BINATIONAL TUBERCULOSIS PROGRAM MANUAL FISCAL YEAR 2027

TEXAS Health and Human Services
Texas Department of State Health Services

Tuberculosis and Hansen's Disease Section

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COEFAR

Comités Estatales de Farmacorresistencia

A state committee in México that ensures patients with drug-resistant (DR) tuberculosis (TB) are properly diagnosed, treated, and managed in accordance with México's National TB guidelines. Per México's federal guidance, each state in México must maintain a COEFAR to address drug-resistant TB.

COFEPRIS

Comisión Federal para la Protección contra Riesgos Sanitarios

A regulatory body of the Mexican government to regulate a variety of health-related products in México, including food safety, pharmaceutical drugs, medical devices, organ transplants, and environmental protection. This regulatory body is equivalent to the United States (U.S.) Food and Drug Administration.

Consulting Physician

A Texas physician with a valid and current license to practice in the State of Texas who acts in an advisory capacity to the binational TB (BNTB) program. This physician provides expert recommendations and may provide oversight to the BNTB program to ensure that Texas standards of care are followed for patients enrolled in the program.

Dictamen

A formal document issued by the COEFAR and GANAFAR to the requesting health department in México that includes treatment recommendations for patients.

doTBal

A two-phased fixed combination of medication dosages available in México, consisting of isoniazid (INH), rifampin (RIF), ethambutol (EMB), and pyrazinamide (PZA) in the intensive phase, and INH and RIF in the continuation phase.

GANAFAR

Grupo Asesor Nacional en Farmacorresistencia

A federal committee composed of México's national TB director, the *Instituto Nacional de Referencia Epidemiológica* (InDRE) mycobacterial laboratory manager, physicians belonging to different health institutions in México with experience managing drug-resistant tuberculosis (DR-TB), and a bioethics representative of the National Human Rights Commission. The GANAFAR responsibilities include:

- Promoting compliance in guiding patient care with DR-TB,
- Reviewing all difficult to treat cases of TB,
- Advising COEFAR on any issues related to DR-TB,
- Reviewing, recommending, and ratifying documents previously approved by COEFAR,

- Updating national TB guidelines,
- Supporting the national TB program in training staff on DR-TB management, and
- Operating as a gateway to access new TB medications such as delamanid and bedaquiline.

Green Light Committee

A committee established by the World Health Organization (WHO) in January 2000 that provides access to affordable, high-quality, second-line TB medications for the treatment of multidrug-resistant tuberculosis (MDR-TB). México may request medications from this committee to treat MDR-TB.

Incentives and Enablers

These are methods employed by TB programs to facilitate adherence to TB treatment. Incentives are small rewards given to the patient and may include gift cards or food vouchers. Enablers help patients complete therapy or attend DOT appointments. This may include transportation vouchers.

Official Mexican Norma

Referred to as the "Norma Oficial Mexicana" for the prevention and control of TB in México. It is the official TB guidelines outlining México's standards for preventing, detecting, diagnosing, and treating TB and latent TB infection (LTBI). It also includes control measures to protect public health. See guidelines here: NOM-006-SSA@-2013.

Patient-Physician Relationship

A patient-physician relationship exists when a physician serves a patient's medical needs. Generally, the relationship is entered into by mutual consent between the physician and the patient (or the patient's surrogate). However, a limited patient-physician relationship may be created without the patient's (or surrogate's) explicit agreement. Such as when a physician provides emergency care or provides care at the request of the patient's treating physician. In circumstances like these, the patient's (or surrogate's) agreement to the relationship is implicit. Read more about patient-physician relationships here.

Regional Mycobacteriology Program

Colloquially known as the "National," "Nacional," "Regional," or "Distrito" Program. The local regional mycobacteriology programs within each Mexican state ensure each patient with TB receives comprehensive care and full access to quality diagnosis and treatment. This program refers patients to the BNTB program if specific criteria are met.
Note: The federal program's official name is the National Program for the Prevention and Control of TB, and the state program is known as the State Mycobacteriology Program.

Secretaría de Salud

Also known as the "Secretariat of Health," it is a department of the Mexican government responsible for social services and other health and human services.

Shadow Chart
A system to include components of a full patient medical record at a different location where the original medical record is housed.

Treating Physician
A physician who is responsible for the overall care of a patient and who provides medical treatment and evaluation to a patient. The treating physician has an ongoing relationship with the patient, known as a patient-physician relationship.

Isoniazid resistance
Resistance to isoniazid (INH), a first-line drug.

Rifampin mono-resistance (RR-TB)
Resistance to RIF, a first-line TB drug; this type of DR-TB is treated similarly to multidrug-resistant TB (MDR-TB).

Multidrug-resistant (MDR-TB)
Resistance to at least RIF and INH.

Pre-extensively drug-resistant (Pre-XDR-TB)
MDR-TB, plus resistance to one of the second-line injectable agents (amikacin, capreomycin, kanamycin) *or* a fluoroquinolone (FQN).

Extensively drug-resistant (XDR-TB)
MDR-TB, plus resistance to one of the second-line injectable agents (amikacin, capreomycin, or kanamycin) **and** an FQN **or** MDR, plus resistance to an FQN and bedaquiline (BDQ) or linezolid (LZD).

I. Introduction

The Binational Tuberculosis Program (BNTB) is within the Department of State Health Services (DSHS) Tuberculosis and Hansen's Disease TB Section (TB Section). Established in 1991, it serves as a formal partnership between Texas and México to reduce TB transmission along the Texas-México border. The program consists of physicians, nurses, managers, and coordinators in Texas-based public health regions (PHR) and local health departments (LHD) working in close collaboration with physicians and nurses in México to provide direct outpatient care services to eligible patients.

The purpose of this manual is to provide guidance to BNTB program sites when implementing TB prevention and care activities for enrolled patients. BNTB programs must follow the standards of care outlined in this document. Treating physicians are responsible for the clinical care of patients managed at each clinic and should collaborate with the Texas binational program when treatment orders extend beyond this manual to ensure fiscal responsibilities are met. Programs will collaborate with partners in México and the DSHS TB Section to ensure procedures in both countries are followed.

The BNTB program follows the guiding principles, mission, and vision of DSHS[1] and the Secretariat of Health in México, including standards set forth by the TB Section. The BNTB program sites are to use the most current version of the manual and have systems in place to implement program activities.

[1] The vision is "A healthy Texas" and the Mission is "to improve the health, safety, and well-being of all Texas. Refer to: https://www.dshs.texas.gov/about-dshs.

II. Background

Among all the states in the United States (U.S.), Texas shares the longest stretch of border with México, spanning 1,254 miles from the Gulf of México to El Paso. It is joined by twenty-eight international bridges and border crossings, including two dams, one hand-drawn ferry, and twenty-five additional crossings that allow commercial, vehicular, and pedestrian traffic. According to the Bureau of Transportation Statistics, approximately 114 million people crossed legally into Texas from México through Texas International Ports of Entry in 2025. Of that number, approximately 19 million pedestrians crossed, while 16 million crossed in personal vehicles. However, millions come to the U.S. each year by other means[2]. According to the Center for Immigration Studies, there are an estimated 14.8 million undocumented immigrants in the U.S. as of May 2025. While the exact number of illegal crossings at the Texas-México border is not known, this suggests a "floating" population.

Beyond the social, political, and economic impact of immigration, there is also a public health impact. TB is among the most significant infectious disease concerns along the Texas/México border. Both Texas and México acknowledge that border cities have a higher incidence of TB, which was pivotal in the combined decision to establish the BNTB program.

Origins of Each Binational TB Program

The first BNTB program was formally established in 1991 with DSHS, Public Health Region (PHR) 9/10, El Paso Department of Public Health, and the Mexican Secretariat of Health, with both countries agreeing to work together in El Paso and in Ciudad Juárez, in the state of Chihuahua, México. This program's name is Juntos, which translates to "together," affirming this partnership.

The Los Dos Laredos Program (translated to "the two Laredos") was established in 1993 with cooperative agreements between Laredo Public Health Department in Laredo, Texas, and Nuevo Laredo, Tamaulipas, México.

Two years later, in 1995, the Grupo Sin Fronteras Program was formally established between DSHS PHR 11 and the Mexican Secretariat of Health in Tamaulipas, México. This program serves the two largest bordering cities, specifically Brownsville-Matamoros, Tamaulipas, and McAllen-Reynosa, Tamaulipas. Grupo Sin Fronteras means "group without borders". The name signifies the alliance between Texas and México, as well as the program's goals to address TB among this population.

In 2010, the newest program, Esperanza y Amistad, was established between DSHS PHR 8 and the Secretariat of Health in Coahuila, México, working in Del Rio-Ciudad Acuña, Coahuila, and Eagle Pass-Piedras Negras, Coahuila, México. Translated as "hope and friendship", the newest program focuses on eliminating TB as a public health threat among this population.

[2] Border Crossing Data Release 2025. Bureau of Transportation Statistics. https://www.bts.gov/newsroom/border-crossing-data-annual-release-2025

Table 1: Binational TB Program Border Cities

BNTB programs	Established	Texas Border	México Border	México State
Juntos	1991	El Paso	Juárez	Chihuahua
Los Dos Laredos	1993	Laredo	Nuevo Laredo	Tamaulipas
Grupo Sin Fronteras	1995	Brownsville McAllen	Matamoros Reynosa	Tamaulipas
Esperanza y Amistad	2010	Eagle Pass Del Rio	Piedras Negras Acuña	Coahuila

III. Map, Organizational Structure, and Directory

There are four Mexican states bordering Texas: Tamaulipas, Nuevo Leon, Coahuila, and Chihuahua. The BNTB program operates six Mexican-based clinics spanning three Mexican states, managed by four TB programs in Texas border cities.

Figure 1: Location of Binational TB Programs along the Texas-México Border

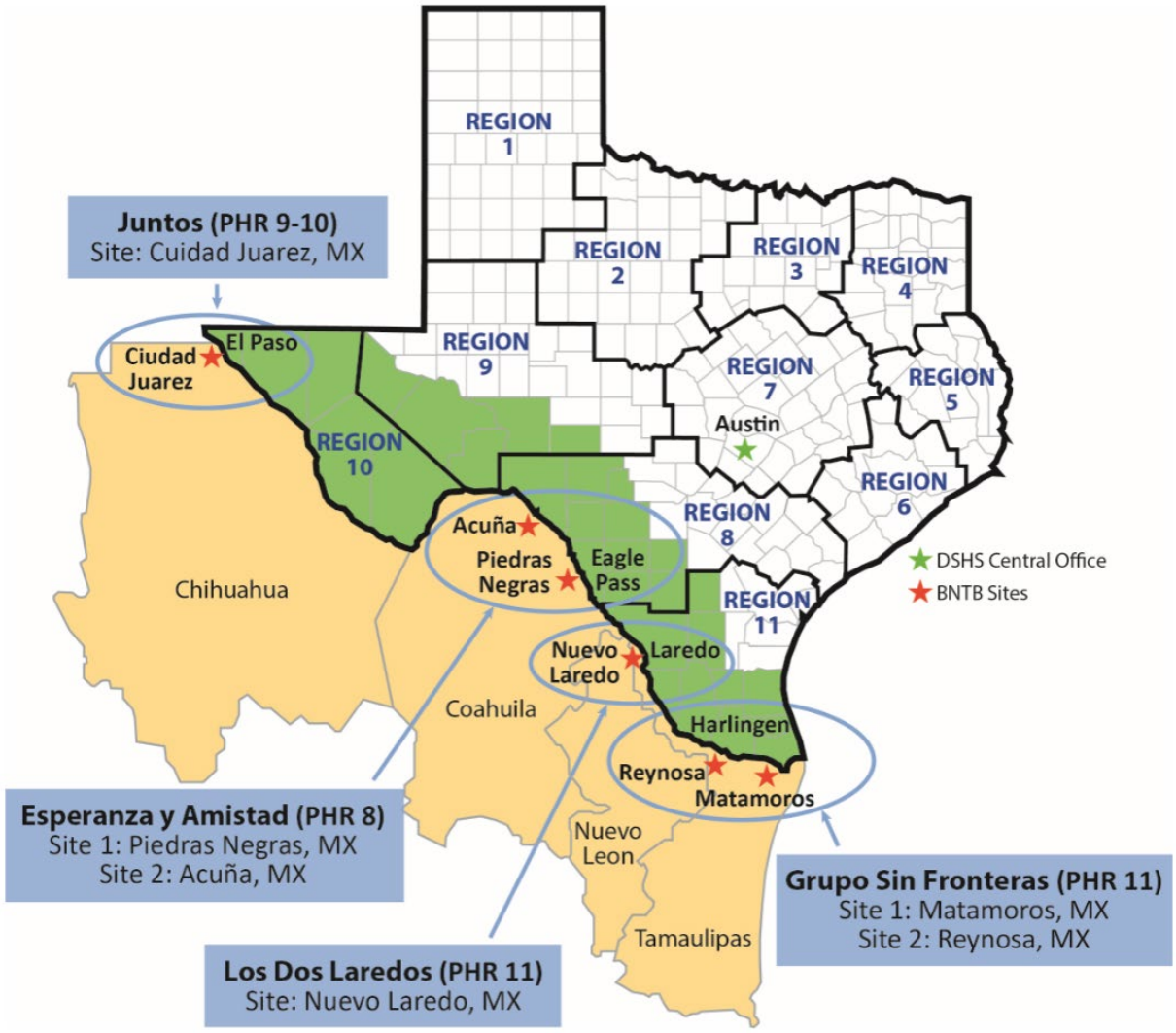


Figure 2 outlines the BNTB program structure. Roles and responsibilities are described in Chapter VII. Roles and Responsibilities.

Figure 2: Binational TB Program Structure

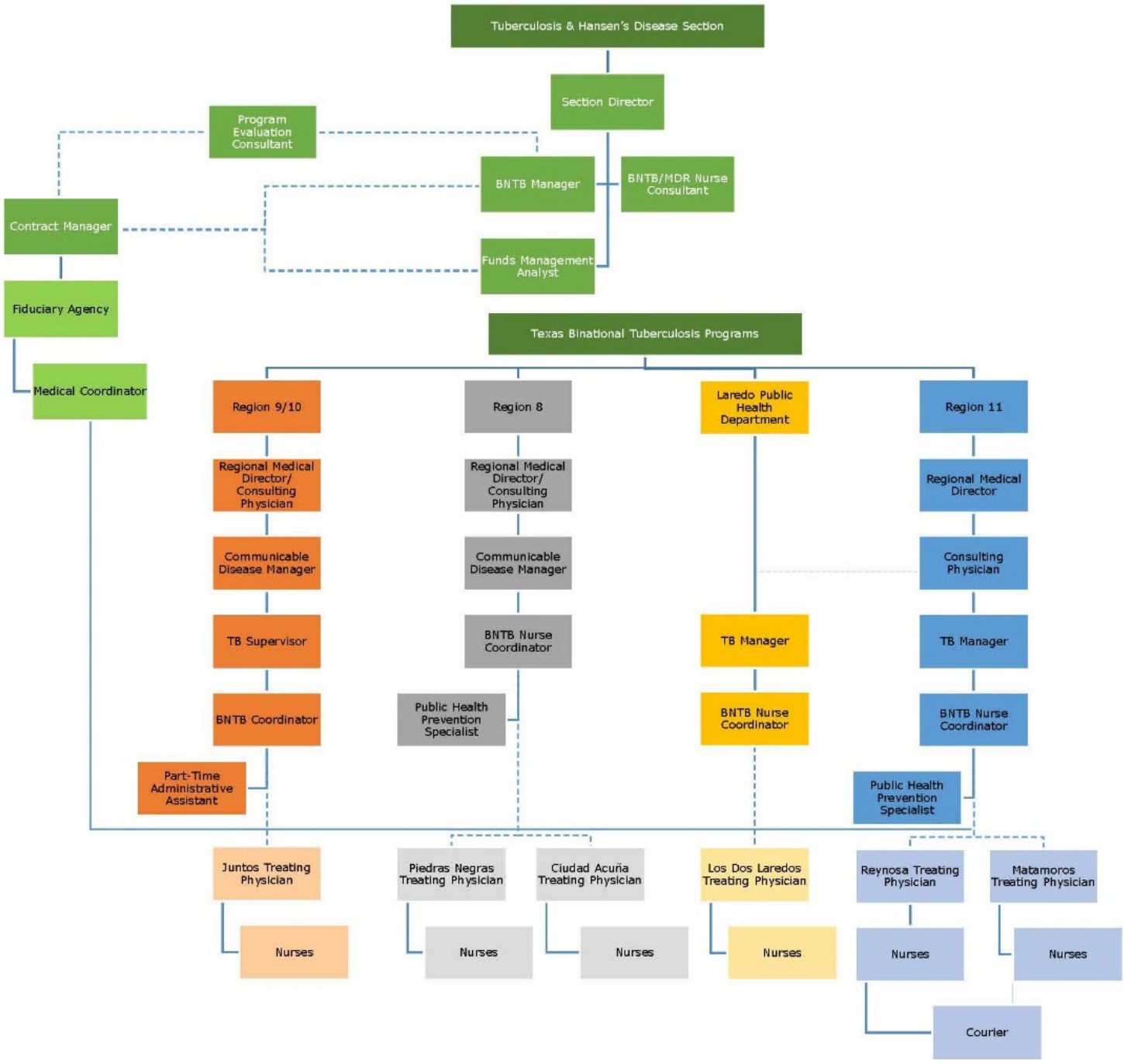


Table 2: Binational TB Program Contact Information

Esperanza y Amistad DSHS PHR 8 *Sites:* Piedras Negras, Coahuila, México Ciudad Acuña, Coahuila, México	1593 Veterans BLVD Eagle Pass, Texas 78852 Phone: 830-758-4274 Fax: 512-206-3949 Tuberculosis.Region8@dshs.texas.gov
Grupo Sin Fronteras DSHS PHR 11 *Sites:* Matamoros, Tamaulipas, México Reynosa, Tamaulipas, México	601 W Sesame Drive Harlingen, Texas 78550 Phone: 956-444-3244 956-444-3205 Fax: 956-444-3295
Juntos DSHS PHR 9/10 *Site:* Ciudad Juárez, Chihuahua, México	401 E Franklin, Suite 210 El Paso, Texas 79901 Phone: 915-834-7792 Fax: 915-834-7722 HSR9-10.CDReporting@dshs.texas.gov
Los Dos Laredos Laredo Public Health Department *Site:* Nuevo Laredo, Tamaulipas, México	2600 Cedar Ave Laredo, Texas 78040 Phone: 956-727-6974 956-795-4911 Fax: 956-724-5789

IV. Program Eligibility, Referrals, and Approval

Eligibility

To be eligible for the BNTB program services, a patient must meet the following criteria:

Patient Eligibility Criteria (must meet at least one):

A. Have confirmed or suspected TB disease.
B. Is a confirmed contact during the infectious period of an enrolled BNTB or Texas patient.
C. Is referred from the U.S. for treatment or follow-up of TB disease or LTBI treatment.

AND

Residency Criteria (must meet at least one):

A. Has dual residency in the U.S. and México. Proof of having a current resident card is required.
B. Lives in México or Texas, reports frequent cross-border activity, and has contact with individuals in México and Texas during their infectious period. Proof of a Texas address must be verified using a DSHS-approved address verification database (e.g., Accurint).

Referrals and Accepting Patients

Prior to accepting a patient, each BNTB program must ensure it has adequate resources to manage the patient. Considerations include the following:

- Know the program's capacity to accept new patients. This includes knowing the program's current patient census and available staffing.
- Obtain patient's consent to be treated by the BNTB program, including directly observed therapy (DOT).
- Obtain the patient's previous treatment history, including non-adherent treatment patterns, from the referring program.
- Know the patient's social risk factors that may potentially impact treatment outcomes.
- Have access to resources to meet the patient's individual needs.

Programs will follow the steps outlined in APPENDIX B: PROCESS FOR ENROLLMENT when accepting or declining a patient into the BNTB program. If accepted, patients should be collaboratively managed with the TB program in México.

BNTB programs should only accept patients from the following:

A. Referrals from the TB program in México.

    1. México must submit form BN-200 to the BNTB program when requesting an eligible patient to be admitted into the program.

B. Referrals from a Texas or U.S. TB Program to the BNTB program.

1. The patient needs continuity of care and is moving into a BNTB program service area in México.
2. An Interjurisdictional TB Notification (IJN) Form will be submitted.
3. Notification should be made with the TB Section IJN coordinator for assistance to determine if the patient will reside in a BNTB service area and when the IJN has been uploaded to the National Electronic Disease Surveillance System (NEDSS). Pertinent patient information and locating information should be included with the IJN to verify the BNTB jurisdiction. See APPENDIX N: INTERJURISDICTIONAL COMMUNICATION.

C. Referrals from the BNTB program to a U.S. Program.

1. The patient must be enrolled in a BNTB clinic in México with suspected or confirmed TB, be a TB contact, or have been diagnosed with LTBI, who needs continuity of care in the U.S.
2. The BNTB coordinator will submit an IJN form with all supporting documents to the TB Section IJN coordinator.

D. Referrals of patients who reside outside a BNTB service area.
1. Submit a Cure TB referral. See the CureTB Transnational Notification form: https://www.cdc.gov/migration-border-health/media/pdfs/Form-CureTBTransnational-v3-508.pdf and upload the form to NEDSS.

E. Referrals from U.S. Immigration and Customs Enforcement (ICE).
1. Patients repatriated to México from ICE facilities in the U.S. should first be referred to the Nacional TB program in México by CureTB.
2. Patients referred to a BNTB clinic by the TB program in México should be accepted only after collaboration between the two programs has been established, the eligibility criteria have been met, and the patient is accepted only as resources allow.

Enrollment Process

BNTB programs will follow a tiered approval process when accepting patients. The detailed process is outlined in APPENDIX B: PROCESS FOR ENROLLMENT and states the following:

A. The BNTB program in México will review the BN-200 or the IJN form to assess eligibility.

B. The treating physician in the BNTB program in México, BNTB coordinators, managers, and the consulting physician will review and collaboratively accept or decline entry into the program.

C. The BNTB program in México will send its decision to accept or decline the patient to the México Regional Mycobacteriology Program.

D. A copy of the BN-200 or the IJN will be kept in the patient's medical record in México and the Texas shadow chart.

V. Stewardship and Accountability

General Requirement

The BNTB programs and the fiduciary agency will implement required TB prevention and care activities and manage resources efficiently, with a focus on stewardship and accountability. The BNTB programs in México are an extension of the PHR and LHD TB programs and receive assistance from them.

Accounts for TB services, such as video directly observed therapy (VDOT), Quest account numbers, DSHS laboratory requisitions, or any requisition containing TB Section billing information, cannot be shared with entities outside the program. The U.S. BNTB program staff must ensure program services are delivered in a manner consistent with DSHS standards. This includes ensuring the appropriate evaluation, treatment, and management of program-enrolled patients. Patients should also be managed according to standards of care with consideration of the Official Mexican TB Norma. Texas consulting physicians, México's treating physicians, and the Regional Mycobacteriology Program in México should collaborate to deliver patient care services successfully.

Activities

A**. The BNTB programs will:**

1. Provide care and make recommendations in evaluating, diagnosing, treating, and monitoring patients with suspected or confirmed TB disease or LTBI who meet program eligibility criteria.
2. Collaborate with the Regional Mycobacteriology Program in México on shared patients referred for treatment of LTBI or TB disease.
3. Provide a written agreement to the Regional Mycobacteriology Program in each Mexican state describing the shared roles and responsibilities in the delivery and co-management of TB services between the BNTB program and the TB program in México, as requested, see Appendix C: Co-Management of Patients Agreement.
4. Document plan of care in the patient's medical record of the collaboration and coordination between the BNTB program and México when co-managing a patient, specifying each program's responsibilities (e.g., the BNTB program provides DOT and the México TB program provides laboratory services, etc.). Programs may use Appendix C: Co-management of Patients Agreement.
5. Maintain a complete shadow chart at the BNTB program in Texas on patients managed in the program.
6. Comply with medication record keeping, including completion of BN-206, as required by 340B policy requirements when using state-purchased medications, regardless of the administration location. Refer to https://dshs.txas.gov/pharmacy-TB Section/340b-drug-discount-program.
7. Adhere to México's reporting requirements for all program-enrolled patients. This will include sharing treatment recommendations with the TB program in México.

8. Develop a written preparedness plan to maintain services where possible and ensure patients have access to medications during unforeseen circumstances (e.g., hurricanes, border closures due to increased violence in the area, etc.). Plans should include how programs would handle medication administration (e.g., five to seven days of self-administered medications or VDOT) and other core case management activities if services were interrupted.
9. Provide contact investigation services outlined in CHAPTER XII. CONDUCT AND MANAGE A TB CONTACT INVESTIGATION.
10. Treat contacts according to the standards of care outlined in CHAPTER IX. MANAGEMENT OF PATIENTS WITH LATENT TB INFECTION, INCLUDING PATIENTS ON WINDOW PROPHYLAXIS.
11. Send and receive referrals for patients as outlined in CHAPTER IV. PROGRAM ELIGIBILITY, REFERRALS, AND APPROVAL.
12. Report to the Regional Mycobacteriology Program in each Mexican state, any direct referrals received from the Migrant Clinicians Network/Health Network (formerly TB Net), CureTB, detention centers, and correctional facilities. These patients may be referred to a BNTB clinic by the TB program in México, but should be accepted only after collaboration between the two programs and only as resources allow.
13. Develop a process for continuity of care for referrals received, including but not limited to ICE, CureTB, U.S. Marshals, etc. A process should be outlined at each program site.
14. Obtain formal consults from a Texas DSHS-recognized medical TB consultant upon identification of a drug-resistant case of TB and for patients outlined in APPENDIX D: MEDICAL CONSULTATION PROCESS.
15. Submit TB Section-designated reports in accordance with DSHS-established deadlines, schedules, and mechanisms.
16. Enter all program-enrolled patients in NEDSS. See CHAPTER XVIII. REPORTING REQUIREMENTS for time requirements.
17. Collaborate with partners in México and FEMAP to ensure appropriate administrative, environmental, and respiratory infection controls are applied to prevent exposure to and transmission of TB.
18. Provide professional education, training, and orientation events to contracted BNTB program staff working in México; the events should be designed to train staff in effectively performing duties that align with DSHS and BNTB program standards of care as outlined in this manual.
19. Respond to medical records requests per local or regional policies.
20. Maintain medical records as required by General Provisions Article VIII, "Records Retention," and by Texas Administrative Code Title 22, Part 9, Chapter 165, §165.1, or by a local and regional record retention policy, whichever has a longer retention policy.
    a) At the end of treatment, the record belongs to the PHR or LHD that oversees the BNTB program. Keeping an electronic version of medical records (EMR/EHR) is legally sufficient for retention in Texas, provided they are stored securely and in compliance with state and federal regulations. If

scanning paper records to destroy the original, ensure the digitization meets quality standards to be considered a legal, compliant record. As of January 1, 2026, Texas law requires all electronic health records to be physically stored within the U.S. (2025 TX SB 1188).

21. Collaborate with the fiduciary agency to maintain accurate and concise staff records. These records should include time and mileage reports for all staff working in México, as well as daily clinical activities.
22. Comply with confidentiality and security standards.
23. Perform self-auditing activities to assess clinical care services and reporting practices to achieve program objectives, including conducting cohort reviews.
24. Collaborate with the fiduciary agency to conduct annual performance reviews of each BNTB contracted employee annually or when any clinical issues arise that need immediate attention.
25. Perform continuous quality improvement activities to achieve performance indicators. Outcome measures will reflect performance during each calendar year. The BNTB program performance indicators align with the DSHS Texas TB Program's Performance Measures outlined in TABLE 13: TEXAS TB PERFORMANCE MEASURES.
26. Obtain, on an annual basis, a permit from the Centers for Disease Control and Prevention (CDC) to legally import biological specimens into the U.S. Track and document each specimen transported into the U.S. See APPENDIX J: BIOLOGICAL SPECIMEN TRANSPORTATION for details and APPENDIX K: SAMPLE BIOLOGICAL SPECIMEN MANIFEST.

VI. Local Binational Tuberculosis Program Procedures

General Requirement

The BNTB programs will maintain procedures to guide staff on delivering core TB prevention and care services. The BNTB program procedures should not conflict with established TB Section standards, requirements, and guidelines. TB Section standards are published in this manual and available on the DSHS TB website at: texastb.org.

Activities

A. Develop and implement written procedures to operationalize the following TB services:

1. Criteria to receive TB services
2. Enrollment to receive TB services
3. Treatment and management of LTBI
4. Treatment and management of suspected or active TB disease
5. Treatment and management of drug-resistant TB disease
6. Treatment and management of contacts to patients with TB disease
7. Contact investigation services
8. Transportation of biological specimens
9. Obtaining second-line medications
10. Sputum collection
11. Directly observed therapy
12. Infection control for TB
13. Case review
14. Cohort review
15. Reporting
16. Surveillance

B. BNTB program staff in Texas and México must review and sign Appendix A: Attestation of Review of BNTB Manual within 30 days of hire. Existing BNTB staff in México must submit a signed copy to the fiduciary agency within 30 days of the start of each new fiscal year, which begins September 1.

    1. It is recommended that BNTB program staff in Texas and México review the BNTB program manual and procedures annually with the BNTB program coordinator, all BNTB program staff, nurse consultants, and any additional licensed or unlicensed staff. This may occur in a one-day in-service to ensure all staff understand the requirements.

C. Ensure written procedures are easily accessible to all staff responsible for TB prevention and care activities in English and Spanish.

D. Revise procedures as appropriate to conform with DSHS standards and best practices.

VII. Roles and Responsibilities

General Requirement

The BNTB programs and contracted staff must deliver services efficiently and competently. This chapter outlines the roles and responsibilities of programs and staff involved in delivering BNTB program services.

A. **The TB Section will:**

1. Oversee BNTB program activities.
2. Include the PHD or LHD program manager, the BNTB coordinator, and the RMD or consulting physician in all communication with the México treating physician.
3. Provide expert nursing consultation.
4. Develop standards for TB prevention, care, and program management in collaboration with BNTB programs.
5. Use the Annual Progress Report (APR) and the Contract Management Section (CMS) reports to monitor and evaluate programs' progress towards meeting performance objectives to determine effectiveness and compliance with essential TB prevention and care standards.
6. Monitor BNTB programs' reports and ensure reports are submitted to the TB Unit by established deadlines.
7. Communicate with DSHS Pharmacy Section and the BNTB programs to ensure availability of medications to treat TB disease and LTBI, including window prophylaxis.
8. Provide laboratory support for diagnostic purposes.
9. Serve as a liaison between the CDC, the fiduciary agency, and other federal and state partners.
10. Serve as a repository for TB data reported to DSHS.
11. Collect and analyze reports from BNTB programs to satisfy grant requirements.
12. Serve as a point of contact for inter-jurisdictional transfers. Patients transferring between a BNTB program and a U.S. TB program will have an IJN submitted to the TB Section.
13. Promote security and confidentiality standards for TB data exchanges through training and communication.
14. Prepare and report aggregate data to CDC.
15. Oversee molecular epidemiology practices, provide technical assistance to investigate transmission patterns, cluster events, and prepare TB epidemiological reports.
16. Provide technical assistance to BNTB programs for accurate submission of TB data.
17. Lead the development and implementation of quality assurance (QA) procedures and activities involved in the delivery of BNTB program services.
18. Evaluate program performance and progress towards meeting Texas TB objectives.
19. Conduct audits of Texas BNTB programs through desktop and onsite reviews.

20. Maintain and distribute the most current version of the BNTB program manual in English and Spanish.

B. **The fiduciary agency will:**

1. Ensure the medical coordinator works with BNTB programs to adhere to program standards and expectations outlined in the BNTB Manual, notify the contracted physician and nurses in México of changes in the BNTB program manual that impact their practice, and ensure the attestation page is signed yearly.
2. Prepare contracts, hire, and select staff to maintain services at the four DSHS BNTB programs in México. Each site in México must maintain the following staff to provide services:
    a) Physician with a current and valid medical license to practice medicine in México;
    b) Nurse(s) with a current and valid license to practice nursing in México;
    c) Outreach worker(s) to perform field investigations and provide DOT as needed
    d) Staff responsible for transporting biologicals or other items needed to and from the BNTB sites in Texas; and
    e) Radiology services to perform, read, and interpret chest x-rays.
3. Conduct interviews for new hires in collaboration with the Texas-based BNTB program manager or supervisor. The BNTB program manager may designate a staff member in the Texas-based program to serve on the interview panel.
4. Ensure programs have adequate telecommunication services, office and medical supplies, and office space to perform daily activities.
5. Ensure direct clinical care staff are screened for TB upon hire and annually when indicated.
6. Schedule annual site visits to each BNTB site in México to ensure adherence to program standards outlined in the BNTB manual and submit written results to the TB Section.
7. Conduct annual performance reviews of each BNTB clinical employee in México and submit findings to CMS.
8. Maintain collaboration with DSHS and each BNTB program site in México and Texas to ensure program needs are met.
9. Notify the TB Section immediately of any situation that may affect the BNTB program operations.
10. Notify the TB Section and share any publication, presentation, or abstracts regarding the BNTB programs' operations, data, or structure prior to presenting or publishing[3].

[3] DSHS is the owner of the data collected or created by the BNTB program. Users must credit DSHS, retain all proprietary notices, and may not modify the data.

11. Provide payment to subcontractors in México in accordance with the TB Section-approved budget.
12. Request and review weekly time and mileage reports from staff in México bi-monthly.
13. Submit a complete and accurate APR by the established deadline; and
14. Monitor budget expenditures and submit fiscal reports by established deadlines for activities involved in the delivery of BNTB program services.

C. **It is the role of the regional or local BNTB program manager or supervisor to:**

1. Read, understand, and follow procedures outlined in the BNTB manual.
2. Supervise the BNTB staff in Texas only.
3. Develop and revise local BNTB program procedures. These procedures should not conflict with those outlined in the BNTB program manual.
4. Assign a nurse to oversee nurse case management activities if the BNTB coordinator is not a nurse.
5. Participate in the annual review and revision of the BNTB program manual and submit updates to the TB Section by the targeted deadline.
6. Communicate with the fiduciary agency and the TB Section, using independent judgment for when to engage one or both.
7. Communicate any of the following routinely with the fiduciary agency: any concerns regarding contractors' performance in México; hiring and selecting contract staff in México, coordinating courier services, and other issues as they arise.
8. Elevate concerns within one business day to the TB Section when there are situations that impact program operations.
9. Communicate with the TB Section routinely on the following: presentations (for review and approval), changes in TB personnel, and updates on program activities.
10. Review and approve presentations, publications, or abstracts in collaboration with regional or DSHS leadership.
11. May assist the fiduciary agency in contracting with a radiology service to perform X-rays for cases and contacts residing in México.
12. Collaborate, as needed, with the fiduciary agency to ensure courier services are available to transport specimens to the U.S.
13. Ensure DSHS data security and confidentiality procedures are maintained and arranged for contracted staff in México to obtain DSHS or LHD email addresses.
    a) All BNTB staff are required to have a work email address. The use of personal email accounts for work-related communication is not permitted, as it compromises DSHS data security and confidentiality standards. Coordinators and program managers must ensure all contracted staff in México are set up with a DSHS or LHD email address prior to beginning work.
14. Provide each contractor with an identification badge or credential that clearly identifies them as contracted staff when traveling to the U.S. for business.

15. Collaborate with the medical coordinator to ensure all contracted clinical staff are fit tested and trained upon hire and annually in using N95 respirators (or their equivalent).
16. Collaborate with the fiduciary agency in hiring and selecting contracted staff in México; and
17. Notify the TB Section of any changes in personnel in the Texas BNTB program, including new hires. Submit the Notice of Change in TB Personnel to TBProgram@dshs.texas.gov.

D. **It is the role of the Texas consulting physician to:**

1. Discuss with the treating physician in México any U.S. treatment guidelines for TB disease and infection and provide treatment recommendations when requested[4].
2. Coordinate with the México physician to ensure medical consultation occurs as outlined in APPENDIX D: MEDICAL CONSULTATION PROCESS. "Curbside consultations" are discouraged, and complete information must be provided to a DSHS-recognized medical TB consultant when medical consultation is requested. Consultation recommendations should be provided in writing to the México treating physician; and
3. Participate and submit recommendations in writing on monthly case review conferences as needed.

E. **It is the role of the BNTB program coordinator* to:**

1. Read, understand, and follow procedures outlined in the BNTB manual and sign attestation annually.
2. Collaborate with the treating physician in México, the program manager, and, in some instances, the Texas consulting physician to accept or decline referrals based on available resources. Submit written responses to the BNTB program in México. See APPENDIX B: PROCESS FOR ENROLLMENT.
3. Assign work to contracted nursing staff providing services in México.
4. Participate in annual reviews of the BNTB manual in collaboration with the BNTB program manager and submit updates to the DSHS BNTB nurse consultant and BNTB program manager by the targeted deadline.
5. Perform nurse case management oversight activities to ensure the following are done according to TB Section standards and CDC's guidelines. These activities include:
    a) DOT and/or VDOT.
    b) Contact investigations.
    c) Medication dispensing.

[4] According to Health and Safety Code Title 3-Occupational Code 151.002 A-12, Texas consulting physicians are licensed to practice in Texas. If a Texas consulting physician's licensure does not extend to México, they are unable to act as the treating physician for patients receiving care in México.

d) Documentation of patient care, including baseline and monthly toxicity assessments.
e) Dose counting.

6. Maintain a complete shadow chart with up-to-date progress notes and applicable TB forms (or their equivalent) at the Texas BNTB program site.
7. Coordinate the completion of necessary documentation with both Texas and México when second-line medications are requested.
8. Ensure medications ordered for enrolled patients are received and delivered without delay to the nurses in México.
9. Inspect medications for accuracy* in regimen and dosage prior to delivery to the nurse in México.
10. Confirm all specimens received for processing at DSHS laboratory and contracted laboratories through DSHS are for enrolled patients only.
11. Ensure specimens are correctly labeled and packaged prior to shipping in accordance with TB specimen shipping and labeling guidelines.
12. Schedule and lead monthly case reviews with México's treating physician, nurses, and Texas consulting physicians.
13. Ensure all documents are received and placed in order prior to submitting for consultation to the Texas consulting physician or a DSHS-recognized medical consultant.
14. Prepare and present educational programs in English and Spanish on services provided by the BNTB program. Presentations must be approved by the BNTB program manager and the TB Section. Once approved, they can be shared with nurses in México for presentations in México.
15. Ensure BNTB patient data is entered into NEDSS by the assigned PHR or LHD staff. See APPENDIX M: GUIDELINES FOR RESPONDING TO THE TB SECTION'S SURVEILLANCE REQUESTS.
16. Review and revise the federal budget impacting their program (this excludes México's budget) in coordination with the BNTB program manager and TB Section.
17. Collaborate with health officials within their local TB programs in México on patients referred to the BNTB program.
18. Complete and submit annual reports to the fiduciary agency by the scheduled deadline.
19. Meet and communicate on a regular basis with México's BNTB staff and México's health officials to discuss caseload and administrative issues.
20. Conduct cohort reviews as specified in APPENDIX I: COHORT REVIEW PROCESS.
21. Maintain an up-to-date line-list of patients in the BNTB program and submit a copy to the TB Section's TB nurse consultant as requested.
22. Review time and mileage reports from nurses and physicians in México on a bi-monthly basis for accuracy on patient workload and submit to the fiduciary agency for approval and payment; and
23. Assist, as needed, the fiduciary agency to contract with one person to transport specimens to the U.S., including obtaining a CDC Import Permit. See APPENDIX J: BIOLOGICAL SPECIMEN TRANSPORTATION.

*Note: If the BNTB program coordinator is not a licensed registered nurse, defer to the manager/supervisor to assign a nurse to perform nurse case management oversight for nursing activities.

Binational TB Programs in México

A. **The BNTB contracted staff in México will:**

1. Maintain communication with Texas-based BNTB program staff on patient management activities.
2. Communicate with the fiduciary agency and the Texas-based BNTB program staff to maintain appropriate personnel to perform clinical care services and outreach activities, including but not limited to:
    a) Physician services
    b) Nurse case management
    c) Directly observed therapy or VDOT
    d) Contact investigation
    e) Referrals and updates
    f) TB education
    g) Reporting
    h) Collection and transport of laboratory specimens
3. Perform work in accordance with CHAPTER VIII. STANDARDS OF CARE.

B. **It is the role of the BNTB medical coordinator to:**

1. Participate in maintaining an up-to-date, comprehensive bilingual BNTB manual, complete with standards of care and established best practices across all BNTB programs.
2. Read, understand, and follow procedures outlined in the BNTB manual and sign attestation annually.
3. Collaborate with the fiduciary agency and each BNTB coordinator to ensure each BNTB program contractor completes an annual review of the program manual.
4. Ensure consistent delivery of clinical practices among all BNTB program clinics in México.
5. Oversee the work performed by all contractors and vendors in México to ensure adherence to U.S. TB regulate QA, safety standards, and standard of care for patients.
6. Develop plans to utilize new TB diagnostic technologies and treatment at each BNTB program site upon approval by DSHS.
7. Communicate and collaborate with BNTB programs' treating physicians on a regular basis to provide guidance as appropriate to facilitate positive and productive relationships with local jurisdictional colleagues.
8. Participate in annual program evaluations at each BNTB program in México.
9. Participate in interviews of new hires and ensure there is collaboration with the Texas-based BNTB program.
10. Participate in training new hires when requested.

11. Conduct annual performance reviews of each BNTB program staff member in México in collaboration with the BNTB Texas program coordinator.
12. Maintain standardized job descriptions for all clinical contractors and prepare formal agreements with all clinical vendors in collaboration with the TB Section and PHRs or LHDs.
13. Function as a back-up as needed to conduct clinical assessments for the diagnosis and treatment of TB and provide direct medical care services, including services for drug-sensitive and drug-resistant cases, at any of the BNTB program sites in accordance with the DSHS-approved clinical standards and México's legal and clinical standards.
14. Attend relevant trainings and conferences to remain up to date with the developments and best practices in the prevention and treatment of TB.
15. Communicate with the BNTB Texas-based program and the TB Section on any updated laboratory testing capabilities in México;
16. Submit to the TB Section a monthly detailed line-list, using the template provided, capturing all enrolled patients per clinic; and
17. Perform other duties as assigned that align with TB prevention and care services.

C. **It is the role of the treating physician in México to:**

1. Read, understand, and follow procedures outlined in the BNTB manual and sign the attestation annually.
2. Review and be familiar with both standards of care for treatment and prevention of TB in the U.S. and México as outlined in CHAPTER VIII. STANDARDS OF CARE.
3. Perform initial and follow-up assessments for patients with suspected or confirmed TB disease, contacts, and LTBI and document in the patient's medical record.
4. Communicate and coordinate the patient's medical care with primary physicians in México, and the Texas consulting physician and/or the RMD when needed.
5. Order and interpret appropriate diagnostic tests.
6. Provide clear directions to contracted nursing staff on expectations of assessment: how often patients should be seen in the clinic, how often orders will be signed, and the method staff will use to communicate with the treating physician.
7. Submit information to the Texas consulting physician, as needed, to ensure adequate treatment recommendations are received from a DSHS-recognized medical TB consultant for DR-TB and/or challenging cases. See APPENDIX D: MEDICAL CONSULTATION PROCESS.
8. Review all documents prior to submission for consultation to ensure correct and current information is submitted.
9. Provide written orders for medication regimens to include dosage, route, and frequency. If verbal orders are given to the nurse, document them in the patient's medical record within one week of providing the verbal order.
10. Review, initial, and date laboratory results and other diagnostic tests.
11. Document and include progress notes in the medical record at least monthly for each patient on treatment for TB disease.

12. Accurately complete patient care documents and provide them to the nurses, who will send them to the BNTB coordinator to maintain a complete shadow chart at the Texas BNTB office. The treating physician will review and sign patient orders prior to submitting them to the nurses and BNTB coordinator.
13. Ensure patients with DR-TB, young children with TB, or other high-risk individuals are managed according to the U.S. standards of care for treatment.
14. Provide TB education to patients and family members to include prevention and transmission, disease process, and consequences of inadequate treatment.
15. Participate in monthly case review conferences with the PHR or LHD BNTB program.
16. Participate in BNTB program conferences, meetings, in-service trainings, and seminars.
17. Coordinate with the appropriate TB local and state physicians in México for the approval and procurement of second-line medications. See Chapter XIV. Management of Medications and Availability.
18. Ensure recommendations by the DSHS-recognized medical TB consultant for the treatment of drug-resistant patients are shared with the National TB Program and the COEFAR and/or GANAFAR.
19. Ensure medications recommended for DR-TB patients are consistent with U.S. treatment guidelines. If not, collaboration between physicians in México and Texas should occur to reach a consensus on the best treatment option for the patient. If an agreement cannot be reached, the consulting physician in Texas and the treating physician in México will determine whether the patient can continue receiving services from the BNTB program.
20. Participate in quarterly meetings with México's Binational Committee, as needed.
21. Perform TB educational activities to health care providers within the service area to increase program awareness and promote referrals to the BNTB program.
22. Communicate with the BNTB program medical coordinator in México any concerns affecting the daily operations of the BNTB program site.
23. Ensure all documents and results are shared with referring physicians in México to comply with México's disease reporting and surveillance procedures; and
24. Maintain a log of daily work activities and mileage and submit to the BNTB program coordinator and the fiduciary agency bi-monthly, see Appendix P: Sample In-Service and Training Roster and Time and Mileage Report.

D. **It is the role of the Nurses in México to:**

1. Read, understand, and follow procedures outlined in the BNTB manual and sign the attestation annually.
2. Perform duties in a professional manner to provide nursing and administrative services as assigned by the BNTB coordinator and the BNTB program manager.
3. Perform duties within the assigned contracted hours.
4. Complete medical and social history BN-202 or equivalent to include initial TB signs and symptoms and date of assessment.
5. Ensure patients have current written medical orders from the treating physician.

6. Conduct physical, developmental, and mental health assessments of patient health needs and perform applicable nursing interventions; communicate findings and results with the treating physician in a timely manner.
7. Ensure patients are started on an adequate treatment regimen and administer medications as prescribed by the treating physician.
8. Coordinate and communicate with the BNTB coordinator the list of patients requiring medications and ensure medications are ready for pick up prior to U.S. border crossing.
9. Verify that medications being collected from the Texas BNTB program align with the list of patients to ensure correct names and dosage prior to leaving the Texas BNTB facility.
10. Ensure patients are assessed according to TB Section standards, see Chapter XX. Conduct Quality Improvement (QI)) Activities, Table 13: Texas TB Performance Measures.
11. Maintain complete medical records (including all required forms) and submit copies to the BNTB coordinator at minimum monthly. Records should be reviewed by the treating physician for accuracy prior to submitting to the BNTB coordinator. See Appendix F: Binational TB Program Clinical Care Forms.
12. Document in the medical record all patient encounters, including phone calls, clinic visits, and home visits.
13. Perform monthly toxicity assessments and document in the patient's medical record. This includes documenting any abnormalities noted (i.e., what the nurse did to address the abnormality); do not administer medications to patients if toxicity screening is not performed, and notify the treating physician. Submit copies to the BNTB coordinator at minimum monthly.
14. Maintain a process to respond to medication toxicity and other concerns reported by the patient.
15. Provide DOT or VDOT to all patients, as prescribed by the treating physician in alignment with DSHS program standards of care. Document all doses taken, missed, or self-administered on BN-206 or its equivalent. See Appendix H: Directly Observed Therapy (DOT) Procedure.
16. Use appropriate measures to ensure patients complete adequate therapy. If the patient does not complete adequate therapy, document all interventions taken to resume therapy.
17. Collect sputum for all patients when indicated, following Appendix G: Sputum Collection Procedure.
18. Assist the treating physician and the BNTB coordinator in gathering all pertinent information to submit for medical consultation.
19. Provide education to all patients on TB prevention, transmission, disease process, treatment, and the consequences of inadequate treatment.
20. Educate health care providers and community-based organizations within the service area to increase awareness of TB and promote referrals to the BNTB program.

21. Educate patients on possible medication side effects, conditions under which medications should be stopped, the need to prevent pregnancy (if applicable), and when to seek immediate medical attention.
22. Provide referrals for medical evaluations as needed.
23. Correctly label, document, and package specimens according to program shipping requirements, including having a list of items transported to Texas. See APPENDIX K: SAMPLE BIOLOGICAL SPECIMEN MANIFEST.
24. Coordinate the transportation of biological specimens for acid-fast bacilli (AFB) testing to the DSHS laboratory. Collaborate with the BNTB program manager and the BNTB coordinator on the transportation schedule.
25. Transport equipment and supplies to and from Texas and México's BNTB program sites.
26. Provide the BNTB program coordinator with information needed to prepare reports for clinical and funding purposes.
27. Participate in BNTB program conferences, meetings, in-service trainings, and seminars.
28. Maintain a detailed log of daily work activities and mileage. Submit the completed log to the BNTB program coordinator and the fiduciary agency on a bi-monthly basis. See APPENDIX P: SAMPLE IN-SERVICE AND TRAINING ROSTER.
29. Participate in monthly case management conferences and quarterly cohort reviews.
30. Perform other duties as assigned that align with TB prevention and care services.

VIII. Standards of Care

General Requirement

Patients in the BNTB program will receive outpatient treatment and care that aligns with U.S. standards of care while taking into account the Mexican TB Norma for the treatment and prevention of TB. Each program must first assess its capacity to manage patients before accepting a patient into the program and confirm patient eligibility (as described in CHAPTER IV. PROGRAM ELIGIBILITY, REFERRALS AND APPROVAL). This chapter outlines the minimum standards of care for referred patients undergoing evaluation and treatment for TB services within the BNTB programs. The intended audience for these standards is authorized staff working in the BNTB programs in Texas and in México.

Activities

A. BNTB programs must review, be familiar with, and readily access recommendations within the following documents:

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. https://academic.oup.com/cid/article/63/7/e147/2196792
2. Official American Thoracic Society/Infectious Diseases Society of America/Centers for Disease Control and Prevention Clinical Practice Guidelines, Clinical Infectious Diseases, Diagnosis of Tuberculosis in Adults and Children. (2016), 64 (2):111-115. https://pubmed.ncbi.nlm.nih.gov/28052967/
3. Updates on the Treatment of Drug-Susceptible and Drug-Resistant Tuberculosis: An Official ATS/CDC/ERS/IDSA Clinical Practice Guideline. Am J Respir Crit Care Med. 2025 Jan 1;211(1):15–33. doi: 10.1164/rccm.202410-2096ST. PMCID: PMC11755361. https://pmc.ncbi.nlm.nih.gov/articles/PMC11755361/pdf/rccm.202410-2096ST.pdf
4. Guidelines for the Treatment of Latent Tuberculosis Infection: Recommendations from the National Tuberculosis Controllers Association and CDC, 2020. cdc.gov/mmwr/volumes/69/rr/pdfs/rr6901a1-H.pdf
5. Testing and Treatment of Latent Tuberculosis Infection in the United States, 3rd Edition, 2023: A Clinical Guide for Health Care Providers and Public Health Programs. https://tbcontrollers.org/resources/tb-infection/clinical-recommendations/.
6. Treatment of Drug-Resistant Tuberculosis, An Official ATS/CDC/ERS/IDSA Clinical Practice Guideline: Executive Summary (2019). American Journal of Respiratory and Critical Care Medicine, 2019. https://www.atsjournals.org/doi/full/10.1164/rccm.201909-1874ST
7. Provisional CDC Guidance for the Use of Pretomanid as part of a Regimen (Bedaquiline, Pretomanid, and Linezolid [BPAL]) to Treat Drug-Resistant Tuberculosis Disease. CDC, 2022. archive.cdc.gov/#/details?url=https://www.cdc.gov/tb/hcp/treatment/bpal.html

8. Recommendations for Use of an Isoniazid-Rifapentine Regimen with Direct Observation to Treat Latent *Mycobacterium tuberculosis* Infection. Treatment of Drug-Resistant Tuberculosis. An Official ATS/CDC/ERS/IDSA Clinical Practice Guideline. American Journal of Respiratory and Critical Care Medicine (2019) https://www.atsjournals.org/doi/full/10.1164/rccm.201909-1874ST
9. Update of Recommendations for Use of Once-Weekly Isoniazid-Rifapentine Regimen to Treat Latent *Mycobacterium tuberculosis* Infection | (2018) MMWR. cdc.gov/mmwr/volumes/67/wr/pdfs/mm6725a5-H.pdf
10. The Spectrum of Tuberculosis from Infection to Disease-TB at a Glance: 3rd Edition. Heartland National TB Center and Mayo Clinic, 2020. https://www.heartlandntbc.org/wp-content/uploads/2021/12/The_Spectrum_of_TB.pdf
11. American Academy of Pediatrics. Committee on Infectious Diseases. (2023). Red Book: Report of the Committee on Infectious Diseases. Red Book, 33rd edition. American Academy of Pediatrics (AAP) https://publications.aap.org/redbook/book/755/Red-Book-2024-2027-Report-of-the-Committee-on.
12. National Tuberculosis Coalition of America (NTCA) Guidelines for Respiratory Isolation and Restrictions to Reduce Transmission of Pulmonary Tuberculosis in Community Settings, *Clinical Infectious Diseases*, 2024; ciae199, https://doi.org/10.1093/cid/ciae199
13. Tuberculosis Risk Factors. CDC, 2024. https://www.cdc.gov/tb/risk-factors/?CDC_AAref_Val=https://www.cdc.gov/tb/topic/testing/whobetested.htm
14. Screening and Testing for HIV, Viral Hepatitis, STD & Tuberculosis in Pregnancy (2024). cdc.gov/pregnancy-hiv-std-tb-hepatitis/php/screening/.
15. An Official ATS Statement: Hepatotoxicity of Antituberculosis Therapy. Am J Respir Crit Care Med. 2006; 174:935-952. https://www.thoracic.org/statements/resources/mtpi/hepatotoxicity-of-antituberculosis-therapy.pdf
16. National Institutes of Health (2026). Federally approved Clinical Practice Guidelines for HIV/AIDS. https://clinicalinfo.hiv.gov/en/guidelines
17. Core Curriculum on Tuberculosis: What the Clinician Should Know. 7th Edition. CDC (2021). cdc.gov/tb/media/Core_Curriculum_TB_eBook.pdf
18. Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis. MMWR 2005; 54(RR15): 1-55. CDC (2021). cdc.gov/mmwr/preview/mmwrhtml/rr5415a1.htm
19. Official Mexican Standard NOM-006-SSA2-2013, for the Prevention and Control of Tuberculosis (2013) https://www.cndh.org.mx/sites/default/files/doc/Programas/VIH/Leyes%20y%20normas%20y%20reglamentos/Norma%20Oficial%20Mexicana/NOM-006-SSA2-2013.pdf

20. Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis. MMWR 2005; 54(RR15): 1-55 http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5415a1.htm
21. México's Guide for the Care of People with Drug-Resistant Tuberculosis. http://www.cenaprece.salud.gob.mx/programas/interior/micobacteriosis/descargas/pdf/guia_tb_mfr_ok.pdf

Minimum Standards of Care

A. Provide Patient-Centered Care in an Outpatient Setting

1. Provide culturally competent education and care using the patient's preferred language, relevant to their age and literacy level, when discussing TB pathology, transmission, treatment options, and plan of care.
2. Identify barriers to care and develop strategies to meet individual patient needs. This may include a plan for incentives and enablers, as well as the coordination of ancillary support services. Programs should collaborate with the fiduciary agency for allocated funds to support incentives and enablers.
3. Develop a DOT patient-centered care plan. VDOT should be considered for all eligible patients. Refer to https://www.dshs.texas.gov/sites/default/files/IDCU/disease/tb/forms/DOCS/VDOT-ClientAgreement.doc.

B. Screening for TB Disease and Latent TB Infection

1. Every patient needing a TB screening who does not have documentation of a previous positive TB screening test should be tested with an interferon gamma release assay (IGRA) or tuberculin skin test (TST).
    a) Use the IGRA test as the preferred TB screening test when TB screening is indicated. The TB Section provides IGRAs at no cost to the BNTB programs.
    b) Per the American Academy of Pediatrics Redbook, 2023rd edition: "Either TST or IGRA testing is acceptable for children of any age". Both the TST and IGRA are unreliable in infants aged four to six months or younger. Screening test results, especially in young children, should be interpreted in conjunction with epidemiological risk factors and clinical assessment. For infants younger than six months, a negative TST or IGRA cannot be confirmed until the infant is six months old, or after the break in contact period, whichever is later.
        i. If the test is positive, refer for medical evaluation.
        ii. If the test is negative, retest at age six months or 8-10 weeks after the break in contact, whichever is later, to confirm a negative test.
            (a) Any infant who is a contact to infectious tuberculosis should be placed on window prophylaxis until the TST or IGRA can be confirmed.
            (b) Consider repeating an IGRA when the initial IGRA result is indeterminate, borderline, or invalid, and a reason for testing persists.

(c) If an IGRA is to be repeated, a new blood sample should be used. In such situations, a repeated test from a new blood sample usually provides interpretable results.

(d) If a second test result is reported as indeterminate, borderline, or invalid, consult with the treating physician whether a TST or CXR should be ordered.

2. Use the TST for patients needing a TB screening if phlebotomy is refused, contraindicated, or ordered by the treating physician.
    a) When using the TST, considerations should be given to results, regardless of a patient's BCG vaccination status.
    b) TST supplies (e.g., syringes and tuberculin purified protein derivative) should be ordered from the DSHS pharmacy using the pharmacy ordering system.
3. Programs shall not order or distribute TST or IGRA supplies to sites, organizations, or clinics outside the BNTB program.

C. **Radiology**

1. Every program must have radiology services available through a contracted facility.
2. Every patient under 18 years of age or diagnosed with HIV infection will have a posterior/anterior (PA) and lateral chest x-ray (CXR) when undergoing evaluation for TB infection or disease, or when a CXR is recommended; patients aged 18 years or older will have a PA CXR.

D. **Location-Appropriate Isolation and Transmission-Based Precautions**

1. Every patient with known or suspected TB disease will be advised to remain in respiratory isolation appropriate for the setting.
2. If home-based isolation is initiated, ensure the patient has a surgical mask and instruct them to wear it in appropriate settings.
3. Follow the criteria for placing patients in and releasing from TB Isolation and restrictions using the DSHS TB Isolation and Restrictions Implementation Guide. Follow these practices:
    a) Children <10 years do not need to be isolated unless they have one or more of the following: cavitation on chest imaging; sputum smear positivity (if sputum was collected); presumed laryngeal TB.
    b) Rule out pulmonary TB prior to releasing patients with extrapulmonary TB, if pulmonary TB has not been ruled out.
    c) Isolation is indicated for patients with confirmed or suspected pulmonary or laryngeal TB, who are non-adherent to or tolerant of anti-TB therapy (ATT).
    d) Nurses should familiarize themselves with the **three levels of restriction**: Extensive, moderate, and low levels, and educate the patient on each applicable restriction level requirement.
    e) All patients in whom isolation is indicated should be placed in **extensive** level restrictions for at least five doses of TB therapy that are observed and

tolerated. This includes AIIR in a congregate setting or separation if a residence, masking (surgical mask for the patient; N-95 masks for healthcare staff), and environmental controls, including ultraviolet (UV) lights, HEPA filters, or home-based ventilation measures such as opening windows and using fans to circulate air outside the home.

f) Patients in high-risk congregate settings (including correctional facilities, inpatient care facilities, high-risk outpatient facilities [i.e., dialysis, HIV centers, cancer infusion centers, dental offices], homeless shelters, and refugee camps or rescue missions) and patients not adherent to or tolerant of an effective drug regimen to which they are likely susceptible should remain in extensive level restrictions until they have the following:
   i. Three consecutive negative AFB sputum smear results;
   ii. Symptom improvement; and
   iii. Have been on multi-drug therapy for TB for at least 5 DOT doses (if they never had a positive AFB sputum smear) or 14 doses (if initially AFB sputum smear positive).

g) Patients who **do not** live in or visit high-risk congregate settings may be considered for release from TB isolation and restrictions after 5-14 DOT doses of an effective drug regimen. Modifications to the restriction level may be considered if not releasing after five doses of an effective TB drug regimen.

h) Prior to releasing any patient from TB isolation and restrictions, consider the setting and contact exposures, as detailed in the DSHS TB Isolation and Restrictions Implementation Guide.

i) A nurse may only release a patient from isolation after written instructions are received by the treating physician. All activities done to ensure the patient's compliance with respiratory isolation should be documented in the patient's medical record.

4. Document in the medical record the date the patient is placed in isolation and the date of release from isolation.
5. Every patient who arrives at the TB clinic and infectiousness is unknown will be given a surgical mask to wear.
6. BNTB México staff will use fit-tested N-95 respirators (or equivalent) in situations that pose a risk of exposure to TB disease and when providing patient care to patients on isolation. BNTB México direct-care staff should be screened for TB yearly. See CHAPTER XVI: INFECTION CONTROL PROCEDURES for details. Results should be readily available to the medical coordinator for yearly review to identify any evidence of gaps in infection control measures.

E. **Laboratory Bacteriology Testing**

1. Laboratory diagnostic testing from the DSHS laboratory in Austin, Texas, is only available for patients enrolled in the program. Testing includes: AFB smears, cultures, nucleic acid amplification tests (NAAT), drug susceptibility testing (DST), and coordination for molecular detection of drug-resistance (MDDR).
2. Every patient for whom sputum is collected, one (ideally the first) sample should be sent for NAAT, unless there is documentation of a polymerase chain reaction (PCR) that tests for RIF resistance or unless DSTs are known.
3. Every patient with sputum confirmed TB disease will have documentation of culture conversion. Culture conversion is documented by the first negative culture in a series of previously positive cultures, with all subsequent cultures remaining negative.
4. Every patient with TB disease must be monitored for smear and culture conversions. Submit consultation as indicated in APPENDIX D: MEDICAL CONSULTATION PROCESS.
5. Every program should obtain supplies necessary to induce sputum (i.e., portable nebulizers) as program resources allow.

F. **Nursing Assessments**

1. Every patient receiving medication for TB disease or LTBI will have at a minimum, a baseline and monthly nursing assessment to include a nursing physical exam and toxicity screening documented in the medical record.
    a) Toxicity screening must be documented on BN-205 or TB-702a (for patients on second-line medications) or their equivalent.
    b) Toxicity screenings must be done according to the patient's drug regimen.
2. Every patient on treatment for LTBI must have documentation in the medical record of all communication with the licensed nurse. Documentation will include at a minimum:
    a) Notes on medication refill information, including drug name, dosage, lot number, and expiration date of medication; and
    b) Response to toxicity questions.

G. **Physician Assessments**

1. Every patient on treatment for TB disease must receive an in-person physical examination by the México treating physician at initial diagnosis. Subsequent examinations should be done as outlined in CHAPTER X. MANAGEMENT OF PATIENTS WITH SUSPECTED OR CONFIRMED TUBERCULOSIS or as determined by the treating physician or as recommended by the consulting physician. All examinations should be clearly documented in the medical record.
2. The México treating physician will review and sign the medical record when orders are updated or revised.
3. Every patient on treatment for LTBI will have a physical evaluation by the México treating physician as outlined in CHAPTER IX. MANAGEMENT OF PATIENTS WITH LATENT TB INFECTION, INCLUDING PATIENTS ON WINDOW PROPHYLAXIS.

4. For patients with LTBI receiving treatment, the México treating physician will review and document in the medical record as outlined in CHAPTER IX. MANAGEMENT OF PATIENTS WITH LATENT TB INFECTION, INCLUDING PATIENTS ON WINDOW PROPHYLAXIS.

H. **Directly Observed Therapy (DOT)**

1. Physicians should write patient-specific orders for each patient.
2. Initiate DOT within one week of treatment orders.
    a) Daily therapy is recommended (either 5x/week or 7x/week).
    b) Nurses should ensure appropriate DOT doses are counted towards completion of therapy.
3. Only México BNTB program staff may administer DOT to patients.
4. Nurses and outreach workers will have written orders from the BNTB treating physician prior to administering medications to patients.
5. Every patient on treatment for TB disease will be treated for the duration of treatment via DOT, whether in person or by VDOT.
    a) VDOT should be considered for all eligible patients and may be utilized when patients are recommended for DOT. See DSHS Video-Enabled Directly Observed Therapy Required and Recommended Activities Manual (Spanish).
    b) When using Scene, adjust patient language under the profile tab. The application is translated into the selected language.
    c) VDOT platforms not supported by the Health Insurance Portability and Accountability Act (HIPAA) should not be used to perform VDOT services (e.g., WhatsApp).
6. Every contact to a case of MDR-TB, if treatment is recommended for LTBI or window prophylaxis, will be treated via DOT or VDOT.
7. Every patient on INH and rifapentine (3HP) may be treated by self-administration at the discretion of the treating physician and with a written order.
8. Every patient under age five is recommended to have DOT or VDOT for LTBI, including those on window prophylaxis.
9. When doTBal cannot be used, all DOT medications will be ordered via the DSHS pharmacy's medication ordering system.

I. **Children and Pediatrics Age 17 and Younger**

1. Every child younger than five years of age who is undergoing evaluation for LTBI or TB disease will have a physical examination by a physician, pediatrician, or licensed clinician.
2. If the guardian refuses therapy for a patient aged 17 years and younger and for whom treatment is recommended for LTBI, the guardian should sign the TB-415a indicating refusal. The guardian receives a copy, and a copy is saved in the México BNTB medical record and the Texas shadow record. Refer patients back to the reporting.

J. **Consultation**

1. Not all patients in the BNTB program require medical consultation.
2. The consultation process is outlined in Appendix D: Medical Consultation Process for recommended or required consultations to the Texas consulting physician or when a consultation should be elevated to a DSHS-recognized TB medical consultant.
3. All consultations should be kept in the patient's medical record in México and the shadow chart in Texas.

K. **Completing Adequate Therapy**

1. Completion of therapy should be based on the total number of doses administered (allowing for minor interruptions in therapy), *not* on the duration of therapy alone.
2. DOT is the standard of care; therefore, every patient will ideally finish therapy as specified by the ordering physician with 100% of doses taken by DOT/VDOT.
3. The initial phase of therapy must be documented before the patient begins therapy for the continuation phase.
4. Drug susceptibility testing should be known prior to discontinuing medications in the initial and continuation phase.
5. At a minimum, when closure at 100% DOT is not possible, ATS 3 patients will have at least 80% of treatment completed by DOT/VDOT at closure. Physicians should ensure the patient has responded to therapy and has received adequate therapy prior to closure.
6. Patients eligible to complete treatment within 12 months must complete therapy within 365 days or less. See Table 13: Texas TB Performance Measures for exclusions.
7. If the patient stops treatment before completing the recommended regimen, close the medical record and document the reason for closure in the medical record. Write any recommendations for follow-up treatment by the treating physician in the medical record. Refer the patient back to the reporting entity and share follow-up recommendations with them.

L. **Contact Investigations (CI)**

1. Perform CIs by screening high-priority contacts of patients with suspected or confirmed pulmonary, pleural, or laryngeal TB disease.
2. Initial interviews are conducted by contracted staff in México within three working days of being notified of a patient with suspected or confirmed TB disease.
3. Every sputum smear-positive case will have at least three contacts identified.
4. Every contact refusing evaluation for LTBI, including patients needing evaluation for window prophylaxis, will be informed of the implications regarding their decision. Complete TB-230a, documenting the patient's refusal, and obtain their signature. A copy will be given to the patient, and a copy will be saved in the patient's Texas and México medical records.

M. **Case Conferences and Cohort Reviews**

1. Conduct monthly case review for all ATS 3, and ATS 5 patients currently on treatment. These should be done with both the Texas BNTB program, the BNTB program staff in México, and the Regional Mycobacteriology Program within each jurisdiction in México. BNTB programs may determine if separate case conferences are held with México's Regional Mycobacteriology Program.
2. Conduct case reviews of contacts on treatment based on the discretion of the México treating physician and/or the Texas consulting physician.
3. Conduct quarterly cohort reviews. See APPENDIX I: COHORT REVIEW PROCESS.

IX. Management of Patients with Latent TB Infection, including Patients on Window Prophylaxis

General Requirements

This chapter outlines the minimum activities required when initiating treatment and providing medical case management for contacts with LTBI. These are not standing delegation orders (SDOs), and nurses must ensure that written or verbal orders are received by the treating physician before carrying them out.

Active TB disease should always be ruled out prior to deciding to treat a patient for LTBI.

Activities

A. **Administrative**

1. Create a medical record for each patient with LTBI and/or who requires window prophylaxis. Medical records will be organized with clear division of sections as determined locally. All entries in the medical record should be signed, dated, and in chronological order with no blank spaces in the progress notes. A line should be drawn through open spaces. Medical records kept at the clinic in México and the shadow chart retained in the Texas program will include at minimum, the following:
    a) BN-200 – Forma de Referido (referral form) if applicable
    b) BN-400A – Report of Case and Patient Services
    c) BN-210 – Latent TB Infection Case Management Plan
    d) BN-202 – TB Initial Health Risk Assessment/History
    e) BN-203 – Education and Counseling Record
    f) BN-205 – TB Toxicity Assessment
    g) BN-206 – Directly Observed Therapy Log
    h) 12-14198a – Patients on 3HP - Dosing and Symptom Monitoring Log
    i) Radiology Reports (initially and repeat results as applicable)
    j) Laboratory Results
    k) Progress Notes
    l) Medical Consultations
    m) Miscellaneous (emails, fax confirmations, etc.)
2. Obtain general consents and disclosures for treatment.
    a) DSHS General Consent and Disclosure (L-36a)
    b) DSHS Consent to Release Confidential Medical Information (Spanish L-30a)
    c) Disclosure and Consent for LTBI Therapy (TB-415a)

B. **Initial Assessment by Nurse in México**

1. Complete an initial health risk assessment/history BN-202 or the equivalent, to include signs, symptoms, risk factors, a list of current medications, and all medical history.
2. Obtain weight, body mass index (BMI), height, and document in the medical record.

3. Conduct initial interviews and develop a case management plan within ten business days of the patient referred to and accepted into the BNTB program. Document on the BN-210 or equivalent.
4. Perform baseline toxicity checks on all patients and document on the BN-205 or its equivalent.
5. Perform baseline laboratory tests, as ordered by the physician. For patients aged 12 years and older, screen for HIV using an approved laboratory-based HIV immunoassay.
6. Educate and assess the patient's understanding of the disease, medications, expectations of treatment, and compliance to achieve completion of preventive therapy, BN-203 or equivalent.
7. Submit copies of the medical record to the BNTB coordinator who maintains an up-to-date shadow chart; provide copies initially, monthly, and at closure or anytime changes are made to the treatment regimen.

C. **Assessment by the Physician in México**

1. Perform and document an initial physical examination on all patients with LTBI, including those who qualify for window prophylaxis. Follow-up physical evaluations should also occur anytime the patient experiences medication toxicity requiring medications to be held.
2. Evaluate and assess the patient anytime there is concern for medication toxicity. There should be clear documentation in the patient's medical record of the physician's evaluation and steps taken to address medication toxicity.
3. Submit a consultation request to the Texas consulting physician anytime clinical guidance is needed or as outlined in APPENDIX D: MEDICAL CONSULTATION PROCESS.
4. Write orders for treatment using the BN-400A or equivalent and provide a copy to the nurse for administration of medication. Ensure a copy is provided to the BNTB coordinator to be kept in the shadow chart.

D. **Texas Consulting Physician**

1. Provide consultation recommendations in writing for patients with LTBI as requested by the México treating physician. See APPENDIX D: MEDICAL CONSULTATION PROCESS.

E. **Chest X-Rays (CXR)**

1. Perform a CXR on all enrolled patients with a positive IGRA or TST prior to initiating treatment for LTBI. An initial CXR is also required for patients eligible for window prophylaxis, regardless of IGRA or TST results.
2. Perform posterior/anterior (PA) CXR on adults aged 18 years or older and, PA and lateral (LA) for those less than 18 years of age or patients with HIV infection, at minimum.
3. Perform a CXR on contacts who are exposed to a person with known or suspected TB regardless of IGRA or TST results. This includes the following contacts:
    a) Children less than five years of age;

b) Persons who are HIV positive;
c) Persons with other immunocompromised conditions or receiving immunosuppressive therapy; or
d) Persons exhibiting signs and symptoms of active TB disease.

4. Shield pregnant females with a lead apron over the abdomen.
5. Perform a CXR on contacts with a documented history of LTBI who never received treatment prior to initiating treatment.
6. Perform a follow-up CXR before continuing treatment for LTBI or window prophylaxis for the following:
    a) Patients who exhibit symptoms suggestive of TB disease,
    b) Patients, who prior to initiation of therapy, did not start treatment for LTBI within one month of the initial CXR showing no abnormalities suggestive of TB disease, and are at high risk of progression to active TB disease,
    c) Patients who have an interruption in treatment for LTBI longer than one month during the first two months of treatment and are at high risk of progression to active TB disease (see list below). Otherwise, reimaging is not necessary unless the patient has symptoms consistent with active TB disease,
    d) Other patients who are not at high risk of progressing to active TB who have not started treatment for LTBI within six months of initial CXR showing no abnormalities suggestive of TB disease, and
    e) Other patients who are not at high risk of progressing to active TB disease who have an interruption of treatment for LTBI and need to be restarted on medications.

The following patients with LTBI are at high-risk of progressing to active TB disease:

1. Children younger than five years of age
2. Patients who have HIV infection or at risk for HIV infection
3. Patients who have an immune compromising condition or other clinical condition that is associated with progression to active TB (such as substance abuse, silicosis, underweight by more than 5%, diabetes, chronic renal failure, gastrectomy, jejunoileal bypass, solid organ transplantation, and head and neck cancer)
4. Patients receiving immunosuppressive therapy
5. Patients within groups having high rates of TB transmission [homelessness, injection drug users] or within groups who work or reside with people who are at high risk for TB in facilities or institutions [hospitals, homeless shelters, correctional facilities, nursing homes, residential homes for those with HIV]
6. Patients* without TB signs and symptoms who have a documented change in TB screening test results from a negative to a positive, and other patients who have been recently infected with TB (such as close contacts of a person with infectious TB disease, patients who have immigrated from areas of the world with high rates of TB).
7. Patients* with pulmonary fibrotic lesions seen on CXR (presumed to be from prior, untreated TB).

**Do not delay treatment if obtaining a CXR on these patients. If needed, start therapy while awaiting coordination of CXR.*

F. **Laboratory Tests**

1. Screen all patients aged 12 years and older for HIV risk factors and offer an HIV test.
2. Screen patients aged 12 years and older for diabetes unless the patient has the appropriate documented diabetes test results from a specimen collected within the last 14 days. Obtain a copy of the results and document them in the patient's medical record.
    a) Screen using, at a minimum, a fasting blood glucose or HbA1c for patients with known diabetes.
    b) Screen using, at a minimum, a random blood glucose test for patients whose diabetes is unknown.
3. Screen the following populations for hepatitis B virus (HBV) with a triple panel test: hepatitis B surface antigen (HBsAg), antibody to hepatitis B surface antigen (anti-HBs), and total antibody to hepatitis B core antigen (total anti-HBc):
    a) Patients aged 18 years and older with no identified HBV risk factors who do not have documentation of ever being screened at least once.
    b) Pregnant women who do not have a documented screening test result during the current pregnancy.
    c) Patients with any of the following risk factors who do not have a documented negative screening test result in the previous 14 days:
        i. Born in the following regions: Western Pacific (includes China, Cambodia, Vietnam, the Philippines, Korea); Africa (Democratic Republic of Congo, Ethiopia, Guinea, Kenya, Eritrea, Sierra Leone); Southeast Asia (Bangladesh, Nepal, India, Myanmar/Burma); Eastern Mediterranean (Afghanistan, Iraq, Kuwait, Pakistan, Yemen, Sudan, Syria). Additional information can be found at: https://wwwnc.cdc.gov/travel/yellowbook/2018/infectious-diseasesrelated-to-travel/hepatitis-b
        ii. U.S. born persons not vaccinated as infants. 3) Persons with behavioral exposures to HBV (e.g., men who have sex with men, past or current injection drug users, history of incarceration). 4) Persons with liver disease or elevated ALT/AST of unknown etiology. 5) Household contacts and sex partners of HBV-infected persons. 6) Persons with HIV. 7) Persons on dialysis.

    If the following applies, do not screen for HBV:

    a) If the patient has a previously documented positive HBV test result, HBV testing does not need to be repeated. Obtain a copy of the results and document them in the patient's medical record.

    For additional information about HBV risk factors and screening recommendations, see https://www.cdc.gov/hepatitis-b/hcp/diagnosistesting/index.html.

4. Screen the following populations for hepatitis C virus (HCV) using an FDA-cleared test for antibody to HCV (i.e., immunoassay, enzyme immunoassay (EIA), or enhanced chemiluminescence immunoassay (CIA) and, if recommended, a supplemental HCV test; refer to https://www.cdc.gov/hepatitis-c/hcp/diagnosistesting/index.html):
    a) Patients aged 18 years and older with no risk factors for HCV who do not have documentation of ever being screened at least once.
    b) Pregnant women who do not have a documented screening test result during the current pregnancy.
    c) Patients with any of the following risk factors who do not have a documented negative screening test result in the previous 14 days:
        i. Current or past injection drug use, including those who injected once or a few times many years ago.
        ii. History of incarceration.
        iii. Have certain medical condition, including persons who:
            (a) Received clotting factor concentrates produced before 1987
            (b) Were ever on long-term dialysis
            (c) With persistently abnormal ALT levels (if known or previously documented.
            (d) Have HIV infection.
        iv. Were prior recipients of transfusion or organ transplants, including persons who:
            (a) Were notified that they received blood from a donor who later tested positive for HCV infection.
            (b) Received a transfusion of blood, blood components or an organ transplant before July 1992.
        v. Being born to a mother with HCV infection.
        vi. Intranasal drug use.
        vii. Receipt of unregulated tattoo.
        viii. Other percutaneous exposures.

    If the following do not apply, do not screen for HCV:

    a) If the patient has a previously documented positive HCV test result, HCV testing does not need to be repeated. Obtain a copy of the results and document in the patient's medical record.

    Additional information can be found at: www.cdc.gov/hepatitisc/hcp/diagnosis-testing/index.html

5. Perform the following laboratory tests on patients receiving treatment for LTBI (including patients on window prophylaxis) age 18 or older under the following circumstances as ordered by the treating physician:
    a) Perform the following blood chemistry tests at <u>baseline</u>:

i. Measure aspartate transaminase (AST), alanine transaminase (ALT), total bilirubin (T Bil), alkaline phosphatase (Alk Phos), and albumin for all patients starting treatment for LTBI who have risk factors for potential hepatotoxicity or other complications, including but not limited to:
   (a) Pregnant patients
   (b) Female patients during the first 3 months postpartum
   (c) Patients with or at risk for hepatitis B virus (HBV), hepatitis C virus (HCV), or other liver disorders
   (d) Patients with other comorbidities or chronic medical conditions
   (e) Patients who use alcohol or recreational drugs (orally or by injection)
   (f) Patients with HIV infection/AIDS
   (g) Patients on medications that affect or are excreted by the liver
ii. Complete blood count (CBC) if starting on a rifamycin.

b) Perform the following blood chemistry tests <u>monthly</u>:
   i. Measurements of AST, ALT, T Bil, and/or Alk Phos if the baseline result is abnormal.
   ii. CBC, if patient will be taking a regimen that includes a rifamycin if the baseline CBC is abnormal.
   iii. Measurements of AST, ALT, T Bil, and Alk Phos for patients with risk factors for hepatotoxicity or other complications, including but not limited to:
      (a) Pregnant patients
      (b) Female patients during the first three months postpartum
      (c) Patients with or at risk for HBV, HCV, or other liver disorder
      (d) Patients with other comorbidities or chronic medical conditions
      (e) Patients who use alcohol or recreational drugs (oral or by injection)
      (f) Patients with HIV infection/AIDS
      (g) Patients on medications that affect or are excreted by the liver

c) Perform the following blood chemistry tests <u>as needed</u>:
   i. Measurement of AST, ALT, T Bili if:
      (a) AST, ALT and/or bilirubin level exceeds more than three times the upper limit of normal in the presence of symptoms, or
      (b) AST, ALT levels exceed more than five times the upper limit of normal with or without symptoms, or
      (c) Bilirubin exceeds two times the upper limit of normal.
   ii. Measurement of complete metabolic panel (CMP) and CBC if signs and symptoms of hepatotoxicity are present, including nausea and vomiting.
   iii. If at any time during treatment the patient has signs and symptoms of liver toxicity, the treating physician should be notified, medications should be held, and the treating physician should provide further instructions/orders to the nurse.

6. For patients younger than 18 years of age, consider performing blood chemistry tests if they have any of the following conditions:

a) Chronic medical conditions,
b) On chronic medications,
c) Increased body mass index (BMI),
d) Pregnancy,
e) Disseminated disease, or
f) Who reports substance use.

Alkaline phosphatase levels vary in children with growth cycles; therefore, special considerations are needed when interpreting pediatric laboratory values.

G. **Treatment**

1. The treating physician should use clinical judgment when deciding to treat a contact with LTBI if the index case does not have drug susceptibility test results. The following should be taken into consideration:
    a) Index case's response to treatment; and
    b) Risks versus benefits of treatment.
2. Treatment for LTBI should begin ideally, but no later than within one month of diagnosis. Otherwise, repeat radiology may be indicated; refer to letter E. Chest - X-Rays.
    a) High-risk contacts in whom window prophylaxis is recommended should begin therapy as soon as possible, but no later than 14 days of identification.
3. The treating physician must provide written orders for LTBI, ensuring the appropriate weight-based dosages are calculated for each patient.
    a) If verbal orders are given to the nurse, the physician should sign the verbal order within one week.
4. The nurses in México and the BNTB coordinator should review the most recent TB medication orders and ensure appropriate weight-based doses are ordered. Keep a copy in the Texas shadow chart. Nurses in México will ensure the patient updates and signs a medication consent to reflect current drug regimens. Provide a copy to the patient and keep a copy in the patient's medical record.
5. Patients declining treatment for LTBI, including patients recommended for window prophylaxis, will be counseled regarding the benefits of therapy and the risk of not taking treatment. Complete the TB 240A, documenting the patient's declination, and obtain their signature. A copy will be given to the patient, and a copy should be saved in the patient's medical records in Texas and México.
6. Counsel female patients of child-bearing age on the impact of rifamycin on hormonal contraception and the need for the addition of a barrier birth-control method.
7. DOT is recommended until completion of therapy for the following patients:
    a) Contacts to multidrug-resistant (MDR) TB, pre-extensively drug-resistant (pre-XDR) TB, or extensively drug-resistant (XDR) TB.
    b) Children aged less than five years should be highly considered for DOT.

c) Intermittent regimens (self-administration) may be considered for select patients on 3HP if specified by the treating physician. Mechanisms to ensure adherence to treatment must be in place.

8. Window prophylaxis is strongly recommended for the following patients:
    a) Children younger than five years of age.
        i. Note: Children less than six months old should continue window prophylaxis until they undergo a repeat TST at six months of age.
    b) Patients with HIV infection*
    c) Patients receiving immunosuppressive therapy for organ transplantation*
    d) Patients taking TNF-α inhibitors*

**Patients in this category are likely to progress to TB disease. Therefore, a complete course of LTBI treatment should be completed if the TB screening test was administered ≥8 weeks after the end of exposure and the TST or IGRA result remains negative.*

H**. Completion of Therapy for LTBI**

Rifamycin-based regimens are preferred for their effectiveness, safety, and high treatment completion rates.

1. Below are the minimum number of doses required, and the corresponding time frame for acceptable completion of therapy.
    a) <u>INH/RPT (3HP)</u> = Preferred regimen strongly recommended for adults and children aged > 2 years of age, including HIV-positive persons, as drug interactions allow.
    b) 12 doses (minimum of 11 doses acceptable) administered in no fewer than 12 weeks (but no more than 16 weeks). Doses must be separated by ≥72 hours to be counted.
    c) <u>4 months of RIF (4R)</u> = Strongly recommended for HIV-negative adults and children of all ages.
        i. 7 days per week for 120 doses taken within 6 months, OR
        ii. 5 days per week for 90 doses administered by DOT within 6 months.
    d) <u>3 months of INH and RIF (3HR)</u> = Preferred treatment for adults and children of all ages and for HIV-positive persons as drug interactions allow.
        i. 7 days per week for 90 doses taken within 4 months.
    e) <u>6 months of INH daily (6H)</u> =
        i. 7 days per week for 180 doses taken within 9 months, OR
        ii. 5 days per week for 129 doses administered by DOT within 9 months.
    f) <u>6 months of twice-weekly INH (6H) (by DOT ONLY)</u> =
        i. Twice weekly for 52 doses administered by DOT within 9 months.
    g) <u>9 months of INH daily (9H)</u> =
        i. 7 days per week for 270 doses taken within 12 months, or
        ii. 5 days per week for 195 doses administered by DOT within 12 months.
    h) <u>9 months of twice-weekly INH (9H) (by DOT ONLY)</u> =

i. Twice weekly for 76 doses administered by DOT within 12 months.

2. For persons treated empirically for TB disease for two months with at least INH, RIF, and pyrazinamide (PZA) and are subsequently determined to have LTBI, this regimen can be considered an effective and complete treatment of LTBI.

I. **Interruptions of Therapy for LTBI**

If the minimum number of doses cannot be completed within the maximum time frame allowed, as described above: H. COMPLETION OF THERAPY for LTBI, treatment should be restarted. Contact the treating physician for instructions.

J. **Monitoring**

1. Educate and monitor patients monthly for signs and symptoms of medication toxicity and provide monthly face-to-face clinical assessments.
    a) Patients taking rifabutin (RBT), should receive baseline and monthly clinical monitoring. Inquire about eye pain, overall vision changes, and/or sensitivity to light.
2. Document on BN-205 or equivalent and report any signs and symptoms of medication toxicity to the physician immediately.
3. Obtain a clinical evaluation with the treating physician as soon as possible if signs and symptoms of toxicity occur. Take appropriate steps as ordered by the treating physician and as designated below:
    a) Conduct laboratory tests as ordered.
    b) Instruct the patient to stop medication, if indicated.
    c) Instruct the patient to follow the following precautions: avoid medications that contain acetaminophen (Tylenol) and avoid alcohol. The nurse should review all medications the patient takes, including over-the-counter medications and supplements. Educate on adequate fluid intake.
    d) If medication is not restarted, educate the patient on the signs and symptoms of active TB, and instruct the patient to report for re-evaluation.
    e) If medication is restarted, continue to monitor monthly and issue medication in accordance with the physician's orders.
4. Document and report any abnormal laboratory results to the treating physician for review.

K. **Review and Close Medical Record**

1. The treating physician in México will review and document in the patient's medical record at the following intervals:
    a) Initially;
    b) At closure; and
    c) Anytime medications are held or changed.
2. Close the patient's medical record using the following dispositions:
    a) Completed adequate therapy; indicate the number of months on medication and number of months recommended

b) Deceased (Cause of death)
c) Moved out of state/country
d) Lost to follow-up
e) Patient chose to stop
f) Adverse drug reaction
g) Provider decision - pregnant, non-TB, or
h) Other

3. Report to the referring entity closure disposition.

X. Management of Patients with Suspected or Confirmed Tuberculosis

General Requirement

This chapter outlines minimum activities to perform when initiating treatment and providing outpatient medical case management for patients with suspected or confirmed TB. These are not SDOs, and programs must ensure that the nurse receives written or verbal orders from the treating physician to carry them out.

When patients are referred to the BNTB program from México's Regional Mycobacteriology TB Program for outpatient TB services, routine communication is required. Communication allows for routine case management updates and helps ensure compliance with disease reporting and surveillance guidelines in México. It also allows for the co-management of patients through a Texas-México partnership.

Activities

A**. Administrative**

1. Collaborate with México's Nacional TB program to provide outpatient case management, DOT, radiology, laboratory, medications, nursing, and physician services as needed.
2. Create a medical record for each patient with suspected or confirmed TB disease. Medical records will be organized with clear division of sections as determined locally using forms in APPENDIX F: BINATIONAL TB PROGRAM CLINICAL CARE FORMS, or their equivalent. All entries in the medical record are signed, dated, and in chronological order with no blank spaces in the progress notes. A line should be drawn through open spaces. Medical records kept at the clinic in México and the shadow chart retained in the Texas program will include at minimum, the following:
    a) BN-200- *Forma de Referido* (referral form) if aplicable
    b) BN-400A - Report of Case and Patient Services
    c) BN-400B – Report of Case and Patient Services
    d) BN-201 - Case Management Plan for Outpatient Care
    e) BN-202 - TB Initial Health Risk Assessment/History
    f) BN-203 - Education/Counseling Record
    g) BN-205 - TB Toxicity Assessment
    h) BN-206 - Directly Observed Therapy Log
    i) TB-231a - Bacteriology Monitoring
    j) Radiology Reports (initially, at 2 months, at closure, and as ordered)
    k) Laboratory Results
    l) TB-700 - Series for drug-resistant patients
    m) TB-902a – Patient Acknowledgment of Conditions for TB Isolation Release
    n) Progress Notes
    o) Contact Investigation Records (12-12062a, TB-340a, TB-341a)
3. Obtain general consents and disclosures for treatment.
    a) DSHS General Consent and Disclosure (L-36a)

b) DSHS Consent to Release Confidential Medical Information (Spanish L-30a)
p) TB-411a - Disclosure and Consent Drug Therapy TB (Spanish)

B. **Initial Assessment by the Nurse in México**

1. Collect and send information to the BNTB program coordinator for review and acceptance or denial into the program. See APPENDIX B: PROCESS FOR ENROLLMENT.
2. Conduct initial interviews and develop a case management plan within five business days of the patient being referred to and accepted into the BNTB program. Document on the BN-201 or equivalent.
3. Complete BN-202 or equivalent to include symptoms, risk factors, and a list of current medications.
4. Perform an appropriate nursing assessment to include current weight, BMI, and height, and document in the patient's medical record.
5. Administer an IGRA test if the patient has suspected or confirmed TB disease, and there is no documentation for receiving a screening test. If the patient is unable to receive an IGRA or refuses phlebotomy, administer a TST.
6. Perform baseline toxicity checks on all patients and document using the BN-205 or equivalent or TB-702a for drug-resistant patients.
7. Educate and assess the patient's understanding of the disease, medications, laboratory tests, expectations of treatment, isolation, and adherence necessary to achieve a cure.
8. Ensure a TB-411a or equivalent is signed and dated any time TB treatment is initiated, changed, or when a new medication is added.
9. Ensure initial assessment and physical examination are performed by a physician in México.

C. **Assessment by México's Treating Physician**

1. Perform an in-person physical examination on patients suspected or confirmed with TB disease at the following intervals:
    a) Initially,
    b) Monthly,
    c) At the end of two months of treatment (eight weeks of therapy or upon completion of the initial phase if greater than eight weeks),
    d) At closure, and
    e) Anytime toxicity signs or symptoms develop requiring medications to be held.
2. Document the patient's status monthly either on BN-400B or progress note and provide a copy to the BNTB coordinator.
3. Review medications for drug interactions. Refer to: https://www.drugs.com/

D. **Texas Consulting Physician**

1. Provide consultation recommendations in writing to the treating physician in México, as requested.

2. When necessary, coordinate clofazimine (CFZ) enrollment. Refer to CHAPTER XIV MANAGEMENT OF MEDICATIONS AND MEDICATION AVAILABILITY.

E. **Chest X-Rays**

1. Perform PA and LA CXRs for patients less than 18 years of age or patients with HIV infection at a minimum. Perform PA for patients aged 18 years and older.
2. Perform CXR without delay on pregnant patients being evaluated for active TB disease. Perform CXR with appropriate shielding, even if in the first trimester, if indicated.
3. Conduct chest x-rays at least, at minimum, in the following intervals:
    a) At baseline,
    b) Upon completion of two months of therapy, and
    c) At or near completion of therapy.
4. Follow-up chest x-rays are not needed for the following:
    a) If a previous chest x-ray (baseline or at two months) is normal,
    b) The patient is diagnosed with extrapulmonary TB disease, and pulmonary TB is ruled out, as evidenced by normal CXR results and negative AFB sputum results if sputum was collected.
5. Send chest X-rays for interpretation with results reviewed by the treating physician.

F. **Sputum Collection**

1. Collect and send sputum specimens to the DSHS laboratory only if the BNTB program accepted the patient into care.
2. Send specimens to the DSHS laboratory in Austin for processing.
    a) Use appropriate requisitions required by the DSHS laboratory.
    b) Use best practices for submitting sputum specimens. This should be as soon as possible or no longer than one week from collection if kept refrigerated.
    c) Transport specimens to the laboratory on cold packs to preserve the specimen as long as possible.
3. Collect three consecutive sputum specimens (for all patients) – ideally 24 hours apart, but at minimum eight hours apart, ideally with no more than 96 hours between the first and the third sputum specimen collection - with at least one specimen collection observed and one collection in the early morning. Sputum collection must occur within seven days before (preferably to) seven days after the medication start date. Copies of the sputum results will be kept in both the main medical record in México and the shadow chart in Texas.
    a) Submit three sputum specimens for AFB smear and culture results.
        i. The DSHS laboratory will perform DST reflexively on the initial *M. tb* culture-positive specimen.
        ii. The DSHS laboratory will repeat the DST if the patient is still *M. tb* culture-positive three months or more after the initial specimen collection date, or upon physician request. Note: The DSHS laboratory reports FQN susceptibilities using ofloxacin testing.

b) For all patients with no laboratory confirmation of a rapid test showing RIF resistance (i.e., GeneXpert), regardless of positive *M. tb* cultures, request NAAT on one of the first three diagnostic sputum specimens and label the initial specimens "1 of 3," "2 of 3," and "3 of 3" unless DST results are known. The laboratory will perform NAAT on only the most suitable specimen.

c) For patients who have an initial AFB sputum smear positive result, and the NAAT is negative, the DSHS laboratory will reflexively perform a second NAAT on a second AFB smear positive specimen if it is available.

i. Repeat NAATs will only be performed if the second specimen is AFB smear positive.

ii. If a second AFB sputum smear positive specimen is not available, contact the treating physician if a repeat NAAT is needed to develop a treatment plan.

4. For patients who have positive initial AFB smears at the time of diagnosis, collect three sputum specimens, with at least one specimen collected in the early morning for AFB smear at least monthly until three consecutive specimens are negative on AFB smear.
5. For all patients, collect up to three sputum specimens, with at least one specimen collected in the early morning, at least once a month until two consecutive specimens (at least one month apart) are negative on culture. (At this point, the patient has reached culture conversion).
6. For all patients with pulmonary disease, if possible, collect one final sputum specimen in the early morning for AFB culture at completion of therapy.
7. For patients with suspected or known extrapulmonary TB, make attempts to collect three sputum specimens ideally 24 hours apart, but at a minimum of eight hours apart.

a) At least one sputum specimen collection should be observed, with one collected in the early morning, even if the CXR is normal, to exclude concomitant pulmonary disease.

b) If gastrointestinal (GI) or genitourinary (GU) TB is suspected, collect stool or urine samples in addition to sputum (as above) and send for NAAT, AFB smear, and culture. In addition, submit any specimen collected on an extrapulmonary site, including cerebral spinal fluid (CSF), aspirates from a lymph node or pleural fluid, peritoneal fluid, and an aspirate from a purulent collection or biopsy site for AFB smear, culture, and NAAT. Coordinate with the receiving laboratory and contact the DSHS state laboratory for submission criteria prior to shipping. See: http://www.dshs.texas.gov/lab/myco_home.shtm.

G. **Isolation**

1. Implement location-appropriate isolation for patients suspected or confirmed to have TB disease. Every effort should be made to ensure the patient adheres to

respiratory isolation restrictions as instructed by the nurse and/or physician in México. Document and sign using the TB-902a or equivalent.
2. Follow the criteria for placing patients in and releasing from TB isolation and restrictions following the DSHS TB Isolation and Restrictions Implementation Guide.

H. **Laboratory**

1. Laboratory tests should be ordered by the treating physician for patients aged 18 or older with suspected or confirmed drug-susceptible TB.
2. Screen patients aged 12 years and older for HIV risk factors and offer an HIV test.
3. For patients aged 12 years and older, screen for diabetes unless the patient has the appropriate documented diabetes test results from a specimen collected within the last 14 days. Obtain a copy of the results and document them in the patient's medical record.
    a) Screen at a minimum using a fasting blood glucose or HbA1c for patients with known diabetes.
    b) Screen at a minimum using a random blood glucose test for patients whose diabetes status is unknown.
4. Perform the following blood chemistry tests at baseline:
    a) Measurement of CBC.
    b) Liver function tests to include at least: AST, ALT, T Bil, Alk Phos, albumin, and creatinine.
5. Perform the following blood chemistry tests monthly:
    a) Measurement of CBC if baseline result is abnormal.
    b) Measurements of AST, ALT, T Bil, and Alk Phos for patients whose baseline results are abnormal, and/or those with risk factors for hepatotoxicity or other complications, including but not limited to:
        i. Pregnant patients
        ii. Female patients during the first three months postpartum
        iii. Patients with or at risk for HBV, HCV, or other liver disorders
        iv. Patients taking medications for other comorbidities or chronic medical conditions that may affect the liver or kidneys
        v. Patients who use alcohol or recreational drugs (orally or by injection)
        vi. Patients with HIV infection/AIDS
        vii. Patients on medications that affect or are excreted by the liver.
6. Perform the following blood chemistry tests, as needed:
    a) Measurement of AST, ALT, and T Bil if:
        i. ALT or AST are more than three times the upper limit of normal in the presence of symptoms,
        ii. ALT or AST are more than five times the upper limit of normal with or without symptoms, or
        iii. Bilirubin exceeds two times the upper limit of normal.
    b) Measurements of a CMP and a CBC if signs or symptoms are compatible with hepatotoxicity, including nausea or vomiting. Contact the treating physician.

Hold the medications, and the treating physician should provide further instructions and orders to the nurse.

c) If at any time during therapy the patient has signs and symptoms of liver toxicity, notify the treating physician, hold the medications, and obtain an AST, ALT, T Bil, Alk Phos, and albumin with physician orders.

d) Therapeutic drug monitoring will be approved on a case-by-case basis after discussion with the treating or consulting physician and the BNTB nurse consultant.

7. Screen for Hepatitis B virus (HBV) and Hepatitis C (HCV) following the criteria outlined in CHAPTER IX. MANAGEMENT OF PATIENTS WITH LATENT TB INFECTION, INCLUDING PATIENTS ON WINDOW PROPHYLAXIS, F. #3 AND #4.

I. Monitoring

1. Educate patient at baseline and monthly on signs and symptoms of drug toxicity and document on BN-205 and/or TB-702a for drug-resistant patients or equivalent.
2. Obtain monthly weights on patients. Weigh the patient the same way each time (e.g., shoes on or off, etc.). Calculate BMI.
    a) Pediatric patients may require weights more frequently as determined by the treating physician. Consideration should be given to very young children whose weight may increase more rapidly.
3. Monitor monthly for adherence to treatment and compliance with DOT.
4. Monitor and document smear and culture conversion as outlined in Section G. Sputum Collection in this chapter.
5. Perform clinical evaluations promptly when signs or symptoms of medication toxicity develop. Hold medications, contact the treating physician, and do not resume until the physician orders their restart.
6. Report and obtain guidance from the BNTB coordinator when special circumstances arise, such as the provision of self-administered medication doses when a patient will have an extended period without access to DOT/DOPT treatment, especially with regard to pediatrics or drug-resistant patients.
7. Perform baseline and monthly clinical monitoring for the following medications:
    a) If patient is taking ethambutol (EMB), include:
        i. Red/green color discrimination using Ishihara plates, and
        ii. Visual acuity using the Snellen chart.
    b) If the patient is taking RBT, inquire about eye pain, overall vision changes, and/or sensitivity to light.
    c) If patient is taking high-dose INH (adults 15mg/kg), include:
        i. Peripheral neuropathy screening.
    d) If patient is taking an FQN (e.g., levofloxacin or moxifloxacin), perform a tendon assessment.

J. **Treatment**

1. Physicians shall provide treatment consistent with the guidelines listed in CHAPTER VIII. STANDARDS OF CARE.
2. Develop a treatment plan **within five business days** of receiving an eligible patient into the program or within five business days of receiving treatment recommendations from the Texas consulting physician.
3. Determine if the patient can be treated with doTBal or if doTBal should continue if already started. See L, Use of doTBal for Drug-Susceptible TB Disease for criteria when doTBal may be used or refer to the Official Mexican Normas for treatment guidelines.
4. If treatment is adequate and no adjustments are needed, the BNTB treating physician should complete and sign the BN-400B with treatment orders. Send a copy to the BNTB coordinator for inclusion in the Texas shadow chart.
5. For patients who cannot take doTBal alone and need an individualized treatment regimen to either augment doTBal or to replace it entirely, the BNTB treating physician may complete and sign the BN-400B. Send a copy to the BNTB coordinator to be kept in the Texas shadow chart, and order medications from the pharmacy ordering system.
6. An alternate short-course TB regimen called **SHINE** may be used in children with non-severe drug-susceptible TB. Consider this regimen for children with minimal disease. Many children identified through screening activities, such as a contact investigation or others recently infected, may be good candidates for this regimen. A consultation with a Texas consulting physician is required. See Appendix D. Medical Consultation Process.
7. Follow the process outlined in Appendix D: Medical Consultation Process for a complete list of recommended or required consultation processes.
8. The BNTB treating physician will provide information to the nurse prior to medication administration. Send a copy to the BNTB coordinator to be kept in the Texas shadow chart.
9. The nurse shall review the most recent TB medication regimen ordered by the physician; a copy should be placed in the medical record including an updated medication consent form.
    a) Verify appropriate weight-based dosage calculations for all patients. For purposes of dosage calculations and treatment regimen selection, a patient is considered a child if the patient is less than 18 years of age and should receive pediatric weight-based dosing of medications.
10. Administer all regimens for TB disease via DOT or VDOT. Physicians will give orders for VDOT if the patient meets the criteria. See Video-Enabled Directly Observed Therapy, Required and Recommended Activities (texas.gov) for inclusion and exclusion criteria.

11. The treating physician will complete and sign BN-400B, at the start of treatment, at the end of two months of therapy, at the end of therapy or anytime there is a change in treatment.
12. Follow guidelines for completion of therapy for drug-susceptible TB disease using U.S. standards of care when doTBal is not used. The traditional standard of care covering six-to-nine months of treatment uses a drug regimen consisting of RIPE to treat active tuberculosis effectively. The following applies when using RIPE:
    a) Completion of therapy is based on the total number of doses administered (allowing for minor interruptions in therapy) not on the duration of therapy (months) alone.
    b) Daily dosing, five or seven days per week, throughout the course of therapy is preferred over intermittent dosing when treating under Texas standards of care and doTBal is not an option. Interventions to support seven days per week, including VDOT, should be arranged, when possible, as intermittent dosing is less efficacious and leads to higher rates of relapse. Patients may self-administer medications on weekends and/or holidays if seven days per week cannot be arranged.
    c) Six months (26 weeks) is generally the minimum duration of treatment.
        i. The eight-week intensive phase must be completed within ten weeks.
        ii. The four-month continuation phase must be completed within six months.
        iii. The six-month regimen must be completed within nine months.
    d) Nine months (39 weeks) is recommended for patients with cavitation on initial chest radiograph and who remain culture positive at completion of two months of therapy. See 15 below for more details related to the extension of therapy.
        i. The eight-week intensive phase must be completed within ten weeks.
        ii. The seven-month continuation phase must be completed within nine months.
        iii. The total nine-month regimen must be completed within 12 months.
14. Refer to Tables 3 and 4 for total DOT doses required for treatment completion for the traditional standard six-to-nine drug regimen (RIPE), per phase:
    a) **Initial phase to total eight weeks**: The initial phase must be documented as completed before counting doses for the continuation phase.
    b) **Continuation phase to total 18 or 31 weeks (INH/RIF):** Doses for the continuation phase should not be counted until the initial phase of treatment has been documented to be appropriately completed.

Table 3: Total DOT Doses, Initial Phase

Regimen	Total DOT Doses For INITIAL PHASE Completion
1	7 days per week for **56** doses administered by DOT in 8 weeks, OR 5 days per week for **40** doses administered by DOT in 8 weeks
2	7 days per week for **56** doses administered by DOT in 8 weeks, OR 5 days per week for **40** doses administered by DOT in 8 weeks
3	3 times weekly for **24** doses administered by DOT in 8 weeks

Table 4: Total DOT Doses, Continuation Phase

Regimen	Total DOT Doses For CONTINUATION PHASE Completion
1a	7 days per week for **126** doses administered by DOT in 18 weeks OR 5 days per week for **90** doses administered by DOT in 18 weeks
1b	7 days per week for **217** doses administered by DOT in 31 weeks, OR 5 days per week for **155** doses administered by DOT in 31 weeks
2a	3 times weekly for **54** doses administered by DOT in 18 weeks
2b	3 times weekly for **93** doses administered by DOT in 31 weeks
3a	3 times weekly for **54** doses administered by DOT in 18 weeks
3b	3 times weekly for **93** doses administered by DOT in 31 weeks

15. Consider the following factors when determining to extend length of treatment:
    a) If PZA cannot be included throughout the initial phase of treatment (minimum of 40 doses given five days per week by DOT or 56 doses given seven days per week by DOT), or those with *M. bovis*, the continuation phase of treatment must be extended to seven months (31 weeks) for a total minimum duration of treatment of nine months (39 weeks).
        i. NOTE: *M*. *bovis* is naturally resistant to PZA. Infection with *M*. *bovis* or PZA-resistant *M. tb* requires a minimum of nine months (39 weeks) of treatment. Consultation is not required for *M*. *bovis*.
    b) Patients with cavitation or extensive pulmonary TB disease on initial CXR and a positive culture result at the time of completing two months (8 weeks) of treatment are at substantially increased risk of relapse. The continuation phase for these patients is recommended to be prolonged to seven months (31 weeks), to complete a total treatment period of 9 months (39 weeks).
    c) Additional factors may be considered when deciding to prolong treatment in patients even when cultures convert by two months if the patient has extensive disease and slow clinical response or underlying chronic disease that increases poor outcome or relapse (e.g., dialysis, TNF alpha therapy, malignancy, diabetes, or any other immunosuppressing condition).

d) The following extrapulmonary TB sites require a longer duration of treatment:
    i. Bone and joint: nine months (39 weeks) of treatment recommended
    ii. Meningitis: nine to twelve months (39-52 weeks) of treatment recommended
    iii. Disseminated/miliary TB in children with HIV: nine to twelve months (39-52 weeks) of treatment recommended
    iv. Any site that is slow to respond should be considered for prolongation of treatment

16. When a decision to treat culture-negative TB disease is considered, an alternative diagnosis must be carefully assessed, and additional diagnostics may be needed.
    a) Culture-negative pulmonary TB is defined as symptomatic or radiographic improvement after two months of RIF, INH, PZA, and EMB (RIPE) treatment in a patient for whom the clinical suspicion for active TB disease is high, AFB cultures were collected and are negative, and an alternative diagnosis/etiology has not been found.
    b) For adult patients, because of a potential for INH-resistance, treatment should be continued with INH, RIF, and EMB for an additional two months to complete a total of four months (18 weeks) of treatment.
    c) For pediatric patients with no identifiable source case, treatment should be continued with INH, RIF, and EMB for an additional four months (18 weeks) to complete a total of six months (26 weeks) of treatment.
    d) EMB can be discontinued if the patient with culture-negative pulmonary TB is a contact to a case and the susceptibilities of that case are known, and no resistance is detected.
    e) For culture-negative extrapulmonary TB, the treating physician determines treatment recommendations, preferably in consultation with a Texas consulting physician.
17. If RIF cannot be included in the treatment regimen, the minimum duration of treatment is 6-18 months (26-78 weeks). A medical consultation is required.

K. **Interruption of Treatment**

The nurse case manager should carefully monitor and address treatment interruptions early on and report them to the treating physician. Consider the number of planned doses and the duration of therapy.

The following guidelines apply for interruption of treatment:

1. Every dose counts and is necessary for the most effective therapy; patients can be at an increased risk of relapse when doses are missed.
2. Non-adherence is a significant risk for patients having unfavorable outcomes: Refer to https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6685538/.
3. In general, the longer the interruption and the earlier the interruption, the more serious the impact of the interruption.

4. DOT doses should be counted daily and monitored weekly, ensuring the patient completes the recommended number of doses each week.
5. The duration of therapy and the number of planned doses must be considered when counting doses.
6. When any interruption occurs during the **initial phase**, the following applies:
    a) If treatment is not completed in ten weeks of the initial phase, treatment should be restarted. Contact the treating physician for instructions.
    b) If any interruption of less than 14 *cumulative days* occurs, *treatment can continue.*
    c) When any interruption of 14 or more cumulative days occurs, the regimen should be restarted. Contact the treating physician for instructions.
        i. If treatment is interrupted for drug intolerance, the patient must be on an adequate empiric regimen (RIP [RIF, INH, PZA], RIE [RIF, INH, EMB], or RPE [RIF, PZA, EMB]) for doses to count towards completion of therapy.
        ii. If susceptibilities are known and there is no resistance to INH, RIF, or a FQN, either levofloxacin or moxifloxacin, then once the patient is on both INH and RIF, or RIF and an FQN, doses can count towards completion of therapy.
    d) When any interruption occurs in the **continuation phase**, the following applies:
        i. Ideally, 100% of doses should be completed. However, if a patient received ≥ 80% of doses in the continuation phase and sputum was AFB smear-negative on initial testing, additional treatment may not be necessary if adherence or other factors (e.g., safety concerns) make completing treatment difficult. Contact the treating physician.
        ii. If a patient received ≥ 80% of doses in the continuation phase and sputum was AFB smear positive on initial testing, continue therapy until all doses are complete.
        iii. If the patient received < 80% of the required doses in the continuation phase and missed *less than three months* of total doses throughout the intensive and continuation phase, continue therapy until all doses (100% of doses) are complete. However, therapy may need to be restarted in the following scenarios:
            (a) A consecutive lapse of > 2 months occurred, or
            (b) Treatment cannot be completed within the required time frame.
        iv. If the patient received < 80% of the required doses in the continuation phase and missed 3 months or more of total doses throughout the intensive and continuation phases, restart therapy.

L. **Use of doTBal for Drug-Susceptible TB Disease**

Apply the following when using doTBal for drug-susceptible TB disease:

1. doTBal is provided by the México Nacional TB Program if the patient does not require a complete individual treatment adjustment.
2. doTBal should not be used in the following circumstances:
    a) Drug-resistant TB,
    b) Patient is on medications that interact with RIF,
    c) Patient's weight is out of range for doTBal < 60kg and > 75kg, and/or
    d) Patient was referred to the BNTB program from the U.S., already on U.S. medications.
3. doTBal may be used if all the following criteria apply and the patient:
    a) Has drug-susceptible TB disease,
    b) Weighs between 60-75 kg,
    c) Has non-cavitary and non-extensive TB disease,
    d) Has baseline normal liver function tests,
    e) Is tolerating doTBal,
    f) Is HIV negative,
    g) Has no kidney disease,
    h) Is not on medications that interact with RIF, and/or
    i) Has not already started on US medications.
4. The treating physician should be familiar and up to date on treatment doses and regimens when using doTBal. Orders should be given correctly and documented using the BN-400B or the equivalent.
    a) Table 5: doTBal Initial Phase* Regimen and Table 6: doTBal Continuation Phase* - S Regimen indicates the dosing, number of doses, and duration requirements for doTBal as indicated by the Norma Oficial Mexicana NOM-006-SSA2-2013.
5. The treating physician should ensure patients on doTBal receive adequate doses prior to stopping treatment and completing as adequate therapy.

Table 5: doTBal Initial Phase* Regimen

Medications	Dosage per Pill	Recommended Dosage
Rifampicina (R)	150 mg	600 mg
Isoniacida (H)	75 mg	300 mg
Pirazinamida (Z)	400 mg	1600 mg
Etambutol (E)	300 mg	1200 mg
**60 total number of doses required for the initial phase* *Duration for the initial dose is 10 weeks, administered Sunday through Saturday.*		

Table 6: doTBal Continuation Phase* - S Regimen

Medications	Dosage per Pill	Recommended Dosage
Isoniacida (H)	400 mg	800 mg
Rifampicina (R)	300 mg	600 mg
**45 total number of doses required for continuation phase* *Duration for the continuation phase is 15 weeks (3.5 months) administered Monday, Wednesday, and Friday.*		

M. **Closing Patient's Medical Record**

Use the following dispositions when closing the patient's medical record and notify the referring jurisdiction:

1. Completion of adequate therapy
    a) Treatment completion within 12 months.
    b) Exceptions to completion of adequate treatment within 12 months apply if:
        i. Patient has RIF-resistant TB (RR-TB), multidrug-resistant TB (MDR-TB), pre-extensively resistant TB (Pre-XDR TB) or extensively resistant TB(XDR-TB);
        ii. Patient is aged 14 or younger with miliary disease; or
        iii. Patient has meningeal disease.
2. Non-TB
3. Deceased
4. Moved out of the country
5. Lost to Follow-up (LTFU)
    a) Make three attempts and document them in the patient's medical record to contact the patient before considering a patient as LTFU, including:
        i. Calling the patient;
        ii. Visiting the patient's residence (when possible); and
        iii. Send a mail notification to follow-up with the TB program, if applicable.

N. **Patient Travel**

Coordinate with the patient and other jurisdictions in Texas or México when a BNTB patient is on treatment for known or suspected TB and intends to travel.

1. The decision to accept a patient's request to travel outside the managing BNTB program area must be carefully considered by the treating physician and the patient.
2. Known or presumed infectious patients should not travel commercially.
3. Infectious patients who cross from Mexico to work in Texas should not be allowed to return to work until respiratory isolation is discontinued. Coordinate a public health response with the appropriate U.S. jurisdiction; provide clinical updates, e.g., response and adherence to treatment, DOT records, isolation plan with return-to-work clearance, and submit an IJN for exposed contacts. Note: Information sharing must comply with relevant data protection, confidentiality, and security standards outlined in Chapter XIX.
4. Follow APPENDIX N: INTERJURISDICTIONAL COMMUNICATION when coordinating travel.

O. **Requesting a Do Not Board (DNB)**

Request a Do Not Board (DNB) or Public Health Border Lookout (LO) consultation for any person with confirmed or suspected TB disease who plans to cross the U.S. border and/or board a commercial aircraft and is infectious or likely infectious, by emailing the DSHS epidemiology team at TBEPI@dshs.texas.gov. See APPENDIX O. DO NOT BOARD AND PUBLIC HEALTH LOOKOUT.

XI. Management of Patients with Drug-Resistant Tuberculosis

General Requirement

This chapter outlines minimum activities to be performed when managing a patient with DR-TB in the BNTB program. The BNTB programs will treat outpatient DR-TB in accordance with U.S. standards of care, in collaboration with and under mutual agreement with the Regional Mycobacteriology Programs.

A. Isoniazid mono-resistant TB – resistance to isoniazid, a first-line TB drug.
B. Rifampin-resistant TB (RR-TB) - mono resistance to rifampin or polyresistance to include rifampin and a first-line TB drug (excluding isoniazid); this type of DR-TB is treated similarly to MDR-TB.
C. Multidrug-resistant TB (MDR-TB) – resistance to at least rifampin and isoniazid.
D. Pre-extensively drug-resistant TB (Pre-XDR TB) – MDR, plus resistance to one of the second-line injectable agents (amikacin, capreomycin, or kanamycin) *or* an FQN.
E. Extensively drug-resistant TB (XDR-TB) – MDR, plus resistance to one of the second-line injectable (amikacin, capreomycin, or kanamycin) *and* a FQN *or* MDR, plus resistance to FQN, and bedaquiline or linezolid.

Activities

A. **Identifying Patients at Risk for DR-TB**

1. Risk factors include:
    a) Previous episodes of TB treatment, usually incomplete treatment.
    b) Worsening clinical and/or radiographic findings while on TB treatment.
    c) Country of origin, history of residence in, or frequent travel to a region or country with a high prevalence of DR-TB.
    d) Exposure to a person with known (or highly suspected) infectious DR-TB.
    e) Exposure to people in congregate settings where DR-TB has been documented.
2. BNTB programs are made aware of DR-TB when:
    a) Rapid testing identified from a GeneXpert-NAAT, or other PCR, indicates RIF resistance.
    b) DST results indicate resistance. Laboratory-confirmed drug resistance is defined as resistance to INH and/or RIF or to any drug other than streptomycin or PZA mono-resistance on drug susceptibility panel testing.
    c) Patient is reported with other laboratory results that indicate resistance, including MDDR or Whole Genome Sequencing (WGS) with RNA polymerase Beta Subunit mutations.

B. **Notify the Treating Physician**

Notify the treating physician immediately when DR-TB is suspected or confirmed.

C. **Seek Consultation**

1. See Appendix D: Medical Consultation Process upon initial suspicion or diagnosis of DR-TB and for a complete list of consultation requirements and recommendations.
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:
        i. Submit initial expert medical consultation **within five business days** of notification of suspected or confirmed drug resistance. This may be an informal notification while awaiting further test results or assessments. The purpose of the initial notification is to rapidly engage expert physician(s) and establish the appropriate plan of care.
        ii. Submit a formal consult when more results are available (e.g., MDDR results, updated bacteriology, radiology, other laboratories, or toxicity assessments).
    b) A patient is prescribed second-line TB medications for DR-TB or for rifamycin intolerance;
    c) The treating physician requests MDDR testing;
    d) Any time treatment regimen changes are needed (e.g., adverse drug reaction or abnormal drug levels);
    e) A patient is approaching the end of DR-TB therapy either due to resistance or intolerance, prior to stopping treatment; and
    f) A patient is a known contact to MDR-TB, Pre-XDR TB, or XDR-TB.)

D. **Notify and communicate with the TB Section nurse consultant**

Notify the nurse consultant directly or at tb.feedback@dshs.texas.gov at the following intervals:

1. Within three business days when DR-TB is suspected or confirmed.
2. When an expert consultation is submitted for RR-TB, or if a rifamycin cannot be used in a regimen, MDR-TB, Pre-XDR TB, or XDR-TB.
3. Prior to ordering BDQ.
    a) Follow the process outlined in the Bedaquiline Ordering Guide.
    b) Provide an initial and monthly update on México's response to assist with medication prior to ordering.
4. As requested for patient updates.

E. **Coordinate with DSHS Laboratory**

Coordinate with DSHS Laboratory to ensure appropriate diagnostic tests are ordered.

1. NAAT with GeneXpert is a rapid PCR test that identifies the presence of deoxyribonucleic acid in the *M. tb* isolate as well as assesses for mutations consistent with RIF 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 the patient has risk factors for DR-TB.

2. If RIF resistance is detected, this may indicate resistance to additional first-line drugs; therefore, further testing would be indicated, such as an MDDR test.
3. The treating physician may request MDDR testing by coordinating with the BNTB coordinator and the Texas consulting physician.
4. DSTs[5] are performed on positive *M. tb* cultures sent to the DSHS laboratory.
    a) If resistance to primary drugs (excluding PZA mono-resistance) is detected, DSHS laboratory will reflexively perform second-line drug panel testing and 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 the specimen was collected at an outside laboratory, coordination with the DSHS laboratory 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 to ensure appropriate testing can be performed.

F. **Notify the Regional Mycobacteriology Program in México**

Notify the Regional Mycobacteriology Program in México and provide a copy of the consultation from the DSHS-recognized medical TB consultant of treatment recommendations to ensure they can be reviewed by the COEFAR/GANAFAR.

G. **Coordinate Medications**

1. Coordinate with México on procurement of medications. TB medications from México should be used whenever possible. See CHAPTER XIV. MANAGEMENT OF MEDICATIONS AND MEDICATION AVAILABILITY.
2. While awaiting México's response for assistance with medication procurement, order medications from DSHS Pharmacy. Ensure treatment regimen meets the U.S. standards of care for the management and treatment of DR-TB. See CHAPTER XIV. MANAGEMENT OF MEDICATIONS AND MEDICATION AVAILABILITY.
3. The BNTB program in México should maintain regular communication with the National TB Program to coordinate medication supply efforts.

[5] 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.

H. **Case Management and Treatment**

Develop a case management plan and implement interventions and treatment activities within ten business days of notification of drug resistance using clinical care forms specific to DR-TB. Use TB 700a series or its equivalent. The following should occur:

1. Chest X-Rays
    a) Perform PA CXRs for patients over age 18 years; PA and LA for patients younger than 18 years of age and patients with HIV.
    b) Perform CXRs for patients with RR/MDR/Pre-XDR/XDR pulmonary TB, at minimum intervals:
        i. During treatment:
            (a) Initially,
            (b) Two months,
            (c) At six months, then
            (d) Every six months until completion of therapy or as recommended by the DSHS-recognized medical TB consultant.
        ii. Post-treatment:
            (a) Every six months for two years, accompanied by a TB signs and symptoms questionnaire, medical evaluation, and weight.
2. Sputum collection
    a) For patients with pulmonary RR/MDR/Pre-XDR/XDR-TB, collect sputum in the following intervals:
        i. At least three consecutive sputum samples each month until AFB smear and culture conversion are documented.
        ii. At least one sputum each month after culture conversion, until treatment is completed.
        iii. At least one sputum every six months for two years after completion of therapy.
3. Isolation
   It is appropriate to be more cautious when releasing DR-TB patients from airborne isolation. Contact the treating physician for release of isolation orders. Document on the TB-902a or equivalent patients' acknowledgment of conditions to release from isolation.

   Release from isolation may be made in consultation with the Texas consulting physician or a DSHS-recognized medical TB consultant. Considerations to release from isolation and restrictions include:
    a) Where the patient is being released to (i.e., congregate settings, or worksites).
    b) Individuals the patient may expose, including household members, small children, or immunocompromised individuals.
    c) Patient’s response to therapy clinically, radiographically, and bacteriologically, and

d) Duration of an effective drug regimen to which the patient is susceptible.

For release from TB isolation and restrictions, refer to: https://www.dshs.texas.gov/sites/default/files/LIDS-TB/publications/isolation-restrictions-implementation-guide.pdf

4. Laboratory

In addition to laboratory requirements for drug-susceptible TB, additional laboratory tests are required for patients with RR/MDR/Pre-XDR/XDR or any patient prescribed second-line medications as specified below for patients aged 18 years or older.

a) Perform the following blood chemistry tests and other laboratory tests at baseline:
   i. CBC and CMP.
   ii. A pregnancy test for females of childbearing age who are starting CFZ, pretomanid (Pa), or on an aminoglycoside, commonly amikacin (AK).
   iii. For patients on bedaquiline (BDQ), include magnesium (Mg), which must be ordered in addition to the CMP.
   iv. For patients on ethionamide (ETA), BDQ, and para-aminosalicylic acid (PAS), include a thyroid-stimulating hormone (TSH) level.
   v. Therapeutic drug monitoring 10–14 days after treatment is initiated; perform the following when ordered by the consulting physician and as resources allow:
      (a) Linezolid (LZD) peak and trough. Trough is done right before the next dose is administered. LZD peak should be done two hours post-dose.
      (b) Moxifloxacin peak level at two hours post dose.

b) Perform the following blood chemistry tests monthly:
   i. CBC and CMP.
   ii. For patients on BDQ, include magnesium.

c) Perform the following blood chemistry tests quarterly and as needed:
   i. For patients on BDQ, ETA, or PAS, include measurement of TSH levels.

d) Perform the following as needed or per consultation:
   i. CBC if moderate or severe anemia or other abnormalities present at baseline.
   ii. Therapeutic drug monitoring.

5. Clinical Monitoring

a) Monthly assessments of medication toxicity specific to each medication are required and must be documented on TB-702a toxicity forms or equivalent.
b) Perform weights at every visit or more frequently as determined by clinical assessments.
c) Perform the following baseline and monthly clinical monitoring for medications as follows:
   i. If the patient is taking aminoglycosides (most commonly AK), include:
      (a) Audiometry screening, and
      (b) Vestibular screening.

ii. If the patient is taking cycloserine (CS), include:
(a) A mental health assessment to include depression and anxiety screening questions.
(b) Ask if patient is experiencing nightmares, hallucinations, aggression, or disorientation.

iii. If the patient is taking CFZ, include:
(a) A mental health assessment to focus on depression symptoms.

iv. If the patient is taking linezolid (LZD), include:
(a) Red/green color discrimination using Ishihara plates
(b) Visual acuity using Snellen chart or other approved visual acuity chart, and
(c) Peripheral neuropathy screening.

v. If the patient is taking a FQN (levofloxacin, moxifloxacin) include:
(a) Tendon assessment.
(b) Mental health assessment for patients on high-dose FQN.

vi. If the patient is taking BDQ, also known as Sirturo, include:
(a) ECG at baseline, two weeks after initiation of treatment and monthly. The treating physician should interpret the ECG within 24 hours of the ECG test or sooner.
- Perform ECG at the designated intervals (preferably Monday-Wednesday in case further interventions such as labs or consultations are needed).
- ECG should be performed at the same time of day each time. ECGs exhibit diurnal variation of up to +/- 75ms during a day.
- A patient with elevated QTc intervals should have one repeat ECG done ≥ 30 minutes apart to confirm the reading.
- Documentation of any symptoms* of prolonged QTc should be included when performing the ECG and results of both provided to the licensed healthcare provider. Ensure the licensed healthcare provider reviews the symptoms and ECG results within 24 hours of test, unless otherwise specified, and documents response in the medical record.

d) Respond to the following based on the ECG results:

i. If QTc is greater than 450 ms (in males) or greater than 470 ms (in females) and patient is asymptomatic*:
(a) Draw CMP plus magnesium, TSH, CBC.
(b) Contact the licensed healthcare provider to review ECG results within 24 hours.
(c) Perform weekly ECGs until normal or until licensed healthcare provider orders otherwise.

ii. If QTc is greater than 500 ms in males or females, and patient is asymptomatic*:
(a) Hold medications.
(b) Draw CMP plus magnesium, TSH, CBC.

(c) Contact the treating physician to review results within 24 hours.
(d) Request that the treating physician consult cardiology or the Texas consulting physician for further guidance.
(e) Repeat ECG in 24-48 hours.
(f) Perform weekly ECGs until normal or the physician orders otherwise.
(g) Do not resume regimen until instructed by the treating physician.

iii. If QTc is greater than 450 ms (in males) or greater than 470 ms (in females) and the patient is symptomatic*:
(a) Refer patient to the emergency department (ED)- ensure there is a referral form that the patient may present to the ED already reviewed by the treating physician, which outlines at minimum: diagnosis, isolation status, current medications, baseline and current ECG results, symptoms, reason for referral to ED, and TB physician contact information.
(b) Do not resume regimen until instructed by the treating physician.

iv. If QTc is greater than 60 ms above baseline and the patient is asymptomatic*:
(a) Draw CMP plus magnesium, TSH, and CBC.
(b) Contact the treating physician to review ECG results within 24 hours for recommendations.

*Symptoms of prolonged QTc include palpitations, tachycardia, light-headedness, fainting/syncope, chest pain, loss of consciousness, and shortness of breath.

Considerations for the treating physician—Correcting the QT interval from ECG readings: The QTc interval is influenced by the heart rate (HR). At a HR of 60, QT = QTc using any of the formulas (Bazett, Fridericia, Framingham, or Hodges). As HR increases, the QTc increases. Most ECG machines in the US use the Bazett formula, which, at higher HR, yields a more prolonged QTc than the Fridericia formula. It is recommended to use the Fridericia formula when calculating corrected QTc intervals as studies examining TB medications and QT prolongation used the Fridericia formula in their assessments and guidance. Consider online calculators (e.g., Corrected QT Interval (QTc) [mdcalc.com]) or manual calculations.

Refer to algorithms for monitoring and managing corrected QT prolongation in patients with DR-TB here:
Guidance on requirements for QTc measurement in ECG monitoring when introducing new drugs and shorter regimens for the treatment of Multi/Extensively Drug-Resistant Tuberculosis.
https://www.challengetb.org/publications/tools/pmdt/Guidance_on_ECG_monitoring_in_NDR_v2.pdf.

6. Treatment
    a) Physicians and nurses should be familiar with the U.S. standards of care for the treatment of DR-TB.
    b) Intervene when diagnostic tests indicate resistance if the patient is on a regimen for drug-susceptible TB, such as rifampin, isoniazid, pyrazinamide, and ethambutol (RIPE).
        i. Consult with the treating physician.
        ii. Consider placing the current drug regimen on hold if the patient is medically stable.
        iii. Request a medical consult from a DSHS-recognized TB medical consultation or RMD for continuation of care.
    c) If treatment recommendations from a DSHS-recognized TB medical consultant or RMD and recommendations from the COEFAR/GANAFAR do not align, physicians both in México and the U.S. should collaborate and come to a unified consensus for the best treatment regimen for the patient. If a unified consensus cannot be met, the last resort would be to decline treatment in the BNTB program.
    d) For patients with INH mono-resistance (low or high level) or INH intolerance, ensure FQN drug susceptibility test result is obtained.
        i. EMB should not be discontinued until DSTs to INH and RIF are known. Discontinuing EMB prior to DSTs and the isolate is subsequently found to be INH resistant, the patient would be at risk for further resistance (as they would essentially have been on RIF+/- PZA therapy).
    e) The treating physician will sign and complete the BN-400B, with treatment regimen, initially, at the end of two months of therapy, then every three months until the end of therapy or anytime there is a change in treatment.
    f) Manage and treat patients in accordance with recommendations from a DSHS-recognized medical TB consultant or RMD and the Texas consulting physician and in collaboration with the Regional Mycobacteriology Program.
    g) Develop a treatment plan **within ten business days** after receiving initial notification of drug-resistance and treatment recommendation from the expert medical consultant or RMD.
    h) Seven days a week of observed dosing is optimal for patients treated for DR-TB. If that is not feasible, consider self-administration for weekend doses.
    i) When BDQ is used, refer to the Bedaquiline (Sirturo) Ordering Guide.
    j) Initial and continuation phases are different for patients on treatment for DR-TB than for patients with drug-susceptible TB. The nurse case manager should carefully monitor treatment interruptions, as any missed doses are concerning and may impact treatment outcomes. Notify the treating physician, as consultation may be necessary when interruptions occur.
    k) When interruptions in BDQ occur, apply the following:
        i. When interruptions occur during the **BDQ loading dose**, apply the following:

(a) For interruptions lasting ≤28 days prior to the loading dose phase completion, the patient should resume intake of any remaining loading doses to complete 14 days; once completed, move to the maintenance dose phase of 200 mg TIW.
(b) For interruptions lasting >28 days, obtain a consult.

ii. When interruptions occur during the **BDQ maintenance dose**, apply the following:
(a) Once BDQ is provided three times/week, missed doses are especially problematic. A single missed dose in one week is missing 33% of the recommended doses/week.
(b) If a dose BDQ is missed during the three times/week schedule, patients may take the missed dose as long as it is administered 24 hours apart from the next dose (and not to exceed 600 mg in a week/7-day period).
(c) Options for interruptions include reloading BDQ at 400 mg/day for one week (7 days) or continuing 200 mg three times/week (maintenance dose). These options depend on how much BDQ the patient had prior to the interruption. Contact the licensed healthcare provider and, when necessary, seek medical consultation.

Please refer to the article: Addressing Bedaquiline treatment interruption in the treatment of drug-resistant TB.
https://pubmed.ncbi.nlm.nih.gov/35768912/.

l. **Completion of therapy**

Completion of therapy should be based on the total number of observed doses administered, the number of treatment weeks, and clinical, radiological, and bacteriological improvement.

XII. Conduct and Manage a TB Contact Investigation

General Requirement

BNTB programs will conduct a CI for people with suspected (ATS 5) or confirmed (ATS 3) pulmonary, pleural, or laryngeal TB disease and evaluate, treat, and monitor their contacts. Programs will also screen high-priority contacts identified from a U.S.-managed case who are referred to the BNTB program. Contacts who reside outside the BNTB program's service area should be referred to the National TB Program.

In general, CIs are conducted the same whether the patient has drug-susceptible TB or drug-resistant TB. The goal of a CI is to find people exposed to TB who are likely to become infected or progress to TB disease to prevent further transmission.

Activities

A. **Initiate a CI or Source Case Investigation**

1. Conduct initial interviews within three working days of a patient being reported to the BNTB program with a suspected or confirmed TB diagnosis.
    a) The interview should be done in the primary language of the patient or their representative (parent or guardian for young children or proxy for patients diagnosed at death or otherwise unable to be interviewed), using an interpreter if needed.
        i. The PHR or LHD overseeing the BNTB program is encouraged to provide access to translation lines under the same conditions available to their regional or local staff. The PHR or LHD must be willing to absorb any associated costs, if applicable.
    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 if staff safety is not an issue.
3. Visit additional sites where transmission may have occurred.
4. TB disease in children under the age of 5 years 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.

Figure 3: Index Case CI and Source Case Investigation Characteristics

Index Case Contact Investigation	Source Case Investigation
• A process to identify, test, and treat persons exposed to infectious TB disease • Looking for persons exposed to TB who may or may not have been infected • Requires first and second round testing, based on break in contact	• A process to identify the source of recent transmission of infectious TB disease • Looking for a person with TB disease who is the likely source of infection for others • Second round testing is not required

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

B. **Determine Infectious Period**

1. Determine infectious period using TB-425a (TB Infectious Period Calculation Worksheet).
2. The infectious period generally begins three months before the onset of symptoms (see TABLE 7: ESTIMATING THE INFECTIOUS PERIOD.)
3. Determine date in which contact was broken based on:
    a) Date of physical separation from the index case; or
    b) Date the index case is no longer considered infectious (i.e., date they are released from isolation).

Table 7: 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

C. **Prioritize all Contacts**

Prioritize all contacts into high, medium, or low categories see TABLE 8: 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., aged 4 and younger, HIV status).
3. Calculate weekly and cumulative exposure hours.
    a) Contacts with greatest duration of time spent with the index case have the highest risk of exposure and should be tested first.
    b) Extend 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.
6. Evaluate for LTBI based on the priority criteria outlined in TABLE 8: GUIDELINES FOR PRIORITIZING CONTACTS, regardless of mask use or physical distancing of 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: Guidelines for Prioritizing Contacts

Index Case Characteristic	Contact Prioritization
Pulmonary, laryngeal, or pleural TB with: • Cavitary lesion on CXR; *or* • AFB sputum smear positive	**HIGH PRIORITY** • All household contacts; *or* • Contact in a congregate setting with high risk of TB transmission (schools, correctional and detention facilities, etc.), *and* with significant frequency and duration of exposure; or • Contacts in other settings with increased risk of TB transmission (e.g., outpatient dialysis centers, cancer infusion centers, 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** • Anyone exposed during the infectious period who does not meet one of the high or medium priority criteria. • Only consider if expansion is warranted.
Suspected or confirmed pulmonary or pleural TB with: • 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** • Anyone exposed during the infectious period who does not meet one of the high or medium priority criteria. • 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 Screenings

1. Conduct first and second round screenings.
2. Initiate screening for high-priority contacts within seven working days of identification.
3. Initiate and complete first round screening within four weeks of identification.
4. Use TST if IGRA is contraindicated or the patient refuses phlebotomy.
5. Avoid testing people with a low risk of infection.
6. Perform a complete evaluation of all high-priority TB contacts. A complete evaluation 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.
    c) A chest radiography 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.
7. Apply the following to contacts with a previous positive IGRA or TST:
    a) Results must be documented. If not documented, administer a screening test.
    b) If documented prior to adequate treatment, perform a symptom screen. If showing signs and symptoms of active TB disease, perform a chest x-ray.
    c) If the patient did not start LTBI treatment or did not complete LTBI treatment, perform a symptom screen and chest x-ray.
8. Apply the following to contacts with previous TB disease:
    a) Previous positive TB disease must be documented. If not documented, administer a screening test.
    b) If contact has documented adequate previous treatment, perform a symptom screen. If showing signs and symptoms of active TB disease, perform a chest x-ray. If active TB disease is suspected, collection of sputum or other specimens for mycobacteriology is recommended (refer to CHAPTER X. MANAGEMENT OF PATIENTS WITH SUSPECTED OR CONFIRMED TUBERCULOSIS).
9. Apply the following to contacts Lost to Follow-Up (LTFU)
    a) Make at least three attempts to contact a TB contact before considering them as LTFU, including:
        i. Calling the contact;
        ii. Visiting the contact's residence if safety is not a concern; and
        iii. Sending a postal mail notification of the contact's need to follow-up with the TB program if services are available in the area.
    b) Document attempts in the progress notes of the contact's record.
    c) Place certified mail notification receipt in the contact's record, if applicable.

10. 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 asymptomatic at second round testing have received a complete evaluation.
    c) If a contact was identified after the first round of screening was initiated, they are still eligible for the second round of screening. Perform one test eight to ten weeks after break in contact for a complete evaluation.
11. For source case investigations, second round testing is not required.

E. **Consider CI Expansion**

Consider CI expansion if the infection rate is high or if TB transmission is detected, see TB-460a, Expansion Analysis Checklist.

1. LTBI among high-priority contacts indicates transmission.
    a) The TB Section 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 four and younger,
    b) A change in TST or IGRA status from negative to positive among contacts between first and second-round testing; and
    c) Contacts diagnosed with TB disease.
3. For source case investigations, expansion should be considered until the infectious source is identified, regardless of the presence or absence of other transmission indicators.
4. As needed, request a consult with the TB Section epidemiologists to discuss whether an expansion to low-priority contacts is warranted. Submit consultation requests through GlobalScape and notify TBEpi@dshs.texas.gov.

F. **Conduct a Follow-up Investigation**

Conduct a follow-up investigation for 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 the location of exposure if safety is not a concern.
3. Coordinate with the regional mycobacteriology program in México if exposure occurred in México.
4. If a Texas dairy or livestock area is identified, contact the TB Section to determine if reporting to appropriate partner state agencies is warranted.

G. **Conduct Interviews**

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 TB-341a.
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 the patient is part of a cluster.

XIII. Managing Contacts to Confirmed or Suspected Tuberculosis Cases

General Requirements

BNTB programs will evaluate, treat, and monitor contacts to suspected or confirmed cases of pulmonary, pleural, or laryngeal TB disease as outlined in CHAPTER IX. MANAGEMENT OF PATIENTS WITH LATENT TB INFECTION, INCLUDING PATIENTS ON WINDOW PROPHYLAXIS.

Contacts referred to the BNTB program for outpatient treatment, where México manages the index case, and for whom the DSTs result is unknown, the BNTB program and the treating physician should use clinical judgment and consider the following prior to admitting the patient into the program and determining treatment:

A. Age of patient
B. Symptomatology of the index case and response to therapy, if available
C. Risk of developing TB disease
D. Risk of drug toxicity (i.e., risk of treatment vs. benefits of treatment)
E. Patient's willingness to initiate and adhere to therapy.

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 and screening tests for high-priority contacts. Use Form TB-460a, Expansion Analysis Checklist, to determine if CI should be expanded. If expansion of the CI is deemed necessary, 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 to 14 calendar days* if:
    a) The initial IGRA or TST result is positive, and no documented history exists of previous adequate LTBI or TB disease treatment;
    b) If the patient is a contact to a case of TB and is at a high risk for progression to active TB, regardless of their TB screening test result *(positive or negative)*, regardless of previous treatment for LTBI or disease, and even if they are identified past the 'window' period:
        i. Children younger than 5 years old.
        ii. Patients who have HIV infection or a high risk for HIV infection.
        iii. Patients with an immunocompromising condition.
        iv. Patients receiving immunosuppressive therapy.
    c) If the patient reports signs and symptoms of TB regardless of IGRA or TST.

*TB programs with on-site radiograph equipment should obtain a chest radiograph within ten calendar days.

4. Assess for TB disease if a contact tests positive and exhibits symptoms of TB disease or has chest radiography suggestive of TB disease.
5. If the IGRA or TST result is positive and the chest radiography is normal or TB disease has been ruled out, consider treatment for LTBI.
6. If a previously positive contact did not complete adequate treatment for LTBI, evaluate for TB disease, which includes a symptom review and a chest radiography. If there is no indication of disease, consider treatment for LTBI.
7. If a previously positive contact completed treatment for LTBI or disease, further treatment may not be required unless recommended by the treating physician. A complete evaluation for contacts with documented prior adequate treatment requires symptom screening.
8. Review and assess the completeness of the contact's medical evaluation.

B. Consider DST Results

Consider DST results of the index case when determining a contact's course of treatment.

1. Obtain a consult from a DSHS-recognized medical TB consultant for all contacts to MDR-TB, pre-XDR or XDR-TB cases who test positive for infection or are a candidate for window prophylaxis.
2. For contacts treated with INH in the past and who are now exposed to an INH-resistant case, treatment with a rifamycin may be needed for the new exposure.
3. Provide DOT or VDOT for contacts to RR, MDR, pre-XDR, or XDR-TB cases who are diagnosed with LTBI; consider VDOT as resources allow.
4. Evaluate for TB disease with a signs and symptoms questionnaire and a chest x-ray for contacts to MDR-TB, pre-XDR or XDR-TB regardless of previous treatment.
5. Obtain a symptom screening and a CXR every six months for a period of two years (from the date of break in contact) for any contact exposed to MDR-TB, pre-XDR or XDR-TB cases with a positive TST or IGRA test, regardless of whether treatment was taken for LTBI.
6. 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.
7. For contacts in which DSTs for the index case are unknown, the treating physician should closely review the records of the index case, if available, and their response to treatment prior to making a treatment recommendation.
    a) Note: The CDC and NTCA recommend short-course, rifamycin-based regimens for treating LTBI. These regimens are preferred over longer isoniazid monotherapy due to higher completion rates and lower toxicity.

C. Review Treatment Regimens

Review Chapter IX. Management of Patients with Latent TB Infection, including Patients on Window Prophylaxis for treatment regimens that may be considered for TB contacts.

1. Document completion of treatment on the appropriate reporting form, such as BN-400A or equivalent.
2. Document reason(s) medication was stopped if treatment was not completed.
3. Conduct minimum monthly reviews of adherence to treatment for LTBI.
4. Conduct minimum monthly reviews to identify adverse reactions to treatment for LTBI.
5. Hold medications and obtain a follow-up chest radiography before continuing treatment for LTBI for contacts receiving treatment for LTBI who develop signs and/or symptoms suggestive of TB disease.

D**. Provide Window Prophylaxis and Manage High Risk Contacts**

Managing high-risk contacts requires identifying conditions that will impact treatment for either LTBI or TB disease.

1. Window prophylaxis is treatment for possible LTBI and should be provided until a complete evaluation is documented. It is provided to vulnerable contacts who:
    a) Are at a high risk of progressing to severe forms of TB (e.g., TB 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, up to ten weeks after their break in contact or last exposure.
2. The decision to provide window prophylaxis is based on the treating physician's evaluation of the patient, ensuring TB disease has been ruled out.
3. Complete evaluation for contacts under five years of age and contacts with HIV infection or other immunocompromising conditions; include a TST or IGRA, symptom screening, physical examination, and a chest X-ray.
4. Contacts who are at a high risk of progression to disease may be recommended for retreatment even if they were treated in the past. Consult with the treating physician.
5. Certain contacts should be offered window prophylaxis: refer to CHAPTER IX. MANAGEMENT OF PATIENTS WITH LATENT TB INFECTION, INCLUDING PATIENTS ON WINDOW PROPHYLAXIS.
    a) If the repeat TB screening test remains negative eight to ten weeks after a break in contact for children under the age of five years, treatment can be discontinued. Infants aged five months or younger should continue window prophylaxis until they undergo a repeat TST or IGRA at six months.

E. **Maintain Medical Record**

Maintain a medical record for each person on treatment for LTBI, including those on window prophylaxis as outlined in CHAPTER IX. MANAGEMENT OF PATIENTS WITH LATENT TB INFECTION, INCLUDING PATIENTS ON WINDOW PROPHYLAXIS. Maintain a complete shadow chart in the Texas BNTB program.

XIV. Management of Medications and Medication Availability

General Requirements

This chapter outlines usage requirements of DSHS-purchased medications and the indications for requesting medications from México.

BNTB programs should establish a process with the Regional Mycobacteriology Programs in México to provide medications when possible. Texas medications may be requested while awaiting procurement from México or when needed to augment México's treatment regimens.

Medications purchased by DSHS under the Federal 340B Drug Pricing Program must only be used for outpatient TB services. However, DSHS-purchased medications can be used for existing BNTB patients when in-patient care is needed. When this occurs, the TB Section must be notified. Programs must adhere to the DSHS 340B Policy and Procedure when using state-purchased TB medications.

Activities

A**. Maintain Effective Relationships**

Develop a pre-arranged agreement between the BNTB program in México and Regional Mycobacteriology Program that details how to obtain medications. Discuss and outline roles and responsibilities of each program, including which program will provide medications and in which circumstances they cannot. BNTB programs should ensure medications are available prior to initiating care.

B. **Order and Distribute Medications.**

The BNTB coordinator will oversee the ordering and distribution of DSHS medications and review medications received against medication orders prior to submitting to the TB clinic in México for treatment of the patient. The BNTB coordinator or nurse assigned to oversee nurse case management activities will ensure that the BNTB program in México:

1. Has enrolled eligible patients in the BNTB program. Created a medical record for the patient.
2. Follows standards of care for DOT or VDOT for outpatient use only, unless authorized by the TB Section, and there is clear documentation of treatment administration.
3. Administers 340B medications to patients enrolled in the BNTB outpatient program via DOT or VDOT, and documents administration of medication on the BN-206.
    a) BN-206 form is subject to random quarterly reviews by DSHS pharmacy as required by the 340 policy.
4. Do not charge patients for medications.

C. **Follow Usage Recommendations for México's First-Line Medications**

The following medications, when readily available in México, may be used in the BNTB program with physician orders and in collaboration with the Regional Mycobacteriology Program:

1. doTBal - Intensive Phase (*Fase Intensiva*)- combination pill given Monday through Saturday, see Figure 4 below.
2. doTBal-S - Continuation Phase (*Fase de Sostén*) –combination pill given Monday, Wednesday, and Friday, see Figure 5.

Figure 4: doTBal Initial Phase

Figure 5: doTBal-S Continuation Phase

D. **Adhere to Usage Requirements of DSHS Medications**

1. Prescriptions for non-controlled drug orders written by practitioners in the Mexican states can be filled by a Texas pharmacy. See Texas State Board of Pharmacy Board

Rules §291.34[6]. Therefore, BNTB treating physicians may write prescription drug orders to receive TB medications.

2. Follow DSHS-established procedures for TB medication inventory management.
    a) The BNTB coordinator will request medications from DSHS pharmacy and reconcile inventory through the DSHS medication ordering system.
    b) Inventory reconciliation must be done at minimum every 30 days in the ordering system. If not done, a new medication order will not be able to be placed. Programs may choose to complete an inventory reconciliation more frequently if desired.
    c) Limit medication orders to a one-month supply. DSHS Pharmacy typically fulfills orders within 24 hours of receipt.
    d) Set maximum stock levels no higher than a one-month average usage.
    e) 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.
    f) Avoid waste by ordering packets for patients new to therapy with individual drugs to avoid waste (e.g., 10 packets of RIF, 10 packets of INH) to maximize usage.
    g) Do not enter patient health information (PHI) in the Pharmacy Inventory Ordering System (PIOS), as it is not HIPAA-compliant.
3. Order medications for patients in **DOT packets** and ensure labeling requirements are met.
    a) Order medications for patients with known or suspected TB disease on in-person DOT or those on directly observed preventive therapy (DOPT) for TB infection (including window prophylaxis) in DOT packets.
    b) Individual/DOT-packaged medications have a shorter expiration date than their original manufacturer's expiration date, typically two to six months after packaging. Therefore, if one medication in the packet expires, the entire packet must be disposed.
4. Order medication packets for **self-administered therapy (SAT) or VDOT** according to pharmacy requirements, which differ from DOT packets.
    a) Self-administered (SAT) packets provided to patients for weekends and holidays, as well as VDOT packets that will remain in a patient's possession, require additional labeling and child-proof packaging.
    b) Refer to DSHS Video-Enabled Directly Observed Therapy Required and Recommended Activities when using VDOT for enrolled patients.
    c) The DSHS Pharmacy Unit offers two different sizes of amber prescription vials with child-resistant lids for programs to provide patients with medications needed for short-term use. Refer to Image 1. Amber Vials for SAT and VDOT. See Appendix E: DSHS Formulary for a list of all supplies.

[6] A prescription for a non-controlled drug from a doctor in Canada or México may be filled by a Texas pharmacy if the prescription is in writing.

d) The label should be prepared and affixed to the zip-closure bag or amber vials by TB program staff providing medications to the patient. The label may be requested in Spanish (request only in one language) and must follow the instructions in Figure 6: Sample Medication Label for Self-Administration or VDOT:
   i. The name and address of the medical director or physician who prescribed the drug;
   ii. The date the drug is delivered to the patient,
   iii. The patient's name; and
   iv. The name, strength, directions for use of the drug(s).

Image 1: Amber vials for SAT and VDOT Packets

- The **40 dram bottles** (left in the image) are about 3.5 inches high by 2 inches wide and can hold 4-6 DOT packets, depending on the number of pills in each packet.
- The **60 dram bottles** (right in the image) are about 5.5 inches high by 2 inches wide and hold 8-12 packets.

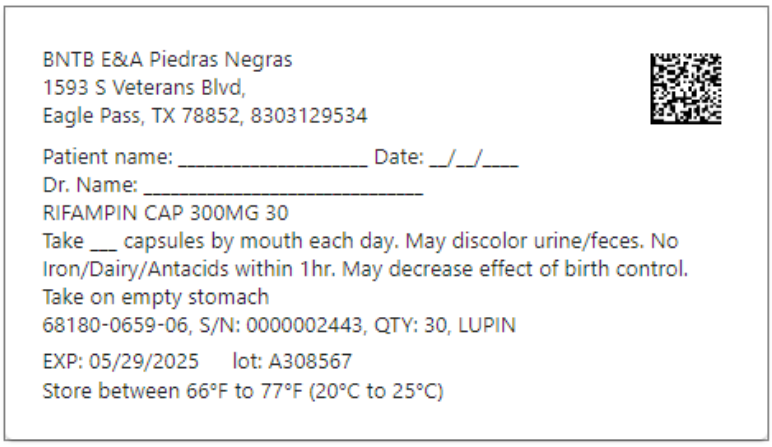
Figure 6: Sample Medication Label for Self-Administration or VDOT

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

Date: 01/01/2023
Physician: John Watson, MD
Patient: Jane Doe
Medications: Rifampin 600mg, Isoniazid 300mg, Pyrazinamide 1000mg, Ethambutol 800mg, Pyridoxine 50 mg
Instructions: Take 2 packets each day

5. Order medication bottles for patients with LTBI in **bulk bottles**. These may be provided to the patient with the following labeling requirements as required by the Texas State Board of Pharmacy (TSBP), Texas Administrative Code (state.tx.us). See Figure 7.
    a) The label may be requested in Spanish, attached to bottles, and include:
        i. Name, address, and telephone number of BNTB Texas office,
        ii. Name and strength of drug; if generic, name of drug manufacturer or distributor,
        iii. Quantity,
        iv. Lot number; and
        v. Expiration date.
    b) The BNTB coordinator, if a nurse (if not a nurse, the BNTB program must designate a nurse), will ensure labeling directions include:
        i. Patient name,
        ii. Date medication is provided,
        iii. Physician name, and directions for use (per TSBP rules, incomplete directions for use may be present and if so, are to be completed by the authorized licensed nurse at time of provision).

Figure 7: Sample Medication Label for Bulk Bottles



Note: Label may vary as printing software is updated.

E. **Order Second-line Medications**

1. Second-line medications are not readily available in México but may be procured after consultation and approval from the GANAFAR committee in México. See Table 9: DSHS Second-Line Medications.
2. Access to these medications depends on the COEFAR's notification to the GANAFAR, the response from the GANAFAR, and whether they are in stock at México's National TB Program. Medications not in stock require the GANAFAR to submit a request through the Green Light Committee, which may take longer.

a) BNTB clinics in México should coordinate with the TB program in their state and develop a plan to determine which medications they can procure in México. Coordinate this plan with the COEFAR and GANAFAR.
b) When a consultation is received from a DSHS-recognized TB medical consultant, the program may order medications in the interim from DSHS pharmacy pending approval from the COEFAR, GANAFAR, and the procurement of medication from México. Do not delay patients' treatment pending medications from México.

3. Consultation with either a Texas consulting physician or a DSHS-recognized medical TB consultant is required before ordering second-line medications, see APPENDIX D: MEDICAL CONSULTATION PROCESS.
    a) Order medications for patients in accordance with the treating physician's orders, DSHS TB formulary, and TB Section requirements. See APPENDIX E: DSHS TB FORMULARY.
    b) Most second-line medications are available through the DSHS Pharmacy ordering system (refer to Table 9). Exceptions:
        i. BDQ (Sirturo)
            (a) Begin the process to request medication from México. Submit patient documentation to the Regional Mycobacteriology Program who will ask the COEFAR and the GANAFAR for medication support. Include with the documentation the DSHS-recognized medical consultant's recommendations and a formal request for medications. Await the COEFAR and the GANAFAR Committee response.
            (b) While awaiting response from the COEFAR and GANAFAR, medications may be ordered from DSHS Pharmacy Unit. Instructions are outlined in the Bedaquiline Ordering Guide.
            (c) Once the GANAFAR reviews the case, they will provide a "Dictamen" to the Regional Mycobacteriology Program with their treatment recommendations. The Dictamen should be shared with the DSHS nurse consultant and uploaded to the patient's investigation in the surveillance and reporting database.
        ii. **CFZ** is an investigational drug only available in the U.S. through a Single Patient Investigational New Drug (SPIND) and may only be prescribed by Institutional Review Board (IRB) enrolled physicians, called investigators.
            (a) Begin process to request medication from México. Submit patient documentation to the Regional Mycobacteriology Program who will ask the COEFAR and the GANAFAR for medication support. Include with the documentation, the DSHS-recognized medical consultant's recommendations and a formal request for medications. Await the COEFAR and the GANAFAR Committee response.
            (b) Once the GANAFAR reviews the case, they will provide a "Dictamen" to the Regional Mycobacteriology Program with their

treatment recommendations. The Dictamen should be shared with the DSHS nurse consultant and uploaded to the patient's ID in the surveillance and reporting database.

(c) While awaiting response from the COEFAR and GANAFAR or if México is unable to provide the medication, adhere to the following:

- Inform the Texas consulting physician 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 Section for coordination.
- Communicate with the IRB-enrolled CFZ prescriber or their designee for next steps in arranging patient enrollment, IRB consent, medication ordering, and monitoring requirements.

Table 9: DSHS 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*	

F. **Medication Compounding**

Use medication compounding for select patient populations. The DSHS Pharmacy Unit performs medication compounding on Mondays, Tuesdays, and Wednesdays in the following situations:

1. When the patient requires a precise dose that is not commercially available (e.g., a dose of 250mg of RIF is ordered, but capsules are only available as 150mg and 300mg).
2. When administrative attempts by the nurse have been exhausted (splitting or crushing tablets, disguising in foods, etc.), compounding is seen as a last resort to support medication administration.
3. When the physician provides a manual signature on the prescription and faxes the prescription to DSHS pharmacy. Manual signatures and faxed prescriptions are legal requirements from the Texas Board of Pharmacy. Electronic signatures and emailed prescriptions are not accepted.
4. Compounded medication may be ordered using any of the following:
    a) Existing orders - via an electronic pharmacy ordering system.
        i. Obtain the prescription (RX) number. This is the number that starts with a 6 in the yellow box of the upper left-hand corner of the RX label.

ii. Follow steps in c) below to order.

b) New orders - via fax to DSHS pharmacy using the prescription form.
   i. An RX number is not available for new orders.
   ii. Fax the DSHS pharmacy the prescription using the Prescription Fax Form; contact the DSHS pharmacy at 340B@dshs.texas.gov for a copy of the form.

c) Enter all compound orders (existing or new) in PIOS following these steps.
   i. Log into PIOS.
   ii. Select TB Bulk, enter Compound Placeholder in the drug field.
   iii. Write the following in provider comments:
      (a) RX # or New RX for faxed orders,
      (b) Patient initials and desired delivery date.
      (c) Additional comments (300 maximum characters) may be written, e.g., "Ship on Monday".

Note: Some compounded medications must be refrigerated and will have a shorter expiration date than DOT medications. Contact the DSHS Pharmacy Unit at (512) 776-7500 for compounding and storage recommendations.

G. **Reconcile Medication Inventory**

1. BNTB programs in Texas will do the following:
   a) Reconcile compound medications in the following way to eliminate the need to reconcile inventory for compounding:
      i. Receive the item as normal in PIOS.
      ii. Mark it as "administered".
      iii. Zero out the quantity.
   b) Maintain a count of DSHS-purchased medications and supplies in both Texas and México's BNTB sites.
   c) Reconcile bulk inventory according to product and lot numbers listed in the DSHS medication ordering system at a minimum every 30 days. Bulk medication inventory refers to bottles of medications and not medication packets.
   d) Transfer of medication is not allowed to other binational clinics, Texas-based clinics (including clinics within the same health department system), or to another facility in México or Texas. However, medication may be used on another enrolled patient within the same clinic. If this occurs, reconcile the medication in the pharmacy ordering system and ensure there is documentation that the medication was provided to another enrolled TB patient.
   e) Only a BNTB program staff can administer DSHS TB medications. Giving medications to another facility to perform DOT or VDOT is in violation of 340B requirements.
   f) Establish protocols and procedures internally for the disposal of expired or non-usable medications.

g) Coordinate with DSHS pharmacy staff to ensure TB orders comply with best practices.

2. Store all DSHS-purchased medications and supplies, at both BNTB programs in Texas and México, properly and securely in accordance with the manufacturer's instructions.

H. **Auxiliary Medications**

1. The TB formulary includes auxiliary medications to support individualized patient care. See APPENDIX E. DSHS FORMULARY. They include but are not limited to:
    a) Anti-emetics,
    b) Corticosteroids, and
    c) Lidocaine.
2. To order auxiliary medications, consider the following options:
    a) The treating physician may write a prescription for the patient to fill at their own pharmacy.
    b) The managing BNTB program may coordinate with the patient's primary care provider to obtain medications.
    c) The treating physician may consider over-the-counter medications that the patient may choose to purchase.
    d) The BNTB program may request medication from the DSHS Pharmacy Unit when the above options have been exhausted. The TB Section reserves the right to request documentation of attempts to obtain auxiliary medications at any time.

XV. Professional Education and Workforce Competency

General Requirement

All new BNTB program staff shall receive professional education, training and orientation and current staff will receive ongoing education and training.

Activities

A. Ensure all persons operating under procedures of the BNTB program, have the requisite experience and/or training to deliver appropriate services.

B. Provide training and orientation to all employees involved in TB activities, including physicians, nurses, contact investigators, outreach workers, administration staff and other support staff.

1. Initial training includes **40 hours** of TB training specific to job duties within 90 days of employment.
2. The following CDC courses are available in Spanish:
    a) CDC "Self-Study Modules on Tuberculosis" are available in Spanish and included as a required training for contract staff.
    CDC | TB | Self-Study Modules on Tuberculosis
    b) Internet course for TB-101
    CDC | TB 101 for Health Care Workers
    c) Podcast for Basic TB Facts
    Public Health Media Library (cdc.gov)
3. Core training topics for TB staff should include the following:
    a) Transmission and pathogenesis of TB
    b) Epidemiology of TB
    c) Diagnosis of LTBI and disease
    d) Treatment of LTBI and disease
    e) TB reporting and notifiable conditions
    f) Drug interactions and toxicity
    g) TB contact investigation
    h) Infectiousness and infection control
    i) Interviewing, investigating, and influencing techniques
    j) Directly observed therapy
    k) TB nurse case management for LTBI, TB disease, and DR-TB
    l) CDC TB surveillance and reporting
4. Licensed BNTB program staff in Texas must complete 16 hours of continuing education and licensed contracted staff in México must complete 10 hours of continuing education each calendar year relevant to each staff member's position.
5. Non-licensed staff in Texas must complete at least 12 hours of training and education annually.
6. The BNTB coordinator or administrating staff member should participate in the TB monthly conference calls or trainings.

7. Ensure monthly case management conferences and cohort reviews include education on TB case management.
8. Conferences and trainings are provided by DSHS PHRs, local health departments and the TB Section. Additionally, specialized trainings are provided by Heartland National TB Center (Heartland) as well as other Centers of Excellence on:
    a) Nurse case management;
    b) Drug interactions and toxicity;
    c) Contact investigation for TB;
    d) Infection control measures;
    e) Patient adherence;
    f) Directly observed therapy; and
    g) Tuberculin skin testing practicum.

C. The fiduciary agency, its contracted staff, and the Texas BNTB program will maintain documentation of training for all employees and contracted staff.

1. Retain logs, see APPENDIX P: SAMPLE IN-SERVICE AND TRAINING ROSTER, for in-house trainings in accordance with local procedures include:
    a) Job titles;
    b) Training dates;
    c) Title of training or course; and
    d) Number of hours.
2. Retain copies of employee training certificates.
3. The BNTB treating physicians must have access to training records to verify those operating under their medical license have the requisite experience and training.
4. Notify the TB Section of newly hired BNTB program staff in México and Texas within 30 days of hire. The BNTB coordinator will submit the Notice of Change of TB Personnel form (TB Forms Resources | Texas DSHS) to TBProgram@dshs.texas.gov.
5. Educate external entities as needed and as resources allow.
    a) Promote the BNTB program during these events on the services and support provided by the program.
    b) Ensure advance written approval for any publication, presentation or abstracts regarding the BNTB program has been obtained from the TB Section director and that the affected PHR and/or LHD in Texas have been notified.
6. Report trainings on the DSHS APR according to contract deadlines.
7. Maintain competency within the Texas BNTB staff to navigate NEDSS. BNTB program managers may choose to require certificates of training completion for each NEDSS training course.

XVI. Infection Control Procedures

General Requirement

The BNTB programs in México in collaboration with the fiduciary agency will apply appropriate administrative, environmental, and respiratory controls to prevent exposure to and transmission of *M. tb*.

Activities

A. **Administrative Control Measures**

Administrative control measures reduce the risk of exposure to persons with infectious TB and may include the following activities:

1. Implement effective work practices for managing patients with TB disease and infection.
2. Ensure separation of infectious or potentially infectious patients from other patients in the clinic.
3. Ensure proper cleaning, sterilization, or disinfection of equipment and surfaces to prevent contamination.
4. Educate, train, and counsel health care workers, patients, and visitors about LTBI and disease.
5. Use posters and signs to remind patients and staff of proper cough etiquette and respiratory hygiene.
6. Screen direct-care staff for TB.
    a) The program must screen direct-care staff for TB upon hire and at least annually to monitor results, conversions, and signs and symptoms. If the screening test is positive, contractual staff will be referred to their primary care provider or the BNTB treating physician.
        i. IGRA is the preferred method for screening.
        ii. New hires with previous positives should present documentation of results and completion of adequate treatment for LTBI or TB disease. If no results are available, retesting is appropriate as determined by the program.
        iii. Any staff with signs and symptoms of TB disease should be referred for a complete medical evaluation regardless of test result before being cleared to return to work.
    b) Maintain documentation in accordance with local procedures and ensure they are readily available to the medical coordinator for yearly review.
7. Be familiar with CDC's recommendations for screening health care personnel (HCP) for TB found in the Centers for Disease Control and Prevention's (CDC's) document "Tuberculosis Screening, Testing and Treatment of U.S. Health Care Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC."

B. **Environmental Control Measures**

Environmental control measures prevent the spread and reduce the concentration of infectious respiratory particles (IRPs) of *M. tuberculosis,* as resources allow, these include:

1. Use local exhaust ventilation (e.g., hoods, tents, or booths) to contain and control the source of infection.
2. Use general ventilation to dilute and remove contaminated air.
3. Use high-efficiency particulate air (HEPA) filtration or ultraviolet germicidal irradiation (UVGI) to clean the air.
4. Control airflow to prevent the contamination of air in adjacent areas.
5. Properly install, operate, and maintain environmental control equipment.

C. **Respiratory Controls**

Respiratory controls consist of the use of personal protective equipment in situations that pose a high risk of exposure to TB disease and include the following:

1. Develop a procedure on respiratory protection, to include the type and size of respirators available to staff, routine inspection and maintenance, and appropriate use.
2. Ensure N-95 respirators are used by staff who are in situations that pose a high risk of exposure to TB disease.
3. Contracted staff must receive fit testing upon hire, yearly, and as needed if there is any change to physical facial structure.
4. Ensure masks are fitted properly on each staff.
5. Educate patients on respiratory hygiene and the importance of cough etiquette and provide surgical masks as needed.
6. Perform droplet nuclei-producing procedures (e.g., sputum collection) outside in a location that protects patient confidentiality if an AIIR room or booth is unavailable.

XVII. Budget Management

General Requirement

The DSHS funds BNTB programs through a cooperative agreement with a fiduciary agency, PHR, and LHD. The funds support Texas-based BNTB program staff and the services provided in México. The fiduciary agency is responsible for developing subcontracts to maintain clinical operations in México, which includes hiring clinical staff; monitoring budget expenses; purchasing supplies; maintaining patient medical records at each clinic site in México; and submitting required reports to DSHS by established deadlines.

The BNTB coordinator must perform the following activities to support the fiduciary agency:

A. Review and validate the weekly time and mileage report, see Appendix P: Sample In-Service and Training Roster, prior to submitting to the fiduciary agency for approval of payment vouchers of Mexican contractors for salaries, mileage, and other allowable reimbursements.
    1. Contractors use a self-reporting, or honor-based, time-tracking system. This means contractors enter their own hours, which are then submitted to their coordinator for approval rather than being recorded through a traditional punch clock. Since coordinators serve as team leads and are responsible for assigning daily work tasks to contractors, they are generally the most knowledgeable about each contractor's work and when it occurs, making them the appropriate individuals to review and validate the reported time and activities.
B. Work closely with the fiduciary agency to determine supplies needed at the clinic site in México.
    1. If the PHR or LHD identifies specific supplies the fiduciary agency cannot provide, the BNTB clinic may obtain them directly.

The BNTB program managers and coordinators in Texas must manage and monitor their own program budgets by accomplishing the following activities:

A. Review and revise the federal budget.
B. Monitor budget expenditures for program operations.
C. Recommend budget revisions for program operations and obtain approval from the TB Section.
D. Notify the TB Section of any changes in personnel, including new hires, by using the Notice of Change in TB Personnel form.

Restricted Activities

The BNTB Program adheres to state and federal funding standards, including funding restrictions and limitations.

A. **Activities in México**

The fiduciary agency must ensure that program activities in México are coordinated as needed with appropriate government authorities and that the necessary licenses, permits, or approvals are obtained.

B. **Limited English Proficiency**

The fiduciary agency must take reasonable steps to ensure that patients with limited English proficiency have meaningful access to TB health services and that there is effective communication between the service provider and the patient. To clarify existing legal requirements, HHS published "Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons." This guidance provides a description of the factors that recipients should consider in determining and fulfilling their responsibilities to individuals with limited English proficiency under Title VI of the Civil Rights Act of 1964.

C. **Limitations**

1. CDC Notice of Funding Opportunity restrictions that must be considered when developing the budget are:
    a) Recipients may use funds only for clinical services that align with the standards of care approved by Texas and México.
    b) Recipients may use funds only for reasonable program purposes, including personnel, travel, supplies, incentives, enablers, and services.
    c) Recipients may not use funds to purchase furniture or equipment costing more than $500 U.S. Any proposed spending must be clearly identified in the budget and approved by the TB Section director.
    d) Reimbursement of pre-award costs is not allowed.
    e) No funds can be used for:
        i. Publicity or propaganda purposes, for the preparation, distribution, or use of any material designed to support or defeat the enactment of legislation before any legislative body.
        ii. The salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, or administrative action.
            (a) Recipients may not use funds for inpatient clinical care.
            (b) Recipients may not use funds to supplant state or local health department funds.
            (c) Recipients may not use funds to purchase medications for treatment.
2. Other activities that are not supported by federal or state funds include the following:

a) Lobbying activities or costs,
b) Non-grant supporting activities,
c) Activities that do not follow standards consistent with state and local laws and ethics,
d) Activities that promote the legalization of any drug or other substance included in Schedule I,
e) Meals and alcoholic beverages,
f) Paying bad debts, fines, and penalties,
g) Termination or suspension costs,
h) Entertainment costs,
i) Fundraising costs,
j) Honoraria,
k) Independent research and development costs,
l) Invention, patent, or licensing costs,
m) Land or building acquisitions, and
n) Library services.

To learn more about the general terms and conditions of discretionary grants and cooperative agreement awards, visit the HHS Grants Policy Statement. The document provides information on the grant process, including the associated authorities and responsibilities.

XVIII. Reporting Requirements

General Requirement

Programs suspected and confirmed TB cases, contacts, and people diagnosed with LTBI must be reported to the TB Section through reporting mechanisms outlined in this chapter. Reporting may include responding to the TB Section requests, emailing the TB Section teams, or entering surveillance data into the Notifiable Electronic Disease Surveillance System (NEDSS). NEDSS is a CDC-developed integrated information system that helps local, state, and territorial public health departments manage reportable disease data and send notifiable disease data to the CDC. NEDSS allows for real-time data entry; therefore, TB programs must adhere to the reporting timelines outlined in this chapter.

Reporting is essential for TB programs to:

A. Ensure case supervision;
B. Ensure completion of appropriate therapy;
C. Ensure completion of timely contact investigations; and
D. Analyze data to determine morbidity, demographic characteristics, and trends so that opportunities for targeted screening for disease or infection can be identified.

Activities

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[7].

BNTB programs will perform the following:

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 people being evaluated for TB disease and started treatment;
    2. All people evaluated for TB infection and started treatment;
    3. People named as a contact, particularly high and medium-risk contacts.

B. Obtain and enter in NEDSS the initial TB intake information within seven days of a notification for all suspected (ATS 5) and confirmed TB cases (ATS 3) (refer to: APPENDIX L: TB INTAKE INFORMATION).

    1. If a patient is suspected of having TB and is pending a complete evaluation, the initial ATS classification should be entered as ATS 5, M. *tb* suspected, diagnosis pending, include the classification date.

[7] Refer to the *NEDSS Data Entry Guide* for reporting surveillance data for TB conditions at dshs.texas.gov/tuberculosis-tb/training/nedss

a) All TB diagnostic tests (e.g., bacteriology results, symptom assessments, radiology, etc.) should be completed within 90-days. Therefore, a patient should not be an ATS 5 for more than 90 days (three months).
b) If the patient suspected of having TB did not receive a complete evaluation and a disposition could not be made, an explanation must be provided and entered in the Notes section of the Supplemental Info tab in NEDSS. If a complete evaluation is still pending after 545 days from the date the LHD or PHR was first notified that a person may have TB (date reported), the TB investigation will be closed by DSHS Epidemiology and Surveillance Branch.

2. Once a TB diagnosis is made, the current ATS classification should be updated and entered as ATS 3 -*M. Tb* disease, clinically active, with the new classification date.
3. If TB is ruled out, update the ATS classification as applicable and enter the updated classification date (refer to: TABLE 10: AMERICAN THORACIC SOCIETY (ATS) TB CLASSIFICATIONS below).

Table 10: American Thoracic Society (ATS) TB Classifications

Classification	Description
0	**No M.TB exposure, Not TB infected** People in this class have no history of exposure and a negative reaction to the tuberculin skin test or IGRA TB blood test (if tested)
1	**M.TB exposure, no evidence of TB infection** People in ATS 1 have a history of exposure but have a negative reaction to the tuberculin skin test or IGRA blood test. Action taken for people in this class depends on the degree and recency of exposure to M. *tb*, as well as the immune status of the exposed person. If there has been significant exposure within 3 months, a follow-up skin/blood test should be performed 8-10 weeks after the last exposure, and in the interim, treatment of latent tuberculosis infection should be considered for some high-risk people, i.e., children less than 5 years old and people with HIV infection.
2	**M.TB infection, no disease** This class is characterized by a positive reaction to the tuberculin skin test (indicate the duration in mm) or an IGRA blood test, negative bacteriologic studies (if performed), but no clinical, bacteriological, or radiographic evidence of active tuberculosis. Treatment of latent tuberculosis infection may be indicated.
3	**M.TB infection, current disease** This category includes all patients with clinically active tuberculosis whose diagnostic procedures are complete. Patients with clinically active TB have clinical, bacteriological, and/or radiographic evidence of current

	tuberculosis. This is established most definitively by the isolation of M. tuberculosis. The patient remains in class III until treatment of the current episode is completed.
4	**M.TB, no current disease** This classification is defined by a history of previous episode(s) of tuberculosis or abnormal stable radiographic findings in people with a positive reaction to tuberculin skin test (indicate mm induration) or IGRA blood test, negative bacteriologic studies (if done), and no clinical and/or radiographic evidence of current disease. People in ATS 4 may never have received chemotherapy, may be receiving treatment for latent infection, or may have completed a previously prescribed course of chemotherapy.
5	**M. TB suspected, diagnosis pending** People should be classified ATS 5 when a diagnosis of tuberculosis is being considered, whether or not treatment has been started, until diagnostic procedures have been completed. Patients should not remain in this class for more than 90 days (3 months). When diagnostic procedures have been completed, the patients' disease should be classified according to one of the four preceding classes.

C. Report in NEDSS all **active TB cases (ATS 3)** to the TB Section within two business days after identification of a laboratory-confirmed TB case, or diagnosis of a clinical case of TB by creating a NEDSS notification. Ensure all applicable information is entered for the TB Section surveillance team to verify case criteria and count status. Refer to: Table 11: Case Criteria

1. When notifications are received, a TB surveillance case consultant will perform QA and assign state case numbers (SCN).
    a) Notify the surveillance team at TBHDSurveillance@dshs.texas.gov prior to making changes to the case status in NEDSS once a confirmed case of TB has been reported and assigned a state case number. Documentation supporting the decision to rule out TB is required and should be attached to the NEDDS investigation.
    b) 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.
    c) 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 ten business days after information is obtained.
    a) Initial 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 the therapy stop date.

Table 11: Case Criteria

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 has recent contact with an active TB case; • Considerable clinical improvement based on symptoms from onset after starting a minimum of 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

Case Criteria
rationale or findings for which the diagnosis was based.

D. Create a **Latent Tuberculosis Infection (2020 TBLISS) investigation** in NEDSS within three business days for a known diagnosis of LTBI. Perform a thorough search of the database before creating investigations. If the patient search results in no matches, a patient file must be created before creating the LTBI investigation.

1. Enter patient and clinical information in NEDSS while the evaluation is in process.
2. An investigation should be created for the following populations with high-risk conditions:
    a) Foreign-born from high-incidence countries;
    b) Newly arrived immigrants and refugees notified through EDN;
    c) Unaccompanied children;
    d) HIV-positive individuals; and
    e) Health care workers with recent TST or IGRA conversion.

E. Obtain and enter in NEDSS the initial TB intake information within seven days of notification for known LTBI (ATS 2). (Refer to: APPENDIX L: TB INTAKE INFORMATION.)

F. Report all patients with LTBI (ATS 2) to the TB Section within ten business days of starting treatment for LTBI by creating a NEDSS notification. Ensure all applicable information is entered for the TB Section to verify LTBI criteria.

1. When notifications are received, a TB Section surveillance case consultant will perform QA and assign an LTBI number.
    a) Enter remaining LTBI data in NEDSS as soon as the information is available, not to exceed ten business days after information is obtained. Treatment and outcome information should be entered in NEDSS for all LTBIs as soon as the treatment is complete or treatment information is available, not to exceed seven days from the 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 **QA protocols and procedures** into surveillance activities.
1. Respond to requests from the TB Section to check any discrepancies between the jurisdiction's case count in NEDSS and the case count in the jurisdiction's log.
2. Respond to requests after receipt or within the timeframe included in the request. Refer to APPENDIX M: GUIDELINES FOR RESPONDING TO DATA QUALITY ASSURANCE REPORTS.

3. Satisfy requirements for QA for TB Surveillance data. (Refer to TABLE 12: REQUIREMENTS FOR QA FOR TB SURVEILLANCE DATA.)

Table 12: Requirements for QA for TB Surveillance Data

Summary of CDC Requirements for QA 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 a written QA protocol for TB surveillance data. 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: • TB Section Surveillance Team • Designated Staff, including TDCJ and Binational TB Programs

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

I. Complete TB-340a and TB-341a, or Mass Contact Spreadsheet, within 90 days of initial source case report in NEDSS. The initial contacts' report requires the following:

1. Part A. Case or suspect case of TB Information
2. Part B. Interview and Exposure Site Information
    a) For every sputum smear-positive case, conduct at least two interviews seven days apart.
    b) Provide a reason if at least three contacts to sputum smear positive cases were not identified.
    c) Provide a reason if the second interview was not conducted.
    d) Provide a reason if no contact investigation was conducted.
3. Part C. Contact Information
    a) Duration of exposure and setting
    b) HIV test results
    c) Priority status
    d) TST or IGRA test results
    e) CXR or other imaging date and interpretation

4. Verify that a complete evaluation was performed. A complete evaluation for the purposes of the CI Aggregate Report consists of a TST or IGRA result. If the result is positive, a CXR result and a diagnosis from a physician should be made, with an ATS classification required. If the result is negative, do not provide an ATS classification until a second TST or IGRA is performed 8-10 weeks after the contact's last exposure to the source case. Once the treating physician makes a diagnosis (e.g., LTBI, TB suspected, closed without evidence of LTBI), the ATS classification can be assigned and entered into NEDSS.
    a) Perform a symptom screen for an evaluation to be complete.
    b) Provide a reason if the evaluation was incomplete.
5. For contacts with LTBI, ATS 2, update NEDSS with contact follow-up information, including:
    a) If treatment was recommended;
    b) If treatment was not recommended, provide a reason;
    c) Treatment start date;
    d) Treatment stop date;
    e) If treatment was completed adequately; and
    f) If contact did not complete treatment adequately, provide the reason.
6. Report contacts who develop active TB disease before submitting the subsequent contacts of those cases. Provide the linking RVCT number of their source case in NEDSS.

J. Report mass screenings (contact investigations > 50 contacts) when using DSHS-purchased supplies. Do not perform mass screenings without prior approval from the TB Section.
    1. List CIs that yield >=50 contacts on the DSHS TB Mass Contact Spreadsheet. Request the most recent version from DSHS TB Epidemiology before use.
    2. Make every effort to educate and inform the "concerned individual" regarding the TB screening process to ensure TB epidemiologic principles are applied at each CI event.
    3. 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.
        a) Mass screenings that are not epidemiologically guided, drain limited resources and yield minimal results.

K. Achieve National TB Indicator Project (NTIP) Objectives and Performance Targets. Texas BNTB programs are required to achieve each measure for CIs outlined in TABLE 13: TEXAS TB PERFORMANCE MEASURES. For a comprehensive list of NTIP objectives and targets, see National TB Program Objectives and Performance Targets for 2025.

L. Report false-positive cases.

1. Determine the need for a false-positive investigation when a patient presents with a single-positive culture or the licensed healthcare provider suspects the clinical presentation is not consistent with culture findings.
2. Initiate the false-positive investigation and review other specimens associated with a false-positive case to ensure they are culture-negative. Contact the originating laboratory to determine the source of the false positive result (e.g., lab contamination vs. specimen collection error). Use genotyping and WGS data to support the investigation.
3. Request assistance as needed. Complete the False Positive Investigation Worksheet or equivalent and submit it to TBEpi@dshs.texas.gov. Upon conclusion, provide a summary of the investigation results to include in the patient record, if warranted.
4. Report any case closed as a false positive to the TB Section's Surveillance Team at TBHDSurveillance@dshs.texas.gov with documentation to justify the change in case status (e.g., amended laboratory report, doctor's note, written medical consult, etc.) within 45 business days of closure.

M. Follow APPENDIX N: INTERJURISDICTIONAL COMMUNICATION when transferring or reporting suspects, cases, or contacts to and from the BNTB program.

N. Report DR-TB by notifying the BNTB nurse consultant and entering information in the NEDSS within three business days of suspected or confirmed drug resistance.
   1. Complete and submit updated information at a minimum every 90 business days for all DR-TB cases until treatment completion in NEDSS.
   2. Submit changes in case management, drug resistance patterns, or residence in any DR-TB case within 72 hours of notification. Changes will be entered in NEDSS, and the BNTB nurse consultant will be notified via email.

P. The fiduciary agency submits the completed APR, and the program managers are responsible for submitting the BNTB APR supplementary form to CMS each year by the established contract deadline (the first business day in April).

Q. Submit completed cohort review documents to the TB Section in accordance with the listed cohort review period and submission schedule via GlobalScape. Notify the Assessment, Compliance, and Evaluation (ACE) team by emailing aceteam@dshs.texas.gov upon upload. See TABLE 14: COHORT PERIOD AND SUBMISSION SCHEDULE for the schedule.

R. Follow México's reporting requirements regarding its monitoring and surveillance reporting system.
   1. BNTB programs will abide by the reporting requirements from the Regional Mycobacteriology Programs in México to ensure reporting of contacts, patients suspected of TB, and cases of TB are reported using their required documents and following their reporting time requirements.

XIX. Confidentiality and Security Standards

General Requirement

BNTB programs must evaluate and treat patients at BNTB clinics in México. Open and maintain the official medical record at the BNTB clinic in México. However, keep, and maintain an up-to-date shadow chart in Texas in accordance with applicable state and federal security and confidentiality standards, policies, and guidelines, including but not limited to Federal Data Security and Confidentiality Guidelines.

Activities

A. Submit documentation of DSHS security and confidentiality training course to the TB Section Operations Coordinator within 30 days of hire.

B. Submit inquiries related to database access and security training to Tbprogram@dshs.texas.gov

C. Complete an annual refresher training course on confidentiality requirements/confidential information security within one year of having taken the previous confidentiality and security course.

D. Submit all appropriate documentation of confidentiality and security training by completing the TB Database Access Requests form https://app.smartsheet.com/b/form/d2b98d7295c24bfb899606edf65b9c18 within ten (10) business days of completing the course. Staff who do not require access to TB databases should submit their security training on the Security Confirmation for Employees Who Do Not Require Database Access Page.

E. BNTB program staff in México who require access to TB Databases will need to keep their DSHS accounts up to date and work with their designated local responsible party (LRP) to submit all necessary forms to request and maintain access to TB Databases.

F. Designate a TB program staff member to serve as the LRP at the regional or local BNTB program in Texas.

G. BNTB program staff (Texas & México) will work closely with their designated LRP to ensure personally identifiable information is kept secure, ensuring that records are maintained in a secure area when not in use, are not left in plain sight, and shredded with a cross-cut feature before disposal.

XX. Conduct Quality Improvement (QI) Activities

General Requirement

BNTB programs will evaluate their performance in meeting key measures, including their processes for maintaining a robust BNTB infrastructure.

Activities

A. Update protocols to support BNTB program performance evaluation and QI activities.

B. Complete and submit the DSHS APR using the TB Section template to TBContractReporting@dshs.texas.gov with a copy to aceteam@dshs.texas.gov once a year on April 1.

C. Conduct quarterly cohort reviews in accordance with the DSHS Tuberculosis Cohort Review Process. See Table 14: Cohort Period and Submission Schedule.

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 (CAP) to improve outcomes.
3. Complete the 12-14064a Cohort Review Summary and each individual presentation form. Submit summary and presentation forms along with a list of counted cases to the TB Section via GlobalScape. Notify the ACE Team of the upload by emailing aceteam@dshs.texas.gov.
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 Texas Performance Measures to assess progress toward achieving state objectives.

1. Identify TB program staff who need access to NEDSS. At a minimum, this should include the TB program manager and binational TB coordinator.
2. Contact the TB Section at TBProgram@dshs.texas.gov for information on obtaining access to NEDSS.

F. Meet the Texas TB Performance Measures. See Table 13: Texas TB Performance Measures.

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 (state.tx.us), regarding retention of medical records.

Table 13: Texas TB Performance Measures

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 at 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
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 U.S. within 60 days of initiating treatment; and/or • not been on treatment for 60 days.	64	64.5	65	65.5	66

Performance Measure (PM)	Benchmark (%)				
	2025	2026	2027	2028	2029
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 the 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 that 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 results 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 Section'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 Section's designated surveillance and reporting database.	91	91.5	92	92.5	93
PM 10: Newly reported TB patients with a positive AFB sputum-smear result have at least three contacts evaluated as part of the contact investigation.	79	79.5	80	81.5	82
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
** 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 the TB Section and the fiduciary agency audits.

1. The fiduciary agency will conduct audits of BNTB clinics in México
    a) The medical coordinator will conduct audits of all BNTB coordinator sites in México based on a routine or targeted need using an approved audit tool.
    b) Once the site is selected, the fiduciary agency will coordinate logistics and provide formal notification that includes the agenda and a selected list of medical chart identification numbers with the BNTB program in México.

c) During the visit, the medical coordinator will conduct medical chart reviews, interview staff, and observation of staff to complete the audit tool.
d) The medical coordinator will prepare a final report detailing findings and specific recommendations to address non-adherence with standards of care outlined in the BNTB manual. The fiduciary agency will submit the audit report to TBContractReporting@dshs.texas.gov.
e) The TB Section will review the audit report and provide feedback and recommendations to the fiduciary agency and affected program.
f) The BNTB program will have 60 days to submit a CAP in response to the final report that addresses each recommendation with a timeline for completing TB activities for monitoring, implementation, and ongoing follow-up by the TB Section. The TB Section will confirm receipt of CAP, and a follow-up visit will be scheduled for the following fiscal year.

2. The TB Section will conduct audits of BNTB programs in Texas.
    a) The TB Section will conduct audits of the Texas BNTB sites based on routine or targeted need using an approved on-site review tool.
    b) Once the site is selected, the BNTB program manager and ACE team will coordinate logistics and provide formal notification that includes the agenda and a selected list of medical chart identification numbers to the BNTB program.
    c) During the audit, reviewers will conduct medical chart reviews, staff interviews, and observe staff performing TB activities to complete the audit review tool.
        i. BNTB programs must ensure that training records and medical chart documentation comply with guidelines in the BNTB manual (relevant chapters) for audits
    d) The TB Section will provide the BNTB program with a final report detailing findings and specific recommendations to address non-compliance with the BNTB manual.
    e) The BNTB program will submit a CAP in response to the final report that addresses each recommendation with a timeline for completing TB activities for monitoring, implementation, and ongoing follow-up by the TB Section.

Appendix A: Attestation of Review of BNTB Manual

I, _____, have read and understand the Binational TB Program Manual provided by the Texas Department of State Health Services TB and Hansen's Disease TB Section, Fiscal Year 2027.

I understand the information and agree to follow the instructions outlined in the Manual.

_____

Signature of Staff Date (MM/DD/YYYY)

Appendix B: Process for Enrollment

Patients may be referred to the BNTB program by a health department in México or the U.S., or self-referred as a walk-in patient. Qualifications for enrollment into the BNTB program are outlined in CHAPTER IV. PROGRAM ELIGIBILITY, REFERRALS AND APPROVAL.

All patients referred to the BNTB program, unless they are walk-ins, will receive a referral form: either a BN-200 *Forma de Referido* or an Interjurisdictional TB Notification (IJN) Form.

A decision to accept or decline entry into the BNTB will be made collaboratively by the treating physician in México, the BNTB coordinator, the BNTB program manager, and, in some instances, the Texas consulting physician. The final decision to admit or decline a patient to the BNTB program should be made within ten (10) business days.

All documents containing protected health information (PHI) should be shared using a protected mechanism approved by DSHS, such as GlobalScape.

Step 1 Initial Interview and Review for Enrollment

A. The **nurse in México** will do the following:
   1. Review the referral form and ensure the patient is eligible for services (see Chapter IV).
   2. Collect all medical records from the referring program. If needed, have the patient sign the L-30a.
   3. Consent for treatment using the TB 411a.
   4. Open a patient medical record.
      a) Each patient with ATS 2, 3, or 5 will have a medical record with designated forms, or their equivalent, as outlined in APPENDIX F: BINATIONAL TB PROGRAM CLINICAL CARE FORMS.
   5. Conduct a patient interview and collect data using the BN-202 or equivalent.
   6. Present documents to the BN treating physician in México for review and approval.
   7. Once approved by the BN treating physician, send all documents to the Texas BNTB coordinator for formal acceptance into the program.
   8. Once the BNTB coordinator receives the response, share the response with the referring entity.

B. The **México treating physician** will do the following:
   1. Review referrals and determine if the patient is eligible for services or should be referred to another provider outside the BNTB program. Prior to approving, consider whether the patient needs a consultation with the Texas consulting physician before acceptance into the program.
      a) For patients **not requiring** a consultation, do the following:
         i. Review the BN referral form and all medical documents.
         ii. Approve or decline services in the program and document in the BN-200**.**

iii. If approved, instruct the nurse to submit all documents to the BNTB coordinator for collaborative approval into the program.
iv. Await response from the BNTB coordinator.

b) For patients **requiring** a consultation, do the following:
i. Review the BN referral form and all medical documents.
ii. Fill out the consultation template. Use Heartland Medical Consultation Form, or the TB-242 DSHS TB Consultation Request Form, or equivalent.
iii. Instruct the nurse to submit all documents to the BNTB coordinator, who in turn will ensure all documents are submitted to the consulting physician.
iv. Await response and treatment recommendations.

c) For patients who are **not eligible** to be served in the BNTB program, referrals or medical records do not need to be forwarded to the BNTB coordinator. Refer the patient back to the Regional Mycobacteriology Program with a response documented on the BN-200.

C. The **BNTB coordinator** will do the following:

1. Review the referral documents for eligibility criteria and reason for enrollment, and ensure the patient is eligible for enrollment into the BNTB program.
2. For patients not requiring consultation, and in collaboration with the treating physician in México, accept or decline the patient for enrollment.
3. For patients requiring a consultation, submit documents to the Texas consulting physician for review.
4. For all patients, if services cannot be provided in the BNTB program, clear documentation should be provided in the appropriate section of the BN-200 referral form.
5. Return the BN-200 form to the México BN program with the response within three business days and retain a copy in the shadow chart in the Texas BN program.
   a) Attach medical consultation recommendations when applicable.
6. If U.S. medications are needed and treatment orders are received by the treating physician in México, the BNTB coordinator may now order medications from DSHS pharmacy. See CHAPTER XIV. MANAGEMENT OF MEDICATIONS AND MEDICATION AVAILABILITY.

D. The **Texas consulting physician** will do the following:
1. Review all information submitted by the BNTB coordinator.
   a) The consulting physician may engage a DSHS-recognized medical TB consultant if needed prior to deciding to accept or refuse entry into the BNTB program.

2. For patients requiring consultation, collaborate with the program manager, the BNTB coordinator, and the treating physician in México to determine if the patient will be accepted into the program.
    a) If accepted, provide in writing treatment recommendations and plan of care. This will be shared with the BNTB coordinator, who will, in turn, share it with the BN treating physician in México.
    b) The Texas consulting physician does not need to fill out or sign the BN-400A or BN-400B; this is done by the treating physician in México, see CHAPTER XIV. MANAGEMENT OF MEDICATIONS AND MEDICATION AVAILABILITY for the process.
    c) If enrollment in the program is declined, document on the BN-200 a clear and detailed rationale for the decision.
    d) Submit documents back to the BNTB coordinator with documentation of acceptance or denial. Instruct the BNTB coordinator to return all the following forms to the BNTB program in México and ensure copies are kept in the shadow chart.
        i. BN-200
        ii. Written recommendations for treatment

Step 2 Initiate Treatment

A. The **treating physician in México** will do the following after formal enrollment into the program:

1. Notify the Regional Mycobacteriology Program in México using the BN-200 of acceptance into the program.
    a) For patients denied access into the program, submit a copy of the BN-200 form to the Regional Mycobacteriology Program in México and include the reason the patient was denied entry into the program.
2. Provide further orders for diagnostics and treatment as recommended in the consultation or as outlined in CHAPTER IX. MANAGEMENT OF PATIENTS WITH LATENT TB INFECTION, INCLUDING PATIENTS ON WINDOW PROPHYLAXIS or CHAPTER X. MANAGEMENT OF PATIENTS WITH SUSPECTED OR CONFIRMED TUBERCULOSIS.
    a) Write all orders on the TB-400s or equivalent. Ensure a copy is provided to the BNTB coordinator to be kept in the Texas TB shadow chart and for ordering medications accordingly.

B. The **Nurse in México** will do the following after formal enrollment into the program:

1. Ensure written, signed orders are received from the treating physician prior to initiating treatment.
2. Coordinate and communicate with the BNTB coordinator on medication procurement.
3. Once medications are received from the BNTB coordinator, the nurse in México must check each patient's medication against the physician's orders to ensure the

correct medication regimen and dosages are received prior to giving to the patient. See CHAPTER XIV. MANAGEMENT OF MEDICATIONS AND MEDICATION AVAILABILITY.

4. Document in the medical record all services performed.
5. Submit required forms to the BNTB coordinator to save in the Texas shadow chart as outlined in CHAPTER IX. MANAGEMENT OF PATIENTS WITH LATENT TB INFECTION, INCLUDING PATIENTS ON WINDOW PROPHYLAXIS or CHAPTER X. MANAGEMENT OF PATIENTS WITH SUSPECTED OR CONFIRMED TUBERCULOSIS.

Appendix C: Co-management of Patients Agreement

[INSERT DATE]
Dear [INSERT REGIONAL MYCOBACTERIOLOGY PROGRAM NAME, JURISDICTION #],

The Texas Department of State Health Services (DSHS) Binational (BN) Tuberculosis (TB) Program in the TB and Hansen's Disease Section (TB Section) oversees TB prevention and care services to reduce the burden of TB along the Texas-México border.

The DSHS-funded BNTB clinic in [INSERT NAME OF CITY, STATE] in México is directed by the guiding principles, mission, and vision of DSHS and the Secretariat of Health in México, including standards set forth by the TB Section.

The Binational TB Program will provide the following TB services:

☐	Contract with a fiduciary agency to hire medical and nursing staff to provide services in México. The current agency is [INSERT NAME HERE]
☐	Provide the Regional Mycobacteriology Program in México, a formal written communication of acceptance or decline of a patient into the BNTB program.
☐	Ensure all referrals have a binational link as outlined in the BNTB manual, and that all health institutions in México (i.e., IMSS, ISSSTE, etc.) first refer patients, including suspected patients of TB, to the Regional Mycobacteriology Program, which in turn will validate the information and send a referral to the BNTB program.
☐	Submit index case information for contacts referred from the U.S./Texas to the Regional Mycobacteriology Program to meet México reporting requirements.
☐	Request additional patient information from the Regional Mycobacteriology Program in a confidential and secure manner.
☐	Evaluate and treat patients following the standards of care outlined in the BNTB manual.
☐	Provide directly observed therapy (DOT) and/or video directly observed therapy (VDOT) to patients following the standards of care outlined in the BNTB manual and the DSHS VDOT Required and Recommended Activities document.
☐	Provide DSHS medications, in the interim, while awaiting a response from México to acquire medications as applicable (i.e., doTBal, personalized treatments for drug-susceptible patients, and second-line medications for drug-resistant patients, bedaquiline, clofazimine, etc.).
☐	Submit diagnostic results and treatment recommendations back to the Regional Mycobacteriology Program on all patients accepted into the BNTB program to facilitate México's reporting requirements to the National Tuberculosis Platform.
☐	Provide routine updates on patient management or contact evaluation activities until services are completed.
☐	Conduct an appropriate contact investigation in accordance with DSHS guidelines and treat contacts in accordance with the standards of care outlined in the BNTB manual.

☐	The following will be performed as recommended by the BNTB physician to meet both U.S. standards for care and Mexican National Standards. 1) Management and treatment of the following: ✓ Contacts with TB infection (LTBI) ✓ Suspected or active TB disease ✓ Drug-resistant disease ✓ Contacts with active TB disease 2) Collection and shipment of specimens to include: ✓ Sputum, urine, or miscellaneous specimens collected for AFB testing ✓ Laboratory tests ✓ Radiology 3) Routine medical evaluations. 4) TB education to patients and families on the prevention of TB transmission, the disease process, and the consequences of inadequate treatment. 5) Conduct TB education activities for health care providers within the service area to promote BNTB and patient referrals through the Regional Mycobacteriology Program.
☐	List other details as appropriate: *(i.e., Drug-resistant patients will only be monitored via DOT. VDOT is not allowed for drug-resistant patients referred from the Regional Mycobacteriology Program).*

The Regional Mycobacteriology Program in México will provide the following:

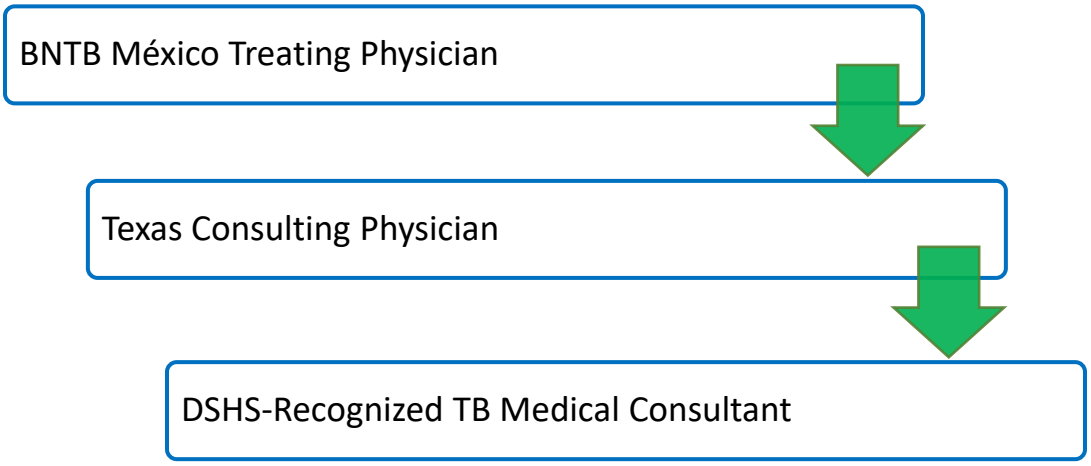
☐	Submit a referral using the BN200 form to the BNTB program for patients suspected or with active TB disease and/or contacts that meet the criteria to receive services as listed in the BNTB manual. Referrals should include any diagnostics collected in México and any other pertinent patient documents.
☐	Verify that all patient information submitted by Health Institutes in México is complete and accurate prior to referring to the BNTB program.
☐	Provide information for patients with a BN link (cases and/or contacts) to quickly identify possible contacts in the U.S. for timely investigation in both countries.
☐	Respond promptly and securely to requests for patient information, ensuring confidentiality.
☐	Provide medications for patients who can continue doTBal as indicated by the BNTB program physician, in accordance with the Official Mexican Tuberculosis Standards (NOM-006-SSa2-2013).
☐	Coordinate with the COEFAR/GANAFAR for patients with drug-resistant TB, as indicated by the Official Mexican Tuberculosis Standards (NOM-006-SSa2-2013) and request second-line medications.
☐	Contact the BNTB program for copies of diagnostics, progress notes, and updates on patient status as needed.

In partnership,

[INSERT BNTB Program Name, Contact Information]

Appendix D: Medical Consultation Process

The BNTB programs shall follow the TB Section's medical consultation process when submitting a request for consultation to either a Texas consulting physician or a DSHS-recognized TB medical consultant. The consultation process includes the following tiered approach:



Not all patients in the BNTB program require a medical consultation. The BNTB treating physician in México may determine whether the patient can continue doTBal based on the patient's status (e.g., response to treatment, improved CXR, etc.) or whether the patient requires only individual weight-specific doses to either replace doTBal or augment it. In these situations, consultations are not required unless the treating physician determines they are needed or the patient meets one of the criteria listed below. Texas physicians do not need to sign the BN-400s for medications to be ordered from the DSHS pharmacy.

Informal "Curbside Consultations" are strongly discouraged, as complete and comprehensive information must be submitted to the medical consultant for an objective assessment of the patient to make the best recommendations.

Consultations with a DSHS-recognized TB medical consultant will first be reviewed by the Texas consulting physician, who will determine whether to elevate to a DSHS-recognized TB medical consultant unless otherwise specified within each program.

Consultation to the Texas Consulting Physician

Consultations with the Texas physician are required or recommended in situations described below.

A. Consultations are **REQUIRED** when any of the following apply:

   1. When INH cannot be used in a treatment regimen due to resistance, intolerance, or drug interaction.
   2. Patients have serious forms of TB, e.g., disseminated or meningeal TB.

3. Patients for whom a short-course regimen is considered.
4. Patient has a positive AFB sputum smear and/or positive sputum culture for *M. tb* after two months of appropriate therapy for TB disease.
5. Second-line medications are prescribed.
    a) RBT can be used interchangeably with RIF in patients with drug interactions. If RBT is used in place of RIF due to drug interactions, a consultation is not required.
    b) For children weighing less than 30kg needing RBT, a consultation is required.

B. Consultations are **highly RECOMMENDED** when:

1. Intermittent therapy is considered either in the initial or continuation phase, including when doTBal is used.
2. Patient has HIV infection and is on or anticipates starting on antiretrovirals.
3. Patient's symptoms or CXR have not improved after the first two months of treatment.
4. Patient is under the age of five years.

Consultation process to a Texas consulting physician

1. The México treating physician may communicate directly with the Texas consulting physician and explain the reason for a consult request. This can be done without first involving the BNTB coordinator. However, a consultation form must subsequently be completed and submitted to the BNTB coordinator. Use TB-242 DSHS Medical Consultation Request Form or the equivalent.
2. The nurses in México will gather all medical documents and submit them to the BNTB coordinator.
3. The BNTB coordinator will collect the following information and submit it to the Texas consulting physician:
    a) Consultation form may be done by the physician in México or the BNTB coordinator, depending on the processes in place within each program.
    b) Complete clinical evaluation to include:
        i. History of present illness beginning with the patient's initial presentation and proceeding chronologically up to the present time, noting any improvements since treatment initiation.
        ii. Prior history of TB exposure, infection, or disease.
        iii. TST or IGRA history and current dates and results.
        iv. Baseline and current chest x-rays/CT/other diagnostic imaging, written reports if possible, and pathology results. A disc of these should be sent if requested.
        v. Bacteriology smears and cultures - this may be submitted by including a log to show trends. MDDR and drug susceptibility reports should be shared when applicable.
        vi. Laboratory – HIV results with CD4 and viral load, baseline, and periodic laboratory monitoring results.

vii. Medical history/medical and drug-resistant risk factors, social and individual risk factors for LTBI or disease.
viii. Medication history – prescription, over the counter, folk, or herbal use.
ix. Current weight, including weight changes in response to therapy.
x. If there is a history of hospitalization, include the admission history, physical exam findings, and hospital discharge summary.

4. The Texas consulting physician will review the documents and submit treatment recommendations in writing to the BNTB coordinator to be shared with México's treating physician.
5. The México treating physician will complete medication orders on the TB-400 and submit them to the BNTB coordinator to order from the DSHS pharmacy.
6. When consultation is obtained from a Texas consulting physician, BNTB clinics will provide a follow-up summary of the patient's status if requested by the Texas consulting physician.

Consultation to a DSHS-Recognized TB Medical Consultant

Consultation from a DSHS-recognized TB medical consultant is required or recommended in situations described below. Exceptions to a DSHS-recognized TB medical consultant may be granted if made by the DSHS Regional Medical Director (RMD). The RMD may request a consult from a DSHS-recognized TB medical consultant as needed. Consultants may be found at DSHS-Recognized Tuberculosis Medical Consultants | Texas DSHS.

A. Consultations are **REQUIRED** when any of the following apply:

1. Patient has laboratory-confirmed drug resistance or is suspected to have drug-resistant TB. (Laboratory-confirmed drug resistance is defined as resistance to INH and/or RIF, or to any drug other than streptomycin on the drug susceptibility panel testing.
    a) An initial notification should occur within three days of laboratory test results showing DR-TB. Include all current known status, including details of the patient, 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.
    b) A formal consult should occur as soon as more test results are known, and a treatment plan has not yet been established.

    Note: If the organism is identified as *M. bovis* with PZA monoresistance, a consultation is not required.
2. Patient with RR, MDR, Pre-XDR, or XDR TB, and
    a) Is reaching the end of treatment and prior to stopping treatment;
    b) Any treatment regimen changes are needed, i.e., adverse drug reaction or abnormal drug levels;
3. Patient is a contact to a case of MDR-TB, Pre-XDR-TB, or XDR-TB, unless otherwise communicated by the RMD or Texas Consulting Physician.
4. The treating physician is requesting MDDR testing.

5. When a rifamycin cannot be used due to intolerance or drug interactions in a regimen for active TB.
6. Patient has positive sputum cultures for *M. tb* after four months of appropriate therapy for TB disease and is a treatment failure.

B. Additional consultation is **highly RECOMMENDED** when a DR-TB patient:

1. Has a change in status;
2. Misses required screenings;
3. Exhibits signs of adverse drug reactions;
4. Is discharged from Texas Center for Infectious Disease (TCID); and/or
5. Any time the treating physician is concerned about the patient.

Consultation Process to DSHS-Recognized TB Medical Consultant

1. The Texas consulting physician, BNTB coordinator, or treating physician will ensure all documentation is in order prior to submitting information. This includes all documents identified in A.3.C.#1 and #2, Consultation Process to Texas Consulting Physician. If the patient is drug-resistant, include the TB-700 TB Drug-O-Gram and Clinical Monitoring Overview, or the equivalent as requested.
2. Requests to Heartland will be routed through the nurse consultants at Heartland, who will review all documents submitted by the Texas consulting physician or BNTB coordinator and prioritize the request. The BNTB coordinator will request a status update on pending consultations from the Heartland nurse consultants via email or phone.
3. Submit all information and radiographs to:

HEARTLAND NATIONAL TB CENTER
2303 SE MILITARY DRIVE
SAN ANTONIO, TEXAS 78223

4. Once Heartland receives all information, recommendations will be provided in writing back to the requester. This may be done by email or as a formal consult request using the agency's letterhead. If no response is received within five business days, email the HTNC nurse consultant and request an update.
5. Place recommendations in the patient's clinic chart and a copy in the patient's shadow chart.
6. The México treating physician will complete medication orders on the TB-400 and submit them to the BNTB coordinator to order from the DSHS pharmacy.
7. When consultation is obtained from a DSHS-recognized TB medical consultant, BNTB programs will provide a follow-up summary of patient status as determined by the consulting physician.

Appendix E: DSHS TB Formulary

The following medications and supplies for outpatient TB management are available to BNTB programs. Place orders via DSHS Pharmacy Inventory Ordering System (PIOS). For further assistance, contact the DSHS Pharmacy Unit at 512-776-7500.

Drug (Name Brand)	Item Description	Route	Comments
Amikacin	Vial	IM, IV	See *CHAPTER XIV* Requires consult
Bedaquiline (Sirturo)	Tablet (Tab)	PO	See *CHAPTER XIV* Requires consult and TB Section approval
Clofazimine	Capsule (Cap)	PO	See *CHAPTER XIV* Requires IRB after TB Section consultation
Cycloserine (Seromycin)	Cap	PO	See *CHAPTER XIV* Requires consult
Ethambutol (Myambutol)	Tab	PO	**First Line**
Isoniazid	Solution /Tab/Vial	PO, IM	**First Line**
Levofloxacin (Levaquin)	Solution/Tab/Vial	PO, IV	See *CHAPTER XIV*
Linezolid (Zyvox)	Suspension (Susp)/Vial	PO, IV	See *CHAPTER XIV* Requires consult
Moxifloxacin (Avelox)	Tab/Vial	PO, IV	See *CHAPTER XIV*
Pretomanid	Tab	PO	See *CHAPTER XIV* 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
Lidocaine (Xylocaine) 1% or 2%	Vial	IM, IV	
Pregnancy Tests	Test	NA	
Simple Syrup (Cherry flavor)	Bottle	PO	For medication administration
X-ray envelopes	Envelopes	NA	
Syringes (1/2”, 27 gauge)	Syringe	NA	

Tubersol	Vial	SC	
Amber RX bottles (child resistant)	Vial	NA	For self-administration DOT or VDOT
Specimen Transport Boxes	Box	NA	Cardboard box + Styrofoam for cold-box specimen shipping
Gel Pack	Gel Pack	NA	For cold-box specimen shipping
Auxiliary Medications			
Azithromycin (Zithromax)	Susp/tab/vial	PO/IV	See *CHAPTER XIV*
Ondansetron	Tab(Orally dissolving tab),Solution	PO	See *CHAPTER XIV*
Dexamethasone	Tab	PO	See *CHAPTER XIV*
Promethazine	Tab	PO	See *CHAPTER XIV*
Prednisone	Tab/Solution	PO	See *CHAPTER XIV*
Prednisolone	Tab/Solution	PO	See *CHAPTER XIV*
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 XIV*
SPF 30 and 50	Cream	External	For patients on Clofazimine ONLY
Alternative TB Medications These drugs may only be prescribed in rare circumstances (e.g., XDR-TB with additional resistance) after coordination with a DSHS-Recognized Medical TB Consultant and TB Section. Some are not commercially available in U.S.			
Para-amino salicylic acid (PAS)	Granules	PO	Contact TB Section (not commercially available in U.S.)
Ethionamide (Trecator)	Tab	PO	Contact the TB Section (not commercially available in the U.S.)
Tedizolid (Sivextro)	Tab	PO	Contact TB Section

Appendix F: Binational TB Program Clinical Care Forms

DSHS clinical care forms are available in Spanish for use in the BNTB program. BNTB programs will use the following forms or their equivalent:

A. ATS 2, and those on window prophylaxis:

1. BN 200 Referral Form - when applicable
2. BN-400A Spanish Report of Case and Patient Services
3. TB-415a Consent LTBI Therapy
4. BN-210 Latent TB Infection Case Management Care Plan
5. BN-202 TB Initial Health Risk Assessment/History
6. BN-205 Toxicity Assessment
7. BN-206 Directly Observed Therapy Log
8. TB-240a Refusal of Treatment for Latent Tuberculosis Infection (if applicable)
9. 12-14198a 3HP Dosing and Symptom Monitoring Log (if applicable)
10. General Consents:
    a) L36a General Consent and Disclosure
    b) L30a Authorization to Release Confidential Medical Information, when applicable

B. ATS 3, 5:

1. BN-200 Referral Form
2. BN-400A Report of Case and Patient Services
3. BN-400B Spanish Report of Case and Patient Services
4. BN-201 Case Management Plan for Outpatient Care
5. BN-202 TB Initial Health Risk Assessment/History
6. BN-203 Education/Counseling Record
7. BN-205 Toxicity Assessment
8. BN-206 Directly Observed Therapy Log
9. TB-231a Bacteriology TB Control Log
10. TB-411a Disclosure and Consent Drug Therapy TB
11. TB-700a-TB-705a series for drug-resistant patients
12. TB-902a Patient Acknowledgment of Conditions for TB Isolation Release
13. General consents:
    a) L36a General Consent and Disclosure
    b) L30a Authorization to Release Confidential Medical Information, when applicable

C. Contact Investigation:

1. TB-208a Tuberculosis Contact Screening Form
2. TB-340a Report of TB Contacts
3. TB-341b Continuation of Report of TB Contacts
4. 12-12062a Contact Investigation Worksheet

5. TB-460a TB Contact Investigation Expansion Analysis Checklist
6. TB-230a Contact Refusal Form (if applicable)
7. TB-425a TB Infectious Period Calculation Sheet

D. Cohort Review:

1. 12-14064a Cohort Review Presentation Form

E. VDOT

1. 12-15760a Mobile Application
2. 12-15761a VDOT Mobile Phone User Agreement
3. 12-15762a VDOT Patient Participation Agreement
4. 12-15763a Video DOT Medication Layout
5. 12-15764a VDOT Patient Instructions

Appendix G: Sputum Collection Procedure

Staff in México must adhere to all standard precautions, including bloodborne and respiratory precautions, when participating in TB sputum collection procedures. Ensure that a physician's order is available prior to sputum collection.

Procedure

1. Verify the patient meets the criteria for TB sputum collection and has been accepted into the BNTB program.
2. Ensure, to the extent possible, that the patient seen for TB sputum collection services is, in fact, who the person claims to be.
3. Obtain the patient's general consent and signature. Consent and signature should be obtained by the nurse responsible for the patient's clinical management. Provide copies of the DSHS Privacy Notice and applicable signed consent forms.
4. Explain to the patient the TB sputum collection process. Discuss with the patient the risks and benefits of sputum collection. Provide the patient with the opportunity to ask questions.
5. Gather required supplies and prepare to collect the sputum sample.
    a) Label the innermost tube with the patient's full name and date of birth before obtaining the TB sputum specimen and before giving container(s) to the patient for home sample collection. Provide the following instructions to the patient:
        i. Rinse mouth well with water to avoid contamination with food particles and mouth bacteria. Ideally, TB sputum specimen collection should occur before eating.
        ii. Inhale deeply two to three times and breathe out hard each time.
        iii. Cough deeply from the chest. A deeply coughed specimen is required (not saliva or nasal secretions).
        iv. Place the open container close to the mouth to collect the TB sputum specimen. The ideal specimen size is 5 to 10 mL, but 3 to 15 mL is acceptable.
        v. Avoid contaminating the inside of the container and lid by contact with the mouth or hand.
        vi. Close lid tightly and place into the TB sputum specimen bag.
        vii. If the patient collects TB sputum specimens at home, instruct the patient to store the TB sputum specimen(s) in a refrigerator until specimens are transported to the clinic as soon as possible.
        viii. If the patient is unable to produce an early morning sputum, suggest that he/she stand or sit in a steamy environment for 15 minutes after running hot water in the shower, if possible.
    b) Supervise at least one (ideally the first) TB sputum collection to document that the patient demonstrates the correct technique.
        i. The first TB sputum specimen can be collected "on-the-spot" at the first patient encounter.
        ii. Three TB sputum samples should be collected at least eight hours apart.

c) If the patient is unable to produce an acceptable TB sputum specimen, follow the procedure below for TB sputum induction, if resources are available.
d) Once a TB sputum specimen is obtained, label and correctly package the specimen according to shipping requirements.
    i. TB sputum specimens must be packed in triple containment with sufficient absorbent material enclosed to absorb the entire volume of liquid. The container used must meet current DOT and United States Postal Service regulations.
    ii. Complete the appropriate lab requisition G-MYCO form.
    iii. Specimens should be refrigerated.
    iv. Specimens should be transported to the U.S. on cold packs and shipped to the laboratory as soon as possible, but no longer than one week.

TB Sputum Induction Procedure

1. Obtain and assemble the nebulizer tubing kit.
2. Attach one end of the air tubing to the compressor unit and the other end to the nebulizer medication cup outlet.
3. With the machine turned off, prepare the nebulizer equipment as per the package instructions. Add approximately 3 mL of sterile 0.9% sodium chloride (NaCl) solution to the nebulizer medication cup.
4. Instruct the patient to close lips around the mouthpiece and to breathe in and out slowly and deeply on the mouthpiece.
5. Turn the compressor on and place the mouthpiece into the patient's mouth.
6. Encourage cough if no spontaneous coughing occurs.
7. Continue procedure until cough is stimulated, adding more sterile 0.9% NaCl solution as needed.
8. When a cough is stimulated, encourage its repetition several times to obtain an adequate specimen (at least 5 mL).
9. Upon completion, turn off the nebulizer.
10. Label and package the TB sputum specimen correctly and legibly. Mark the lab requisition as "induced specimen".
11. Disassemble mouthpiece and disinfect nebulizer according to manufacturer instructions.
12. Document in the patient's medical record the procedure used to collect sputum, the amount and description of sputum collected, and other circumstances affecting collection. (i.e., Patient instructed on collection of natural induction. Successfully observed patient collect 5 mL of thick, yellow secretions tinged with blood without difficulty. Patient given sputum containers to collect #2 and #3 at home and refrigerate after collection. The nurse will collect from the patient at home on day #3, or the patient will deliver to the clinic).

Appendix H: Directly Observed Therapy (DOT) Procedure

DOT is the standard of care for patients in the BNTB program, outlined in CHAPTER VIII. STANDARDS OF CARE in this manual.

Staff providing DOT should be a contractor of the fiduciary agency and have undergone training in providing DOT, including medication identification and toxicities.

Procedure

1. Verify the medication in the TB DOT packets and acknowledge receipt of the DOT packets. If the person providing DOT is not a nurse, ensure that a nurse has reviewed the DOT packets prior to providing them to the patient.
2. Ensure, to the extent possible, that the person seen for TB DOT services is, in fact, who the person claims to be.
3. Provide your name and contact information to the patient.
4. Ensure that the patient's consent and signature have been obtained by the nurse responsible for the clinical management of the patient. If consent and signature have not been obtained, then obtain consent and signature in accordance with agency policy and provide copies of the DSHS Privacy Notice and applicable signed consent forms.
5. Determine safety prior to making a home visit. Consult the National program if there are any alerts for the area.
6. Arrive at the agreed-upon place at the designated time with the patient's medication(s).
7. Document missed appointments on the Tuberculosis Directly Observed Therapy Log (BN-206 or their equivalent) when the patient is not found at the agreed place at the agreed time.
    a) If unsafe conditions exist or if you feel threatened, leave as safely and quickly as possible. Immediately call 911, or the alternate number used in some areas if necessary. Once you are in a safe place, notify your treating physician or the nurse responsible for the patient's clinical management.
    b) Medications should not be left at the home or outside the home unless given directly to the patient.
8. Observe the first dose of TB medications. The first dose should be observed by a nurse or a physician. If the patient's first dose of TB medication cannot be observed by a nurse or physician, immediately notify the nurse responsible for the patient's clinical management.
9. Complete and sign the Patient/DOT Provider Agreement BN-206 or TB-704a for drug-resistant patients upon initiation of TB DOT, and at the beginning of each month of TB DOT. Ensure the patient signs and dates the form.
10. Complete the adverse reaction screening questions listed on the Tuberculosis Directly Observed Therapy Log BN-206 or TB-704a for drug-resistant patients.
    a) If the patient reports any symptoms noted with a double asterisk or noted as adverse reactions, do not give the medication to the patient. Contact the nurse or the treating physician responsible for the patient's clinical management for instructions.

11. Provide the medication packet to the patient and ensure the patient has a drink available.
12. Observe the patient ingest all medications from each TB DOT dose packet. The patient should be continuously observed from the time the TB DOT dose packet(s) are given until all the medication is ingested. Never leave a TB DOT dose packet for later unless it is for self-administration. Self-administered doses CANNOT be recorded as DOT.
13. If the patient is unable to ingest the entire dose, contact the treating physician responsible for the clinical management of the patient for instructions.
14. If the patient is suspected of not swallowing the medication, inspect the patient's mouth, including under the tongue.
15. If the patient is suspected of vomiting medication after the visit, wait 30 minutes before leaving the patient.
16. Document the dose of medication observed and place initials on the Tuberculosis Directly Observed Therapy Log BN-206 or TB-704a for drug-resistant patients or their equivalent.
17. Request the patient's initials as confirmation of the dose of medication observed on the Tuberculosis Directly Observed Therapy Log BN-206 or TB-704a for drug-resistant patients.

Appendix I: 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 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:

A. Examined the patient's clinical status
B. Adequacy of the patient's regimen
C. Treatment adherence and completion
D. 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 and ongoing, providing an opportunity to review individual patient care. They allow for immediate analysis of a patient's progress and plans to address any needed changes to treatment and management. As cohort reviews are a retrospective analysis of treatment outcomes, they provide an opportunity to review case data to address systemic programmatic concerns regarding the overall management of TB patients, improve patient care and programmatic performance, and 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.

Cohort Periods

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

Table 14: 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 (Jul 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

Cohort Teams

1. 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:
   a) BNTB Regional or Local Program Manager/TB Supervisor
   b) BNTB Coordinator and/or Nurse Case Manager
   c) BNTB Nurse in México
   d) BNTB Treating Physician

2. If available, the following participants may also be a part of the team:
   a) BNTB Texas Consulting Physician
   b) BNTB Manager/CDC Public Health Advisor
   c) BNTB Nurse Consultant
   d) BNTB Program Evaluation Consultant
   e) BNTB Data analyst or epidemiologist
   f) Contact investigator – if applicable
   g) DOT worker – if applicable

Reporting Requirements for Cohort Reviews

1. The Cohort Review Presentation Form shall be used to collect and present patient information during the cohort review meetings.
2. The Cohort Review Summary Form shall provide summarized and quantifiable data from all counted cases and associated contacts presented at each quarterly cohort review.
3. The Cohort Review List of Counted Cases shall be used to list counted cases presented at each quarterly cohort review.
4. Submit by the dates identified in TABLE 14: COHORT PERIOD AND SUBMISSION SCHEDULE, the above forms using GlobalScape, or as specified by the TB Section.

Cohort Review Resources

The following links provide information on cohort review models:

- The CDC Understanding the TB Cohort Review Process Instruction Guide, 2006.

Appendix J: Biological Specimen Transportation

Services

Auspicious Laboratory, Quest, the University of Florida- Infectious Disease Pharmacokinetics Laboratory, and DSHS laboratories in Austin and Harlingen perform testing for patients undergoing evaluation for LTBI and TB disease. These tests include mycobacteriology, hematology, chemistry, and special tests. The list of all tests performed at the DSHS laboratories is available in the Laboratory Services Manual.

CDC Import Permit

The CDC Import Permit Program (IPP) began using BioPermit as the newest secure electronic information system for import permits in February 2026, replacing eIPP. Information from eIPP did not transfer to BioPermit. Each BNTB program coordinator and Laboratory Safety Officer is responsible for completing the necessary CDC forms and the follow-up process to renew their permit to transport and receive biological specimens from México to the U.S., in compliance with federal regulations (42 CFR 71.54).

1. All CDC import permit applications must be submitted electronically using BioPermit.
2. All applicants are required to have a Secure Access Management Services (SAMS) account to access BioPermit.
    a) If a SAMS account exists, email BioPermitSupport@cdc.gov and provide the SAMS username for IPP to link the SAMS account with BioPermit.
    b) If a SAMS account does not exist, fill out and submit the BioPermit Support Request Form.
3. Once SAMS credentials are obtained and BioPermit linked,
    a) Go to sams.cdc.gov.
    b) Login with username (email) and password.
    c) The SAMS Landing page should load with the middle section shown as “My Applications.”
    d) Under “My Applications,” note the section called “BioPermit.” Select the link to go to the permittee portal. First-time users to BioPermit, select “Create New Agent Application.” Once approved through BioPermit, access will be given to use the “Renew Agents Application.”
        i. Start the application or renewal process at least a month before the current permit expires.
4. Since samples will be sent to multiple labs, enter the TB agent and other agents like HIV and Hepatitis in multiple lines, as many labs where it would be sent to be processed and tested.
    a) A permit is valid to import to a specific location. Since samples are being imported from the BNTB locations listed on the permit, the recipient laboratory must also have a permit. Please contact the TB Section for assistance in obtaining a copy of the laboratories' BioPermits, or contact each laboratory’s safety officer to verify that their permit is up to date.

5. Remember, when applying
    a) The BNTB program coordinator must be the "Primary Permittee" and should include the TB Program Manager as backup.
        i. The contact information must be accurate. If there are any concerns at the port of entry, Customs and Border Protection (CBP) will contact the Primary Permittee to corroborate the accuracy of the importation.
    b) Multiple users may be added. All nurses and couriers can be added as "Sender." Make sure the name matches the person's legal name.
        i. Inform the nurses and courier always to declare the importation and have extra copies of the permit and the specimen manifest to provide to CBP at the time of crossing.
6. For detailed instructions and additional information, please view the BioPermit Training Webinar and review the FAQ to understand the requirements and the system.
7. Once approved, send a copy of the permit to the TB Section for record-keeping.
8. Shipping instructions and the use of the samples manifest remain the same. See APPENDIX K: SAMPLE BIOLOGICAL SPECIMEN MANIFEST.

Note:

- For previous system users of "eIPP" download any active permits, if applicable. These records did not transition to BioPermit. eIPP will completely shut down on 12/31/2026.
- For all laboratories, being BSL-3, having the U.S. Department of Agriculture importation permit, or other certifications and permits, does not eliminate the need for the CDC BioPermit to be able to receive and process BNTB specimens.

Shipping

Packing must conform to federal regulations (49 CFR 171-180). Apply the following:

1. The diagnostic specimens, such as excreta, blood, and its components, as well as other tissues and fluids that are human materials being transported only for the purpose of diagnosis or investigation, are assigned as a Category B infectious substance (UN 3373). In accordance with the U.S. Department of Transportation's Hazardous Materials Regulations and international organizations (International Air Transport Association Dangerous Goods Regulations; International Civil Aviation Organization; and International Air Transport Association), Category B is low- or moderate-risk specimens. For safe transportation, the packaging, label, and shipping should meet the following conditions:
    a) Triple pack the specimens in the following:
        i. Leakproof primary receptacle; multiple primary receptacles should be individually wrapped or separated.
        ii. Leakproof secondary receptacle; and
        iii. Rigid or strong outer packaging
    b) If the specimen is a liquid, place sufficient absorbent material between the primary and secondary receptacles to absorb the entire contents so that, during transport,

any release or leak of a liquid substance will not reach the outer packaging and will not compromise the integrity of the cushioning material.

2. Specimens must already be at the desired temperature (e.g., frozen or refrigerated) prior to placing them in the box for transport.
   a) If shipping specimens at refrigerated temperature (2-8°C), include ice packs or gel packs outside of the secondary container, add extra absorbent material, and note temperature handling conditions on the rigid outer packaging.
3. When multiple fragile primary receptacles are placed in a single secondary packaging, they should be either individually wrapped or separated to prevent contact between them.
4. Place a list of contents and paperwork between the secondary receptacle and outer packaging.
5. A biohazard symbol must be present on either the primary or secondary container.
6. Label outer package with:
   a) Proper shipping name: "Biological Substance, Category B" adjacent to the UN 3373 certification mark.
   b) Shipper and consignee identification (name, address, and telephone); and
   c) Package orientation arrows
7. Figure 8: Biological Substance Category B Packaging System outlines how to pack and label specimens for transport to the U.S. Upon arrival in the U.S., specimens are sent to the DSHS laboratory for AFB smears, AFB cultures, and drug susceptibility testing.
8. Ensure the following when transporting specimens with a permit:
   a) Only list individuals on the permit who are transporting specimens from México to the U.S.,
   b) Do not keep food or beverages near specimens, and
   c) Personal stops cannot be made during specimen transport.

Submitting to Laboratories

BNTB program coordinators may use the FedEx account supplied by the TB Section to ship approved specimens to DSHS laboratories in Austin and Harlingen, as well as DSHS-contracted laboratories. For the different courier packages and supplies available to programs, verify the formularies and order them through DSHS Pharmacy Inventory Tracking System, Quest Quanum, and FedEx.

1. Include with each specimen a completed laboratory specimen submission form (G-MYCO for Austin's laboratory or F-40-B for South Texas laboratory) containing all pertinent patient information, including specimen type and name of requesting physician. Programs must request a fillable form from each laboratory.
2. Please see the Tuberculosis Specimen Shipping Guide for more details.

Figure 8: Biological Substance Category B Packaging System

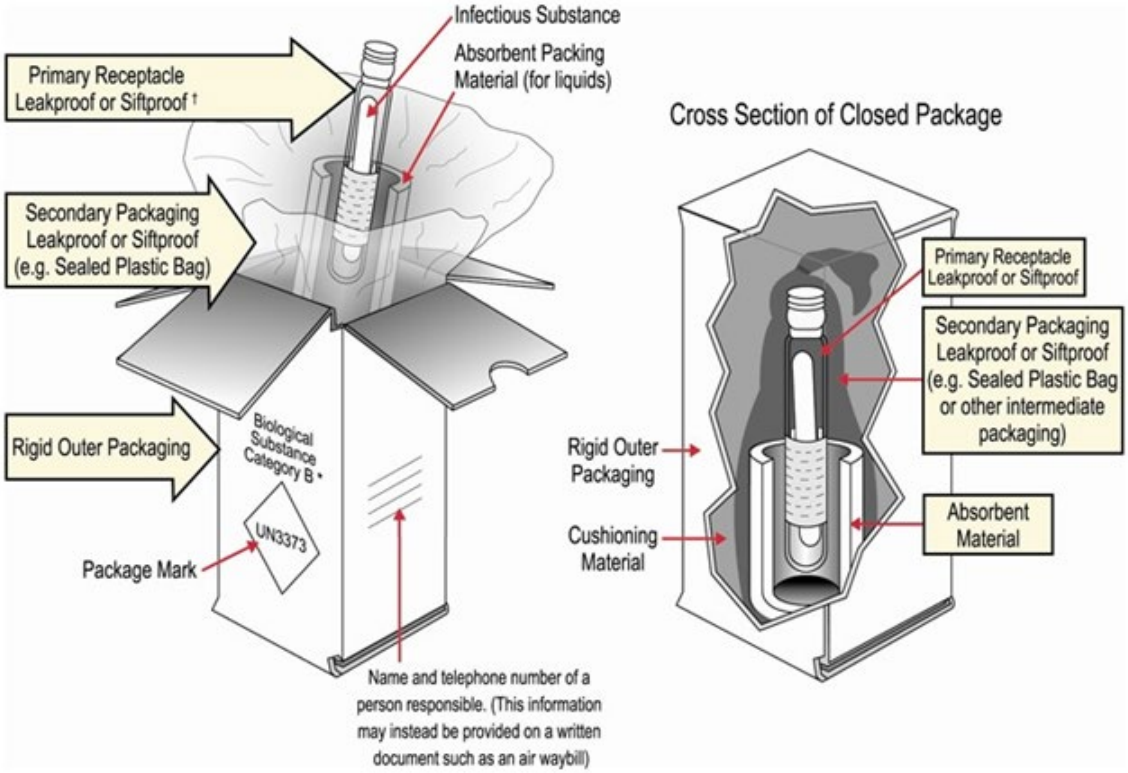
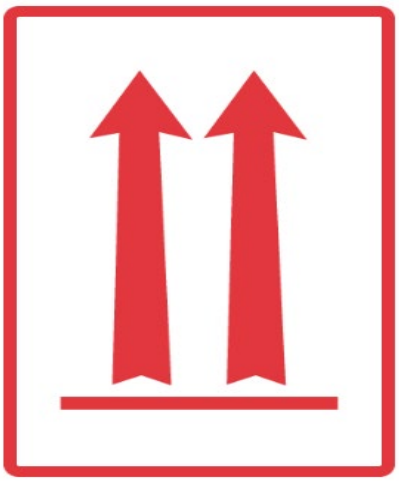


Image from CDC Packaging and Transporting Infectious Substances.

Figure 9: Biological B Specimen Labeling/Marking

These labels may be printed or ordered from *FedEx*.

Print this label and use it when shipping dry ice via *FedEx*.



Place an orientation label if it contains 50ml or more of liquid per primary container, or if it contains dry ice.

Appendix K: Sample Biological Specimen Manifest

A list of specimens being imported into Texas should be provided to the U.S. Customs and Border Protection (CBP) as part of the Customs Declaration 6059B, or CBP Form 7523 can be used. Please attach the list to the CDC Import Permit. Completed laboratory manifest or itemized invoices may be used as the importation manifest.

Manifest Example:

Texas Department of State Health Services
Tuberculosis and Hansen's Disease Unit
Binational Tuberculosis Program

Description of Article: Biological specimens of human origin for testing purposes to diagnose and treat tuberculosis (TB). Patients are enrolled in the Binational TB Program. The test will be performed at a Texas Department of State Health Services Laboratory.

CDC Permit #: _____ Total # of Specimens: _____ Commercial Value: $0.00

Number of specimens per type:

____ Sputum

____ Blood

____ Bronchial lavage

____ Excreta

____ Pleural effusion

____ Gastric fluid

____ Spinal fluid

____ Tissue

____ Urine

____ Other: _____

Samples are appropriately triple-packed as UN 3373.

Appendix L: TB Intake Information

Obtain the following information at intake within seven days of notification for anyone being evaluated for TB (includes ATS 2, 3, and 5). Not all information will be known at intake. Obtain the remaining information as soon as the patient has a confirmed TB diagnosis (*).

TB Intake Information	
Information as per NEDSS Investigation Tabs	**Description (please note that not all may be applicable to the BNTB programs)**
Patient Information	▪ Full name ▪ Date of birth ▪ Sex at birth ▪ If female, was the patient pregnant at the time of diagnostic evaluation? ▪ Physical address, city, county, Zip code with 4-digit extension (verified) ▪ Within/Outside city limits ▪ Census tract ▪ Ethnicity ▪ Race, extended race if Asian, Native Hawaiian, or Other Pacific Islander
Case Information	▪ Jurisdiction ▪ Initial ATS ▪ Initial ATS classification date ▪ Current ATS 3* ▪ Current ATS III 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 the country
TB History	▪ Has the patient been previously diagnosed with TB disease or LTBI?
Tuberculosis	▪ Country of birth ▪ If the country of birth is not the 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 a U.S. reporting area, has the patient been in the U.S. for 90 days or more? ▪ Status at TB diagnosis* ▪ Initial reason evaluated for TB

TB Intake Information	
Information as per NEDSS Investigation Tabs	**Description (please note that not all may be applicable to the BNTB programs)**
	▪ Symptoms/start date ▪ Diabetic at diagnostic evaluation ▪ Current smoking status at diagnostic evaluation ▪ 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. ▪ Diagnostic Testing -Response required for each test type, indicate if Not Done. ▪ Chest Imaging -response required, indicate if Not Done.
TB Disease Only*	▪ Site(s) of TB disease* ▪ Therapy/start date
LTBI Only (ATS 2 only)	▪ Therapy/start date

Appendix M: Guidelines for Responding to the TB Section's Surveillance Requests

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

The binational coordinator and designated surveillance point of contact will receive QA reports and requests from the TB Section on a routine basis (i.e., monthly or quarterly), depending on the type of request. Deadlines for each report/request will be included in the TB Section's communication.

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

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

Response to Requests

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

Appendix N: Interjurisdictional Communication

BNTB programs must ensure communication occurs with jurisdictions when a patient with an ATS classification of 2, 3, or 5, and contacts travel or move to a U.S. jurisdiction, and follow-up care is needed.

There are two types of communication channels:

A. Formal communication – using the National TB Controllers Association (NTCA) Interjurisdictional (IJN) form.
B. Informal communication – direct clinic-to-clinic phone calls, emails, or other forms of sharing patient information.

Activities

A. **When a patient plans temporary travel to the U.S.**

1. Plan, coordinate, and communicate informally (and formally when requested) with the receiving jurisdiction.
2. Within two business days of the BNTB program becoming aware of a patient's temporary travel plans (or has already traveled), identify the address where the patient will be staying or is currently staying. *Temporary travel is defined as 30 days or less to a U.S./Texas jurisdiction.*
3. Notify the Texas DSHS TB Section's IJN Coordinator within two business days that the BNTB program becomes aware of the patient's travel plans, that the patient will be in, or already is in, their jurisdiction temporarily, and determine which TB clinic in Texas should be contacted in case coordination of care may be needed. If the patient is moving to a non-Texas state, notify the Texas IJN Coordinator and the state's IJN Coordinator. The list of IJN contacts for each state can be found on the National Tuberculosis Controllers Association (tbcontrollers.org).
4. Coordinate the sharing of information as directed by the receiving jurisdiction. This includes sharing any requested medical records.
    a) The receiving jurisdiction must be notified of any patient on treatment for active TB, and as a courtesy, the BNTB program may want to provide details of a contact or person on treatment for LTBI.
    b) The receiving jurisdiction will determine the best way to coordinate care while the patient is in their jurisdiction.
    c) If the BNTB program plans to keep the patient on VDOT, this courtesy notification must still be made.
5. Programs may provide up to 30 days' worth of medications for a patient on treatment for TB disease or LTBI. Anything longer than 30 days warrants formal communication as outlined below.

B. **When a patient plans a permanent move to the U.S., or when temporary travel plans change, or the travel is longer than 30 days**

1. Plan, coordinate, and communicate informally and formally with the receiving jurisdiction.
2. Within two business days that the BNTB program becomes aware of a patient's plan to move (or has already moved and will not be returning to México), or remain in the U.S. longer than 30 days or when temporary travel plans change and assistance from the receiving state is needed, contact the Texas IJN coordinator (and another state's IJN coordinator if patient moved to a non-Texas state) to inform them of the patients move or intent to move to their jurisdiction or state.
3. Coordinate the sharing of information with the receiving local TB clinic as directed by the receiving state's IJN coordinator. This includes sharing of any medical records with the state and/or receiving local jurisdiction, and ideally a clinician-to-clinician phone call to share patient information and ensure continuity of care (i.e., a nurse-to-nurse handover).
4. Within one business day of notifying the receiving state, complete an IJN form, attach the completed IJN form and necessary medical records to the patient's investigation in NEDSS, update the address information, and update the appropriate fields in NEDSS to reflect the move. The most recent IJN form is available at National Tuberculosis Controllers Association (tbcontrollers.org).
5. Notify the Texas IJN Coordinator by email that the IJN has been attached to the investigation in NEDSS. The Texas IJN Coordinator's responsibilities include:
   a) Sending the IJN form and medical records to the receiving jurisdiction or state TB program by fax, and send follow up email to request receipt confirmation, and
   b) Logging the IJN referral for tracking purposes
6. Follow-up with the receiving jurisdiction or state to ensure completion of therapy and document the patient's outcome in NEDSS.

C. **Accept IJN transfers from Texas/U.S. to México**

1. When patients move to a Binational program geographical area in México from a Texas jurisdiction or U.S. state, an IJN referral form and medical records will be sent to the DSHS TB Section's Texas IJN Coordinator, whose responsibility includes:
   a) Create an investigation in NEDSS;
   b) Log the IJN referral for tracking purposes;
   c) Attach the IJN referral and medical records to the investigation; and
   d) Send an email to the receiving jurisdiction within two business days of receipt of the IJN form.
2. When the referring state or jurisdiction requests follow-up information on the evaluation outcome or treatment outcome of the patient who moved from the U.S. to México, the Texas IJN Coordinator will inform the receiving BNTB program of the

request. The receiving BNTB program will communicate directly with the referring program within 1 week of the follow-up request, either by phone, email, or via the IJN Follow-up Form.

3. For contacts living in México who were identified to an index case in the U.S., the referring jurisdiction will provide the index case susceptibilities when known and any other relevant information for México to develop a proper treatment plan for the contact.

Appendix O. Do Not Board and Public Health Lookout

CDC has the authority to place an individual on a Do Not Board (DNB) list to prevent the spread of infectious disease. This includes preventing a person who may be considered infectious from receiving a boarding pass and traveling by commercial aircraft either departing from or entering in the U.S.

The Public Health Lookout (LO) ensures that a person placed on the DNB would be detected if attempts to enter the U.S. through any port of entry (e.g., seaport or land border crossing) or leave through an airport or seaport. The LO prompts government officials if a person on the list arrives in the U.S., so that the person can be evaluated and referred for additional public health follow-up if needed.

The DNB/LO are used for people with suspected or confirmed TB, including MDR-TB.

Case Criteria

CDC requires meeting specific criteria to initiate a DNB/LO. Individuals must meet the first criteria AND at least one of the subsequent three criteria:

The individual is known or reasonably believed to be infectious, or reasonably believed to have been exposed to a communicable disease, and may become infectious **AND**

1. They are unaware of their diagnosis; or have been advised regarding diagnosis and are non-adherent with public health recommendations; or are unable to be located, **OR**
2. They are at risk of traveling on a commercial flight or traveling internationally by any means, **OR**
3. They need to be placed on DNB/LO list in response to a public health outbreak or to help enforce a public health order.

To request a DNB or LO consultation for any person with confirmed or suspected TB who plans to cross the U.S. border and/or board an airplane, email the DSHS epidemiology team at TBEpi@dshs.texas.gov.

Please complete and submit DSHS Form 12-12065 and copies of medical records, lab results, and radiology reports to the epidemiology team. The following information is required:

A. **Demographics**
   1. Patient name, date of birth, sex at birth, race, and ethnicity
   2. Physical Address (México and if applicable, U.S. physical address), country of birth, passport number and issuing country, traveler's citizenship status in the U.S., i.e., legal permanent resident, visa-holder, fiancée, etc.
   3. Other information if available: email address and phone numbers (cell or landlines)

B. **Medical Evaluation**
   1. Reason evaluated for TB.

2. TB history, including but not limited to signs and symptoms of illness, date of symptom onset, and previous LTBI or TB disease.
3. Brief summary about concerns with compliance.

C. **Treatment History**
1. Current TB medication, including start dates.
2. Prior TB treatment history, if any.

D. **Laboratory**
1. Sputum smears for AFB.
2. NAAT/probe or PCR with Xpert.
3. Culture
4. MDDR or rapid drug resistance testing, if done.
5. DST

E. **Radiology**
1. Chest radiograph (CXR) report, with date performed.
    a) Indicate the presence or absence of cavitation and the extent of disease.
2. Chest CT report, if available.
    a) Indicate the presence or absence of cavitation and the extent of disease.

F. **Travel**
1. Intended dates of travel.
2. Intended method of travel.
    a) Airline, flight number, departing and arriving airports, booking confirmation number for flights if available.
    b) Usual Port of Entry for land border crossing.

Follow-up

1. Once an initial call is held by the epidemiology team with the requesting program, a decision will be made to contact CDC if the patient meets the qualifications to be placed on the DNB/LO list.
2. Prior to scheduling a formal call with CDC, the PHR or LHD must have an interception plan in place, which includes the following:
    a) Describe the steps that will be taken if the patient presents to board a plane or cross the border.
    b) Consider providing transportation if the patient needs hospitalization or isolation.
    c) Consider if the patient is intercepted during or outside regular business hours.
3. The Epidemiology Team will contact CDC and submit a formal request to review the case.
4. Once reviewed, CDC will schedule a call with all parties involved (DSHS TB Section Director, Surveillance and Epidemiology Manager, Epidemiology Team Lead and Point of

Contact, Clinical Care Team, PHR or LHD Case Manager, Nurse, Program Manager, Local Health Authority (LHA), and CDC travel restriction groups).
    a) The treating health department will provide a patient summary and any up-to-date information on the call.
    b) These calls do not guarantee the patient will be placed on the DNB/LO list. A decision will be made at the end of the call.
5. If the patient is placed on the DNB/LO list, CDC will send an official letter describing the DNB/LO and the responsibilities of the patient to the DSHS Epidemiology team. The letter will be attached to the NEDSS, and the jurisdiction will be notified.
    a) CDC will mail a written notification to the patient via FedEx, and a copy will be shared with the health department.
    b) The jurisdiction is responsible for sharing the letter with the patient.
6. The Epidemiology team will request routine/regular updates from the jurisdiction regarding the case's clinical and travel plan status.
7. If CDC elects not to place the patient on the DNB/LO list, the Epidemiology team will continue to follow up with the jurisdiction until the request is closed.

Removing patients from DNB/LO list

To be removed from the list, the case must meet the criteria for non-infectiousness according to the CDC Travel Restrictions Algorithm. The criteria for non-infectiousness are:

1. If there is no RIF resistance, the criteria are based on smear and radiology
    a) AFB smear-positive OR cavitation on chest imaging
        i. 3 consecutive negative AFB smears, 10 doses of medication in 14 days via DOT, and continues medication through travel
    b) AFB smear-negative AND no cavitation on chest imaging
        i. 3 consecutive negative AFB smears, 5 doses of medication in 7 days via DOT, and continues medication through travel
2. If there is at minimum RIF resistance, in addition to 10 doses of medication and negative smears, there must be two consistent negative cultures.

Appendix P: Sample In-Service and Training Roster

Topic: _____

Trainer/Educator: _____

Date: _____

Location: _____

Number of Hours: _____

Print Name	Signature

Appendix Q: TB Contact Investigation and Evaluation Information

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

TB Intake Information	
Information as per NEDSS Investigation Tabs	**Description (please note that not all may be applicable to the BNTB programs)**
Patient Information	▪ Full name ▪ Date of birth ▪ Sex at birth ▪ Reporting address (physical), city, county, zip code with 4-digit extension at diagnosis
Case Information	▪ Jurisdiction ▪ Current ATS 3* ▪ Current ATS 3 date*
TB History	▪ Has the patient been previously diagnosed with TB disease or LTBI? ▪ Previous positive TST (if applicable) ▪ Previous positive TST administered date (if applicable) ▪ Previous positive TST read date (if applicable) ▪ Previous positive IGRA (if applicable) ▪ Previous positive IGRA collection date (if applicable)
Tuberculosis	▪ Initial reason evaluated for TB ▪ TB symptom screening results and date ▪ Medical and Social Risk Factors (if applicable) ▪ Diagnostic Testing – TST, IGRA ▪ Sputum bacteriology (if applicable) ▪ Chest Imaging (if applicable)
Comprehensive TB Treatment Details (if applicable)	▪ Initial Treatment Type ▪ Current treatment type ▪ Medications (repeating block)
LTBI Only (ATS 2 only)	▪ Therapy start date ▪ Initial LTBI regimen ▪ Therapy Stop Date ▪ Reason Therapy Stopped

Appendix R: Sample Weekly Time and Mileage Report

Name of Employee	Title	Binational Program

Date/ Day of week	Time of Visit/ Time of Activities		Starting point	Ending point	Activities Performed	Miles Traveled Km/Miles
	Start	End				
Example 5/12/2025 Monday	8:00 am	8:30 am	1234 Mockingbird Dr., Reynosa, México	1819 Blueberry Lane Reynosa, México	DOT, blood draw	7km/4.35 miles
5/12/2025 Monday	8:30 am	9:00 am	1819 Blueberry Lane, Reynosa, México	Clinic address, Reynosa, México	Traveled to the clinic for the day	10km/6.2 miles
5/12/2025 Monday	9:00 am	5:00 pm	n/a	n/a	Phone calls, reviewed labs, pt. clinic visit x1, collected sputum, labs, and provided DOT (detailed information here of the day's activities in the clinic)	n/a
5/13/2025 Tuesday	8:00 am	5:00 pm	n/a	n/a	(Detailed information here of the day's activities in the clinic)	n/a
					Total Km/miles	

Date:	Signature:

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