TEXAS Health and Human Services

Texas Department of State Health Services

Texas Tuberculosis Manual

Fiscal Year 2025

Tuberculosis and Hansen's Disease Unit

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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 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 funded TB programs;
- Ensures consistent TB prevention and care practices apply 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) 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*. Funded programs should not charge patients in column A 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, they should not charge patients in column A for a balance or copays that insurance does not cover.

LHD TB programs requesting reimbursement for TB services may also consider enrolling as TB Medicaid providers. To enroll, the LHD completes the *DSHS Medicaid Provider Application,* located at dshs.texas.gov/sites/default/files/IDCU/disease/tb/forms/PDFS/TBMedicaidApplication.pdf, and submit it 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 the Texas Medicaid and Healthcare Partnership (TMHP), to begin the official Medicaid application process.

Funded TB programs shall provide services to the following program-eligible patients:

A. People with suspected or confirmed TB disease caused by the *Mycobacterium tuberculosis* (*M. tb*) complex, which includes *M. tb* and *M. bovis*. Refer to dshs.texas.gov/sites/default/files/IDCU/disease/tb/policies/EpiCaseCriteriaforTB.pdf.

    1. *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 infections. 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 of developing TB disease. Refer to *Table 1: Prioritizing Evaluation for TB Services* and *Chapter XII. Conduct Targeted Testing* for more information.

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 DSHS form TB-409.

C. Patients with no risk factors for latent TB infection or progression to TB disease.

Table 1: Prioritizing Evaluation for TB Services

A	B	C
Program-Eligible Patients Who Should be Evaluated Routinely	**Program-Eligible Patients Who May 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. • Anyone reported from the EDN, and immigrants from areas of the world with high rates of TB who are seeking permanent residence, after full evaluation from a Civil Surgeon* or who have entered the United States through a government-sponsored program. • Children aged 4 and younger with a positive TB test. • Children aged 5 and older with risk factors for TB exposure as identified on the *Tuberculosis Questionnaire for Children* (dshs.texas.gov/idcu/disease/tb/faqs/#students) ***and*** who have a positive TB screening test, when treatment for TB infection is requested of the R/LHD.	• Children aged 5 and older who were referred for a TST/IGRA based on risk factor(s) identified on the *Tuberculosis Questionnaire for Children* (dshs.texas.gov/idcu/disease/tb/faqs/#students) and who do not have resources for medical care** outside the TB program. • Anyone with a positive TB screening test ***and*** medical risk factors for developing TB disease, who do not have resources for medical care** outside the R/LHD. This most commonly includes people with HIV, people on immunosuppressant medications, or people taking tumor necrosis factor (TNF) alpha inhibitors. • People who work or reside with other people at high risk for TB in facilities or institutions such as hospitals, homeless shelters, correctional facilities, nursing homes, and residential homes for those with HIV as determined by epidemiological data to support testing and treatment†. • Other non-U.S.-born individuals not referred from EDN or a civil surgeon* seeking service for TB infection and who do not have resources for medical care** outside the TB program.	• Patients who are reported to the R/LHD because of a non-tubercular mycobacteria (NTM) but who are not suspected of having TB disease. • Patients with no risk factors for latent TB infection or progression to TB disease who are referred to the R/LHD for TB screening.

**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 Federally Qualified Health Centers (FQHCs) 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.

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 TB programs' 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. work 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 and cluster events;

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 and 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 TB Unit's surveillance and reporting database;

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, evaluate, and determine compliance of TB programs;

B. monitor and evaluate TB programs' progress towards performance objectives to determine effectiveness and compliance with essential TB prevention and care standards and the Texas TB Manual;

C. oversee targeted testing initiatives;

D. develop and oversee cohort review activities;

E. oversee correctional TB screening, reporting, and monitoring activities;

F. conduct onsite review activities and scheduled site visits for funded TB programs; and

G. monitor distribution of state-purchased supplies to R/LHDs and Chapter 89-designated 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*, dshs.texas.gov/tuberculosis-tb/tb-funded-programs.
   3. DSHS, TB Unit Standards, dshs.texas.gov/disease/tb/programs.shtm
   4. DSHS, *TB Standards for Texas Correctional and Detention Facilities*, dshs.texas.gov/sites/default/files/IDCU/disease/tb/policies/TBCorrectionalStandards.pdf.
   5. 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*, dshs.texas.gov/tuberculosis-tb/tb-funded-programs/texas-dshs-tb-program/binational-tb-program-manual.
   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:
   1. *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.
   2. *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/.
   3. *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.
   4. 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
   5. CDC, *Aggregate Reports for Tuberculosis Program Evaluation: Training Manual and User Guide*, 2005. cdc.gov/tb/publications/pdf/arpes_manualsm1.pdf.
   6. 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.

7. CDC, *IGRA Blood Test Fact Sheet*, 2016. cdc.gov/tb/hcp/testing-diagnosis/interferon-gamma-release-assay.html?CDC_Aaref_Val=https://www.cdc.gov/tb/publications/factsheets/testing/igra.htm.
8. CDC, *2020 Report of Verified Case of Tuberculosis (RVCT) Instruction Manual*, August 2021. cdc.gov/tb/programs/rvct/instructionmanual.pdf
9. CDC, CDC's *Program Evaluation Journey, June 2018.*
10. 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.
11. CDC, *Tuberculin Skin Testing (TST) Fact Sheet*, 2016. cdc.gov/tb/hcp/testing-diagnosis/tuberculin-skin-test.html?CDC_Aaref_Val=https://www.cdc.gov/tb/publications/factsheets/testing/skintesting.htm.
12. Curry International Tuberculosis Center, *Drug-Resistant Tuberculosis: A Survival Guide for Clinicians*, Third edition. currytbcenter.ucsf.edu/products/view/drug-resistant-tuberculosis-survival-guide-clinicians-3rd-edition.

C. Federal and state regulations and statutes (including but not limited to):

1. Texas Tuberculosis Code, Texas Health and Safety Code, Chapter 13, Subchapter B. statutes.capitol.texas.gov/Docs/HS/htm/HS.13.htm.
2. Communicable Disease Prevention and Control Act, Texas Health and Safety Code, Chapter 81. statutes.capitol.texas.gov/Docs/HS/htm/HS.81.htm.
3. 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.
4. Control of Communicable Diseases, Texas Administrative Code (TAC), Title 25, Part 1, Chapter 97, Subchapter A. sos.texas.gov/tac/index.shtml.
5. Tuberculosis Screening for Jails and Other Correctional Facilities, TAC, Title 25, Part 1, Chapter 97, Subchapter H. sos.texas.gov/tac/index.shtml.
6. Medical Records, TAC, Title 22, Part 9, Chapter 165, Rule §165.1. sos.texas.gov/tac/index.shtml.
7. 340B Drug Pricing Program. 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 (i.e., 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;

I. 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 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 https://www.dshs.texas.gov/tuberculosis-tb/training/nedss. 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 the TB Unit's surveillance and reporting database;

N. verify American Thoracic Society (ATS) classifications based on current TB Epidemiology Criteria and Surveillance Definitions Guide 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 the TB Unit's TB surveillance and reporting database as listed on either the DSHS forms TB-342 and TB-343 for any contact investigations where the source/index case is residing in a correctional facility or DSHS forms TB-340 and TB-341 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 the TB surveillance and reporting database 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 child-care 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 dshs.texas.gov/hivstd/policy/procedures/2016-01).

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 and procedures are published on DSHS' TB website, texastb.org. 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
    5. 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. Contact investigation
    13. Patient confidentiality and security
    14. Incident reporting
    15. Cluster and outbreak investigations
    16. False positive investigations
    17. Directly observed therapy
    18. Use of video enabled technology for directly observed therapy
    19. Sputum collection
    20. Emergency planning that would impact TB services (i.e., natural disasters that could disrupt DOT)

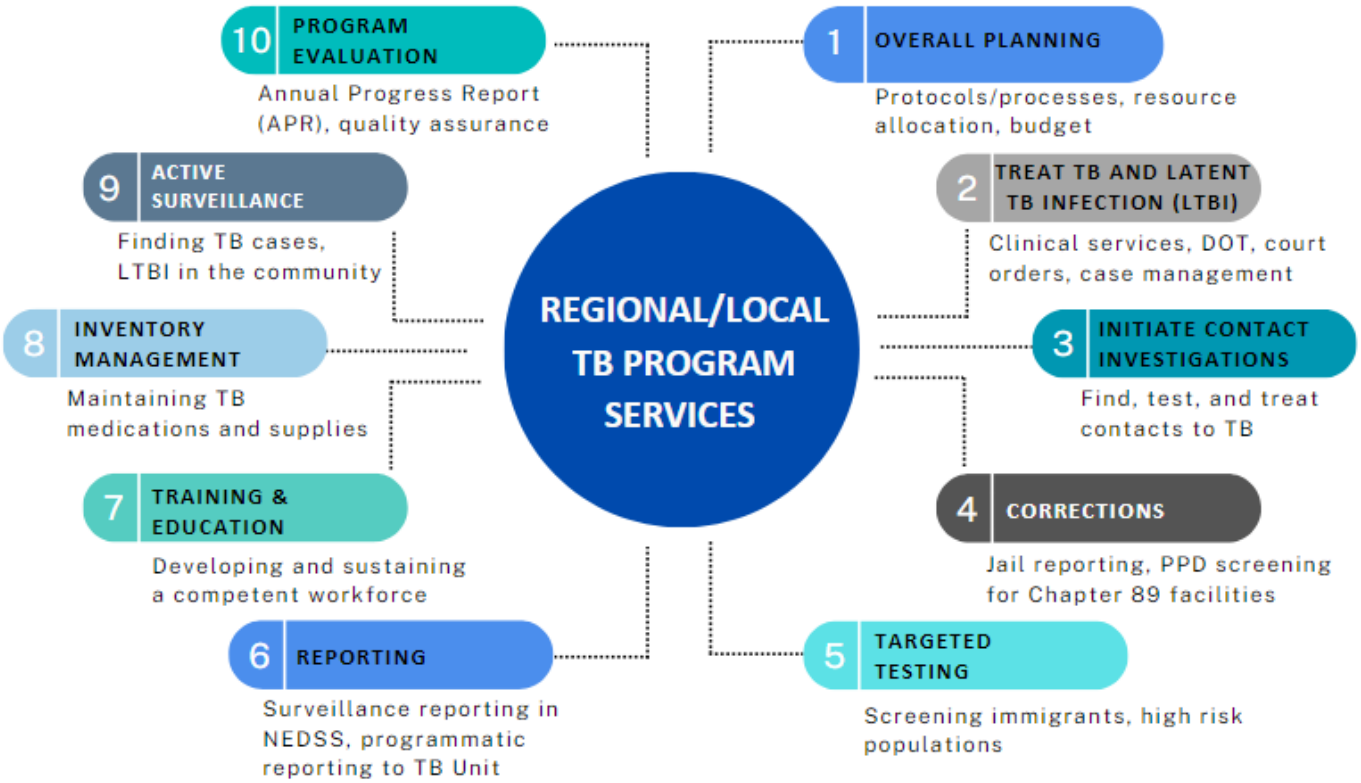
B. Ensure written protocols are easily accessible to all staff responsible for TB prevention and care activities.

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 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 nursing training manual for continuity, engaging the DSHS public health region 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, Tuberculosis and Hansen's Disease 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 Standing Delegation Orders (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 medical TB 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, regional medical director, local health authority) at least yearly or when changes occur.

B. Provide patient-centered care.
    1. 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 services on the DSHS intranet. Refer to https://online.dshs.texas.gov/services/translation-interpretation. 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%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 *DSHS Video-Enabled Directly Observed Therapy Required and Recommended Activities Manual* when using VDOT for eligible patients. Refer to dshs.texas.gov/sites/default/files/IDCU/disease/tb/policies/TBVDOTPolicy.pdf.
5. Telemedicine may be considered for medical case management of patients evaluated by the TB program, as determined by the licensed healthcare provider. 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 Texas statute: statutes.capitol.texas.gov/Docs/OC/htm/OC.111.htm.

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 program must have radiology services available, whether in-house 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 local health authority.
    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 licensed healthcare provider are issued and once criteria for release from isolation are met. The licensed healthcare provider 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.
    1. TB Programs may 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. TB programs must have the capacity to 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. TB Programs must 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. Utilize the TB Unit's TB Shipping Guide to support timely specimen submissions.

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. Perform routine patient assessments.
    1. Every patient on a medication regimen for TB disease or infection will have at minimum, a baseline and monthly nursing assessment with a physical exam and toxicity screening documented in the medical record.
    2. Toxicity screening must be performed according to drug regimen.
    3. Programs should ensure the licensed healthcare provider 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, ideally monthly, but at minimum at 26 weeks, or any time the patient status changes requiring medical interventions;
        d) at closure;
        e) any time medications are held due to signs or symptoms of toxicity or other reasons; and
        f) as determined by the licensed healthcare provider 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 licensed healthcare provider 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 directly observed therapy (DOT).
    1. Every patient with an ATS classification of 3 or 5 will be placed on DOT for the duration of treatment, unless otherwise ordered by the licensed

healthcare provider.
    a) Daily therapy is preferred (either 5x/week or 7x/week) to intermittent therapy where possible.
    b) DOT must be initiated as soon as possible, but no longer than one week of outpatient treatment initiation.
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 pre-approved by the TB Unit. NOTE: the licensed healthcare provider 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.
6. VDOT may be used by TB programs when patients are recommended for DOT.

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, licensed healthcare provider will provide a letter advising treatment.
    a) A copy of the letter will be maintained in the patient's medical record.
    b) The licensed healthcare provider may consider additional steps such as a Child Protective Services (CPS0 notification) Refer to *Appendix B: Sample Letter for Child Window Prophylaxis* for a sample correspondence.

K. Seek expert consultation when indicated.
1. Treatment for TB disease may become complicated in the presence of drug-resistance, if the patient is aged 17 years and younger, with co-infection with HIV, or the presence of other medical issues. In these or other circumstances where expert recommendations are needed, seek consultation through DSHS recognized TB medical consultants.(refer to dshs.texas.gov/disease/tb/consultants.shtm.)
2. A list of required and recommended reasons for consultation is listed in the SDOs.
3. When a consultation is required, the consultation and results (recommendations) must be kept in the medical record.

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. Licensed healthcare providers 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 of 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 licensed healthcare provider.

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.
   3. Submit an incident report to the TB Unit 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 (use DSHS form TB-230 or equivalent).

N. 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;
   c) 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 licensed healthcare provider, 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 licensed healthcare provider (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 licensed healthcare provider;
   b) ensure patients are started on adequate therapy;
   c) 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 licensed healthcare provider 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 licensed healthcare provider 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 SDOs for Tuberculosis Prevention and Care; 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 licensed healthcare providers (i.e., private physicians), state and federal correctional and detention 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.

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 Local Health Authority (LHA) to support this collaboration.
3. When treatment orders are written by an external licensed healthcare provider, 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 verses 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.

4. 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.

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 class 2, 3, 5 and contacts in the TB surveillance and reporting database. The R/LHD may utilize 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 for that facility. (Refer to *Chapter XIII. Inventory Management of Medication and Supplies*). R/LHD should guide contact investigation activities in Chapter-89 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 health care services.	**TDCJ is a reporting jurisdiction similar to an R/LHD.** TDCJ manages and enters all data for class 3, 5, and contacts directly in the TB surveillance and reporting database. Central Office staff may assist with contact investigation data entry if TDCJ is short-staffed. TDCJ Office of Public Health receives all initial case reports and closures from their contracted providers and enters in the TB surveillance and reporting database. They do not report to the R/LHD **unless** an offender is released while on treatment for TB. TDCJ Office of Public Health sends the IJN form

External Provider/ Facility	Primary TB Management	Reporting Responsibilities, Case Management Collaboration*, and Contact Investigation
		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 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 Texas Administrative Code 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 class 3, 5, and contacts into the TB surveillance and reporting database if the detainee has stayed 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 any state-purchased TB medications to an ICE facility.** 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 class 3, 5 and contacts in the TB surveillance and reporting database. High-risk populations with TB infection referred to an R/LHD must also be entered in the TB surveillance and reporting database. 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 the TB surveillance and reporting database. **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.
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 recommendations (i.e., release from isolation, Cis, etc.).	**Each shelter must report TB to their R/LHD.** The R/LHD enters all RVCT and case management data for class 2, 3, 5, and contacts in the TB surveillance and reporting database. The R/LHD sends IJNs to the receiving jurisdiction as described in *Chapter XVI. Interjurisdictional Notifications In and Out of State*. Any collaboration of case management activities will be made on a situational basis. R/LHD may guide screening activities for CI in UAC shelters. 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.
Bureau of Prisons (BOP)	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 Texas Administrative Code Title 25, Part 1, Chapter 97.** The R/LHD will provide TB services when requested by BOP. The R/LHD must enter all RVCT data, case management data for class 2, 3, and 5, and contacts into the TB surveillance and reporting database.

External Provider/ Facility	Primary TB Management	Reporting Responsibilities, Case Management Collaboration*, and Contact Investigation
		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.
Inpatient Care Facilities – i.e., hospital, long-term care facility, acute-care rehabilitation center	The facility's attending physician, medical director, licensed healthcare provider 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 class 2, 3, 5, and contact investigations in the TB surveillance and reporting database. 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 provide any state-purchased TB medications to an in-patient facility,** 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 the TB surveillance and reporting database at least monthly while inpatient. The R/LHD should collaborate with facility and choose 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/LHD should guide screening activities for contact investigations in inpatient facilities and may use program funds for testing. Testing activities should be coordinated with facility administrators.

External Provider/ Facility	Primary TB Management	Reporting Responsibilities, Case Management Collaboration*, and Contact Investigation
External Healthcare Providers (e.g., private providers)	The external licensed healthcare provider 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 a contact investigation (CI), as needed.
Texas Center for Infectious Disease (TCID)	TCID is the only DSHS-operated inpatient facility for TB in Texas. TCID also provides outpatient care for Hansen's disease.	The R/LHD receives case management data while patient is in TCID and must update the TB surveillance and reporting database at least quarterly. The R/LHD communicates with TCID on plans to refer a patient to TCID for admission. TCID informs referring R/LHD of patients release from TCID. Medications are provided by TCID and will be coordinated with the R/LHD upon discharge.
** If a facility is not providing DSHS standards of care for the treatment of TB, the R/LHD is responsible for communicating concerns with the local health authority (LHA) and/or regional medical director to guide collaboration efforts.* *† Refer to Chapter XX. Monitor Surveillance, Reporting, and Case Management Activities in Correctional and Detention Facilities.*		

B. Establish and maintain a medical record for each person with suspected or confirmed TB disease.
    1. Organize medical records with sections clearly divided and labeled. See #9 for required sections.
    2. Ensure all documents are securely attached to the medical record.
    3. Provide accurate and complete documentation.
    4. Date and sign all entries in the progress notes and draw a line through each blank section.
    5. Document in chronological order with the most recent information placed on top.
    6. Draw a single line through errors and initial.
    7. Do not document outside the margins.
    8. Establish a locally approved list of abbreviations.
    9. The medical record should have clearly divided sections

(recommended sections in bold, below) and must include at minimum the information as per the following DSHS forms or equivalent[1]:

a) Demographics, Case Information, and Current Orders
- (1) TB-400A (Report of Case and Patient Services) – completed initially.
- (2) TB-400B (Report of Case and Patient Services) – completed initially and updated when indicated.

b) 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) Medical History
- (1) TB-202 (Tuberculosis Health Assessment/History)

d) Bacteriology Results

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)

h) Directly Observed Therapy Logs
- (1) TB 206 (DOT Log)

i) Consent Forms and Control Orders
- (1) L 36 (General Consent and Disclosure)
- (2) L 30 (Consent to Release Confidential Medical Information)
- (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

l) 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 TB-410 (known as the "TB Control Order") before being discharged or released to outpatient

[1]*The TB Unit's surveillance and reporting database is not a medical record; however, it may contain elements of what is typically maintained in a medical record. To avoid duplicate entries, content from the database may be printed and saved in the medical record.*

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 travel restrictions while infectious.
    a) Except for healthcare-associated visits, direct patients to refrain from travel outside the home until patient has met criteria to discontinue A.2.
    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, DSHS form TB-410 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.
    1. 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 DSHS form TB-201 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 does not align with DSHS treatment standards.
        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/fqhcmain.shtm).
b) Indigent patients may qualify for medical assistance in their county of residence (see hhs.texas.gov/services/health/county-indigent-health-care-program).
c) See *Appendix F: Additional Patient Services* for more patient 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 for services.
   2. Patients classified as 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.* https://www.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 DSHS form 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 provide to 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) AFB smear results and bacteriology (see *Table 6: Acid Fast Bacilli Smear Classification Results*);
    d) 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); 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 DSHS form TB-410 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

Diagnosis Type	Specimen Needed
	○ 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
Cyst/cavity	Focal spaces or "holes" in the lung: both indicate the absence of 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
Opacity	A circumscribed area that appears nearly white (i.e., denser) than 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 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 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, or kanamycin) *or* a fluoroquinolone; and

Category	Sensitivity Patterns
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 https://www.cdc.gov/tb/php/dear-colleague-letters/2022-xdr-surveillance-definitions.html?CDC_AAref_Val=https://www.cdc.gov/tb/publications/letters/2022/surv-def-xdr.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	Infectiousness of Patient
4+/numerous (>9/field)	>10/field	Strongly positive	Probably very infectious
3+/few-numerous (1-9/field)	1-10/field or >10/field	Strongly positive	Probably very infectious
2+/few (1-9/10 fields)	<1/field or 1-10/field	Moderately positive	Probably infectious
1+/rare (1-9/100 fields)	<1/field	Moderately positive	Probably infectious
Actual number of AFB seen (no plus sign) (1-2/300 fields)	1 or 2 AFB seen on entire smear	Weakly positive†	Probably infectious
No acid-fast bacilli seen	No AFB seen on direct smear	Negative	Probably not infectiousβ

** 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.

B Criteria for determining whether a patient may be considered noninfectious are discussed in Module 5: "Infectiousness and Infection Control" of the CDC's Self-Study Modules on Tuberculosis.

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 that retain color after a fluorochrome staining. Under a microscope they appear rod-shaped 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 *M. tb* organisms	• A positive culture confirms diagnosis of *M. tb*. • Culture results assist in monitoring response to treatment. • ***Positive results*** should be reported to the clinician as soon as possible. • ***Negative results*** 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 medical TB consultant.
NAAT *48 hours*	Used for rapid detection of *M. tb* DNA or RNA in patient specimen.	• Assists in the ability to rapidly diagnose or exclude *M. tb*. • 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. • ***Positive results*** should be communicated to the clinician immediately. • ***Negative results*** 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 Results	Definition	Purpose and Implications for Clinical Management
Polymerase Chain Reaction (PCR) *48 hours*	Testing technique used to amplify small segments of *M. tb* DNA in a specimen. PCRs are a type of NAA technique.	• Same as NAAT. • Rapid test to help identify *M. tb* more quickly than conventional culture methods. • Does not distinguish between viable, disease-related organisms and nucleic acid persisting from prior disease. • Ensure a culture is in progress. • 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. *NOTE: preliminary PCRs showing rifampin resistance should be reported to the R/LHD while further testing is pending*.
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 *M. tb* DNA.	• Detects the presence of *M. tb* and the most common mutations in the rpoB gene that confer rifampin resistance. • Ensure an Xpert test is in progress as not all laboratories that perform NAA testing use the Xpert test that result in a rifampin result. • Ensure culture is in progress. • 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 medical TB 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.

Test* and *Timeframe* for Results	Definition	Purpose and Implications for Clinical Management
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 licensed healthcare provider and a DSHS-recognized medical TB consultant. • See *Appendix H: Requesting Molecular Detection of Drug Resistance (MDDR)* for criteria and submitting process.
Drug Susceptibility Testing (DST) *First-line DST: 17 days after positive MTB culture* *DSHS Austin Laboratory reports Isoniazid, both concentrations, and Rifampin at 11 to 14 days after positive M. tb culture*	Tests *M. tb* 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 state laboratory in Austin will automatically test an initial positive culture for susceptibly to all first-line anti-TB medications and ofloxacin. • 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 *M. tb*. • Consult required with a DSHS recognized TB medical consultant if resistance to isoniazid and/or rifampin is identified.
Minimum Inhibitory Concentration (MIC)† *Varies 4-12 weeks*	Test using a series of 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.
TB Genotyping using Whole Genome Sequencing†β (WGS)	Examines genetic relatedness of isolates by expanding coverage of the genome to	• Allows for comparison and establishes relatedness between *M. tb* isolates. Provides greater resolution than previous genotyping methods (GENType) for investigating recent transmission and can detect mutations (see also rpoB alert, below).

Test* and *Timeframe* for Results	Definition	Purpose and Implications for Clinical Management
	approximately 90%.	• 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 accessed through TB GIMS. If not available, a request may be made by contacting TB Unit epidemiologists. • Whole-genome single nucleotide polymorphism analysis (wgSNP) comparison trees (the plots that explain how closely related isolates are form each other) are automatically performed on concerning clusters identified by CDC. • Can be used to support false positive investigations, contact investigations, and cluster investigations.
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 Medical TB Consultant as soon as possible.

** 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.
B 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 Medical TB Consultant if the exact regimen is not outlined in the SDOs.

2. Provide DOT and document on DSHS form TB-206 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 medication 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/IDCU/disease/tb/forms/PDFS/TherapeuticDrugMonitoringProcess.pdf.
5. Report deaths among known or suspected TB cases to the TB Unit using the *DSHS Weekly Report of New Concerning Tuberculosis Event* form found here: dshs.texas.gov/sites/default/files/LIDS-TB/forms/WeeklyReportNewConcerningTBEvents.docx. 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 in the progress notes of patient's medical record.
      c) Place certified mail notification receipt in the patient's medical chart.

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 licensed healthcare provider 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 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 Lookout list.** Refer to cdc.gov/port-health/travel-restrictions.
5. Submit a DNB/LO request to the TB Unit epidemiology team using DSHS form 12-12065 (*TB Travel Restrictions Request Form*) 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 licensed healthcare provider, the local health authority (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 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 Epidemiology 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

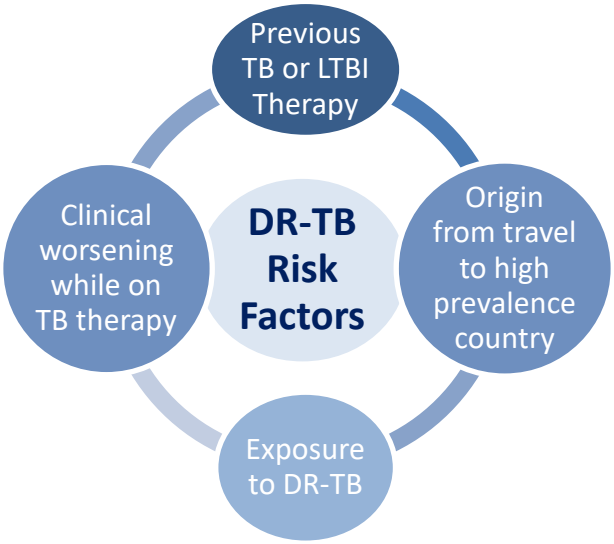
TB programs will participate in the TB Unit's DR-TB monitoring program. The purpose of the DR-TB monitoring program is to collect, analyze, describe, and respond to data used in the prevention and care of DR-TB in Texas. This includes monitoring the following:

- Rifampin mono-resistant TB (RR-TB)-resistance to rifampin, a first-line TB drug; 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; and
- Extensively drug resistant TB (XDR-TB)-MDR, plus resistance to one of the second-line injectable agents (amikacin, capreomycin, or kanamycin) *and* a fluoroquinolone *or* MDR, plus resistance to a fluoroquinolone, and Bedaquiline or Linezolid.

Activities

A. Identify patients at risk for DR-TB. 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 and Hansen's Disease Unit, 2024

B. Seek consultation from a DSHS-recognized TB medical consultant or DSHS regional medical director and notify the TB Unit Nurse Consultant within three days upon initial diagnosis or suspicion of DR-TB, whichever is sooner. Contact information for the DSHS-recognized medical TB consultants is found here: https://www.dshs.texas.gov/tuberculosis-tb/tb-education-training-resources/dshs-recognized-tuberculosis-medical.
    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:
            (1) 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 regional medical director 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 results) 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 consultants are familiar with the patient status at discharge;

f) a patient is approaching end of therapy and 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 Drug-O-Gram as per the TB-700 or equivalent. Refer to dshs.texas.gov/disease/tb/forms.shtm#cm.

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; therefore, further testing would be indicated, such as an MDDR test.
   3. Request MDDR testing when appropriate. See *Appendix H: Requesting Molecular Detection of Drug Resistance (MDDR)*.
   4. DSTs[2] are run on positive *M. tb* cultures sent to the DSHS laboratory.
      a) If resistance to primary drugs (excluding pyrazinamide mono-resistance) is detected, DSHS laboratory will reflexively set up 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.
      c) If specimen was collected at an outside laboratory, consultation with a DSHS-recognized medical TB consultant is recommended to ensure further testing is performed.
   5. Outside laboratories or hospitals may also report resistance from rapid tests such as PCR; coordination with outside laboratories is recommended.

[2] 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.

a) Collaborate with the outside laboratory send initial isolate indicating resistance to DSHS laboratory for either confirmatory testing or further diagnostics as soon as possible, e.g., MDDR.

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 licensed healthcare provider.
   2. Consider holding current drug regimen when able (i.e., patient is medically stable).
   3. Request a medical consult from a DSHS-recognized medical TB consultant for continuation of care.[3]

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.
   3. 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 medical TB consultant.

F. Order medications after consultation with a DSHS-recognized medical TB consultant 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 clinical care forms specific to DR-TB (TB-700 series) or their equivalent. Monthly assessments of medication toxicity specific to each medication are required and must be documented on DSHS toxicity forms or equivalent.

H. Submit updates in the TB surveillance and reporting database 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. Participate on the DSHS quarterly DR-TB case conference calls as scheduled

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

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 out-patient 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 will submit the TB-706 Case Conference Presentation template for each patient to be discussed, three days prior to the scheduled call. All information should be completed on the form and reflected in the surveillance and reporting database. Incomplete forms will be returned to the submitter for correction.
3. Programs will submit the TB-706 by the end of their scheduled month for patients being managed with second-line medications due to a rifamycin intolerance. The DR-TB Nurse Consultant will review and follow up with the nurse case manager for any questions.

J. 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.

K. Manage patients in accordance with recommendations from a DSHS-recognized medical TB consultant and the licensed healthcare provider for duration of therapy.

VII. Conduct and Manage a Tuberculosis Contact Investigation

General Requirement

TB programs will conduct a CI for people with suspected (class 5) or confirmed (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 toTB disease to prevent further transmission.

Activities

A. Initiate a CI or source case investigation.
   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 DSHS form 12-12062 CI 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 of possible recent transmission from an adult in the child's social environment. Members of the child's household should be evaluated. Only one round of testing is required.

B. Determine infectious period using DSHS form TB-425 (*TB Infectious Period Calculation Worksheet*).
   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.

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 ≤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 a CI without first prioritizing contacts. Unfocused testing 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 8: Estimating the Infectious Period

Index Case Characteristics						Infectious Period
TB Symptoms		AFB Sputum Smear (+) Result		Cavitary CXR		
Yes	No	Yes	No	Yes	No	
√			√		√	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

** Abnormal CXR consistent with TB or bacteriology*

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 Guidelines for the Investigation of Contacts of Persons with Infectious TB: Recommendation from the National TB Controllers Association and CDC and Guidelines for Using QuantiFERON®-TB Gold Test for Detecting Mycobacterium tuberculosis Infection, United States, 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 for individuals at risk for TB. 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, including contacts started on window prophylaxis.
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.

10. 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 (see DSHS form TB-460, *Expansion Analysis Checklist*).
   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. As needed, request a consult with DSHS TB Unit epidemiologists to discuss whether an expansion to low priority contacts is warranted. Submit consultation requests through TBEpi@dshs.texas.gov.

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 epidemiologists to determine if reporting to appropriate partner state agencies is warranted.

G. Notify the TB Unit epidemiology team of large-scale screenings 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; and/or
   - media involvement.

   1. Submit either the DSHS form 12-12063 (*TB Corrections Incident Report*) for any large-scale or concerning CI in a correctional facility,

DSHS form 12-12104 (*TB Incident Report*) for all other CIs, or equivalent via the TB surveillance database and notify TB unit epidemiologists via TBEpi@dshs.texas.gov.

2. Seek consultation with TB Unit epidemiologists. Consultations should occur before testing is initiated.
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;
    f) evaluation results for first and second round screening; and
    g) other relevant details.
4. Mass 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.
5. Submitting data through the DSHS form 12-12104 or 12-12063 does not replace data entry in the TB surveillance and reporting database.

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 DSHS form TB-341 and in the TB surveillance and reporting database.
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.
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 staff as needed.
5. Use the DSHS forms TB-342 and TB-343 to report investigations in correctional settings.
6. Mass screenings in correctional setting that meet the criteria outlined in subsection G, should be reported using the DSHS form 12-12062 for corrections.
7. All applicable CI forms are located here: dshs.texas.gov/tuberculosis-tb/texas-dshs-tb-program-tb-forms-resources#ci.

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 epidemiologists 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 contacts within two weeks of notification.
3. Complete the DGMH TB Air Contact Investigation Outcome Reporting Form and submit it via GlobalScape to the TB Unit within a month of notification. Notify TB unit epidemiologists 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.
   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*.

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;
        b) 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 licensed healthcare provider. 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 medical TB 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 DSHS form TB-400A 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.
   6. 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);
      b) 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 licensed healthcare provider'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-α 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-α 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.
   1. Organize medical records with sections clearly divided and labeled. See #9 for required sections.
   2. Ensure all documents are securely attached to the medical record.
   3. Provide accurate and complete documentation.
   4. Date and sign all entries in the progress notes and draw a line through each blank section.
   5. Document in chronological order with the most recent information placed on top.
   6. Draw a single line through errors and initial.
   7. Do not document outside the margins.
   8. Establish a locally approved list of abbreviations.
   9. The medical record should have clearly divided sections (recommended sections in **bold**, below) and must include at minimum the information that is asked on the following DSHS forms or equivalent:
      a) **Demographics, Case Information**
         (1) TB-400A (Report of Case and Patient Services)- completed initially and when orders change.
      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)
         (3) TB-415 (Medication Consent for LTBI Therapy)
      i) **Outside Records**, i.e., primary care provider records.

j) **Medical Consults**
k) **Progress Notes**
l) **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 Rif-susceptible TB infections as indicated in the SDOs.
   2. Short course regimens are preferred to six-or nine-month INH regimens.
   3. Licensed healthcare providers 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 licensed healthcare provider. 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 licensed healthcare provider 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 licensed healthcare provider 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 licensed healthcare provider suspects the clinical presentation is not consistent with culture findings.

B. Notify the local health authority 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 *False Positive Investigation Worksheet* or equivalent.
   2. Contact the originating laboratory to determine source of false positive result (e.g., laboratory contamination vs. specimen collection error).
   3. Use 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. Submit a completed *False Positive Investigation Worksheet* with supporting documentation.
   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 licensed healthcare provider 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 in case 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. 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:
   1. People from countries with a high prevalence of TB, defined as countries with a TB rate ≥20 cases/100,000 (see World Health Organization who.int/tb/country/data/profiles/en/ and *Table 10: Prioritizing Evaluation of TB Infection for Foreign-Born People*).

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,	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
	employment, fiancé and diversity-based such as "lottery" visas) See travel.state.gov/content/travel/en/us-visas/immigrate.html.		
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. 3. Applicant has confirmed extra-pulmonary TB. Civil Surgeons will report LTBI to TB programs after a diagnosis of TB infection is made. Civil surgeons are responsible for initial TB testing including CXRs and can treat 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 (i.e., Uniting for Ukraine): dhs.gov. • U.S. Citizenship and Immigration Services that define parole status. Refer to uscis.gov/humanitarian/humanitarianpublicbenefitparoleindividualsoutsideUS.	R/LHD	Reporting to TB program may vary based on 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 Exam Site	How they are referred to the TB program
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 Available 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 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/content/travel/en/us-visas/tourism-visit/visitor.html.	*May* be required for a medical exam at the discretion of the consular officer overseas or immigration officer at the U.S. port of entry.	Incidentally if evaluated by a clinician; may self-refer. Evaluate as resources allow.
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/content/travel/en/us-visas/other-	N/A	Incidentally if evaluated by a clinician after interruption in travel and stay in U.S.; may self-refer. Evaluate as resources allow.

Category	Description	Medical Exam Site	How they are referred to the TB program
	visa-categories/transit.html.		
Adapted from: CDC Immigrant and Refugee Health. (2014, May 15). Tuberculosis: Refugee Health Domestic Guidance. https://www.cdc.gov/immigrant-refugee-health/hcp/domestic-guidance/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,	Individuals diagnosed with extrapulmonary TB with normal

Classification	Definition
Extrapulmonary TB	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 Newly Arrived Refugees. CDC Stacks. https://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 *Table 12: 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 Tuberculosis Technical Instructions for Civil Surgeons.
      (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 *Technical Instructions*, 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.

Table 12: 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 Information	☐ Pre-populated.
Section C	
Date of Initial U.S. Medical Evaluation	☐ Record date of initial evaluation.
IGRA or TST	☐ 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-related 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	☐ 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 "Not Verifiable." ☐ 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 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	☐ 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 Disposition	☐ Record date when medical director or consulting physician has completed the evaluation, if determined that the evaluation

Date	cannot be completed for one of reasons listed.
Evaluation Disposition	☐ 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 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."
Diagnostic	☐ Mark the box corresponding to CDC diagnostic classification as listed. ☐ Treatment is inappropriate for diagnoses of class 1 or 0. The EDN system will create an error message if treatment is recommended 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 (*Complete 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 TB infection." ☐ *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 Completed	☐ 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 "No" 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).

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.

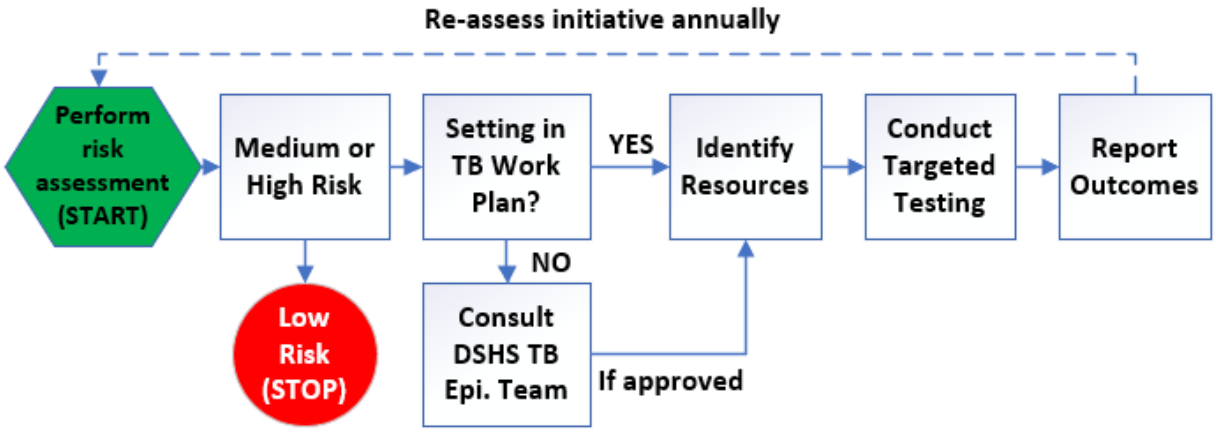
B. Ensure TB Unit guidelines are followed for each new targeted testing initiative.

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 DSHS form TB-500 (*Congregate Settings TB Risk Assessment*) found here: dshs.texas.gov/tuberculosis-tb/texas-dshs-tb-program-tb-forms-resources#targeted.
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 contacts, 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 DSHS form 12-14427 (*Targeted Testing Monthly Report*) to the TB Unit no later than the 15th day of the following month to GlobalScape. Notify the Continuing Quality Improvement Team by sending an email to CQIteam@dshs.texas.gov 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 3: Targeted Testing Workflow Process*.

Figure 3: Targeted Testing Workflow Process



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 DSHS form TB-500.
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 Epidemiology team before initiating.
4. If targeted testing will be performed at a correctional or detention facility, consult the Continuing Quality Improvement team prior to initiating.
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 epidemiology team before initiating testing at a non-congregate 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 Epidemiology team before initiating.
        (1) Annual TB testing of health care 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. See hrsa.gov/opa/eligibility-and-registration/specialty-clinics/tuberculosis/. 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 policy requirements when using state-purchased TB medications. Refer to https://www.dshs.texas.gov/pharmacy-unit/340b-drug-discount-program.

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;
   4. 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 third-party 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. 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) to maximize usage.

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 4: Sample Medication Label for DOT Packets 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 4: Sample Medication Label for DOT Packets for Self-Administration or VDOT

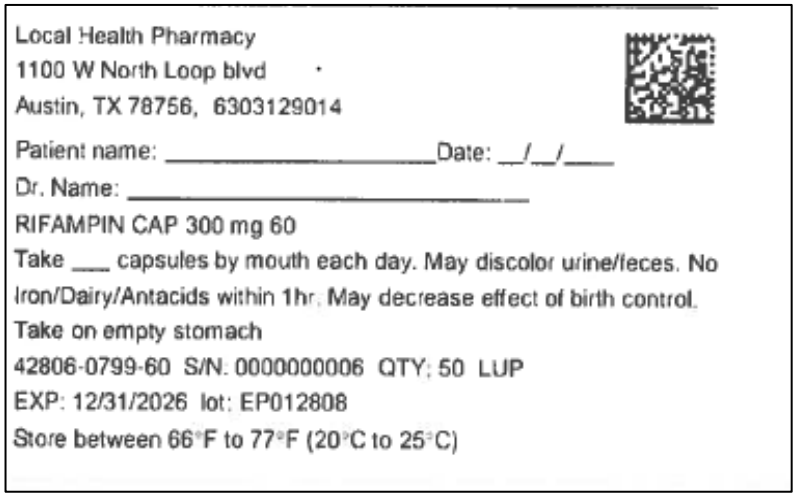
TB Program Name HERE
123 Main St.
City, TX 77000
Phone 123-456-7891

01/01/2024
John Watson, MD
Jane Doe

Medications: Rifampin 600mg, Isoniazid 300mg, Pyrazinamide 1000mg, Ethambutol 800mg, Pyridoxine 50mg
Instructions: Take 2 packets each day

4. Refer to *DSHS Video-Enabled Directly Observed Therapy Required and Recommended Activities Manual* when using VDOT for eligible patients at dshs.texas.gov/idcu/disease/tb/policies.
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), Rule Title 22, Texas Administrative Code §291.93 (refer to *Figure 5: Sample Medication Label for Bulk Bottles*).
    a) The label must be printed and attached to bottles for self-administered 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 5: Sample Medication Label for Bulk Bottles



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 13: 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 medical TB consultant is required before ordering second-line medications unless the medication is listed as part of 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 other purchases are pending (refer to Bedaquiline Ordering Guide).
        (2) **Clofazimine** (CFZ) is an investigational drug that may only be prescribed by Institutional Review Board (IRB) enrolled physicians, called investigators or co-investigators. The TB Unit, in collaboration with DSHS Regional and Local Health Operations (RLHO), holds an IRB for CFZ use. If CFZ is recommended, do the following:
            (i) Inform the licensed healthcare provider that IRB enrollment is required; identify if the physician has access to CFZ through an IRB. NOTE: DSHS Regional Medical Directors are investigators. Contact the TB Unit for coordination.
            (ii) If the licensed healthcare provider is unable secure CFZ through an established IRB, contact the TB Unit Drug-Resistant TB Monitoring Program Nurse Consultant for next-steps.

Table 13: 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 (i.e., 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 bedside, disguising in foods, etc.) and compounding is seen as a last resort to supported medication

administration.

3. 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 additions[4]. 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 representatives where 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.

[4] NOTE: 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.

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 correctional TB screening plan (TB-805) indicates the R/LHD as the providing entity. Refer to 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 89-designated facilities by engaging in the following activities:
         (1) Review the Correctional TB Screening Plan (TB-805) 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 the *Monthly Correctional TB Report* (DSHS form 12-11462) and reads a high majority of tests placed (>80%).
         (3) 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.
         (4) Ensure the facility is not delinquent in submitting their *Monthly Correctional TB Report Form* (DSHS form 12-11462) and *Report of TB Conditions* (DSHS form 12-11461) to the TB program.
         (5) Ensure the facility has exhausted their current supply and does not have PPD stockpiled.
         (6) 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:
   a) 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 monthly.
   f) Obtain the DSHS form 12-14427 *Targeted Testing Monthly* Report from each facility.
   g) Review DSHS form 12-14427 *Targeted Testing Monthly Report* 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 cqiteam@dshs.texas.gov 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 children[5] 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 304B 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.

[5] 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 TB Questionnaire.

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 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., TB surveillance and reporting database, 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.
   2. 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.
   3. Ensure local laboratories promptly report positive results such as acid-fast 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.
   1. 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

Funded programs must report suspected and confirmed TB cases, contacts, and people diagnosed with LTBI to the TB Unit through reporting mechanisms outlined in this chapter. Reporting may include responding to TB Unit requests, emailing TB Unit teams, 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 the 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 they can identify opportunities for targeted screening for disease or infection.

NEDSS allows for real-time data entry; therefore, TB programs must adhere to the reporting timelines outlined in this chapter.

Funded R/LHD TB programs will report the following surveillance data into NEDSS using this guidance:

A. Create a **Tuberculosis RVCT 2020 investigation** 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.

    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 *NEDSS Data Entry Guide* for reporting surveillance data for TB conditions at dshs.texas.gov/tuberculosis-tb/training/nedss.

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.
    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 14: American Thoracic Society (ATS) TB Classifications* below).

Table 14: American Thoracic Society (ATS) TB Classifications

Classification	Description
0	No *M. tb* exposure, not TB infected
1	*M. tb* exposure, no evidence of TB infection
2	*M. tb* infection, no disease
3	*M. tb* infection, current disease
4	*M. tb*, no current disease
5	*M. tb* suspected, diagnosis pending

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 surveillance team to verify case criteria and count status. (Refer to *Table 15: Case Criteria and Count Status.*)

1. When notifications are received, a TB 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 15: 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. https://www.cdc.gov/tb/media/pdfs/Report-of-Verified-Case-of-Tuberculosis-RVCT.pdf.

D. Create an **investigation for LTBI (TBLISS)** in NEDSS within three business days for a known diagnosis of LTBI. An investigation should be created for the following populations with high-risk conditions:
    1. foreign-born from high-incidence countries;
    2. status adjusters*
    3. newly arrived immigrants and refugees notified through EDN;
    4. unaccompanied children;
    5. HIV-positive individuals; and
    6. health care workers with recent TST or IGRA conversion.

    *Civil surgeons may treat status adjusters or refer to the R/LHD. All treatment information for status adjusters should be entered in NEDSS and indicate whether management is provided by a public health program.

    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 *NEDSS Data Entry Guide* for reporting surveillance data for TB conditions at dshs.texas.gov/tuberculosis-tb/training/nedss for more information.

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 **LTBI** (**ATS class 2)** investigations to the TB Unit within two business days of starting treatment for LTBI by creating a notification in NEDSS.
    1. When notifications are received, a TB Unit surveillance case consultant will perform QA and assign an LTBI number.
    2. Complete information must be entered in NEDSS before an LTBI number will be assigned. (Refer to *Appendix S: TB Intake Information* for required information.)
    3. Enter remaining LTBI data in NEDSS as soon as the information is available.
        a) Treatment and outcome information should be entered in NEDSS as soon as treatment for LTBI 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:
    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 the TB surveillance and reporting database and the case count in the jurisdiction's log.
    2. Respond to requests within one week or five business days after receipt or within the timeframe included in the request. (Refer to *Appendix R: Guidelines for Responding to TB Unit Surveillance Requests for Missing Report of Verified Case of TB (RVCT) Data*.)
    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 16: Requirements for Quality Assurance for TB Surveillance Data*.)
    5. Adhere to the TB Case Count and Case Review Schedule. Refer to *Table 17: TB Case Count and Case Review Schedule*. Ensure timely case reporting to meet deadlines outlined in the schedule.

Table 16: 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 the TB surveillance and reporting database 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 17: TB Case Count and Case Review Schedule

Action	Deadline
2024 Fourth Quarter Case Count and Case Review	January 31
2025 First Quarter Case Count and Case Review	April 30
2025 Second Quarter Case Count and Case Review	July 31
2025 Third Quarter Case Count and Case Review	October 31
2025 Final Case Count and Case Review	January 15

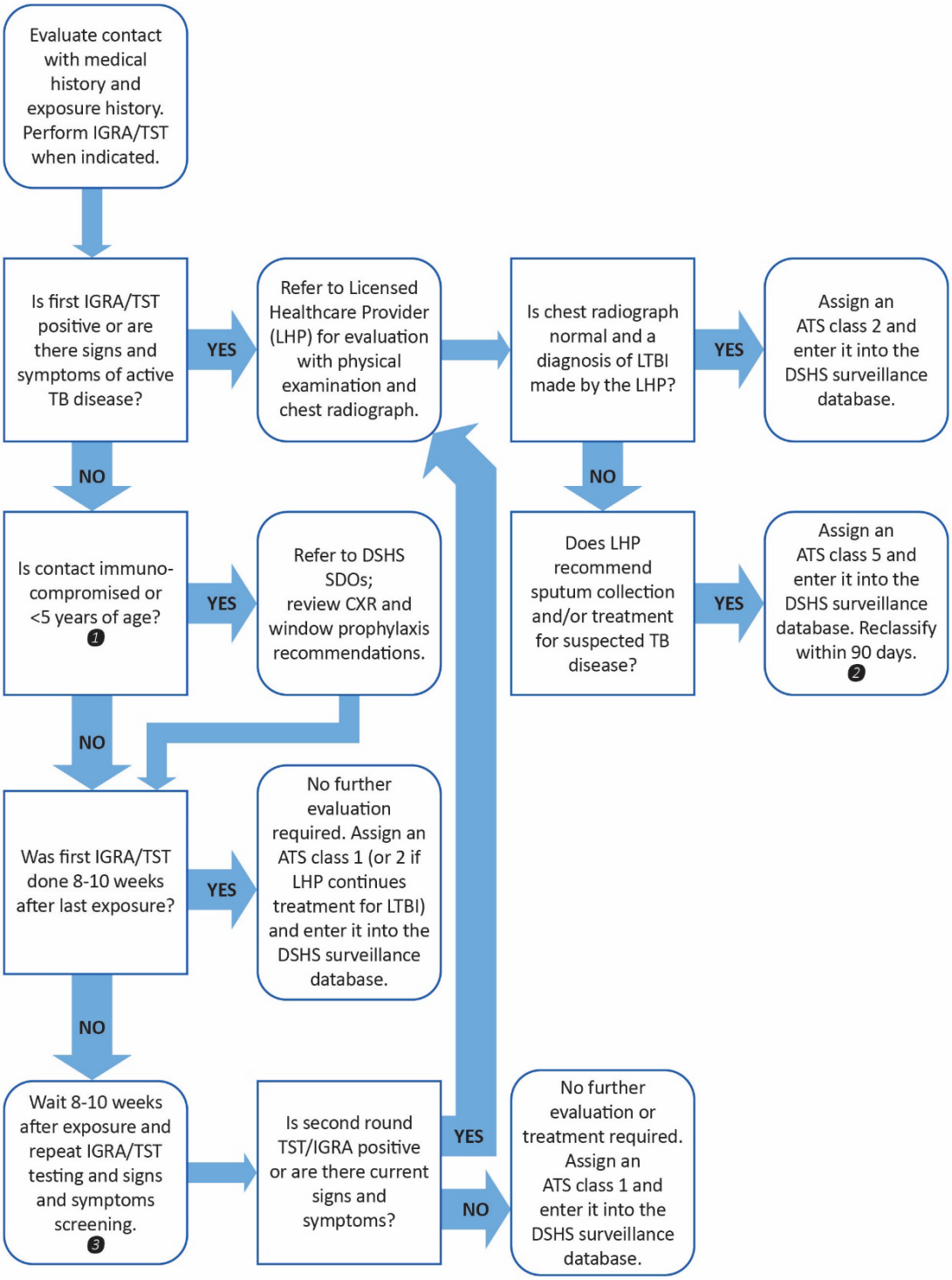
I. Enter **contact investigation information** in NEDSS using data obtained in forms TB-340 and TB-341, or TB-342 and TB-343, within 90 days of initial source case report.
    1. The initial contacts' report requires the following:
        a) Part A. Index Case/Suspect Information
        b) Part B. 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.

c) Part C. Contact Information
(1) Name
(2) Date of birth
(3) Duration of exposure and setting
(4) HIV test results
(5) 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 the following:
   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 licensed healthcare provider 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 6: Assigning ATS Classifications to TB Contacts*
   a) Contacts that do not meet the criteria for a complete evaluation should not be assigned and 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 6: Assigning ATS Classifications to TB Contacts



1 *Any contact < 5 years and/or HIV positive must have CXR performed, ideally at first round testing, regardless of TST/IGRA results.*
2 *Contacts with a positive IGRA who start RIPE therapy for suspected TB (ATS Class 5) and who after 2 months are closed as non-TB, should be considered fully treated for TB infection (Note: ensure both RIF **and** PZA were given for 2 months as part of RIPE).*
3 *Do not enter ATS classification in state surveillance database (i.e., THISIS) until the contact has been evaluated 8-10 weeks after last exposure.*

Funded R/LHD TB programs will report the following surveillance data to the TB Unit through various mechanisms:

A. Report each Friday **concerning events** to the TB Unit Epidemiology Team TBEpi@dshs.texas.gov using the DSHS Weekly Report of Concerning TB Events form. Concerning events are:
   1. all newly reported confirmed TB disease cases among children younger than five years of age;
   2. cases with RR-TB, MDR-TB, pre-XDR TB or XDR-TB confirmed via a nucleic acid amplification test, molecular drug susceptibility testing, or phenotypic drug susceptibility testing; and/or
   3. any death in a person with known or suspected TB disease.

B. 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.
   1. 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.

C. Report **adverse drug reactions resulting in hospitalization or death**.
   1. Submit form 12-12274 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.
   2. 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.

D. 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.
   1. 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).
   2. Review all other specimens associated with a false-positive case to ensure they are culture-negative.

E. Notify the TB Unit Epidemiology Team of **concerning or large-scale screening CIs** within 48 hours. Concerning CIs involve:
   1. Media sensitive exposures
   2. Exposures with ≥ 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.
6. Submit DSHS form 12-12104 (*TB Incident Report*) via the TB surveillance database or Globalscape and notify TB unit epidemiologists via TBEpi@dshs.texas.gov.
7. Correctional exposures should be submitted using the DSHS form 12-12063 (*TB Corrections Incident Report*).
8. Contact a TB Unit epidemiologist to discuss:
    a) clinical presentation of the patient;
    b) medical and social history of the patient;
    c) screening method and results including test dates (initial round of testing);
    d) second round testing dates (planned);
    e) radiologic and bacteriologic status including NAAT results;
    f) infectious period;
    g) contact investigation forms;
    h) description of environmental assessment or planned environmental assessment;
    i) incident command response plan;
    j) results of epidemiologic assessment and next steps; and
    k) other relevant details.
9. Submit timely written updates to the TB Unit Epidemiology Team as updates are available (or as requested) that may include:
    a) NAAT results;
    b) environmental assessment to determine specific areas in which exposure occurred and the exposure period;
    c) stratification of contacts by risk;
    d) scheduled and actual dates of screening;
    e) screening methods (i.e., IGRA/TST);
    f) evaluation results based on risk stratification (all high-risk contacts should be tested first to determine the need for expansion); and
    g) other relevant details.
10. Submit a final epidemiologic update to the TB Unit after the investigation is closed.

F. Report **mass screenings** (contact investigations $\geq$ 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.

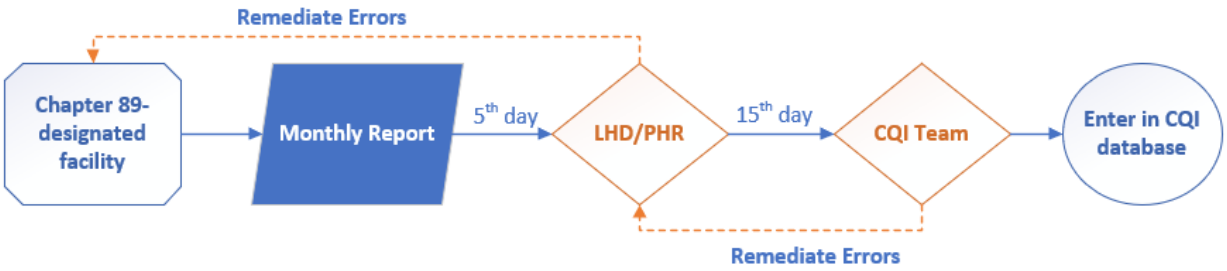
2. Use sound epidemiologic principles at each CI event to ensure appropriate people are identified for screening and to determine specific environments in which transmission may have occurred.
3. Mass screenings that are not epidemiologically guided drain limited resources and yield minimal results.

G. Conduct **airline exposure** screening based on notifications received from the TB Unit via CDC Division of Global Migration and Health (DGMH).
   1. TB Unit epidemiologists will contact TB programs to provide the demographic and contact information of people exposed during the flight per CDC DGMH.
   2. TB programs must:
      a) notify airline contacts and instruct them to report to their program site for TB screening;
      b) screen contacts;
      c) complete and submit the DGMH TB Air Contact Investigation Outcome Reporting Form to the TB Unit Epidemiology Team via GlobalScape within one month of notification; and
      d) provide RVCT and contacts to surveillance staff for data entry into the TB surveillance and reporting database.

H. Report **potential airline exposure** to the TB Unit's Epidemiology Team.
   1. TB Programs shall notify the TB Unit's 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.

I. Review and submit designated reports received from **correctional and detention facilities** identified as Chapter 89 according to Texas Health and Safety Code Chapter 89 requirements to the TB Unit via GlobalScape.
   1. Collect the *Monthly Correctional TB Report* (DSHS form 12-11462) and *Report of TB Conditions* (DSHS form 12-11461) 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 correctional and detention facilities on correcting identified quality assurance errors or completing the *Monthly Correctional TB Report and Report of TB Conditions.*
   4. Submit the *Monthly Correctional TB Report* and *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 7: Correctional TB Reporting Workflow*.

Figure 7: Correctional TB Reporting Workflow



J. Complete and submit the **DSHS Annual Progress Report (APR)** using the TB Unit template to TBContractReporting@dshs.texas.gov once a year on April 1.

K. 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-State and Out-of-State

General Requirement

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

Programs can find the IJN form and procedures on the National TB Coalition of America (NTCA) website: https://www.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, programs must complete the IJN form with the available information. If the 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. Do not print and rescan the IJN form. Find the instructions on how to complete the IJN form on the NTCA website: https://www.tbcontrollers.org/docs/resources/IJN_CompanionGuide_2022_08_10_FINAL.pdf. Programs can find contact information for national TB programs here: https://www.tbcontrollers.org/community/statecityterritory/.

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

- LTBI (ATS class 2): Programs must complete a cover sheet and IJN form for LTBI, located at: IJN_Form_2022_08_10_FINAL_TBInfection.pdf (tbcontrollers.org).
- Cases and suspected TB cases (ATS classes 3 and 5): Programs must complete a cover sheet and the two Active/Possible TB forms, located at: IJN_Form_2022_08.10_FINAL_ActiveTB.pdf (tbcontrollers.org).
- Contacts: Programs must complete a cover sheet and the two contact forms, located at: IJN_Form_2022_08.10_FINAL_ContactInvestigation.pdf (tbcontrollers.org).

Activities

A. Plan, coordinate, and communicate informally with the receiving jurisdiction when a patient plans temporary travel out of state.
    1. Identify the address where the patient will stay or is staying 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 stay or is staying. Temporary travel is 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.
    2. 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 identifies the local jurisdiction or TB clinic that they should contact 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 referring jurisdiction notifies the receiving state of any patient on treatment for TB disease and LTBI.
        b) The receiving state determines how best to coordinate care while the patient is in their jurisdiction.
        c) If the referring jurisdiction plans to keep the patient on VDOT, they should inform the receiving jurisdiction.
    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 when the patient's temporary travel is longer than 30 days. The referring jurisdiction submits the appropriate IJN form and related records to the TB Unit's IJN coordinator. Local jurisdictions must attach forms and records to NEDSS (refer to *Figure 8: Interjurisdictional Notifications 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 they need assistance from the receiving state, the referring jurisdiction contacts 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 completes the required form. The

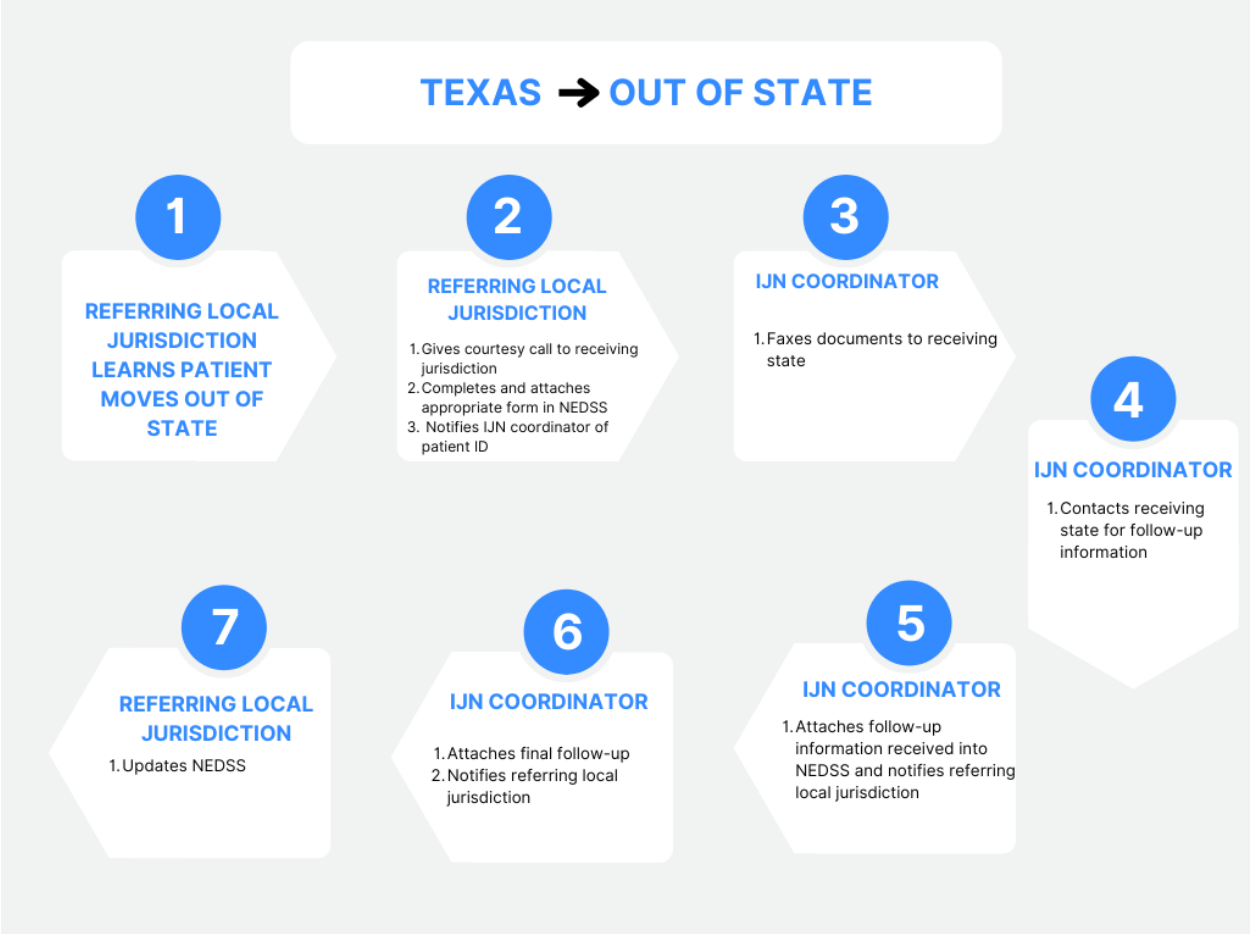
referring local jurisdiction attaches the completed form and pertinent medical records to the supplemental information tab in NEDSS. They complete the "Moved" section in the "TB Disease Only" tab in NEDSS. The referring local jurisdiction notifies the TB Unit's IJN coordinator via email after they attach IJN forms and documentation to the NEDSS investigation. They should enter the NEDSS investigation ID in the subject line.

c) Within three business days of receiving the notification, the IJN coordinator forwards 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 notifies the referring local jurisdiction that the NEDSS investigation has the documentation attached. The local jurisdiction must enter the update(s) in NEDSS within three days of the notification.
f) This process repeats monthly until the local jurisdiction receives the final follow-up.

2. 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 they have already moved and will not return to Texas), remain in another state longer than 30 days, or when temporary travel plans change and they need assistance from the receiving state, the referring local jurisdiction must complete the required form.
        (1) The referring local jurisdiction attaches the completed forms and pertinent medical records to the supplemental information tab in NEDSS.
        (2) The referring local jurisdiction completes the "Moved" section in the "TB Disease Only" tab in NEDSS.
        (3) The referring local jurisdiction must notify the IJN coordinator by email after they have attached the IJN forms and additional documentation to the NEDSS investigation.
        (4) The jurisdiction should enter the NEDSS investigation ID 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 notifies the referring local jurisdiction that the NEDSS investigation has the documentation attached. The local jurisdiction must enter the update(s) in NEDSS within three days of the notification.

e) This process repeats monthly until the local jurisdiction receives a final follow-up.

Figure 8: Interjurisdictional Notifications from Texas to Out of State



C. Plan, coordinate, and communicate formally when a patient plans a permanent move into Texas or a Texas Binational TB Program from another state, when temporary travel plans change, or when the travel is longer than 30 days (refer to *Figure 9: Interjurisdictional Notifications 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 creates a patient file, opens an investigation in NEDSS, and attaches the documents in the supplemental information tab. The IJN coordinator notifies the receiving local jurisdiction of the incoming case and the attachments.
    b) Within three business days of receiving the notification, the receiving local jurisdiction confirms that they reviewed the

documents. The receiving local jurisdiction continues to update NEDSS throughout the duration of treatment.

c) Within two weeks of receiving confirmation from the receiving local jurisdiction that they reviewed the attachments, the IJN coordinator requests 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 its accuracy.

(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 faxes the follow-up form(s) to the referring state within three business days.

e) This process repeats monthly until the receiving state receives a final follow-up.

2. 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 creates a patient file, opens an investigation in NEDSS, and attaches the documents in the supplemental information tab. The IJN coordinator notifies the receiving local jurisdiction of the incoming case and the attachments.

b) Within five business days of receiving the notification, the receiving local jurisdiction confirms that they reviewed the documents. The receiving local jurisdiction continues to update NEDSS throughout the duration of treatment.

c) Within four weeks of receiving a confirmation from the receiving local jurisdiction that they reviewed the attachments, the IJN coordinator requests a follow-up via email to provide to the referring state.

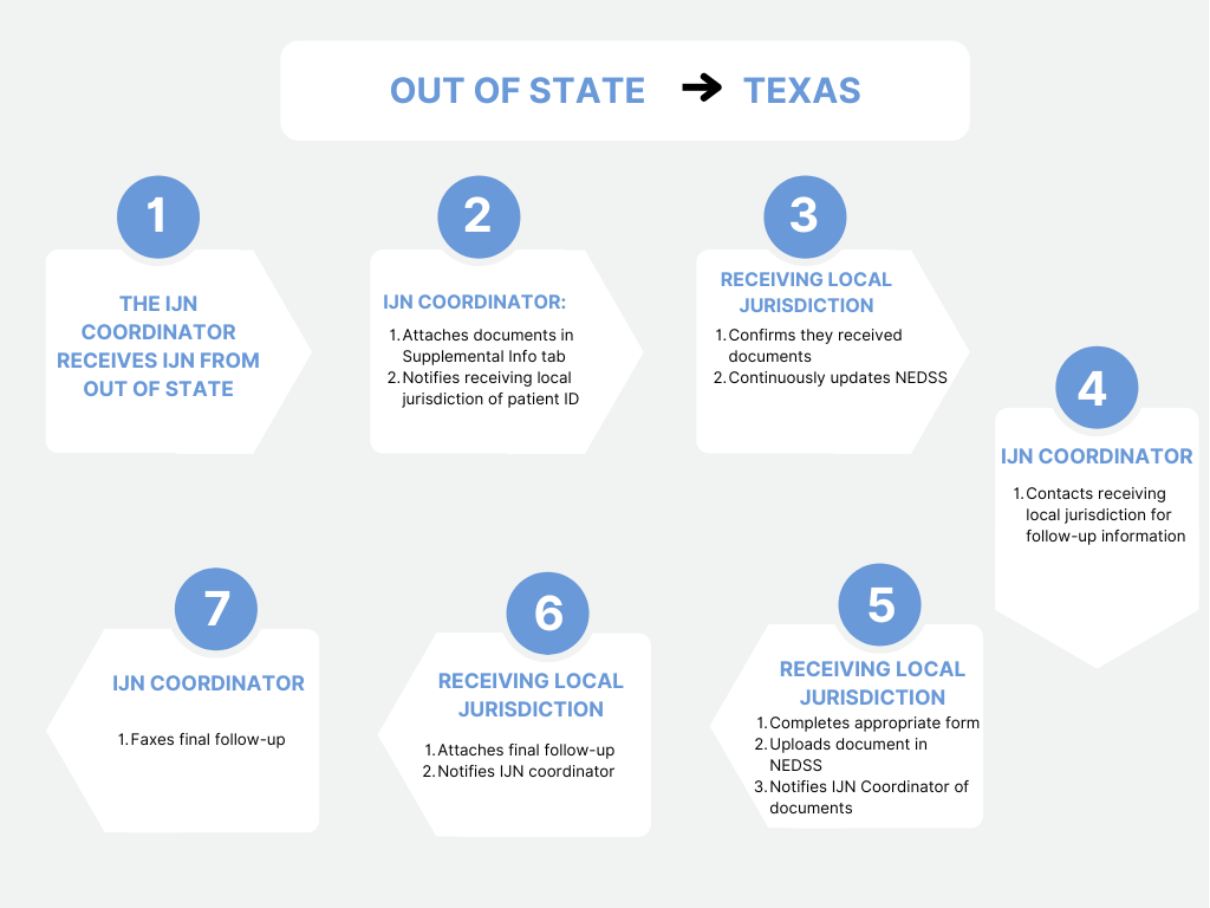
d) Within five business days of receiving the follow-up request, the receiving local jurisdiction must complete the appropriate form(s) and make necessary updates to the form(s) to ensure its accuracy.

(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 faxes the follow-up form(s) to the referring state within three business days.

e) This process repeats monthly until the receiving state receives a final follow-up.

Figure 9: Interjurisdictional Notifications from Out of State to Texas



D. Collaborate with the CDC's CureTB program for moves from out of country to Texas or going out of country from Texas.
   1. CureTB is a collaborative program between the CDC and the 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
   2. Treat moves coming from or to Mexico, where a binational TB program exists, as out-of-state moves. IJN documentation is required. These moves do not go through CureTB.
   3. International moves:

a) Treat moves in or out of the United States as out-of-state moves; however, complete a CDC CureTB form 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. Find instructions to complete the form here: https://www.cdc.gov/migration-border-health/media/pdfs/Form-CureTBTransnational-v3-508.pdfCureTB Transnational Notification (cdc.gov).
   (2) For contacts, complete the contact and source investigation notification form. Find instructions to complete the form here: CureTB Contact/Source Investigation (CI/SI) Notification (cdc.gov).

E. Plan, coordinate, and communicate formally when a patient plans a permanent move between two different R/LHDs (refer to *Figure 10: Interjurisdictional Notifications Between Texas Jurisdictions*).
   1. Procedure for a patient with TB disease (ATS class 3) moving between local jurisdictions:
      a) Within one business day of a referring local jurisdiction becoming aware of a patient's plan to move (or they have already moved and will not return), remain in another local jurisdiction longer than 30 days, or when temporary travel plans change and they need assistance from the receiving local jurisdiction, 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 pertinent medical records to the supplemental information tab in NEDSS.
         (2) The referring local jurisdiction must complete the "Moved" section in the "TB Disease Only" tab in NEDSS.
         (3) The referring local jurisdiction must notify the IJN coordinator and receiving local jurisdiction via email once the NEDSS investigation has the IJN form(s) and additional documentation attached.
         (4) The referring local jurisdiction should enter the NEDSS investigation ID in the subject line.
      c) Within three business days of receiving the notification email from the referring local jurisdiction, the IJN coordinator transfers ownership of the patient file to the receiving local jurisdiction and notifies both jurisdictions via email.

d) The receiving local jurisdiction is responsible for the data entry that occurs while the patient is in their jurisdiction. This includes updating missing information, entering updates, and entering and updating TB medications, laboratory results, etc. while managing the patient.
e) Even though the patient is outside of the referring local jurisdiction's care, they are still responsible for following up on the TB event. They may do this via email to request updates. They are also responsible for updating final culture results or drug susceptibility tests (DSTs) on the initial specimen that were reported to them. They must ensure that NEDSS reflects the results. They should then notify the receiving jurisdiction so that the current licensed healthcare provider is aware of the laboratory results.
f) Once the patient completes therapy, the referring local jurisdiction enters closure information and ensures Report of a Verified Case of TB (RVCT) variables are complete. The referring local jurisdiction is responsible for updating the case verification and criteria met in NEDSS. This allows the referring jurisdiction (who did not manage but ultimately "counts" this case) to review the care and ensure adequate therapy was completed.
g) Any deviation from the procedures outlined above requires 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. 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 they have already moved and will not return), remain in another local jurisdiction longer than 30 days, or when temporary travel plans change and they need assistance from the receiving local jurisdiction, the referring local jurisdiction must attach the completed IJN form(s) and pertinent medical records to the supplemental information tab in NEDSS.
        (1) The referring local jurisdiction must complete the "Moved" section in the "TB Disease Only" tab in NEDSS.
        (2) The referring local jurisdiction must notify the IJN coordinator and receiving local jurisdiction via email once the NEDSS investigation has the IJN forms and additional documentation attached.

(3) The referring local jurisdiction should enter the NEDSS investigation ID in the subject line.

b) Within five business days of receiving the notification email from the referring local jurisdiction, the IJN coordinator transfers ownership of the patient file to the receiving local jurisdiction and notifies both jurisdictions via email.

c) The receiving local jurisdiction is then responsible for the data entry that occurs while the patient is in their jurisdiction. This includes updating missing information, entering updates, and entering and updating TB medications, laboratory results, etc. while managing the patient.

d) Although the patient is outside the referring local jurisdiction's care, they are responsible for following up on the TB event. They may do this via email to request updates. They are also responsible for updating final culture results or DSTs on the initial specimen that were reported to them. They must ensure that NEDSS reflects the results. They should then notify the receiving jurisdiction so that the current licensed healthcare provider knows of the laboratory results.

e) Once the patient completes therapy, the referring local jurisdiction enters the closure information.

f) Any deviation from the procedures outlined above requires 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 10: Interjurisdictional Notifications 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 (refer to DSHS form TB-500);
      c) developing and implementing a written TB infection control plan (refer to *Appendix K: 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 health care 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 health care 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.
    3. 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 check-out. 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 L-30 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. Health Care 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) The frequency of subsequent tests may be determined by the medical director. Direct-care TB staff should be tested at least annually.

2. Document results of TB personnel screening and respond to any TB test conversions. TB Programs must:
   a) Complete the TB-603 Tuberculosis (TB) Screening of TB Personnel form, 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 TB-604 Report of Tuberculosis Test Conversion in TB Personnel form 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.

Activities

A. Ensure all people providing services under the SDOs or equivalent protocols and procedures have the requisite experience and/or training to deliver appropriate services. Refer to *Appendix L: TB Training and Education Resources with Sample Template to Document TB Staff Training* for TB training and education resources.

B. Provide orientation and training to all employees involved in TB activities, including physicians, nurses, contact investigators, outreach workers, case registry staff, receptionists, and other support staff.
    1. Initial training includes 40 hours of TB training specific to job duties within 90 days of employment:
        a) Use CDC *Self-Study Modules on Tuberculosis* for the initial training (refer to cdc.gov/tb/education/ssmodules/).
        b) For registry, surveillance staff and other staff assigned to input data into the TB Unit's surveillance and reporting database, initial training includes CDC *RVCT Self-Study Modules* (refer to cdc.gov/tb/programs/rvct/).
    2. Core training topics for TB program 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.
    3. 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.

4. TB program managers, nurses, contact investigators, and data entry staff must participate in the TB Unit orientation *after* three months of hire, when offered by the TB Unit.
5. TB program staff must participate in the monthly TB conference calls and other required conference calls or trainings.
6. TB program staff must complete 16 hours of ongoing education each calendar year relevant to each staff member's position.
7. Staff responsible for data entry must complete TB Unit database trainings (refer to C below).
8. Attend TB trainings to include, but not limited to, webinars provided by Heartland National TB Center as well as other Centers of Excellence (COE) and National Tuberculosis Controllers Association as relevant to their position.
9. Participate in DSHS TB Unit trainings where offered.

C. Ensure all staff performing TB services are competent in navigating the TB Unit's surveillance and reporting database and take TB Unit trainings specific to data entry. Program managers may choose to document training completion.

D. Maintain documentation of training for all employees and contracted staff.
   1. Retain logs (refer to *Appendix M: Sample In-Service and Training Roster*) for in-house trainings in accordance with local protocols and procedures, including:
      a) job titles;
      b) training dates;
      c) training or course titles; and
      d) number of hours.
   2. Retain copies of employee training certificates.
   3. Each medical director and/or local health authority must have access to training records to verify that those operating under their medical license have the requisite experience and training.

E. Notify the TB Unit of newly hired TB program managers, nurses, contact investigators, and case registry staff within 30 days of hire. Submit the *Notice of Change of TB Personnel* (found at dshs.texas.gov/disease/tb/forms.shtm) to TBProgram@dshs.texas.gov.

F. Educate external stakeholders.
   1. As resources allow, provide TB education and training to:
      a) schools;
      b) correctional facilities;
      c) community health care 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 *Appendix N: Sample Stakeholder Training/Education Roster*) 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 Programs at no additional cost to contractors.

F. Invoices should be submitted for the services provided based on the Purchase Order (PO) service dates and not exceed the PO amount for that service period.

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 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 *Texas Administrative Code, Chapter 97, Rule 97.191*, 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 services needs; and coordinating treatment provision, care, and services between various agencies to ensure continuity while incarcerated and during post-release.
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 expose 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.

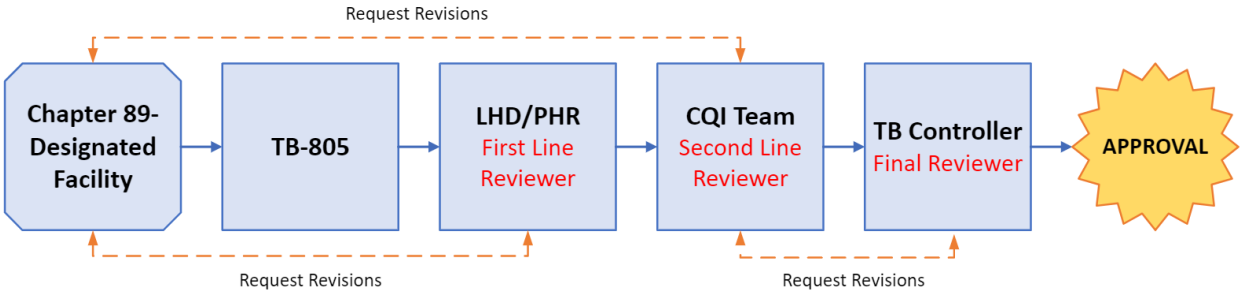
7. Ensure that contacts start and complete treatment for TB infection or TB disease, as indicated.

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).
1. Perform first-line quality assurance review and submit the DSHS form 12-11462 (*Monthly Correctional TB Report)* and DSHS form 12-11461 (*Report of TB Conditions*) to GlobalScape by the 15th day of the following month. Send an email to CQIteam@dshs.texas.gov upon upload.
2. 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.
3. Do not provide state purchased IGRA supplies to correctional and detention facilities.
4. Chapter 89-designated facilities must submit the *Monthly Correctional TB Report* and *Report of TB Conditions* to the TB program by the 5th day of the following reporting month.
a) Monitor monthly correctional TB reports 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.
5. Review correctional TB screening plans for completion and accuracy. Refer to *Figure 11: TB-805 Review Process*.
a) Correctional TB screening plans are renewed each year. Chapter 89 facilities must submit DSHS form 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 form 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 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 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 11: TB-805 Review Process



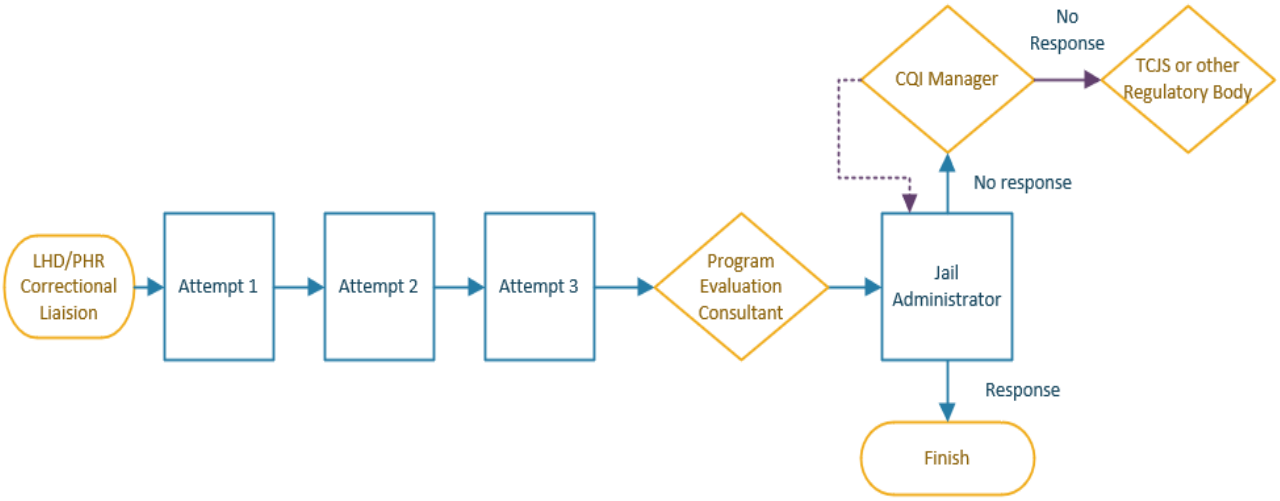
F. Maintain adequate records relevant to TB prevention and care.
   1. Funded programs must retain correctional TB screening plans for five years.
   2. Funded programs must retain monthly correctional TB reports for three years.

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 Monthly Correctional TB Report and Report of TB Conditions or Correctional Tuberculosis Screening Plan.
   2. 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.

H. Submit monthly correctional TB reports according to the assigned deadlines. To ensure the timely receipt of the statutory documents, the CQI Team will utilize the following notification processes if there is no communication from the R/LHD about a delay.

1. Escalate notifications for any delinquent reports from a Chapter-89 designated facility. Refer to *Figure 12: Escalated Notification Workflow Process.*
    a) The R/LHD will make three documented attempts to receive the monthly report by the 15th day of the following month.
    b) The R/LHD will contact the CQI Program Evaluation Consultant (PEC), notifying the PEC of the attempts.
    c) The CQI PEC will reach out to 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, an escalated notification to the Texas Commission on Jail Standards (TCJS) or other regulatory body will occur.

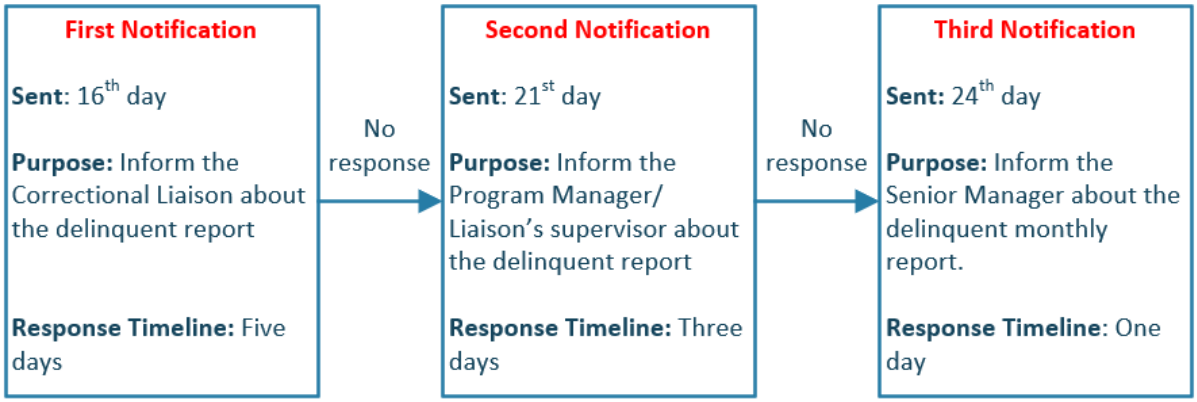
Figure 12: Escalated Notification Workflow Process



2. Review the tiered notification process followed by the DSHS CQI team for delinquent notifications. Refer to *Figure 13:Tiered Notification Workflow Process.*
    a) Beginning the 16th day of the following report month, the CQI team will send a first notification to the correctional liaison for the report. The response time requested is within five days.
    b) If a response is not received, a second notification to the correctional liaison and program manager or correctional liaison supervisor will be sent on the 21st day of the following report month. The response time requested is within three days.
    c) If a response is not received, a third notification to the correctional liaison, program manager, correctional liaison supervisor, and senior manager will be sent on the 24th day of

the following report month. The response time requested is within one day.

Figure 13: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 TB Manual.
    2. Ensure medical record documentation to include and follow current *Texas Administrative Code requirements, Title 22, Part 9, Chapter 165, Rule §165.1.*
    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 L: TB Training and Education Resources with Sample Template to Document TB Staff Training*.

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 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 minimum, this should include the TB Program Manager.
   2. Email the TB Program at TBProgram@dshs.texas.gov for information on obtaining access to NTIP.

F. Meet Texas TB Performance Measures (refer to *Table 18: 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 General Provisions Article VIII "Records Retention" and by Texas Administrative Code Title 22, Part 9 Chapter 165, §165.1, regarding retention of medical records.

Table 1818: 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: • do not have a positive sputum culture; • are not started on treatment; • are diagnosed at death; • died within 60 days of initiating treatment; • moved outside the US within 60 days of initiating treatment; and/or • not been on treatment for 60 days.	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 *M. tb* complex are tested for drug susceptibility with results documented in the medical record and in the TB Unit's designated surveillance and reporting database.	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 the TB Unit's designated surveillance and reporting database.	91	91.5	92	92.5	93

Performance Measure (PM)	Benchmark (%)				
	2025	2026	2027	2028	2029
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
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.* *† Report results to DSHS according to the surveillance reporting schedule.*					

G. Prepare for and participate in TB Unit site visits.
   1. The TB Unit will conduct on-site reviews of R/LHDs based on a routine or targeted need.
      a) DSHS regional TB program staff shall provide technical assistance and support to LHDs and may be asked to participate in on-site 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 notify the TB program with a formal notification that includes an agenda, a selected list of medical chart identification numbers, and the DSHS TB Unit Onsite Review Tool.
4. During the on-site 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 on-site 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 efforts to support patients diagnosed with TB disease in adhering to the treatment plan. When those efforts fail, TB programs will seek court-ordered management for patients whose actions pose a public health threat as a last resort. Court-ordered management ensures that:

- non-adherent TB patients complete an adequate course of TB treatment;
- patients receive appropriate evaluation and care when treatment is interrupted due to patient's violation of the terms of the signed control order; and
- the public is protected from infectious TB patients who have refused voluntary isolation when their actions pose a public health threat.

If the Health Authority and/or licensed healthcare provider 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 regional medical director, 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."* Refer to statutes.capitol.texas.gov/Docs/HS/htm/HS.81.htm#81.081.

Activities

A. Ensure the following is done before initiating court-ordered management:
    1. Patient has been issued the *Health Authority Control Order* (DSHS form TB-410) acknowledging understanding of treatment and compliance expectations.
        a) This document should be signed by the patient, the local health authority (LHA), and a witness.
            (1) Programs should have a policy in place when the health authority does not sign the TB-410. Refer to Health and Safety Code, 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 as long as 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.
4. Document any breach of expectations outlined on DSHS form TB-410 (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 medical consultant.
   4. A description of non-compliant behaviors and the steps taken to address non-compliance to include all attempts taken to contact the patient.
   5. Documentation from the clinician, health authority, or DSHS-recognized medical consultant if the patient has converted to smear negative but is expected to become infectious again.

C. Begin the court-ordered management process.
   1. 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) Public Health Regional Medical Director (if applicable)
      c) TB Program Manager
      d) Nursing Supervisor (if applicable)
      e) Local Health Authority
      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:
         dshs.texas.gov/tcid/courtmgmt.shtm
   2. The TCID admission process must be followed and transportation[6]

[6] **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

arranged by the managing jurisdiction.

a) TCID serves as the designated facility for patients who are court-ordered for extended management 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.

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 local health authority for signature:
      a) Exhibit A (DSHS form 86749_1), which will need to be notarized.
      b) Exhibit B, *Health Authority Control Order* (TB-410) and Exhibit 1A, which includes all medical notes, reports, etc.
      c) Once complete and signed by the LHA, DSHS form 86749_1, TB 410 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 health authority or licensed healthcare provider 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

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.

will need to be fax to the designated facility by the TB program. e.g., TCID.

e) Follow internal procedure for transfer of patient.

E. Initiate court-ordered Motion for Protective Custody (MPC). This option is only available if the patient is contagious at the time the order is sought and the patient has the potential of fleeing and the licensed healthcare provider has determined an MPC is needed. **NOTE:** TCID will not hold a patient with an MPC.
   1. Ensure that a facility has been secured prior to submitting an MPC. TCID is not a holding facility and will not accept patients with an MPC. This holding facility serves 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.

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 (DSHS form TB-410). 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.

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, including, but not limited to:

- DSHS Policy 302.001, *Release of TB/HIV/AIDS and STD Data*, dshs.texas.gov/hivstd/policy/policies/302-001.
- Federal HIV/AIDS Security and Confidentiality Guidelines, cdc.gov/nchhstp/programintegration/docs/pcsidatasecurityguidelines.pdf.
- DSHS Procedure 2016.01, *TB/HIV/STD Section Confidential Information Security*, dshs.texas.gov/hivstd/policy/procedures/2016-01.
- DSHS Policy 2011.01, *Confidential Information Security*, dshs.texas.gov/hivstd/policy/policies/2011-01.
- DSHS Policy 2011.04, *Breach of Confidentiality Response*, dshs.texas.gov/hivstd/policy/policies/2011-04.

Activities

A. Submit documentation to the DSHS TB/HIV/STD (THS) Section Security Officer to confirm that all staff and subcontractors working on activities outlined in this TB Manual receive yearly training on the DSHS Security and Confidentiality Training 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 DSHS Security and Confidentiality Training within 30 days of hire.

D. Ensure that all staff successfully complete the DSHS Security and Confidentiality Training 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 acton 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 serveas the Local Responsible Party (LRP). The LRP will:
    1. 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.
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 TBHIVSTD.AccountRequests@dshs.texas.gov 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 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.shtm.
3. Maintain a current list of authorized staff with permission to view and work with confidential information in accordance with the DSHS TB/HIV/STD Local Responsible Party Handbook, 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 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 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.shtm.

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.shtm.
    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 DSHS TB/HIV/STD Local Responsible Party (LRP) Handbook 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 19: Milestones and Nursing Interventions for TB Patients*.

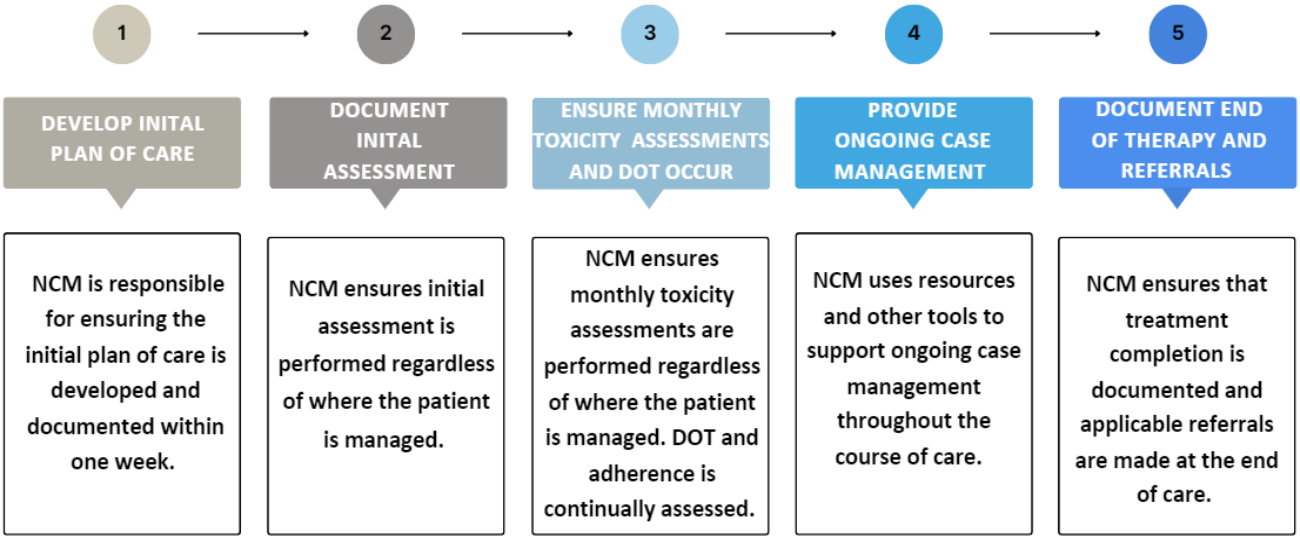
This appendix describes those responsibilities of NCMs managing patients with known and suspected TB disease.

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 DSHS Standing Delegation Orders (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 14: Overview of TB Nurse Case Manager Responsibilities.

Figure 14: Overview of TB Nurse Case Manager Responsibilities



Source: Texas Department of State Health Services, Tuberculosis and Hansen's Disease Unit, 2024.

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 licensed healthcare provider (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 compliance 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 19: Milestones and Nursing Interventions for TB Patients

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 *M. tb* per SDOs and/or LHP order. If testing was performed by an external/hospital laboratory, pro-actively 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 <u>never</u> 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 licensed healthcare provider (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 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.
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.	

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 licensed healthcare provider.

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

<insert date>

<insert provider address>

Subject: <insert patient name and DOB>

Dear <insert private provider's name>:

The <insert PHR/LHD> TB Program requires a monthly status report on the above-named 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>

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

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

Medical Update Form[7]

Patient: **Date of Visit:**

Date of most recent physical exam: **Weight:**

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:

☐ TST	☐ IGRA
Date administered: Date read:	Type of IGRA: Date:
Millimeter reading:	Result:

HIV Status:

Date TB treatment initiated:

Number of doses completed:

If completed, date of completion:

Comments:

[7] Adapted from: Global TB Center. (2024). *Tuberculosis Case Management: A Guide for Nurses*. Rutgers New Jersey Medical School. https://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 http://www.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 hhs.texas.gov/doing-business-hhs/provider-portals/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 hhs.texas.gov/services/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 Health Care Needs

Children with Special Health Care Needs (CSHCN) provides medically necessary care to eligible Texas children with special health care 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 hhs.texas.gov/services/disability/children-special-health-care-needs-program; cshcndshs.texas.gov; Toll-free: 1-800-252-8023.

General Primary and Specialty Services

Federally Qualified Health Centers

Federally Qualified Health Centers (FQHCs) provide comprehensive health care 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 Health Care Program

The County Indigent Health Care Program (CIHCP) was established by the Indigent Health Care and Treatment Act authorized by the 69th Texas Legislature in 1985. CIHCP provides health care services to eligible residents through counties, hospital districts and public hospitals in Texas. Programs are administered in accordance with Chapter 61, Health And Safety Code and Texas Administrative Code, Title 25, Part 1, Chapter 14.

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 health care 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 http://www.tachc.org.

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 health care, 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 https://www.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: ☐ **Male** ☐ **Female**	**Nurse Case Manager:**	
Diagnosis: (e.g., *MDR-TB, disseminated TB*)		
Co-morbidities/TB risk factors: (e.g., *diabetes, HIV, history of incarceration*)		
TB History: (e.g., *previous TB treatment, regimen, date of completion*)		
Resistant to:		
Susceptible to:		
Treatment Start Date:	**Initial Treatment Regimen (medications):**	
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	☐ Fever/Chills ☐ Loss of appetite ☐ Weakness ☐ Night sweats ☐ Weight loss ☐ Chest pain ☐ Other:	
Weight at diagnosis/BMI: /		

Bacteriology: *(Include date collected, specimen type, test, and results)*

Date Collected	Specimen Type/Test	Results

Converted cultures? ☐ Yes ☐ No Date Converted:
Isolation status:

Chest X-ray: *(indicate what was noted on report)*
Baseline Date: ☐ Normal ☐ Cavitary ☐ Non Cavitary
Read:

Current Date: ☐ Normal ☐ Cavitary ☐ Non Cavitary
Read:

Current Status

Current weight/BMI: /

Current laboratory results: (attach if needed)

HIV results: ☐ **Negative** ☐ **Positive (if applicable)**
CD4: **Viral load:**

Abnormal laboratory results:

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 at diagnosis, e.g., appetite improved, decreased cough, more energy*):

Adherence to treatment:

Reason for consult:

Sample 2: Routine Consult

Patient Name:	**Age:**
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)*	
Medications: (*list dosages, start/stop dates, 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 MDDR User Guide (cdc.gov) 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 dshs.texas.gov/idcu/disease/tb/consultants).

DSHS Process for Submitting MDDR

First, ensure patient meets one or more of the above criteria. A consult from a DSHS-recognized 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
benjamin.alpers@dshs.texas.gov	jan.owen@dshs.texas.gov
Phone: 512-776-2699	Phone: 512-776-2687

B. If indication is "Other situations considered on a case-by-case basis," secure written consult from a DSHS-recognized 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 *Chapter XIII*; Requires consult*
Bedaquiline (Situro)	Tablet (Tab)	PO	See *Chapter XIII*; Requires consult*
Clofazimine	Capsule (Cap)	PO	See *Chapter XIII*; Requires IRB after TB Unit Consultation*
Cycloserine (Seromycin)	Cap	PO	See *Chapter XIII*; Requires consult*
Ethambutol (Myambutol)	Tab	PO	**First-line**
Ethionamide (Trecator)	Tab	PO	See *Chapter XIII*; Requires consult*
Isoniazid	Solution (Soln)/Tab/Vial	PO, IM	**First-line**
Levofloxacin (Levaquin)	Soln/Tab/Vial	PO, IV	See *Chapter XIII*; Requires consult*
Linezolid (Zyvox)	Suspension (Susp)/Vial	PO, IV	See *Chapter XIII*; Requires consult*
Moxifloxacin (Avelox)	Tab/Vial	PO, IV	See *Chapter XIII*; Requires consult*
Pretomanid	Tab	PO	See *Chapter XIII*; Requires consult*
Pyrazinamide	Tab	PO	**First-line**
Pyridoxine (Vitamin B-6)	Tab	PO	
Rifabutin (Mycobutin)	Cap	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	PO	
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 Medications			
Azithromycin (Zithromax)	Susp/tab/vial	PO/IV	
Ondansetron	Tab, ODT (orally dissolving tablet)	PO	See *Chapter XIII*
Dexamethasone	Tab	PO	See *Chapter XIII*
Promethazine	Tab	PO	See *Chapter XIII*
Prednisone	Tab	PO	See *Chapter XIII*
Prednisolone	Tab	PO	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 consultation requirements.*

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[8], 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 Texas State Board of Pharmacy (TSBP Rule Title 22, Texas Administrative Code §291.93), a medication label with the following information must be printed and attached to bottles for self-administered medications (refer to *Chapter XIII. Inventory Management of Medications and Supplies*):
    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).

[8] *Follow all security standards when mailing information to patients. Verify mailing procedures with local responsible party (LRP).* Refer to dshs.texas.gov/hivstd/policy/procedures/2016-01.

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)** https://www.cdc.gov/tb/media/12_Dose_Regimen_for_LatentTBInfection_Med_Tracker_Checklist_English.pdf
   - **Rifampin** https://www.cdc.gov/tb/communication-resources/4r-medication-tracker.html
   - **Isoniazid** https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/008678s028lbl.pdf
   - **Moxifloxacin (Avelox)** accessdata.fda.gov/drugsatfda_docs/label/2013/021085s057,021277s054lbl.pdf
   - **Levofloxacin (Levaquin)** accessdata.fda.gov/drugsatfda_docs/label/2018/020634s070lbl.pdf#page=52-
   - **Bedaquiline (BDQ)** https://www.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 mailing[9] 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 Texas Occupations Code, Title 3, Chapter 158. 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:
    1. 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:

[9] *Follow all security standards when mailing information to patients. Verify mailing procedures with local responsible party (LRP).* Refer to dshs.texas.gov/hivstd/policy/procedures/2016-01.

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: 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 control plan is _____.

Administrative Controls

A written copy of the TB infection control plan is located at _____ and is available for inspection during regular business hours.

Ensure that TB prevention education and training is provided to staff, contractors, and interns upon hire. Training topics include:

1. Mode of TB transmission
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 TB-603 Tuberculosis (TB) Screening of TB Personnel or equivalent form.
   b. Documenting and investigating TB test conversions in TB personnel
      1) Document using the TB-604 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:

A. General Ventilation
   1. _____is responsible for implementing schedule of preventive maintenance in accordance with manufacturer's instructions.
   2. The current log is located at _____.
   3. Historic records are filed in _____.

B. 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 _____.
   3. 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 ☐ smoke test, ☐ tissue test, or ☐ other visual check.
   3. Negative pressure checks are documented using the _____ log. The current log is located at _____.
   4. Historic records are filed in _____.

D. High-Efficiency Particulate Air (HEPA) Filters (location):
   1. _____ is responsible for implementing schedule of preventive maintenance in accordance with manufacturer's instructions.
   2. The current log is located at _____.
   3. Historic records are filed in _____.

E. Ultraviolet Germicidal Irradiation (location):
   1. _____ is responsible for implementing schedule of preventive maintenance in accordance with manufacturer's instructions.
   2. The current log is located at _____.
   3. Historic records are filed in _____.

Respiratory Protection Program

The facility's respirator protection program is in accordance with Occupational Safety and Health Administration (OSHA) Respiratory Protection Standard 29CFR 1910.134.

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

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 fit-testing:
   1. people entering rooms in which patients with suspected or confirmed TB disease are being isolated;

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-tested, along with the date of fit-testing, manufacturer, model number, and size of the respirator that was fit-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 check" of the respirator each time the respirator is used, in accordance with manufacturer's recommendations.

TB Infection Control Plan

Date Created:
Approved by:

_____ _____
Director/Deputy Director Date

_____ _____
Medial Director Date

_____ _____
TB Program Manager Date

Date of Reviewed:

By:_____

Date of Reviewed:

By:_____

Date of Reviewed:

By:_____

Appendix L: TB Training and Education Resources with Sample Template to Document TB Staff Training

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, followed by 16 hours of continuing education and training each calendar year. Staff supporting the TB program (whether funded with TB funds or non-TB funds) but not using or required to sign the SDOs need training and education relevant to the position as determined by the TB program manager and/or medical director.

Training and education resources:

Training Resources	Reference
TB 101 for Health Care Workers	cdc.gov/tb/webcourses/tb101/
TB Core Curriculum*	cdc.gov/tb/hcp/education/core-curriculum-on-tuberculosis.html?CDC_AAref_Val=https://www.cdc.gov/tb/education/corecurr/
CDC TB Self-Study Modules (1-9)*	cdc.gov/tb/hcp/education/self-study-modules-on-tuberculosis.html?CDC_AAref_Val=https://www.cdc.gov/tb/education/ssmodules/
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	heartlandntbc.org/calendar/
Heartland TB Intensive	
Heartland Pediatric TB Intensive	
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*	https://www.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., Research Rounds, TB Brown Bag sessions); maintain training rosters. • Skills training (e.g., phlebotomy, TST, sputum collection). • Local case study review; and • Conference or online webinar attendance (e.g., National TB Coalition of America [NTCA], Texas Public Health Association, CDC TB Centers of Excellence).
***** *Training recommended to be completed within the first 90 days of hire as applicable to staff position.*	

Appendix M: Sample In-Service and Training Roster

Topic:_____

Trainer/Educator: _____

Date: _____

Location: _____

Number of Hours: _____

Printed Name	Signature

Appendix N: Sample Stakeholder Training/Education Roster

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 period of time and in a defined geographic area. The review occurs after the cases are counted and within the time frame in which most cases 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 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 the 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 any treatment and patient management concerns identified during a case 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, it provides 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 Periods

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

Table 190: 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
4th 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.

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:

- Medical reviewer
- Data analyst or epidemiologist
- Contact Investigator
- DOT Worker
- Social Worker
- Clinicians
- Laboratory Personnel

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 TB and Hansen's Disease Unit.

Cohort Review Resource

The following links provide information on cohort review models:

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

Appendix P: 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 15: 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.shtm
   - NEDSS access**: https://www.dshs.texas.gov/tuberculosis-tb/nedss**

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 TBContractReporting@dshs.texas.gov 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 *Monthly Correctional TB Report* (DSHS form 12-11462) and *Report of TB Conditions* (DSHS form 12-11461) 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 *Monthly Correctional TB Report* (DSHS form 12-11462) and *Report of TB Conditions* (DSHS form 12-11461) via GlobalScape by the 15th day of the following month.
   - Chapter 89-designated facilities must submit the *Correctional Tuberculosis Screening Plan* (DSHS form TB-805) to CongregateSettings@dshs.texas.gov 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 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 *Correctional Tuberculosis Screening Plan* (DSHS form TB-805) to

CongregateSettings@dshs.texas.gov for final review and approval before the current Screening Plan expiration date.

6. Reporting Deaths Among TB Cases

- Report when a person with known or suspected TB expires. The report must be sent to the TB Unit the following Friday using the DSHS Weekly Report of New Concerning Tuberculosis 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 the TB Unit's surveillance and reporting database 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 Tuberculosis Specimen Shipping Guide.

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

- Complete the *Notice of Change of TB Personnel* form for any changes in TB personnel. This ensures the staff will be added to the TB Unit's distribution email listserv. The form is located here: dshs.texas.gov/sites/default/files/thsvh/files/TBPersonnelNotice.pdf
- 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
  - 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 DSHS form 12-12104 or 12-12063 to the patient record in the state's TB surveillance database or submit via GlobalScape and send an email notification to TBEpi@dshs.texas.gov.

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 TB-604 to the TB Unit within 60 days of initial test at TB.Feedback@dshs.texas.gov.

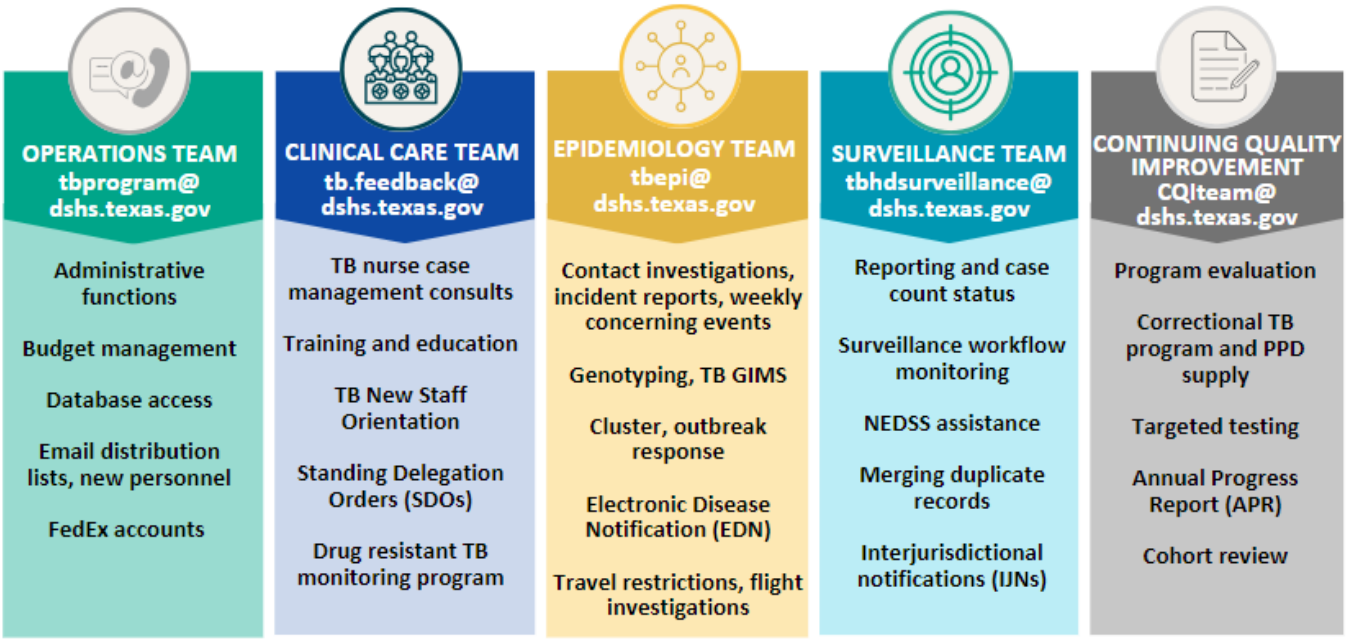
15. Submitting Travel Alerts: DNB/LO Alerts

- For patients that are candidates for a Do Not Board and Public Health Lookout alert, submit DSHS form 12-12065 and contact the 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 TBEpi@dshs.texas.gov.

Figure 15: Contacting the TB Unit



Source: Texas Department of State Health Services, Tuberculosis and Hansen's Disease Unit, 2024.

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:
1.1	Have all members of TB Case Registry team completed their training? • How many members? _____ • 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 Health Care 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			
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:
4.1	Maintain a Registry of TB Records: • Cases-contacts • Suspects-contacts • LTBI's referred or targeted testing			

4.0	Case Detection Requirements	Yes	No	If no, plan for improvement:
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			

7.0	Data Timeliness Requirements	Yes	No	If no, plan for improvement:
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			

9.0	**Maintains log for TB employees and other entities and dates of training and presentations.**	**Yes**	**No**	**If no, plan for improvement:**
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 TB Unit Surveillance Requests for Missing Report of Verified Case of TB (RVCT) Data

TB programs' designated case registrars should communicate with the DSHS TB Unit's surveillance team based on these guidelines and timeframes:

- During the 'crunch' period of **December-January** when the provisional year-end TB case count and World TB Day RVCT data is due to CDC, TB case registrars should **respond to requests for missing RVCT data within 3 business days.**
- During the 'crucial crunch' period of **February**-**March** when the *final* year-end TB case count and all RVCT variables are due to CDC, case registrars should **respond to requests for missing RVCT data within 2 business days.**
- During the 'non-crunch' period of **April-November**, TB case registrars should **respond to requests for missing RVCT data within one week of request or five business days** to ensure missing RVCT data are collected and entered since these are needed for the funding formula, the Annual Progress Report, and National TB Indicators Project (NTIP) performance indicators. This prevents a last-minute rush for data entry during the crunch period.
    - If the TB case registrar does not respond to the request for missing RVCT data within the request timelines, the surveillance case consultant will notify the R/LHD TB program manager to inform them of the request and ask for a response to the request within 3 business days.
    - If the TB program manager does not respond to the request for missing RVCT data from the case consultant within 3 days of notification, the TB epidemiology and surveillance manager will contact the TB program manager requesting a response to the request.
    - If the requested data is not entered after this request within 5 days of the initial notification to the TB program manager, the TB epidemiology and surveillance manager will inform the TB and Hansen's Disease Unit director. The TB and Hansen's Disease 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**
Patient	▪ 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	▪ Has the patient been previously diagnosed with TB disease or LTBI?
Tuberculosis	▪ 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*

TB Intake Information	
Information as per NEDSS Investigation Tabs	**Description**
	▪ 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 Medical Risk Factors: ▪ Diabetic at diagnostic evaluation ▪ End 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

TB Intake Information	
Information as per NEDSS Investigation Tabs	**Description**
TB Disease Only*	▪ Date of illness onset or symptom start date ▪ Site(s) of TB disease* ▪ Therapy start date ▪ Initial drug regimen
LTBI Only (ATS class 2 only)	▪ Therapy start date ▪ Initial LTBI regimen
Comprehensive TB Treatment Details*	▪ Individual medications ▪ Drug start/stop dates

Appendix T: 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
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
LHD	Local Health Department
LTFU	Lost to Follow-Up
MAC	*Mycobacterium avium* complex
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
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
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