

Texas Tuberculosis Manual Fiscal Year 2026



Tuberculosis and Hansen's Disease Unit

Created: September 12, 2012 Revised: August 31, 2025



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I. Introduction

The Texas Tuberculosis (TB) Manual sets forth procedures established by the Texas Department of State Health Services (DSHS) Tuberculosis and Hansen's Disease Unit (TB Unit) to ensure all TB programs receiving state funding or in-kind support from DSHS public health regions (PHRs) achieve TB performance standards. The TB Manual:

- serves as a prescriptive document to design and maintain a TB program;
- outlines the expectations and responsibilities of all funded TB programs;
- assures consistent TB prevention and care practices are applied throughout Texas; and
- provides a blueprint to assess performance outcomes based on quality indicators.

Providing TB Services to Eligible Patients Regardless of Ability to Pay

Funded TB programs in regional and local health departments (R/LHDs, also referred to as TB programs) shall determine eligibility for TB services and provide services without consideration of a patient's ability to pay. To determine eligibility, refer to *Table 1: Prioritizing Evaluation for TB Services*. Patients in column A should not be charged for services. Funded programs may choose to charge patients in column B, as determined locally. Local health department (LHD) TB programs may utilize third party billing regardless of a patient's priority; however, patients in column A should not be charged a balance or copays that insurance does not cover.

LHD TB programs requesting reimbursement for TB services may also consider enrolling as a TB Medicaid Provider. To enroll, the LHD completes the <u>DSHS Medicaid Provider Application</u> and submits to the TB Unit for review and approval. Once approved, the TB Unit prepares an approval letter which the submitter must include in their submission to Texas Medicaid & Healthcare Partnership (TMHP) to begin the official Medicaid application process and renewals.

Funded TB programs shall provide TB services to the following programeligible patients:

- A. People with suspected or confirmed TB disease caused by *Mycobacterium* tuberculosis (M. tb) complex to include M. tb and M. bovis. Refer to <u>DSHS Epi</u> Case Criteria and Case Definitions for Public Health Surveillance.
 - Mycobacterium bovis-Bacille Calmette-Guerin (M. bovis-BCG) is not reportable to the Centers for Disease Control and Prevention (CDC). BCG, an attenuated strain of M. bovis, is widely used as an adjunctive therapy for superficial bladder cancer. Intravesical administration of BCG has been associated with systemic infection. Disseminated infection due to M. bovis is otherwise uncommon. The decision to use state funded resources (i.e., medications and personnel) to treat M. bovis-BCG should only be considered after consultation with a DSHS-recognized TB medical

consultant or regional medical director (RMD).

- B. Contacts to a person with suspected or confirmed TB disease.
- C. Immigrants, including those referred to TB programs from the Electronic Disease Notification (EDN) System (See Chapter XI. Manage Electronic Disease Notification System and Other Foreign-Born Referrals).
- D. People at risk for developing TB disease (refer to *Table 1: Prioritizing Evaluation for TB Services* and *Chapter XII. Conduct Targeted Testing* for more information).

All funded TB programs must provide core TB program services outlined in this TB Manual for program eligible patients, unless otherwise informed¹ by the TB Unit.

Funded TB programs shall NOT provide services to the following ineligible patients:

- A. Patients who are reported to the R/LHD because of a non-tubercular mycobacteria (NTM) but who are not suspected of having TB disease.
- B. Patients who are closed as non-TB and identified as having *Mycobacterium avium* complex (MAC) or other nontuberculous mycobacteria (NTM) may not be treated using state-purchased medications longer than 30 days. Refer to <u>TB-409 (Acknowledgement of Understanding)</u>.
- C. Patients with no risk factors for latent TB infection or progression to TB disease seeking TB screening with a tuberculin skin test (TST) or Interferon Gamma Release Assay (IGRA) for administrative purposes (i.e., employment).

¹ The TB Unit will notify funded R/LHD TB programs if core TB services may be impacted due to natural disasters, funding changes, or otherwise unexpected occurrences.

Table 1: Prioritizing Evaluation for TB Services

	Α	В	С
	Program-Eligible Patients Who Should be Evaluated Routinely	Program-Eligible Patients Who Should Be Evaluated As Resources Allow	Non-Eligible Patients
•	Anyone in whom there is known, or a suspicion of, TB disease. Contacts to a person with known or suspected TB disease. High-risk immigrants*: Who have a class A, B1, children under age 5 years with B2, or B3 TB classification reported from EDN; or are status adjusters and have been referred for further TB screening/evaluation by a civil surgeon (e.g., sputum specimen collection); or who have entered the United States through a government-sponsored program and require a domestic TB screening. Children aged 4 and younger with a positive TB screening test. Children aged 5 and older with TB risk factors identified on the Tuberculosis Questionnaire for Children and who have a positive TB screening test, when treatment for TB		_
	infection is requested of the R/LHD.	resources for medical care** outside the TB program.	

^{*}Refer to Chapter XI. Manage Electronic Disease Notification System and Other Foreign-Born Referrals.

^{**}Resources for medical care may include Medicare providers, Texas Health Steps providers, community sliding scale clinics, and <u>Federally Qualified Health Centers (FQHCs)</u> who may be able to provide TB screening and treatment for TB infection. The R/LHD may choose to evaluate and treat patients if it is determined that these entities are unable to adequately address the patient's TB needs.

[†]Refer to Chapter XII. Conduct Targeted Testing.

TB Unit Responsibilities

The TB Unit, also referred to as central office, administers TB program services by allocating funds to R/LHDs to perform TB prevention and care activities statewide. The TB Unit establishes core elements to design a funded TB program, prepares and maintains standards of care, and develops methods to deliver appropriate services. The TB Unit provides laboratory support, medications, testing supplies, courier transport, epidemiological, nursing, and medical consultation services to funded TB programs to enhance service delivery capacity. For a comprehensive list of services provided to R/LHD TB programs, see *TB Resources*.

The vision of the TB Unit is a Texas free of TB and the mission is to eliminate TB as a public health threat.

The TB Unit performing programmatic activities will:

- A. distribute funds to R/LHDs to maximize the delivery of authorized services to eligible patients;
- B. monitor LHD budget expenditures on a quarterly basis. If annual expenditures are consistently below projected amounts, the budget may be decreased;
- C. provide expert nursing consultation;
- D. oversee binational TB program activities;
- E. develop standards for TB prevention and care in Texas;
- F. collaborate with DSHS Pharmacy to ensure availability of medications and supplies to treat TB disease and infection;
- G. provide Texas-specific TB training directly or in collaboration with Heartland National TB Center (HNTC) and other partners;
- H. oversee molecular epidemiology practices and provide technical assistance to investigate transmission patterns, cluster alerts, and outbreaks;
- I. prepare TB epidemiologic reports;
- J. prepare and report aggregate TB data to CDC;
- K. oversee TB prevention and care in high-risk populations, including correctional facilities, community corrections, homeless shelters, and other congregate settings;
- L. develop and revise standards and regulations;
- M. serve as a liaison with CDC, other federal and state partners; and

N. serve as point of contact for international activities involving TB prevention and care.

The TB Unit performing surveillance and reporting activities will:

- A. promote active surveillance activities among TB programs receiving state funding;
- B. collect and analyze reporting data entered into the National Electronic Disease Surveillance System (NEDSS);
- C. serve as repository for TB data reported to DSHS;
- D. collect and analyze reports from TB programs to satisfy TB grant requirements;
- E. facilitate interjurisdictional patient transfers;
- F. promote security and confidentiality standards for TB data exchanges;
- G. provide technical assistance to funded TB programs for accurate submission of TB data to the TB Unit; and
- H. serve as a liaison to CDC's Division for TB Elimination (DTBE) surveillance team.

The TB Unit performing quality improvement and evaluation activities will:

- A. Assess and monitor TB programs' compliance with essential components and standards outlined in the Texas TB Manual;
- B. evaluate program performance and progress toward objectives to determine effectiveness in essential TB prevention and care standards;
- C. oversee targeted testing initiatives;
- D. develop and oversee cohort review activities;
- E. oversee correctional TB screening, reporting, and monitoring activities;
- F. conduct desktop and onsite review activities and schedule on-site visits to funded TB programs; and
- G. monitor distribution of state-purchased supplies to R/LHDs and Chapter 89designated facilities.

DSHS TB Unit, PHRs, and LHDs must comply with the following regarding TB prevention and care activities:

- A. Texas References:
 - 1. DSHS, Standing Delegation Orders and Standing Medical Orders for



- Tuberculosis Prevention and Control, dshs.texas.gov/disease/tb/programs.shtm#sdo
- 2. DSHS, *Texas Tuberculosis Manual*, <u>dshs.texas.gov/tuberculosis-tb/tb-funded-programs</u>.
- 3. DSHS, TB Unit Standards, <u>dshs.texas.gov/tuberculosis-tb/tb-funded-programs</u>
- 4. DSHS, *TB Standards for Texas Correctional and Detention Facilities*, dshs.texas.gov/sites/default/files/IDCU/disease/tb/policies/TBCorrectionalStandards.pdf.
- DSHS, Video-Based Directly Observed Therapy, Required and Recommended Activities, dshs.texas.gov/sites/default/files/IDCU/disease/tb/policies/TBVDOTPolicy.pdf.
- 6. DSHS, *Binational TB Program Manual*, <u>dshs.texas.gov/tuberculosis-tb/tb-funded-programs/texas-dshs-tb-program/binational-tb-program-manual</u>.
- 7. DSHS, *Epi Case Criteria for TB*, dshs.texas.gov/sites/default/files/IDCU/disease/tb/policies/EpiCaseCriteriaforTB.pdf.
- B. CDC's Morbidity and Mortality Weekly Report (MMWR), American Thoracic Society, and Other State and Peer-Reviewed References:
 - Updates on the Treatment of Drug-Susceptible and Drug-Resistant Tuberculosis: An Official ATS/CDC/ERS/IDSA Clinical Practice Guideline. Am J Respir Crit Care Med. 2025 Jan 1;211(1):15–33. pmc.ncbi.nlm.nih.gov/articles/PMC11755361/pdf/rccm.202410-2096ST.pdf
 - 2. Official American Thoracic Society/Centers for Disease Control and Prevention/Infectious Diseases Society of America Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis, Clinical Infectious Diseases, 2016. 63 (7): e147-e195. cdc.gov/tb/publications/guidelines/pdf/clin-infect-dis.-2016-nahid-cid_ciw376.pdf.
 - 3. Official American Thoracic Society/Infectious Diseases Society of America/Centers for Disease Control and Prevention Clinical Practice Guidelines: Diagnosis of Tuberculosis in Adults and Children, 2016. idsociety.org/practice-guideline/diagnosis-of-tb-in-adults-and-children/.
 - 4. Update of Recommendations for Use of Once-Weekly Isoniazid-Rifapentine Regimen to Treat Latent Mycobacterium tuberculosis Infection, 2018. cdc.gov/mmwr/volumes/67/wr/mm6725a5.htm.
 - 5. American Journal of Respiratory and Critical Care Medicine, *Diagnostic Standards and Classification of Tuberculosis in Adults and Children*, Vol. 161, 1376-1395, 1999. atsjournals.org/doi/epdf/10.1164/ajrccm.161.4.16141?role=tab
 - 6. CDC, Aggregate Reports for Tuberculosis Program Evaluation: Training Manual and User Guide, 2005. stacks.cdc.gov/view/cdc/11753.
 - 7. CDC, Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis, MMWR, Vol. 54 (RR15), 1-43, 2005.



cdc.gov/mmwr/indrr 2005.html.

- 8. CDC, *IGRA Blood Test Fact Sheet*, 2016. cdc.gov/tb/hcp/testing-diagnosis/interferon-gamma-release-assay.html.
- 9. CDC, 2020 Report of Verified Case of Tuberculosis (RVCT) Instruction Manual, August 2021. cdc.gov/tb/programs/rvct/instructionmanual.pdf
- 10.CDC, CDC's Program Evaluation Journey, June 2018.
- 11.CDC, Targeted Tuberculin Testing and Treatment of Latent TB Infection (LTBI), MMWR, Vol. 49 (RR6), 1-43, 2000. cdc.gov/mmwr/PDF/rr/rr4906.pdf.
- 12.CDC, *Tuberculin Skin Testing (TST) Fact Sheet*, 2016. cdc.gov/tb/hcp/testing-diagnosis/tuberculin-skin-test.html.
- 13.Curry International Tuberculosis Center, *Drug-Resistant Tuberculosis: A Survival Guide for Clinicians*, Third edition.

 <u>currytbcenter.ucsf.edu/products/view/drug-resistant-tuberculosis-survival-guide-clinicians-3rd-edition</u>.
- C. Federal and state regulations and statutes (including but not limited to):
 - 1. Texas Tuberculosis Code, Texas Health and Safety Code, Chapter 13, including Sec. 13.006 and Subchapter B: statutes.capitol.texas.gov/Docs/HS/htm/HS.13.htm.
 - 2. Texas Tuberculosis Code, Texas Health and Safety Code, Chapter 31: statutes.capitol.texas.gov/Docs/HS/htm/HS.31.htm
 - 3. Communicable Disease Prevention and Control Act, Texas Health and Safety Code, Chapter 81 including Sec. 81.050 and Sec. 81.092: statutes.capitol.texas.gov/Docs/HS/htm/HS.81.htm.
 - 4. Screening and Treatment for Tuberculosis in Jails and Other Correctional Facilities, Texas Health and Safety Code, Chapter 89. statutes.capitol.texas.gov/Docs/HS/htm/HS.89.htm.
 - 5. Control of Communicable Diseases, Texas Administrative Code (TAC), Title 25, Part 1, Chapter 97, Subchapter A. sos.texas.gov/tac/index.shtml.
 - Tuberculosis Screening for Jails and Other Correctional Facilities, TAC, Title 25, Part 1, Chapter 97, Subchapter H. sos.texas.gov/tac/index.shtml.
 - 7. Task Force of Border Health Officials, Texas Health and Safety Code, Chapter 120, Sec. 120.051: statutes.capitol.texas.gov/Docs/HS/htm/HS.120.htm#120.051.
 - 8. Medical Records, TAC, Title 22, Part 9, Chapter 165, Rule §165.1. sos.texas.gov/tac/index.shtml.
 - 9. <u>340B Drug Pricing Program</u>. Health Resources & Services Administration, June 2024.

II. Program Stewardship and Accountability

General Requirement

TB programs will implement a comprehensive TB program and manage resources in an effective manner that focuses on stewardship and accountability. Accounts for TB services (e.g., Quest account numbers, medication ordering accounts, therapeutic drug monitoring requisitions containing TB Unit billing information, etc.) cannot be shared with entities outside the R/LHD.

Funded R/LHD TB programs will:

- A. implement a comprehensive TB prevention and care program, monitor budget expenditures, maintain accurate, and concise records;
- B. develop and maintain TB protocols;
- C. provide services to evaluate, treat, and monitor patients with suspected or confirmed TB disease without consideration of a patient's ability to pay;
- D. initiate public health follow up through TB contact investigations (CIs);
- E. provide services to evaluate, treat, and monitor contacts to suspected or confirmed cases of pulmonary, pleural, or laryngeal TB disease without consideration of a patient's ability to pay;
- F. initiate court-ordered management when needed;
- G. provide treatment services for at-risk people diagnosed with TB infection without consideration of a patient's ability to pay;
- H. provide services to evaluate, treat, and monitor class A and B immigrants and refugees without consideration of a patient's ability to pay;
- develop and maintain TB surveillance mechanisms for early identification and reporting;
- J. serve as the point of contact for hospitals, private laboratories, correctional, and detention facilities identified as meeting Chapter 89 requirements of the Texas Health and Safety Code, and other reporting entities within jurisdiction;
- K. submit requested data to the TB Unit in adherence to reporting schedules;



- L. request access to the TB Unit's TB surveillance and reporting database by following instructions on the TB Unit's NEDSS website. Refer to <u>dshs.texas.gov/tuberculosis-tb/training/nedss</u>. Take TB training courses as outlined by the TB Unit and submit helpdesk tickets for issues;
- M. identify at least one designated and one back-up person at each TB program responsible for entering data into NEDSS;
- N. verify American Thoracic Society (ATS) classifications based on current <u>DSHS</u> <u>Epi Case Criteria and Case Definitions for Public Health Surveillance</u> for suspected and confirmed cases of TB and latent TB infection before data entry;
- O. submit notifications and updates for confirmed cases to the TB Surveillance Team according to set schedules;
- P. serve as the point of contact for intra/interjurisdictional patient transfers, ensuring the Interjurisdictional Notification (IJN) form is used and that NEDSS records are transferred in state between referring and receiving jurisdictions;
- Q. enter CI data into NEDSS as listed on either the TB-342 (Report of a Tuberculosis (TB) Exposure in a Correctional Setting, Part A: Index Case Information) and TB-343 (Report of a Tuberculosis (TB) Exposure in a Correctional Setting, Part B: Contact Information) for any contact investigations where the source/index case is residing in a correctional facility or TB-340 (Report of People Exposed to TB) and TB-341 (Continuation Report of People Exposed to TB) for all other contact investigations for evaluation of contacts and verify ATS classification for the TB Unit to prepare and report contact aggregate data to CDC;
- R. complete items in assigned workflows in NEDSS or task those items to other staff within reporting jurisdiction;
- S. review TB epidemiologic reports provided by DSHS and provide feedback;
- T. participate in monthly TB conference calls, work groups, surveys, and other meetings;
- U. perform targeted testing based on epidemiologic assessments;
- v. serve as local subject matter experts on screening recommendations for community partners including, but not limited to, licensed adult and childcare facilities;
- W. apply appropriate administrative, environmental, and respiratory controls to prevent exposure to and transmission of TB;



- X. provide professional education, training, and orientation for new TB program staff and maintain continuing education for current TB program staff;
- Y. host and coordinate staff trainings based on RVCT and quality assurance (QA), the IJN process, and surveillance reporting;
- Z. monitor surveillance, reporting, and case management activities in correctional facilities;
- AA.update local protocols to guide QA activities, perform continuous quality improvement activities to achieve Texas performance measures, and perform self-auditing activities to assess clinical care services and reporting practices;
- BB.submit designated reports using established deadlines, schedules, and DSHS-approved mechanisms; and
- CC.promote security and confidentiality standards for TB data exchanges and storage. Refer to *Chapter XXIII. Confidentiality and Security Standards*.

III. Conduct Overall Planning and Develop Protocols to Maintain Scope of Tuberculosis Services

General Requirement

TB programs will develop and maintain protocols that align with the TB Manual and TB Unit standards. The scope of services for funded TB programs is shown in *Figure 1: Scope of TB Services.*

TB Unit standards, forms, recommendations, and procedures are published on DSHS' TB website, <u>texastb.org</u>. R/LHD protocols must not contradict TB Unit requirements and guidelines.

Activities

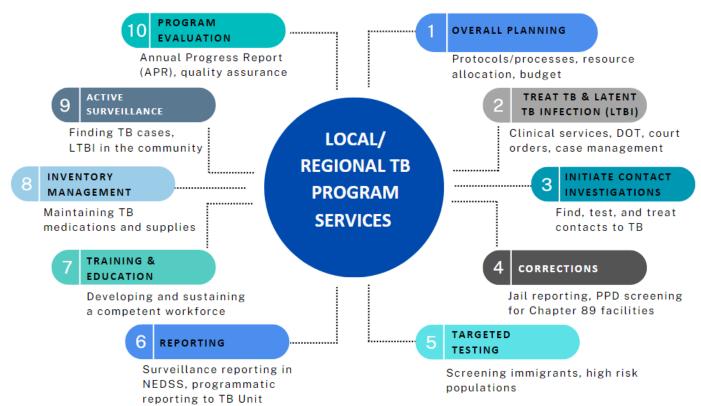
- A. Develop and implement written protocols that outline how the following are operationalized within R/LHD TB programs:
 - 1. Program administration
 - 2. Training
 - 3. Reporting
 - 4. Surveillance
 - Infection control
 - 6. High risk population screening and evaluation
 - 7. Discharge planning and continuity of care
 - 8. Cohort review
 - 9. Program evaluation
 - 10. Laboratory testing for TB
 - 11. Case management
 - 12. Maintaining medical records for TB patients
 - 13. Medication usage and stewardship
 - 14. Contact investigation
 - 15. Patient confidentiality and security
 - 16. Incident reporting
 - 17. Cluster and outbreak investigations
 - 18. False positive investigations
 - 19. Directly observed therapy (DOT), including when used, the use of video enabled technology for DOT
 - 20. Sputum collection procedures
 - 21. Emergency planning that would impact TB services (i.e., natural disasters that could disrupt DOT)
- B. Ensure written protocols are easily accessible to all staff responsible for TB prevention and care activities.
- C. Review protocols at least once every three years and revise as appropriate to



conform to DSHS standards and best practices.

- D. Develop a plan for continuation of TB services when staff changes occur.
 - 1. Each funded TB program must have a licensed healthcare provider (LHP) available for patient care. When the TB program's LHP is absent (due to temporary or permanent leave), the program must ensure a designated LHP is identified. Engaging the authorizing physician and/or local health authority (LHA) may be needed.
 - 2. Each funded TB program must have nursing services for patient care. When a TB nurse is absent (due to temporary or permanent leave), the program must ensure a designated nurse is available to assume nursing care and case management of patients.
 - a) The nurse must have the ability to provide direct care services as per the DSHS SDOs and/or work with the LHP or authorizing physician for patient-specific orders.
 - b) R/LHDs with one TB nurse must have a plan for continuation of nursing services. This may include cross-training other R/LHD nurses, ensuring staff are fit-tested with TB respirators, using a locally developed training manual for continuity, engaging the PHR and the TB Unit to supplement training if needed, and/or contracting nursing services until a full-time nurse can be hired.

Figure 1: Scope of TB Services



Source: Texas Department of State Health Services, TB Unit, 2024

IV. Standards of Care for Tuberculosis Services

General Requirement

Tuberculosis programs will follow the minimum standards of care for patients receiving TB prevention and care services in Texas. The minimum standards, in accordance with the DSHS Texas TB Manual and TB Unit <u>Standing Delegation</u> <u>Orders</u> (SDOs), are intended for authorized TB program staff working in R/LHDs. Each TB program will have systems in place to ensure activities in this chapter are met.

Activities

- A. Adopt standards of care as outlined in the TB Unit's SDOs.
 - 1. The TB Unit is responsible for developing and updating SDOs that are consistent with national guidelines and recommendations from DSHS-recognized TB medical consultants.
 - a) TB programs may choose to adopt the DSHS SDOs or develop their own.
 - b) If TB programs develop local SDOs, they must meet the minimum standards outlined in the DSHS SDOs.
 - c) TB programs may add their name and logo to the DSHS SDOs. They may also elect to use the DSHS SDOs to develop local protocols.
 - 2. Orders cannot be removed from the DSHS SDOs, but the authorizing physician may elect to add additional orders or modify the format.
 - 3. TB program staff authorized to carry out SDOs must sign attestation pages from the SDOs.
 - a) DSHS SDOs are revised yearly. The TB program manager and program staff should review SDOs after each release. This may occur via a one-day in-service training to ensure a thorough understanding of the SDOs. In-service trainings are an ideal time to collect staff signatures.
 - b) Attestation pages must be kept at the R/LHD and made available upon request by the TB Unit.
 - c) SDOs must be reviewed and signed by the authorizing physician responsible for TB services (e.g., contracted TB physician, RMD, LHA) at least yearly or when changes occur.
- B. Provide patient-centered care.
 - Provide culturally competent education and care and consider preferred language, age and literacy level when discussing TB pathology, transmission, treatment options and plan of care. DSHS programs may use language and translation services on the DSHS intranet. Refer to <u>online.dshs.texas.gov/services/translation-interpretation</u>. LHDs must have translation services available.
 - 2. Assess and identify variables that may impact patient's adherence to

- therapy. Consider court-ordered therapy as a last, not initial, resort to adherence to the treatment plan.
- 3. Identify barriers to care and develop strategies to meet individual patient needs. This may include a plan for incentives and enablers and coordination of ancillary and support services. Examples of incentives and enablers can be found here:

 health.state.mn.us/diseases/tb/lph/incentives.html#:~:text=What%2
 - health.state.mn.us/diseases/tb/lph/incentives.html#:~:text=What%20are%20they%3F,to%20be%20elaborate%20or%20expensive.
- 4. Develop a DOT patient-centered plan. Consider limitations to travel and support the patient in DOT, using their preferred location and time where possible. Video-enabled DOT (VDOT) should be considered for eligible patients where possible. Refer to <u>DSHS Video-Enabled Directly</u> <u>Observed Therapy Required and Recommended Activities</u> when using VDOT for eligible patients.
- 5. Telemedicine may be considered for medical case management of patients evaluated by the TB program, as determined by the LHP. If telemedicine is utilized, ensure the standards of care for TB are maintained. R/LHDs should develop written processes for how telemedicine is addressed based on local regulations and guidelines and following the Texas Occupations Code, Title 3, Chapter 111.
- C. Prioritize referrals and screen for TB disease and latent TB infection.
 - 1. Any program-eligible patient referred or seeking evaluation for TB at a funded TB program should be prioritized for services (refer to *Table 1: Prioritizing Evaluation for TB Services*).
 - a) Patients with known or suspected TB disease must be prioritized for evaluation within three business days of the report.
 - 2. Every patient who qualifies for services should be screened using an IGRA as the preferred TB screening test.
 - a) The TB Unit provides IGRAs at no cost to TB programs. IGRAs should only be used among populations described in this document.
 - 3. TSTs may be used for patients who qualify for services and who refuse or cannot tolerate phlebotomy.
 - a) Tubersol is the TB Unit's recommended purified protein derivative (PPD) for TST placement. It is available at the DSHS Pharmacy Unit.
 - 4. TSTs and IGRAs should not be used interchangeably for confirmatory testing purposes, as only persons at risk for TB are eligible for program services. Refer to the DSHS SDOs for reasons a confirmatory test may be considered on a case-by-case basis.
- D. Ensure the availability of radiology services.
 - 1. Every TB program must have radiology services available, whether inhouse or through a contract or local partnership.
- E. Implement location-appropriate isolation (home based or negative pressure

air-borne infection isolation room [AIIR] if in-patient or in a congregate setting).

- 1. A nurse may place a patient in isolation by issuing the patient a TB control order signed by the LHA.
- 2. Patients released from isolation will have the date of release documented in the medical record. A nurse may release a patient from isolation after written instructions by the LHP are issued and once criteria for release from isolation are met. The LHP may determine if the SDOs suffice for written instruction or if they prefer reviewing all requests before release from isolation.
- F. Ensure completion of specimen testing. TB programs should do the following:
 - 1. Submit specimen collected from eligible patients to the DSHS laboratories in Austin or South Texas. For fee schedules, resupply forms, submission criteria, and to request account access, refer to dshs.texas.gov/laboratory-services/laboratory-testing-services-manual-forms-laboratory-fee-schedule.
 - 2. Obtain natural and induced sputum specimens when indicated.
 - 3. TB programs that do not have sputum induction booths may purchase portable nebulizers using locally budgeted TB funds. Hypertonic solution for nebulization is available through the DSHS Pharmacy if 0.9% sodium chloride does not yield an adequate sample (refer to Appendix I: DSHS TB Formulary).
 - 4. Ensure all specimens positive for *M. tb* by Nucleic Acid Amplification Test (NAAT) or polymerase chain reaction (PCR) are followed by culture and drug susceptibility testing. Ship at least one isolate, preferably the initial isolate, to the DSHS Laboratory for genotyping.
 - 5. Ensure all specimen submitted for drug-susceptibility tests (DSTs) are tested for first-line TB drugs (rifampin, isoniazid, pyrazinamide, and ethambutol) as well as fluroquinolones (most commonly with ofloxacin) if resources allow. This testing is available from the DSHS laboratory in Austin.
 - 6. Utilize the TB Unit's <u>TB Specimen Shipping Guide</u> for timely specimen submission.
- G. Initiate clinical evaluations and start treatment promptly, when indicated.
 - 1. Every person with an ATS classification of 3 or 5 in whom treatment is recommended should begin therapy within one week of identification (if outpatient).
 - 2. Every person with an ATS classification of 2 in whom treatment for latent TB infection is recommended should begin therapy within one month of identification.
 - a) Refer to DSHS SDOs if treatment begins after one month, as repeat diagnostics (i.e., radiology) may be indicated.
 - 3. High risk contacts for whom window prophylaxis is recommended should begin therapy as soon as possible, but no later than within 14 days of identification.

- a) Window prophylaxis is designed to prevent a vulnerable contact from developing TB disease during a "window period" after TB exposure and before confirmatory testing. Therefore, a physical exam, radiology, and treatment must be prompt. Refer to Chapter VIII. Manage Contacts to Confirmed or Suspected TB Cases for more details.
- H. Ensure routine patient assessments are performed by authorized licensed personnel.
 - 1. Every patient on a medication regimen for TB disease or infection will have at minimum, a baseline and monthly nursing or LHP assessment with a physical exam and toxicity screening documented in the medical record.
 - 2. Toxicity screening must be performed according to drug regimen.
 - 3. TB programs should ensure the LHP has reviewed and signed the medical record for patients with an ATS classification of 3 or those who are ATS class 5 on treatment for TB disease, at the following intervals, at minimum:
 - a) upon treatment initiation;
 - b) at eight weeks of therapy or upon completion of the initial phase (if greater than 8 weeks);
 - c) during the continuation phase, monthly, or any time the patient status changes requiring medical interventions;
 - d) any time medications are held due to signs or symptoms of toxicity or other reasons;
 - e) at closure; and
 - f) as determined by the LHP when orders are updated or need to be revised.
 - 4. For patients with an ATS classification of 2 who are receiving treatment for TB infection, there must be documentation of communication between a licensed nurse and patient at least monthly. Additional documentation must include:
 - a) review of the medical record by the LHP upon treatment initiation, at closure, and anytime during the course of care as needed and as reported by the licensed nurse;
 - b) a physical exam and/or toxicity screening as per the DSHS SDOs; and
 - c) medication refill information, including drug name, dosage, lot number, and expiration date, provided to the patient or designee.

I. Provide DOT.

- 1. Every patient with an ATS classification of 3 or 5 will be placed on DOT for the duration of treatment.
 - a) Daily therapy is recommended (either 5x/week or 7x/week). Refer to DSHS SDOs for dosing options.
 - b) DOT must be initiated as soon as possible, but no longer than



- one week of outpatient treatment initiation.
- c) VDOT may be used by TB programs when patients are recommended for DOT. Refer to <u>Recommendations for Use of Video Directly Observed Therapy During Tuberculosis Treatment</u>
 <u>United States, 2023 | MMWR.</u>
- 2. Patients on isoniazid and rifapentine (3HP) may be treated by self-administration therapy (SAT) with a physician's order.
- 3. DOT for TB infection is highly recommended for patients aged four and younger, as resources allow.
- 4. DOT packets should be ordered through the DSHS pharmacy medication ordering system.
- 5. If self-administration is needed temporarily to accommodate holidays, travel, or a patient moving out of Texas, programs may provide up to one month's worth of DOT packets. Any more than that should be preapproved by the TB Unit. NOTE: the LHP may determine how many doses of self-administration will "count" towards completion of adequate therapy; however, DOT must be provided for at least 80% of the total treatment. Refer to *L. Ensure the completion of adequate therapy*, below.
- J. Manage pediatric patients aged 17 and younger.
 - 1. The initial evaluation for TB disease or TB infection in patients aged five and younger will include a physical examination by a physician or other licensed clinician.
 - 2. If parents or guardians of patients aged 17 and younger decline treatment for TB infection, including window prophylaxis, LHP will provide a letter advising treatment.
 - a) A copy of the letter will be maintained in the patient's medical record.
 - b) The LHP may consider additional steps such as a Child Protective Services (CPS) notification. Refer to *Appendix B:* Sample Letter for Child Window Prophylaxis for a sample correspondence.
- K. Seek expert consultation when indicated.
 - Treatment for TB disease may become complicated in the presence of drug-resistance, if the patient is aged 17 years and younger, with coinfection with HIV, or the presence of other medical issues. In these or other circumstances where expert recommendations are needed, seek consultation through <u>DSHS-recognized TB medical consultants</u> or DSHS RMDs. The DSHS RMDs may provide consultation for their regions.
 - 2. A list of required and recommended reasons for consultation is listed in the SDOs.
 - When a consultation is required, the consultation and results (recommendations) must be kept in the medical record and uploaded into NEDSS when requested by the TB Unit.

- L. Ensure completion of adequate therapy.
 - 1. Ideally, every patient with TB disease will complete therapy as specified in the SDOs with 100% of doses taken by DOT.
 - 2. When closure at 100% DOT is not possible, patients should have at least 80% of treatment for TB disease completed by DOT. LHPs should ensure the patient has responded to therapy and has received adequate therapy prior to closure.
 - 3. TB cases eligible to complete treatment within 12 months must complete therapy within 365 days or less.
 - 4. Follow minimum doses for treatment completion for TB infection, as specified in the DSHS SDOs.
 - 5. If the above criteria are not met and the decision to close a case is made, reason for closure despite adequate therapy must be documented in the medical record, with recommendations for any follow up made by the LHP.
 - a) **Special circumstances**: if a patient is end of life (i.e., in hospice care) and the patient and/or their guardian refuse TB therapy, ensure the following occurs:
 - i. Include the LHP and LHA in the discussion and case management plan. The LHA may consider if not treating the patient could pose a public health threat. Ensure communication and decisions are clearly documented in the patient's medical record. All efforts should be made to continue TB therapy for the purpose of stopping TB transmission and protecting contacts.
 - ii. Consider if a medical consultation is necessary. Submission may include asking about alternate treatment options that the patient could tolerate, if intolerance to pills is a reason for refusing therapy.
 - iii. If patient is infectious, R/LHDs must ensure measures are maintained to stop TB transmission. Provide instructions on appropriate isolation within the home. Identify and manage high-risk individuals (children, immunocompromised, etc.).
 - iv. If the decision is made to stop TB therapy, document rationale in the medical record and ensure that other medical providers involved in the patient's care (e.g., hospice staff) are aware and maintain infection control measures.

M. Initiate contact investigations.

- 1. Every person with known or suspected pulmonary, laryngeal, or pleural TB must have a CI initiated within three working days.
- 2. Every person who has acid-fast bacillus (AFB) sputum smear positive results must have at least three identified contacts.
- Submit TB form 12-12104 (TB Incident Report) or 12-12063 (TB
 Corrections Incident Report) to the TB Unit Epidemiology team for large-scale or concerning CIs.



- 4. Every contact will have a complete evaluation and be referred for treatment when indicated. Patients who decline a complete evaluation for TB infection, including patients needing evaluation for window prophylaxis, will be informed of the implications regarding their decision. Documentation of this communication will be kept in the patient's medical record using the TB-230 (Refusal to Complete and Evaluation for TB Infection) or equivalent.
- N. Develop and maintain processes to capture clinical information, reporting data, and referral services.
 - DSHS TB Unit maintains forms and resources that may be used to capture patient information and document case management and CI activities. TB Unit forms are available at https://www.dshs.texas.gov/tuberculosis-tb/texas-dshs-tb-program-tb-forms-resources.
 - 2. R/LHDs may develop additional forms and resources to support TB activities.
 - 3. In general, forms that require physician signature should not be presigned if they can be used for medical orders that would require the signature of a licensed healthcare provider.
 - a) If pre-signed forms are required to perform certain TB activities (e.g., referrals, medical records requests, etc.), the R/LHD must maintain a local policy or procedure document regarding how pre-signed forms are used. This document must include a review and approval by the authorizing physician and reviewed at least every three years.
- O. Clarify roles and responsibilities of TB program staff.
 - 1. It is the role of the TB program manager to:
 - a) ensure the essential components of a TB program are operationalized. Each chapter in this document contains the essential components. Also refer to cdc.gov/mmwr/volumes/69/rr/rr6907a1.htm;
 - b) develop and assess TB case management strategies to support treatment completion.
 - (1)TB case management is the coordinated effort of a multidisciplinary team in providing prevention and care services for people with known or suspected TB disease or TB infection. This includes medical care, nursing education and assessments, outreach services such as the provision of directly observed therapy (DOT), and social support.
 - (2) Strategies may include case review, cohort review, a system to assign team members to newly reported patients and utilizing TB funding to support care.
 - c) ensure resources are in place to support TB prevention and care activities; this includes, but is not limited to, nurse case

- management, contact investigations, and community partnerships.
- d) develop QA processes for internal program evaluation and problem-solve issues of concern; if necessary, contact the TB Unit for additional support; and
- e) serve as the point of contact to the TB Unit and disseminate key information shared by the TB Unit, as applicable.
- 2. It is the role of the authorizing physician when executing SDOs to:
 - a) review and sign SDOs initially and annually;
 - b) work with the TB program manager to ensure staff understand SDOs and are provided the opportunity to ask clarifying questions;
 - ensure a process exists to respond to signs and symptoms of medication toxicity or other patient concerns when reported by the licensed nurse;
 - d) provide clear expectations to staff working under SDOs regarding the frequency of physician assessments, process of obtaining signed medical orders from the LHP, and communication with TB program staff; and
 - e) ensure a process exists for seeking medical consultation when needed (i.e., coordination between physician and nurse).
- 3. It is the role of the LHP (the treating physician) who writes orders for and manages the patient (if different from the authorizing physician who signs the SDOs) to:
 - a) assume medical care for patients with TB infection and TB disease (known or suspected);
 - b) be available to the nurse regarding clarification of medical orders or plan of care, as necessary; and
 - c) ensure all patients, especially patients with drug-resistant TB (DR-TB), pediatric patients, or other high-risk patients, are managed according to the standards of care for treatment as outlined in the SDOs.
- 4. It is the role of the nurse case manager to:
 - a) ensure all patients have current medical orders from the LHP;
 - b) ensure patients are started on adequate therapy;
 - ensure routine assessment of patients per the TB Manual and SDOs are performed;
 - (1) if a required toxicity screening does not occur, the nurse is responsible for communicating with the LHP as medications should not be administered to patients for which screening cannot be completed.
 - d) acknowledge and follow SDOs when directed by the authorizing physician;
 - e) document assessments and monthly toxicity screenings, including documentation of interventions performed related to any abnormal findings; and
 - f) notify the LHP regarding concerns or questions on medical



orders or plan of care.

Refer to *Appendix A: The Role of the TB Nurse Case Manager* for more details on the responsibility of the TB nurse case manager.

V. Manage Patients with Suspected or Confirmed Tuberculosis Disease

General Requirement

It is the responsibility of TB programs to ensure patients receive timely evaluation, follow up and, when indicated, treatment for TB. This evaluation and follow up should occur either directly or indirectly by the R/LHD:

- Directly, through case management, DOT, radiology, laboratory, nursing, and physician services performed by the R/LHD staff.
- Indirectly, through close collaboration with external medical partners (e.g., nursing homes, physicians' offices) when a direct provision of services is not performed by the R/LHD. This collaboration includes establishing routine communication channels, delineation of duties, and frequent monitoring to ensure DSHS standards are maintained.

This chapter outlines all activities to manage patients with suspected or confirmed TB disease.

TB programs will:

- provide services to evaluate, treat, and monitor patients with suspected or confirmed TB disease, regardless of ability to pay;
- ensure TB patients are appropriately managed, regardless of their jurisdiction;
- adhere to procedures outlined in the DSHS TB SDOs; and
- collaborate with R/LHD partners for TB prevention and care.

Activities

- A. Collaborate with healthcare entities such as hospitals, long-term care facilities, external LHPs (i.e., private physicians), correctional facilities and other congregate settings to ensure appropriate management and treatment of patients with suspected or confirmed TB disease. All coordination of care should be documented in the medical record. Refer to *Table 2: Coordination of Care for TB Management (below)* for responsibilities of R/LHDs when a patient is managed by an external provider or facility.
 - 1. It is the TB program's responsibility to provide nurse case management oversight and collaborate with external facilities to ensure DSHS TB
 standards of care are followed **regardless of where the patient is being managed**.
 - 2. When necessary, consult with the TB program's medical director and/or LHA to support this collaboration.
 - 3. When treatment orders are written by an external LHP, the nurse implementing the orders should ensure they align with the standards of

care outlined in the DSHS SDOs, as signed by the authorizing physician. When orders do not align with DSHS standards of care (i.e., treatment orders differ from recommendations by a DSHS recognized medical TB consultant or the LHP is ordering self-administered medications versus DOT), state purchased medications cannot be used until the nurse has written concurrence with his/her R/LHD's authorizing physician. The concurrence should be kept in the medical record.

Table 2: Coordination of Care for TB Management

External Provider/ Facility	Primary TB Management	Reporting Responsibilities, Case Management Collaboration*, and Contact Investigation
Texas Health and Safety Code Chapter 89 (Chapter 89- Designated Correctional Facility)†	Varies; refer to the Correctional TB Screening Plan (TB-805).	 Each facility must report TB to their R/LHD. The R/LHD enters all RVCT and case management data for ATS-class 2, 3, 5 and contacts in NEDSS. The R/LHD may utilize the Texas Administrative Code (TAC), Title 25, Part 1, Chapter 97, Rule §97.178 to work directly with facilities in their jurisdiction to ensure reporting timelines are met. The R/LHD may review medication orders but shall not supply medications directly to Chapter 89-designated facilities unless the R/LHD serves as the TB medical provider listed on the Correctional TB Screening Plan. (Refer to Chapter XIII. Inventory Management of Medication and Supply). R/LHD should guide contact investigation activities in Chapter 89-designated correctional facilities. Testing activities should be coordinated with facility administrators.
Texas Department of Criminal Justice (TDCJ)†	TDCJ independently diagnoses, treats, and manages TB within their facilities. TDCJ contracts with Texas Tech Health Science Center (TTHSC) and University of Texas Medical Branch (UTMB) for healthcare services.	 TDCJ is a reporting jurisdiction similar to a R/LHD. TDCJ manages and enters all data for ATS-class 3, 5, and contact investigations directly in NEDSS. TDCJ Office of Public Health receives all initial case reports and closures from contracted providers and enters in NEDSS. TDCJ does not report to the R/LHD unless an inmate is released while on TB treatment. TDCJ Office of Public Health sends the IJN form to the state IJN coordinator if an offender is released while on TB treatment. The state's IJN coordinator sends IJN to the receiving jurisdiction. The R/LHD shall not provide state-purchased TB medications and/or TB

External Provider/ Facility	Primary TB Management	Reporting Responsibilities, Case Management Collaboration*, and Contact Investigation
		screening supplies to a TDCJ prison. TDCJ procures medications and supplies to perform TB services.
Immigration and Customs Enforcement (ICE)†	ICE independently diagnoses, treats, and manages TB within ICE-operated facilities. This occurs through the ICE Health Service Corps (IHSC) or an ICE-contracted medical group responsible for care within ICE facilities.	 ICE must report TB to the R/LHD as per the TAC Title 25, Part 1, Chapter 97. The R/LHD may provide recommendations for care when requested by ICE. The R/LHD must enter all RVCT data and case management data for ATS-class 3, 5, and contacts into NEDSS even if the detainee has not been in the U.S. ≥ 90 days. The R/LHD should refer to DSHS Tuberculosis Standards for Texas Correctional and Detention Facilities and ICE's National Detention Standards to ensure reporting timelines are met. If a detainee is released to a U.S. jurisdiction while on TB treatment, the R/LHD sends an IJN form to the jurisdiction as described in Chapter XVI. Interjurisdictional Notifications In and Out of State. ICE informs CureTB of detainees being deported out of the U.S. while on TB treatment. The R/LHD should not provide state-purchased TB medications to ICE facilities. Screening for contacts incarcerated in an ICE facility should be conducted by ICE, without use of state-purchased resources.

External Provider/ Facility	Primary TB Management	Reporting Responsibilities, Case Management Collaboration*, and Contact Investigation
Detention Facilities that House U.S. Marshalls Service (USMS) Prisoners†	Prisoners in USMS custody may be housed in county or federal detention centers. Defer to each facility regarding TB management policies, generally overseen by the facility's medical director.	 Each facility housing USMS prisoners must report TB to their R/LHD. The R/LHD enters all RVCT and case management data for ATS-class 3, 5 and contacts in NEDSS. High-risk populations with TB infection referred to an R/LHD must also be entered in NEDSS. The R/LHD should coordinate with the medical director of the facility to ensure treatment guidelines are followed and that reporting protocols are understood to ensure timely reporting and entry in NEDSS. The R/LHD should not provide any state-purchased TB medications to an inmate in USMS custody. Screening for contacts currently in USMS custody should be conducted by USMS, without use of state-purchased resources. R/LHD may offer guidance on screening activities for CIs when requested by USMS or a detention facility.
Bureau of Prisons (BOP)	BOP independently diagnoses, treats, and manages TB. Defer to each facility regarding TB management policies, generally overseen by the facility's medical director.	 BOP must report TB to the R/LHD as per the TAC Title 25, Part 1, Chapter 97. The R/LHD will provide TB services (e.g., assistance with case management) when requested by BOP. The R/LHD must enter all RVCT data, case management data for ATS-class 2, 3, and 5, and contacts into NEDSS. The R/LHD should refer to DSHS Tuberculosis Standards for Texas Correctional and Detention Facilities and BOP's Federal Bureau of Prisons Clinical Guidance to meet reporting timelines. The R/LHD should not provide any state-purchased TB medications to a BOP facility. Screening for contacts currently in a BOP facility should be conducted by BOP, without use of state-funded resources.
Unaccompanied Children (UAC) Shelter	UAC shelters operate under the directive of the Office of Refugee Resettlement (ORR). Each shelter may defer to their R/LHD for case management	 Each shelter must report TB to their R/LHD. The R/LHD enters all RVCT and case management data for ATS-class 2, 3, 5, and contacts in NEDSS. The R/LHD sends IJNs to the receiving jurisdiction; see Chapter XVI. Interjurisdictional Notifications In and Out of State. ORR has policies around communicable

External Provider/ Facility	Primary TB Management	Reporting Responsibilities, Case Management Collaboration*, and Contact Investigation
	recommendations (i.e., release from isolation, CIs, etc.).	disease control and medical services; refer to acf.gov/orr/policy-guide-section-3#3.1 . Each UAC shelter must inform the ORR medical team of any new cases and will receive guidance on medical care and treatment. • Shelters may refer children to the R/LHD for treatment; in those cases, the R/LHD may provide DOT to the patient. Alternatively, shelters may choose to treat the patient within the shelter; if so, they must use medications provided by ORR. • Any collaboration of additional case management activities will be made on a case-by-case basis, as determined by the R/LHD and shelter staff. • Each shelter uses their own funding to procure screening supplies; therefore, state-funded resources should not be provided to a shelter to conduct CI activities. • R/LHD may offer guidance on screening activities for CIs.

External Provider/ Facility	Primary TB Management	Reporting Responsibilities, Case Management Collaboration*, and Contact Investigation
Inpatient Care Facilities – i.e., hospital, long- term care facility, acute-care rehabilitation center	The facility's attending physician, medical director, LHP or equivalent is responsible for treating TB while the patient receives in-patient care. They may request recommendations from the R/LHD.	 The inpatient facility must report TB to the R/LHD. The R/LHD enters all RVCT and case management data for ATS-class 2, 3, 5, and contact investigations in NEDSS. The R/LHD should collaborate on a plan of care and treatment recommendations. In complex TB cases such as evidence of rifampin resistance, ensure a consult is submitted to a DSHS-recognized TB medical consultant. The R/LHD should not distribute state-purchased TB medications to a hospital, as this is a breach of the 340B Drug Pricing Program. DOT should be reported to the R/LHD which would most commonly be in the form of a medication administration record (MAR). The R/LHD should enter all RVCT and case management information into NEDSS. The R/LHD should collaborate with facility to collect and submit specimen to DSHS laboratories if approved by the facility. The R/LHD sends IJNs to the receiving jurisdiction as described in Chapter XVI. Interjurisdictional Notifications In and Out of State. R/LHDs should guide screening activities for CIs in inpatient facilities and may use program funds for testing. Testing activities should be coordinated with facility administrators.
External Healthcare Providers (e.g., private providers)	The external LHP may manage the TB patient in collaboration with the R/LHD (for example, the R/LHD may provide nursing and DOT services).	 The R/LHD will assign a nurse case manager to ensure TB standards of care are followed, monthly toxicity assessments are documented, DOT is provided, and interventions are performed when necessary. The R/LHD must also ensure there is a clear agreement with the external provider, as per Appendix C: Sample TB Program and Private Physician Agreement Letter. The R/LHD is responsible for entering all RVCT reporting variables into the DSHS reporting database. The R/LHD is responsible for conducting the CI, as needed.
Texas Center for Infectious Disease (TCID)	TCID is the only DSHS-operated inpatient facility for TB in Texas. TCID also provides	 The R/LHD receives case management updates and must enter into NEDSS while patient is admitted to TCID. The R/LHD communicates with TCID on plans to refer a patient to TCID for admission. TCID

External Provider/ Facility	Primary TB Management	Reporting Responsibilities, Case Management Collaboration*, and Contact Investigation
	outpatient care for Hansen's disease.	 informs referring R/LHD of patients release from TCID. Medications are provided by TCID and will be coordinated with the R/LHD upon discharge. The R/LHD is responsible for conducting the CI, as needed.

^{*} If a facility is not providing <u>DSHS standards of care</u> for the treatment of TB, the R/LHD is responsible for communicating concerns with the LHA and/or regional medical director to guide collaboration efforts.

- B. Establish and maintain a medical record for each person with suspected or confirmed TB disease. Medical records may be maintained in an electronic medical record (EMR) or on paper.
 - 1. Organize medical records with sections clearly divided and/labeled. See #10 for required sections for paper records.
 - 2. Ensure all patient-specific documents are securely attached (if paper) to the medical record. This may include laboratory results (e.g., genotyping results with clinical significance or electronic laboratory reports [ELRs] that are obtained from NEDSS or other databases), consultation emails, hand-signed consents, photographs, or other information gathered for patient care. See #9 below.
 - 3. Provide accurate and complete documentation.
 - 4. Date and sign all entries in the progress notes; if written on paper, draw a line through each blank section.
 - 5. Document in chronological order with the most recent information placed on top (if a paper record).
 - 6. Draw a single line through errors and initial (if a paper record) or notate errors (as per EMR).
 - 7. Do not document outside the margins if documenting on paper.
 - 8. Establish a locally approved list of abbreviations (e.g., noting "wt." for "weight"). Maintain the list in a locally approved and designated place for consistency and clarity among records.
 - 9. EMRs² should contain the relevant information that is captured on applicable <u>DSHS TB Unit forms</u>. Programs may choose to use TB forms as templates in the EMR or use the TB Unit forms as a guide for pertinent medical record documentation that apply to the patient.

[†] Refer to Chapter XX. Monitor Surveillance, Reporting, and Case Management Activities in Correctional and Detention Facilities.

² EMRs replace the need for paper records and therefore may not contain exact matches of a TB form. For example, a TB 400A may not be an exact template in an EMR, but the relevant information captured on the TB 400A should be included in the medical record. In addition, information that is entered or electronically imported into NEDSS may be printed and attached to the medical record to avoid duplicate data entry.

- 10. Medical records should have clearly divided sections (recommended sections in bold, below, especially if paper records) and must include at minimum the information as per the following <u>DSHS TB Unit forms</u> or their equivalent:
 - a) Demographics, Case Information, and Current Orders
 - (1) TB-400A (*Report of Case and Patient Services*) completed initially to capture demographics, risk factors, and any LTBI history.
 - (2) TB-400B (Report of Case and Patient Services) completed initially; when orders and diagnostics change; as needed; at closure to capture reporting details, initial diagnostics, drug regimens, bacteriology and radiology, and current orders by the LHP.
 - b) TB Case Management Plan and Patient Education
 - (1) TB-201 (Case Management Plan for Outpatient Care)
 - (2) TB 203 (Education/Counseling Record)
 - (3) TB-204 (Tuberculosis Forms/Literature Checklist)
 - (4) TB-700 series (if drug resistant)
 - c) TB Medical History
 - (1) TB-202 (Tuberculosis Health Assessment/History)
 - **d) Bacteriology Results** (e.g., AFB smears, cultures, DSTs, molecular tests, other test results if there is clinical impact)
 - (1)TB-231 (Bacteriology TB Control) or TB-703 (TB Bacteriology Monitoring Log)
 - e) Radiology Reports (performed initially, at 2 months, at closure, as ordered)
 - **f)** Laboratory Results (i.e., CMP, CBC, LFTs, HIV, etc.)
 - g) Monthly Toxicity Assessments
 - (1) TB-205 (Toxicity Assessment), if drug susceptible
 - (2) TB-702 (*Toxicity Assessments for Clients on Second-Line Medications*) if applicable
 - h) Directly Observed Therapy Logs
 - (1) TB 206 (*DOT Log*)
 - Note: If video DOT was provided, a printout of (at minimum) a monthly summary (as per page 2 of the DOT log) should be included in the medical record so that adherence is clearly documented. At the end of treatment, a summary of all doses may be printed and retained in the medical record.
 - i) Consent Forms and Control Orders
 - (1) L 36 (General Consent and Disclosure)
 - (2) L 30 (Consent to Release Confidential Medical Information) indicated only if medical record is released to an external entity or provider.
 - (3) TB-409 (Acknowledgement of Understanding)
 - (4) TB-410 (Order to Implement and Carry Out Measures for Patients with TB)
 - (5) TB-411 (Disclosure and Consent for Drug Therapy)



- **j) Outside Records**, i.e., TCID summaries, hospital discharge summaries, medication administration records (MARs), etc.
- k) Medical Consults
- I) Progress Notes
- m)Miscellaneous (email communication, fax confirmations, etc.).
- C. Coordinate and document discharge planning with in-patient facilities or correctional facilities for patients being released to outpatient care. The following discharge planning criteria should be met:
 - 1. A specific plan exists for follow-up care, regardless of management facility.
 - 2. When possible, patients should be served the <u>TB-410</u> (the "TB Control Order") before being discharged or released to outpatient care.
 - 3. Patient is started on the standard multi-drug TB treatment regimen and DOT arranged.
 - 4. No infants or children aged four and younger or people with immunocompromising conditions are present in the household of an infectious patient (when possible).
 - 5. Patient is advised of TB isolation and restriction status.
 - a) Except for healthcare-associated visits, direct patients to refrain from travel outside the home until patient has met criteria to discontinue isolation.
 - b) Direct patients traveling for healthcare-associated visits to wear a surgical mask for the duration of travel and visit and notify the receiving agency before visit.
- D. Obtain acknowledgment and consent for treatment and care.
 - 1. Maintain signed consents and acknowledgements (DSHS or local equivalent) in the patient's medical record.
 - 2. If the patient moves to another jurisdiction, the <u>TB-410 (Order to Implement and Carry Out Measures for a Client with TB)</u> and acknowledgment/consent forms must be prepared by the receiving jurisdiction and submitted to the patient for signature.
- E. Develop a treatment and case management plan.
 - Develop an initial treatment and case management plan for each patient within one week of receiving the report of a new ATS class 3 or 5 and document on the <u>TB-201 (Tuberculosis Case</u> <u>Management Care Plan)</u> or equivalent.
 - a) TB programs must maintain oversight of patients receiving TB care from private providers outside the R/LHD to ensure DSHS treatment standards are followed. State-purchased medications cannot be used to support a medication regimen that do not align with DSHS treatment standards, i.e., self-administration of TB medications, regimen falls outside of DSHS recognized medical consultation recommendations, etc.



- b) Create a written agreement describing the shared roles and responsibilities in the delivery of TB care services between a private provider and the TB program.
 - (1) Present a written plan to the private provider and patient to ensure proper treatment, coordination of care and reporting.
 - (2) See Appendix C: Sample TB Program and Private Physician Agreement Letter and Appendix D: Sample Correspondence Letter for Patients Treated by Private or Community Providers for sample correspondence.
- 2. Facilitate the establishment of and identify a medical home for each patient. Regardless of patient's insurance status, identify community resources that serve patients, including indigent patients and the uninsured, and refer as appropriate. Referrals would include any findings made by the TB program that require medical intervention including, but not limited to, non-tubercular mycobacterium, diabetes, and/or HIV. When applicable, provide referrals for patients needing primary or specialty clinical care:
 - a) Uninsured patients may be referred to FQHCs to ensure they have access to primary and specialty care (see dshs.texas.gov/chpr/fghcmain.shtm).
 - b) Indigent patients may qualify for medical assistance in their county of residence (see https://hrs.texas.gov/services/health/county-indigent-health-care-program).
 - c) See Appendix F: Additional Patient Services for more services.
- F. Implement initial infection control practices (see *Chapter XVII. Implement Infection Control Procedures* for more information).
 - 1. Place a surgical mask on patients arriving at the TB clinic forservices.
 - 2. Patients classified as ATS-class 3 or 5 based on the ATS classification system should be placed in location-appropriate isolation (air-borne infection isolation room [AIIR]) if in a congregate setting or respiratory isolation if home-based (refer to Chapter 6 of the Core Curriculum on Tuberculosis: What the Clinician Should Know, Seventh Edition. cdc.gov/tb/hcp/education/core-curriculum-on-tuberculosis.html). Maintain documentation in the medical record unless criteria for release from isolation is met as outlined in the SDOs.
- G. Provide and document initial and ongoing patient education.
 - 1. Provide patient education on:
 - a) Transmission and pathogenesis of TB;
 - b) means to decrease transmission and the need for infection control;
 - c) rationale for DOT;
 - d) seriousness and importance of completing treatment;
 - e) significance of conducting a complete and thorough CI;



- f) protected health information (PHI);
- g) adverse drug reactions and drug interactions of TB medications;
- h) the need for patients to discuss adverse drug reaction symptoms and other treatment concerns with nurse case manager as soon as they occur;
- i) consequences of non-adherence to treatment; and
- j) unobserved specimen collection.
- 2. Document initial and ongoing education and counseling on <u>DSHS form</u> TB-203 or equivalent.
- H. Conduct TB screening and evaluation in accordance with DSHS SDOs.
 - 1. Determine the appropriate TB screening method based upon:
 - a) patient age;
 - b) Bacillus Calmette-Guerin (BCG) status; and/or
 - c) other factors outlined in the SDOs.
 - 2. Conduct and document the medical evaluation.
 - a) Screen for TB signs and symptoms;
 - b) Collect patient medical and social history;
 - c) Conduct physical exam; and
 - d) Collect sputum specimens per SDOs and/or clinical specimens if warranted (see *Table 3: Types of Specimens Collected to Diagnose TB Disease*).
 - 3. Screen for existing comorbid conditions (e.g., diabetes, HIV, hepatitis B and C, per SDOs). Collect the following diagnostic results and share with treating provider for review and signature:
 - a) Baseline TB screening test results;
 - b) CXR (see Table 4: Common Terminology Used on a Chest X-Ray Report);
 - c) Drug susceptibility test (DST) results (see *Table 5: Drug Susceptibility Patterns*). Extended drug susceptibility testing must be performed on all isolates with resistance to first-line agents (isoniazid, rifampin, and ethambutol);
 - d) AFB smear results and bacteriology (see Table 6: Acid Fast Bacilli Smear Classification Results); and
 - e) Additional TB testing as needed for a diagnosis (see *Table 7: TB Diagnostic* Testing).
 - 4. Ensure shipment of initial isolate to DSHS laboratory in Austin for genotyping regardless of the laboratory that performed AFB smear and culture tests.
 - 5. Prepare a written TB control order for people with suspected (ATS class 5) or confirmed TB disease (ATS class 3).
 - a) Use <u>DSHS form TB-410</u> or equivalent. This form is required even if patient refuses to sign. Document the date and time provided to patient.
 - b) Prepare written control order in patient's preferred language,

ideally within three days of classification.

c) Document in the medical record if an interpreter or guardian read the control order to patient before patient signed it.

Table 3: Types of Specimens Collected to Diagnose TB Disease

Diagnosis Type	Specimen Needed		
Pulmonary or laryngeal TB	 Sputum (phlegm from deep in the lungs). If a pulmonary TB diagnosis cannot be established with sputum collection, other procedures may be necessary (e.g., bronchoscopy, gastric aspiration). Laryngeal TB may be diagnosed from clinical signs and symptoms (i.e., hoarseness) or by biopsy. 		
Extra-pulmonary TB	 Anatomic sites include but are not limited to: Urine or stool cerebrospinal fluid pleural fluid pus or other aspirated fluid biopsy specimens blood (heparinized) 		

Adapted from "Controlling Tuberculosis in the United States: Recommendation from the American Thoracic Society, CDC, and Infectious Diseases Society of America", by Centers for Disease Control and Prevention, 2005, Morbidity and Mortality Weekly Report, 54(RR-12), cdc.gov/mmwr/preview/mmwrhtmR/LHDr5412a1.htm.

Table 4: Common Terminology Used on a Chest X-Ray Report

CXR Finding	Meaning
Consolidation	Often referred to as an ill-defined opacity
	Focal spaces or "holes" in the lung: both indicate the absence of
Cyst/cavity	lung tissue; a cavity being more likely to be TB, and generally
	indicative of greatest infectiousness
Fibrosis	May or may not be active disease and requires further evaluation
Granuloma	A small, calcified nodule, usually not indicative of active disease
	A circumscribed area that appears nearly white (i.e., denser) than
Opacity	its surroundings; may be parenchymal, pleural, within the chest
	wall or external to the patient
Lymphadenopathy	Enlarged lymph nodes seen as soft tissue densities: usually more
Lymphadenopathy	indicative of active disease in a child
Miliary	Many tiny nodules resembling millet seeds scattered throughout
Nodule	Discrete opacity measuring two to 30 millimeters (mm) in diameter
Mass	Discrete opacity (nodule) greater than 30 mm in diameter; often
11055	indicative of a carcinogenic process

Table 5: Drug Susceptibility Patterns

Category	Sensitivity Patterns	
Pan-sensitive	Sensitive to streptomycin, isoniazid, rifampin, ethambutol, and pyrazinamide	
Mono-resistant	Resistant to one first-line anti-TB drug only	
Poly-resistant	Resistant to at least two first-line anti-TB medications (but not both isoniazid and rifampin)	
Multi-drug resistant	Resistant to both isoniazid and rifampin	
Pre-extensively drug-resistant*	Resistant to both isoniazid and rifampin plus resistance to one of the second-line injectable agents (amikacin, capreomycin, ckanamycin) <i>or</i> a fluoroquinolone; and	
Extensively drug- resistant*	Resistant to isoniazid and rifampin, plus resistance to one of the second-line injectable agents (amikacin, capreomycin, or kanamycin) and a fluoroquinolone or Resistant to isoniazid and rifampin, plus resistance to a fluoroquinolone, and bedaquiline or linezolid.	

^{*} CDC surveillance definitions updated on January 18, 2022. Refer to archive.cdc.gov/#/details?url=https://www.cdc.gov/tb/php/dear-colleague-letters/2022-xdrsurveillance-definitions.html. Adapted from Tuberculosis Nursing: A Comprehensive Guide to Patient Care, Second ed., National Tuberculosis Controllers Association, 2011.

Table 6: Acid Fast Bacilli Smear Classification Results

Quantity Reported*	DSHS Laboratory Quantitation	Smear Result
4+/numerous (>9/field)	>10/field	Strongly positive
3+/few- numerous (1-9/field)	1-10/field or >10/field	Strongly positive
2+/few (1-9/10 fields)	<1/field or 1-10/field	Moderately positive
1+/rare (1-9/100 fields)	<1/field	Moderately positive
Actual number of AFB seen (no plus sign) (1-2/300 fields)	1 or 2 AFB seen on entire smear	Weakly positive [†]
No acid-fast bacilli seen	No AFB seen on direct smear	Negative

^{*} Reporting methods may vary by laboratory. Check with your laboratory for specific interpretation. † Laboratories may report these smear results as "doubtful" or "inconclusive" based on CDC guidelines.

Adapted from Core Curriculum on Tuberculosis: What the Clinician Should Know, Sixth ed., Centers for Disease Control and Prevention, 2013; Tuberculosis Nursing: A Comprehensive Guide to Patient Care, Second ed., National Tuberculosis Controllers Association, 2011.

Table 7: TB Diagnostic Testing

Test* and Timeframe for Results	Definition	Purpose and Implications for Clinical Management
AFB Smear 24 hours	Mycobacteria retain color after a fluorochrome staining. Under a microscope they appear rodshaped and fluorescent.	 Presence may indicate TB disease but does not confirm a diagnosis, as some AFB are non-tuberculosis mycobacterium (NTM) disease. The amount of AFB detected may correlate with infectiousness of a patient and the decrease in quantitation of AFB reported may be used to follow effectiveness of treatment (e.g., as treatment progresses, the number of AFB detected should decrease.) Test results should be correlated with patient clinical and radiological findings. Negative smears do not exclude TB disease.
AFB Culture and Identification 21 days (for most positive cultures) up to 6 weeks. NOTE: A specimen with a heavy M. tb load can be M. tb culture positive in 4 to 5 days	Test to identify viable <i>M. tb</i> organisms	 A positive culture confirms an <i>M. tb</i> diagnosis. Culture results assist in monitoring response to treatment. <i>Positive results</i> should be reported to the clinician as soon as possible. <i>Negative results</i> should be used in correlation with the patient's clinical and radiological findings and treatment recommendations by the clinician. Culture positive after 4 months of appropriate therapy is deemed as treatment failure. Consult required with a DSHS-recognized TB medical consultant.
NAAT 48 hours	Used for rapid detection of <i>M. tb</i> DNA or RNA in patient specimen.	 Assists in the ability to rapidly diagnose or exclude <i>M. tb</i>. While NAATs are more sensitive than AFB smear results, they do not replace AFB smear and/or culture results. Does not distinguish between viable, disease-related organisms and nucleic acid persisting from prior disease. Interpret results in the context of the clinical situation and AFB smear results. <i>Positive results</i> should be communicated to the clinician immediately. <i>Negative results</i> should be correlated with patient clinical and radiological findings in consultation with the treating clinician. See algorithm for NAAT interpretation and Response in SDOs.

Test* and Timeframe for	Definition	Purpose and Implications for
Results		Clinical Management
Polymerase Chain Reaction (PCR) 48 hours	Testing technique used to amplify small segments of <i>M. tb</i> DNA in a specimen. PCRs are a type of NAA technique.	 Same as NAAT. Rapid test to help identify <i>M. tb</i> more quickly than conventional culture methods. Does not distinguish between viable, disease-related organisms and nucleic acid persisting from prior disease. Ensure a specimen is submitted for AFB smear and culture testing. Some clinicians request the cycle threshold (Ct) values, which provides the number of cycles necessary to detect the nucleic acid target of the PCR test. Collaborate with the laboratory to assist in obtaining these results when rifampin resistance is detected. <i>NOTE: not all PCRs test for rifampin resistance. Programs must ensure that if a PCR is performed at a laboratory outside DSHS, rifampin mutations are tested (unless DST results are known). Preliminary PCRs showing rifampin resistance should be reported to the R/LHD while further testing is pending.</i>
Cepheid GeneXpert Test (Xpert) commercial name is Cepheid MTB/RIF Assay 48 hours	NAA test used for rapid diagnosis of TB disease and rifampin resistance on both AFB smear negative and smear positive specimens. The Xpert test is based on PCR technology that utilizes probes (A-E) that bind to different sections of the rpoB gene of <i>M. tb</i> DNA.	 Detects the presence of <i>M. tb</i> and the most common mutations in the rpoB gene that confer rifampin resistance. Ensure a specimen is submitted for AFB smear and culture testing. Interpret laboratory results along with clinical, radiographic, and other laboratory findings. Obtaining and evaluating rifampin resistant Xpert results, including the Ct values and the probe results, should be guided by a consultation with a DSHS-recognized TB medical consultant. If a mutation is detected, this mutation must be confirmed and identified by sequencing such as the MDDR testing. Not all mutations result in rifampin resistance; however, until further results are available, appropriate steps should be taken. Refer to <i>Chapter VI. Treatment of Drug-Resistant Tuberculosis</i>.
Drug Susceptibility Testing (DST) First-line DST: 17 days after	Tests <i>M. tb</i> organism to determine susceptibility or resistance to specific drugs.	 Indicates if the patient's TB disease can be treated with first-line TB medications or not. NOTE: the DSHS laboratory in Austin will automatically test an initial positive culture for susceptibly to all first-line anti-TB medications and ofloxacin.

Test* and Timeframe for Results	Definition	Purpose and Implications for Clinical Management
positive MTB culture (DSHS laboratory reports rifampin and both isoniazid concentrations at 11 to 14 days after positive M. tb culture)		 Results are critical for patient management, treatment regimen, and duration of therapy. Ensure that DSTs are in progress if the AFB culture results are positive for <i>M. tb</i>. Consult required with a DSHS recognized TB medical consultant if resistance to isoniazid and/or rifampin is identified.
Molecular Detection of Drug Resistance (MDDR) [†] 7 to 10 business days	Test to identify mutations that may cause resistance to multiple groups of drugs.	 MDDR does not replace DSTs but assists the clinician with useful information to guide treatment when drug resistance to at least rifampin and/or isoniazid is known or suspected. The presence of mutations is a way to detect potential drug resistance rapidly and accurately. The absence of mutations decreases the likelihood of resistance but is not a guarantee of susceptibility. Results should be shared with the LHP and a DSHS-recognized TB medical consultant. See Appendix H: Requesting Molecular Detection of Drug Resistance (MDDR) for criteria and submitting process.
Minimum Inhibitory Concentration (MIC) [±] Varies 3-6 weeks	Test using drug concentrations; the result is the lowest concentration that inhibits bacterial growth.	 Some situations may require an MIC that is useful for clinical management of a patient. Should be ordered and followed in close consultation with a DSHS recognized TB medical consultant.
RNA polymerase Beta Subunit (rpoB) alert [†]	rpoB is a gene (not a test) found in the TB bacteria. Mutations in this gene can be associated with rifampin resistant TB.	 A rpoB alert means the patient is likely resistant to at least rifampin. NOTE: rpoB genes are present in all MTBC isolates. The alert identifies a MUTATION was detected in this gene by WGS. The alert may not reflect routine DSTs. CDC reports rpoB alerts to DSHS laboratory and R/LHDs are made aware of rpoB alerts by the DSHS nurse consultant. Notify the treating clinician immediately. Consult with DSHS-recognized TB medical consultant as soon as possible.

Test* and Timeframe for Results	Definition	Purpose and Implications for Clinical Management
TB Genotyping using Whole Genome Sequencing †β (WGS)	Examines genetic relatedness of isolates by sequencing approximately 90% of the genome.	 Allows for comparison and establishes relatedness between <i>M. tb</i> isolates. Provides greater resolution than previous genotyping methods (GENType) for investigating recent transmission and can detect mutations (see also rpoB alert, below). Can add value to conventional contact investigations and help aid in identifying links between cases. Allows monitoring the progress toward eliminating TB transmission more accurately. When combined with epidemiologic data, genotyping helps identify persons with TB involved in the same chain of recent transmission and to distinguish between persons whose TB disease is a result of TB infection acquired in the past. Ensure initial isolate has been submitted to DSHS laboratory for genotyping regardless of the laboratory that performed AFB smear and culture results. WGS results are reported through TB GIMS in the CDC SAMS portal and entered in NEDSS by the TB Unit Epidemiology team. Whole-genome single nucleotide polymorphism analysis (wgSNP) comparison trees (the plots that explain how closely related isolates are form each other) for concerning clusters are performed at the request of the TB Unit Epidemiology team to CDC and can be downloaded from TB GIMS. Can be used to support false positive investigations, CIs, cluster investigations, and outbreak detection.
Next-Generation Sequencing (NGS) 2-5 weeks after M. tb culture identification	NGS data is used to target eight genes associated with primary and fluoroquinolone drug resistance by detecting mutations (variants).	 Used in conjunction with conventional DSTs to support development of a suitable drug regimen. Primary means of PZA susceptibility testing. May alert submitter to possible <i>M. bovis</i> or <i>M. bovis BCG</i> organism when His57Asp variant in the <i>pncA</i> gene is detected.

^{*} Most tests are performed at the DSHS State Laboratory in Austin and/or South Texas and are available at most commercial laboratories. The DSHS State Laboratory will ship isolates to references laboratories when indicated.

[†] Performed at the Centers for Disease Control and Prevention (CDC) Reference Laboratory. ‡Performed at California Department of Public Health Microbial Diseases Laboratory Branch.

^β Performed at Michigan Department of Health & Human Services Bureau of Laboratories and CDC.

- I. Initiate standard therapy as ordered.
 - 1. Treatment for drug susceptible TB includes two phases:
 - a) Initial treatment phase: most commonly with isoniazid (INH), rifampin (RIF), ethambutol (EMB), and pyrazinamide (PZA) for the first eight (8) weeks or until susceptibilities are known.
 - b) Continuation treatment: most commonly with INH and RIF for the remaining months.
 - c) Variations to a) and b) above may occur when novel TB regimens are established. Refer to the DSHS SDOs for a list of current, approved TB regimens, or follow recommendations from a DSHS-recognized TB medical consultant if the exact regimen is not outlined in the SDOs.
 - 2. Provide DOT and document on <u>TB-206 (DOT Log)</u> or equivalent.
 - a) DOT is the standard of care in Texas. Provide DOT to all patients with suspected or confirmed TB disease. Patients with suspected TB should continue DOT until TB is ruled out.
 - b) Indicate clearly which medications are provided. Note any medication changes on the log and sign.
 - c) Document every directly observed dose of medication administered to the patient.
 - d) If a patient takes self-administered doses on the weekend, and/or holidays, do not count the number of weekend and holiday doses towards completion of therapy.
 - e) Document all self-administered doses and missed doses.
 - f) Pursue appropriate actions for missed DOT or clinic appointments, up to and including court-ordered management.
- J. Ensure patients are managed and respond to therapy.
 - 1. Monitor and document baseline and monthly adherence to treatment, response to treatment and drug side effects or adverse reactions.
 - 2. Conduct monthly follow-up laboratory tests and assessments in accordance with the SDOs; document results and subsequent interventions as necessary.
 - 3. Initiate a consult from a DSHS-recognized TB medical consultant as indicated.
 - a) Indicators for consultation are listed in the SDOs.
 - b) Consults from DSHS-recognized TB medical consultants are required for any patient with DR-TB, as outlined in the SDOs.
 - c) See *Appendix G: Medical Consultation Templates* for medical consultation templates.
 - 4. Consider serum drug level testing for patients not responding adequately to therapy or patients with risk factors for poor absorption of medication. See *Therapeutic Drug Monitoring Process* at dshs.texas.gov/sites/default/files/LIDS-TB/forms/TherapeuticDrugMonitoringProcess.pdf.
 - 5. Report deaths among known or suspected TB cases to the TB Unit

Epidemiology team using the DSHS Weekly Report of New Concerning Tuberculosis Event form found here: dshs.texas.gov/sites/default/files/LIDS-TB/forms/TB-350.pdf. If cause of death is likely TB, investigate events surrounding the death to determine if the death was preventable. Communicate findings with the TB Unit when requested.

- 6. Refer to Appendix A: The Role of the TB Nurse Case Manager regarding all case management priorities and responsibilities when managing patients with ATS class 3 and 5.
- K. Close the patient's medical record using any one of the following dispositions:
 - 1. Completion of adequate therapy
 - a) Treatment completed within 12 months.
 - b) Exceptions to completion of adequate treatment within 12 months apply if:
 - (1) patient has rifampin resistant TB (RR-TB), multi-drug resistant TB (MDR-TB), pre-extensively resistant TB (Pre-XDR TB), or extensively resistant TB (XDR-TB);
 - (2) patient is aged 14 or younger with miliary disease; or
 - (3) patient has meningeal disease.
 - 2. Non-TB
 - 3. Deceased
 - 4. Moved out of country
 - 5. Lost to Follow Up (LTFU)
 - a) Make at least three attempts to contact a TB patient before considering a patient as LTFU, including:
 - (1) calling the patient;
 - (2) visiting the patient's residence; and
 - (3) sending a certified-mail notification of the patient's need to follow up with clinic.
 - b) Document attempts, as well as the certified mail notification receipt, in the patient's medical record.
- L. Coordinate with the patient and other jurisdiction(s) when a patient on treatment for known or suspected TB intends to travel.
 - 1. The decision to accept a patient's request to travel outside the managing jurisdiction must be carefully considered by the R/LHD in collaboration with the LHP and patient.
 - 2. Known/presumed infectious patients shall not travel via commercial means. (Refer to M, below).
 - 3. Travel is not recommended until DSTs are known, in the event drug resistance is identified and isolation is then extended.
 - 4. Coordinate planned and accepted in-state or intrastate travel on a case-by-case basis. Refer to *Chapter XVI. Interjurisdictional Notifications In and Out of State*.



- 5. Travel outside the U.S. is not recommended for most patients on treatment for TB disease during care. The R/LHD must discuss potential outcomes including unexpected changes in travel plans, travel restrictions, possible delays in returning to the U.S., or delays in therapy if travel outside the U.S. occurs. Consideration should be made for the following:
 - a) How would the patient obtain TB medications if travel was extended, or medications lost/destroyed?
 - b) How would care for TB be managed if the patient developed an illness (i.e., COVID-19) and could not travel back to the U.S.?
 - c) If placed on VDOT, how would doses be counted should technical problems with video uploading occur?
 - d) What care would be available should adverse reactions occur?
- M. Request a Do Not Board (DNB) or Public Health Lookout (LO) consultation for any person with confirmed or suspected TB who plans to cross the U.S. border and/or board a commercial aircraft and is infectious or likely to be infectious, by emailing the DSHS TB Unit Epidemiology team at TBEpi@dshs.texas.gov.
 - 1. Placing an individual on a Do Not Board (DNB) list prevents them from receiving a boarding pass and traveling by commercial aircraft departing from or arriving in the U.S.
 - 2. The Public Health Lookout (LO) is a travel intervention tool that prompts a public health review of an individual if they attempt to enter the U.S. through air, land, or seaports of entry. It is indicated when an individual entering the U.S. needs to be put in contact with public health authorities to ensure appropriate public health management of a communicable disease.
 - 3. The DNB/LO travel restrictions are monitored and enforced by CDC and the Department of Homeland Security (DHS).
 - 4. Every person placed on the DNB list by CDC is automatically placed on the Public Health Lookout list. Refer to cdc.gov/port-health/travel-restrictions.
 - 5. Submit a DNB/LO request to the TB Unit Epidemiology team using 12-12065 (Do Not Board/Public Health Lookout Consultation Request) for any patients that meet the following criteria:
 - a) The patient is known or believed to be infectious or is likely to become infectious prior to/during travel.
 - b) The patient is unaware of, or is likely to be noncompliant with, public health recommendations against commercial air travel or travel outside the U.S. Evidence to support non-adherence includes disregard for isolation recommendations, violation of Control Order or signed treatment contract, or evidence that the individual has compelling reasons to travel before receiving clearance by the R/LHD TB program.
 - c) The R/LHD TB program must have reason to believe the person will attempt to fly on a commercial aircraft or leave the U.S., as

- supported by a history of frequent travel, record of ticket purchase, new ticket reservation, or stated intent to travel by the individual, a relative, or another credible source.
- d) Programs must have a concrete plan of action when a patient is intercepted by DHS partners before a DNB/LO request is submitted to the CDC. The plan should include an Order for Protective Custody, and/or a plan to transport and house the patient.
- 6. To place a patient on the DNB/LO list:
 - a) Seek consultation with TB Unit epidemiologists to review criteria. TB epidemiologists will convene a meeting with the LHP, the LHA, and the nurse case manager to discuss addition criteria and a plan of action for when the patient is intercepted.
 - b) If criteria are met, the TB Unit Epidemiology team will submit a DNB/LO request to CDC Division of Global of Migration and Health (DGMH) team.
 - c) If CDC and DHS agree the patient should be added to the DNB/LO list, a letter will be issued to the patient informing them of the travel restrictions.
 - d) The LHA or designee will notify the DSHS TB Epi team in writing when the agreed upon criteria for release from DNB/LO are met.
 - e) The TB Unit will notify the federal partners. After removal from the DNB/LO list, a new letter is issued to the patient indicating travel restrictions are no longer in place.

VI. Treatment of Drug-Resistant Tuberculosis

General Requirement

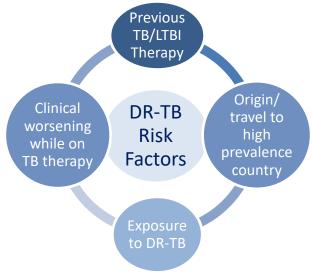
TB programs will participate in the TB Unit's DR-TB monitoring program. The purpose of the program is to collect, analyze, describe, and respond to data used in the prevention and care of DR-TB in Texas. This includes monitoring the following:

- Rifampin-resistant TB (RR TB) mono resistance to rifampin or polyresistance to include rifampin and a first-line TB drug (excluding isoniazid); this type of DR-TB is treated similarly to MDR-TB;
- Multi-drug resistant TB (MDR TB) resistance to at least rifampin and isoniazid;
- Pre-extensively drug resistant TB (Pre-XDR TB) MDR, plus resistance to one
 of the second-line injectable agents (amikacin, capreomycin, or kanamycin)
 or a fluoroquinolone (FQN); and
- Extensively drug resistant TB (XDR TB) MDR, plus resistance to one of the second-line injectables (amikacin, capreomycin, or kanamycin) and a FQN or MDR, plus resistance to a FQN, and bedaquiline or linezolid.

Activities

- A. Identify patients at risk for DR-TB (refer to *Figure 2: Identifying DR-TB Risk Factors*). Risk factors include:
 - 1. Previous episodes of TB treatment, usually incomplete treatment;
 - 2. worsening clinical and/or radiographic findings while on TB treatment;
 - 3. country of origin, history of residence in, or frequent travel to a region or country with a high prevalence of DR-TB;
 - 4. exposure to a person with known (or suspected) DR-TB; and/or
 - 5. exposure to people in congregate settings where drug resistance has been documented.

Figure 2: Identifying DR-TB Risk Factors



Source: Texas Department of State Health Services, Tuberculosis Unit, 2024

- B. Seek consultation from a <u>DSHS-recognized TB medical consultant</u> or DSHS RMD and copy the TB Unit nurse consultant within three days upon initial diagnosis or suspicion of DR-TB, whichever is sooner.
 - 1. TB programs are made aware of drug resistance when:
 - a) a patient presents with known risk factors for DR-TB;
 - b) laboratory testing supports a DR-TB diagnosis:
 - rapid testing identified from a GeneXpert-NAAT, or other PCR indicates rifampin resistance; preliminary results should be reported to the R/LHD as soon as possible while awaiting further testing;
 - (2) DST results indicate resistance. Laboratory-confirmed drug resistance is defined as resistance to isoniazid and/or rifampin or to any drug other than streptomycin or pyrazinamide mono- resistance on drug susceptibility panel testing; and/or
 - (3) patient is reported to the TB program with other laboratory results that indicate resistance including Molecular Detection of Drug Resistance (MDDR) or Whole Genome Sequencing (WGS) with rpoB mutations.
 - 2. At minimum, consultation with a DSHS-recognized TB medical consultant or RMD is **required** when:
 - a) a patient has laboratory indications of drug resistance:
 - (1) an initial notification should occur **within three days** of laboratory test result showing DR-TB. Include relevant patient demographics, risk factors for DR-TB, symptoms, test results, medications, and significant findings, until a more formal consult can be made. The purpose of the initial notification is to rapidly engage expert physician(s) and ensure the right plan of care is established.
 - (2) a formal consult should occur as soon as more diagnostics have resulted (i.e., MDDR, updated bacteriology, radiology, or laboratory tests) to determine a DR-TB regimen and case management plan.
 - b) a patient is prescribed second-line TB medications for DR-TB;
 - c) the licensed healthcare provider is requesting MDDR testing;
 - d) any time treatment regimen changes are needed, i.e., adverse drug reaction or abnormal drug levels;
 - e) upon hospital discharge (including TCID) and at least quarterly when treated as an outpatient. This will ensure medical consultants are familiar with the patient status at discharge;
 - f) a patient is approaching end of therapy <u>and</u> prior to stopping treatment; and
 - g) a patient is a contact to MDR-TB, Pre-XDR TB, or XDR-TB.

- 3. Additional consultation is strongly recommended when the patient:
 - a) has a change in status;
 - b) misses required screenings or required doses;
 - c) exhibits signs of adverse drug reactions; or
 - d) any time the licensed healthcare provider is concerned about the patient's status.
- 4. All submitted DR-TB follow-up consultations will include a <u>TB-700 (*TB Drug O Gram and Clinical Monitoring Overview*)</u> or equivalent.
- C. Coordinate with DSHS Laboratory to ensure appropriate diagnostic tests are ordered. See *Table 7: TB Diagnostic* Testing for definition, purpose, and clinical implications.
 - 1. NAAT with GeneXpert is a rapid PCR test that identifies the presence of deoxyribonucleic acid (DNA) in the *M. tb* isolate as well as assesses for mutations consistent with rifampin resistance.
 - a) NAAT with GeneXpert should be performed on at least one respiratory specimen unless drug susceptibility tests are known.
 - b) For non-respiratory specimens, coordinate with the laboratory for rapid testing if patient has risk factors for DR-TB.
 - 2. If rifampin resistance is detected, this may indicate resistance to additional first-line drugs.
 - a) Submit a specimen to DSHS laboratory for prompt DST testing to include fluoroquinolone testing.
 - b) Request an MDDR in coordination with DSHS laboratory in Austin (or locally designated laboratory). See *Appendix H:* Requesting Molecular Detection of Drug Resistance (MDDR).
 - 3. DSTs³ are performed on positive *M. tb* cultures sent to the DSHS laboratory.
 - a) If resistance to primary drugs (excluding pyrazinamide monoresistance) is detected, DSHS laboratory will reflexively perform second-line drug panel testing and will communicate directly with the submitter.
 - b) Some second-line medications cannot be tested at the DSHS laboratory; therefore, programs should communicate directly with the laboratory to coordinate additional testing.
 - 4. Outside laboratories or hospitals may also report resistance from rapid tests such as PCR; coordination with outside laboratories is recommended.
 - a) Collaborate with the outside laboratory to send initial isolate indicating resistance to DSHS laboratory for confirmatory testing and/or further diagnostics such as MDDR as soon as possible.

³ Although there are significant advantages offered by rapid molecular assays, growth-based susceptibility testing remains an integral diagnostic test to confirm molecular results. Both tests together provide the most complete information on the susceptibility of the isolate.



- D. Intervene when diagnostic tests indicate resistance if the patient is on therapy for drug-susceptible TB, such as rifampin, isoniazid, pyrazinamide, and ethambutol (RIPE).
 - 1. Consult with the LHP.
 - 2. Consider holding current drug regimen when able (i.e., patient is medically stable).
 - 3. Request a medical consult from a DSHS-recognized TB medical consultant for continuation of care.⁴
- E. Outpatient management is preferred if the patient is medically stable. Programs may consider admission to TCID and coordinate discharge when applicable.
 - 1. Admission for initial stabilization may be an option but not required.
 - 2. Admissions should be coordinated with the TCID admissions nurse.
 - a) Submit admission requests to TCIDAdmissions@dshs.texas.gov. Provide supporting documentation for the TB admissions nurse to review, as applicable and when requested.
 - TCID discharge summaries are recommendations for continued outpatient care and should not be considered as current physician orders.
 - a) TB programs are responsible for ensuring written orders are received for the patient from the local TB clinician, who may adopt the TCID orders in their entirety or make modifications after consultation from a DSHS-recognized TB medical consultant.
 - b) TB programs are responsible for ensuring all treating and diagnostic information is entered into NEDSS even if the patient is hospitalized.
- F. Order medications after consultation with a DSHS-recognized TB medical consultant or DSHS RMD and provide adequate therapy (see *Chapter XIII. Inventory Management of Medications and Supplies* for ordering details).
- G. Document case management and treatment activities on the TB Unit forms specific to DR-TB (<u>TB-700 series</u>) or their equivalent. Monthly assessments of medication toxicity specific to each medication are required and must be documented.
- H. Submit updates in NEDSS and notify the DR-TB nurse consultant of changes in drug resistance pattern, case management, or residence on DR-TB cases within 72 hours of notification.
- I. Report TB cases with drug resistant TB (except for isoniazid mono-

⁴ If the patient is hospitalized, request that the treating provider seek consultation with Heartland National TB Center.



resistance) confirmed by nucleic acid amplification test, molecular drug susceptibility testing, or phenotypic drug susceptibility testing to the TB Unit Epidemiology team using the <u>DSHS Weekly Report of New Concerning</u> Tuberculosis Event form.

- J. Participate on the DSHS quarterly DR-TB case conference calls as scheduled for each jurisdiction. Invitations will be sent to applicable programs approximately one month in advance.
 - 1. The purpose of the calls is to foster state-wide expertise in the outpatient management of DR-TB, and to provide updates on the patient's current status, issues, needs, and goals to ultimately achieve cure and prevent relapse.
 - 2. Programs must be prepared to present; use the TB-707 to guide presentations when necessary.
 - 3. Requested documents should be uploaded to NEDSS three days prior to the conference call.
 - 4. TB program managers are responsible for ensuring a nurse is available to present (including if the primary nurse case manager is unavailable).
- K. Maintain communication with the TB Unit nurse consultant, including but not limited to:
 - 1. submitting requests for information in a timely manner;
 - 2. responding to case management inquiries; and
 - 3. outlining interventions taken to prevent or respond to medication toxicity.
 - 4. Managing patients in accordance with recommendations from a DSHS-recognized TB medical consultant and the LHP for duration of therapy. If orders do not align among both entities, notify the TB Unit's DR-TB nurse consultant within one week for guidance.

VII. Conduct and Manage a Tuberculosis Contact Investigation

General Requirement

TB programs will conduct a contact investigation (CI) for people with suspected (ATS-class 5) or confirmed (ATS-class 3) pulmonary, pleural, or laryngeal TB disease and evaluate, treat, and monitor their contacts. In general, contact investigations are conducted the same whether the patient has drug susceptible TB or drug resistant TB. The goal of a CI is to find people exposed to TB who are likely to become infected or progress to TB disease to prevent further transmission.

Activities

- A. Initiate an index case CI or source case investigation (see *Figure 3: Index Case CI and Source Case Investigation Characteristics*).
 - 1. Conduct the initial interview within three working days of a patient being reported to the TB program with suspected or confirmed TB.
 - a) The interview should take place in the primary language of the patient or their representative (parent or guardian for young children or proxy for patients diagnosed at death), using an interpreter if needed. Document interpreter services on the 12-12062 (Contact Investigation Worksheet) or equivalent.
 - b) Patients who are AFB sputum smear positive and/or with chest radiography revealing cavitation must have the second interview seven days after the initial interview.
 - 2. Visit the primary residence of a patient within three working days of initial report.
 - 3. Visit additional sites where transmission may have occurred.
 - 4. TB disease in children under 5 years old is a sentinel event suggesting possible recent transmission from members of the child's environment and warrants a source case investigation. Members of the child's household should be evaluated for TB disease. Only one round of testing is required in a source case investigation

Figure 3: Index Case CI and Source Case Investigation Characteristics

Index Case Contact Investigation

- A process to identify, test, and treat persons exposed to infectious TB disease
- Looking for persons exposed to TB who may or may not have been infected
- Requires first and second round testing, based on break in contact

Source Case Investigation

- A process to identify the source of recent transmission of infectious TB disease
- Looking for a person with TB disease who is the likely source of infection for others
- Second round testing not required

Source: Texas Department of State Health Services, TB Unit, 2025

- B. Determine infectious period using <u>TB-425 (TB Infectious Period Calculation Worksheet)</u>.
 - 1. The infectious period generally begins three months before the onset of symptoms (refer to *Table 8: Estimating the Infectious Period*).
 - 2. Determine date in which contact was broken based upon:
 - a) date of physical separation from the index case; or
 - b) date the index case is no longer considered infectious based on bacteriology and treatment duration.

Table 8: Estimating the Infectious Period

Index Case Characteristics								
TB Symptoms		AFB Sputum Smear (+) Result		Cavitary CXR		Cavitary CXR		Infectious Period
Yes	No	Yes	No	Yes	No			
~			V		√	Three months before symptom onset or first positive finding* consistent with TB disease (whichever is longer)		
~		~		✓		Three months before symptom onset or first positive finding* consistent with TB disease (whichever is longer)		
	√		√		√	Four weeks before the date of suspected TB diagnosis		
	√	√		√		Three months before first positive finding* consistent with TB disease		
* Abnorma	Abnormal CXR consistent with TB or bacteriology							

- C. Prioritize all contacts into high, medium, or low categories (see *Table 9: Guidelines for Prioritizing Contacts*).
 - 1. Consider index case characteristics (e.g., site of TB disease, AFB sputum smear results).
 - 2. Consider contact characteristics (e.g., age \leq 4, HIV status, etc.).
 - 3. Calculate weekly and cumulative exposure hours.
 - a) Contacts with greatest duration of time spent with case have highest risk of exposure and should be tested first.
 - b) Expand testing to other contacts with less exposure only if significant transmission is observed.
 - 4. Consider exposure setting (e.g., size, indoors/outdoors, windows).
 - 5. Do not initiate testing without first prioritizing contacts. Unfocused testing, compromises the effectiveness of the CI, is not cost-effective and drains limited resources.
 - 6. Mask use and physical distancing of contacts (i.e., for COVID-19) during the index case's infectious period should not change the usual

contact investigation process. Contacts should be evaluated for TB based on the priority criteria outlined in *Table 9: Guidelines for Prioritizing Contacts*. Programs should continue to follow recommendations outlined in *Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis* issued by CDC.

Table 9: Guidelines for Prioritizing Contacts

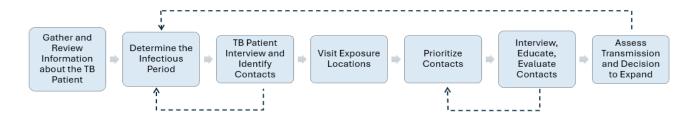
Index Case Characteristic	Contact Prioritization		
Pulmonary, laryngeal, or pleural TB Cavitary lesion on CXR; or AFB sputum smear positive	 High Priority All household contacts; or Contact in a congregate setting (schools, correctional and detention facilities, etc.) and with significant frequency and duration of exposure. Any hours of exposure for: Children <5 years; or Contact with medical risk factors (e.g., HIV, immune compromising condition); or Contact exposed during specific medical procedures (bronchoscopy, sputum induction or autopsy). Medium Priority Anyone 5-15 years who does not meet one of the high priority criteria; or Contacts with significant frequency and duration of exposure. Low Priority Only consider if expansion is warranted. 		
Suspected or confirmed pulmonary or pleural TB Abnormal CXR consistent with TB disease; and AFB sputum smear negative; and Might be NAAT positive and/or AFB culture positive	 High Priority All household contacts; and Contacts with significant frequency and duration of exposure. Any hours of exposure for: Children <5 years; or Contact with medical risk factors (e.g., HIV, immune compromising condition); or Contact exposed during specific medical procedures (bronchoscopy, sputum induction, or autopsy). Medium Priority Contact in a congregate setting (schools, detention facilities, etc.); and Contacts with significant frequency and duration of exposure. Low Priority Only consider if expansion is warranted. 		

Adapted from <u>Guidelines for the Investigation of Contacts of Persons with Infectious TB:</u>
<u>Recommendation from the National TB Controllers Association and CDC</u> and <u>Guidelines for Using QuantiFERON®-TB Gold Test for Detecting Mycobacterium tuberculosis Infection, United States,</u>
Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, 54(RR-15), 2005.

- D. Conduct first and second round screening.
 - 1. Initiate screening for high priority contacts within seven working days of identification.
 - 2. Initiate and complete first round screening within four weeks of identification.
 - 3. IGRA is the preferred testing method. TST may be used if IGRA is contraindicated or patient refuses phlebotomy.
 - 4. Avoid testing people with low risk of infection.
 - 5. A complete evaluation of a TB contact generally includes:
 - a) a contact interview to obtain relevant medical history, including specific questions about symptoms of TB disease, previous positive IGRA or TST, and/or previous treatment for TB disease or infection;
 - b) administration, reading, and interpretation of a TST or IGRA. It is not recommended to test a person with both a TB skin test and an IGRA (refer to cdc.gov/tb/hcp/testing-diagnosis);
 - c) a chest x-ray where indicated (refer to the DSHS SDOs); and/or
 - d) collection of sputum or other specimens for mycobacteriology testing for contacts suspected of having TB disease.
 - 6. Contacts with a previous positive IGRA or TST:
 - a) Previous positive IGRA or TST results must be documented. If not documented, administer a screening test.
 - b) Perform a TB signs and symptoms screening questionnaire.
 - c) If contact does not have documentation of completion of adequate therapy for LTBI, perform a chest x-ray.
 - d) Further evaluation may be indicated based on the contact's past history and current presentation during the CI. Refer to the DSHS SDOs for further guidance.
 - 7. Contacts with previous TB disease:
 - a) Previous TB disease must be documented. If not documented, administer screening test.
 - b) Perform a TB signs and symptoms screening questionnaire.
 - c) Chest x-ray may be indicated if contact has current signs or symptoms of TB or is high-risk.
 - d) Further evaluation may be indicated based on the contact's past history and current presentation during the CI. Refer to the DSHS SDOs for further guidance.
 - 8. Contacts Lost to Follow Up (LTFU)
 - a) Make at least three attempts to contact a TB contact before considering them as LTFU, including:
 - (1) calling the contact;
 - (2) visiting the contact's residence; and
 - (3) sending a certified-mail notification of the contact's need to follow up with the TB program.
 - b) Document attempts in the progress notes of contact's record.

- c) Place certified mail notification receipt in the contact's chart.
- 9. Begin second round screening eight to ten weeks after break in contact or after the end of the index case's infectious period, whichever is first.
 - a) Retest all contacts whose initial IGRA or TST results were negative after documented contact break with the index or after the end of the index case's infectious period, including contacts started on window prophylaxis. Contacts should be tested with the same screening test used during the first round of testing.
 - b) Contacts whose IGRA or TST results are negative and who are asymptomatic at second round testing have received a complete evaluation.
 - c) If a contact was identified after first round screening was initiated, they are still eligible for second round screening.
 Perform one test eight to ten weeks after break in contact for a complete evaluation.
 - d) For source case investigations, second round testing is not required.
- E. Consider CI expansion if the infection rate is high or if TB transmission is detected. Refer to <u>TB-460 (*TB Contact Investigation Expansion Analysis Checklist*).</u>
 - 1. TB infection among high priority contacts indicates transmission.
 - a) The TB Unit generally uses an infection rate of ≥ 20%. This percentage should be modified based on sentinel events and local data.
 - b) An investigation should not be expanded without first reviewing screening results among high priority contacts.
 - 2. Other indicators of transmission include:
 - a) positive tests in contacts aged 4 and younger;
 - b) positive tests in contacts that are HIV positive or otherwise immunocompromised;
 - c) a change in TST or IGRA status from negative to positive among contacts between first and second-round testing; and
 - d) contacts diagnosed with TB disease.
 - 3. For source case investigations, expansion should be considered until the infectious source is identified, regardless of the presence or absence of other transmission indicators.
 - 4. As needed, request a consultation with TB Unit Epidemiology team to discuss whether an expansion tolow priority contacts is warranted. Submit consultation requests by emailing TBEpi@dshs.texas.gov.
 - 5. Refer to Figure 4: Steps in a CI.

Figure 4: Steps in a CI



Source: Texas Department of State Health Services, TB Unit, 2025

- F. Conduct a follow-up investigation for all TB isolates identified as *M. bovis*:
 - 1. Ask about a history of consuming raw, unpasteurized dairy products or exposure to livestock.
 - 2. If exposure to either is identified, investigate location of exposure.
 - 3. If a Texas dairy or livestock area is identified, contact the TB Unit Epidemiology team (tbepi@dshs.texas.gov) to determine if reporting to appropriate partner state agencies is warranted.
- G. Notify the TB Unit Epidemiology team of large-scale or concerning CIs within 48 hours of meeting following criteria:
 - > 50 people identified for screening in a single location;
 - > 25 people in a child daycare or K-12 school;
 - media involvement; and/or
 - any other exposures deemed concerning by the R/LHD
 - 1. Submit either the DSHS form 12-12063 (TB Corrections Incident Report) for any large-scale or concerning CI in a correctional facility or 12-12104 (TB Incident Report) for all other CIs. Attach the form to the patient's investigation in NEDSS and email TBEpi@dshs.texas.gov to notify the TB Unit Epidemiology team.
 - 2. The TB Unit Epidemiology team will review the submitted Incident Report form and schedule a consultation meeting with the R/LHD, if necessary. Consultations must occur before testing is initiated. Consultation will include but is not limited to discussion of:
 - a) clinical presentation, bacteriologic status, and radiologic results;
 - b) medical and social history;
 - c) infectious period;
 - d) environmental assessment of site(s) of transmission;
 - e) incident response plan, including screening dates and tests to be used;
 - f) contact investigation forms;
 - g) second round testing dates (planned);
 - h) results of epidemiologic assessment and next steps; and
 - i) other relevant details.
 - 3. Submit timely written updates to the TB Unit as updates are available. These may include:



- a) bacteriologic or radiologic results;
- b) environmental assessments;
- c) contact prioritization;
- d) screening dates;
- e) screening methods (TST/IGRA);
- f) evaluation results for first and second round screening; and
- g) other relevant details.
- 4. Submit a final update to the TB Unit Epidemiology team after the investigation is closed.
- 5. Large-scale screenings using DSHS-purchased supplies should not be performed without prior TB Unit approval. TB testing activities should not include low-priority contacts unless further expansion is warranted.
- 6. Submitting information through the DSHS form 12-12104 (*TB Incident Report*) or 12-12063 (*TB Corrections Incident Report*) does not replace data entry in NEDSS.
- H. Conduct interviews throughout the patient's treatment period.
 - 1. For all contacts, document the date of identification and the date of break-in-contact with the index on the <u>TB-341 (Continuation Report of People Exposed to TB)</u> and in NEDSS.
 - 2. Re-interview patient one to two weeks after initial interview to obtain and/or clarify missing data. Consider using different interviewers.
 - 3. Additional patient and contact interviews may be required when:
 - a) drug susceptibility results indicate drug resistance; or
 - b) genotyping results indicate patient is part of a cluster.
- I. Coordinate CI activities with medical staff and administrators in congregate settings within the TB program's jurisdictions. Refer to *Table 2: Coordination of Care for TB Management.*
 - 1. Collect names and evaluation results of contacts in congregate facilities.
 - 2. Collect names and locating information for community contacts.
 - 3. Provide technical assistance and guidance when necessary.
 - 4. Consult TB Unit Epidemiology team as needed.
 - 5. Use the <u>TB-342 and TB-343</u> to report investigations in correctional settings.
 - 6. Large-scale screenings in correctional setting that meet the criteria outlined in subsection G, should be reported using form 12-12063 (TB Corrections Incidence Report).
 - 7. All applicable CI forms are located here: <u>dshs.texas.gov/tuberculosis-tb/texas-dshs-tb-program-tb-forms-resources#ci</u>.
- J. Conduct airline exposure screening based on notifications received from the TB Unit Epidemiology team via CDC Division of Global Migration and Health (DGMH).
 - 1. TB Unit Epidemiology team will provide contact information for people

- exposed to an infectious TB case on any flight that lasted 8 hours or more.
- 2. TB program staff will locate contacts and complete screening. Initiate evaluation of airline contacts within two weeks of notification.
- 3. TB program staff will complete the DGMH TB Air Contact Investigation Outcome Reporting Form. Submit the completed form and screening test results via NEDSS or GlobalScape to the TB Unit Epidemiology team within one month of notification. Notify the TB Unit Epidemiology team of the submission via TBEpi@dshs.texas.gov.
- K. Follow CI guidance in special circumstances.
 - 1. Coordinate CI activities in correctional and detention facilities.
 - a) Maintain a formal collaboration between public health officials, the R/LHD, and correctional facility. If collaboration has not been established before a CI is needed, creating this relationship as part of the investigation is necessary.
 - b) Conduct an interview to identify contacts and determine an inmate's infectious period.
 - c) Provide TB education and counseling to patient.
 - d) Assess TB transmission risk based on the index case's degree of infectiousness, length of exposure to index, environmental factors, and contact characteristics (e.g., HIV infection).
 - e) Evaluate contacts identified based on priority classification outlined on *Table 9: Guidelines for Prioritizing Contacts* (TB testing may be conducted by the TB program or the facility medical staff under the strict guidance of the TB program).
 - (1) Because of rapid turnover of inmates and crowding, ensure there is a process of assigning priority schemes. Unless tracking records for inmates who were in a confined space with an infectious TB patient allow a determination that aggregate expose was brief (e.g., <8 hours), these contacts should be assigned high priority.
 - (2) High priority contacts who are transferred, released, or paroled from a correctional facility before medical evaluation for TB should be traced and evaluated.
 - (3) Ensure that contacts start and complete treatment for TB infection or TB disease, as indicated.
 - Submit <u>DSHS form 12-12063 (TB Corrections Incident Report)</u> as indicated based on the number of contacts identified and type of congregate setting.
 - 2. Coordinate CI activities in congregate settings.
 - a) Maintain a formal collaboration between public health officials, R/LHD, and congregate setting facility. If collaboration has not been established before a CI is needed, creating this relationship as part of the investigation is necessary.



- b) Provide TB education and counseling to patient.
- c) Information should be shared with managers, supervisors, or administrators only be shared on a need-to-know basis.
- d) Assess TB transmission risk based on the index case's degree of infectiousness, length of exposure to index, environmental factors, and contact characteristics (e.g., HIV-infection).
- e) Evaluate contacts identified based on the priority classification outlined in *Table 9: Guidelines for Prioritizing Contacts* (TB testing may be conducted by the TB program or the congregate setting facility medical staff under the strict guidance of the TB program).
- f) Ensure that contacts start and complete treatment for TB infection or TB disease, as indicated.
- g) If possible, testing for contacts identified in a congregate setting should be performed on site. Testing activities should be done in coordination with facility officials (e.g., managers, supervisors, or administrators). Refer to *Table 2: Coordination of Care for TB Management*.
- h) Submit <u>DSHS form 12-12104 (*TB Incident Report*)</u> as indicated based on the number of contacts identified and type of congregate setting.

VIII. Manage Contacts to Confirmed or Suspected Tuberculosis Cases

General Requirement

TB programs will evaluate, treat, and monitor contacts to suspected or confirmed cases of pulmonary, pleural, or laryngeal TB disease in accordance with current DSHS SDOs.

Activities

- A. Evaluate high priority contacts. Consider testing results of high priority contacts before addressing any medium or low priority contacts.
 - 1. Conduct medical evaluations of high priority contacts. If the CI is expanded, evaluate medium-priority contacts before expanding to low priority contacts.
 - 2. Face-to-face physician medical evaluation at diagnosis is preferable for initiation of treatment or resumption of medications.
 - 3. Obtain chest radiography within 10-14 calendar days for contacts, as specified in the DSHS SDOs (R/LHDs with onsite radiograph equipment should obtain a CXR within 10 calendar days and if offsite, within 14 days). This includes, but is not limited to, contacts who:
 - a) have a positive initial IGRA or TST result, and no history exists of a previously positive TB test;
 - are high risk for progression to TB disease, regardless of previous history of TB infection or disease, and regardless of initial IGRA or TST result; or
 - c) report signs and symptoms of TB regardless of IGRA or TST result.
 - 4. Assess for TB disease if a contact tests positive and exhibits symptoms of TB disease and/or has an abnormal chest radiography.
 - 5. If the IGRA or TST result is positive and the chest radiography is normal and/or TB disease has been ruled out, consider treatment for TB infection.
 - 6. If a previously positive contact did not complete adequate treatment for TB infection, evaluate for TB disease, which includes a symptom review and a chest radiography. If there is no indication of disease, consider treatment for TB infection.
 - 7. If a previously positive contact completed treatment for TB infection, further treatment may not be required unless recommended by the LHP. A complete evaluation for contacts that completed previous adequate treatment requires symptom screening.
 - 8. Review and assess completeness of the contact's medical evaluation once evaluation is complete.
- B. Consider the index's DST results when determining a contact's treatment.

- 1. All contacts to RR, MDR-TB, pre-XDR or XDR TB cases who test positive for infection or are a candidate for window prophylaxis must receive a consult from a DSHS-recognized TB medical consultant.
- 2. For contacts treated with INH in the past and are now exposed to an INH-resistant case, treatment with a rifamycin may be needed for the new exposure.
- 3. Provide DOT for contacts to MDR, pre-XDR, or XDR TB cases who are diagnosed with TB infection; consider VDOT as resources allow.
- 4. For previous positive contacts who are now a contact to MDR-TB, pre-XDR, or XDR-TB regardless of previous treatment, evaluate for TB disease with a signs and symptoms questionnaire and a chest x-ray.
- 5. Any contact exposed to MDR-TB, pre-XDR, or XDR TB cases with a positive TST or IGRA test should receive symptom screening and a CXR every six months for a period of two years (from the date of break in contact), regardless of whether treatment was taken for TB infection.
- C. Follow DSHS SDOs in determining treatment regimens.
 - 1. Provide medications in accordance with DSHS SDOs.
 - 2. Document completion of treatment on the appropriate reporting form such as <u>TB-400A</u> (*Report of Case and Patient Services*) or equivalent.
 - 3. Document reason(s) medication was stopped if treatment was not completed.
 - 4. Conduct minimum monthly reviews of adherence to treatment for TB infection.
 - 5. Conduct minimum monthly reviews to identify adverse reactions to treatment for TB infection.
 - Contacts receiving treatment for TB infection who develop signs and/or symptoms suggestive of TB disease should have medications held and receive a follow-up chest radiography before continuing treatment for TB infection.
- D. Provide window prophylaxis until a complete evaluation is documented.
 - 1. Window prophylaxis is treatment for *possible* latent TB infection. It is provided to vulnerable contacts who:
 - a) are at high risk of progressing to severe forms of TB (i.e., meningitis);
 - do not have current TB signs or symptoms, have a negative TB screening test and a CXR not consistent with TB on first-round screening; and
 - c) are prophylactically treated for TB infection during a "window period" between their TB exposure until their second-round screening test can be confirmed eight to ten weeks after their break in contact or last exposure.
 - 2. The decision to provide window prophylaxis is based on a LHP's evaluation of the patient, ensuring TB disease has been ruled out prior

to therapy.

- 3. All efforts should be made to begin window prophylaxis as soon as possible, but no longer than 14 days after identification; treatment should be provided by directly observed preventative therapy (DOPT) where possible.
- 4. The following groups should be offered window prophylaxis:
 - a) Children under five years of age
 - b) Patients with HIV infection
 - c) Patients receiving immunosuppressive therapy for organ transplantation
 - d) Patients taking TNF-a inhibitors
- 5. If the repeat TB screening test remains negative eight to ten weeks after break in contact for children under five years of age, window prophylaxis treatment can be discontinued.
 - a) Infants aged five months and younger should continue window prophylaxis until they undergo a repeat TST or IGRA at six months of age. Refer to the DSHS SDOs for more details.
- 6. If the repeat TB screening test remains negative eight to ten weeks after break in contact to index case (beyond the window period), it is recommended that the following groups complete a full course of treatment for latent TB infection, as per DSHS SDOs:
 - a) Patients with HIV infection
 - b) Patients receiving immunosuppressive therapy for organ transplantation
 - c) Patients taking TNF-a inhibitors
- E. Maintain a medical record for each person on treatment for TB infection, including those on window prophylaxis. Refer to *Chapter IX. Manage Patients with Tuberculosis Infection*.

IX. Manage Patients with Tuberculosis Infection

General Requirements

It is the responsibility of the R/LHD to ensure patients with TB infection are offered and encouraged to complete treatment for TB infection.

Activities

- A. Establish and maintain a medical record for each person with TB infection. Medical records may be maintained in an EMR or on paper.
 - 1. Organize medical records with sections clearly divided and/labeled. See #10 for required sections for paper records.
 - Ensure all patient-specific documents are securely attached (if paper) or uploaded (if EMR) to the medical record. This may include laboratory results (e.g., electronic laboratory reports [ELRs] that are obtained from NEDSS or other databases), consultation emails, hand-signed consents, photographs, or other information gathered for patient care. See #9 below.
 - 3. Provide accurate and complete documentation.
 - 4. Date and sign all entries in the progress notes; if written on paper, draw a line through each blank section.
 - 5. Document in chronological order with the most recent information placed on top (if a paper record).
 - 6. Draw a single line through errors and initial (if a paper record) or notate errors (as per EMR).
 - 7. Do not document outside the margins if documenting on paper.
 - 8. Establish a locally approved list of abbreviations (e.g., noting "wt." for "weight"). Maintain the list in a locally approved and designated place for consistency and clarity among records.
 - 9. EMRs⁵ should contain the relevant information that is captured on applicable <u>DSHS TB Unit forms</u>. Programs may choose to use TB forms as templates in the EMR or use the TB Unit forms as a guide for pertinent medical record documentation that apply to the patient.
 - 10.Paper medical records should have clearly divided sections (recommended sections in bold, below). Records must include at minimum the information as per the following <u>DSHS TB Unit forms</u> or equivalent⁴:
 - a) **Demographics, Case Information**
 - (1) TB-400A (Report of Case and Patient Services)-

⁵ EMRs replace the need for paper records and therefore may not contain exact matches of a TB form. For example, a TB 400A may not be an exact template in an EMR, but the relevant information captured on the TB 400A should be included in the medical record. In addition, information that is entered or electronically imported into NEDSS may be printed and attached to the medical record to avoid duplicate data entry.

completed initially and when orders change; as needed; at closure.

b) Case Management Plan and Patient Education

- (1) TB 203 (Education/Counseling Record)
- (2) TB-204 (*Tuberculosis Forms/Literature Checklist*) may be modified with locally preferred literature.
- c) **Medical History**
 - (1) TB-202 (*Tuberculosis Health Assessment/History*) applicable sections only.
- d) **Radiology Reports** (performed initially, as ordered)
- e) **Laboratory Results** (i.e., CMP, CBC, LFTs, HIV, etc.)
- f) Monthly Toxicity Assessments
 - (1) TB-205 (*Toxicity Assessment*)
- g) Directly Observed Therapy Logs and Treatment Orders
 - (1) TB 206 (DOT Log) if applicable
- h) Consent Forms
 - (1) L 36 (General Consent and Disclosure)
 - (2) L 30 (Consent to Release Confidential Medical Information) if releasing confidential information
 - (3) TB-415 (Medication Consent for LTBI Therapy)
- i) **Outside Records**, i.e., primary care provider records.
- j) Medical Consults
- k) Progress Notes
- I) **Miscellaneous** (email communication, fax confirmations, etc.).
- B. Conduct and document an evaluation in accordance with DSHS SDOs.
 - 1. Screen for TB signs and symptoms.
 - 2. Collect patient medical and social history.
 - 3. Conduct physical exam and nursing assessment.
 - 4. Collect baseline laboratory as indicated in the DSHS SDOs.
 - 5. Obtain chest x-ray prior to starting treatment for TB infection.
 - 6. Screen for existing comorbid conditions (e.g., diabetes, HIV, hepatitis B and C, per SDOs).
- C. Provide and document initial and ongoing patient education to include:
 - 1. transmission and pathogenesis of TB;
 - 2. rational for DOT, if applicable;
 - 3. importance of completing treatment;
 - 4. adverse drug reactions and drug interactions of medications; and
 - 5. the need for patients to discuss adverse drug reaction symptoms and other concerns with nurse case manager as soon as they occur.
- D. Initiate treatment as ordered.
 - 1. Follow the recommended drug regimens for treatment of INH-and Rifsusceptible TB infections as indicated in the SDOs.
 - 2. Short course regimens are preferred to six-or nine-month INH regimens.

- 3. LHPs should familiarize themselves with drug-drug interactions to provide the best treatment options for the patient.
- 4. Provide DOT until completion of therapy for the following patients:
 - a) Those prescribed intermittent regimens (self-administration may be considered on select patients on 3HP if specified by the LHP. Refer to DSHS SDOs).
 - b) Contacts to RR-TB, MDR-TB, pre-XDR TB, or XDR-TB.
 - c) Children less than five years old should be highly considered for DOT.
- 5. Follow indications for window prophylaxis as per the DSHS SDOs.
- E. Conduct baseline and monthly clinical monitoring and evaluation for TB medication toxicity.
 - 1. If signs or symptoms of medication toxicity develop, obtain a clinical evaluation with the LHP as soon as possible.
 - 2. Conduct monthly follow-up laboratory tests and assessments as indicated, document results and interventions as necessary.
 - 3. If TB signs or symptoms develop during treatment for TB infection, notify the LHP immediately.
- F. Close the patient's medical record using the following dispositions:
 - 1. Completed adequate therapy; indicate number of months on medication and number of months recommended
 - 2. Deceased (cause)
 - 3. Moved out of state/country to
 - 4. Patient chose to stop treatment
 - 5. Adverse drug reaction
 - 6. Provider decision-pregnant, non-TB
 - 7. Lost to Follow Up:
 - a) For high-risk patients, make at least three attempts to contact the patient before considering a patient as LTFU, including:
 - (1) calling the patient;
 - (2) visiting the patient's residence; and
 - (3) sending a certified-mail notification of the patient's need to follow-up with clinic.
 - b) Document attempts in the patient's medical record.
 - c) Place certified mail notification receipt in the patient's medical record.

X. Manage False Positive Investigations

General Requirement

TB programs will manage false positive investigations in accordance with local protocols and procedures. TB programs may initiate a false positive investigation independent of the TB Unit but should notify the TB Unit when a new false positive investigation is initiated.

Activities

- A. Determine the need for a false positive investigation when:
 - 1. a single positive culture for M. tb exists for a patient; and/or
 - 2. the LHP suspects the clinical presentation is not consistent with culture findings.
- B. Notify the LHA if a false positive investigation is warranted and consider consulting with a DSHS-recognized TB medical consultant.
- C. Initiate the false positive investigation.
 - 1. Complete the <u>False Positive Investigation Worksheet</u> or equivalent.
 - 2. Contact the originating laboratory to determine source of false positive result (e.g., laboratory contamination vs. specimen collection error).
 - 3. Consult with the TB Unit Epidemiology team to obtain and review genotyping and whole genome sequencing data to support the investigation.
 - 4. Upon conclusion, provide a summary of the investigation results to include in the patient record, if warranted.
- D. Request TB Unit assistance as needed.
 - 1. Attach the completed <u>False Positive Investigation Worksheet</u> with supporting documentation to the patient's record in NEDSS and email TBepi@dshs.texas.gov to notify the TB Unit Epidemiology team.
 - 2. The TB Unit will convene a meeting to discuss findings and provide documentation to the requesting TB program summarizing investigation results and conclusions. This summary will only be offered if DSHS is engaged and coordinates the investigation.
 - 3. The TB Unit cannot provide treatment recommendations or confirm/refute the possibility of false positive culture results. TB is a clinical diagnosis and the patient's treatment plan should always be directed by clinical findings as determined by the LHP in conjunction with laboratory information.
- E. Report closed cases due to false positive results to the TB Unit Surveillance team with supporting documentation (e.g., amended laboratory report, medical consultation, provider notes) justifying change incase status within 45 days of closure.

XI. Manage Electronic Disease Notification System and Other Foreign-Born Referrals

General Requirement

TB programs will screen and evaluate non-U.S. born persons referred to the R/LHD for a TB evaluation based on their TB classification as assigned by a panel physician or civil surgeon. This includes accepting referrals from the Electronic Disease Notification (EDN) system or referred by the LHD refugee program.

The EDN is a national web-based system developed and supported by CDC that provides overseas TB screening and treatment information and domestic follow-up information for refugees and immigrants with health conditions requiring medical follow up upon their arrival to the U.S.

Activities

- A. Prioritize referrals and evaluate the following non-U.S. born people for TB in accordance with DSHS SDOs:
 - People from countries with a high prevalence of TB, defined as countries with a TB rate ≥20 cases/100,000 (see who.int/tb/country/data/profiles/en/ and Table 10: Prioritizing Evaluation of TB Infection for Foreign-Born People).
 - 2. Prioritize class A and B immigrants (see *Table 11: Immigrant Classifications in EDN*).
 - a) Priority should be given to class A and B1 designations. These are individuals who may have active TB or who are HIV positive, but not infectious.
 - b) The next priority is children under age 5 years with a TB class B2. These are children diagnosed with LTBI.
 - c) Next, prioritize class B3. These are individuals considered close contacts to someone with TB.
 - d) Finally, screen class B0s and class B2s over age 5 years, as resources allow.
 - 3. Status adjusters.
 - a) Civil surgeons must not refer applicants to a health department for IGRA testing or chest x-ray; all IGRAs and chest x-rays ordered by civil surgeons must be performed independently of a health department unless the civil surgeon is part of the health department.
 - b) If an applicant has a positive IGRA, but has no signs or symptoms of tuberculosis disease, a negative chest x-ray, and no known HIV infection, the civil surgeon should provide a diagnosis. If the diagnosis is a classification of Class B2 TB, latent TB infection, the civil surgeon should report to the health department of jurisdiction. Civil surgeons should communicate

proactively with the health department in their jurisdiction to coordinate reporting.

Table 10: Prioritizing Evaluation of TB Infection for Foreign-Born People

Category	Description	Medical Exam Site	How they are referred to the TB program		
High Priority for Services Provided by the TB Program					
Refugees	A person who comes from another country after fleeing war, persecution, or other reasons and are unwilling or unable to return to that country because of persecution or a well-founded fear of persecution because of race, religion, nationality, membership in a social group, or political opinion.	Contracted LHDs that perform refugee health assessment activities.	Referred by the LHD refugee health program for refugees who have a positive TB screening result. The R/LHD TB program is responsible for additional evaluation and treatment when indicated.		
Immigrants Seeking Formal Permanent Residence	A person who comes from another country to live in the U.S. Citizens of foreign countries who would like to obtain permanent resident status in the U.S. must obtain visas (i.e., family, employment, fiancé and diversity-based such as "lottery" visas) See travel.state.gov/content/travel/en/us-visas/immigrate.html.	Initial screening occurs via a panel physician overseas. Upon U.S. arrival, evaluation occurs at the R/LHD.	Referred through the EDN system once the panel physician provides a TB classification. TB programs must perform a full evaluation.		

Category	Description	Medical Exam Site	How they are referred to the TB program
Status Adjusters	People in the U.S. applying for adjustment of status to a permanent resident of the U.S.	Initial screening occurs via a civil surgeon domestically.	Referred from a civil surgeon when: 1. There is suspicion of TB disease. 2. Applicant has HIV infection (regardless of screening results). 3. Applicant has confirmed extra-pulmonary TB. If an applicant has a positive IGRA, but has no signs or symptoms of TB disease, a negative chest x-ray, and no known HIV infection, the civil surgeon should provide a diagnosis. If the diagnosis is a classification of class B2 TB, LTBI, the civil surgeon should report to the health department. Civil surgeons must not refer applicants to a health department for IGRA testing or chest x-ray; all IGRAs and chest x-rays ordered by civil surgeons must be performed independently of a health department unless the civil surgeon is part of the health department. The civil surgeon may offer treatment for LTBI.
Parolees	Populations who are fleeing war or violence and who enter the U.S. seeking permanent residence. These immigrants may seek humanitarian parole once in the U.S., as directed by various federal agencies: • Department of Homeland Security that outline various parolee programs	R/LHD	Reporting to TB program may vary based on the government program. New arrivals may self-report or be referred by a sponsor or a LHD refugee program. Parolees may need an attestation regarding their TB screening.

Category	Description	Medical	How they are referred to
Category	-	Exam Site	the TB program
	 (i.e., Uniting for Ukraine): dhs.gov. U.S. Citizenship and Immigration Services that define parole status. Refer to uscis.gov/humanitarian/humanitarianp ublicbenefitparolein dividualsoutsideUS. 		
Unaccompanied Children (UAC)	According to the Office of Refugee Resettlement (ORR), an UAC is " a child who (A) has no lawful immigration status in the United States; (B) has not attained 18 years of age; and (C) with respect to whom: 1) there is no parent or legal guardian in the United States; or 2) no parent or legal guardian in the United States available to provide care and physical custody." Refer to acf.hhs.gov/orr/policy-guidance/unaccompanied-children-program-policy-guide.	Initial screening occurs at a shelter housing UAC.	UAC are transferred to the custody of the ORR and initial screenings occur at ORR-designated facilities. A custodian from a designated ORR-facility will accompany child to the R/LHD if further evaluation services are needed.
Prioritize Based	on Local Resources A	vailable at the	R/LHD
Other Immigrants	Include migrants entering the U.S. with or without documentation.	N/A	Incidentally if evaluated by a clinician; may self-refer. Evaluate as resources allow.
Non-Immigrants	Tourists, students, and specialty workers who obtain visas for non-permanent stays in the U.S.; these visas do not permit the person to live	May be required for a medical exam at the discretion of the consular officer	Incidentally if evaluated by a clinician; may self-refer. Evaluate as resources allow.

Category	Description	Medical Exam Site	How they are referred to the TB program
	indefinitely in the U.S. They include Business (B-1), Tourism (B-2), Student (B, F, or M), and Visas for temporary travel. Refer to travel.state.gov/cont ent/travel/en/usvisas/tourismvisit/visitor.html.	overseas or immigration officer at the U.S. port of entry.	
Short-Term Transit	Transit (C) Visas for people traveling in immediate and continuous transit through the U.S. to another country. See travel.state.gov/cont ent/travel/en/us-visas/other-visa-categories/transit.ht ml.	N/A	Incidentally if evaluated by a clinician after interruption in travel and stay in U.S.; may self-refer. Evaluate as resources allow.

Adapted from: CDC Immigrant and Refugee Health. (2014, May 15). Tuberculosis: Refugee Health Domestic Guidance. cdc.qov/immigrant-refugee-health/hcp/domestic-quidance/tuberculosis.html.

- B. Evaluate immigrants with an A or B Classification referred from EDN System.
 - 1. Use the EDN system to access records assigned to the TB program.
 - a) All funded local TB programs and public health regions must access EDN to view notification of immigrants' arrival in their jurisdiction and evaluate all class A and B immigrants assigned to their jurisdiction (refer to *Table 11: Immigrant Classifications in EDN*). Contact the TB Unit to obtain EDN access.
 - b) Identify at least two people to be assigned to retrieve notifications, enter evaluation and treatment on the TB Worksheet, and perform a final review of the TB Worksheet.
 - c) Notify the receiving jurisdiction when a class A or B immigrant moves and enter the new address in the EDN. By providing the new location in EDN, CDC will initiate the transfer and reassign all electronic information to the receiving jurisdiction. Note: once a new address is entered, this patient is no longer visible in the referring jurisdiction's queue.
 - d) Contact the TB Unit Epidemiology team via TBEpi@dshs.texas.gov for any questions on EDN referrals.

Table 11: Immigrant Classifications in EDN

Classification	Definition
Class A, TB Disease	All applicants who have TB disease, including those with extrapulmonary TB who have a CXR suggestive of pulmonary TB regardless of sputum smear and culture results.
Class B0, Pulmonary TB	Individuals who were diagnosed with TB disease by the panel physician or presented to the panel physician while on TB treatment and successfully completed Division of Global Migration and Health (DGMH)-defined DOT under the supervision of a panel physician prior to immigration.
Class B1, Pulmonary TB	Individuals who have TB signs and symptoms, a physical exam or CXR suggestive of TB disease, or have known HIV infection, but have negative AFB sputum smears and cultures and are not diagnosed with TB disease. Or individuals diagnosed with TB disease by the panel physician but who did not receive treatment through DGMH-defined DOT under a panel physician and return after treatment and completion of 1-year wait period.
Class B1, Extrapulmonary TB	Individuals diagnosed with extrapulmonary TB with normal CXR and negative sputum AFB smears and cultures.
Class B2 TB, LTBI	Individuals who have a positive TST or a positive IGRA but otherwise have a negative evaluation for TB. If the individual is a contact with a TST ≥5mm or + IGRA, they will receive a B2 and a B3 classification.
Class B3 TB, Contact Evaluation	Applicants who are a recent contact to a known TB case, regardless of IGRA or TST results. If the IGRA or TST is positive and there is no evidence of TB disease, there will be two classifications, B2 and B3; if negative, B3 only.
Adapted from: Centers for Disease Control and Prevention. (2012, April 16). Guidelines for Screening for Tuberculosis Infection and Disease During the Domestic Medical Examination for Novely, April 2018, CDC Stacks, stacks and population (2018).	

Newly Arrived Refugees. CDC Stacks. stacks.cdc.gov/view/cdc/30686.

- 2. Initiate an appropriate medical evaluation within 30 days of notification and document on the Follow-Up Worksheet (see Appendix P: Electronic Disease Notification (EDN) Follow-Up Worksheet).
 - a) Contact the patient within three working days of notification to schedule an evaluation.
 - b) If a phone number is not available or if there is no response to the phone call within seven working days, send a letter to the home address listed in the EDN documents.
 - c) If the only address listed is for a sponsor agency, contact the sponsor agency to verify the patient's address.
 - d) If there is no response to the letter within ten working days from date sent, conduct a home visit.

- e) If all attempts to locate patient have failed, close the record and enter "lost to follow up" on the EDN TB Follow-Up Worksheet.
- 3. Complete the medical evaluation for all class-B immigrants within 120 days of notification.
 - a) Review all pre-departure medical records.
 - b) Obtain a thorough medical history to include:
 - (1) previous history of TB;
 - (2) signs and symptoms of TB disease;
 - (3) prior BCG vaccination;
 - (4) prior treatment TB treatment;
 - (5) prior diagnostic evaluation for TB; or
 - (6) history of family or household contact with a known person having a history of TB disease, treatment for TB disease, or diagnostic evaluation suggestive of TB.
 - c) Consider the following for children in this population:
 - (1) A history of recurrent pneumonia, failure to thrive, and/or recurrent or persistent fevers. Any of these should increase the provider's index of suspicion.
 - (2) Children experience higher rates of extrapulmonary TB disease, including meningitis and disease of the middle ear and mastoid, lymph nodes, bones, joints, and skin.
 - d) For more details, see CDC's guidance for TB screening during the domestic medical examination for newly arrived refugees: CDC Guidance for TB Screening for Arrived Refugees.
- 4. Evaluate and treat status adjusters referred to the R/LHD after evaluation from a civil surgeon.
 - a) Evaluate status adjusters referred by a civil surgeon to the R/LHD for TB disease management based on recommendations outlined in the SDOs and CDC's <u>Tuberculosis Technical</u> <u>Instructions for Civil Surgeons</u>.
 - (1) Status adjusters with an abnormal chest x-ray suggestive of infectious tuberculosis disease, clinical signs and symptoms suggestive of infectious tuberculosis disease, known extra-pulmonary TB, or known HIV infection will be referred to the R/LHD for further evaluation.
 - (2) Referrals will include the IGRA result, chest x-ray report and images, description of any signs or symptoms, the approximate date of U.S. arrival, and reason for referral.
 - (3) Per CDC's <u>Technical Instructions</u>, R/LHD must collect sputum for AFB smear and culture with three early morning specimen collected at least 24 hours apart, preferably on consecutive days, with each specimen observed. If not possible, R/LHDs should follow at minimum sputum collection criteria as per SDOs.



- (4) For patients with negative culture results for whom infectious tuberculosis has been ruled out, the R/LHD should sign the referral section of USCIS form I-693. For patients with positive culture results, form I-693 should only be signed after completion of adequate tuberculosis disease treatment and at least two consecutive negative cultures are obtained.
- b) Status adjusters with LTBI will be reported to the R/LHD via EDN. Evaluation for persons with LTBI should be completed by the civil surgeon.
 - (1) Civil surgeons can treat status adjusters for LTBI. Alternatively, the R/LHD may also treat status adjusters for LTBI.

XII. Conduct Targeted Testing

General Requirement

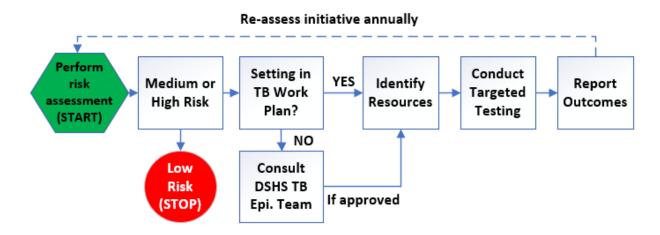
Targeted testing is a strategy to identify, screen, evaluate, and treat populations at high risk for TB infection or increased risk for progression to TB disease. Following this principle, targeted testing should only be conducted among groups at high risk and discouraged in those at low risk. TB programs will identify medium to high-risk groups in congregate and non-congregate settings for which testing for TB infection and disease is justified. Dependent on an epidemiological assessment that explains a critical need, TB programs will conduct targeted testing according to DSHS standards.

Activities

- A. Develop a targeted testing initiative to identify and treat population groups at high risk for TB exposure or associated with an increased risk of progression of TB infection to TB disease.
- B. Ensure TB Unit guidelines are followed for each new targeted testing initiative.
 - 1. Make a site selection only when an epidemiologic risk assessment determines the facility or group is considered high-risk for TB and targeted testing is a reasonable response to prevent a recurrence of TB disease transmission. Use the TB-500 (Congregate Settings TB Risk Assessment).
 - 2. Identify the necessary resources for follow-up medical evaluation and treatment before initiating testing activities. Base decisions to conduct targeted testing on the ability to provide treatment services. A decision to test is a decision to treat.
 - a) Offer treatment for TB infection unless medically contraindicated once TB disease has been ruled out.
 - b) Document the clinician's reason in the medical records as to why treatment was not recommended (e.g., alcohol addiction, drug abuse, mental illness, unstable housing, deportation, etc.).
 - 3. Focus TB testing activities *only* among medium to high-risk groups in congregate settings or non-congregate settings. Unfocused population-based testing is not cost-effective and drains limited resources.
 - 4. Use the DSHS form TB-207 (Targeted Tuberculin/IGRA Testing Screening Form). Complete this form for any client receiving or requesting a tuberculin skin test, such as persons targeted for screening, or walk-ins requesting a test. This form can be used as a screening tool to determine if testing is indicated and as a tool to document risk prior to testing. It can also be used to document a symptom review for a person with a history of TB infection or disease.
 - 5. Conduct testing using TST or IGRA in accordance with DSHS-approved age requirements.
 - 6. Assess effectiveness of targeted testing projects based on:

- a) TB infection and TB disease yield;
- b) likelihood of identifying infected people that will progress from TB infection to TB disease (risk classification); and
- c) TB infection and TB disease treatment completion rates.
- 7. Base the decision to *continue* targeted testing by performing annual assessments, if not sooner to determine if the sites:
 - a) continue to have risk factors for TB, as determined by the risk assessment;
 - b) report high percentages of TB infection, as determined locally; and/or
 - c) yield high rates of treatment completion (for example, over 80%). Note: If selected sites do not show a continued epidemiologic need or do not yield locally determined rates of infection or treatment completion, the decision to discontinue routine targeted testing should be made.
- 8. Document targeted testing activities. Submit the <u>12-14427 (Targeted Testing Monthly Report)</u> to the TB Unit no later than the 15th day of the following month to GlobalScape. Notify the Continuing Quality Improvement (CQI) team by sending an email to <u>Cqiteam@dshs.texas.gov</u> when the report has been uploaded.
- 9. Track people who start and/or complete treatment for TB infection or TB disease.
- 10. Include targeted testing activities on the DSHS Annual Progress Report (APR). Refer to *Figure 5: Targeted Testing Workflow Process*.

Figure 5: Targeted Testing Workflow Process



Source: Texas Department of State Health Services, TB Unit, 2023

- C. Identification of groups at risk for developing TB disease in congregate settings.
 - 1. Complete a TB risk assessment for where a targeted testing initiative is being considered. Use the <u>TB-500 (*TB Risk Assessment Form*)</u>.
 - 2. Targeted testing projects may be offered in medium or high-risk congregate settings to include:
 - a) homeless shelters;
 - b) nursing homes;
 - c) dialysis centers;
 - d) residential facilities; and
 - e) migrant farm worker camps.
 - 3. If targeted testing will be performed in a site outside of those listed above, consult the TB Unit Epidemiology team before initiating.
 - 4. If targeted testing will be performed at a correctional or detention facility, consult the CQI team before initiating it.
 - 5. Provide guidance to medium and high-risk facilities operating or starting a TB screening program.
- D. Identification of groups at risk for developing TB disease in non-congregate settings.
 - 1. Consult the TB Unit Epidemiology team before initiating testing at a noncongregate site.
 - 2. Evaluate the following at-risk populations for increased risk of progression of TB infection to TB disease in accordance with DSHS SDOs. Groups include:
 - a) Some medically underserved, low-income populations defined locally as having an increased prevalence of TB disease.
 - b) People who inject illicit drugs or other groups of high-risk substance users (e.g., injection drug users, heroin, etc.).
 - c) Healthcare facilities may consider using annual TB screening for certain groups at increased occupational risk for TB exposure (e.g., pulmonologists or respiratory therapists) or in certain settings if transmission has occurred in the past (e.g., emergency departments). Consult the TB Unit Epidemiology team before initiating.
 - (1) Annual TB testing of healthcare personnel is not recommended unless there is known exposure or ongoing transmission.

XIII. Inventory Management of Medications and Supplies

General Requirement

TB programs will order and store DSHS-purchased supplies and medications in accordance with DSHS standards. DSHS purchases medications under the Federal 340B Drug Pricing Program to support outpatient TB treatment services provided by DSHS-funded TB programs. Due to these federal requirements, medications shall not be distributed outside the TB program for patients for whom there is not a current medical record at the TB clinic. This includes not distributing medications to in-patient facilities, correctional, or detention facilities (unless pre-approved by the TB Unit). All funded TB programs must adhere to the DSHS 340B Policies and Procedures when using state-purchased TB medications.

Activities

- A. Follow DSHS-established criteria for the use of TB program medications.
- B. Designate a staff member to oversee the ordering and management of DSHS-purchased medications to ensure that:
 - 1. medications are used for outpatient treatment of TB disease or TB infection only (including window prophylaxis);
 - 2. medications are used for patients who have a medical record established at the clinic providing the medication;
 - 3. the TB program supplying medications to the patient retains overall responsibility for the care of the patient;
 - medications and supplies are used in a prudent manner and not distributed to entities for which TB programs do not provide treatment oversight;
 - 5. TB programs do not charge patients for medications or seek thirdparty reimbursement (including Medicaid reimbursement), as medications are provided to TB programs at no cost; and
 - 6. TB programs do not distribute or supply state-purchased medications to jails and other facilities in which the patients receiving the medications are not under the direct medical care of that TB program.
- C. Follow DSHS-established procedures for TB medication inventory management.
 - 1. Order TB medications and reconcile inventory through the DSHS medication ordering system.
 - 2. Limit medication orders to a one-month supply, as the DSHS Pharmacy typically fulfills orders within 24 hours of receipt.
 - 3. Set maximum stock levels no higher than a one-month average usage.
 - 4. Monitor and manage use of TB medications and testing supplies furnished by DSHS in accordance with first expiring/first-out (FEFO) principles of inventory control.
 - 5. To maximize usage, avoid waste by ordering packets for patients new

to therapy with individual drugs to avoid waste (e.g., 10 packets of Rifampin, 10 packets of Isoniazid).

- D. Order medications for patients in DOT packets or bulk bottles and ensure labeling requirements are met.
 - 1. Order medication for patients with known or suspected TB disease on DOT or those on directly observed preventative therapy (DOPT) for TB infection (including window prophylaxis) in DOT packets.
 - 2. DOT-packaged medications have a shorter expiration date than their original manufacturer expiration date, typically two to six months after packaging. Therefore, if one medication in the packet expires, the entire packet must be disposed.
 - 3. Order medication packets for SAT or VDOT. These may be ordered in the same way as DOT packets from the DSHS Pharmacy. If medications will be in the patient's possession, certain labeling requirements must be met for packaging (e.g., amber zip-closure bag) containing DOT packets.
 - a) The label should be prepared and affixed to the zip-closure bag by TB program staff providing medications to the patient. The label must include (refer to Figure 6: Sample Medication Label for Self-Administration or VDOT):
 - (1) the name and address of the medical director or physician who prescribed the drug;
 - (2) the date the drug is delivered to the patient;
 - (3) the patient's name; and
 - (4) the name, strength, directions for use of the drug(s).

Figure 6: Sample Medication Label for Self-Administration or VDOT

TB Program Name HERE 123 Main St. City, TX 77000 Phone 123-456-7891

01/01/2024 John Watson, MD Jane Doe, DOB 1/1/1990

Medications: Rifampin 600mg, Isoniazid 300mg, Pyrazinamide 1000mg, Ethambutol

800mg, Pyridoxine 50mg

Instructions: Take 2 packets each day

- 4. Refer to <u>DSHS Video-Enabled Directly Observed Therapy Required and Recommended Activities</u> when using VDOT for eligible patients.
- 5. Order medication bottles for patients with TB infection. These may be provided to the patient with the following labeling requirements as required by the Texas State Board of Pharmacy (TSBP), TAC Title 22, Part 15, Chapter 291, §291.93 (refer to Figure 7: Sample Medication

Label for Bulk Bottles).

- a) The label must be printed and attached to bottles for selfadministered medications and include:
 - (1) name, address, and telephone number of clinic;
 - (2) name and strength of drug; if generic, name of drug manufacturer or distributor;
 - (3) quantity;
 - (4) lot number; and
 - (5) expiration date.
- b) The authorized, licensed nurse will ensure the labeling directions include:
 - (1) patient name;
 - (2) date medication is provided;
 - (3) physician name; and
 - (4) directions for use (per TSBP rules, incomplete directions for use may be present and if so, are to be completed by the authorized licensed nurse at time of provision).

Figure 7: Sample Medication Label for Bulk Bottles

Local Health Pharmacy 1100 W North Loop blvd Austin, TX 78756, 6303129014		
Patient name:Date:/_/	-	
Dr. Name:		
RIFAMPIN CAP 300 mg 60		
Take capsules by mouth each day. May discolor urine/feces. No		
Iron/Dairy/Antacids within 1hr. May decrease effect of birth control.		
Take on empty stomach		
42806-0799-60 S/N: 0000000006 QTY: 50 LUP		
EXP: 12/31/2026 lot: EP012808		
Store between 66°F to 77°F (20°C to 25°C)		

NOTE: Label may vary as printing software is updated.

- E. Order medications for patients in accordance with provider orders, the DSHS TB formulary (refer to *Appendix I: DSHS TB Formulary*) and TB Unit requirements. The following types of medications are available to TB programs:
 - 1. First-Line Medications
 - 2. Second-Line Medications (refer to *Table 12: Second-Line Medications*)
 - a) Second-line medications may be ordered for:
 - (1) patients intolerant to first-line drugs;
 - (2) patients resistant to first-line drugs;
 - (3) patients with TB pathology requiring second-line medications (i.e., TB meningitis); and/or
 - (4) contacts to patients with resistance to first-line drugs

who are recommended treatment for TB infection.

- b) Consultation with a DSHS-recognized TB medical consultant or RMD is required when ordering second-line medications for DR-TB unless the medication is listed on a TCID-discharge summary. TB programs may be required to show documentation of consultation at any time *upon request* by the TB Unit.
- c) Most second-line medications are available via the DSHS pharmacy unit's ordering system. Exceptions:
 - (1) **Bedaquiline** (BDQ) is available through assistance programs (PAPs) (i.e., Johnson and Johnson Patient Assistance Foundation). Application to a PAP should begin immediately upon receiving orders. Coordinate with the TB Unit nurse consultant to obtain BDQ from the DSHS pharmacy for short-term use while pending other purchases (refer to <u>Bedaquiline Ordering Guide</u>).
 - (2) **Clofazimine** (CFZ) is an investigational drug that may only be prescribed by Institutional Review Board (IRB) enrolled physicians, called investigators or coinvestigators. The TB Unit, in collaboration with DSHS Regional and Local Health Operations (RLHO), holds an IRB for CFZ use, and DSHS RMDs are enrolled prescribers. If CFZ is recommended, do the following:
 - (i) Inform the LHP that IRB enrollment is required; identify if the physician has access to CFZ through an IRB outside of DSHS.
 - (ii) If the LHP is unable secure CFZ through an established IRB, contact the TB Unit's clinical care team (TB.feedback@dshs.texas.gov). After collaboration with the DSHS region, the RMD will coordinate the use of CFZ.
 - 1. The DSHS IRB requires a separate consent for CFZ that is only available to DSHS IRB-enrolled providers.
 - 2. CFZ is ordered via Novartis and shipped directly to the health department where the patient is managed.

Table 12: Second-Line Medications

Drug Type*	Name of Medication
Injectable Agents	Amikacin
Fluoroquinolones	levofloxacin, moxifloxacin
Bacteriostatic Agents	bedaquiline, cycloserine, ethionamide, para-aminosalicylic acid (PAS), pretomanid
Other Oral Agents	clofazimine, linezolid
* Second-line medications include, but are not limited to, these groups.	

- 3. Auxiliary medications
 - a) Additional medications are available on the TB formulary to support individualized patient care. They include, but are not limited to:
 - (1) anti-emetics;
 - (2) corticosteroids; and
 - (3) lidocaine.
 - b) To order auxiliary medications, programs have the following options:
 - (1) The TB provider may write a prescription for the patient to fill at their own pharmacy.
 - (2) The managing TB program may coordinate with the patient's medical home to obtain the medications (including linking the patient to a FQHC or community clinic and ensuring the patient signs consents to share medical information).
 - (3) The provider may consider over-the-counter medications that the patient may choose to purchase.
 - (4) The managing program may request the medication via the DSHS pharmacy when the above options have been exhausted. The TB Unit reserves the right to request documentation of attempts to obtain auxiliary medications at any time.
- F. Mail medications to patients when in-person provision is not possible (refer to *Appendix J: Medication Mailing Processes*).
- G. Utilize medication compounding for select patient populations. The DSHS Pharmacy Unit will support medication compounding on Mondays, Tuesdays, and Wednesdays in the following situations:
 - 1. When the patient requires a precise dose that is not commercially available (e.g., a dose of 250mg of rifampin is ordered; however, capsules are only available as 150mg and 300mg).
 - 2. When administrative attempts by the nurse have been exhausted (splitting or crushing tablet, disguising in foods, etc.) and compounding is seen as a last resort to supported medication administration.
 - The physician has provided a manual signature on the prescription and faxed the prescription to DSHS pharmacy. Manual signatures and faxed prescriptions are the legal requirement from the Texas Board of Pharmacy. Electronic signatures and emailed prescriptions will not be accepted.

Compounded medications must often be kept refrigerated and have a shorter expiration than DOT medications. Contact the DSHS Pharmacy Unit at 512-776-7500 when compounding is needed.

H. Request non-formulary medications and supplies when needed to directly

support TB patient care.

- 1. The TB Unit convenes a Pharmacy and Therapeutics (P&T) Committee to maintain fiscally responsible ordering practices and to review requests for formulary additions⁶. Committee members include: the DSHS infectious disease medical officer or designee, DSHS pharmacist(s), the pharmacy procurement officer, TB Unit nurse administrator, and additional TB Unit or Regional and Local Health Operations (RLHO) representatives when necessary.
- 2. Any person may ask to add a medication or supply to the TB formulary. The request must include responses to the following questions in an email to the TB Unit nurse administrator allowing 30 days to review and if approved for the medication to be available:
 - a) What medication/medications are being requested? (Specify doses where applicable.)
 - b) Is this medication necessary for any TB patient or for a specific patient or population? Please specify.
 - c) Is this medication vital for TB treatment? If yes, please specify.
 - d) Without this medication, is there potential harm to the patient that could result in serious disability, hospitalization, or death?If yes, specify.
 - e) Is TB disease, TB infection, or a TB medication the cause of the condition that the medication treats? If yes, please specify.
 - f) Does literature support the need for this medication specifically for TB patients? If yes, please specify.
 - g) Will this medication directly impact a patient's ability to be cured of TB? If yes, please specify.
 - h) What monitoring is required while a patient is on this medication?
 - i) Is this medication available over the counter or through other means in the community (i.e., primary care)? If no, please specify.
 - j) Does providing this medication align with the scope (mission and vision) of the TB Unit?
- I. Manage and monitor distribution of purified protein derivatives (PPD) and TST supplies for:
 - 1. Chapter 89-designated correctional and detention facilities:
 - a) Distribute PPD and TST supplies (e.g., syringes) to correctional facilities that meet the *Texas Health and Safety Code Chapter* 89 requirements as needed and only if the approved <u>TB-805</u> (*Correctional TB Screening Plan*) indicates the R/LHD as the providing entity. Refer to

⁶ The P&T Committee must consider state resources, scope, and mission of TB Unit (the scope is the treatment of TB infection and disease, and the mission is to eliminate TB as a public health threat) and external availability of medications before adding medications or supplies to the TB formulary.



- statutes.capitol.texas.gov/Docs/HS/htm/HS.89.htm .
- b) State-purchased testing supplies can only be used to screen incarcerated persons in Chapter 89-designated facilities and cannot be used for employee and/or volunteer screening.
- c) Manage and monitor supply requests received from Chapter 89designated facilities by engaging in the following activities:
 - (1) Review the TB-805 (Correctional TB Screening Plan) to determine if the facility lists the TB program as the entity to provide PPD and TST supplies. If the Correctional TB Screening Plan does not list the TB Program as the entity that provides PPD and TST supplies, the request must be denied, and the requestor notified. Facilities identified as meeting Chapter 89 qualifications are required to maintain an updated and accurate Correctional TB Screening Plan annually.
 - (2) Review orders to ensure the facility is requesting a reasonable amount of supply to match their monthly averages, as noted on 12-11462 (Monthly Correctional TB Report) and reads a high majority of tests placed (>80%).
 - (3) Ensure that orders are placed in PIOS using the correct account (e.g., facility name C/O Health Department name).
 - (4) Ensure inmates are screened appropriately and there is a limited amount of duplicate testing. The facility should only routinely test inmates who have not been screened in the past 12 months in previous bookings. The facility should not retest documented prior positives.
 - (5) Ensure the facility is not delinquent in submitting their 12-11462 (Monthly Correctional TB Report Form) and 12-11461 (Report of TB Conditions) to the TB program.
 - (6) Ensure the facility submits the *Tuberculosis Testing*Supply Request Form for Chapter 89-Designated
 Facilities document monthly along with their 12-11462
 (Monthly Correctional TB Report) and Report of TB
 Conditions forms.
 - (7) Ensure the facility has exhausted their current supply and does not have PPD stockpiled.
 - (8) Ensure the facility is only testing inmates who will likely remain at the facility for longer than 7 days.
- d) Maintain a monthly inventory of PPD and TST supplies provided to each correctional facility.
- e) Adjust quantity distributed based on trends in usage.
- f) Halt distribution of PPD and TST supplies if monthly reports of usage are not provided by the receiving facility.

- 2. Community-based organizations serving medium to high-risk populations based on an environmental risk assessment:
 - Prepare and sign a memorandum of agreement (MOA) for each entity determined by the TB program to receive PPD and TST supplies.
 - b) The memorandum of agreement should clearly explain the distribution, storage, and reporting process including indicators that may halt or discontinue receiving PPD and TST supplies (including but not limited to yearly evaluation of treatment completion rates).
 - c) Distribute PPD and syringes to community-based organizations when an epidemiologic assessment determines the selected facility is considered medium to high-risk for TB and targeted testing is a reasonable response to prevent a recurrence of TB disease transmission.
 - d) For-profit sites must purchase their own supplies, particularly if they choose to establish their testing initiatives, which may not align with sound epidemiological practices.
 - e) Maintain a monthly inventory of PPD and TST supplies provided to each facility.
 - f) Obtain the <u>12-14427 (Targeted Testing Monthly Report)</u> from each facility.
 - g) Review <u>12-14427</u> (<u>Targeted Testing Monthly Report</u>) submitted by each targeted testing facility to determine use. Once reviewed, upload the form via GlobalScape by the 15th day of the following month. Notify <u>cqiteam@dshs.texas.gov</u> of the upload.
 - h) Adjust quantity distributed to targeted testing sites based on trends in usage.
 - i) Halt distribution of PPD and TST supplies if monthly reports of usage are not provided by the receiving facility.
 - j) Follow the process for targeting testing; see *Ch. XII. Conduct Targeted Testing* under Activities B. Ensure TB Unit guidelines are followed for each new targeted testing initiative.
- J. Avoid using or distributing state-purchased tubersol and TST supplies in populations or in settings not approved by the TB Unit. State-purchased tubersol and TST supplies are NOT approved for use in the following groups:
 - 1. Foreign-born people from high prevalence countries aged two and older who do not refuse phlebotomy.
 - 2. Schools, hospitals, or other congregate settings not identified for a targeted testing project (refer to *Chapter XII. Conduct Targeted Testing* for more information).
 - 3. Low-risk adults and children who are requesting testing for administrative reasons.

- 4. School-aged children⁷ who request testing for school.
- K. Reconcile medication inventory.
 - 1. Maintain a count of DSHS-purchased medications and supplies.
 - 2. Reconcile bulk inventory according to product and lot numbers listed in the DSHS medication ordering system at minimum every 30 days. Bulk medication inventory refers to bottles of medications, as opposed to medication packets.
 - 3. Transfer of medications is not allowed to other clinics (this includes sub-clinics within the same R/LHD system), per DSHS 340B medication policy (refer to https://www.dshs.texas.gov/pharmacy-unit/340b-drug-discount-program). However, medication may be used on another eligible patient within the same clinic. If this occurs, reconcile the medication in PIOS and ensure local documentation that the drug was provided to an eligible TB patient.
 - 4. Establish protocols and procedures for the disposal of expired/non-usable medications.
 - 5. Coordinate with DSHS pharmacy staff to ensure TB orders comply with best practices.
 - 6. Store all DSHS-purchased medications and supplies properly and securely in accordance with manufacturer's instructions.

⁷ The TB program should not be the primary source of TB testing in school-aged children. First, they should be referred for screening at their school or primary care office, an immunization clinic, or to a Medicaid provider (Medicaid providers must follow TB screening guidelines under *Texas Health Steps*). If the child has no alternate resources for school screening, they may be tested with an IGRA if they present with risk factors for TB as evidenced by their answers to the <u>TB Questionnaire</u>.

XIV. Conduct Surveillance Activities

General Requirement

Develop and maintain TB surveillance mechanisms for early identification and reporting. Conducting TB surveillance is a core public health function. The on-going and systematic collection, analysis, interpretation, and dissemination of surveillance data allow TB programs to target resources and interventions that will provide the most impact in eliminating TB.

- These surveillance data are essential in describing morbidity and mortality, monitoring trends in TB incidence and prevalence, detecting potential outbreaks, and defining high-risk groups.
- TB data are needed to evaluate TB control programs, identify deficiencies, and allocate resources. To perform these important functions, it is essential that surveillance data be collected and reported in an accurate, complete, and timely manner.

The National Tuberculosis Surveillance System (NTSS), located in the Division of Tuberculosis Elimination (DTBE), Centers for Disease Control and Prevention (CDC), is the national repository of TB surveillance data in the United States. Although R/LHDs share TB surveillance data with the CDC, the responsibility and authority for TB surveillance rests with the R/LHD. As with any reportable disease, the completeness of TB reporting reflects how actively R/LHDs solicit case report information.

 CDC receives data on TB cases from reporting jurisdictions through a standardized data collection form, the Report of Verified Case of Tuberculosis (RVCT). The 2020 RVCT assists funded TB programs in gathering accurate and useful data. Refer to Box 1: Impact of RVCT Data regarding benefits of quality data and negative outcomes of inaccurate data.

Box 1: Impact of RVCT Data

Benefits of RVCT Data:

- Increased ability to assess program performance, completeness of data collection, and accuracy of reporting.
- Improved data for program planning and policy development (e.g., personnel, resources, funding).
- Facilitation of patient services (e.g., quality of care, continuity of care, sharing of accurate information with patient and health facilities).

Negative effects of Inaccurate, Incomplete, or Unknown RVCT Data:

- Inaccurate follow up of services to patients.
- Inadequate resources (e.g., funding, staff, facilities, drugs, and supplies).
- Inaccurate evaluation and policy development.
- Misrepresentation of the public health burden of TB.
- Inability to measure TB program indicators that are based on surveillance data.

Activities:

- A. Comply with the following:
 - 1. Designate at least one person with the ability to work on surveillance and case registry activities and at least one back-up person in their absence.
 - 2. Provide hardware and software necessary to conduct case registry activities (e.g., NEDSS, access to web-based training and tools, GlobalScape access, etc.).
 - 3. Complete pre-requisite trainings (refer to Appendix Q: Case Detection, Accuracy, Completeness, Timeliness, Security and Confidentiality (DACTS) Audit Tool).
 - 4. Maintain data security and confidentiality standards (refer to *Chapter XXIII. Confidentiality and Security Standards* for more information).
- B. Participate in **active surveillance** to promptly identify people with TB disease. Active surveillance requires R/LHDs to directly contact and interact with healthcare facilities or individual providers to ensure prompt disease reporting. It promotes complete reporting and is used in conjunction with specific epidemiologic investigations.
 - 1. Contact providers who deliver TB services to at-risk populations or hospital infection control practitioners to increase case reporting at least monthly.
 - Communicate with HIV/STD or general surveillance program staff in the R/LHDs to identify unreported HIV/TB co-infections at least quarterly.
 - a) Maintain documentation of these activities.
 - b) Report educational activities on the APR.
 - Ensure local laboratories promptly report positive results such as acidfast bacilli through the Electronic Laboratory Reporting System and notify the R/LHD.
- C. Educate and train providers and other key facilities on reporting and surveillance.
 - Provide annual education and training to at least four of the following sites (at least two in-person sessions and the additional training(s) may be through written communication-mailouts, letters, etc.):
 - a) Hospitals
 - b) HIV clinics
 - c) Homeless shelters
 - d) Drug rehabilitation facilities
 - e) Indigent care facilities
 - f) Kidney dialysis facilities
 - g) Locally determined site (where clear rationale to site selection was chosen; site must have a role in diagnosing TB or is at-risk for TB transmission.)

- 2. Training must include, but is not limited to, TB case definition, when to report, how to report, and Texas legal reporting requirements (refer to dshs.texas.gov/idcu/investigation/conditions/).
- 3. Report training activities in the APR to the TB Unit.
- D. Conduct case investigations on suspected TB cases.
 - 1. Conduct investigations on suspected TB cases requested by the TB Unit within 24 hours of notification. The request for information will be based on the following circumstances when RVCT data has not been submitted by the R/LHD TB program:
 - a) Culture confirmation for *M. tb* or *M. bovis* from genotyping
 - b) Notification of DR-TB from the TB Unit's DR-TB Monitoring Program
 - c) EDN notification or referral or transfer of ownership
 - d) Vital statistics (death certificate) or a medical examiner's report
 - e) Hospital admission or discharge summary
 - f) Pharmacy records dispensing TB drugs
 - g) DSHS Infectious Disease Prevention Unit (IDPU) report of communicable disease
 - h) Receipt of an out of state IJN; provide status update within 4 weeks of notification
 - i) Initiation of a CI
 - j) Unreported source case identified

XV. Data Reporting Requirements

General Requirement

All suspected and confirmed TB cases, contacts, and people diagnosed with LTBI, must be reported to the TB Unit through reporting mechanisms outlined in this chapter. Reporting may include responding to TB Unit requests, emailing TB Unit teams, and/or entering surveillance data into the TB electronic database known as the Notifiable Electronic Disease Surveillance System (NEDSS).

NEDSS is a CDC-developed integrated information system that helps local, state, and territorial R/LHDs manage reportable disease data and send notifiable disease data to CDC.

Reporting is essential for TB programs to:

- ensure case supervision;
- ensure completion of appropriate therapy;
- ensure completion of timely contact investigations; and
- analyze data to determine morbidity, demographic characteristics, and trends so that opportunities for targeted screening for disease or infection can be identified.

NEDSS allows for real time data entry; therefore, TB programs must adhere to the reporting timelines and requirements for entering surveillance data into NEDSS, as outlined in this chapter.

Activities

A. Create a **Tuberculosis (2020 RVCT) investigation**⁸ in NEDSS within three business days of notification for the following, unless the investigation was already created by an electronic laboratory report (ELR):

- 1. all persons being evaluated for TB;
- 2. persons named as a contact;
- 3. persons suspected of having TB; and
- 4. persons with confirmed TB disease.

B. Obtain and enter in NEDSS the initial TB intake information within seven days of notification for all suspected (ATS-5) and confirmed TB cases (ATS-3). Refer to *Appendix S: TB Intake Information* for initial intake information.

⁸ A thorough search of the database should always be conducted before creating investigations. If the patient search results in no matches, a Patient File must be created before creating the TB investigation. Refer to the <u>Texas NEDSS Data Entry Guide for TB Programs</u> for reporting surveillance data for TB conditions at <u>dshs.texas.gov/tuberculosis-tb/training/nedss</u>.

- 1. If suspected of having TB, the initial ATS classification should be entered as ATS 5-pending diagnosis, with the classification date.
 - a) Within the 90-day period, all diagnostic tests for TB should be completed. Therefore, a patient should not be an ATS class 5 for more than 90 days (three months).
- 2. Once a TB diagnosis is made, the current ATS classification should be updated and entered as ATS class 3-*M. tb* disease, clinically active, with the new classification date.
- 3. If TB disease is ruled out, update the ATS classification as applicable and enter the updated classification date (refer to *Table 13: American Thoracic Society (ATS) TB Classifications* below).

Table 13: American Thoracic Society (ATS) TB Classifications

Classification 0	No M. tb exposure, not TB infected Persons in this class have no history of exposure and a negative reaction to the tuberculin skin test or IGRA TB blood test (if tested).
1	M. tb exposure, no evidence of TB infection Persons in class 1 do have a history of exposure but have a negative reaction to the tuberculin skin test or IGRA blood test. Action taken for persons in this class depends on the degree and recency of exposure to M. tuberculosis, as well as the immune status of the exposed person. If there has been significant exposure within 3 months, a follow-up skin/blood test should be performed 8-10 weeks after last exposure and in the interim, treatment of latent tuberculosis infection should be considered for some high-risk persons, i.e., children less than 5 years old and persons with HIV infection.
2	M. tb infection, no disease Persons in class 2 have a positive reaction to the tuberculin skin test (indicate mm in duration) or IGRA blood test, negative bacteriologic studies (if done), and no clinical, bacteriological, or radiographic evidence of active tuberculosis. Treatment of latent tuberculosis infection may be indicated.
3	M. tb infection, current disease Class 3 includes all patients with clinically active tuberculosis whose diagnostic procedures are complete. If the diagnosis is still pending, the person should be classified as a tuberculosis suspect (Class 5). To fit into Class 3, a person must have clinical, bacteriological, and/or radiographic evidence of current tuberculosis. This is established most definitively by isolation of M. tuberculosis. A person who had past tuberculosis and who also currently has clinically active disease belongs in Class 3.
4	M. tb, no current disease This classification is defined by a history of previous episode(s) of tuberculosis or abnormal stable radiographic findings in a person with a positive reaction to tuberculin skin test (indicate mm induration) or IGRA blood test, negative bacteriologic studies (if done), and no clinical and/or

Classification	Description
	radiographic evidence of current disease. Persons in Class 4 may never have received chemotherapy, may be receiving treatment for latent infection, or may have completed a previously prescribed course of chemotherapy.
5	M. tb suspected, diagnosis pending Persons should be so classified when a diagnosis of tuberculosis is being considered whether or not treatment has been started, until diagnostic procedures have been completed. Persons should not remain in this class for more than 3 months. When diagnostic procedures have been completed, the person should be placed in one of the preceding classes.

Adapted from: Diagnostic Standards and Classification of Tuberculosis in Adults and Children, The Official Statement of the American Thoracic Society and the Centers for Disease Control and Prevention, July 1999. stacks.cdc.gov/view/cdc/5660.

- C. Report all patients with **TB disease (ATS class 3)** to the TB Unit within two business days after identification of a laboratory, confirmed TB case, or diagnosis of a clinical case of TB by creating a notification. Ensure all applicable information is entered for the TB Unit to verify case criteria and count status. (Refer to *Table 14: Case Criteria and Count Status.*)
 - 1. When notifications are received, a TB Unit surveillance case consultant will perform quality assurance (QA) and assign state case numbers (SCN).
 - a) A recurrent TB case will be counted as a new case if the recurrence occurred *after* 12 months from the last known date when TB treatment was stopped from the previous episode.
 - b) It will not be counted as a new case if the recurrence occurred within 12 months from the last known date when TB treatment was stopped.
 - 2. Enter remaining TB case data in NEDSS as soon as the information is available, not to exceed seven days after information is obtained.
 - a) Initial drug susceptibility test (DST) results should be manually entered in NEDSS on all culture-confirmed cases as soon as an initial susceptibility report is available, if not reported electronically.
 - b) Treatment and case outcome information should be entered in NEDSS for all cases as soon as treatment is complete or treatment information is available, not to exceed seven days from therapy stop date.

Table 14: Case Criteria and Count Status

Case Criteria

Laboratory Confirmed

- Isolation of *M. tuberculosis* from a clinical specimen, OR
- Demonstration of *M. tuberculosis complex* from a clinical specimen by nucleic acid amplification test, OR
- Demonstration of acid-fast bacilli in a clinical specimen when a culture has not been or cannot be obtained or is falsely negative or contaminated.

Clinical Case (Pulmonary or Extra-pulmonary)

Pulmonary

Site of TB disease contains one or more of the following: Pulmonary, Pleural, or Lymphatic – Intrathoracic, and:

- Positive TST or positive IGRA for *M. tuberculosis;* and
- Chest imaging study, consistent with TB; and
- Initial drug regimen, started on at least two anti-TB medications.

Extra-pulmonary or both Pulmonary and Extra-pulmonary

Site of TB Disease contains one of the following: Adrenal; All teeth, gums and supporting structures; Anal; Appendix; Blood; Blood vessel; Bone and joint; Bone marrow; Brain; Breast; Cardiac valve; Colon; Duodenal; Epiglottis and larynx; Esophageal; Extrahepatic duct; Eye and ear appendages; Fetus and embryo; Gallbladder; Heart; Jejunum and ileum; Lip; Liver; Lymphatic Other; Lymphatic Unknown; Meninges; Middle ear and mastoid cells; Mouth region; Nasal; Nasopharyngeal; Other; Pancreatic; Paranasal sinus part; Pericardial; Peritoneal cavity; Pharyngeal; Pituitary; Placenta, umbilical cord and implantation site; Rectum; Salivary gland; Skin; Spinal cord; Splenic; Stomach; Genitourinary system; Lymphatic system of axilla; Lymphatic system of neck; Nervous system; Subcutaneous tissue; Thymus gland; Thyroid and/or parathyroid; Tongue; Tonsil and adenoid; Trachea; and:

- Positive TST or positive IGRA for M. tuberculosis; and
- Signs and symptoms compatible with TB; and
- Initial drug regimen started on at least two anti-TB medications.

Clinical Case by Provider Diagnosis

- Autopsy Report report must be provided;
- Child recent contact to TB disease case;
- Considerable clinical improvement based on symptoms from onset after starting minimum two anti-TB medications;
- Not done or negative TST/IGRA and considerable improvement on abnormal chest X-Ray/chest imaging; and
- TB expert consult documentation must be provided that may indicate the provider's rationale or findings for which the diagnosis was based.

Count Status

A counted TB case exists when the NTSS reporting area (each of the 50 states, New York City, the District of Columbia, and the eight U.S.-affiliated island reporting areas) determines that a verified case has not already been counted in another NTSS reporting area or by another country that is not an NTSS reporting area.

For specific scenarios for count status, refer to 2020 RVCT Instruction Manual, page 70. cdc.gov/tb/media/pdfs/Report-of-Verified-Case-of-Tuberculosis-RVCT.pdf.

- D. Create a **Latent Tuberculosis Infection (2020 TBLISS) investigation**⁹ in NEDSS within three business days for a known diagnosis of LTBI. An investigation should be created for populations with high-risk conditions:
 - 1. foreign-born from high-incidence countries;
 - 2. status adjusters¹⁰
 - 3. newly arrived immigrants and refugees notified through EDN;
 - 4. unaccompanied children;
 - 5. HIV-positive individuals;
 - 6. healthcare workers with recent TST or IGRA conversion; and
 - 7. Inmates diagnosed in Chapter 89-designated facilities, if resources allow.
- E. Obtain and enter in NEDSS the initial intake information within seven days of notification for known LTBI (ATS class 2). Refer to *Appendix S: TB Intake Information*.
- F. Report all patients with LTBI (ATS class 2) to the TB Unit within two business days of starting treatment for LTBI by creating a notification in NEDSS. Ensure all applicable information is entered for the TB Unit to verify LTBI criteria.
 - 1. When notifications are received, a TB Unit surveillance case consultant will perform QA and assign an LTBI number.
 - 2. Enter remaining LTBI data in NEDSS as soon as the information is available, not to exceed seven days after information is obtained.
 - a) Treatment and outcome information should be entered in NEDSS for all LTBIs as soon as treatment is complete or treatment information is available, not to exceed seven days from treatment stop date.
 - G. Maintain a digital or electronic log of all TB cases reported or counted in the jurisdiction by county and year with the following:

⁹ A thorough search of the database should be conducted before creating investigations. If the patient search results in no matches, a patient file must be created before creating the LTBI investigation. Refer to the <u>Texas NEDSS Data Entry Guide for TB Programs</u> for reporting surveillance data for TB conditions at <u>dshs.texas.qov/tuberculosis-tb/training/nedss</u> for more information.

¹⁰ Civil surgeons must not refer applicants to a health department for IGRA testing or chest x-ray; all IGRAs and chest x-rays ordered by civil surgeons must be performed independently of a health department unless the civil surgeon is part of the health department. Civil surgeons may treat status adjusters and all treatment information for status adjusters should be entered in NEDSS and indicated whether management is provided by a public health program.

- 1. Name
- 2. Date of birth
- 3. City/County address and jurisdiction
- 4. Contact information
- 5. Database investigation ID
- 6. State Case Number (SCN)
- H. Incorporate quality assurance (QA) protocols and procedures into surveillance activities.
 - 1. Respond to requests from TB Unit surveillance case consultants to check any discrepancies between the jurisdiction's case count in NEDSS and the case count in the jurisdiction's log.
 - 2. Respond to requests after receipt or within the timeframe included in the request. Refer to *Appendix R: Guidelines for Responding to Data Quality Assurance Reports*.
 - 3. Reclassify suspected TB cases as soon as data are available to classify as a confirmed TB case or as not a verified case of TB. This should not take longer than 90 days after the initial ATS class 5 classification.
 - 4. Satisfy requirements for QA for TB Surveillance data. Refer to *Table 15: Requirements for Quality Assurance for TB Surveillance Data*.
 - 5. Adhere to the TB Case Count and Case Review Schedule. Refer to *Table 16: TB Case Count and Case Review Schedule*. Ensure timely case reporting to meet deadlines outlined in the schedule.

Table 15: Requirements for Quality Assurance for TB Surveillance Data

Summary of CDC Requirements for Quality Assurance for TB Surveillance Data

TB programs will incorporate protocols and procedures into surveillance activities to ensure:

- Case detection (finding, counting, and reporting all TB cases);
- data accuracy (accuracy of data abstracted from original patient records, registry data, and data entered in NEDSS and transmitted to CDC);
- data completeness;
- timeliness; and
- data security and confidentiality.

Develop written protocols to QA of TB surveillance data and develop and implement plans for continued improvement and ongoing monitoring.

 Describe how each of the QA components (case detection, data accuracy, data completeness, data timeliness, data security, and confidentiality) is being conducted.

Qualified participants of the QA Process:

- TB Unit Surveillance team
- Designated staff, including TDCJ and Binational TB Programs

Source: Quality Assurance for Tuberculosis Surveillance Data: A Guide and Toolkit, 2013

Table 16: TB Case Count and Case Review Schedule

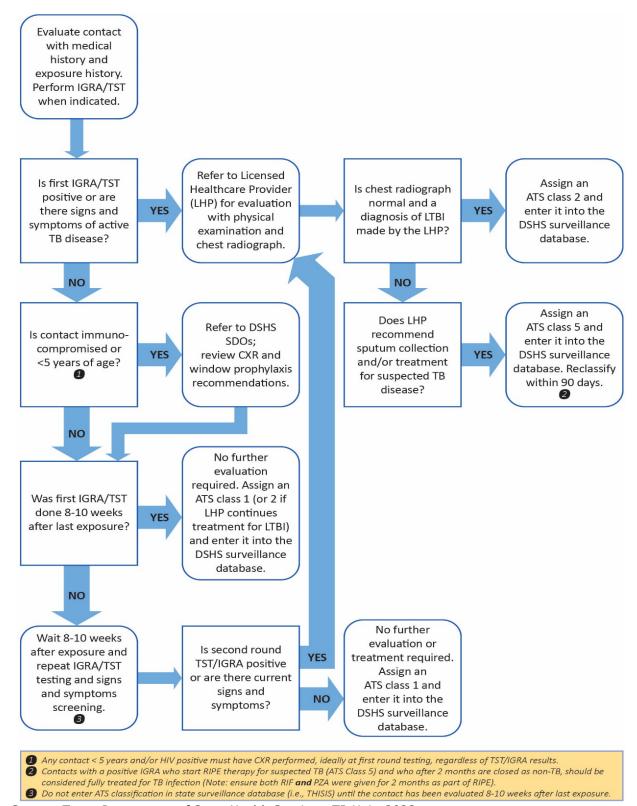
Action	Deadline
2025 Third Quarter Case Count and Case Review	October 31, 2025
2025 Final Case Count and Case Review	January 15, 2026
2026 First Quarter Case Count and Case Review	April 30, 2026
2026 Second Quarter Case Count and Case Review	July 31, 2026

- I. Enter **contact investigation information** in NEDSS. It is recommended to enter initial contact investigation information within 60 days of the suspected or confirmed TB case being identified. Data collection using the DSHS forms TB-340 (*Report of People Exposed to TB*) and TB-341 (Continuation Report of People Exposed to TB), or TB-342 and TB-343, or equivalent, should be maintained for record keeping.
 - 1. The initial contacts' report requires the following:
 - a) Part A. Index Case/Suspect Information
 - b) Part B. Interview and Exposure Site Information
 - (1) For every sputum smear positive case, conduct at least two different interviews seven days apart. Interviews should be documented in the surveillance database.
 - (2) Provide reason fewer than three contacts to sputum smear positive cases were identified.
 - (3) Provide reason if second interview was not conducted
 - (4) Provide reason if no contact investigation was conducted.
- J. Enter **contact evaluation information** in NEDSS. It is recommended to enter initial contact information within 60 days of the contact being identified.
 - 1. Part C. Contact Information
 - (1) Name
 - (2) Date of birth
 - (3) Duration of exposure and setting
 - (4) HIV test results
 - (5) Contact priority status
 - (6) TB signs and symptoms screening
 - (7) Previous disease or LTBI information
 - (8) TST/IGRA test results
 - (9) CXR or other imaging date and interpretation
 - (10) Prophylactic treatment information, if applicable
 - 2. Verify that a complete evaluation was performed. A complete evaluation for the purposes of the CI Aggregate Report consists of:
 - a) TB signs and symptom screening and one or more TST or IGRA result 8-10 weeks after break in contact or end of index case infectious period, whichever is earliest.
 - b) If the result is positive, a CXR result and a diagnosis from a LHP

should be made.

- c) Perform a symptom screen for an evaluation to be complete.
- d) Provide reason if evaluation was incomplete.
- 3. Assign an ATS classification for contacts named in a CI once the evaluation is complete. Refer to *Figure 8: Assigning ATS Classifications to TB Contacts*.
 - a) Contacts that do not meet the criteria for a complete evaluation should not be assigned an ATS classification.
- 4. For contacts with LTBI, update NEDSS with contact follow-up information including:
 - a) If treatment was recommended;
 - b) If treatment was not recommended, provide reason;
 - c) Treatment start date;
 - d) Treatment regimen;
 - e) Treatment stop date;
 - f) If treatment was completed adequately; and
 - g) If contact did not complete treatment adequately, provide reason.
- 5. Update contacts' treatment outcome in NEDSS no later than three months from the date the contact stopped treatment.
- 6. Report contacts who develop TB disease before submitting the subsequent contacts of those cases. Provide the linking state case number of their source case in NEDSS.

Figure 8: Assigning ATS Classifications to TB Contacts



Source: Texas Department of State Health Services, TB Unit, 2023



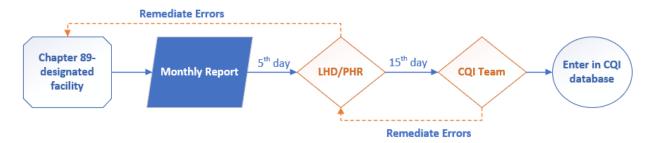
- K. Report each Friday **concerning TB events** to the TB Unit Epidemiology team by submitting the <u>DSHS Weekly Report of Concerning TB Events form</u> to TBepi@dshs.texas.gov. The total number of concerning TB events must be reported each Friday, even if there are zero events for each category. Concerning events include all:
 - 1. Newly reported confirmed TB disease cases among children younger than five years of age;
 - 2. TB cases with drug resistant TB (except isoniazid resistance) confirmed by nucleic acid amplification test, molecular drug susceptibility testing, or phenotypic drug susceptibility testing; and/or
 - 3. any death in a person with confirmed or suspected TB disease.
- L. Report **DR-TB** by notifying the DR-TB nurse consultant and entering information in NEDSS within three business days of suspected or confirmed drug resistance.
 - 4. Enter changes in case management, drug resistance patterns, or residence in any DR-TB case within three days of notification. Notify the DR-TB nurse consultant via email when event is updated.
- M. Report adverse drug reactions resulting in hospitalization or death.
 - 1. Submit form 12-12274 (Adverse Drug Reaction) to the DSHS pharmacy to notify them of the event (phone 512-776-7500). A DSHS pharmacist will review the information and contact the sender as needed to determine if a report to the Food and Drug Administration (FDA) is necessary.
 - While the Adverse Reaction report is intended to inform the DSHS
 Pharmacy and TB Unit of the occurrence, it is the responsibility of the
 treating prescriber to intervene and make changes to regimens when
 indicated.
- N. Report any TB case closed as **false-positive** due to laboratory contamination or other reason to the TB Unit Surveillance team with documentation to justify change in case status (e.g., amended laboratory report, doctor's note, written medical consult, etc.) within 45 business days of closure.
 - The DSHS TB Unit will assist TB programs' investigation of false positives either due to laboratory contamination or another misdiagnosis (refer to *Chapter X. Manage False Positive Investigations* for more information). Submit the <u>False Positive Investigation</u> worksheet as indicated.
 - 2. Review all other specimens associated with a false-positive case to ensure they are culture-negative.
- O. Report large-scale or concerning CIs to the TB Unit Epidemiology team within 48 hours. Submit <u>12-12104</u> (<u>TB Incident Report</u>) or <u>12-12063</u> (<u>TB Corrections Incident Report</u>) via the TB surveillance database or GlobalScape and notify the TB Unit Epidemiology team via

TBEpi@dshs.texas.gov. Concerning CIs involve:

- 1. Media sensitive exposures
- 2. Exposures with \geq 50 contacts in a single site
- 3. Child daycare or K-12 school exposures with ≥25 contacts
- 4. Any other exposure deemed concerning by the program
- 5. Other locations of interest include, but are not limited to, academic institutions, day care centers, nursing homes, hospitals, correctional facilities (including community corrections), homeless shelters, airline exposures, and other work settings. See Chapter VII. Conduct and Manage a Tuberculosis Contact Investigation for additional information.
- 6. Submit a final update to the TB Unit Epidemiology team after the investigation is closed.
- P. Report **large-scale screenings** (contact investigations ≥ 50 contacts) when using DSHS TB Unit-purchased supplies. Do not perform mass screenings without prior TB Unit approval.
 - 1. Make every effort to educate and inform all parties involved in the investigation regarding the TB screening process to ensure TB epidemiologic principles are applied at each CI event.
 - 2. Use sound epidemiologic principles at each CI event to ensure appropriate people are identified for screening and to determine specific environments in which transmission may have occurred.
 - 3. Mass screenings that are not epidemiologically guided drain limited resources and yield minimal results.
- Q. Conduct airline exposure screening based on notifications received from the TB Unit Epidemiology team via CDC Division of Global Migration and Health (DGMH).
 - TB Unit Epidemiology team will provide contact information for people exposed to an infectious TB case on any flight that lasted 8 hours or more.
 - 2. TB program staff will locate contacts and complete screening. Initiate evaluation of airline contacts within two weeks of notification.
 - a) TB program staff will complete the DGMH TB Air Contact Investigation Outcome Reporting Form and submit it via NEDSS or GlobalScape to the TB Unit Epidemiology team within one month of notification. Notify the TB Unit Epidemiology team of the submission via TBEpi@dshs.texas.gov.
- R. Report **potential airline exposure** to the TB Unit Epidemiology team.
 - 1. TB Programs shall notify the TB Unit Epidemiology team of any person with confirmed or suspected TB who:
 - a) traveled by commercial aircraft on a flight greater than eight hours; and
 - b) the person was diagnosed within three months of the flight.

- S. Review and submit reports received from **correctional and detention facilities** identified as Chapter 89-designated facilities according to <u>Texas</u> <u>Health and Safety Code Chapter 89</u> requirements to the TB Unit via GlobalScape.
 - Collect the <u>12-11462</u> (<u>Monthly Correctional TB Report</u>) and <u>12-11461</u> (<u>Report of TB Conditions</u>) from Chapter 89 correctional and detention facilities by the 5th day of the following month.
 - 2. Perform first-line review and quality assurance of both reports for accuracy and completion.
 - 3. Provide technical assistance and guidance to Chapter 89-designated correctional and detention facilities on correcting identified quality assurance errors or completing the 12-11462 (Monthly Correctional TB Report) and 12-11461 (Report of TB Conditions)
 - 4. Submit 12-11462 (Monthly Correctional TB Report) and 12-11461 (Report of TB Conditions) to the TB Unit, via GlobalScape by the 15th day of the following month. Send an email notification of the upload to cqiteam@dshs.texas.gov.
 - 5. Refer to Figure 9: Correctional TB Reporting Workflow.

Figure 9: Correctional TB Reporting Workflow



Source: Texas Department of State Health Services, TB Unit, 2023

- T. Complete and submit the **DSHS Annual Progress Report (APR)** using the TB Unit template to <u>TBContractReporting@dshs.texas.gov</u> with a copy to <u>cqiteam@dshs.texas.gov</u> once a year on April 1.
- U. Submit completed **cohort review documents** in accordance with the listed cohort review period and submission schedule (refer to *Chapter XXI. Conduct Continuing Quality Improvement Activities to Maintain a Robust Tuberculosis Program Infrastructure*) to the TB Unit via GlobalScape. Notify the CQI team by sending an email to cqiteam@dshs.texas.gov upon upload.

XVI. Interjurisdictional Notifications In and Out of State

General Requirement

Interjurisdictional communication ensures uninterrupted treatment and case management for patients who move between TB reporting jurisdictions. The interjurisdictional process is followed when a patient with ATS classification of 2, 3, or 5 and contacts travel in and out of state. Referring jurisdictions must complete the Interjurisdictional Notification (IJN) form to facilitate communication between the TB Unit and receiving jurisdictions.

The IJN form and procedures can be found on the National TB Coalition of America (NTCA) website: tbcontrollers.org/resources/interjurisdictional-transfers/.

There are two types of communication channels:

- Formal communication using the NTCA IJN form.
- Informal communication direct clinic-to-clinic phone calls, emails, or other forms of sharing patient information.

When using formal communication, the IJN form must be completed with all available information. If all information is not available, include an explanation in the comments section.

Attach the IJN form in NEDSS in its original pdf form. This allows recipients to have editing access. The IJN form must not be printed and rescanned. The instructions on how to complete the IJN form can be found on the NTCA website: tbcontrollers.org/docs/resources/IJN CompanionGuide 2022 08 10 FINAL.pdf. Contact information for national TB programs can be found here: tbcontrollers.org/community/statecityterritory/.

This chapter outlines when to use specific IJN forms for each ATS classification:

- LTBI (ATS class 2): a cover sheet and IJN form for LTBI must be completed.
 The IJN form is located at: _
 IJN Form 2024 TB Infection Continued Care FINAL.pdf
- Cases and Suspected TB cases (ATS class 3 and 5): a cover sheet and the two pages for Active/Possible TB must be completed. The IJN form is located at: IJN_Form_2024_Active_Disease_FINAL.pdf
- Contacts: a cover sheet and the two pages for Contacts must be completed.
 The IJN form is located at: IJN_Form_2024_Contact_Investigation_FINAL.pdf

Activities

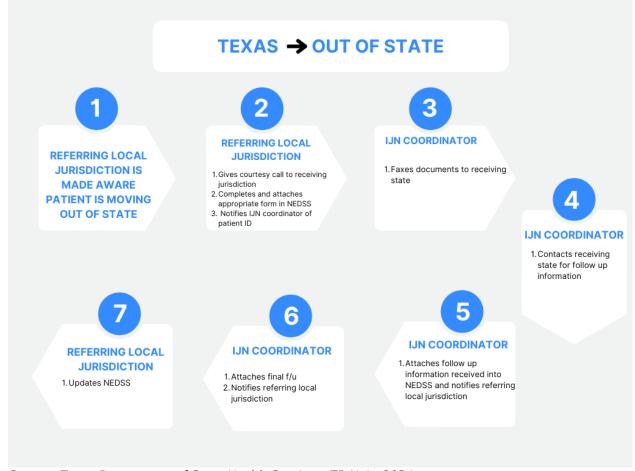
- A. **For interstate travel (between states)**, plan, coordinate, and communicate *informally* with the receiving jurisdiction when a patient plans temporary travel out of state.
 - 1. Within two business days in which a jurisdiction becomes aware of a patient's temporary travel plans (or has already traveled), identify the

address where the patient will be/is staying. **Temporary travel is defined as staying for 30 days or less in another state.** Examples of temporary travel include brief stays with relatives, business trips, extended vacations, seasonal work, etc.

- Notify the receiving state's IJN coordinator within two business days of becoming aware of the patient's travel plans. The receiving state IJN coordinator will identify the local jurisdiction or TB clinic that should be contacted to facilitate coordination of care.
- 3. Coordinate the sharing of information as directed by the receiving state's IJN coordinator or receiving jurisdiction. This includes sharing any medical records as requested.
 - a) The receiving state must be notified of any patient on treatment for TB disease and LTBI.
 - b) The receiving state will determine how best to coordinate care while the patient is in their jurisdiction.
 - c) If the referring jurisdiction plans to keep patient on VDOT, the receiving jurisdiction should be informed.
- 4. Programs may provide up to 30 days' worth of medications for a patient on treatment for TB disease or LTBI. Any out-of-state travel extending longer than 30 days will require formal communication.
- B. Plan, coordinate, and communicate *informally* and *formally* when a patient plans a permanent move out of state, when temporary travel plans change, or patient's temporary travel is longer than 30 days. The appropriate IJN form and related records must be submitted to the TB Unit's IJN coordinator. Local jurisdictions must attach all forms and records in NEDSS (refer to *Figure 10: Interstate Moves from Texas to Out of State*).
 - 1. Procedure for a patient with TB disease (ATS class 3) moving out of Texas to another state:
 - a) Within one business day of a jurisdiction becoming aware of a patient's plan to move (or has already moved and will not be returning to Texas) or plans to remain in another state longer than 30 days, or when temporary travel plans change and assistance from the receiving state is needed, the referring jurisdiction will contact the receiving state's IJN coordinator to inform them of the patient's move or intent to move to their state.
 - b) Within three business days of notifying the receiving state, the referring local jurisdiction must complete the required form. The referring local jurisdiction must attach the completed form and any pertinent medical records to the supplemental information tab in NEDSS. The "Moved" section in the "TB Disease Only" tab in NEDSS must be completed by the referring local jurisdiction. The referring local jurisdiction must notify the TB Unit's IJN coordinator via email after IJN forms and all documentation are attached to the NEDSS investigation. The NEDSS investigation ID should be entered in the subject line.

- c) Within three business days of receiving the notification, the IJN coordinator will forward the documentation to the receiving state.
- d) Within the following two weeks, the IJN coordinator will request follow up information from the receiving state.
- e) Within five days of receiving the follow up information from the receiving state, the IJN coordinator will notify the referring local jurisdiction that documentation has been attached to the NEDSS investigation. The local jurisdiction must enter the update(s) in NEDSS within three days of the notification.
- f) This process will repeat monthly until the final follow up is received.
- 2. Adhere to the following procedure for a patient with LTBI (ATS class 2), suspected TB disease (ATS class 5), or contacts moving out of Texas to another state:
 - a) Within five business days of a jurisdiction becoming aware of a patient's plan to move (or has already moved and will not be returning to Texas), or remain in another state longer than 30 days, or when temporary travel plans change and assistance from the receiving state is needed, the referring local jurisdiction must complete the required form.
 - (1) The referring local jurisdiction must attach the completed forms and any pertinent medical records to the supplemental information tab in NEDSS.
 - (2) The "Moved" section in the "TB Disease Only" tab in NEDSS must be completed by the referring local jurisdiction.
 - (3) The referring local jurisdiction must notify the IJN coordinator by email after the IJN forms and additional documentation have been attached to the NEDSS investigation.
 - (4) The NEDSS investigation ID should be entered in the subject line.
 - b) Within five business days of receiving the notification, the IJN coordinator will forward the documentation to the receiving state.
 - c) Within the following four weeks, the IJN coordinator will request follow-up information from the receiving state.
 - d) Within five days of receiving the follow up information from the receiving state, the IJN coordinator will notify the referring local jurisdiction that documentation has been attached to the NEDSS investigation. The local jurisdiction must enter the update(s) in NEDSS within three days of the notification.
 - e) This process will repeat monthly until final follow up is received.

Figure 10: Interstate Moves from Texas to Out of State



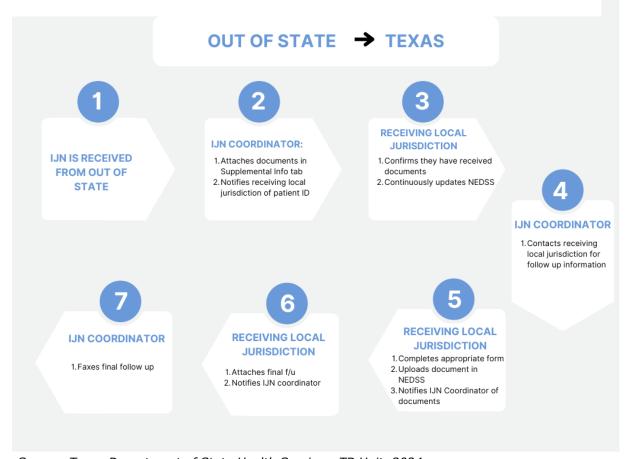
Source: Texas Department of State Health Services, TB Unit, 2024

- C. Plan, coordinate, and communicate formally when a patient plans a permanent move into Texas or a Texas Binational TB Program from another state, or when temporary travel plans change, or the travel is longer than 30 days (refer to Figure 11: Interstate Moves from Out of State to Texas).
 - 1. Procedure for a patient with TB disease (ATS class 3) moving into Texas from another state:
 - a) Within three business days of receiving the initial IJN from the referring state, the IJN coordinator will create a patient file, open an investigation in NEDSS, and attach the documents in the supplemental information tab. The IJN coordinator will notify the receiving local jurisdiction of the incoming case and the attachments.
 - b) Within three business days of receiving the notification, the receiving local jurisdiction will confirm they have reviewed the documents. The receiving local jurisdiction will continue to update NEDSS throughout the duration of treatment.



- c) Within two weeks of receiving confirmation from the receiving local jurisdiction that they have reviewed the attachments, the IJN coordinator will request a follow up via email to provide to the referring state.
- d) Within five business days of receiving the follow up request, the receiving local jurisdiction must complete the appropriate form(s) and make necessary updates to the form(s) to ensure it is accurate.
 - (1) The receiving local jurisdiction must attach the forms in the supplemental info tab in NEDSS and notify the IJN coordinator via email.
 - (2) The IJN coordinator will fax the follow up form(s) to the referring state within three business days.
- e) This process will repeat monthly until final follow up is submitted.
- 2. Adhere to the following procedure for a patient with LTBI (ATS class 2), suspected TB disease (ATS class 5), or contacts moving into Texas from another state:
 - a) Within five business days of receiving the initial IJN from the referring state, the IJN coordinator will create a patient file, open an investigation in NEDSS, and attach the documents in the supplemental information tab. The IJN coordinator will notify the receiving local jurisdiction of the incoming case and the attachments.
 - b) Within five business days of receiving the notification, the receiving local jurisdiction will confirm they have reviewed the documents. The receiving local jurisdiction continue to update NEDSS throughout the duration of treatment.
 - c) Within four weeks of receiving a confirmation from the receiving local jurisdiction that they have reviewed the attachments, the IJN coordinator will request a follow up via email to provide to the referring state.
 - d) Within five business days of receiving the follow up request, the receiving local jurisdiction must complete the appropriate form(s) and make necessary updates to the form(s) to ensure it is accurate.
 - (1) The receiving local jurisdiction must attach the forms in the supplemental info tab in NEDSS and notify the IJN coordinator via email.
 - (2) The IJN coordinator will fax the follow up form(s) to the referring state within three business days.
 - e) This process will repeat monthly until final follow up is submitted.

Figure 11: Interstate Moves from Out of State to Texas



Source: Texas Department of State Health Services, TB Unit, 2024

- D. For **international moves**¹¹, collaborate with the CDC's CureTB program when a patient from out of the country moves to Texas or a Texas patient moves out of the country.
 - 1. CureTB is a collaborative program between the CDC and San Diego County TB program that connects people with TB to healthcare services as they move between the U.S. and other countries. R/LHDs, healthcare providers, and others can refer patients to CureTB for assistance with accessing ongoing TB care abroad. CureTB can also help health officials and providers locate TB treatment health records for their patients in different countries. CureTB refers patients with (confirmed or probable) TB disease to the public health system in their destination country. CureTB Contact Information:

Email: CureTB@cdc.gov; Phone: (619) 542-4013

¹¹ Treat moves to or from Mexico for patients in the <u>Texas Binational TB Program</u> as intrastate moves. IJN documentation is required. These moves do not go through CureTB.



- 2. International moves:
 - a) Moves in or out of the U.S. will be treated as out of state moves; however, a CDC CureTB form should be completed instead of the IJN form, depending on the ATS classification of the case.
 - (1) For patients with active or suspected TB disease or LTBI, complete the CDC CureTB Transnational Notification form. Instructions can be found here:

 cdc.gov/migration-border-health/media/pdfs/Form-CureTBTransnational-v3-508.pdfCureTB Transnational-Notification (cdc.gov).
 - (2) For contacts, complete the contact/source investigation notification form. Instructions can be found here: <u>CureTB Contact/Source Investigation</u> (CI/SI) Notification (cdc.gov).
- E. **For intrastate moves (within Texas),** plan, coordinate, and communicate formally when a patient plans a permanent move between Texas jurisdictions or those moving to or from Mexico where a binational TB program. Refer to *Figure 12: Intrastate Moves Between Texas Jurisdictions*.
 - 1. Procedure for a patient with TB disease (ATS class 3) moving between local jurisdictions:
 - a) Within one business day that a referring local jurisdiction becomes aware of a patient's plan to move (or has already moved and will not be returning) or remain in another local jurisdiction longer than 30 days, or when temporary travel plans change and assistance from the receiving local jurisdiction is needed, the referring local jurisdiction will contact the receiving local jurisdiction to inform them of the patient's move or intent to move to its jurisdiction.
 - b) Within three business days of notifying the receiving local jurisdiction, the referring local jurisdiction must complete the appropriate IJN form(s).
 - (1) The referring local jurisdiction must attach the completed forms and any pertinent medical records to the supplemental information tab in NEDSS.
 - (2) The "Moved" section in the "TB Disease Only" tab in NEDSS must be completed by the referring local jurisdiction.
 - (3) The referring local jurisdiction must notify the IJN coordinator and receiving local jurisdiction via email once the IJN form(s) and additional documentation have been attached to the NEDSS investigation.
 - (4) The NEDSS investigation ID should be entered in the subject line.



- c) The referring jurisdiction maintains ownership of the investigation and is responsible for all data entry in NEDSS throughout this patient's course of care.
- d) The receiving jurisdiction is responsible for providing monthly updates throughout the patient's course of care by attaching follow-up IJNs to the investigation. Any deviation from procedures outlined above, require a written agreement between both jurisdictions (i.e., an email between program managers).
 - (1) It is the responsibility of the referring jurisdiction to ensure NEDSS is updated.
 - (2) The receiving jurisdiction is responsible for entering case management information in NEDSS during the period in which the patient remains in their jurisdiction.
- 2. Adhere to the following procedure for a patient with LTBI (ATS class 2), suspected TB disease (ATS class 5), or contacts moving between Texas R/LHDs:
 - a) Within five business days that a referring local jurisdiction becomes aware of a patient's plan to move (or has already moved and will not be returning) or remain in another local jurisdiction longer than 30 days, or when temporary travel plans change and assistance from the receiving local jurisdiction is needed, the referring local jurisdiction must attach the completed IJN form(s) and any pertinent medical records to the supplemental information tab in NEDSS.
 - (1) The "Moved" section in the "TB Disease Only" tab in NEDSS must be completed by the referring local jurisdiction.
 - (2) The referring local jurisdiction must notify the IJN coordinator and receiving local jurisdiction via email once the IJN forms and additional documentation have been attached to the NEDSS investigation.
 - (3) The NEDSS investigation ID should be entered in the subject line.
 - b) The referring local jurisdiction maintains ownership of the investigation and is responsible for all data entry in NEDSS throughout this patient's course of care. The receiving local jurisdiction is responsible for providing monthly updates throughout the patient's course of care by attaching follow-up IJNs to the investigation.
 - c) Any deviation from procedures outlined above, require a written agreement between both jurisdictions (i.e., an email between program managers).
 - (1) It is the responsibility of the referring jurisdiction to ensure NEDSS is updated.
 - (2) The receiving jurisdiction is responsible for entering case management information in NEDSS during the

period in which the patient remains in their jurisdiction.

Figure 12: Intrastate Moves Between Texas Jurisdictions



XVII. Implement Infection Control Procedures

General Requirement

TB programs will apply appropriate administrative, environmental, and respiratory measures to prevent exposure to and transmission of *M. tb*.

Activities

- A. Develop a TB infection-prevention plan to include administrative, environmental, and respiratory protection measures.
 - 1. Administrative measures that reduce the risk of exposure to people with infectious TB may include:
 - a) assigning responsibility for TB infection control to a designated staff member;
 - b) conducting a TB risk assessment as per <u>TB-500 (*TB Risk Assessment Form*);</u>
 - c) developing and implementing a written TB infection control plan (refer to Appendix L: Sample TB Infection Control Plan);
 - d) ensuring the availability of recommended laboratory processing, testing, and reporting of results;
 - e) implementing effective work practices for managing patients with TB disease and infection;
 - f) ensuring proper cleaning, sterilization, or disinfection of equipment and surfaces to prevent contamination;
 - g) educating, training, and counseling healthcare workers, patients, and visitors about TB infection and disease;
 - h) screening direct care TB personnel for TB (refer to F);
 - i) applying epidemiology-based prevention principles, including the use of setting-related TB infection-control data;
 - j) using posters and signs to remind patients and staff of proper cough etiquette and respiratory hygiene; and
 - k) coordinating efforts with high-risk healthcare or congregate settings to reduce and prevent exposure to TB.
 - 2. Environmental measures that prevent the spread and reduce the concentration of infectious respiratory particles (IRPs) may include:
 - a) using local exhaust ventilation (e.g., hoods, tents, or booths) to contain and control the source of infection;
 - b) using general ventilation to dilute and remove contaminated air;
 - c) using high-efficiency particulate air (HEPA) filtration and/or ultraviolet germicidal irradiation (UVGI) to clean the air; and
 - d) controlling airflow to prevent the contamination of air in areas adjacent to airborne infection isolation (AII) rooms.
 - 3. A respiratory protection program further reduces the risk of exposure to infectious respiratory particles that have been expelled into the air from a patient with infectious TB and may include:



- a) developing protocols and procedures on respiratory protection to include the type and size of respirators available to staff, routine inspection/maintenance, and appropriate use; and/or
- b) providing N-95 fit-testing to employees who share the same air space with patients suspected or diagnosed with infectious TB disease including:
 - (1) fit-testing employees at risk for exposure to infectious respiratory particles:
 - (i) upon initial hire and then annually;
 - (ii) when physical changes (e.g., weight loss, growth of facial hair) alter the fit of the respirator; and/or
 - (iii) whenever a different respirator is used (e.g., size, style, make, model).
 - (2) maintaining documentation of employee fit-testing in accordance with local record retention policies and procedures.
- c) using N-95 respirators in situations that pose a high risk of exposure to TB disease;
- d) initial and annual training of healthcare workers on personal respiratory protection; and
- e) educating patients on respiratory hygiene and the importance of cough etiquette procedures and providing surgical masks as needed.
- B. Ensure all environmental control equipment is properly installed, operated, and maintained.
 - 1. Outline the responsibility and procedures for all environmental control equipment maintenance in a written TB infection control plan.
 - 2. Maintain a log of all environmental control equipment maintenance in accordance with local retention policies and procedures.
 - Document training required for the proper operation of environmental control equipment and retain in accordance with local policies and procedures.
- C. Ensure separation of infectious or potentially infectious patients from other patients in the clinic (e.g., separate clinic spaces or appointment times).
 - 1. Determine degree of infectiousness (refer to DSHS SDOs).
 - 2. Review DSHS SDOs to determine when a patient is no longer deemed infectious.
- D. Provide guidance on infection prevention measures in special circumstances.
 - 1. When a patient with known or suspected infectious TB disease expires, provide guidance where necessary.
 - a) TB organisms may remain viable for 24-48 hours. Ensure those managing the person's body are aware of the TB status.



Individuals performing embalming need to be aware of expelling any air from the lungs during the process so as not to create infectious respiratory particles. Masking is recommended.

- b) Embalmed bodies should be placed in a sealed casket or other sealed container.
- 2. When a patient with known or suspected infectious TB does not have adequate housing, funded TB programs may consider supporting hotel/motel accommodations and/or work with community-based organizations to provide appropriate accommodations. Each program should develop a local process for this accommodation, as allowed by the R/LHD. General recommendations include the following:
 - a) Unhoused patients or those needing separate accommodations may be housed in a motel with a door that is accessed directly to outside air (and not with entrance or exits via shared hallways).
 - b) The motel manager should be made aware of the isolation status so that arrangements can be made to address linens, towels, supplies, and cleaning of the room upon patient checkout. Motel staff should not come into the room while the patient remains infectious but may leave supplies outside the room.
 - c) Patients should consent to the release of their isolation status to support this arrangement on the <u>L-30 (Consent to Release Confidential Medical Information</u>) or equivalent; however, the motel manager should only be provided general information about isolation and when the patient is removed from isolation without specifics of the TB diagnosis.
 - d) The patient should be advised to maintain isolation as required and as per the case management plan.
 - e) For details, refer to *Tuberculosis Infection Control: A Practical Manual for Preventing TB*. (2023). Curry International Tuberculosis Center currytbcenter.ucsf.edu/product/guide/tuberculosis-program-manual-template.
- E. Perform procedures that produce infectious respiratory particles (e.g., bronchoscopy, sputum collection/induction) in an AIIR or booth, if available. For clinics without these capabilities, sputum specimens must be collected outside in a location that protects patient confidentiality.
- F. Monitor effectiveness of TB infection control measures.
 - 1. Screen direct care TB personnel for TB. Refer to CDC. (2019). Tuberculosis Screening, Testing and Treatment of U.S. Healthcare Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC. Refer to: cdc.gov/tb/publications/guidelines/infectioncontrol.htm).



- a) TB programs should screen all direct care TB staff upon hire with an IGRA to establish a baseline unless:
 - (1) the new hire has documentation of a previous positive IGRA test result; or
 - (2) the new hire has documentation of adequate treatment completion for TB infection or TB disease.
- b) TB programs should screen all direct care TB staff annually.
 - (1) The frequency of any additional tests may be determined by the medical director.
- c) Screening supplies provided by the TB Unit may be used for baseline and annual testing of direct care TB staff but should not be used for staff who do not share an airspace with TB patients (i.e., other health department staff in non-TB programs whose program requires TB testing). When DSHS-purchased supplies such as IGRA are used to screen employees, indicate "TB employee screening" on the submission form before sending to Quest Diagnostics, Inc. for processing.
- 2. Document results of TB personnel screening and respond to any TB test conversions. TB programs must:
 - a) Complete the <u>TB-603</u> (*Tuberculosis* (*TB*) Screening of *TB*Personnel), or equivalent, annually. Maintain records of TB screening in the R/LHD according to local personnel records retention policies.
 - b) Report TB test conversions to the TB Unit within 60 days of the screening date. Document on <u>TB-604</u> (*Report of Tuberculosis* <u>Test Conversion in TB Personnel</u>) and send to the TB Unit nurse administrator.

XVIII. Maintain a Competent Workforce

General Requirement

TB programs will provide professional education, training, and orientation for new TB program staff and continuing education for current TB program staff.

TB programs will identify a point of contact responsible for ensuring all staff have the minimum initial and ongoing competencies relevant to their roles in TB. This point of contact, known as the TB education designee, must ensure staff education is documented and maintained in personnel records, according to local policies and procedures.

Activities

- A. Ensure all staff providing services under the SDOs or equivalent protocols have the requisite experience and/or training to deliver appropriate services.
- B. Provide **initial orientation and training** to all staff involved in TB activities, including physicians, nurses, program managers, contact investigators, outreach workers, case registry staff, administrative and other support staff.
 - 1. Initial orientation and training for all staff includes **40 hours** of education specific to job duties, to be obtained within 90 days of employment; this includes but is not limited to:
 - a) For all staff, CDC *Self-Study Modules on Tuberculosis*¹² (refer to cdc.qov/tb/education/ssmodules/).
 - b) For program managers, case registry, surveillance, and other staff assigned to NEDSS data entry, training includes CDC *RVCT Self-Study Modules* (refer to cdc.gov/tb/programs/rvct/).
 - c) For TB program managers, case registry staff, nurses and other staff who enter data into NEDSS, this includes NEDSS training courses for R/LHDs (see <u>dshs.texas.gov/tuberculosis-tb/nedss#courses</u>).
 - d) For authorized staff who sign and follow SDOs, initial training and evaluation of competence is required before performing services independently; refer to DSHS SDOs.
- C. Provide **annual training and education** to all TB staff.
 - 1. The designated number of annual hours depends on each staff

¹² Modules may be accessed through CDC's TRAIN platform (https://www.train.org/cdctrain/welcome) In TRAIN, self-study modules 1–5 are course SS4834 and modules 6–9 are course WB4556R. The self-study modules 1–5 are available for CE credits through midnight on June 1, 2026; modules 6–9 are available for CE credits through midnight on February 14, 2026. Courses should still be taken even if CE credit is not available. NOTE: some content is outdated because of new guidelines for drugresistant and drug-susceptible TB treatment published in 2025. Updated guidelines can be found here: https://www.cdc.qov/tb/hcp/clinical-quidance/index.html.



member's role in TB to include:

- a) For authorized nurses who provide services under SDOs and/or LHP orders, 16 hours of training and education are required. Refer to DSHS SDOs for details.
 - NOTE: Nurses are required to obtain 20 hours of Continuing Education (CE) every two years. Refer to bon.texas.gov/education continuing education.asp.ht ml). CEs awarded may be applied to the 16 hours required for TB, and any additional hours may be obtained outside of CEs (refer to F, below).
- b) For non-licensed staff who provide services under SDOs and/or LHP orders, at least **12 hours** of training and education are required annually. Continuing evaluation of competence is performed annually by the authorizing physician, the staff's supervisor, or clinical designee (refer to DSHS SDOs).
- c) For non-licensed staff who do not provide services under SDOs but support the TB program (e.g., program managers, case registrars, administrative staff) at least 12 hours of training and education are required annually.
- d) For physicians providing TB patient services (i.e., authorizing physicians, licensed healthcare providers), the required number of hours specific to TB can be determined by the physician's supervisor or designee.
 - NOTE: Physicians are required to obtain 48 hours of CEs every two years. Refer to tmb.state.tx.us/page/resources-cme-for-md-dos. It is recommended that TB physicians obtain at least 16 hours (CE or other) in TB, annually.
- D. Ensure staff attend required training and educational activities relevant to their role in TB. Refer to in *Appendix M: TB Training and Education Resources*. Recommended training and education can also be used to obtain the relevant number of hours initially and annually.

1. Required training includes:

- a) Initial training listed in A, above.
- b) DSHS TB Unit's TB New Staff Orientation event, held quarterly in Austin, Texas. This is required for TB program managers, nurses, contact investigators, case registrars/data entry staff after three months of hire, when offered by the TB Unit.
- c) Monthly TB virtual conference calls hosted by the DSHS TB Unit. This is required for, at minimum, the TB program manager or their designee responsible for sharing information with staff who are unable to attend these calls.
- d) For nurses with less than one year of experience in TB, attend nurse case management trainings offered by Heartland National TB Center (HNTC). Virtual trainings are required within the first

year of hire (or as soon as offered by HNTC if the trainings have occurred after the hire date). In-person trainings are highly recommended. Training schedules and registration are found on the HNTC website: heartlandntbc.org/calendar/.

2. Recommended trainings include:

- a) DSHS TB Unit trainings and webinars (note, these are shared with R/LHD TB programs via email, when offered).
- b) Webinars and in-person conferences provided by <u>Heartland</u>
 <u>National TB Center</u> as well as CDC's <u>Centers of Excellence (COE)</u>
 and the <u>National TB Coalition of America (NTCA)</u>.
- c) CDC's TB 101 course (see cdc.gov/tb/hcp/education/tb-101-for-health-care-workers-continuing-education.html).
- d) CDC's Core Curriculum course (see cdc.gov/tb/hcp/education/core-curriculum-on-tuberculosis.html).
- e) Skills-based training offered locally.
- f) Research articles, case studies, and other locally-designed training activities to increase knowledge and competency around TB prevention and care.
- g) Annual review of SDOs, Texas TB Manual, and any local policies and procedures that are updated periodically. This training can be designed by the TB program manager in collaboration with the medical director or other clinical designee.
- E. To maintain a competent TB workforce, the TB education designee must ensure core and specialized training topics for TB program staff include material relevant to the staff members' role in TB.
 - 1. Core training for all staff includes:
 - a) transmission and pathogenesis of TB;
 - b) epidemiology of TB;
 - c) diagnosis of TB infection and disease;
 - d) treatment for TB infection and disease;
 - e) TB reporting and state of Texas notifiable conditions;
 - f) cultural awareness; and
 - g) interpreter utilization.
 - 2. Specialized training topics based on duties and responsibilities include:
 - a) drug interactions and medication toxicity;
 - b) TB CI;
 - c) TB surveillance in hospitals and institutions;
 - d) infectiousness and infection control;
 - e) patient adherence;
 - f) interviewing, investigating, and influencing techniques;
 - g) directly observed therapy;
 - h) TB nurse case management for TB infection, TB disease, and drug resistant TB;



- i) TB program management; and
- j) CDC TB surveillance and reporting.
- F. Maintain documentation of training for all staff (including contractors).
 - 1. TB education designees must maintain documentation of initial and annual staff training in each staff member's file. It is recommend that this is obtained from staff at least monthly.
 - 2. Documentation of required hours may occur with the following:
 - a) Certificates of attendance showing the number of hours attended.
 - b) CEs offered by credentialed entities showing the number of credits (hours) awarded.
 - c) For training and education where a certificate is not awarded, TB education designees may award hours depending on length of training activity. Document hours using a training log or locally-designated system. Refer to Sample A in *Appendix N: Sample TB Training and Education Logs.* Training logs should include:
 - job titles;
 - training dates;
 - training or course titles; and
 - number of hours.
 - 3. Each medical director and/or LHA must have access to training records to verify that those operating under their medical license have the requisite experience and training.
- G. Notify the TB Unit of newly hired TB staff, including TB program managers, nurses, contact investigators, and case registry staff within 30 days of hire. Submit the *Notice of Change in TB Personnel* to TBProgram@dshs.texas.gov.
- H. Educate external stakeholders.
 - 1. As resources allow, provide TB education and training to:
 - a) schools;
 - b) correctional facilities;
 - c) community healthcare providers;
 - d) homeless shelters; and
 - e) social service providers who may serve populations at high risk for TB or where the consequences of disease transmission could be severe.
 - 2. Maintain documentation (refer to Sample B in *Appendix N: Sample TB Training and Education Logs*) of all external stakeholder TB trainings (including hours, topics, dates, group type, and number of participants) in accordance with local retention protocols and procedures.
 - 3. Report stakeholder trainings on the DSHS APR.

XIX. Monitor Budget Expenses

General Requirement

LHDs will monitor budget expenses and maintain records in accordance with DSHS contract general provisions. Public health regions will monitor budget expenses and maintain records as outlined in DSHS policies.

Activities

- A. LHD TB programs are allowed a 25% maximum deviation from total DSHS funds to shift between direct cost categories (except equipment).
 - 1. If the budget transfer exceeds 25% of the total contract, alone or cumulatively, a formal contract amendment is required.
 - a) Contractors shall provide notification of the budget transfer by submission of a revised Categorical Budget Form to the System Agency Contract Manager, highlighting the areas affected by the budget transfer.
 - b) After review, the System Agency Contract Manager shall provide notification of acceptance to the contractor via email, upon receipt of which the revised budget shall be incorporated into the contract.
 - 2. LHDs must notify the DSHS Contract Management Section (CMS) of any requests to shift funds between direct categories of their award, including any equipment and indirect requests. The equipment threshold is currently \$5,000.
 - 3. LHDs must notify the DSHS Contract Management Section (CMS) of any request for changes to Personnel listed on the approved budget template within five days of change.
- B. Submit requests for reimbursement or payment by the last business day of the month following the month in which expenses were incurred or services provided.
- C. Lapse no more than one percent of federal and state funds. Lapsing above the maximum percentage may impact future allocations.
 - 1. At the beginning of each state fiscal year, maximize the use of federal funds FIRST as lapses may impact future CDC funding.
 - 2. Personnel should be spent according to the monthly percent allocation in the approved budget template for both TB federal and TB state funding. Salary savings due to vacancies can be reallocated to another approved contractual category except regional salary savings.
 - 3. The TB Unit reserves the right to decrease funding amounts as the result of budgetary shortfalls and/or due to lapsing more than one percent of total funds.
- D. Notify CMS if personnel change requires a contract amendment.



- E. TB funded budgets should not allocate funds for services provided by DSHS TB Unit at no additional cost to contractors.
- F. Invoices should be submitted for the services provided based on the Purchase Order (PO) service dates. Invoices should not exceed the PO amount for that service period. Email invoices@dshs.texas.gov and CMSInvoices@dshs.texas.gov.
- G. All submitted invoices should be accompanied with a completed support document that aligns with the approved budget.

XX. Monitor Surveillance, Reporting, and Case Management Activities in Correctional and Detention Facilities

General Requirement

TB programs will monitor and participate in TB prevention and care activities in correctional and detention facilities, except TDCJ. The goals of correctional TB activities are early detection (case-finding), containment, treatment, and prevention in correctional and detention facilities. Refer to *Table 2: Coordination of Care for TB Management* for details of care coordination at each facility.

The TDCJ is responsible for directing TB care-related services within all prison units and community corrections under their purview. The TDCJ Health Services Division oversees medical services provided by contractors in state prisons and has the statutory authority and responsibility to ensure access to care, monitor the quality of care, investigate medical grievances, and conduct operational review audits of healthcare services.

Regardless of size and ownership, all correctional and detention facilities in Texas, including federal prisons, state prisons, local jails, and community correction facilities are subject to the provisions of the Communicable Disease Prevention and Control Act (Texas Health and Safety Code, Chapter 81, Rule§ 81.065, 2016) and other applicable federal and state laws.

Activities

- A. Provide technical assistance on TB prevention and care including nursing care, case management, and contact investigations for all correctional and detention facilities, except TDCJ, and monitor compliance with state laws.
- B. Promote TB screening and treatment.
 - 1. Offer guidance to promote appropriate and timely screening practices (e.g., symptom screening, testing with TST or IGRA).
 - 2. Provide medical oversight for TB cases, TB infections, suspects, and contacts.
 - 3. Provide consultation for TB infection treatment among high-risk groups.
 - 4. The initiation of treatment for TB infection should include consideration and planning for the likelihood of the patient continuing and completing treatment under supervision or being released from the facility before completion of treatment.
 - 5. Provide guidance that the CDC does not recommend testing a person with a TST and an IGRA (i.e., confirmatory testing).
- C. Participate in discharge planning and continuity of care activities.
 - 1. Facilitate discharge planning for inmates with suspected or confirmed TB who are scheduled to be released or transferred to other correctional facilities or jurisdictions.



- 2. Facilitate planning for inmates diagnosed with TB infection and currently on treatment who are scheduled to be released or transferred to other correctional facilities or jurisdictions.
- 3. Follow up to ensure that TB cases and suspects continue TB treatment at the TB clinic nearest their residence or at the receiving correctional facility.
 - a) Per the <u>TAC</u>, <u>Title 25</u>, <u>Part 1</u>, <u>Chapter 97</u>, <u>Rule §97.191</u>, regardless of size and ownership, all correctional facilities must assure continuity of care for inmates receiving TB treatment.
 - b) Continuity of care and services includes and is not limited to, identifying an inmate's educational, medical, or psychological needs; developing a plan to meet treatment, care, and service needs; and coordinating treatment provision, care, and services between various agencies to ensure continuity while incarcerated and post-release.
 - c) Ensure Chapter 89–designated correctional facilities have a written continuity of care plan. Contact cqiteam@dshs.texas.gov for a sample plan or any resources related to the continuity of care plan.
- 4. Provide continuity of care for employees and any inmates released to the community who are undergoing treatment for TB disease or infection.
- 5. Provide technical consultation to ensure adequate precautions are taken while transporting patients between correctional facilities or detention centers.
- 6. Refer foreign nationals to CURE-TB or Migrant Clinicians Network for continuity-of-care coordination outside the U.S. (refer to dshs.texas.gov/disease/tb/surv.shtm).
- D. Coordinate, plan, and/or actively participate in CIs.
 - 1. Maintain a formal collaboration between public health officials, R/LHD, and correctional facility. If collaboration has not been established before a CI is needed, creating this relationship as part of the investigation is necessary.
 - 2. Provide TB education and counseling to patient.
 - a) Review HIV testing policies, procedures, and aggregate statistics of the facility. If inmates have not been offered voluntary counseling, testing, and referral for HIV infection, and TB exposure is suspected, offering voluntary HIV counseling, testing, and referral is strongly recommended.
 - 3. Conduct an interview to identify contacts and to determine an inmate's infectious period.
 - 4. Provide TB education and counseling to patient.
 - 5. Assess TB transmission risk based on the index case's degree of infectiousness, length of exposure to index, environmental factors, and contact characteristics (e.g., HIV infection).



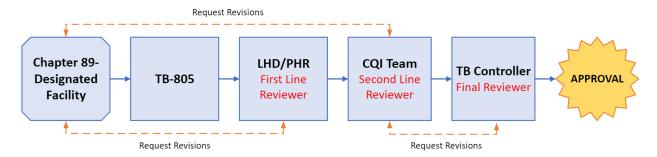
- 6. Evaluate identified contacts based on CDC priority classification (TB testing may be conducted by the TB program or the facility medical staff under the strict guidance of the TB program).
 - a) Because of rapid turnover of inmates and crowding, ensure there is a process of assigning priority schemes. Unless tracking records for inmates who were in a confined space with an infectious TB patient allow a determination that aggregate exposure was brief (e.g., <8 hours), these contacts should be assigned high priority.
 - b) High-priority contacts who are transferred, released, or paroled from a correctional facility before medical evaluation for TB should be traced.
- 7. Ensure contacts start and complete treatment for TB infection or TB disease, as indicated.
- E. Provide oversight for Texas Health and Safety Code Chapter 89-designated facilities (refer to statutes.capitol.texas.gov/Docs/HS/htm/HS.89.htm).
 - Perform first-line quality assurance review and submit the 12-11462 (Monthly Correctional TB Report) and 12-11461 (Report of TB) Conditions) to GlobalScape by the 15th day of the following month. Send an email to cgiteam@dshs.texas.gov upon upload.
 - 2. Ensure Chapter 89-designated facilities submit the *Tuberculosis Testing Supply Request Form* along with their <u>12-11462 (Monthly Correctional TB Report)</u> and <u>12-11461 (Report of TB Conditions)</u> forms.
 - 3. To the extent funds are available, distribute Purified Protein Derivative (PPD) and syringes to correctional facilities that meet Texas Health and Safety Code, Chapter 89 criteria upon their request (refer to Chapter XIII. Inventory Management of Medications and Supplies for ordering and distribution criteria).
 - a) If PPD and syringes will be provided, ensure their current approved Correctional Tuberculosis Screening Plan reflects the R/LHD as the provider.
 - b) Ensure orders are placed in PIOS using the correct account (e.g., facility name C/O Health Department name)
 - 4. Do not provide state-purchased IGRA supplies to correctional and detention facilities.
 - 5. Chapter 89-designated facilities must submit the 12-11462 (Monthly Correctional TB Report), 12-11461 (Report of TB Conditions), and TB Testing Supply Request form to the TB program by the 5th day of the following month.
 - a) Monitor 12-11462 (Monthly Correctional TB Report) and TB Testing Supply Request forms to ensure the number of TB tests reported justifies the amount of PPD and syringes provided.
 - b) Address suspected misuse of state funded supplies immediately with the correctional facility and report to the TB Unit.

- 6. Review correctional TB screening plans for completion and accuracy. Refer to *Figure 13: TB-805 Review Process*.
 - a) Correctional TB screening plans are renewed each year.

 Chapter 89-designated facilities must submit the TB-805

 (Correctional Tuberculosis Screening Plan) directly to the R/LHD and copy CongregateSettings@dshs.texas.gov between mid-September and November 1 each year.
 - b) The R/LHD reviews the screening plans for accuracy, completion and request revisions from Chapter 89 facilities. R/LHDs must complete their review and provide feedback to the Chapter 89 facility within two weeks (10 business days) of receiving the TB-805.
 - c) The R/LHD submits the corrected and complete screening plan and screening plan checklist to CongregateSettings@dshs.texas.gov and copy cqiteam@dshs.texas.gov
 - d) The CQI team reviews the screening plan and requests any revisions directly to the Chapter 89 designated facility.
 - e) The Chapter 89 facility sends the revised screening plan to CongregateSettings@dshs.texas.gov for final review.
 - f) The CQI team sends the approved screening plan and approval letter to the Chapter 89-designated facility with copies sent to TB program managers and correctional liaisons. The approval period covers January through December each year for all plans submitted on time during the submission and review period.

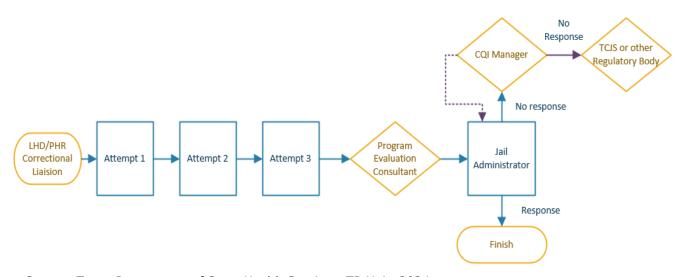
Figure 13: TB-805 Review Process



- F. Maintain adequate records relevant to TB prevention and care.
 - 1. Correctional TB screening plans must be retained for five years.
 - 2. The 12-11462 (Monthly Correctional TB Report) and 12-11461 (Report of TB Conditions) must be retained for three years.
- G. Provide training, education, and/or technical assistance to correctional facility staff and report on the DSHS APR.

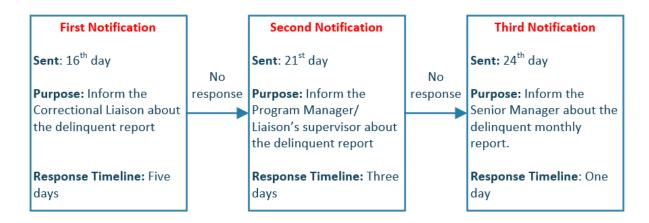
- 1. Training includes but is not limited to, how to complete the 12-11462 (Monthly Correctional TB Report), 12-11461 (Report of TB Conditions), or Correctional Tuberculosis Screening Plan.
- Technical assistance includes but is not limited to, developing an infection control plan, strengthening a current infection control plan, or developing a continuity of care plan. Contact the CQI team at <u>cqiteam@dshs.texas.gov</u> for a sample continuity of care plan or additional resources.
- H. Submit 12-11462 (Monthly Correctional TB Report) and 12-11461 (Report of TB Conditions) according to the assigned deadlines. If there is no communication from the PHR or LHD about a delay in receiving the reports, the CQI team will initiate an escalated communication process to ensure timely receipt of statutory documents.
 - Notifications will be escalated for reports not received from a Chapter-89 designated facility. Refer to Figure 14: Escalated Communication Workflow Process.
 - a) The R/LHD will make three documented attempts to receive the monthly report from the Chapter 89-designated facility by the 15th day of the following month.
 - b) The R/LHD will contact the CQI Program Evaluation Consultant (PEC), to notify the PEC of the attempts.
 - c) The CQI PEC will contact the Jail Administrator on behalf of the R/LHD.
 - d) If the PEC is unsuccessful in their attempt, the CQI Manager will contact the Jail Administrator.
 - e) If the CQI Manager is unsuccessful in the attempt, the notification will be escalated to the Texas Commission on Jail Standards (TCJS) or other regulatory bodies.

Figure 14: Escalated Communication Workflow Process



- 2. Notifications will be escalated when correctional reports are not submitted by TB programs to the DSHS CQI team. Refer to *Figure 15: Tiered Notification Workflow Process*.
 - a) Beginning the 16th day of the following month, the CQI team will send the first notification to the correctional liaison. The response time requested is within five days.
 - b) If a response is not received within five days, a second notification will be sent to the correctional liaison to include the program manager or correctional liaison's supervisor. The response time requested is within three days.
 - c) If a response is not received within eight days of the first notification, a third notification will be sent to the correctional liaison, program manager, correctional liaison supervisor, and will include the TB program's senior manager or director. The response time requested is within one day.

Figure 15: Tiered Notification Workflow Process



XXI. Conduct Continuing Quality Improvement Activities to Maintain a Robust Tuberculosis Program Infrastructure

General Requirement

TB programs will evaluate their performance in meeting key measures including their process to maintain a robust TB infrastructure. TB programs will implement practices that meet clinical and reporting quality assurance (QA) standards and ensure the appropriate use of state and federal funds. This includes performing internal audits as well as participating in TB Unit site visits.

Activities

- A. Update protocols and procedures to support TB program performance evaluation and CQI.
- B. Perform self-audits.
 - 1. Designate staff to review program practices to ensure services are delivered in accordance with DSHS program standards and as outlined in the Texas TB Manual.
 - 2. Ensure medical record documentation as per the <u>TAC, Title 22, Part 9, Chapter 163, Rule §163.1</u> requirements.
 - 3. Develop a checklist to ensure the completeness of medical record documentation.
 - 4. Ensure that all funded TB program staff are current on TB-related trainings, according to the job position. Refer to *Appendix M: TB Training and Education Resources* and *Appendix N: Sample TB Training and Education Logs.*
- C. Conduct cohort reviews in accordance with the frequency (annual or quarterly) designated in the DSHS *Tuberculosis Cohort Review Process* (refer to *Appendix O: Cohort Review Process*).
 - 1. Compare treatment completion and contact evaluation rates by cohort periods and years to assess program progress.
 - 2. Identify trends that support or hinder effective TB prevention and care activities.
 - a) Identify outcomes that fall short of local, state, and/or national performance objectives.
 - b) Develop corrective action plans to improve outcomes.
 - 3. Complete the Cohort Review Summary and each individual presentation form. Submit the summary and presentation forms, along with a list of counted cases, to the TB Unit via GlobalScape.
 - 4. TB programs with fewer than six counted cases in a given year may conduct a yearly cohort review due by December 31 of the following year.
- D. Perform routine case management review and document findings.

- 1. Establish a case management or case review schedule.
- 2. Identify deviations from established standards of care.
- 3. Address needed changes in treatment and case management.
- E. Use NTIP and Texas Performance Measures (PM) to assess progress toward achieving state and national objectives.
 - 1. Identify TB program staff who need access to NTIP. At a minimum, this should include the TB Program Manager.
 - 2. Email the TB Program at <u>TBProgram@dshs.texas.gov</u> for information on obtaining access to NTIP.
- F. Meet Texas TB Performance Measures (refer to *Table 17: Texas TB Performance Measures*: 2025-2029).
 - 1. If a program's performance falls short of desired benchmarks, DSHS may (at its sole discretion) require additional measures to improve performance on a timeline set by DSHS.
 - 2. Maintain documentation used to calculate performance measures as required by <u>General Provisions Article VIII "Records Retention"</u> and by <u>TAC Title 22, Part 9, Chapter 163, §163.2</u>, regarding retention of medical records.

Table 17: Texas TB Performance Measures: 2025-2029

Performance Measure (PM)		Benchmark (%)				
	2025	2026	2027	2028	2029	
PM 1: Newly reported TB cases must have an HIV test performed unless there is documented evidence of an HIV-positive result or the patient refuses. Exclude TB cases who: are diagnosed at death; and/or aged 11 and under at the time of diagnosis.	91	92.7	93.2	94	94.5	
PM 2: All suspected and confirmed TB patients are placed on DOT any time during the course of treatment.* Exclude TB cases who: are diagnosed at death; are not recommended for treatment; and/or have not started on treatment.	92	92.3	92.5	93	93.5	
PM 3: Newly reported suspected and confirmed cases of TB are started on the standard four-drug regimen. Exclude TB cases who: are diagnosed at death; are not recommended for treatment; and/or have not started on treatment.	94	94.2	94.4	94.7	95	

Performance Measure (PM)		Benchmark (%)					
	2025	2026	2027	2028	2029		
PM 4: Newly reported patients aged 12 and older for whom TB was identified in the pleura or other respiratory site must have sputum collected and tested for AFB smear and culture results.† Exclude TB cases who: • are diagnosed at death; • aged 12 years and under; and/or has a site of TB disease that is not respiratory.	94	94.7	95.7	96.6	97		
PM 5: Newly reported cases of TB with AFB-positive sputum culture results must have documented conversion to sputum culture-negative within 60 days of initiation of treatment. Exclude TB cases who:	64	64.5	65	65.5	66		
PM 6: Newly diagnosed TB cases that are eligible to complete treatment within 12 months must complete therapy within 365 days or less. Exclude TB cases who: • have TB in the central nervous system; • have TB in bone, joint, or skeletal system; • are diagnosed at death; • die before or during treatment; • are resistant to rifampin; • have meningeal TB disease; • are age 14 or younger with either miliary disease or a positive blood culture for TB; and/or • cases who moved outside of the U.S.	87	87.5	88	88.5	89		
PM 7: Increase the proportion of culture-confirmed TB cases with genotyping result reported.	98.5	98.7	99	99	99		
PM 8: TB cases with initial cultures positive for <i>M. tb</i> complex are tested for drug susceptibility with results documented in the medical record and in NEDSS.	93	94	95	96	97		
PM 9: Newly reported TB patients with a positive AFB sputum-smear result have a defined infectious period documented in the medical record and in NEDSS.	91	91.5	92	92.5	93		
PM 10: Newly reported TB patients with a positive AFB sputum-smear result have at least three contacts evaluated as part of the contact investigation.	79	79.5	80	81.5	82		

Performance Measure (PM)	Benchmark (%)					
	2025	2026	2027	2028	2029	
PM 11: Newly identified contacts identified through the contact investigation that are associated with a sputum AFB smear-positive TB case are evaluated for TB infection and disease.	69	69.5	70	70.5	71	
PM 12: Contacts identified to an AFB smear positive patient and for whom TB infection was diagnosed must be started on treatment for TB infection within a week of diagnosis.	66	66.5	67	67.5	68	
PM 13: Contacts identified to an AFB smear positive patient and for whom treatment was initiated for TB infection must complete treatment within the recommended time frame.	82	82.5	83	83.5	84	
PM 14: For class-B immigrants and refugees whose overseas CXR results indicate consistent with TB, increase the proportion whose medical evaluation was initiated within 30 days of notification.	51	51.5	52	52.5	53	
PM 15: For class-B immigrants and refugees whose overseas CXR results indicate consistent with TB, increase the proportion whose evaluation was completed within 120 days of notification.	48	48.5	49	49.5	50	
PM 16: For class-B immigrants and refugees whose overseas CXR results indicate inconsistent with TB and subsequent evaluation in the U.S. reclassifies patient as having TB infection, increase the proportion who start treatment for TB infection.	55	56	57	57.5	58	
PM 17: For class-B immigrants and refugees whose overseas CXR results indicate inconsistent with TB and subsequent evaluation in the U.S. reclassifies patient as having TB infection, increase the proportion who complete treatment for TB infection.	82	82.5	83	83.5	84	

^{*} CDC recommends treatment initiation for TB patients with positive AFB sputum-smear results within 7 days of specimen collection.

- G. Prepare for and participate in TB Unit site visits.
 - 1. The TB Unit will conduct onsite reviews of R/LHDs based on a routine or targeted need.
 - a) DSHS regional TB program staff may provide technical assistance and support in onsite reviews of LHDs in their jurisdiction.
 - 2. Once a site is selected, the CQI team will coordinate logistics with the TB program manager.
 - 3. The Contract Management Section will send a formal notification to the TB program that includes an agenda, a selected list of medical chart

[†] Report results to DSHS according to the surveillance reporting schedule.



identification numbers, and the <u>DSHS TB Unit Onsite Review Tool</u>.

- 4. During the onsite visit, the TB Unit will review medical charts, conduct staff interviews, and perform direct observation to complete the Onsite Review Tool.
 - a) Ensure that TB program training records and medical chart documentation comply with the guidelines in the Texas TB Manual (relevant chapters) for onsite reviews.
- 5. The TB Unit will provide the R/LHD with a final report detailing findings and specific recommendations to address non-compliance with the Texas TB Manual.
- 6. The R/LHD will submit a Corrective Action Plan (CAP) in response to the final report that addresses each recommendation with time-limited activities for monitoring, implementing, and ongoing follow-up by the TB Unit.

XXII. Court-Ordered Management

General Requirement

TB programs will make every effort to support patients diagnosed with TB disease with adhering to the treatment plan. When all efforts to support care fail and the patient exhibits non-adherence, potentially posing a public health threat, TB programs will seek court-ordered management as a last resort. Court-ordered management ensures that:

- 1. TB patients complete an adequate course of TB treatment.
- 2. Patients receive appropriate evaluation and care when treatment is interrupted due to patient's violation of the terms of the signed control order.
- 3. The public is protected from infectious TB patients who are non-adherent with isolation.

If the LHA and/or LHP determines that without treatment the patient will pose a public health threat, programs may consider court proceedings on patients who are not infectious but rather, non-adherent with their treatment plan.

The process outlined in this chapter should facilitate processes between the TB program, the RMD, and local county/city attorney to establish legal justification for isolation and to establish a process that works well within their jurisdiction. Refer to Health and Safety Code, Chapter 1, Communicable Diseases, Subchapter E. Control, 81.081. "A health authority has supervisory authority and control over the administration of communicable disease control measures in the health authority's jurisdiction unless specifically preempted by the department." See statutes.capitol.texas.gov/Docs/HS/htm/HS.81.htm#81.081.

Definitions

Application for Extended Management (DSHS form 86963 1): Also referred to as Motion for Extended Management (MEM). This is the application to the court for the management of a person with a communicable disease. This refers to the full application that is used in the court order process.

Motion for Protective Custody (MPC) (DSHS form 86964 1): Also referred to as Order of Protective Custody (OPC). An order to have the patient detained in appropriate isolation for a short period of time. This option is only available if the patient is an immediate threat to the public at the time the order is sought.

Non-adherent: Failure to comply with the health authority's written control order (<u>DSHS form TB-410</u>). Examples include but are not limited to missing medication and failure to follow respiratory isolation which precludes safe and effective TB therapy and presents a potential for public health impact.

Activities

- A. Ensure the following is done before initiating court-ordered management:
 - 1. Patient has been issued the *Health Authority Control Order* (<u>DSHS</u> <u>form TB-410</u>) acknowledging understanding of treatment and adherence expectations.
 - a) This document should be signed by the patient, the LHA, and a witness.
 - (1) Programs should have a policy in place when the health authority does not sign the TB-410. Refer to <u>Health and Safety Code</u>, Sec. 81.082 Administration of Control Measures.
 - (2) TB-410 must be complete with patient name, date of birth, and diagnosis must be complete before the LHA signs. Patient signature should be the final signature.
 - (3) A rubber stamp signature is legally binding if the person who uses the signature stamp is either the person the stamp represents or someone legally authorized to use the stamp on their behalf.
 - b) Maintain clear documentation if the patient refuses to sign.
 - 2. Patients with suspected or confirmed TB disease understand their role in receiving treatment and care for TB.
 - 3. Patients understand services they will receive from the TB program for successful treatment outcomes.
 - Document any breach of expectations outlined on <u>DSHS form TB-410</u> (e.g., missed DOT, attempts to reach patient) in the patient's medical record.
- B. Include the following in the patient's medical record:
 - 1. A description of the physical and mental condition of the patient.
 - 2. The degree of infectiousness.
 - 3. Proposed threat to public health and supporting documentation of clinician, health authority, or DSHS-recognized TB medical consultant.
 - 4. A description of non-adherent behaviors and the steps taken to address non-adherence to include all attempts taken to contact the patient.
 - 5. Documentation from the clinician, health authority, or DSHSrecognized TB medical consultant if the patient has converted to smear negative but is expected to become infectious again.
- C. Begin the court-ordered management process.
 - The TB program nurse will request court ordered management and initiate the process ensuring the following are notified of an impending application for Court Ordered Managed Care and/or Order of Protective Custody.
 - a) Medical director (if LHD requesting application)
 - b) DSHS RMD (if applicable)



- c) TB program manager
- d) Nursing supervisor (if applicable)
- e) LHA
- f) Jurisdiction's district attorney (DA)
- g) **DSHS Office of General Counsel:**

Department of State Health Services 1100 W. 49th Street Austin, TX 78756 512-458-7236

- h) Texas Center for Infectious Disease (TCID): dshs.texas.gov/regional-local-health-operations/texas-centerinfectious-disease/court-ordered-management.
- 2. The TCID admission process must be followed and transportation ¹³ arranged by the managing jurisdiction.
 - a) TCID serves as the designated facility for patients who are court-ordered for extended management (MEM) in Texas.
 - b) TCID **will not** accept patients with an MPC as it is not a holding facility. For patients with an MPC, the TB program must secure a holding facility before this motion.
 - c) All patients will need to have a medical clearance indicating they are medically stable prior to TCID admission, even if the patient is housed at a jail infirmary.
- D. Initiate court-ordered management proceedings for Extended Management (MEM). Forms can be found at dshs.texas.gov/idcu/disease/tb/forms/#court.
 - 1. Complete the *Health Authority's Affidavit of Medical Evaluation* (DSHS form 86749 1) which is Exhibit A of the application. This document should specify reasons an order for commitment is being sought. Indicate these reasons on Line 7. This form must be filed in the district court in the county where the person resides, is found, or is receiving court ordered health services.
 - 2. Present the following to the LHA for signature:
 - a) Exhibit A (<u>DSHS form 86749 1</u>), which will need to be notarized.
 - b) Exhibit B, *Health Authority Control Order* (TB-410) and Exhibit 1A, which includes the following:
 - All progress notes including documentation of missed appointments, and attempts to locate for continued treatment,

¹³ **Texas Health & Safety Code Sec. 81.179. Transportation of Person.** (a) The court shall order the sheriff or constable to transport the person to the designated healthcare facility. (b) A female shall be accompanied by a female attendant during conveyance to the healthcare facility. (c) The health authority or department shall instruct the sheriff or constable on procedures that may be necessary in transporting the person to prevent the spread of disease.



- Bacteriology results,
- Radiology reports,
- DOT logs including missed doses with outreach documented attempts to locate patient,
- · Consult recommendations for treatment, and
- All other documentation supporting notifications to patient to adhere to therapy (i.e., certified letters from the medical director).
- c) Once complete and signed by the LHA, <u>DSHS form 86749 1</u>, <u>TB 410</u> and Exhibit 1A information will need to be faxed to the DSHS General Counsel's office at 512-776-7751.
- 3. The Office of General Counsel will obtain the Commissioner of Health Concurrence and provide this document to the TB program by fax. The original concurrence will be mailed to the TB program to be placed in the patient's medical record. The TB program must wait for the commissioner's concurrence to move forward with court ordered management proceedings.
- 4. Once all forms are completed and the commissioner's concurrence has been received, provide the above forms to the DA, and follow local procedures as directed by the local attorney, who will likely file an Original Petition for either an MPC or MEM.
 - a) The LHA or LHP will be asked to testify when a MEM is petitioned. It is recommended that the nurse case manager also attend this hearing as directed by the local attorney.
 - b) The local attorney will ask the court to appoint a lawyer for the patient and submit the necessary documents to the court.
 - c) Notify TCID that all paperwork has been filed with the court and final commitment approval is pending.
 - d) If approval for commitment has been granted, the signed MEM will need to be fax to the designated facility (e.g., TCID) by the TB program.
 - e) Follow internal procedure for transfer of patient.
- E. Initiate court-ordered Motion for Protective Custody (MPC) only if the patient is contagious at the time the order is sought, and the patient has the potential of fleeing, and the LHP has determined an MPC is needed. NOTE: TCID will not detain a patient with an MPC.
 - 1. Ensure that a facility has been secured prior to submitting an MPC. TCID is not a detaining facility and will not accept patients with an MPC. Holding facilities serve as placement for the patient until the judge issues the final order for a MEM.
 - 2. Complete Activity #1 through #4 as stated above except for the commissioner's concurrence as this is not needed for an MPC.
 - 3. The attorney will file an MPC and Writ of Commitment to the judge. TB program staff are not asked to testify for this hearing.



- 4. Once signed, the attorney will forward the signed documents to the TB program.
- 5. Follow internal procedure for transfer of patient.
- F. Additional forms used for Court Ordered Management are located at dshs.texas.gov/disease/tb/forms/#court.

XXIII. Confidentiality and Security Standards

General Requirement

TB programs will perform activities outlined in this plan in accordance with applicable state and federal security and confidentiality standards, policies, procedures, and guidelines.

Activities

- A. Submit documentation to the TB program coordinator to confirm that all staff and subcontractors working on activities outlined in this TB Manual receive yearly training on the <u>DSHS Security and Confidentiality Training</u> with a passing score of 85% or above.
- B. Submit inquiries related to database access and security training to TBHIVSTD.AccountRequest@dshs.texas.gov.
- C. Ensure that newly hired staff successfully complete the <u>DSHS Security and Confidentiality Training</u> within 30 days of hire.
- D. Ensure that all staff successfully complete the <u>DSHS Security and Confidentiality Training</u> yearly, within one year of having taken the previous training.
- E. Submit appropriate documentation of security and confidentiality training to TBHIVSTD.AccountRequest@dshs.texas.gov within ten (10) days of completing course.
- F. Designate and identify a HIPAA Privacy Officer authorized to act on behalf of the TB program in developing and implementing requirements outlined in federal and state privacy laws.
- G. Designate a TB program staff (e.g., TB Program Manager) to serve the Local Responsible Party (LRP). The LRP will:
 - Ensure appropriate protocols and procedures are in place for handling confidential information, releasing confidential TB/HIV/STD data and for rapid response to suspected privacy incidents of protocol and/or confidentiality.
 - a) Local protocols and procedures must comply with DSHS policies and procedures. Refer to Appendix K: Privacy and Information Security for additional DSHS procedures around confidential information.
 - b) TB Programs may choose to adopt DSHS policies and procedures as their own.
 - 2. Approve and validate (provide signature) any program staff requiring access to TB/HIV/STD confidential information.
 - a) The LRP will grant authorization to program staff who have a

work-related need to view confidential information.

- (1) Complete the LRP fields on the Account Request form.
- (2) Contact <u>TBHIVSTD.AccountRequests@dshs.texas.gov</u> and copy the person requesting access. The email should include:
 - (i) a statement verifying this person is under your authority;
 - (ii) person's security training certificate;
 - (iii) access request form;
 - (iv) confidentiality agreement;
 - (v) acceptable use agreement form; and
 - (vi) Notice of Change in TB Personnel form.

DSHS will return access requests that do not include the required documents. Email should only request access for one person. Requests for multiple employees will not be accepted. Maintain email correspondence as part of your records. All current forms and instructions are at dshs.texas.gov/thsvh/account.

- Maintain a current list of authorized staff with permission to view and work with confidential information in accordance with the <u>DSHS</u> <u>TB/HIV/STD Local Responsible Party Handbook</u>, Required Documentation Section.
- 4. Maintain copies of current confidentiality forms and training certifications (e.g., personnel files, staff training records).
- 5. Ensure staff members including IT personnel, contractors, mailroom, and custodial staff with access to identifiable public health data complete the DSHS Security and Confidentiality Training yearly.
- 6. Submit TB database account deactivation forms within two business days of employee resignation/termination or transfer to TBHIVSTD.AccountRequests@dshs.texas.gov and a copy TBProgram@dshs.texas.gov. The email should include:
 - a) a statement verifying this person is under your authority;
 - b) person's security training certificate;
 - c) account deactivation form; and
 - d) Notice of Change in TB Personnel form.

DSHS will return requests that do not include the required documents. Maintain email correspondence as part of your records. All current forms and instructions are at dshs.texas.gov/thsvh/account.

- 7. Consult with the THS Section Security Officer on suspected privacy incidents of protocol and confidentiality in compliance with the DSHS TB/HIV/STD Breach of Confidentiality Response Policy.
 - a) Investigate and complete privacy incident reports.
 - b) Limit or restrict access to confidential information for an involved user until the privacy incident investigation is complete.
 - c) Establish and/or enforce corrective and/or disciplinary actions when needed.



- 8. Submit required quarterly reports on time. See *Local Responsible Party Checklist* at dshs.texas.gov/hivstd/policy/security.
 - a) Ensure computers and networks meet DSHS security standards.
 - b) Submit requests for TB/HIV/STD systems user account terminations to TBHIVSTD.AccountRequest@dshs.texas.gov within one business day of identifying the need for account termination.
 - c) Identify local point of contact for changes in user access to secure data, secure network, secure reason, and for receipt of notifications once a user account is terminated.
 - d) Transfer secure data electronically via GlobalScape.
 - e) Maintain a visitor's log for people entering secured areas. The LRP must conduct quarterly reviews of this log.
 - f) Verify user password changes occur at least every 90 days.
 - g) Ensure that portable devices used to store confidential data are encrypted and approved by the LRP.
- H. Ensure confidential data are:
 - 1. Maintained in a secure area when not in use;
 - 2. not left in plain sight; and
 - 3. shredded with a cross-cut feature before disposal.
- I. See <u>DSHS TB/HIV/STD Local Responsible Party (LRP) Handbook</u> for other roles and responsibilities.

Appendix A: The Role of the TB Nurse Case Manager

Funded TB programs in R/LHDs must ensure essential case management services are provided for persons with latent TB infection (ATS class 2), contacts needing preventive "window" prophylaxis, and patients with known or suspected TB disease (ATS class 3 and 5). When services are provided by nurse case managers (NCMs), there are overarching responsibilities of the nurse in service delivery to ensure each patient reaches their therapy goals. Refer to *Table 18: Milestones and Nursing Interventions for TB Patients*.

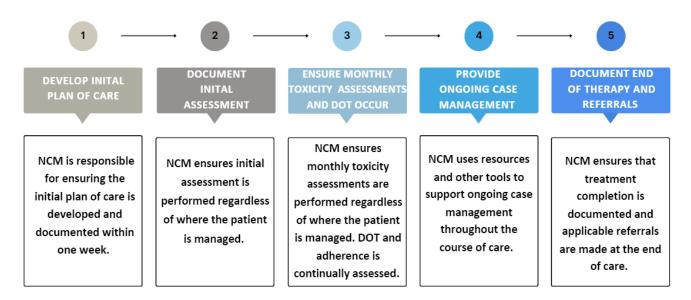
This appendix describes those responsibilities of NCMs managing patients with known and suspected TB disease.

Nurse Case Manager Responsibilities

Authorized Licensed Nurses (Registered Nurses [RNs] or Licensed Vocational Nurses [LVNs]), must have training and observed competency before providing patient services independently, as specified in the <u>DSHS Standing Delegation Orders</u> (SDOs) for Tuberculosis Clinical Services Provided by Authorized Licensed Nurses.

R/LHD managers should ensure services provided are within the scope of practice for each nursing discipline and applicable oversight is provided. Refer to Figure 16: Overview of TB Nurse Case Manager Responsibilities.

Figure 16: Overview of TB Nurse Case Manager Responsibilities



NCMs are responsible for the following:

1) Develop and document the nursing plan of care.

The NCM is responsible for ensuring initial plan of care is developed promptly. DSHS SDOs and any orders from the LHP guide screening, laboratory, and diagnostics when planning for an initial visit. Assign a NCM and healthcare team.

- Document initial care plan within one week, including plan to initiate outpatient DOT within five days if treatment is indicated.
- Coordinate and facilitate initial plan of care with facility if patient is managed outside the R/LHD (e.g., hospital, long term care, jail, etc.)
- Review and obtain copies of laboratory results, bacteriology, and radiology results and plan for additional specimen collection at initial visit if indicated.
- Ensure a TB screening test (IGRA or TST) result is obtained for all ATS class 3 regardless of bacteriology findings on initial report (refer to DSHS SDOs).
- Document nursing plan of care on TB-201 or equivalent.

2) Document initial nursing assessment of the patient.

NCM ensures initial assessment is performed. This baseline evaluation provides important clinical information that will help determine response to treatment throughout the course of care. DSHS SDOs guide screening, laboratory, and diagnostic needs.

- Collect:
 - Medical history and TB symptom screening; document on TB-202 or equivalent.
 - Baseline toxicity assessment; document on TB 205 or equivalent.
 - Laboratory specimen, bacteriology, or other diagnostics as ordered, and as per DSHS SDOs.
- Obtain consents:
 - General Consent and Disclosure (L-36)
 - Consent for TB Drug Therapy (TB-411)
 - Acknowledgement of Understanding (TB-409)
 - Authorization to Release Confidential Medical Information (L-30)
 - Any additional indicated consents
- Document date patient placed on TB respiratory isolation.
- Ensure the initial dose of each new TB medication is provided by an authorized licensed nurse with emergency supplies readily available, when possible, as described in DSHS SDOs; document all DOT doses on TB-206 or equivalent.
- Document patient education on the plan of care, DOT agreement, and other patient-specific education material (e.g., importance of medication adherence); document on TB-201 and TB-203 or equivalent.

3) Ensure monthly toxicity assessments are completed.

NCM ensures monthly toxicity assessments are performed according to drug and

regimen, regardless of where the patient is managed. DOT adherence is continually assessed with interventions documented when missed or self-administered doses occur.

- Ensure toxicity assessments are documented monthly, assessing side effects associated with each drug prescribed; document on TB-205 or equivalent.
- Ensure appropriate interventions are implemented as necessary for addressing side effects or adverse reactions with intervention(s) and outcome(s) documented.
- Ensure monthly laboratory, bacteriology, and radiology tests are ordered and obtained, as per DSHS SDOs and/or LHP orders.
- Provide summary of DOT dose counts weekly and monthly; intervene if
 patient misses doses intermittently by addressing adherence and notifying
 the LHP. Best practice is to evaluate and intervene weekly for missed doses.
- Assess and re-educate on adherence to plan of care.

4) Provide ongoing case management.

Ongoing case management must be maintained throughout the course of care and documented on the TB-201 or equivalent. This includes communicating with LHP as needed to address gaps in care. NCM is responsible for evaluating milestones and intervening as necessary to assist patient is reaching those milestones (refer to *Table 19: Milestones and Nursing Interventions for TB Patients*). Tools to support case management include DSHS SDOs, Texas TB Manual, TB Unit forms, Therapeutic Drug Monitoring (TDM) Process, Medical Consultation, Incentive/Enablers, Translation Services, and Training/Education.

- Provide patient centered care by offering appropriate services when needed, such as social services, translation services, behavioral health referrals, and incentives/enablers when available.
- Link patient to primary care if they do not have an established medical home.
- Submit medical consultation when requested by LHP and when indicated in the DSHS SDOs.
- Request serum drug levels when indicated (i.e., not converting smears in two months, uncontrolled diabetic with no symptom improvement, etc.).
- Ensure collaboration and coordination with external providers is documented and clearly established at onset.
- Intervene early if patient misses DOT doses routinely.

5) Document end of therapy and provide follow up referrals if necessary.

NCM coordinates any final testing as ordered and provides case information to the LHP who verifies treatment completion. The NCM and LHP must ensure the patient responded to therapy and received adequate therapy prior to closure.

- Summarize total DOT doses, notes any missing doses, and clarifies any gaps or interruptions in therapy for the LHP's review prior to closure.
- Link to referral services after treatment, as indicated.
- Provide education to patient about follow-up needs and provides treatment completion letter/documentation.

Table 18: Milestones and Nursing Interventions for TB Patients

Time of	M*!	No
Timeline	Milestone	Nursing Intervention
At diagnosis/ initial report	Patient should be aware of plan of care and understand their current TB status.	Sign necessary consents and discuss plan of care. Provide TB case management plan and discuss any barriers; partner with patient as necessary to develop a plan that promotes successful treatment.
	Patient should have specimen collected as per DSHS SDOs to ensure TB diagnosis and successful treatment can be achieved. Note: NCMs must work with hospitals and laboratories as necessary if initial specimen is collected outside the R/LHD.	Collect and/or coordinate with diagnostic laboratory to ensure specimen is tested for <i>M. tb</i> per SDOs and/or LHP order. If testing was performed by an external/hospital laboratory, proactively communicate to ensure the specimen is available for necessary TB testing (i.e., NAA, smear, culture, DSTs). If necessary, request specimen be submitted to DSHS Austin laboratory.
After 5 DOT doses of adequate therapy	Earliest possible timeframe to release from TB isolation if the patient never had a positive sputum smear result (as well as other factors; refer to DSHS SDOs).	Review bacteriology results, adherence to DOT, and any change in symptoms. If ready for release from isolation, contact the LHP for order. Remind patient about TB isolation procedures and use of masking (surgical mask for patient, N-95 or equivalent for R/LHD staff) until patient is released from isolation.
First few weeks of adequate therapy, not to exceed 6-8 weeks	Patient should have improvement in TB signs and symptoms.	Monitor TB signs/symptoms early in care; communicate with LHP if worsening TB symptoms. Considerations for patients slow to respond to therapy may include collecting serum drug levels, reviewing any issues with DOT adherence, and/or repeating bacteriology testing.
6-8 weeks	Sputum culture results and drug susceptibility tests (DSTs) should be available.	Contact the processing laboratory for results; coordinate with DSHS TB Unit DR-TB nurse if further diagnostics are needed (i.e., MDDR). Communicate with LHP when DSTs are known, as drug regimen may need adjusting.



Timeline	Milestone	Nursing Intervention
6-8 weeks	EMB may be discontinued by LHP when DSTs known, and isolate is susceptible to INH and RIF.	Contact the LHP as soon as DSTs are known and anticipate modified drug regimen, as per DSHS SDOs.
8 weeks	Patient should complete the initial phase after 8 weeks/40 or 56 DOT doses dependent on frequency ordered.	Count DOT doses and ensure adequate length of therapy; re-evaluate adherence; communicate with LHP regarding DOT doses taken and anticipate move to continuation phase when applicable.
8 weeks/ 40 (or 56) doses	PZA may be discontinued by LHP.	Count PZA doses and provide treatment details to LHP. Clarify length of treatment if patient did not receive PZA in initial phase (as per DSHS SDOs).
8 weeks	Patient moves to continuation phase of therapy after 2-month CXR, completion of initial phase, and LHP evaluation.	Coordinate patient evaluation by LHP: include radiology results, symptom screening compared to baseline, DOT doses and adherence, as well as any bacteriology results.
	Patient should have culture conversion (if no conversion at 3 months seek consultation; at 4 months patient is at treatment failure).	Communicate with LHP regarding additional interventions needed. Seek consultation if indicated.
6 months	For patients recommended a 6-month course of therapy: Patient may reach treatment completion for drug susceptible TB after completing all recommended doses by DOT.	Review DOT doses and document final dose count. Ensure patient received the projected number of doses as per regimen (refer to DSHS SDOs). Follow any orders for final
9 months	For patients recommended a 9-month course of therapy: Patient may reach treatment completion for drug susceptible TB after completing all recommended doses by DOT.	bacteriology and or radiology. Obtain order for closure from the LHP after their evaluation. Provide patient education on maintaining their TB treatment records, and any R/LHD or other referral follow up recommended post therapy. Document closure date in the medical record.

Note: These milestones provide over-arching timeframes for NCM to be aware of but may vary depending on the patient. These milestones do not replace the need to ensure patient specific orders are obtained by the LHP. Interventions are followed as per the DSHS SDOs and/or orders from the LHP.



Appendix B: Sample Letter for Child Window Prophylaxis

<insert date>

<insert patient name> <insert patient address> <insert city, state, zip code>

Dear <insert name of parent/guardian>,

I have recommended that your child, <name of child>, take preventive treatment (medicine) to stop <him/her> from getting tuberculosis. Your child was exposed to someone with tuberculosis. Taking medicine will decrease their chance of becoming sick.

Children aged 4 and younger exposed to tuberculosis are at greatest risk of quickly developing life-threatening disease. To prevent this from happening, your child must take medicine observed by (name of R/LHD) for at least the next < number of weeks recommended > weeks.

We will do a second tuberculosis skin test in <number of weeks> weeks. If the test is negative, we will stop the medicine. If the test is positive, we must continue the medicine for <length of treatment> to stop the infection from developing into tuberculosis disease.

If you do not give your child this important medicine, you will endanger your child's health. This may result in the (name of the R/LHD) contacting Child Protective Services. I hope that we can work together to ensure the health of your child.

Please contact <phone number here> with your questions or concerns.

Sincerely,

<insert your name, title, contact information>

Appendix C: Sample TB Program and Private Physician Agreement Letter

<insert date>

Dear <insert private provider's name>,

On <date reported to TB Program>, our office was notified that <insert patient's name/DOB> had <insert diagnostic findings, e.g., "an abnormal CXR showing cavitation, AFB sputum was smear positive">. He/she was reported to <insert PHR/LHD> and upon my review, he/she has been diagnosed with <suspected/confirmed> Mycobacterium tuberculosis.

We discussed this case on <date> and you have indicated that you will remain the patient's treating physician. You have also agreed to coordinate care with <R/LHD> in the following way:

<insert private provider's name> will:

<list below in detailed bulleted form, such as:>

- Follow the prescribed TB regimen based on TB program recommendations (regimen is based on state and national guidelines for the treatment of drug-susceptible TB).
- Perform monthly laboratory tests as indicated and recommended by the TB program.
- Perform routine physical exams.
- Refer to radiology when indicated.
- List other details as appropriate.

The <R/LHD> TB Program staff will:

<list below in detailed bulleted form, such as:>

- Order medications from the DSHS pharmacy.
- Provide directly observed therapy (DOT) on ___(days) to this patient.
- Provide DOT results monthly for visibility of patient's adherence to treatment.
- Contact your office ___(frequency) for copies of diagnostics, progress notes and updates in patient status.
- Collect__(frequency) sputum samples for AFB smear and culture and send results to your office.
- Keep the patient in airborne infection isolation until (criteria here).
- Maintain contact with your office (frequency) until completion of therapy.
- Conduct an appropriate contact investigation following DSHS guidelines.

Thank you for your partnership. Please contact <Insert point of contact, e.g., MD or TB Program Manager/Nurse Case Manager> with concerns or changes in the patient's plan of care.

Sincerely,

<insert your name, title, contact information>



Appendix D: Sample Correspondence Letter for Patients Treated by Private or Community Providers

Letter template¹⁴

<insert date=""></insert>
<insert address="" provider=""></insert>
Subject: <insert and="" dob="" name="" patient=""></insert>
Dear <insert name="" private="" provider's="">:</insert>

The <insert PHR/LHD> TB Program requires a monthly status report on the abovenamed patient under your care for the treatment of tuberculosis.

Please complete all sections of the attached Medical Update Form and return within seven days to <insert name of recipient, physical address, and fax number>. Please include additional radiology and/or laboratory results of acid-fast bacilli testing such as smear, culture, or sensitivity results.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) indicates that protected health information (PHI) can be shared for public health, without individual authorization, to a public health authority. See [45 CFR 164.512(b)].

Thank you for your partnership. Please contact our office at <insert number> with questions.

Sincerely,

<Insert Your name, Title, contact information>

¹⁴ Adapted from: Global TB Center. (2024). *Tuberculosis Case Management: A Guide for Nurses*. Rutgers New Jersey Medical School. globaltb.njms.rutgers.edu/educationalmaterials/productfolder/tbcasenurse.php



Appendix E: Sample Medical Update Form for Patients Treated by Private or Community Providers

Medical Update Form¹⁵

Patient:	Da	Date of Visit:	
Date of most recent physical exam:	W	eight:	
Symptoms:			
☐ Cough (if present specify): ☐ Productive ☐ Unproductive	☐ Hemoptysis	□ Fever	
☐ Weight loss	☐ Fatigue	☐ Chest pain	
☐ Decreased appetite	☐ Night sweats	☐ Chills	
Medications, frequency, and dosages: Bacteriology: Results of most recent chest X-ray (if abnormal, please indicate whether X-ray is stable, worsening or improving): TST or IGRA results:			
	1		
☐ TST	□ IGRA		
Date administered:	Type of IGRA:		
Date read:	Date:		
Millimeter reading:	Result:		
HIV Status: Date TB treatment initiated: Number of doses completed: If completed, date of completion: Comments:			

¹⁵ Adapted from: Global TB Center. (2024). *Tuberculosis Case Management: A Guide for Nurses*. Rutgers New Jersey Medical School. globaltb.njms.rutgers.edu/educationalmaterials/productfolder/tbcasenurse.php.

Appendix F: Additional Patient Services

This is a list of federal, state, and county services available to patients who may need help supporting their medical care outside of tuberculosis disease management. These agencies cover many aspects of medical care, from primary health services to low-cost pharmacies to clinics that support patients regardless of their residency. Refer patients to agencies or programs depending on need.

General Social Care

Find Help.org

Findhelp.org is a social care network promoting education, financial, and healthcare, care for the larger community. Its mission is to connect people to the help they need with dignity and ease. Refer to findhelp.org.

Services for Children

Texas Health Steps

One of the benefits of Texas Health Steps is case management for those who need it. Case management helps families with Medicaid get services their children need—whether the services are for medical or dental needs, medical supplies and equipment, school or education issues or other issues. Refer to https://health-services-providers/case-management-providers-children-pregnant-women.

Children's Health Insurance Program/Medicaid

The Children's Health Insurance Program (CHIP) and Medicaid are jointly funded state-federal programs developed to help Texas families obtain and utilize affordable coverage for uninsured children (ages 0-18). CHIP helps families who earn too much money to qualify for Medicaid but cannot afford to buy private insurance. Programs generally cover regular checkups, immunizations, prescription drugs, laboratory tests, X-rays, and hospital visits. Cost sharing for prescription drugs is based on family income as a percentage of the Federal Poverty Income Level (FPL). Refer to https://doi.org/10.103/journal.com/health/medicaid-chip/medicaid-chip-programs-services/programs-children-adults-disabilities/programs-children-families/childrens-medicaid-chip. 1-877-KIDS-NOW (1-877-543-7669).

Children with Special Healthcare Needs

Children with Special Healthcare Needs (CSHCN) provides medically necessary care to eligible Texas children with special healthcare needs. The bi-yearly program is the payer of last resort. CSHCN offers services including primary care, specialty care, durable equipment, transportation, and medicines Refer to <a href="https://historycommons.org/historyco



General Primary and Specialty Services

Federally Qualified Health Centers

Federally Qualified Health Centers (FQHCs) provide comprehensive healthcare services to underserved communities. Many of the Texans they serve are indigent, uninsured, and underserved. Some FQHCs offer additional services, such as dental, mental health or substance abuse treatment. FQHCs are community organizations with defined target populations and service areas. Services are provided to Medicare, Medicaid, CHIP, Insured and Uninsured people. Patients may be eligible for services based on their family income and a sliding fee schedule. For more information, refer to dshs.texas.gov/chpr/fqhcmain.shtm.

County Indigent Healthcare Program

The County Indigent Healthcare Program (CIHCP) was established by the Indigent Healthcare and Treatment Act authorized by the 69th Texas Legislature in 1985. CIHCP provides healthcare services to eligible residents through counties, hospital districts and public hospitals in Texas. Programs are administered in accordance with Texas Health And Safety Code, Chapter 61 and TAC, Title 26, Part 1, Chapter 363, Rule §363.59.

Eligibility requirements apply, including household income. CIHCP offers a full range of services, including primary care, specialty care, durable equipment, and medicines. For more information, refer to hhs.texas.gov/services/health/county-indigent-health-care-program.

Texas Association of Community Health Centers

The Texas Association of Community Health Centers (TACHC) is a private, non-profit membership association that represents safety-net healthcare providers in Texas. TACHC members include Community and Migrant Health Centers, Health Center Networks and other providers who strive to meet the healthcare needs of the uninsured and underserved.

TACHC serves as the federally designated primary care association for Texas. For more information, refer to <u>tachc.org</u>.

Other Benefits and Resources

Medicaid

Medicaid is a jointly funded state-federal healthcare program established in Texas in 1967. The Social Security Act specifies a set of benefits that state Medicaid programs must provide and a set of optional benefits that states may choose to provide. Eligibility requirements apply. Services may include inpatient/outpatient hospital, laboratory and X-ray services, physician services, nursing facility care, home healthcare, and Texas Health Steps

medical and dental plan for people aged 20 and younger. Refer to tmhp.com.

Your Texas Benefits

This site allows you to apply online for health and human services, including Medicaid, Children's Medicaid, CHIP, and other programs. Refer to tmhp.com.

2-1-1 Texas

2-1-1 Texas, a program of the Texas Health and Human Services Commission, is committed to helping Texas citizens connect with the services they need. Call 211 or click on link below to locate services in your community. For more information, refer to 211texas.org.

Low-Cost Pharmacies and Medications

Medication Assistance Programs

Many pharmaceutical companies, non-profit organizations and state/national agencies provide access to low-cost medications prescribed by healthcare providers. Visit the site below for a list of resources for low or no-cost prescription medicines, including eligibility requirements and contact information. For more information, refer to staterxplans.us/texas.html.

Transportation Services

Modivcare

Modivcare is a leading provider of non-emergency medical transportation, personal and home care, and nutritional meal delivery, affording over 34 million members better access to care in their communities. For more information, refer to modivcare.com.



Appendix G: Medical Consultation Templates

Sample 1: Complex Patient

Date Submitted:		PHR/LHD:		
Case Demographics				
Name:		Date of Birth:	Age:	
Treating Provider:				
Sex:		Nurse Case Manag	er:	
Diagnosis: (e.g., MDR-TB, disseminate	ed TB)			
Co-morbidities/TB risk factors: (e.g	., diabete	es, HIV, history of inc	arceration)	
TB History: (e.g., previous TB treatment, regimen, date of completion)				
Resistant to:				
Susceptible to:				
Treatment Start Date:		Initial Treatment I (medications):	Regimen	
Changes in Treatment Regimen : (e.g., if injectable for how long patient received injectable; please provide drug-o-gram or equivalent)				
Current TB Regimen: (medication/doses list with dates started or provide drug-o-gram)				
Symptoms at Diagnosis: Cough Productive Non-productive Hemoptysis SOB Weight at diagnosis/BMI:	☐ Lo ☐ W ☐ Ni ☐ W ☐ Cr	ever/Chills ess of appetite eakness ght sweats eight loss nest pain ther:		
		,		



Bacteriology: (Include date collected, specimen type, test, and results)			
Date Collected	Specim	en Type/Test	Results
Converted cultures? Isolation status:	□ Yes □	□ No Date Conv	erted:
Chest X-ray: (indicate wi			
Baseline Date: Read:	□ Normal	□ Cavitary □ Non Cav	ritary
Current Date:	□ Normal	☐ Cavitary ☐ Non Cav	/itary
Read:	□ Normal	in cavitary in Norr Car	rical y
	Curre	ent Status	
Current weight/BMI:	/		
Command Inhamatania wasa		d - d \	
Current laboratory res HIV results: ☐ Nega		eegeg) ive (if applicable)	
CD4:	Viral load:	ive (ii applicable)	
Abnormal laboratory re	esults:		
ECG (BDQ)	□ Normal	□ Abnormal	□ Changes
Visual Acuity: (EMB, LZD or RBT)	□ Normal	☐ Abnormal	☐ Changes
Ishihara Plates: (EMB, RBT or LZD)	□ Normal	□ Abnormal	□ Changes
Neuropathy Checks (INH, LZD)	□ Normal	□ Abnormal	☐ Changes
Hearing Test (Injectable)	□ Normal	□ Abnormal	☐ Changes
Psychological Evaluation (CS, CFZ)	□ Normal	□ Abnormal	☐ Changes
(Any abnormal results or changes to baseline provide detailed forms showing trends)			
Current Symptoms: (Compare with symptoms Adherence to treatment:			
at diagnosis, e.g., appetite improved, decreased			
cough, more energy):			
Reason for consult:			



Sample 2: Routine Consult

Patient Name:	Age:		
NAC - 1 -			
Weight:	Medical history:		
TB history:	TB risk factors:		
Signs and symptoms upon admission	to clinic/hospital:		
Imaging results: (e.g., CXRs, CT scans)		
HIV result (if applicable): CD4: Viral load:	CBC: (baseline and most recent)		
CMP: (baseline and most recent):	Results of therapeutic drug monitoring: (if applicable)		
Other laboratory results: (as applicable	le)		
Medications: (list dosages, start/stop do	ates, dates of interruption in therapy)		
Bacteriology: (list test, specimen type, collection date, and result)			
Current status of patient: (provide details of clinical status, DOT, etc.)			
Reason for consult: (clearly state reason for consultation)			

Appendix H: Requesting Molecular Detection of Drug Resistance (MDDR)

The MDDR test is a way to detect potential drug resistance rapidly and accurately in *Mycobacterium tuberculosis* complex (MTBC). MDDR is performed on positive MTB cultures or on patient specimens that are positive by NAAT such as the PCR, see <u>MDDR User Guide (cdc.gov)</u> for acceptable samples. MDDR is performed at the Centers for Disease Control (CDC) Reference Laboratory.

Indications for Submitting MDDR

Isolates of MTBC and NAAT positive processed specimens may be submitted by U.S. Public Health Laboratories for MDDR if one or more of the following criteria is met:

- Known multi-drug resistant (MDR) TB (by culture-based drug-susceptibility testing [DST]);
- Known rifampin resistance (by NAAT or by culture-based DST);
- Contact to known MDR-TB case;
- Previously treated for MTB;
- From a country with a high rate of drug resistant TB;
- Travel to/lived in a country with a high rate of drug resistant TB;
- Patients where the result of drug resistance will predictably have a high public health impact (e.g., daycare workers, nurses);
- Patient is known to have certain adverse reactions to critical anti-TB drug (e.g., unable to tolerate rifampin); and/or
- Other case-by-case scenarios (*seek consultation from a DSHS-recognized TB medical consultant.* Refer to <u>dshs.texas.gov/idcu/disease/tb/consultants</u>).

DSHS Process for Submitting MDDR

First, ensure patient meets one or more of the above criteria. A consult from a DSHS-recognized TB medical consultant is highly recommended and is required once DR-TB is confirmed.

A. Contact the DSHS State Laboratory via phone or email.

Primary contact: Secondary contact:

Benjamin Alpers Jan Owen

<u>benjamin.alpers@dshs.texas.gov</u> <u>jan.owen@dshs.texas.gov</u> Phone: 512-776-2687

B. If indication is "Other situations considered on a case-by-case basis," secure written consult from a DSHS-recognized TB medical consultant.

If the above indications are **not** met, the state laboratory must notify the requestor to obtain a written consult from a DSHS-recognized TB medical consultant **before** submitting request for MDDR.

Appendix I: DSHS TB Formulary

The following medications and supplies for outpatient TB management are available first to TB programs approved by the TB and Hansen's Disease Unit. Place orders via DSHS Pharmacy or contact the DSHS Pharmacy at 512-776-7500.

Drug (Name Brand)	Item Description	Route	Comments	
Amikacin	Vial	IM, IV	See <i>Chapter XII</i> ; Requires consult*	
Bedaquiline (Situro)	Tablet (Tab)	РО	See <i>Chapter XIII</i> ; Requires consult*	
Clofazimine	Capsule (Cap)	РО	See <i>Chapter XIII</i> ; Requires IRB after TB Unit Consultation*	
Cycloserine (Seromycin)	Сар	РО	See <i>Chapter XIII</i> ; Requires consult*	
Ethambutol (Myambutol)	Tab	PO	First-line	
Ethionamide (Trecator)	Tab	PO	See <i>Chapter XIII</i> ; Requires consult*	
Isoniazid	Solution (Soln)/Tab/Vial	PO, IM	First-line	
Levofloxacin (Levaquin)	Soln/Tab/Vial	PO, IV	See <i>Chapter XIII</i> ; Requires consult*	
Linezolid (Zyvox)	Suspension (Susp)/Vial	PO, IV	See <i>Chapter XIII</i> ; Requires consult*	
Moxifloxacin (Avelox)	Tab/Vial	PO, IV	See <i>Chapter XIII</i> ; Requires consult*	
Pretomanid	Tab	РО	See <i>Chapter XIII</i> ; Requires consult*	
Pyrazinamide	Tab	РО	First-line	
Pyridoxine (Vitamin B-6)	Tab	PO		
Rifabutin (Mycobutin)	Сар	PO	First-line	
Rifampin	Cap/Vial	PO, IV	First-line	
Rifapentine (Priftin)	Tab	PO	First-line	
Other Supplies				
Sterile Water for Injection	Vial	IM, IV		
Hypertonic saline (3%)	Vial	Nebulized	For sputum induction	

Drug (Name Brand)	Item Description	Route	Comments
Lidocaine (Xylocaine) 1% or 2%	Vial	IM, IV	
Pregnancy Tests	Test	NA	
Simple Syrup (Cherry flavor)	Bottle	РО	
X-ray envelopes	Envelopes	NA	
Syringes (1/2", 27 gauge)	Syringe	NA	
Tubersol	Vial	SC	
Amber RX bottles	Vial	NA	For self-admin. DOT
Specimen Transport Boxes	Box	NA	Cardboard box for cold-box specimen shipping
Gel Pack	Gel Pack	NA	For cold-box specimen shipping
	Auxiliary Mo	edications	
Azithromycin (Zithromax)	Susp/tab/vial	PO/IV	
Ondansetron	Tab, ODT (orally dissolving tablet)	РО	See Chapter XIII
Dexamethasone	Tab	РО	See Chapter XIII
Promethazine	Tab	РО	See Chapter XIII
Prednisone	Tab	РО	See Chapter XIII
Prednisolone	Tab	РО	See Chapter XIII
Lubriderm Advanced Lotion	Cream	External	For patients on Clofazimine ONLY
Lubriderm SPF 15	Cream	External	For patients on Clofazimine ONLY
Lidocaine/Prilocaine 2.5% cream	Cream	External	See Chapter XIII
SPF 30 and 50	Cream	External	For patients on Clofazimine ONLY
* See DSHS SDOs for medical		n a n t a	

Appendix J: Medication Mailing Processes

Patients with Latent TB Infection Requiring Bulk Bottles

Medications prescribed for the treatment of latent TB infection may be mailed to patients when needed. Before mailing ¹⁶, ensure the patient understands all instructions regarding their prescription. This includes when to stop taking the medicine and when to contact the clinic if they experience any symptoms of medication toxicity. Remind the patient of upcoming follow-up appointments. Finally, instruct the patient to keep medication out of reach of children and in a secure area of the home.

Order bulk bottles of medications and child-resistant amber prescription vials via the Pharmacy Inventory Ordering System (PIOS).

TB programs shall not distribute or supply state-purchased medications to jails and other entities for which the patient receiving the medications are not under the direct care of the TB program.

The following must be included in the mailed package:

- A. As required by the <u>Texas State Board of Pharmacy (TSBP)</u>, <u>TAC Title 22</u>, <u>Part 15</u>, <u>Chapter 291</u>, §291.93), a medication label with the following information must be printed and attached to bottles for self-administered medications (refer to <u>Chapter XIII</u>. <u>Inventory Management of Medications and Supplies</u>):
 - 1. Name, address, and telephone number of clinic
 - 2. Name and strength of drug if generic, name of manufacturer or distributor of drug
 - 3. Quantity
 - 4. Lot number
 - 5. Expiration date
- B. The authorized, licensed nurse will complete the labeling directions to contain:
 - 1. Patient name
 - 2. Date medication provided
 - 3. Physician name
 - 4. Directions for use (per TSBP rules, incomplete directions for use may be present and if so, are to be completed by the authorized, licensed nurse at time of provision).

¹⁶ Follow all security standards when mailing information to patients. Verify mailing procedures with local responsible party (LRP).



- C. A medication fact sheet using patient friendly language should be given to patients to reflect current prescription. Contact local pharmacist or the DSHS Pharmacy Unit for details. Sample fact sheets that may be used are:
 - Isoniazid/Rifapentine (3HP)

 cdc.gov/tb/media/12 Dose Regimen for LatentTBInfection Med Trac

 ker Checklist English.pdf
 - Rifampin cdc.gov/tb/communication-resources/4r-medicationtracker.html
 - Isoniazid accessdata.fda.gov/drugsatfda_docs/label/2016/008678s028lbl.pdf
 - Moxifloxacin (Avelox) accessdata.fda.gov/drugsatfda docs/label/2013/021085s057,021277s 054lbl.pdf
 - Levofloxacin (Levaquin) accessdata.fda.gov/drugsatfda docs/label/2018/020634s070lbl.pdf#p age=52-
 - Bedaquiline (BDQ)
 accessdata.fda.gov/drugsatfda docs/label/2012/204384s000lbl.pdf
- D. A letter in the patient's preferred language explaining how to take the medication, any scheduled toxicity assessments, and contact information for the clinic. Sample language is:

Hello (Patient),

As discussed on our phone call of (date), the (TB program's name) will mail your medications for TB infection. This package contains a (one-month/four week) supply of (name of medication here). Please take the medication as prescribed below and as stated on the enclosed (Name of Fact Sheet) drug fact sheet and bottle(s).

- You have been prescribed: (Name of Medication)
- You should take this medicine as follows: (dosage, frequency)
- The physician who has prescribed this medication is: (Name here)
- Their contact is: (Insert MD direct contact or R/LHD contact)

The TB program must follow up with you at least (weekly/monthly) while you take this medication. Your scheduled phone calls for (enhanced self-administration [ESAT], toxicity assessments, etc.) are:

Dates here

Do not take the medication if you have symptoms or reactions as listed on the fact sheet. Contact the nurse right away at (contact numbers[s] here). Please call the (TB program contact here) if you have questions.

Thank you,

(TB Program Staff)



Patients with Known or Suspected TB Disease or Those on Observed Preventative Therapy for TB Infection (Including Window Prophylaxis) Requiring Medication Packets

When mailing¹⁷ or providing directly observed therapy (DOT) or directly observed preventative therapy (DOPT) packets for self-administration (i.e., weekend/holiday doses) or for VDOT, TB programs must follow guidance recommended by the Texas State Board of Pharmacy (TSBP).

The TSBP recommendations are to reclassify DOT packets to fall under physician provision of medications per <u>Texas Occupations Code</u>, <u>Title 3</u>, <u>Chapter 158</u>. This states that a physician may provide medications to a patient, free of charge, as part of an indigent pharmaceutical program for adherence to a course of treatment.

Before providing the medication, ensure the patient understands all instructions regarding their prescription. This includes when to stop taking the medicine and when to contact the clinic if they experience any symptoms of medication toxicity. Remind the patient of upcoming follow-up appointments. Finally, instruct the patient to keep medication out of reach of children and in a secure area of the home.

When physicians or their designees provide medications in this manner, there are labeling requirements that must be met in accordance with Texas Dangerous Drug Act, Section 483.042(a)(2).

The following must occur:

- A. Place the allotted number of DOT packets in a light-resistant amber Ziploc bag and place a medication label on the outside of the bag. The label must contain the required information printed or handwritten by the clinician/nurse at the time medication is provided to the patient. (Refer to *Chapter XIII*.

 Inventory Management of Medications and Supplies). The label must include:
 - Name and address of medical director or physician who prescribed the drug
 - 2. Date drug is delivered to patient
 - 3. Patient name

4. Name, strength, and directions for use of drug(s).

- B. Provide patients with a medication fact sheet. Contact the DSHS Pharmacy or TB Unit nurse consultant for the *Facts and Comparisons* fact sheets.
- C. If mailing medications, include a letter in the patient's preferred language explaining how to take the medication, any follow up toxicity assessments needed, and information on contacting the clinic. Sample language is:

¹⁷ Follow all security standards when mailing information to patients. Verify mailing procedures with local responsible party (LRP).

Hello (Patient),

As discussed on our phone call of (date), the (TB program name) will mail your medications for (video DOT [VDOT], etc.).

This package contains a (two-week/one-month, etc.) supply of medications prescribed for the treatment of TB disease. Please take the medication as prescribed below and as stated on the enclosed bag of medication packets.

- You have been prescribed: (Name of Medication)
- You should take this medicine as follows: (dosage, frequency)
- The physician who has prescribed this medication is: (Name here)
- Their contact is: (Insert either MD direct contact or R/LHD contact)

The TB program must follow up with you at least (daily/monthly) while you take this medication. Your scheduled phone calls for toxicity assessments are:

Dates here

Do not take the medication if you have symptoms or reactions as listed on the fact sheet. Contact the nurse right away at (contact numbers[s] here). Please call the (TB program contact here) if you have questions.

Thank you,

(TB Program Staff)

Contact the DSHS Pharmacy at 512-776-7500 with questions regarding labeling or ordering of supplies.

Appendix K: Privacy and Information Security

Adhere to Health and Human Services (HHS) and DSHS security requirements for confidential information, privacy, and protected health information (PII). Local health departments should develop local policies that, at minimum, align with HHS' and DSHS' as per below.

HHS Information Security

- A. Texas HHS agencies must maintain the integrity and confidentiality of their information and information resources to ensure their security and availability is not compromised.
- B. HHS IT Data Classification Standard (HHS IT DCS) establishes the requirements for classifying and protecting HHS system data based on the level of sensitivity of data.
 - 1. Sensitivity of HHS data are classified into 3 categories:
 - a) *Public* (e.g., agency publications, press releases, public web postings)
 - b) Agency Sensitive (e.g., legal information such as contracts and non-disclosure agreements, financial information, internal organization charts and contact lists, internal communications, internal operational procedures); and
 - c) Confidential (e.g., client information, workforce information, privileged work product, personally identifiable information (PII), protected health information (PHI) and Sensitive Personal information (SPI)).
 - 2. The HHS IT DCS provides the minimum requirements for protecting each category of HHS data for the following business purposes: Transmission (Internal and External), Marking, Printing, Storage, Archiving or Destroying and Physical Security.
 - 3. Below is the requirement for **External email transmission** that contains confidential information:
 - a) External transmission of confidential information (i.e., PHI, PII and SPI) should not be included in subject line of emails (also applies to Internal transmission);
 - all recipients (and senders) have to be authorized to receive an email that contains distribution lists (also applies to Internal Transmission); and
 - c) emails must be sent encrypted.

Privacy

A. Confidential Information means any communication or record (whether oral, written, electronically stored or transmitted, or in any other form) provided to or made available to a contractor, or that a contractor may create, receive, maintain, use, disclose or have access to on behalf of HHS that consists of or



- includes Personally Identifiable Information (PII), Sensitive Personal Information (SPI), and/or Personal Health Information (PHI).
- B. The focus of regulation for medical privacy below is the federal law, although state privacy laws may also apply.
 - 1. Health Insurance Portability and Accountability Act (HIPAA) protects individually identifiable health information that is transmitted and maintained in any form and is referred to as PHI. That includes information that:
 - a) Identifies an individual, either on its own or when used with other available information.
 - b) Relates to an individual's past, present, or future physical or mental health or condition.
 - c) Relates to an individual's healthcare, or the past, present, or future payment for the individual's healthcare.
 - 2. DSHS is a hybrid entity (i.e., an entity where certain business and program areas are covered by HIPAA and others are not). Business Associates of covered business and program areas are also covered under HIPAA. The following are the DSHS covered business and program areas under HIPAA:
 - a) Healthcare providers include the Texas Center for Infectious Disease (TCID) and regional offices providing case management or other direct client services we bill for (excludes public health outreach, epidemiology, or surveillance services).
 - b) Healthcare clearinghouses include the DSHS Centralized Billing System (CBS).
 - c) Internal Affiliates include the Center for Health Statistics, Health Information Resources Branch, Quality assurance or performance management units for DSHS programs designated as healthcare components, Revenue Management Services, Newborn Screening Unit, and the Central & South Texas Laboratories.
 - d) Business Associates to DSHS Programs include Office of General Counsel and Texas-Wide Integrated Client Encounter System (TWICES).
 - 3. HIPAA Minimum Necessary Standards of PHI and other types of confidential information:
 - a) DSHS workforce members must make reasonable efforts to limit PHI and other types of confidential information to the minimum necessary to accomplish the intended purpose of the requested, permitted, or authorized use or disclosure.
 - b) DSHS managers must make reasonable efforts to limit access to PHI and other confidential information to workforce members who require access to perform their job duties.
 - c) The minimum necessary requirements **do not** apply to:
 - Disclosures to or requests by a healthcare provider for treatment;
 - Uses or disclosures made to the individual;



- Uses or disclosures made pursuant to an authorization required by HIPAA;
- Disclosures to the United States Secretary of Health and Human Services in accordance with the requirements of HIPAA;
- Uses or disclosures that are required by law; or
- Uses or disclosures which are required for compliance with applicable requirements of HIPAA.

Appendix L: Sample TB Infection Control Plan

Purpose

According to the Centers for Disease Control and Prevention (CDC), people who work or receive care in high-risk congregate settings are among those at higher risk for becoming infected with *Mycobacterium tuberculosis* (*M. tuberculosis*). Therefore, it is necessary to have a tuberculosis (TB) infection control plan as part of a general infection control program to ensure:

- prompt detection of TB;
- airborne precautions; and
- treatment of people suspected or confirmed to have TB disease.

To ensure the safety of the work environment, the following TB infection control plan should be implemented.

General Outline

The TB infection control plan is based on three (3) levels of prevention, listed by levels of hierarchy:

- Administrative measures that reduce the risk of exposure to people with infectious TB.
- Environmental measures that prevent spread and reduce the concentration of infectious droplet nuclei.
- Respiratory protection or the use of personal protective equipment (PPE) prevent exposure from individuals with suspected or infectious TB.

Responsibility

The person responsible for the implementation and maintenance of the TB infection on the implementation and maintenance of the TB infection plan is		
Administrative Controls		
A written copy of the TB infection control plan is located at	and	

Ensure that TB prevention education and training is provided to staff, contractors,

1. Mode of TB transmission

and interns upon hire. Training topics include:

is available for inspection during regular business hours.

- 2. TB sign and symptoms
- 3. TB risk factors
- 4. TB disease vs. TB infection
- 5. Disinfection practices for equipment and exam rooms
- 6. Proper use of environmental and respiratory controls



- A. The facility provides TB screening or requests proof of TB clearance before or upon employment.
- B. Patients with suspected or confirmed TB disease are separated from other patients. A surgical mask is placed on the patient if an airborne infection isolation room (AIIR) is not available.
- C. Posters and signs are used throughout the facility to remind patients, visitors, and staff of proper cough etiquette.
- D. Initial and ongoing TB education is provided to people receiving TB prevention and care services.
- E. Testing and evaluating clinic personnel at higher risk of becoming infected with TB disease, including:
 - a. Reviewing results of TB screening for employees at least annually
 - 1) Document using the <u>TB-603</u> Tuberculosis (TB) Screening of TB Personnel or equivalent form.
 - b. Documenting and investigating TB test conversions in TB personnel
 - 1) Document using the <u>TB-604</u> Report of Tuberculosis Conversion(s) in TB Personnel or equivalent form.
- G. Maintaining documentation in accordance with local record retention policies and procedures.

Environmental Prevention

This facility utilizes the following method(s) of environmental measures:

Α.	Gener	al Ventilation
	1.	is responsible for implementing schedule of preventive maintenance in accordance with manufacturer's instructions.
	2.	The current log is located at
		Historic records are filed in
В.	Local	Exhaust Ventilation
	1.	is responsible for implementing schedule of preventive maintenance in accordance with manufacturer's instructions.
	2.	The current log is located at
		Historic records are filed in
C.	AIIR (location):
	1.	AII rooms meet CDC criteria.
	2.	Negative pressure is monitored daily by The method of monitoring is \square smoke test, \square tissue test, or \square other visual check.
	3.	Negative pressure checks are documented using the log. The current log is located at
	4.	Historic records are filed in



1910.134.

Texas Department of State Health Services

1. 2.	Efficiency Particulate Air (HEPA) Filters (location): is responsible for implementing schedule of preventive maintenance in accordance with manufacturer's instructions. The current log is located at Historic records are filed in
1. 2.	riolet Germicidal Irradiation (location): is responsible for implementing schedule of preventive maintenance in accordance with manufacturer's instructions. The current log is located at Historic records are filed in
Respiratory	y Protection Program
The facility's	respirator protection program is in accordance with Occupational

A. In this facility, the following brand/model of N-95 respirator(s) are used to protect staff ______.

Safety and Health Administration (OSHA) Respiratory Protection Standard 29CFR

- B. Respirators are purchased by _____
- C. Initial fit-testing is provided to employees who work in assignments that may require use of an N-95 respirator.
- D. Before fit-testing, a medical evaluation is conducted to determine the employee's ability to wear a respirator.
- E. Fit-testing is repeated once a year and whenever a different respirator is used.
- F. A medical re-evaluation is obtained if an employee reports medical signs or symptoms that are related to the ability to use a respirator or if observations during fit-testing indicate a need for a medical evaluation.
- G. If a staff person's weight changes significantly, or if facial/dental alterations occur within a year, the staff person will request that a fit test be repeated to ensure adequate respirator fit.
- H. The use of N-95 respirators is prohibited for any staff member who has facial hair that comes between the sealing surface of the face piece and the face of the wearer, because it is impossible to get a sufficient seal.
- I. In this facility, staff with the following duty assignments require respirator fittesting:
 - 1. people entering rooms in which patients with suspected or confirmed TB disease are being isolated;



Date of Reviewed:

Texas Department of State Health Services

- 2. people present during cough-inducing or aerosol-generation procedures with patients with suspected or confirmed TB disease;
- 3. people who transport patients with suspected or confirmed TB disease;
- 4. people who conduct maintenance on environmental control equipment; and
- 5. other people based upon risk for TB exposure.

J. A current list of staff who have been fit testing, manufacturer, model number, tested, is located					
K. A fit-test qualifies the staff person to wear only the specific make, model, and size respirator for which an acceptable fit-test result was achieved.					
L. Staff wearing a respirator do a "seal che respirator is used, in accordance with it					
TB Infection Co	ntrol Plan				
Date Created: Approved by:					
Director/Deputy Director	Date				
Medial Director	Date				
TB Program Manager	Date				
Date of Reviewed:					
By:	-				
Date of Reviewed:					
Ву:	-				

Appendix M: TB Training and Education Resources

Designated staff using and signing the DSHS TB Standing Delegation Orders (SDOs) or local equivalent, must have training and competency in TB care. Staff must complete 40 hours of initial training and education within 90 days of hire; licensed nurses must receive 16 hours of continuing education and training each calendar year and non-licensed TB staff must receive at least 12 hours each calendar year.

Training and Education Resources

Training Resources	Reference		
TB 101 for Healthcare Workers	cdc.gov/tb/webcourses/tb101/		
TB Core Curriculum*	<pre>cdc.gov/tb/hcp/education/core-curriculum-on- tuberculosis.html?CDC AAref Val=https://www.cdc.gov/tb /education/corecurr/</pre>		
CDC TB Self-Study Modules (1-9)*	<pre>cdc.gov/tb/hcp/education/self-study-modules-on- tuberculosis.html?CDC AAref Val=https://www.cdc.gov/tb/ /education/ssmodules/</pre>		
CDC RVCT Instruction Manual*	cdc.gov/tb/programs/rvct/instructionmanual.pdf		
DSHS TB Orientation (after 90 days of hire)	Email the TB Unit clinical care team: tb.feedback@dshs.texas.gov		
Heartland TB Nurse Case Management			
Heartland TB Intensive			
Heartland Pediatric TB Intensive	heartlandntbc.org/calendar/		
Heartland TB Contact Investigation			
TST Competency Checklist (TB-905)	dshs.texas.gov/disease/tb/forms/		
Curry Center Guidelines for the Treatment of Drug Susceptible TB Webinar*	currytbcenter.ucsf.edu/trainings/2016-atscdcidsa-clinical- practice-guidelines-treatment-drug-susceptible- tuberculosis		
Vision and Hearing Certification	R/LHD training; contact regional office		
NEDSS TB Trainings*	dshs.texas.gov/tuberculosis-tb/nedss		

Training Resources	Reference
Yearly continuing education and training	 Education and training as required by CD or TB manager (or designee). May include: Local yearly training (e.g., blood borne pathogens); may vary. Continuing education required for certification/professional license renewal; may vary. Yearly review of SDOs, TB Manual or other guidance documents; maintain training rosters. DSHS webinars (e.g., DSHS Grand Rounds, TB Brown Bag sessions); Skills training (e.g., phlebotomy, TST, sputum collection). Local case study review; Research articles; and Conference or online webinar attendance (e.g., National TB Coalition of America [NTCA], Texas Public Health Association, CDC TB Centers of Excellence).

^{*}Trainings which should be completed within the first 90 days of hire as applicable to staff position.

Appendix N: Sample TB Training and Education Logs

Document training and education provided to TB staff and stakeholders.

T.		lours Required with		
Date of Training	Name of Training		Certificate Provided? (if yes, include copy)	# of
	Annual Trair	ning (Hours**	Required)	
Date of Training	Name of Training	Training Provided By	Certificate Provided? (if yes, include copy)	# of Hours Received

TB education designee name/signature:

Sample B: Training/Education Log - Stakeholder Training

Topic:	
Trainer/Educator:	
Date:	
Location:	
Group Type:	
Format:	
Number of Hours:	
Printed Name	Signature

Appendix O: Cohort Review Process

Cohort review is a systematic and retrospective review of the management of patients with TB disease and their contacts. A "cohort" is a group of TB cases counted over a specific time period and in a defined geographic area. The review occurs after the cases are counted and within the time frame; most are expected to complete treatment.

Cohort review is used as a tool to review and present patient outcomes and to monitor and evaluate program performance. At a cohort review, cases presented are:

- 1. examined for the patient's clinical status;
- 2. reviewed for adequacy of the patient's regimen;
- 3. reviewed for treatment adherence and completion; and
- 4. reviewed for results of the contact investigation.

Case review is a systematic regular review of individual patient progress presented by a case manager. It is a fundamental component of case management and is an ongoing process for each patient. Plans should be made to immediately address treatment and patient management concerns identified during the review.

The Difference Between Cohort Reviews and Case Reviews

Case reviews are real-time, ongoing and provide an opportunity to review individual patient-specific care. They allow for immediate analysis of a patient's progress and plans to address any needed changes to treatment and management. As cohort reviews are a retrospective analysis of treatment outcomes, they provide an opportunity to review case data to address systemic programmatic concerns regarding the overall management of TB patients to improve patient care and programmatic performance and to promote efficiency.

Process

To promote consistent TB case management practices, program accountability, and high TB evaluation and treatment completion rates, TB programs will hold quarterly cohort reviews. Cohort reviews are integral to TB prevention and care activities and provide a systematic retrospective review of the management of cases and contact investigations. DSHS public health regional TB programs will work with low morbidity LHDs in their jurisdiction to implement cohort reviews.

Cohort Teams

The cohort review process relies on the participation of various members involved in TB services at the program level. A cohort review should include at a minimum the following participants:

- 1. TB program manager
- 2. Nurse case manager
- 3. Supervisor

If available, the following participants should also be a part of the team:

- 1. Medical reviewer
- 2. Data analyst or epidemiologist
- 3. Contact investigator
- 4. DOT worker
- 5. Social worker
- 6. Clinicians
- 7. Laboratory personnel

Cohort Periods

TB programs will schedule cohort reviews on a quarterly basis following the timelines identified in the following table:

Table 19: Cohort Review Period and Submission Schedule

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

TB programs with fewer than six counted cases in a given year may conduct a yearly cohort review due by December 31 of the following year.

Reporting Requirements for Cohort Reviews

- The **Cohort Presentation Form** shall be used to collect and present patient information during the cohort review meetings.
- The **Cohort Review Summary Form** shall provide summarized and quantifiable data from all counted cases and associated contacts presented at each quarterly cohort review.
- The **Cohort Review List of Counted Cases** shall be used to list counted cases presented at each quarterly cohort review.

Submit, by the dates identified in Cohort Period and Submission Schedule, the above forms using GlobalScape, or as specified by the DSHS TB Unit.

Cohort Review Resource

Centers for Disease Control and Prevention (CDC)
 Understanding the TB Cohort Review Process Instruction Guide, 2006

Appendix P: Electronic Disease Notification (EDN) Follow-Up Worksheet

The TB Follow-Up Worksheet is used to document the initial evaluation of an arrival with a					
TB class condition. A complete evaluation requires a diagnosis, and when indicated, a treatment start date.					
Sections A & B					
Demographic & Jurisdictional □ Pre-populated. Information		Pre-populated.			
		Section C			
Date of Initial U.S. Medical Evaluation		Record date of initial evaluation.			
 Administer TB screening test (IGRA or TST). Record date, brand, and results of IGRA or TST used and interpretation (for people with TB class-B conditions or TB-relation abnormalities on CXR, a TST of ≥ 5 mm is considered positive Record if a history of previous positive IGRA or TST. 					
U.S. Review of Pre- Immigration CXR/ I-693		Arrivals should bring their pre-immigration CXR film(s) or disk with them to exam. If the pre-immigration CXR is not available, mark "No." If the pre-immigration CXR did not have the patient's name and date of birth, mark "Unknown." Record physician's interpretation of pre-immigration CXR. Do not copy overseas panel physician's interpretation of pre-immigration CXR into EDN follow-up worksheet (FUW).			
U.S. Domestic CXR		Record interpretation of CXR ordered by the medical director or consulting physician. Do not copy overseas panel physician's interpretation of pre-immigration CXR into EDN FUW. If your medical director or consulting physician does not perform a CXR, mark "No."			
Comparison		Compare pre-immigration CXR/I-693 to U.S. CXR and chose one option that best represents your clinician's impression of the comparison. If the pre-immigration CXR is not available, mark "Unknown."			
U.S. Review of Pre- Immigration Treatment/ I- 693		Record interpretation of pre-immigration TB treatment based on review of patient-provided pre-immigration documents and information.			
U.S. Microscopy/ Bacteriology		Collect specimen(s) for AFB smear and culture. Document specimen type, collection date, and results. Report suspected pulmonary or extrapulmonary TB disease to TB Unit within one working day. Do not wait for culture confirmation.			
		Section D			

Evaluation	☐ Record date when medical director or consulting physician has
Disposition	completed the evaluation, if determined that the evaluation
Date	cannot be completed for one of reasons listed.
Evaluation Disposition in	 □ If the evaluation was completed, check the box "Completed evaluation." Indicate whether treatment was recommended. If so, indicate whether for TB disease or TB infection. □ If the evaluation was initiated but not completed, check box "Initiated Evaluation/Not Completed." Select reason(s) why evaluation was not completed from list provided. Check all that
U.S.	apply and write or enter other reasons beside "Other, specify." ☐ If the evaluation was never initiated, check the box "Did not initiate evaluation." Choose the reason(s) why the evaluation was never initiated from the list provided. Check all that apply and write/enter other reasons beside "Other, specify."
	☐ Mark the box corresponding to CDC diagnostic classification as
B	listed. ☐ Treatment is inappropriate for diagnoses of class 1 or 0. The EDN system will create an error message if treatment is recommended
Diagnosis	for either of these diagnoses. If diagnosis is class 3, mark the site(s) of disease and contact Surveillance Unit to report. Contact TB Unit epidemiologist if assistance is needed completing section D4.
Section E (Com	plete this section only if treatment was recommended in Section D2)
U.S. Treatment Initiated	 □ If treatment was initiated, mark "Yes" and specify "for TB disease or LTBI." □ Treatment must comply with CDC recommendations. Patients diagnosed at class 2 or class 4 should receive treatment unless contraindicated. □ Consult the DSHS SDOs or TB Unit if uncertain which regimen to prescribe. □ Treatment for class 3 should rely on DOT and be provided through the patient's R/LHD TB program. □ If treatment was not initiated, mark "No" and specify the reason in the appropriate boxes. □ Check all that apply and enter other reasons next to "Other (specify)."
Treatment Start Date	□ Specify date treatment was started (mm/dd/yyyy).□ Leave this section blank until treatment has stopped.
U.S. Treatment	□ Save the worksheet in EDN, but do not submit until treatment has completed or ended. □ Mark the appropriate box to indicate whether treatment was completed or if it is unknown whether treatment was completed. □ If treatment was not completed, mark "Treatment Discontinued/"
Completion Status and Dates	Stopped" and specify the reason in the appropriate boxes. Check all that apply and enter other reasons next to "Other (specify)." If treatment was completed, specify the date next to "Treatment Completion Date" (mm/dd/yyyy). If treatment was initiated but not completed, specify the date treatment ended (date patient stopped taking treatment) next to
	"Treatment End Date" (mm/dd/yyyy).

Appendix Q: Case Detection, Accuracy, Completeness, Timeliness, Security and Confidentiality (DACTS) Audit Tool

DACTS Audit Tool

1.0	Training Requirements	Yes	No	If no, plan for improvement:
	Have all members of TB Case Registry team completed their training?			
1.1	How many members?			
1.1	How many completed?			
	How many did not complete?			
1.2	Basic TB Facts			
1.3	Core Curriculum on Tuberculosis, Seventh Edition 2021			
1.4	Diagnostic Standards and Classification of TB in Adults and Children; American Journal of Respiratory Critical Care Medicine 2000; Volume 161			
1.5	Guidelines for the Investigation of Contacts of Persons with Infectious Disease; MMWR 2005, 54 (No RR-15, 1-37)			
1.6	Aggregate Reports for TB Program Evaluation, Training Manual and Users Guide			
1.7	RVCT Instructions Manual			
1.8	A Guide and Toolkit for QA for TB Surveillance Data			
1.9	TB101 for Healthcare Workers Refer to cdc.gov/tb/webcourses/TB101/			
1.10	TB Unit Orientation			
1.11	Annual Workshop			
1.12	Monthly TB Surveillance Conference Calls			
1.13	TBNN Workgroup			

2.0	System Access Requirements	Yes	No	If no, plan for improvement:
2.1	Do all team members have access to the necessary systems to perform their surveillance duties?			
2.2	GlobalScape			
2.3	Access to state and federal training websites			
2.4	NEDSS			
2.5	PHLIMS/Labware – Public Health Laboratory Information Management System			

Texas Department of State Health Services

2.0	System Access Requirements	Yes	No	If no, plan for improvement:
2.6	NTIP – National TB Indicators Project System			
2.7	NTSS – National Telecommunications Surveillance System			
2.8	TB GIMS – TB Genotyping Information Management System			
2.9	EDN – Electronic Disease Notification System			

3.0	Protocol Requirements	Yes	No	If no, plan for improvement:
3.1	Written Protocol for Surveillance QA			
3.1	Case Detection			
3.2	Data Accuracy			
3.3	Data Completeness			
3.4	Data Timeliness			
3.5	Data Security and Confidentiality			
3.6	Plan for Improvement			

4.0	Case Detection Requirements	Yes	No	If no, plan for improvement:
	Maintain a Registry of TB Records:			
4.1	 Cases-contacts 			
4.1	 Suspects-contacts 			
	 LTBI's referred or targeted testing 			
4.1a	Record Inventory			
4.2	Establish liaisons with appropriate reporting sources to enhance quality assurance of TB surveillance data			
4.3	Develop and implement active case detection activities			
4.4	Evaluate the completeness of reporting of TB cases to the surveillance system			

5.0	Data Accuracy Requirements	Yes	No	If no, plan for improvement:
5.1	Evaluate accuracy or validity of RVCT data			
5.2	Assess knowledge, skills, and abilities of staff and provide training if needed			
5.3	Provide training on Data Entry Standards			
5.3a	Adhere to Data Stamping policy			
5.2b	Adhere to complete record search			

6.0	Data Completeness Requirements	Yes	No	If no, plan for improvement:
6.1	Maintain Completeness of all RVCT variables			
6.2	Match TB and HIV Case Registries			
6.3	Evaluate programmatic performance by using TB surveillance data at least once a year			

7.0	Data Timeliness Requirements	Yes	No	If no, plan for improvement:
7.1	Report all newly diagnosed cases of TB to the TB Unit according to schedule			
7.1a	Persons with known TB			
7.1b	Persons with suspected TB			
7.1c	Contacts to persons with infectious TB			
7.1d	IJNs			
7.1e	Persons with TB Infection			
7.2	Submit complete RVCT reports to the TB Unit according to schedule			
7.3	Analyze TB surveillance data at least quarterly			
7.4	Evaluate programmatic performance by using TB surveillance data at least once a year			

8.0	Security and Confidentiality Requirements	Yes	No	If no, plan for improvement:
8.1	List of the minimum standards required for data sharing and use of surveillance data for public health action			
8.2	Guidelines on how to initially assess the TB program's data security and confidentiality policies and procedures			
8.3	Checklist for conducting ongoing assessment of TB program compliance with the data security and confidentiality guidelines			
8.4	Questions and answers to clarify issues regarding the data security and confidentiality guidelines			
8.4a	Guidelines filed with Surveillance Procedures Manual			
8.4b	Records in locked cabinet, in locked room			
8.4c	Fax machine and copier in locked room			
8.4d	Use only iron key flash drives for storing working files containing data			
8.4e	Data files have a back-up system			

9.0	Maintains log for TB employees and other entities and dates of training and presentations.	Yes	No	If no, plan for improvement:
9.a	Log for TB employees			
9.aa	Date, name of employee, jurisdiction or clinic, and name of training			
9.b	Log for other entities			
9.bb	Date, employee, entity, name of training, and number of participants			

10.0	Maintains personal folder of training materials in common or shared drive.	Yes	No	If no, plan for improvement:
10.a	Slide Presentations from conferences and workshops			
10.b	World TB Day Presentations			
10.c	TB Surveillance Brown Bag Presentations			
10.d	"What is TB?" Questions and Answers Test			
10.e	NEDSS Instructions and Updates			
10.f	Other Training Documents			

Appendix R: Guidelines for Responding to Data Quality Assurance Reports

The TB Unit will periodically review information reported by R/LHD TB programs via NEDSS to identify missing, unknown, and inconsistent data. These efforts aim to ensure timely and accurate reporting. The TB Unit Epidemiology team will build reports that will be shared with R/LHD TB programs to review the status of TB data.

The TB program manager and designated surveillance point of contact will receive data quality assurance reports and requests from the TB Unit on a routine basis (i.e., monthly, quarterly) based on the type of request. Deadlines for each report/request will be included in the communication from the TB Unit.

Reports and requests include but are not limited to the following:

- 1. Missing or unknown RVCT variables:
 - Includes cases that are missing at least one RVCT element or cases that have been sent with an 'Unknown' response.
 - Some variables may be "truly unknown," and no response or update is necessary.
- 2. Inconsistent data:
 - Outlines inconsistencies in certain data elements.
 - Information may be "truly inconsistent," and no response or update is necessary.
- 3. Content validation:
 - Outlines errors in certain data elements.
- 4. Contact investigation and evaluation:
 - Includes missing and/or incomplete data required to determine if a contact is fully evaluated.
- 5. Rejected NEDSS notifications:
 - Refer to QA Feedback form attached to the investigation. Once data entry is complete and/or the issue has been resolved, a new notification should be created.

Response to Requests

- 1. If there is no response from the TB program or noticeable improvement in data quality over time, the TB Unit staff will notify the TB Unit epidemiology and surveillance manager. The TB Unit epidemiology and surveillance manager will notify the TB program manager of the request.
- 2. If there is no response or improvement after the TB epidemiology and surveillance manager becomes involved, the manager will inform the TB Unit director. The TB Unit director will notify the director of the R/LHD program.

Appendix S: TB Intake Information

The following information should be entered in NEDSS within seven days of notification for anyone being evaluated for TB (includes ATS class 2, 3, and 5). Not all information may be known at intake; updates should be entered in NEDSS as they become available. The information indicated with an asterisk (*) should be entered as soon as the patient has a confirmed TB diagnosis.

	TB Intake Information					
Information as per NEDSS Investigation Tabs	Description					
<u>Patient</u>	 Full name Date of birth Sex at birth If female, was patient pregnant at time diagnostic evaluation was initiated? Reporting address (physical), city, county, zip code with 4-digit extension at diagnosis Within city limits? Census tract Ethnicity Race, extended race if Asian or Native Hawaiian or Other Pacific Islander 					
Case Information	 Jurisdiction Initial ATS Initial ATS classification date Current ATS classification 3* Current ATS classification 3 date* Date reported Case already counted by another reporting area If counted by another U.S. reporting area, state case number (SCN) If counted by another country, specify country Does this case meet the Texas criteria of a binational TB case? 					
TB History Tuberculosis	 Has the patient been previously diagnosed with TB disease or LTBI? Country of birth If country of birth is not U.S., date of first U.S. arrival 					
	 Eligible for U.S. citizenship or nationality at birth Countries of birth for primary guardian(s) (pediatric: <15 years old cases only) Country of usual residence If not U.S. reporting area, has patient been in U.S. for 90 days or more? Status at TB diagnosis* Initial reason evaluated for TB TB symptoms reported and onset date for each Occupation and Industry; ever (specific to the potential associations between workplace exposures and TB) and current 					

TB Intake Information					
Information as per NEDSS Investigation Tabs	Description				
TB Disease Only*	Medical Risk Factors: Diabetic at diagnostic evaluation Hold Stage renal disease HIV/AIDS Other immunocompromise (other than HIV/AIDS) Post organ transplantation TNF-alpha antagonist therapy Viral hepatitis (B or C only) Cancer – head and/or neck Cancer – other Chronic renal disease Hemodialysis Gastrectomy or jejunoileal bypass COVID-19 co-infection Silicosis Skin test conversion - increase of 10 mm or more within 2 years Weight 10% less than ideal body weight Other medical risk factor(s); specify Social Risk Factors: Heavy alcohol use in the past 12 months Injecting drug use in the past 12 months; specify Noninjecting drug use in the past 12 months; specify Current smoking status at diagnostic evaluation Homeless in the past 12 months Homeless ever Resident of correctional facility at diagnostic evaluation? If yes, type of facility Resident of long-term care facility at diagnostic evaluation? If yes, type of facility Resident of other congregate setting at diagnostic evaluation? If yes, type of facility Lived outside of the U.S. for more than 2 months (uninterrupted) Diagnostic Testing - Response required for each test type, indicate if Not Done Chest Imaging - Response required, indicate if Not Done Date of illness onset or symptom start date				
The bisease only	 Site(s) of TB disease* Therapy start date Initial drug regimen 				
LTBI Only (ATS class 2 only) Comprehensive TB Treatment Details*	 Therapy start date Initial LTBI regimen Individual medications Drug start/stop dates 				



Appendix T: TB Contact Investigation and Evaluation Information

The following information highlights some of the variables used to determine the evaluation status and treatment outcomes for contacts to TB cases. This **is not a comprehensive list** of all surveillance and clinical information that should entered in NEDSS.

TB Cor	TB Contact Investigation and Evaluation Intake Information				
Information as per NEDSS Investigation Tabs	Description				
<u>Patient</u>	 Full name Date of birth Sex at birth Reporting address (physical), city, county, zip code with 4-digit extension at diagnosis 				
Case Information	 Jurisdiction Current ATS classification* Current ATS classification date* 				
TB History	 Has the patient been previously diagnosed with TB disease or LTBI? Previous positive TST (if applicable) Previous positive TST administered date (if applicable) Previous positive TST read date (if applicable) Previous positive IGRA (if applicable) Previous positive IGRA collection date (if applicable) 				
Tuberculosis	 Initial reason evaluated for TB TB Symptom Screening and date (Y/N) Medical and Social Risk Factors (if applicable) Diagnostic Testing - TST, IGRA Sputum bacteriology (if applicable) Chest Imaging (if applicable) 				
Comprehensive TB Treatment Details (if applicable)	 Initial Treatment Type Current treatment type Medications (repeating block) 				
LTBI Only (ATS class 2 only)	 Therapy start date Initial LTBI regimen Therapy Stop Date Reason Therapy Stopped 				

TB Contact Investigation and Evaluation Intake Information	
Information as per NEDSS Investigation Tabs	Description
<u>Contact</u> <u>Investigation</u>	TB exposure repeating block

^{*}ATS classification should not be entered until the contact has been fully evaluated for TB.

Appendix U: Resources, References, and Timeframes for Reporting to the TB Unit

The following is a list of reporting and contact information to the DSHS TB Unit. Refer to *Figure 17: Contacting the TB Unit* for the applicable contacts for each TB Unit team.

1. Requesting Access to DSHS Databases

- Process overview: dshs.texas.gov/thsvh/account
- NEDSS access: <u>dshs.texas.gov/tuberculosis-tb/nedss</u>

2. Reporting Adverse Drug Reactions Resulting In Hospitalization Or Death

Notify DSHS Pharmacy Unit at 512-776-7500.

3. Submitting the Annual Progress Report (APR)

 Submit DSHS Annual Progress Report to <u>TBContractReporting@dshs.texas.gov</u> by April 1 of the current year.

4. Submitting Quarterly Cohort Review

• Submit via GlobalScape and email cqiteam@dshs.texas.gov of the upload.

5. Correctional Monthly Reports and Correctional TB Screening Plans

- Chapter 89-designated facilities must submit the <u>12-11462 (Monthly Correctional TB Report)</u> and <u>12-11461 (Report of TB Conditions)</u> to the TB Program by the 5th day of the following month.
- R/LHD TB programs must perform first-line quality assurance review and submit the <u>12-11462 (Monthly Correctional TB Report</u>) and <u>12-11461 (Report of TB Conditions</u>) via GlobalScape by the 15th day of the following month.
- Chapter 89-designated facilities must submit <u>TB-805 (Correctional Tuberculosis Screening Plan)</u> to <u>CongregateSettings@dshs.texas.gov</u> 90 days before the current screening plan expiration date. Effective January 2024, all screening plan's approval will be from January 1 to December 31 each year.
 - a) The TB Unit will forward the screening plan to the R/LHD for first-line review.
 - b) The R/LHD will have 30 days to conduct a first-line review with provide technical assistance and guidance to the Chapter 89 designated facilities for remediation of any identified errors.
 - c) DSHS Central Office requires a minimum of 60 days for review and approval.
 - d) The R/LHD will submit the <u>TB-805 (Correctional Tuberculosis Screening Plan)</u> to <u>CongregateSettings@dshs.texas.gov</u> for final review and approval before the current Screening Plan expiration date.

6. Weekly Report of New Concerning Tuberculosis Events

Report TB deaths, TB cases in children under 5 years of age, and DR-TB.
The report must be sent to the TB Unit Epidemiology team the following
Friday using the <u>DSHS Weekly Report of New Concerning Tuberculosis</u>
Events form.

7. Reporting Drug Resistant TB (RR, MDR, Pre-XDR, XDR-TB)

- Notify the TB Unit nurse consultant within three days anytime RR-TB, MDR-TB, Pre-XDR-TB, or XDR-TB is suspected.
- Submit changes in case management, drug resistance patterns, or residence on DR-TB case to the DR-TB nurse consultant within three days of notification; ensure NEDSS is updated to reflect changes.

8. Requesting Access to FedEx Accounts and Specimen Shipping

• To set up accounts or order more shipping supplies, see the <u>Tuberculosis</u> <u>Specimen Shipping Guide</u>.

9. Reporting Change of TB Personnel and Requesting Access to TB Unit Email Distribution Lists

- Complete the <u>Notice of Change in TB Personnel</u> form for any changes in TB personnel. This ensures the staff will be added to the TB Unit's distribution email listsery.
- Send to TBProgram@dshs.texas.gov no later than the 5th of each month when changes in staff occur to include:
 - Legal name change
 - New hire
 - Resignation
 - o Promotion/salary increase or decrease
 - New email

10. Submitting TB Incident Reports

- Report concerning contact investigations and/or large-scale screenings to the TB Unit Epidemiology team within 48 hours of meeting the criteria for an incident report.
- Attach <u>12-12104 or 12-12063</u> to the patient record in NEDSS or submit via GlobalScape and send an email notification to <u>TBEpi@dshs.texas.gov</u>.

11. Reporting Targeted Testing

• Report outcomes of targeted testing by the 15th day of the following month to GlobalScape and notify cqiteam@dshs.texas.gov of the upload.

12. Completing the SDOs attestation

 Must be signed by all staff and kept at the R/LHD; this must be made available to the TB Unit upon request.

13. Requests for Second-Line Medications

Copies of a medical consultation recommending second-line medications

from a DSHS recognized TB medical consultant or Regional Medical Director (RMD) must be made available to the TB Unit upon request and kept in the medical record, when consultation is required.

14. Report of TB Test Conversion of TB Personnel

• Send the <u>TB-604 (Report of TB Test Conversion in TB Staff)</u> to the TB Unit within 60 days of initial test at <u>TB.Feedback@dshs.texas.gov</u>.

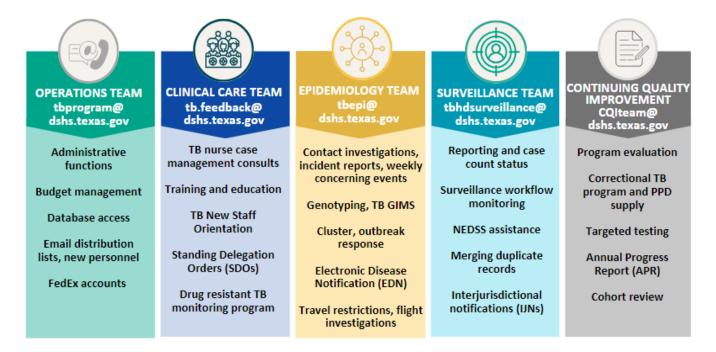
15. Submitting Travel Restriction (DNB/LO) Requests

 For patients that are candidates for a Do Not Board and Public Health Lookout (DNB/LO), submit the <u>12-12065 (Do Not Board/Public Health Lookout Consultation Request)</u> and contact the TB Unit Epidemiology team at TBEpi@dshs.texas.gov to review criteria.

16. Reporting False-Positive Investigations

 Notify the TB Unit of any false-positive investigations by contacting the Epidemiology team at <u>TBEpi@dshs.texas.gov</u>.

Figure 17: Contacting the TB Unit



Source: Texas Department of State Health Services, TB Unit, 2024.



Appendix V: List of Acronyms

AFB Acid-Fast Bacillus

AII Airborne Infection Isolation

APR Annual Progress Report

ATS American Thoracic Society

BCG Bacillus Calmette-Guerin

BDQ Bedaquiline

CDC Centers for Disease Control and Prevention

CFZ Clofazimine

CI Contact Investigation

CMS DSHS Contract Management Section

CPS Child Protective Services

CQI Continuing Quality Improvement

DGMH CDC Division of Global Migration and Health

DNA Deoxyribonucleic Acid

DOPT Directly-Observed Preventative Therapy

DOT Directly-Observed Therapy

DACTS Case Detection, Accuracy, Completeness, Timeliness, Security, and

Confidentiality

DR-TB Drug-Resistant Tuberculosis (resistance to at least rifampin)

DSHS Texas Department of State Health Services

DST Drug Susceptibility Test

DTBE CDC Division for TB Elimination

EHR Electronic Health Record
EMR Electronic Medical Record

EDN Electronic Disease Notification

ELR Electronic Laboratory Reporting

FDA U.S. Food and Drug Administration

FEFO First-Expiring/First-Out

FQHC Federally Qualified Health Center

FUW Follow-Up Worksheet

HNTC Heartland National TB Center

ICE U.S. Immigration Customs Enforcement Agency

IGRA Interferon Gamma Release Assay

IJN Interjurisdictional Notification

LHA Local Health Authority

LHD Local Health Department

LHP Licensed Healthcare Provider

LTFU Lost to Follow-Up

MAC Mycobacterium avium complex

MAR Medication Administration Record

M. tb BCG Mycobacterium bovis-Bacille Calmette-Guerin

MDDR Molecular Detection of Drug Resistance

MDR-TB Multi-drug resistance

MMWR Morbidity and Mortality Weekly Report

MPC Motion for Protective Custody

MTBC Mycobacterium tuberculosis Complex

NAAT Nucleic Acid Amplification Test

NEDSS National Electronic Disease Surveillance System

NTCA National TB Coalition of America

NTIP National TB Indicators Project

PCR Polymerase Chain Reaction

PHI Protected Health Information

PHR Public Health Region

PIOS Pharmacy Inventory Ordering System

PPD Purified Protein Derivative

Pre-XDR-TB Pre-Extensively Drug Resistance

QA Quality Assurance

RIPE Rifampin, Isoniazid, Pyrazinamide and Ethambutol

R/LHD Regional/Local Health Department

RMD Regional Medical Director

rpoB RNA-polymerase Beta subunit

RR-TB Rifampin Mono-Resistance

RVCT Report of Verified Cases of TB

SAT Self-Administration Therapy

SDOs Standing Delegation Orders

SMOs Standing Medical Orders

SQA Surveillance Quality Assurance

TAC Texas Administrative Code

TB Tuberculosis

TBNN TB Network News

TCID Texas Center for Infectious Disease

TDCJ Texas Department of Criminal Justice

THMP Texas Medicaid & Healthcare Partnership

TNF Tumor Necrosis Factor

TSBP Texas State Board of Pharmacy

TST Tuberculin Skin Testing

UOT Unit Operations Team

VDOT Video-Enabled Directly Observed Therapy

XDR-TB Extensively Drug Resistance