

# Texas Department of State Health Services Tuberculosis and Hansen's Disease Branch

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#### **Purpose and Scope of Onsite Review**

As a component of the program evaluation plan for the Tuberculosis and Hansen's Disease Branch (TB

Branch), local and regional TB programs will undergo periodic onsite review. Onsite reviews will be conducted to:

- 1. Assess compliance with the Texas TB Work Plan
- 2. Investigate specific concerns related to the delivery of TB prevention and care services
- 3. Investigate specific concerns related to TB case surveillance and reporting, and
- 4. Ensure that TB prevention and care services meet the needs of the targeted populations.

Review teams will consist of key staff from the TB Branch. The designated point of contact for TB Branch program evaluation planning will act as team lead. During the onsite review, team members may collect relevant data from medical chart review, direct observation, and interviews, as appropriate. Most reviews will be completed in two to three days.

#### **Preparing for the Onsite Review**

The onsite review team-lead will coordinate the visit and provide the Contract Management Section (CMS) with a list of sites selected for review. CMS will notify a local TB program of its selection for an onsite review, identify TB program areas for review, and provide a copy of the onsite review tool and agenda. The TB Branch will provide notification to a regional TB program. TB programs selected for review will receive notification 30 – 45 days



prior to a scheduled visit. The review team may request and/or review the following information in advance of the

visit:

- Summary information about the local or regional TB program
- TB program primary point of contact and key personnel
- Annual case reports
- Expenditure reports
- Annual progress reports
- National TB Indicators Project (NTIP) and National TB Program Objectives, and
- Cohort reviews.

Local and regional TB programs must submit any requested information no later than ten business days prior to the visit.

**Entrance meeting**. The team lead will schedule an entrance meeting to introduce onsite review team members to local or regional TB program staff and provide an overview of planned activities. The review team will meet daily to discuss preliminary findings and observations, which may result in revisions to the initial agenda.

**Document and case review.** The onsite review team will utilize a data-informed method of sampling cases for review. Documentation review may include, but is not limited to:



- Policies and procedures
- TB infection control plans
- Targeted testing reports
- TB staff training records
- Confidentiality agreements
- Incident reports
- Visitor logs
- Self-audit tools
- DACTS Audit Tool for State-Designated Case Registrars, and
- Privacy incident reports.

**Direct observation.** Direct observation of day-to-day clinic operations will be conducted as necessary to evaluate implementation of TB prevention and care activities.

**Interviews.** Individual interviews may be conducted with persons knowledgeable about TB program activities to further inform the data collection process.

**Exit interview.** At the end of the visit, the team lead will facilitate an exit interview with local or regional TB program staff to informally discuss:



- Key program strengths noted during the review
- Preliminary findings
- Suggestions on how to enhance compliance with the Texas TB Work Plan
- Challenges or barriers to Texas TB Work Plan implementation as expressed by TB program staff
- Areas in which the local/regional TB program could benefit from technical assistance and/or additional training; and
- Next steps, to include preparation of a corrective actions plan (CAP) when appropriate.

The exit meeting is meant to be an informal discussion. Official findings of the review will be presented in a written report after the visit.

#### **Onsite Review Follow Up**

The written report will acknowledge positive aspects of the local or regional TB program and identify areas in which the program is not in compliance with the Texas TB Work Plan. The report will include recommendations on how to enhance TB program performance and address the need to prepare a CAP, when appropriate. It is the responsibility of local and regional TB programs to formulate a CAP for any areas of noncompliance identified during the onsite review. The CAP will be subject to review by the TB Branch and should also include time-limited activities



that address all areas of concern. The TB Branch will monitor the implementation of CAP activities and provide

ongoing follow up.



#### **Onsite Review Tool**

**Purpose and Scope of an Onsite Review:** The onsite review will be used to evaluate local and regional TB program performance. Criteria within this tool is based upon the Texas TB Work Plan. During a given visit and as appropriate, the onsite review team may engage in activities such as:

- conducting client record and other document reviews;
- observing day-to-day clinic operations; and
- interviewing program staff.

**Goal of an Onsite Review:** The overall goal is to ensure the alignment of the Texas TB Work Plan with local and regional TB program prevention and care activities.

 Designated Point of Contact for Onsite Review: For questions regarding onsite reviews, please contact

 [insert TB Branch Point of Contact}

 Section I: Program Overview

 Local/Regional Health Department: Click or tap here to

 PHR: Click or tap here to enter text.

enter text.	
Date: Click or tap to enter a date.	Last Review: Click or tap to enter a date.
Contact Person: Click or tap here to enter text.	Phone: Click or tap here to enter text.
Title: Click or tap here to enter text.	Email: Click or tap here to enter text.
Date CMS Notified: Click or tap to enter a date.	Date of TB Program Notified: Click or tap to enter a date.



Year	2015	2016	2017	2018	2019	Median
Number of cases	Click or tap here to enter text.					

TB Program Personnel				
Name/Title	% Federal Funds	% State Funds	% Other Funds	Certification/License (e.g., RN, MD)
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.

## Vacant TB Program Positions



Title	# Length of vacancy (years/months)
Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.

Budget Monitoring			
*Did the TB program lapse > 1% of federal funds during the last grant cycle? (Jan 1 – Dec 31)	□ Yes	□ No	If yes, how much? Click or tap here to enter text.
*Did the TB program lapse > 1% of state funds during the last grant cycle? (Sep 1 – Aug 31)	□ Yes	□ No	If yes, how much? Click or tap here to enter text.



Reason for lapses >1%: Click or tap here to enter text.



Section II: TB Work Plan Criteria (FY 20) **Conduct Overall Planning and** Not Α N/A Met Comments **Develop Policies** Met Written policies and procedures are 1 accessible to TB Program staff Policies and procedures have been 2 reviewed and/or revised within the last three years TB program staff sign 3 acknowledgement of local TB program policies and procedures A list of community resources is 4 maintained for client's requiring additional assistance **Implement Infection Control** Not В Met Comments N/A Met **Procedures** A written TB infection control plan and/or policies and procedures 1 include: A designated point of contact/staff for TB infection 1a control



1b	Documentation of an environmental risk assessment		
1c	Procedures for maintaining environmental control equipment		
2	Employee annual TB screening is provided based upon risk for exposure		
3	Posters and signs are used throughout the clinic to remind clients and staff of proper respiratory hygiene		
4	Local exhaust ventilation, high- efficiency particulate air (HEPA) filtration, and/or ultraviolet germicidal irradiation are used to remove/inactivate Mycobacterium tuberculosis (M.tb)		
5	Airflow is controlled to prevent contamination of air in areas adjacent to airborne infection isolation (AII) room		
6	Routine maintenance of environmental control equipment is documented		



7	Training on the use of environmental control equipment is documented				
8	A staff member is designated to conduct N-95 respirator fit testing				
9	Staff who may share the same air space as clients suspected of or diagnosed with infectious TB are N- 95 fit tested upon hire and then every 12 months subsequently				
10	Documentation of employee N-95 respirator fit testing is maintained in accordance with local records retention procedures				
11	Clients with suspected or confirmed infectious TB are separated from other clients during clinic visits				
С	Maintain a Competent Workforce	Met	Not Met	N/A	Comments
1	Staff responsible for the delivery of services have signed acknowledgement of DSHS/local TB standing delegation orders (SDOs)				



2a	40 hours of TB training specific to job duties within 90 days of hire				
2b	Completion of CDC's <i>Self-Study</i> Modules for Tuberculosis				
2c	16 hours of annual continuing education relevant to position				
2d	Completion of TB Branch Orientation after at least 3 months of hire				
2e	Completion of CDC <i>RVCT Self-Study Modules</i> for case registry and surveillance staff within 90 days of hire				
3	TB education and training provided to external stakeholders is reported on the Annual Progress Report (APR)				
D	Confidentiality and Security Standards	Met	Not Met	N/A	Comments
1	Maintains a visitor's log for individuals entering secured areas				
E	Initiate and Maintain Self- Auditing Practices	Met	Not Met	N/A	Comments



1	A checklist is used to ensure the completeness of patient records				
2	SDOs are reviewed and signed annually by the physician responsible for TB services				
F	Conduct Continuing Quality Improvement Activities to Maintain a Robust TB Infrastructure	Met	Not Met	N/A	Comments
1	Conducts quarterly cohort reviews				
G	Court-Ordered Management	Met	Not Met	N/A	Comments
1	Seeks consultation with DSHS or local attorney on cases requiring court-ordered management				
2	Medical record includes a signed Order to Implement and Carry Out Measures for a Client with Tuberculosis (TB 410); additional documentation includes:				



I	Conduct Targeted Testing	Met	Not Met	N/A	Comments
1	Medications are kept in a locked storage cabinet or a controlled- access area				
н	Medication Ordering	Met	Not Met	N/A	Comments
2e	The Commissioner of Health Concurrence letter				
2d	The Health Authority's Affidavit of Medical Evaluation (DSHS form 86749_1)				
2c	A description of non-compliant behaviors				
2b	The degree of infectiousness and the proposed public health threat (e.g., AFB smear count, cavitary disease)				
2a	A description of the client's physical and/or mental status				



J	Monitor Surveillance, Reporting, and Case Management Activities in Correctional and Detention Facilities	Met	Not Met	N/A	Comments
5b	Completes evaluation within 120 days of notification				
5a	Initiates evaluation within 30 days of arrival/notification				
4	Evaluates Class B immigrants and refugees:				
3	Documents targeted testing activities on DSHS Annual Progress Report				
2	Submits targeted testing monthly reports (TB EF12-14427)				
1	Documents targeted testing services on TB-207 (or equivalent)				



1	Submits Monthly Correctional TB reports to TB Branch (TB EF-12-11462)				
2	Submits Positive Reactors/Suspects/Cases Report (TB EF-12-11461)				
3	Submits Correctional Tuberculosis Screening Plans (TB EF-12-11463)				
к	Conduct Surveillance to Identify Unreported Individuals with Suspected or Confirmed TB	Met	Not Met	N/A	Comments
1	A designated staff member performs surveillance and case registry activities at least 85% of the time				
2	At least one person is designated				
	as backup case registry				



L	Reporting	Met	Not Met	N/A	Comments
1	Reports all TB cases (ATS classification 3 and ATS classification 5) to Surveillance Team within 45 days (see RVCT); initial report includes:				
1a	Date reported				
1b	Complete name				
1c	Date of birth				
1d	Race/ethnicity				
1e	Country of origin, if born outside of the U.S.				
1f	Date of entry into U.S.				
1g	Laboratory data required to meet case definition				
1h	Count status and date counted				
1i	Verification of TX residency				
1j	Facility/shelter name (if diagnosed while in facility or shelter)				



1k	Initial drug susceptibility results		
2	Maintains electronic or written log of cases within jurisdiction by county and year, to include name, D.O.B., address, contacts, and RVCT (state case number)		
3	Submits report of contacts within 90 days of initial case report (see TB-340, TB-341 or mass contact spreadsheet); report includes:		
3a	Case/suspect information		
Зb	HIV results		
3c	TST/IGRA results		
3d	CXR results		
3e	Status of evaluation; if not complete, reason indicated		
4	Submits follow-up within 90 days of initial case report for contacts NOT placed on treatment for TB infection (see TB-341)		



5	Submits follow-up within 1 year of initiation for contacts placed on treatment for TB infection (see TB-341)		
6	Submits initial susceptibility report on culture-confirmed cases with 45 days of laboratory notification (see RVCT – Follow Up I)		
7	Submits case completion report on culture confirmed cases within 90 days of treatment stop date (see RVCT – Follow Up II)		
8	Submits RVCT, TB-340/341 for closed TB suspects (ATS class 5) within 90 days of initial report		
9	Processes and manages interjurisdictional referrals (IJNs) to include (if case selected was an IJN transferred out to another jurisdiction):		
9a	Confirmed receipt of medical documentation by receiving health department		
9b	Confirmed completion of treatment		



м	Manage Tuberculosis Cases and Suspects	Met	Not Met	N/A	Comments
1	All the following consents are signed and placed in the client's medical record: TB-409, TB-410, TB 411/TB 411a, L-36				
2	Documentation of collaboration with health care institutions, hospitals, long-term care and correctional facilities to ensure management of clients with suspected/confirmed TB disease upon notification				
3	Discharge planning is documented with inpatient facilities for clients released to outpatient care				
4	A treatment and case management plan are documented within 1 week of diagnosis for persons suspicious for TB disease (see TB-201 or equivalent)				



5	A written agreement details the shared roles of a private physician and TB program regarding client's treatment plan				
6	Expert consultation available when 2 <sup>nd</sup> line medications are ordered				
7	<i>Screening for TB disease and/or infection includes:</i>	Met	Not Met	N/A	Comments
7a	TST or IGRA based upon client's age, BCG status, or other factors				
7b	Medical evaluation/review is documented at a minimum: initially, 8 weeks, 26 weeks, and at closure (per TB 201)				
7c	Client medical and social history documented (see TB 400 A and or TB 202)				
7d	Signs and symptom screening documented (see TB 202)				



7e	Initially, 3 sputa collected at least 8-24 hours apart for AFB testing of smear, culture and PCR when applicable (see DSHS SDOs)		
7f	3 consecutive specimens collected every 2 weeks until AFB smear negative X3 when pulmonary disease suspected or known		
7g	Collection of clinical specimens for AFB testing until culture conversion documented: 3 sputum specimens collected once a month until 2 consecutive specimens were negative at least one month apart		
7h	1 final sputum collected or attempted at end of therapy		
<b>7</b> i	Drug susceptibility testing (DST) results documented		
<b>7</b> j	Initial NAAT performed on one of the first 3 diagnostic sputum specimens for clients with no lab confirmation of a rapid test showing rifampin resistance		



7k	Extended drug susceptibility for isolates with resistance to first line drugs				
8	The client's medical record includes:	Met	Not Met	N/A	Comments
8a	Clear section dividers (including client name and DOB on each page)				
8b	Date and signature for all progress note entries				
8c	Documentation in chronological order				
8d	Blank spaces are drawn through and there is no documentation outside of margins				
8e	Assignment of nurse case manager and other team members is documented (see TB-201 or equivalent)				
8f	Source and date of initial report to the TB program				
9	<i>Initiation of therapy and initial/continuation phase:</i>	Met	Not Met	N/A	Comments



9a	Signed physician's order for treatment of TB (see TB-400B or equivalent); order includes drug required dosage and current weight		
9b	Implementation of treatment was started within 3 days of written medical provider order. If not, new order was received		
9c	RIPE initiated on Class III and V patients within 7 days unless otherwise documented on case management plan (see M, 5 above)		
9d	Prescribed medications are consistent with known DST		
9e	PZA discontinued after 40 doses unless reason documented		
9f	EMB discontinued once Isoniazid susceptibilities known		
9g	Documentation indicating reason for changes in medication regimen (see TB-400B or equivalent)		



9h	Documentation indicating reason(s) for withholding of medication				
9i	Documentation of medical provider's evaluation for clients who fail to respond clinically or remain culture positive after 2 months of treatment				
10	<i>Clinical monitoring of TB disease or TB infection:</i>	Met	Not Met	N/A	Comments
10a	CXR at completion of 2 months of TB treatment regardless of culture results unless initial sputum were negative and initial CXR was normal				
10b	CXR at end of treatment on clients with abnormal CXR's				
11	Medication Toxicity Monitoring:	Met	Not Met	N/A	Comments
11a	<b>Baseline</b> clinical monitoring, medication toxicity, response to treatment, and medication side effects are documented; TB-205 or equivalent				



11b	<b>Monthly</b> clinical monitoring, medication toxicity, response to treatment, and medication side effects are documented; TB-205 or equivalent				
11c	Initial and ongoing client education (see TB-203 or equivalent)				
11d	Visual acuity is documented for clients on EMB and Rifabutin				
11e	Ishihara is documented for clients on EMB and Rifabutin				
12	Laboratory:	Met	Not	N/A	Comments
			Met	N/ A	



12b	Baseline measurements of CBC and testing to include: AST, ALT, total bilirubin, alkaline phosphate, albumin, and creatinine; results documented for clients age 18 and older		
12c	Monthly measurements of CBC and testing to include: AST, ALT, total bilirubin, alkaline phosphate, and creatinine. Testing documented for clients age 18 and older if the baseline results are abnormal and/or in clients with risk factors for hepatotoxicity (see DSHS SDOs)		
12d	Baseline testing for HBV and HCV for clients with risk factors		
12e	Baseline testing for HIV for clients 13 years or older unless previous documentation is available and copy of result in client record		
12f	Testing for diabetes for clients 13 years or older unless previous documentation is available and copy of result in client record		



13	DOT and completion of therapy:	Met	Not Met	N/A	Comments
13a	Documentation of completion of therapy includes length and doses per the minimum required doses per SDO's Table 1				
13b	80% of treatment at end of therapy is completed by DOT				
13c	Documentation of DOT log (TB- 206) or equivalent; entries are complete; including adherence to treatment, response to treatment, medication side effects, or adverse reactions				
13d	Treatment completed within 12 months for cases closed as "completion of adequate therapy" (exceptions: MDR/XDR TB, rifampin resistance, meningeal disease, < 15 years of age with miliary disease)				
13e	Supporting documentation if DOT is not provided				



13f	Cases closed as lost to follow-up include documentation of 3 attempts to contact client and method of contact				
13g	Client's medical record includes reason for case closure (see TB- 400B or equivalent)				
14	For drug resistant clients or on second-line medications:	Met	Not Met	N/A	Comments
14a	Submits TB-400 to TB Branch for drug resistant cases within 5 days of notification and every 90 days until completion of treatment				
14b	Submits changes in case management, drug resistance patterns, or residence on any DRTB case to the TB Branch within 72 hours of notifications				
14c	Expert consultation letter/email regarding second-line medications for clients diagnosed with drug-resistant TB				



14d	*Expert consultation letter/email AND provider justification regarding second-line medication for clients <b>NOT</b> diagnosed with drug-resistant TB				
14e	Documentation of assessments according to Expert Consult recommendation i.e. EKG's, labs, etc.				
14f	RIPE treatment was placed on hold when diagnostic tests indicated resistance; if not, documentation for continuation of RIPE is documented				
N	Conduct and Manage a TB Contact Investigation (CI)	Met	Not Met	N/A	Comments
1	Initial interview of client conducted within 3 days of initial report to TB program				
2	Visit to primary residence with 3 days of initial report to TB program				



3	Interview is conducted in primary language of client; interpreter is used when necessary (see CI worksheet)		
4	AFB smear positive cases with cavitary disease have a 2 <sup>nd</sup> interview within 7 days of initial interview		
5	Documentation of estimated infectious period		
6	A minimum of 3 contacts are elicited for sputum AFB smear positive cases		
7	Contacts are assessed for risk exposure; assessment includes (see TB-340/341 or equivalent):		
7a	Exposure setting		
7b	Exposure length (hours/week)		
7c	Break in contact		
8	Prioritization of contacts into high, medium, and low categories		



9	Initiates screening for high priority contacts within 7 days		
10	IGRA is used as the preferred method of TB screening for contacts 2 years of age or older		
11	TST is used if contact is unable to receive IGRA or refused phlebotomy		
12	First round screening is initiated within 4 weeks of contact identification		
13	Second round screening is initiated 8 – 10 weeks from break in contact		
14	Second round screening includes contacts with negative TST/IGRA results during first round screening		
15	For cases with relapse of TB disease, prior contacts with negative results are rescreened in addition to new contacts		
16	Subsequent interviews are conducted as needed (e.g. suspected drug resistance, cluster involvement)		



17	Subsequent interviews are conducted using different interviewers				
18	TB Incident report (TB EF12- 12104) is submitted for mass/concerning CI (e.g., $\geq$ 50 contacts in a single exposure setting)				
19	CIs in congregate settings include:	Met	Not Met	N/A	Comments
19a	List of facility contacts and evaluation results				
19b	List of community contacts and locating information				
20	<i>CI expansion and supporting documentation provided based upon factors such as:</i>	Met	Not Met	N/A	Comments
20a	Rate of infection among contacts				
20b	Positive screening results in children less than 5 years of age				
20c	Conversion from negative to positive between first and 2 <sup>nd</sup> round screening				



20d	Contacts diagnosed with TB disease				
ο	Manage Contacts to Confirmed or Suspected TB Cases	Met	Not Met	N/A	Comments
1	High priority contacts receive a full medical evaluation (including CXR for children under 5 years)				
2	Contacts with a documented history of TB infection receive a full evaluation				
3	Asymptomatic contacts with CXRs not suggestive of TB disease are offered treatment for TB infection				
4	Contacts receive initial and ongoing education (see TB-203 or equivalent)				
5	A DSHS-recognized expert TB consultant provides treatment recommendations for contacts to MDR/XDR TB cases				
6	Window prophylaxis is provided to high risk contacts (e.g., children <5 years of age, HIV-positive)				



7	Contacts on short term regimens (3HP) receive 12 DOT-administered doses of medication within 16 weeks of treatment initiation				
8	Treatment stop date and reason for discontinuation is documented on TB-400 A (or equivalent)				
9	For high risk contacts:	Met	Not Met	N/A	Comments
9a	Repeat CXR is obtained if treatment for TB infection is not started within 1 month of initial CXR				
9b	Prior to the re-initiation of treatment, a repeat CXR is obtain if treatment is disrupted for more than 1 month during the during the first 2 months				
10	For all other contacts (non-high risk):	Met	Not Met	N/A	Comments
10a	Repeat CXR is obtained if treatment for TB infection is not started within 3 months of initial CXR				
10b	Prior to the re-initiation of treatment, a repeat CXR is obtained if treatment is disrupted for more than 3 months				