycin, audiometry measurements must be made and a screen performed for balance when standing and walking. Additional tests may be ordered as recommended by the physician in accordance with ATS/CDC/IDSA TB treatment guidelines.

E. A complete treatment and case management plan must be developed and initiated according to ATS/CDC/IDSA guidelines and recommendations of the Texas Department of Health (initial phase to include four TB drugs, [INH, RIF, PZA, EMB] continued until drug susceptibility results are reported and evaluated by the case manager and physician). If PZA is contraindicated for the patient, this must be documented in the medical record. The initial treatment plan should be developed within one week of diagnosis (i.e. within one week of initiation of therapy for a person suspected to have TB or within one week of identification of a person's having a positive culture). The plan must include:

1. The use of DOT for all cases and suspects until the recommended course of

therapy is completed. If DOT is not used, then the rationale for not using DOT is to be documented in the patient's medical record.

2. Educating patients about adverse reactions, recurrence of symptoms, compliance with treatment and consequences of non-compliance (court-ordered management);

3. Referring patients for other medical and social services as necessary;

4. Use of incentives to assure adherence to DOT when indicated;

5. A licensed nurse, physician or physician assistant will monitor patients at least monthly for drug toxicity and response to therapy. Additional review of the progress of the patient should be conducted according to local or regional health department policy.

F. A consultation must be requested from a TBED 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. Written documentation that the consultation occurred and that 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.

G. All TB cases and suspects must be reported within one working day to the local health authority, or if there is no local health authority, to the Texas Department of Health public health region director. [Texas Health & Safety Code ANN. §97.2 - §97.6 (Vernon 1992)]. Reports of TB cases and suspects should be sent to the Tuberculosis Elimination Division in Austin on the TB-400 A&B forms.

H. All TB cases must receive a written control order at the beginning of treatment. A signed control order is to be placed in the patient's medical record. This control order must either be in the patient's preferred language or the medical record must document that an interpreter read the order to the patient or their guardian before they signed. Patients who are identified as non-compliant with treatment must be placed under court-ordered management, [Texas Health & Safety Code ANN. §81.082(d) (2, 3, & 7) (Vernon 1992)].

I. A contact investigation must be conducted for every new TB case or suspect. The TB patient must be thoroughly interviewed within three days of initial examination and the results recorded in the patient's medical record. The completed initial and final report of contacts to a tuberculosis case or suspect (TB-340/TB-341 form) must be sent to the Tuberculosis Elimination Division of the Texas Department of Health unless a specific exemption is granted by the Data Section Manager of the TB Elimination Division.

J. Consultation from a TBED recognized expert physician is encouraged for cases less than 15 years of age or with HIV infection. A consult from a TBED recognized expert physician must be obtained 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.

K. All TB cases and suspects must be treated without consideration of ability to pay. When a patient works in one jurisdiction and lives in another, the two jurisdictions shall work together to accommodate the patient's preferences for place of treatment.

L. Provide initial and ongoing education to the patient regarding the epidemiology, transmission and pathogenesis of tuberculosis; means to decrease transmission; need to complete therapy; rational for directly observed therapy and contact investigation; confidentiality of patient information, common side effects and drug interactions of TB medications; need to discuss these with the nurse case manager or physician when they occur; and signs and symptoms associated with disease relapse.

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Section Three

Management of Contacts to Known or Suspected Cases of TB

A. Identification and determination of exposure risk for all household, social, occupational and other close contacts to the TB case are to be initiated within seven days of the initial report of a TB suspect/case. The initial evaluation of contacts for infection and disease must be completed within three weeks of the report of the TB case/suspect.

Evaluation consists of interviewing all contacts to obtain their relevant medical history, including previous positive tuberculin reaction and/or previous treatment for TB and may include a tuberculin skin test administered and read; a chest radiograph; and collection of sputum or other samples for examination.

If the initial PPD test result is negative, a second test is to be administered within 10 to 12 weeks after the contact has been broken (client died, hospitalized, quarantined, no longer in household, or on adequate DOT and three consecutive negative sputum smears/cultures). Children less than 4 years of age, HIV infected individuals, and other immunosuppressed persons should be placed on treatment for latent TB infection pending the outcome of the second skin test if the initial PPD test result is negative, the chest x-ray is normal, and the individual has no symptoms of TB.

If the repeat skin test remains negative and contact with the source case has been broken, therapy for latent TB infection (LTBI) may be discontinued with the following exceptions. If the second skin test is negative, infants less than 6 months old and HIV infected individuals with advanced immunodeficiency should be evaluated for continuation and completion of treatment for LTBI based on evidence of transmission of infection in other high priority contacts.

If the repeat skin test is positive, refer for chest x-ray and evaluation.

B. If the skin testing of close contacts reveals that the rate of positive skin test results (the infection level) in this group exceeds that expected for the general population, the investigation must proceed to the next concentric circle of contacts – those who come in contact with the patient less frequently than the close contacts. This group may include frequent household visitors, close relatives, and friends. The investigation should stop when the rate of skin test positivity in the tested group is no higher than the expected rate for the general population in the community.

C. Priority for initiating contact investigations should be given to 1) those who are contacts to sputum smear positive, culture confirmed cases; 2) those who are contacts to sputum smear positive suspects; 3) those who are contacts of a child five years of age or less who is diagnosed with TB disease; 4) those who are contacts of a case or suspect with no pulmonary or laryngeal involvement. Among the contacts to a TB case or suspect, priority for evaluation and follow-up must be given to contacts who are less than five years of age, HIV infected or immunosuppressed.

D. Evidence that second tuberculin skin testing for contacts that are initially negative reactors is administered 90 days from the date contact was broken must be documented on the forms TB-340/TB-341.

E. Provide education to the contacts regarding the epidemiology, transmission and pathogenesis of tuberculosis; rational for contact investigation; confidentiality of patient information, steps in the diagnostic process, the difference between latent TB infection and TB disease, and signs and symptoms associated with TB disease.

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Section Four

Management of Patients on Treatment for Latent TB Infection (LTBI)

A. Prior to treatment for LTBI, the patient with a positive reaction to a tuberculin skin test should have chest x-ray with no abnormalities indicative of tuberculosis and exhibit no symptoms suggestive of tuberculosis. 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. A signed consent form is to be placed 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.

B. If treatment for LTBI is not started within 2 months of the chest x-ray showing no abnormalities indicative of tuberculosis or the patient begins to exhibit symptoms suggestive of tuberculosis, a new chest x-ray or other diagnostic procedures should be examined prior to start of therapy for latent TB infection.

C. If risk factors for potential adverse drug reactions are identified, appropriate baseline lab tests should be ordered. Patients on treatment for LTBI are to be monitored by a licensed nurse, physician or physician assistant at least monthly for drug toxicity.

D. Directly observed therapy will be provided to all contacts diagnosed with LTBI who are less than five years of age or HIV positive. Directly observed therapy may be provided to other high-risk persons as resources allow.

E. Patients who receive at least one dose of medication for LTBI should be reported to the TB Elimination Division of the Texas Department of Health using the TB-400 forms. The TB Elimination Division should be notified when the patient has completed treatment or stopped medication for some other reason.

F. Treatment for LTBI must be provided without consideration of the patient's ability to pay. When a patient works in one jurisdiction and lives in another, the two jurisdictions shall work together to accommodate the patient's preferences for place of treatment.

G. Provide initial and ongoing education to the patient regarding the epidemiology, transmission, pathogenesis of tuberculosis; need to complete therapy; confidentiality of patient information, rational for directly observed therapy; common side effects and drug interactions of TB medications; need to discuss these 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.

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Section Five

Surveillance / Reporting

A. Surveillance:

Local health departments must demonstrate proactive community surveillance systems for tuberculosis in that a designated TB staff person contacts selected health care providers (hospitals, pulmonologists, ENT specialists, and other clinic/hospital settings where individuals with TB symptoms would seek medical attention). Additional surveillance activities should focus on private laboratories, pharmacies and local repositories for certificates of death. Targeted testing and screening programs are considered part of the surveillance system.

B. Reporting:

Basic reporting requirements to the TBED include:

1. Reporting 100% of all TB cases on the TB-400, parts A and B with all the fields complete and submitting update TB-400B forms on all cases whenever a change occurs. TB clinics have 7 working days to submit TB-400s to the local health department. Local health departments have 7 working days to submit TB-400s to their regional office. Regional offices have 7 working days to submit TB-400s to the TB Elimination Division. Metropolitan health departments have 7 working days to submit TB-400s to the TB Elimination Division.

2. Submit 100% of all initial and last positive culture lab reports and drug susceptibilities as well as the first negative culture report after the last positive. (Note: for culture reports that originate from a TDH laboratory, this requirement is automatically met. For culture reports not originating from a TDH lab, a copy of the lab report must be submitted.) The dates of sputum and culture conversion must be documented on the TB-400B. Furthermore, the collection dates for the last positive sputum culture and the first negative sputum culture must be separated by at least 7 days. The patient's medical record must document the reason if it is impossible to obtain a culture negative sputum sample.

3. Reporting 100% of all TB suspects on the TB-400, parts A and B with all data fields complete and submitting update TB-400 B forms on all suspects when changes occur. (Use the same time guidelines as for submitting TB-400s for TB cases.) The standard for reclassifying a suspect (ATS classification 5) is within 90 days of the initial report.

4. In submitting an initial report of contacts on forms TB-340 and TB-341, TB clinics have 14 days to submit forms to local health departments. Local health departments have 7 days to submit forms to regional offices. Regional offices have 7 days to submit forms to the TB Elimination Division. Metropolitan health departments have 14 days to submit forms to the TB Elimination Division. A final report must be

submitted after all contacts have stopped taking treatment for latent TB infection. Exceptions to this timeline may be granted by the TB Elimination Division.

5. Submitting (within 7 days of notification of intent to move) the Interjurisdictional Tuberculosis Notification (NTCA 5-2002) forms to the TB Elimination Division for all TB cases, suspects, patients under treatment for latent TB infection, and contacts moving out of state.

6. Submitting (within 30 days of notification of intent to move) the Interjurisdictional Tuberculosis Notification Follow-up (NTCA 5-2002) forms to the TB Elimination Division for all TB cases, suspects, patients under treatment for latent TB infection, and contacts moving out of state.

7. Submitting (within 7 days of notification of intent to move) a Referral Form (TDH TB-220) to the receiving health department for all TB cases, suspects, patients under treatment for latent TB infection, and contacts moving out of local jurisdiction but within Texas.

8. Submitting (within 7 days of notification of intent to move) the International Tuberculosis Notification (rev. 22 Feb 2000) forms to the TB Elimination Division for all TB cases, suspects, patients under treatment for latent TB infection, and contacts moving out of the United States.

9. Contacting, evaluating, and reporting presumptive diagnosis and recommendations for treatment of disease or LTBI for all Aliens With Tuberculosis (Class A, B1, B2), on Notice of Arrival/Report form CDC 75.17 or 75.18.

10. Retaining patient medical records in accordance with TDH policy.

11. Submitting a TB-400, parts A and B, for all persons with latent TB infection who take at least one dose of medicine. A final report on the TB-400 part B should be submitted at the completion of the person's treatment.

12. All medical records and communications about medical records shall be maintained and conducted in a way that protects the confidentiality and privacy of the patients. Patients shall be advised of their rights to privacy in accordance with federal regulations and the policies of the Texas Department of Health.

Note: The TB Elimination Division has prepared a series of checklists to assist you in completing the TB-400 forms correctly.

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Section Six

Infection Control

A. Policies and procedures in accordance with the "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Facilities, 1994." are to be implemented in each TB program.

B. Administrative measures:

1. Suspected or confirmed infectious TB cases must be separated from other clinic patients (separate areas or appointments).

2. Suspected or confirmed infectious TB cases must be provided surgical masks and facial tissues.

3. Procedures that generate large amounts of droplet nuclei (bronchoscopy, sputum collection/induction) should be conducted in negative pressure isolation rooms or booths, if available. For clinics without these capabilities, sputum specimens must be collected outside.

4. In areas without separate TB clinic facilities, TB patients must be scheduled when other clinic patients are not present.

5. A negative pressure isolation room shall be used for the examination, evaluation, and treatment of suspected or confirmed infectious patients. These rooms must meet the specifications outlined in § C below.

6. TB staff with negative skin test results must be screened at least annually according to the 1994 CDC recommendations.

7. A respiratory protection program (respirators) shall be implemented for all employees who share the same air space with suspected or confirmed infectious cases.

C. Minimum specifications for isolation spaces for known or suspected contagious tuberculosis:

1. No fewer than 12 air changes per hour with no recirculation of the unfiltered exhaust air from isolation space into the ventilation system (no fewer than six air changes per hour in rooms built before 1995).

2. An isolation space must have negative pressure, achieved either by exhausting a minimum of 10% or 50 cubic feet per minute (CFM) more exhaust air than the amount of supply air for the isolation space, whichever is greater.

3. Isolation space exhaust systems and air supply systems must be designed to

maximize air mixing.

4. The doors to an isolation space must be equipped with automatic door closures.

5. Air exhausted from an isolation space shall be ducted directly outside the building and must not pass unducted through other areas unless it has passed through a HEPA filtration system.

6. The air exhaust discharge from an isolation space shall be located above the roof at a minimum of 25 feet from any air intake with velocity sufficient to prevent reentry.

7. Air from an isolation space shall be continuously exhausted through ducted systems maintained at a negative pressure relative to the pressure of normally occupied areas of the building.

8. The isolation space exhaust system may have a speed control for the exhaust fan, so that the air exhaust flow can be decreased when the space is not being used as a means of isolation of patients.

9. The ducted exhaust system shall be labeled at minimum 10 foot intervals in accordance with NFPA 704.

10. An isolation space shall be sealed to the maximum extent possible to prevent air leakage.

11. The receptionist area shall be isolated from clients, preferably by means of a sneeze barrier, and shall be at a positive air pressure relative to the immediately surrounding area.

Section Seven

Targeted Testing of High Risk Groups

A. TB programs shall develop effective working relationships with drug treatment centers, homeless shelters, community based organizations, jails and other correctional facilities, and agencies providing services to migrants, refugees and other foreign born individuals, as well as those with HIV/AIDS, to assure screening of community high risk groups.

B. Targeted high risk groups must include:

1. Foreign born persons from areas of high TB incidence including immigrants arriving with Class A, B1 or B2 waivers/notifications;

2. Medically under-served, low-income populations, including high-risk racial and ethnic groups;

3. Persons with HIV infection or AIDS, and individuals at high risk of contracting HIV: injecting drug and other illicit drug users; those who trade sex for drugs;

4. Locally identified high prevalence groups including migrant workers or homeless persons; and

5. County jails of 100 beds or more are legislatively mandated by the Texas Health & Safety Code ANN. §89 (Vernon 1992 & Supp. 1996) to conduct tuberculosis screening, treatment and reporting programs.

C. Evaluation of foreign born and other ethnic populations may require the use of trained interpreters such as contracting entity personnel, private telephone (or on-site) interpreting services or contractual interpreters from local organizations serving these populations. Staff should be trained to work in cross cultural settings and know the requirements to provide language services to persons with limited English proficiency.

D. When screening programs identify persons suspected or known to have active tuberculosis, those persons must receive appropriate treatment and case management as described in "Management of TB Cases and Suspects."

When screening programs identify persons with LTBI, those persons must be evaluated to determine whether they would benefit and should be offered treatment of LTBI or whether other conditions would contraindicate such treatment.

E. Priority for directly observed treatment of LTBI for persons identified in targeted testing programs should be given as resources permit to:
- children under five years of age,
- HIV infected persons,
- persons with compromised immune systems,
- persons who are recently infected,
- persons with other factors linked to an increased risk for progression to disease.

F. TB programs shall record the number of persons sought, enlisted, or registered for targeted testing. Programs must record the persons sought for targeted testing by the activity used to seek or find the persons (i.e. project, individual, administrative, or referral). Programs must record whether the persons sought for targeted testing are in a recognized medical or population TB risk group.

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Section Eight

Professional Education and Training

Professional education consists of: (1) the education and training of new employees and (2) the continuing education of TB staff.

This training shall be provided to all employees involved in TB activities including physicians, nurses, investigators, outreach workers, medical records clerks, receptionists, and other support staff.

Within 60 days of employment, all new employees will receive 40 hours of tuberculosis training specific to their duties and responsibilities. Each year employees will 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 shall be retained and made available upon request by the TB Elimination Division.

Suggested topics for training of personnel include

- Transmission and Pathogenesis of Tuberculosis;
- Epidemiology of Tuberculosis;
- Diagnosis of Tuberculosis Infection and Disease;
- Treatment of Tuberculosis Infection and Disease;
- Drug Interactions and Toxicity;
- Contact Investigation for Tuberculosis;
- Tuberculosis Surveillance and Case Management in Hospitals and Institutions;
- Infectiousness and Infection Control;
- Patient Adherence to Tuberculosis Control;
- Interviewing, Investigating and Influencing Techniques;
- Medical Record Keeping and Management;
- Budgeting and Fiscal Management;
- Operations Management;
- Directly Observed Therapy;
- TB Nurse Case Management Training;
- Cultural Awareness;
- Interpreter Utilization

Suggested reading materials include:

- Controlling Tuberculosis in Correctional Facilities, CDC 1995;
- Self Study Modules on Tuberculosis (modules 1-5), CDC 1995;
- Supplemental Self Study Modules on Tuberculosis (modules 6-9) CDC, January 2000;
- Core Curriculum on Tuberculosis, Fourth Edition, CDC, 2000;
- Prevention and Treatment of Tuberculosis Among Patients With Human Immunodeficiency Virus: Principals of Therapy and Revised Recommendations, CDC 1998;
- Treatment of Tuberculosis, ATS/CDC/IDSA 2003;

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- Guidelines for Preventing the Transmission of *Mycobacterium Tuberculosis* in Health Care Facilities, CDC 1994;
- Diagnostic Standards and Classification of Tuberculosis in Adults and Children (CDC) 2000;
- Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection (CDC) 2000.
- Update: Adverse Event Data and Revised American Thoracic Society/CDC Recommendations Against the Use of Rifampin and Pyrazinamide for Treatment of Latent Tuberculosis Infection – United States, 2003, (CDC)

Training and continuing education is also available through conferences, meetings, classes provided by the Tuberculosis Education Center*, various professional associations and other resources.

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1-800-TEX-LUNG

Section Nine

Patient and Provider Communication

Consent forms, control orders, and patient education materials should be sight translated by a trained interpreter and/or provided in appropriate languages for limited English speaking clients. Provider-patient communications with LEP (limited English proficient) clients should be supported with trained interpreters fully bilingual in the client's language.

The United States Department of Health and Human Services (HHS) has published policy guidance on Title VI's prohibition against national origin discrimination as it affects limited English proficient persons. (Federal Register: August 30, 2000; Vol. 65, No. 169; pp 52762-52774). The purpose of this policy guidance is to clarify the responsibilities of providers of health and social services who receive federal financial assistance from HHS, and assist them in fulfilling their responsibilities to limited English proficient (LEP) persons, pursuant to Title VI of the Civil Rights Act of 1964. The policy guidance reiterates HHS' longstanding position that in order to avoid discrimination against LEP persons on grounds of national origin, health and social service providers must take adequate steps to ensure that such persons receive the language assistance necessary to afford them meaningful access to their services, free of charge.

All TB Programs should become familiar with the various recommendations, requirements, options, and resources in the policy guidance.

Section Ten

Quality Assurance

A. Each program should develop and implement a plan to assure the quality of the TB prevention and control services that it provides.

B. The plan should include a system to

1. Review and revise policies,

2. Provide ongoing medical record reviews to assure conformity to standards,

3. Observe interactions between staff and clients during the provision of services,

4. Evaluate clients with adverse outcomes and document actions taken to prevent future adverse outcomes,

5. Monitor the outcomes of services provided and TB program performance through measurable indicators,

6. Implement training or other interventions designed to improve the effectiveness of the program as revealed by the measurable indicators.

C. Each program shall notify the TB Elimination Division within 2 working days of any serious adverse outcomes resulting in hospitalization or death that may have been caused by the medications used to treat tuberculosis disease or latent tuberculosis infection.

D. Each program shall calculate program performance measures and report them to the TB Elimination Division on a monthly basis. They shall send to the TB Elimination Division a narrative describing program goals and accomplishments every six months.