

The purpose of this document is to provide authority for specific acts of tuberculosis (TB) clinical services under authority of Rule Title 22, Texas Administrative Code §193.2, Standing Delegation Orders.

Standing delegation orders (SDOs) and standing medical orders (SMOs) are written instructions, orders, rules, regulations or procedures prepared by a physician. SDOs provide authority and a plan for use with patients presenting themselves prior to being examined or evaluated by a physician. SMOs provide authority and direction for the performance of certain prescribed acts for patients which have been examined or evaluated by a physician. SDOs and SMOs are distinct from specific orders written for a particular patient.

The intended audience for these orders is registered nurses and licensed vocational nurses working in Texas Department of State Health Services (DSHS) Health Service Regions.

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Standing Delegation Orders

A. Method Used for Development, Approval and Revision

This SDO and the relevant attachments shall be:

1. Developed by the TB and Refugee Health Services Branch.
2. Reviewed and signed at least annually by the authorizing physician, a physician licensed by the Texas Medical Board who executes this SDO.
3. Revised as necessary by the TB SDO Revision Workgroup, the DSHS Infectious Diseases Medical Officer, the Regional Medical Directors, and/or the TB and Refugee Health Services Branch.

B. Level of Experience, Training, Competence, and Education Required

To carry out acts under this SDO, an authorized licensed nurse must:

1. Be an employee or contractor of the Texas Department of State Health Services.
2. Be currently licensed to practice by the Texas Board of Nursing.
3. Be currently certified in Basic Life Support.
4. Have reviewed, are familiar with, and able to readily access the recommendations within the following documents:
 - a. Recommendations for Human Immunodeficiency Virus (HIV) Screening in Tuberculosis (TB) Clinics Fact Sheet.
<http://www.cdc.gov/tb/publications/factsheets/testing/HIVscreening.htm>
 - b. AIDSInfo Clinical Guidelines Portal. <http://aidsinfo.nih.gov/guidelines>
 - c. Core Curriculum on Tuberculosis: What the Clinician Should Know, 6th Edition. CDC, 2013.
http://www.cdc.gov/tb/education/corecurr/pdf/corecurr_all.pdf
 - d. Managing Drug Interactions in the Treatment of HIV-related Tuberculosis. CDC, June 2013.
http://www.cdc.gov/tb/publications/guidelines/TB_HIV_Drugs/default.htm
 - e. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6209a1.htm?s_cid=rr6209a1_e
 - f. Recommendations for Use of an Isoniazid–Rifapentine Regimen with Direct Observation to Treat Latent *Mycobacterium tuberculosis* Infection. MMWR. 2011; 60(48):1650–1653.
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6048a3.htm?s_cid=mm6048a3_w
 - g. Updated Guidelines for Using Interferon Gamma Release Assays to Detect *Mycobacterium tuberculosis* Infection — United States, 2010. MMWR. 2010; 59(5):1-25.
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5905a1.htm?s_cid=rr5905a1_e

- h. Updated Guidelines for the Use of Nucleic Acid Amplification Tests in the Diagnosis of Tuberculosis. MMWR. 2009; 58(1):7-10.
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5801a3.htm?s_cid=mm5801a3_e
- i. Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings. MMWR. 2006; 55(RR14):1-17.
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm>
- j. An Official ATS Statement: Hepatotoxicity of Antituberculosis Therapy. Am J Respir Crit Care Med. 2006; 174:935-952.
<http://www.thoracic.org/statements/resources/mtpi/hepatotoxicity-of-antituberculosis-therapy.pdf>
- k. Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005. MMWR 2005; 54(RR17):1-141.
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm?s_cid=rr5417a1_e
- l. 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>
- m. Controlling Tuberculosis in the United States Recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. MMWR. 2005; 54(RR12):1-81.
<http://www.cdc.gov/MMWR/preview/MMWRhtml/rr5412a1.htm>
- n. Targeted Tuberculin Skin Testing and Treatment of Latent Tuberculosis Infection in Children and Adolescents. Pediatrics. 2004; 114(s4):1175-1201.
http://pediatrics.aappublications.org/content/114/Supplement_4/1175.full
- o. Tuberculosis Associated with Blocking Agents Against Tumor Necrosis Factor – Alpha - California, 2002–2003. MMWR. 2004; 53(30):683-686.
<http://www.cdc.gov/MMWR/preview/MMWRhtml/mm5330a4.htm>
- p. Treatment of Tuberculosis. MMWR. 2003; 52 (RR11):1-77.
<http://www.cdc.gov/MMWR/preview/MMWRhtml/rr5211a1.htm>
Errata: Treatment of Tuberculosis. MMWR. 2005; 53(51&52):1203.
<http://www.cdc.gov/MMWR/preview/MMWRhtml/mm5351a5.htm>
- q. Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection. MMWR. 2000; 49(RR06):1-54.
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4906a1.htm>
Update: Adverse Event Data and Revised American Thoracic Society/CDC Recommendations Against the Use of Rifampin and Pyrazinamide for Treatment of Latent Tuberculosis Infection – United States, 2003. MMWR. 2003; 52(31):735-739.
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5231a4.htm>
- r. Diagnostic Standards / Classification of TB in Adults and Children. Am J Respir Crit Care Med. 2000; 161:1376-1395.

- <http://www.cdc.gov/tb/publications/PDF/1376.pdf>
- s. Recommendations for Prevention and Control of Tuberculosis among Foreign-Born Persons. MMWR. 1998; 47(RR16):1-26.
<http://www.cdc.gov/MMWR/preview/MMWRhtml/00054855.htm>
- t. Screening for Tuberculosis and Tuberculosis Infection in High-Risk Populations Recommendations of the Advisory Council for the Elimination of Tuberculosis. MMWR. 1995; 44(RR11):18-34.
<http://www.cdc.gov/MMWR/preview/MMWRhtml/00038873.htm>
- u. Tuberculosis Control Laws - United States, 1993 Recommendations of the Advisory Council for the Elimination of Tuberculosis. MMWR. 1993; 42(RR15).
<http://www.cdc.gov/mmwr/preview/mmwrhtml/00030715.htm>
- v. Prevention and Control of Tuberculosis in Migrant Farm Workers Recommendations of the Advisory Council for the Elimination of Tuberculosis. MMWR. 1992; 41(RR10).
<http://www.cdc.gov/MMWR/preview/MMWRhtml/00032773.htm>
- w. Prevention and Control of Tuberculosis Among Homeless Persons Recommendations of the Advisory Council for the Elimination of Tuberculosis. MMWR. 1992; 41(RR5):001.
<http://www.cdc.gov/MMWR/preview/MMWRhtml/00019922.htm>
- x. Prevention and Control of Tuberculosis in Facilities Providing Long-Term Care to the Elderly Recommendations of the Advisory Council for the Elimination of Tuberculosis. MMWR. 1990; 39(RR10):7-20.
<http://www.cdc.gov/MMWR/preview/MMWRhtml/00001711.htm>
5. Have undergone the following initial or continuing evaluation of competence relevant to TB clinical services within 12 months prior to signing and providing TB clinical services under this SDO:
- Initial evaluation of competence is performed by the nurse's supervisor and consists of verification that the authorized licensed nurse possesses a valid nursing license and 40 hours of continuing education or training relevant to TB clinical services, skills training and mentoring, including the CDC's "Self-Study Modules on Tuberculosis" (<http://www.cdc.gov/TB/education/ssmodules/>).

If the nurse's supervisor is not a licensed clinician, a licensed nurse or authorizing physician responsible to oversee the clinical practice of the authorized licensed nurse shall be responsible for observation of the required clinical skills.

For nurses whose primary job duties are with the TB program, this training and evaluation of competence must occur within 90 days of employment. For other nurses, this training and evaluation of competence must occur before TB clinical services are independently provided by the nurse.

- Continuing evaluation of competence is performed annually by the nurse's supervisor, or clinical designee, and consists of verification that the authorized licensed nurse possesses a valid nursing license, 16 hours of continuing education or training relevant to TB clinical services, as approved by the nurse's supervisor, and periodic observation of the required clinical skills.

If the nurse's supervisor is not a licensed clinician, a licensed nurse or authorizing physician responsible to oversee the clinical practice of the authorized licensed nurse shall be responsible for observation of the required clinical skills.

6. Have reviewed and signed this SDO, **ATTACHMENT 1: *Attestation of Authorized Licensed Nurse***, within 12 months prior to providing services under this SDO.

C. Method of Maintaining a Written Record of Authorized Licensed Nurses

A record of the authorized licensed nurse who completes the required training and demonstrated competence shall be documented and maintained by the nurse's supervisor in the Health Service Regional office.

D. Authorized Delegated Acts

Authorized licensed nurses may evaluate and provide TB clinical services under this SDO to clients who are suspected of having, or confirmed to have, TB infection or TB disease, or are a contact to a confirmed or suspected TB disease case.

It is the intent of all parties that the acts performed under this SDO shall be in compliance with the Texas Medical Practice Act, the Texas Nursing Practice Act, the Texas Pharmacy Act, and the rules promulgated under those Acts.

E. Procedures and Requirements to be Followed by Authorized Licensed Nurses

1. Adhere to all TB infection control precautions when participating in TB clinical services.
2. Utilize interpreter services to facilitate client and provider communication as it relates to limited English proficient (LEP) clients.
3. Establish that the client is suspected of having or confirmed to have TB infection or TB disease or is a contact to a confirmed or suspected TB disease case.
4. Ensure, to the extent possible, that the client seen for TB clinical services is, in fact, who the person claims to be.
5. Obtain client's consent and signature in the preferred language of the client in accordance with agency policy and provide copies of the DSHS HIPAA privacy notice and

applicable signed consent forms.

- **DSHS General Consent and Disclosure** (L-36), available at: www.dshs.state.tx.us/rls/pubs/GeneralConsentForm042010.pdf
- **DSHS Privacy Notice**, available at: <http://www.dshs.state.tx.us/hipaa/privacynotices.shtm>

6. Take a personal and medical history.
7. Perform an appropriate physical examination and record the physical findings.
8. Perform the medical screening as described in **ATTACHMENT 2: Medical Screening**.
9. Obtain diagnostic tests appropriate to the services provided. Explain the test(s) and the risk and benefits of each one. Provide the opportunity for the client to ask questions.
 - a. **Tuberculosis Screening Tests:** If the TB screening has been performed previously, obtain a copy of the results and document in the medical record. If not, perform TB screening test, as described in **ATTACHMENT 3: TB Screening Tests**, unless otherwise instructed.

If TST is performed, then read and interpret the TST result within 48 – 72 hours.

DO not administer TST if any of the following apply. Contact your supervisor, or the nurse responsible for management of the TB client, for instructions. (From:

<http://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm114924.pdf> and <http://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm114912.pdf>)

- Allergy to any component of TUBERSOL or APLISOL or an anaphylactic or other allergic reaction/hypersensitivity to a previous test of tuberculin PPD
 - Severe reaction to previous TST such as ulceration, necrosis, blistering, bullae, anaphylaxis
 - Documented active TB
 - A clear history of treatment for TB infection or disease
 - Extensive burns or eczema
 - Immunization with a live virus vaccine within the last 4-6 weeks. Note: TST may be given on the same day as immunization with a live-virus vaccine; otherwise, TST testing should be delayed for 4-6 weeks after vaccination. Live virus vaccines include: measles, mumps, rubella, varicella, yellow fever, oral polio.
- b. **Labs:** If labs have been collected within the last 14 days, obtain a copy of the results and document in the medical record. If not, draw blood for the appropriate labs as described in **ATTACHMENT 4: Labs**, unless otherwise instructed.
 - c. **Chest X-Ray (CXR):** Evaluate the need for a CXR, as described in **ATTACHMENT 5: Chest X-Ray**. If CXR has been performed within the allowed time frame, obtain a copy of the results (and images, if available) and document in the medical record. If not, refer for CXR, unless otherwise instructed.

- d. **Sputum Collection:** Evaluate the need for sputum collection, as described in **ATTACHMENT 6: *Sputum Collection***. If sputum has been collected within the allowed time frame, obtain a copy of the results and document in the medical record. If not, collect sputum, unless otherwise instructed.
- If the client is unable to produce an acceptable sputum specimen, collect an induced sputum specimen, if resources are available. Otherwise, contact the physician for instructions.
10. Label and package specimens correctly and legibly, according to laboratory guidelines and regional procedures. Submit specimens to an approved laboratory for processing. Document all test collection dates, test type, circumstances affecting collection, and results in the client's medical record.
11. Document in the client's medical record that all diagnostic test results were reviewed.
12. Obtain a consult from a DSHS-recognized Expert TB Physician for the following clients or if the physician, DSHS Health Service Region, or DSHS TB and Refugee Health Services Branch has management concerns.
- a. Client is a contact to a case of multidrug-resistant (MDR)- or extensively drug-resistant (XDR)-TB. (Required)
 - b. Client has laboratory-confirmed drug resistance or is suspected to have drug resistant-TB. (Required)
- Laboratory confirmed drug resistance is defined as resistance to isoniazid (INH) and/or rifampin or to any drug other than streptomycin on drug susceptibility panel testing. Consultation must occur within three days of laboratory notification.
- Drug resistance should be considered in any client with:
- known exposure to an individual with drug-resistant TB
 - residence in a setting with high rates of primary drug-resistant TB, such as a country or area with high rates of drug-resistant TB in newly diagnosed individuals
 - persistently positive smear or culture results at or after four months of treatment
 - previous TB treatment, particularly if it was not directly observed or was interrupted for any reason
- c. Client has positive sputum cultures for *M. tuberculosis* complex (*M.tb*) after four months of appropriate therapy for TB disease and is deemed a treatment failure. (Required)
 - d. Client has been prescribed a 2nd line medication. (Required)

- e. Client has HIV infection and is on antiretrovirals or anticipates starting on antiretrovirals. (Recommended)
 - f. Client has complex medical comorbidities. (Recommended)
 - g. Client is under the age of five years. (Recommended)
 - h. Client's symptoms have not improved after the first two months of treatment. In addition, if the client has not improved radiographically and microbiologically after the first two months of treatment, consider consultation. (Recommended)
 - i. Client has positive sputum smear for Acid-fast bacilli and/or positive sputum culture for *M.tb* after two months of appropriate therapy for TB disease. (Recommended)
 - j. Client has treatment interrupted for more than two weeks in the initial phase of therapy for TB disease. (Recommended)
 - k. Client has treatment interrupted for more than three months in the continuation phase of therapy for TB disease. (Recommended)
13. Explain the risks of TB infection and/or TB disease. Discuss with the client the diagnosis and the evidence for it and the risks and benefits of treatment options. Provide the opportunity for the client to ask questions.
14. For clients suspected or confirmed to have TB disease, provide the Order to Implement and Carry Out Measures for a Patient with Tuberculosis ("Control Order"), signed and dated by the local health authority, for the client to review, if not provided already. Explain the Control Order and risks of violation of the Control Order. Provide the opportunity for the client to ask questions. Have the client review and sign the Control Order. Provide a copy of the Control Order to the client.
- If the client has questions the nurse cannot answer, contact the local health authority.
 - If the client violates the Control Order, immediately notify the physician treating the client and the local health authority who signed the control order.
15. If the client has not seen a physician, arrange for the client to be evaluated by a physician, if physician services are available. Otherwise send all of the pertinent information to the authorizing physician for review and orders.

For verbal or telephone orders, or for telephonic reporting of critical test results, verify the complete order or test result by recording the complete order or test result in the client's medical record and "reading-back" the complete order or test result. Receive confirmation from the physician who gave the order or received the test result. All verbal or telephone orders should be reviewed and countersigned or confirmed by written communication as soon as possible, ideally within one week.

16. The authorized licensed nurse shall review the most recent medication regimen ordered by the physician, a copy of which is placed in the medical record, and should seek out/consult with a trusted drug information source (e.g., DSHS Library access to “Facts and Comparisons,” DSHS pharmacist, prescribing physician) to verify possible medication interactions and document in the client’s record.

17. Administer (for directly observed therapy (DOT)) or provide (for self-administered therapy) medications consistent with the most recent physician order. Counsel the client regarding possible side-effects, conditions under which medications should be stopped and the clinic contacted, and the need to prevent pregnancy, if applicable.
 - a. All regimens for TB disease and intermittent regimens for TB infection must be provided via DOT until completion of therapy. Intermittent dosing of treatment for TB disease facilitates DOT. ***However, daily therapy (five to seven days per week) given as DOT has lower risk of treatment failure or relapse and should be used as resources allow, especially for clients with extensive disease or very complex medical conditions.***

 - b. The initial dose of each new TB medication should be given, when able, by a licensed nurse with emergency supplies readily available. The client should be asked to remain for 30 minutes for observation of adverse reactions.

 - c. For purposes of dosage calculations and treatment regimen selection, a client is considered a child if the client is <18 years old and should receive pediatric weight-based dosing of medications as described in **ATTACHMENT 7: Medications**, Table 6. Ensure appropriate weight-based dosage calculations for all clients.

 - d. If medication(s) are to be self-administered by the client, provide the medication(s) to the client with a completed medication label.
 - i. As required by the Texas State Board of Pharmacy (Rule Title 22, Texas Administrative Code §291.93), the following information will be pre-printed on the medication label for self-administered medications:
 - The name, address, and telephone number of the clinic
 - The name and strength of the drug--if generic name, the name of the manufacturer or distributor of the drug
 - Quantity
 - Lot number and expiration date

 - ii. The authorized license nurse will complete the labeling directions so that it contains the following information:
 - The client's name
 - Date medication is provided
 - The physician's name
 - Directions for use (per Texas State Board of Pharmacy rules, incomplete

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directions for use may be present and if so, are to be completed by the authorized licensed nurse at time of distribution)

38TH ST PHARMACY
7111 W 38TH ST STE C-3
AUSTIN, TX 78705

DR _____ DATE _____

NAME _____

TAKE _____ CAPSULE(S) EACH DAY
TAKE 1 HOUR BEFORE OR 2 HOURS AFTER MEALS
MAY DECREASE EFFECTIVENESS OF BIRTH CONTROL PILLS
RIFAMPIN CAP 150 MG #30
VERSAPHARM PKG BY WP/KC

Expire _____
Control _____



N3 61748-015-30 6

See sample label:

- e. If medications are to be administered by DOT, verify the medications administered are the same as the medications ordered, provide the DOT packet(s) to the client, and observe the client ingesting all medication in each DOT dose packet.
18. If any of the following is true, contact the physician. Do not initiate treatment until physician instructions are given.
- a. The medication prescribed for TB disease or TB infection is not consistent with recommended regimens as described in ATTACHMENT 7.
 - b. The medication prescribed for a client co-infected with TB disease and HIV infection is ordered to be given twice-weekly.
 - c. The medication prescribed for TB disease or TB infection is not appropriate for the client's weight and/or age as described in ATTACHMENT 7.
 - d. The medication prescribed for TB disease or TB infection is not consistent with
 - Available and known drug susceptibilities for TB disease.
 - Consult recommendations from a DSHS-recognized Expert TB Physician.
 - e. Contraindications or significant drug interactions exist with non-TB medications the client is currently taking and the TB medication prescribed.
 - f. Client is suspected or known to be pregnant.
 - g. Client has active hepatitis or end stage liver disease.
 - h. Laboratory test results exceed the normal range.
19. Immediately discontinue treatment if any of the following occurs. Obtain testing as described in ATTACHMENT 3 and consult the physician before restarting any medications.
- a. Aspartate aminotransferase (AST) and/or alanine aminotransferase (ALT) level exceed three times the upper limit of normal in the presence of symptoms.
 - b. AST and/or ALT level exceed five times the upper limit of normal (with or without

- symptoms).
- c. Lab monitoring results reveal a significant change, as defined by the physician, in white blood cell count, hemoglobin, or platelet count.
 - d. Lab monitoring results reveal a significant increase, as defined by the physician, in bilirubin and/or alkaline phosphatase (alk phos) levels.
 - e. Client reports symptoms or has signs that could be attributed to medication toxicity.
 - f. Client on treatment for TB infection develops signs or symptoms of TB disease.
20. Interruptions of therapy:
- a. When an interruption of < 14 days occurs during the initial phase of treatment for TB disease, the treatment can continue. If total initial phase treatment is not completed in three months, the treatment will need to be restarted. Contact the physician for instructions.
 - b. When an interruption of \geq 14 days occurs in the initial phase of treatment for TB disease, the treatment regimen will need to be restarted. Contact the physician for instructions.
 - c. When < 80% of planned doses in the continuation phase of treatment for TB disease is completed and an interruption of fewer than three months occurs, the treatment can continue. Collect three sputum specimens for AFB smear and culture. If repeat sputum culture is positive for *M.tb*, contact the physician for instructions.
 - If total continuation phase treatment is not completed in six months, the treatment will need to be restarted. Contact the physician for instructions.
 - d. When < 80% of planned doses in the continuation phase of treatment for TB disease is completed and an interruption of three months or more occurs, the treatment will need to be restarted. Collect three sputum specimens for AFB smear and culture and contact the physician for instructions.
 - e. When \geq 80% of planned doses in the continuation phase of treatment for TB disease is completed and an interruption occurs, additional treatment may not be necessary. However, clients who initially had sputum smears positive for AFB should receive additional therapy. Contact the physician for instructions.
 - f. When an interruption occurs during treatment for ***TB infection***, a medical examination and symptom screen to rule out active TB disease is required before restarting therapy. If the client has symptoms consistent with active TB disease, a CXR is required before treatment is restarted. **See ATTACHMENT 5: Chest X-Ray** for additional details. Contact the physician for a determination on whether the treatment already taken can count towards completion or if treatment needs to be

restarted from the beginning.

21. Determine completion of therapy based on total number of doses administered (allowing for minor interruptions in therapy) - not on duration of therapy alone.

Below are the *minimum* number of doses required, based on regimens listed in ATTACHMENT 7, Table 1, and the corresponding time frame for acceptable completion of therapy. Every attempt should be made to help the client *not* miss any doses.

a. For clients with TB disease

i. Initiation phase:

- Regimen 1: 7 days per week for 56 doses administered in 8 weeks, OR 5 days per week for 40 doses administered in 8 weeks.
- Regimen 2: 7 days per week for 14 doses administered in 2 weeks, then twice weekly for 12 doses administered in 6 weeks, OR 5 days per week for 10 doses administered in 2 weeks, then twice weekly for 12 doses administered in 6 weeks.
- Regimen 3: Thrice weekly for 24 doses administered in 8 weeks.
- Regimen 4: 7 days per week for 56 doses administered in 8 weeks, OR 5 days per week for 40 doses administered in 8 weeks. Regimen 4 is used if pyrazinamide (PZA) cannot be included in the initial regimen or if the TB isolate is determined to be resistant to PZA. Minimum duration of therapy is a total of 9 months.

ii. Continuation phase:

- Regimen 1a: 7 days per week for 126 doses given in 18 weeks, OR 5 days per week for 90 doses given in 18 weeks.
- Regimen 1b: Twice weekly for 36 doses given in 18 weeks.
- Regimen 2a: Twice weekly for 36 doses given in 18 weeks.
- Regimen 3a: Thrice weekly for 54 doses given in 18 weeks.
- Regimen 4a: 7 days per week for 217 doses given in 31 weeks, OR 5 days per week for 155 doses given in 31 weeks.
- Regimen 4b: Twice weekly for 62 doses given in 31 weeks.

iii. When regimens vary from above, are extended, or change frequently, doses from each phase should be converted to “daily dose equivalents.” Use the minimum numbers for daily dosing of each phase when making a determination of adequate number of doses to complete therapy. Consult the physician or the regional or TB Branch Nurse Consultant for assistance, if needed.

- For example, for 5 days/week dosing, 40 doses should be given for the initiation phase and 90 doses should be given for the continuation phase.
 - For twice weekly doses, multiply the total number of twice weekly doses by 2.5 (5 days per week ÷ 2 doses per week) to total the daily dose equivalents for the twice weekly regimen.
 - For thrice weekly doses, multiply the total number of thrice weekly

- doses by 1.67 (5 days per week ÷ 3 doses per week) to total the daily dose equivalents for the thrice weekly regimen.
- Add all daily dose equivalents together to calculate the total doses given (as measured by a 5 days per week regimen).
 - Numbers that are not whole numbers should be rounded down.
- iv. Exceptions to the length of therapy described above:
- The following extrapulmonary TB sites:
 - Bone and joint: 6 - 9 months (26 - 39 weeks) of treatment recommended
 - Meningitis: 9 - 12 months (39 - 52 weeks) of treatment recommended
 - Disseminated/miliary TB in a child: 9 - 12 months (39 - 52 weeks) of treatment recommended
 - Any site that is slow to respond should be considered for prolongation of treatment
 - *M. bovis* infection: minimum of 9 months (39 weeks) of treatment
 - Culture-negative TB – defined as symptomatic or radiographic improvement after 2 months of treatment without another apparent diagnosis- treatment should be continued with INH and rifampin alone for an additional two months to complete a total of 4 months (18 weeks) of treatment.
 - If rifampin cannot be included in the initial regimen, the minimum duration of treatment is a total of 12 - 18 months (52 - 78 weeks).
 - Clients who have cavitation on the initial CXR and a positive culture after 2 months (8 weeks) of treatment completed are at substantially increased risk of relapse. The continuation phase of treatment for these clients is recommended to be prolonged to 7 months (31 weeks), to complete a total treatment period of 9 months (39 weeks).
- b. For clients with TB infection (see ATTACHMENT 7, Table 5):
- i. INH/RPT (by DOT) = 11 or 12 doses administered within 16 weeks; doses must be separated by ≥ 72 hours to be counted.
 - ii. 4 months of rifampin (ADULTS ONLY) = 120 doses (or 86 doses for 5 days per week dosing) administered within 6 months.
 - iii. 6 months of rifampin (CHILDREN) = 180 doses (or 129 doses for 5 days per week dosing) administered within 9 months.
 - iv. 9 months of INH = 270 doses (or 193 doses for 5 days per week dosing) administered within 12 months.
 - v. 9 months of twice-weekly INH (by DOT) = 76 doses administered within 12 months.

- vi. 6 months of INH (ADULTS ONLY) = 180 doses (or 129 doses for 5 days per week dosing) administered within 9 months.
- vii. 6 months of twice-weekly INH (ADULTS ONLY by DOT) = 52 doses administered within 9 months.

F. Client Record-Keeping Requirements

TB forms available at: <http://www.texastb.org/forms/#clinic>

Authorized licensed nurses must accurately and completely report and document each medical visit in a medical record prepared in accordance with DSHS policy and regional procedures, which will include:

1. The client's name, address, date of birth.
2. The client's personal health history, the client's status including signs and symptoms, and physical examination findings.
3. An accurate and detailed description of the nursing care rendered on each medical visit, including client teaching activities and the names of personnel involved in evaluation and treatment at each visit.
4. Actions carried out under these standing orders.
5. Any additional physician orders.
6. Medications administered, prescribed by the physician, or provided to the client.
7. Client response(s), if any.
8. Contacts with other health care team members concerning significant events regarding client's status.
9. Documentation that the appropriate forms, including informed consent, are completed and included in the medical record, and copies, when applicable, are provided to the client. If an interpreter is used, the name of the interpreter must be documented.
10. Documentation that the client received the *DSHS Privacy Notice*.

G. Scope of Supervision Required

This SDO gives the authorized licensed nurse authority to perform the acts described in this SDO in consultation with the authorizing physician as needed.

H. Specialized Circumstances to Immediately Communicate with the Authorizing Physician

Specific circumstances that the authorized licensed nurse providing services under this SDO should immediately contact the physician by phone include, but are not limited to:

1. Medical direction or consultation is needed.
2. Client has violated the signed *Order to Implement and Carry Out Measures for a Patient with Tuberculosis*.

In an emergency situation, the authorized licensed nurse is to call 911, provide first aid services as authorized in the regional emergency SDO, and contact his/her supervisor and/or the physician by phone as soon as possible.

I. Limitations on Setting

Authorized licensed nurses can provide services under these standing orders in the clinic setting, in the client's home, or other field settings when the physician can be contacted by phone.

J. Date and Signature of the Authorizing Physician

This SDO shall become effective on the date that it is signed by the authorizing physician, below, and will remain in effect until it is either rescinded, upon a change in the authorizing physician, or at the end of business on the last day of the current DSHS fiscal year (August 31, 2015), whichever is earlier.

Authorizing Physician's Signature: _____

Authorizing Physician's Title: _____

Printed Name: _____

Effective Date: _____

Emergency Contact Information: _____

ATTACHMENT 1: *Attestation of Authorized Licensed Nurse*

I, _____ have:
printed name of authorized licensed nurse

Read and understand the *DSHS Standing Delegation Orders/Standing Medical Orders: TB Clinical Services Provided by Registered Nurses and Licensed Vocational Nurses, FY2014-15* (“SDO”) that was signed by

Dr. _____ on _____
printed name of authorizing physician date of authorizing physician’s signature

- I agree that I meet all qualifications for authorized licensed nurses outlined in the SDO.
- I agree to follow all instructions outlined in the SDO.

Signature of Authorized Licensed Nurse

Date

ATTACHMENT 2: *Medical Screening*

- A. **Clients suspected or confirmed to have TB disease** will have the following medical screening:
1. Baseline and monthly clinical monitoring and evaluation for TB medication toxicity.
 - If client is taking ethambutol, this is to include red/green color discrimination using Ishihara plates and visual acuity using Snellen chart.
 - If client is taking an aminoglycoside, this is to include audiometry and vestibular screening until the aminoglycoside is discontinued.
 2. Clinical evaluation as soon as feasible when signs or symptoms of medication toxicity develop.
- B. **Clients with TB infection (including clients on window prophylaxis)** will have the following medical screening:
1. Baseline and monthly clinical monitoring and evaluation for TB medication toxicity.
 2. Clinical evaluation as soon as feasible when signs or symptoms of medication toxicity develop.

ATTACHMENT 3: TB Screening Tests

TB screening tests may include tuberculin skin test (TST) and interferon gamma release assays (IGRA):

An IGRA is preferred for testing the following groups or individuals aged five years and older: There is no preference for the use of one IGRA over another.

- **High-risk individuals who have previously received BCG**
- Congregate settings, for employees and residents
- Persons with diabetes or on dialysis
- Immunocompromised persons
- Persons undergoing contact investigation
- Persons who work with TB clients
- Persons anticipated to receive TNF- α inhibitors or other biologic response modifiers

TST is preferred for testing clients less than five years of age.

Routine testing with both a TST and an IGRA is not generally recommended. However, there are situations in which testing with both an IGRA and a TST may be considered:

1. When the initial test (TST or IGRA) is negative in the following situations:
 - i. when the risk for infection, the risk for progression, and the risk for a poor outcome are increased (e.g., when persons with HIV infection or children aged younger than five years are at increased risk for *M.tb* infection) or
 - ii. when clinical suspicion exists for active tuberculosis (such as in persons with symptoms, signs, and/or radiographic evidence suggestive of active tuberculosis) and confirmation of *M.tb* infection is desired.

In such clients with a negative initial test result, a positive result from a second test as evidence of infection increases detection sensitivity. However, multiple negative results from any combination of these tests cannot exclude *M.tb* infection.

2. When the initial test is positive in the following situations:
 - i. when additional evidence of infection is required to encourage compliance (e.g., in foreign-born health-care workers who believe their positive TST result is attributable to BCG) or
 - ii. in healthy persons who have a low risk for both infection and progression.

In the first situation, a positive IGRA might prompt greater acceptance of treatment for LTBI as compared with a positive TST alone.

In the latter situation, requiring a positive result from the second test as evidence of infection increases the likelihood that the test result reflects infection. For the second situation, an alternative is to assume, without additional testing, that the initial result is a false positive or that the risk for disease does not warrant additional evaluation or treatment, regardless of test

results. Steps should be taken to minimize unnecessary and misleading testing of persons at low risk.

3. Repeating an IGRA or performing a TST might be useful when the initial IGRA result is indeterminate, borderline, or invalid and a reason for testing persists. A second test also might be useful when assay measurements from the initial test are unusual, such as when
 - the Nil value is higher than typical for the population being tested (e.g., IFN- γ concentration for Nil by QFT-G or QFT-GIT >0.7 IU/ml for most of the U.S. populations),
 - the Nil value is appreciably greater than the value obtained with *M.tb* antigen stimulation (e.g. when IFN- γ concentration for Nil by QFT-G is 0.35 IU/ml greater than the concentration obtained with either ESAT-6 or CFP-10 stimulation, or when the number of spots for Nil by T-Spot is four spots greater than the number with either ESAT-6 or CFP-10 stimulation), or
 - the Mitogen value is lower than is expected for the population being tested (e.g., the Mitogen Response by QFT-G or QFT-GIT is <0.5 IU/ml, or the number of spots in the mitogen well by T-Spot is <20).

If an IGRA is to be repeated, a new blood sample should be used. In such situations, repeat testing with another blood sample usually provides interpretable results.

Note: PPD injection should be expected to boost anamnestic immune responses measured by IGRA originating from *M.tb* infection, but not from BCG vaccination or in non-sensitized persons. The effect appears to be more apparent in those individuals who are already IGRA positive and when IGRA testing performed greater than 3 days after TST.

The following clients may have a TB screening test:

1. All clients undergoing evaluation for TB disease.
2. All clients undergoing evaluation for TB infection.
3. All contacts classified as having high or medium priority and who do not have a documented previous positive TST or IGRA result or previous TB disease.
 - If the initial TB screening test is negative, administer a second TB screening test 8 to 10 weeks after the last exposure.
 - See ATTACHMENT 7 for indications for window prophylaxis and recommendations to complete a full course of treatment for TB infection (beyond the window period) even if a TB screening test administered eight weeks or more after the end of exposure is negative.

TST Interpretation:

An induration of 5 mm or more is considered to be positive for:

1. HIV-infected persons

2. Recent contacts to a known TB case
3. Individuals with fibrotic changes on chest radiograph consistent with old TB
4. Persons with organ transplants and other immunosuppressed persons (such as taking the equivalent of greater than 15 mg/d prednisone for longer than 1 month or taking tumor necrosis factor - alpha antagonists)

An induration of **10 mm or more** is considered to be positive for:

1. Recent arrivals (less than five years) from high-prevalence countries
2. Injection drug users
3. Residents and employees of high-risk congregate settings: correctional facilities, nursing homes and other healthcare or long-term care facilities, residential facilities for AIDS patients, and homeless shelters
4. Mycobacteriology laboratory personnel
5. Persons with high-risk clinical conditions: silicosis, diabetes mellitus, chronic renal failure, some hematologic disorders (e.g., leukemias and lymphomas), other specific malignancies (e.g., carcinoma of the head or neck and lung), weight loss of > 10% of ideal body weight, gastrectomy, jejunioileal bypass
6. Children younger than years of age, or infants, children, and adolescents exposed to adults in high-risk categories

An induration of **15 mm or more** is considered to be positive in individuals with no known risk factors for tuberculosis.

Negative reaction: An induration less than the specified criteria based on risk factors shows either a lack of tuberculin sensitivity or a low grade sensitivity that most likely is not caused by *M.tb*. A negative test does not rule out the presence of tuberculosis.

Positive Reaction: An induration greater than or equal to the specified criteria based on risk factors indicates infection with *M.tb*.

ATTACHMENT 4: *Labs*

Labs to be collected may include interferon-gamma release assay (IGRA), complete blood count (CBC), plasma glucose, aspartate aminotransferase (AST), alanine aminotransferase (ALT), total bilirubin, alkaline phosphatase (alk phos), albumin, creatinine, glucose, uric acid, HIV, CD4 count and/or percentage, hepatitis B serology, and hepatitis C serology.

A. *Clients suspected or confirmed to have TB disease* will have the following labs collected under the following circumstances:

At Baseline:

1. Baseline measurements of CBC, AST, ALT, total bilirubin, alk phos, albumin, creatinine, and HIV.
 - If client has a previously documented positive HIV test result, HIV testing does not need to be repeated.
 - If client has a documented HIV-negative test result from a specimen collected within the last 14 days, HIV testing does not need to be repeated.
2. For clients age 13 years and older, screen for diabetes with a random plasma glucose. If program resources allow, the A₁C or a 2-hour plasma glucose value after a 75-g oral glucose tolerance test should be used for diabetes screening.
 - Routine testing of children <13 years old is not recommended.
 - Diabetes is diagnosed at a glucose ≥ 200 mg/dl. For those clients, referral should be made for diabetes evaluation, as resources allow. Provide basic diabetes information regarding the impact of diabetes on TB and the client's overall health.
3. Baseline measurement of CD4 count (and/or CD4 percentage for pediatric clients) if client has known HIV infection. (Results may be obtained from the HIV provider, if available.)
4. Baseline testing for hepatitis B virus (HBV) infection if the client has any of the following risk factors for HBV:
 - All persons born in a geographic region with HBsAg prevalence $\geq 2\%$ (e.g., much of Eastern Europe, Asia, Africa, the Middle East, and the Pacific Islands)
 - Persons with behavioral exposures to HBV (e.g., men who have sex with men, past or current injection drug users, history of incarceration)
 - Persons receiving cytotoxic or immunosuppressive therapy
 - Persons with liver disease of unknown etiology
5. Baseline testing for hepatitis C virus (HCV) infection without prior ascertainment of HCV risk factors for clients born during 1945 through 1965 (if no documentation of prior HCV testing) or if the client has any of the following risk factors for HCV:
 - Currently inject drugs
 - Ever injected drugs, including those who injected once or a few times many years ago

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- History of incarceration
- Have certain medical conditions, including persons :
 - who received clotting factor concentrates produced before 1987
 - who were ever on long-term hemodialysis
 - with persistently abnormal ALT levels
- Were prior recipients of transfusions or organ transplants, including persons who:
 - were notified that they received blood from a donor who later tested positive for HCV infection
 - received a transfusion of blood, blood components or an organ transplant before July 1992

Monthly:

1. Monthly measurements of any test whose baseline result is abnormal (excluding hepatitis serologies).
2. Monthly measurements of AST, ALT, total bilirubin, alk phos, and albumin for clients with risk factors for hepatotoxicity or other complications, including but not limited to:
 - Pregnant clients
 - Female clients during the first three months postpartum
 - Clients with or at risk for hepatitis B, hepatitis C, or other liver disorder
 - Clients with other comorbidities or chronic medical conditions
 - Clients who use alcohol or recreational drugs (orally or by injection)
 - Clients with HIV infection/AIDS
 - Clients on medications that affect or are excreted by the liver

As Needed:

1. Measurement of AST, ALT, total bilirubin, alk phos, and albumin if AST and/or ALT level exceeds more than three times the upper limit of normal in the presence of symptoms or more than five times the upper limit of normal with or without symptoms present. Hold medication and contact the physician for instructions.
2. Measurement of AST, ALT, total bilirubin, alk phos, and albumin if there is a significant increase, as defined by the physician, in bilirubin and/or alk phos. Hold medication and contact the physician for instructions.
3. Measurement of CBC if there is a significant change, as defined by the physician, in white blood cell count, hemoglobin, or platelet count. Hold medication and contact the physician for instructions.
4. Measurement of uric acid if the client develops acute arthritis. Hold medication and contact the physician for instructions.
5. Measurement of CBC, AST, ALT, total bilirubin, alk phos, albumin, and creatinine if the client reports symptoms or has signs that could be attributed to medication toxicity. If

symptoms or signs are compatible with hepatotoxicity, only measurement of AST, ALT, total bilirubin, alk phos, and albumin is necessary. Hold medication and contact the physician for instructions.

B. **Clients with TB infection (including clients on window prophylaxis)** will have the following labs collected under the following circumstances:

At Baseline:

1. For clients age 13 years and older, HIV testing. Routine testing of children <13 years old is not recommended, unless risk factors for HIV infection are present.
 - If client has a previously documented positive HIV test result, HIV testing does not need to be repeated.
 - If client has a documented HIV-negative test result from a specimen collected within the last 14 days, HIV testing does not need to be repeated.
2. For clients age 13 years and older, screen for diabetes with a random plasma glucose. If program resources allow, the A₁C or a 2-h plasma glucose value after a 75-g oral glucose tolerance test should be used for diabetes screening.
 - Routine testing of children <13 years old is not recommended.
 - Diabetes is diagnosed at a glucose ≥ 200 mg/dl. For those clients, referral should be made for diabetes evaluation, as resources allow. Provide basic diabetes information regarding the impact of diabetes on TB and the client's overall health.
3. Baseline measurement of CD4 count (and/or CD4 percentage for pediatric clients) if client has known HIV infection. (Results may be obtained from the HIV provider, if available.)
4. Baseline measurements of AST, ALT, total bilirubin, alk phos, and albumin for all clients starting treatment for TB infection and who have risk factors for potential hepatotoxicity or other complications, including but not limited to:
 - Pregnant clients
 - Female clients during the first 3 months postpartum
 - Clients with or at risk for hepatitis B, hepatitis C, or other liver disorder
 - Clients with other comorbidities or chronic medical conditions
 - Clients who use alcohol or recreational drugs (orally or by injection)
 - Clients with HIV infection/AIDS
 - Clients on medications that affect or are excreted by the liver
5. Baseline testing for hepatitis B virus (HBV) infection if the client has any of the following risk factors for HBV:
 - All persons born in a geographic region with HBsAg prevalence $\geq 2\%$ (e.g., much of Eastern Europe, Asia, Africa, the Middle East, and the Pacific Islands) Persons with behavioral exposures to HBV (e.g., men who have sex with men, past or current injection drug users, history of incarceration)

- Persons receiving cytotoxic or immunosuppressive therapy
 - Persons with liver disease of unknown etiology
6. Baseline testing for hepatitis C virus (HCV) infection without prior ascertainment of HCV risk factors for clients born during 1945 through 1965 (if no documentation of prior HCV testing) or if the client has any of the following risk factors for HCV:
- Currently inject drugs
 - Ever injected drugs, including those who injected once or a few times many years ago
 - History of incarceration
 - Have certain medical conditions, including persons:
 - who received clotting factor concentrates produced before 1987
 - who were ever on long-term hemodialysis
 - with persistently abnormal ALT levels
 - Were prior recipients of transfusions or organ transplants, including persons who:
 - were notified that they received blood from a donor who later tested positive for HCV infection
 - received a transfusion of blood, blood components or an organ transplant before July 1992

Monthly:

1. Monthly measurements of any test whose baseline result is abnormal (excluding hepatitis serologies).
2. Monthly measurements of AST, ALT, total bilirubin, alk phos, and albumin for clients with risk factors for hepatotoxicity or other complications, including but not limited to:
 - Pregnant clients
 - Female clients during the first three months postpartum
 - Clients with or at risk for hepatitis B, hepatitis C, or other liver disorder
 - Clients with other comorbidities or chronic medical conditions
 - Clients who use alcohol or recreational drugs (orally or by injection)
 - Clients with HIV infection/AIDS
 - Clients on medications that affect or are excreted by the liver

As Needed:

1. Measurement of AST, ALT, total bilirubin, alk phos, and albumin if AST and/or ALT level exceeds more than three times the upper limit of normal in the presence of symptoms or more than five times the upper limit of normal with or without symptoms present. Hold medication and contact the physician for instructions.
2. Measurement of AST, ALT, total bilirubin, alk phos, and albumin if there is a significant increase, as defined by the physician, in bilirubin and/or alk phos. Hold medication and contact the physician for instructions.
3. Measurement of CBC if there is a significant change, as defined by the physician, in

white blood cell count, hemoglobin, or platelet count. Hold medication and contact the physician for instructions.

4. Measurement of uric acid if the client develops acute arthritis. Hold medication and contact the physician for instructions.
5. Measurement of CBC, AST, ALT, total bilirubin, alk phos, albumin, and creatinine if the client reports symptoms or has signs that could be attributed to medication toxicity. If symptoms or signs are compatible with hepatotoxicity, only measurement of AST, ALT, total bilirubin, alk phos, and albumin is necessary. Hold medication and contact the physician for instructions.

ATTACHMENT 5: *Chest X-Ray (CXR)*

For clients up to age 18, CXR should include posterior-anterior and lateral views.
For adult clients, CXR should include at least posterior-anterior view.

Pregnant clients evaluated for active TB disease should undergo CXR with appropriate shielding without delay, even in the first trimester.

A. The following clients will have an **initial** CXR:

1. **Clients suspected or confirmed to have TB disease:**

- a. All clients exhibiting signs and symptoms of pulmonary TB.
- b. Clients with suspected or known extra-pulmonary TB to assess for the presence of pulmonary involvement.

2. **Clients with TB infection (including clients on window prophylaxis):**

- a. Clients exhibiting signs and symptoms of active TB.
- b. Clients newly identified as infected with TB based upon a positive TST or positive IGRA.

3. **Clients undergoing evaluation as part of a contact investigation:**

- a. Clients newly identified as infected with TB based upon a positive TST or positive IGRA.
- b. Clients who are contacts to a TB case and have documentation of a prior positive TB screening test.
- c. Clients who are contacts to a TB case and are at high risk of progression to active TB disease regardless of their TB screening test result:
 - Children age four and under
 - Clients who have HIV infection or at high risk for HIV infection
 - Clients who have an immunocompromising condition
 - Clients receiving immunosuppressive therapy

4. **Clients who are recent immigrants who have been referred to the health department for evaluation through the Electronic Disease Notification system (EDN) or who are recent immigrants and self-refer to the health department for services.**

B. The following clients will have a **follow-up** CXR:

1. **Clients suspected or confirmed to have TB disease:**

- a. For clients with cultures positive for *M.tb* at diagnosis, a CXR at completion of two month of treatment may be useful by is not essential.

- b. For clients with negative initial cultures, a CXR is necessary after two months of treatment.
- c. All clients should have a CXR near or at the end of treatment to serve as a new baseline for future evaluations. If a previous CXR (baseline or at two months) is negative, an end of treatment CXR is not necessary.
- d. Follow-up CXRs are not necessary for clients with extrapulmonary TB disease, if initial sputum collection results are negative and initial CXR is normal.

2. Clients with TB infection (including clients on window prophylaxis):

- a. Clients who report or begin to exhibit symptoms suggestive of TB disease should have a follow-up CXR before continuing on treatment for TB infection.
- b. The following clients at high risk of progressing to active TB disease:
 - Younger than one year old
 - Those co-infected with HIV
 - Those with an immunocompromising condition
 - Those receiving immunosuppressive therapyAnd who have not started treatment for latent TB infection within one month of the initial CXR showing no abnormalities suggestive of TB disease must have a repeat CXR showing no abnormalities suggestive of TB disease prior to the initiation of therapy.
- c. All other clients who are not at high risk of progressing to active TB disease and who have not started treatment for TB infection within six months of the initial CXR showing no abnormalities suggestive of TB disease must have a repeat CXR showing no abnormalities suggestive of TB disease prior to the initiation of therapy.
- d. The following clients at high risk of progressing to active TB disease:
 - Younger than one year old
 - Those co-infected with HIV
 - Those with an immunocompromising condition
 - Those receiving immunosuppressive therapyAnd who have an interruption in latent TB infection treatment longer than one month during the first two months of treatment must have a repeat CXR showing no abnormalities suggestive of TB disease prior to the re-initiation of therapy. Otherwise, reimaging is not necessary unless the client has symptoms consistent with active TB disease.
- e. All other clients who are not at high risk of progressing to active TB disease and who have an interruption in latent TB infection treatment longer than two months must have a repeat CXR showing no abnormalities suggestive of TB disease if the prior CXR was performed greater than six months ago.

ATTACHMENT 6: *Sputum Collection*

Because sputum specimens may have culture results that fluctuate from positive to negative to positive over a period of time before true conversion occurs, collection dates for last positive sputum culture and the first consistently negative sputum culture must be separated by at least seven days.

A. Clients suspected or confirmed to have PULMONARY TB disease:

1. For all clients, collect three consecutive sputum specimens at least eight hours apart, with at least one specimen collection observed and one collection in early morning. Sputum collection must occur within seven days before (preferable) to seven days after medication start date.
 - a. Submit three sputum specimens for Acid-fast bacilli (AFB) smear and culture. The DSHS Laboratory will perform drug susceptibility testing (DST) reflexively on the initial *M.tb* culture positive specimen. 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.
 - b. Submit the initial diagnostic sputum specimen on cold pack. If there is no laboratory-confirmed diagnosis of *M.tb*, request nucleic acid amplification testing (NAA) on the initial diagnostic sputum specimen.
2. For clients who have positive initial AFB smears at the time of diagnosis, collect three sputum specimens, with at least one specimen collection in early morning and if possible, another specimen collection observed, for AFB smear every two weeks until three consecutive specimens are negative on AFB smear.
3. For all clients, collect up to three sputum specimens, with at least one specimen collection in early morning and, if possible, another specimen collection observed, for AFB smear and culture at least once a month until two consecutive specimens (at least one month apart) are negative on culture.
4. For clients who have completed < 80% of planned doses in the continuation phase of TB treatment and have an interruption of therapy, collect three sputum specimens, with at least one specimen collection in early morning and if possible, another specimen collection observed, for AFB smear and culture.
5. For clients with multi-drug resistant-TB, collect at least one sputum specimen, with at least one specimen collection in early morning and if possible, another specimen collection observed, for AFB smear and culture at least once a month, if possible, for AFB smear and culture monthly until treatment completed.
6. For all clients, if possible, collect one final sputum specimen in early morning for AFB culture at completion of therapy.

B. Clients confirmed to have *EXTRAPULMONARY TB* disease:

1. For clients with suspected or known extrapulmonary TB, attempts should be made to collect three sputum specimens, with at least one specimen collection observed and one collection in early morning, even if the CXR is normal, in order to exclude concomitant pulmonary disease.
 - a. Submit three sputum specimens for AFB smear and culture. The DSHS Laboratory will perform DST reflexively on the initial *M.tb* culture-positive specimen. 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.
 - b. Submit the initial diagnostic sputum specimen on cold pack. If there is no laboratory-confirmed diagnosis of *M.tb*, request NAA on the initial diagnostic sputum specimen.
2. For all clients with extrapulmonary TB disease, collect up to three sputum specimens, with at least one specimen collection in early morning and, if possible, another specimen collection observed, for AFB smear and culture at least once a month until two consecutive specimens (at least one month apart) are negative on culture.
3. For clients whose initial sputum results are positive, collect follow-up sputum as described in section A. *Clients suspected or confirmed to have PULMONARY TB disease.*

C. Clients with *TB* infection (including clients on window prophylaxis):

1. For clients who develop signs and symptoms suggestive of TB disease, collect three consecutive sputum specimens at least eight hours apart, with at least one specimen collection observed and one collection in early morning.
 - a. Submit three sputum specimens for AFB smear and culture. The DSHS Laboratory will perform DST reflexively on the initial *M.tb* culture-positive specimen. The DSHS Laboratory will repeat the DST if the patient is still *M.tb* culture positive three month or more after the initial specimen collection date, or upon physician request.
 - b. Submit the initial diagnostic sputum specimen on cold pack. If there is no laboratory-confirmed diagnosis of *M.tb*, request NAA on the initial diagnostic sputum specimen.
2. For clients with CXR findings suggestive of prior, healed TB infection, collect three consecutive sputum specimens at least eight hours apart, with at least one specimen collection observed and one collection in early morning.
 - a. Submit three sputum specimens for AFB smear and culture. The DSHS Laboratory will perform DST reflexively on the initial *M.tb* culture-positive specimen. 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.
 - b. Submit the initial diagnostic sputum specimen on cold pack. If there is no laboratory-confirmed diagnosis of *M.tb*, request NAA on the initial diagnostic sputum specimen.
 - c. Results of AFB smears and cultures must be negative before treatment for TB

- infection is started.
3. For clients with HIV infection and respiratory symptoms, even if the CXR is normal. Prior to or at the initiation of therapy, collect three consecutive sputum specimens at least eight hours apart, with at least one specimen collection observed and one collection in early morning.
 - a. Submit three sputum specimens for AFB smear and culture. The DSHS Laboratory will perform DST reflexively on the initial *M.tb* culture-positive specimen. 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.
 - b. Submit the initial diagnostic sputum specimen on cold pack. If there is no laboratory-confirmed diagnosis of *M.tb*, request NAA on the initial diagnostic sputum specimen.
 - c. Results of AFB smears and cultures must be negative and respiratory symptoms must be explained by another etiology before treatment for TB infection is started.

ATTACHMENT 7: Medications

A. Clients suspected or confirmed to have TB disease:

TABLE 1. Drug Regimens for Culture-Positive Pulmonary TB caused by *Drug-Susceptible* Organisms

Initial phase			Continuation phase		
Regimen	Drugs*	Interval and Total Doses Required for Completion of Initial Phase	Regimen	Drugs*	Interval and Total Doses [†] Required for Completion of Therapy
1	INH RIF PZA EMB	Seven days per week for 56 doses given in eight weeks OR Five days per week for 40 doses given in eight weeks	1a	INH/RIF	Seven days per week for 126 doses given in 18 weeks OR Five days per week for 90 doses given in 18 weeks
			1b [‡]	INH/RIF	Twice weekly for 36 doses given in 18 weeks
2	INH RIF PZA EMB	Seven days per week for 14 doses given in two weeks, then twice weekly for 12 doses given in six weeks OR Five days per week for 10 doses given in two weeks, then twice weekly for 12 doses given in six weeks	2a [‡]	INH/RIF	Twice weekly for 36 doses given in 18 weeks
3	INH RIF PZA EMB	Three times weekly for 24 doses given in eight weeks	3a	INH/RIF	Three times weekly for 54 doses given in 18 weeks
4	INH RIF EMB	Seven days per week for 56 doses given in eight weeks OR Five days per week for 40 doses given in eight weeks	4a	INH/RIF	Seven days per week for 217 doses given in 31 weeks OR Five days per week for 155 doses given in 31 weeks
			4b	INH/RIF	Twice weekly for 62 doses given in 31 weeks

Definition of abbreviations: EMB = Ethambutol; INH = isoniazid; PZA = pyrazinamide; RIF = rifampin.

* When INH is used, pyridoxine supplementation should be given to the following: pregnant women, infants receiving INH and breastfeeding, clients with diets likely deficient in pyridoxine, clients with paresthesia, or clients who have a risk factor for paresthesia (e.g., HIV//AIDS, alcohol use, diabetes).

† Clients with cavitation on initial chest radiograph and positive cultures at completion of 2 months of therapy should receive a 7-month (31 week; either 217 doses [daily] or 62 doses [twice weekly]) continuation phase.

‡ **Not recommended for HIV-infected patients with CD4+ cell counts <100 cells/μl.**

Table adapted from Treatment of Tuberculosis. MMWR. 2003; 52(RR11). <http://www.cdc.gov/mmwr/pdf/rr/rr5211.pdf>

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TABLE 2. Doses of First-Line Antituberculosis Drugs for Adults and Children

Drug	Preparation	Adults/children	Doses		
			Daily	2x/wk	3x/wk
Isoniazid (INH)*	Tablets (100 mg, 300 mg); elixir (50 mg/5 ml)	Adults (max.)	5 mg/kg (300 mg)	15 mg/kg (900 mg)	15 mg/kg (900 mg)
		Children (max.)	10–15 mg/kg (300 mg) See TABLE 6	20–30 mg/kg (900 mg) See TABLE 6	—
Rifampin	Capsule (150 mg, 300 mg); (powder may be suspended for oral administration –Contact Pharmacy Branch for details)	Adults (max.)	10 mg/kg (600 mg)	10 mg/kg (600 mg)	10 mg/kg (600 mg)
		Children (max.)	10–20 mg/kg (600 mg) See TABLE 6	10–20 mg/kg (600 mg) See TABLE 6	—
Pyrazinamide	Tablet (500 mg, scored)	Adults	See TABLE 3	See TABLE 3	See TABLE 3
		Children (max.)	30-40 mg/kg (2.0 g) See TABLE 6	50 mg/kg (2.0 g) See TABLE 6	—
Ethambutol	Tablet (100 mg, 400 mg)	Adults	See TABLE 4	See TABLE 4	See TABLE 4
		Children (max.)	15–25 mg/kg (1.0 g) See TABLE 6	50 mg/kg (2.5 g) See TABLE 6	—

* When INH is used, pyridoxine supplementation should be given to the following: pregnant women, infants receiving INH and breastfeeding, clients with diets likely deficient in pyridoxine, clients with paresthesia, or clients who have a risk factor for paresthesia (e.g., HIV//AIDS, alcohol use, diabetes).

Table adapted from Treatment of Tuberculosis. MMWR. 2003; 52(RR11). <http://www.cdc.gov/mmwr/pdf/rr/rr5211.pdf>

TABLE 3. Suggested Pyrazinamide Doses, Using Whole Tablets, for Adults Weighing 40–90 Kilograms

	Weight (kg)*		
	40–55	56–75	76–90
Daily, mg (mg/kg)	1,000 (18.2–25.0)	1,500 (20.0–26.8)	2,000+ (22.2–26.3)
Thrice weekly, mg (mg/kg)	1,500 (27.3–37.5)	2,500 (33.3–44.6)	3,000+ (33.3–39.5)
Twice weekly, mg (mg/kg)	2,000 (36.4–50.0)	3,000 (40.0–53.6)	4,000+ (44.4–52.6)

* Based on estimated lean body weight.

† Maximum dose regardless of weight.

Table adapted from Treatment of Tuberculosis. MMWR. 2003; 52(RR11). <http://www.cdc.gov/mmwr/pdf/rr/rr5211.pdf>

TABLE 4. Suggested Ethambutol Doses, Using Whole Tablets, for Adults Weighing 40–90 Kilograms

	Weight (kg)*		
	40–55	56–75	76–90
Daily, mg (mg/kg)	800 (14.5–20.0)	1,200 (16.0–21.4)	1,600+ (17.8–21.1)
Thrice weekly, mg (mg/kg)	1,200 (21.8–30.0)	2,000 (26.7–35.7)	2,400+ (26.7–31.6)
Twice weekly, mg (mg/kg)	2,000 (36.4–50.0)	2,800 (37.3–50.0)	4,000+ (44.4–52.6)

* Based on estimated lean body weight.

† Maximum dose regardless of weight.

Table adapted from Treatment of Tuberculosis. MMWR. 2003; 52(RR11). <http://www.cdc.gov/mmwr/pdf/rr/rr5211.pdf>

B. Clients with TB infection (including clients on window prophylaxis):

TABLE 5. Recommended Drug Regimens for Treatment of TB Infection

Drug(s)	Duration	Dose	Frequency	Interval and Total Doses Required for Completion of Therapy
Isoniazid (INH)* and Rifampin (RPT) <i>Not recommended for:</i> -Children <2 years old -Clients with HIV and taking antiretrovirals -Clients who are pregnant or expecting to become pregnant -Clients with TB infection, or clients who are contacts to a TB case, that is resistant or suspected to be resistant to INH or a rifamycin	3 months	Adults and children 12 years and over: INH: 15 mg/kg rounded up to the nearest 50 or 100 mg; 900 mg maximum RPT: 10.0–14.0 kg: 300 mg 14.1–25.0 kg: 450 mg 25.1–32.0 kg: 600 mg 32.1–49.9 kg: 750 mg ≥50.0 kg: 900 mg maximum Children 2 – 11 years old: Not recommended but can be considered on a case-by-case basis Children under age 2: Contraindicated	Once weekly†	12 (minimum of 11 acceptable within 16 weeks) Doses must be separated by ≥72 hours to be counted. INH-RPT treatment cannot be administered in less than 12 weeks.
Rifampin (RIF)	4 months	Adult: 10 mg/kg Children: Not recommended Maximum dose: 600 mg	Daily	120 (86 for 5 day/week) within 6 months
	6 months	Children: 10-20mg/kg Maximum dose: 600mg	Daily	180 (129 for 5 day/week) within 9 months
Isoniazid (INH)*	9 months	Adult: 5 mg/kg Children: 10-15 mg/kg Maximum dose: 300 mg	Daily	270 (193 for 5 day/week) within 12 months
		Adult: 15 mg/kg Children: 20-30 mg/kg Maximum dose: 900 mg	Twice weekly†	76 within 12 months
	6 months	Adult: 5 mg/kg Children: Not recommended Maximum dose: 300 mg	Daily	180 (129 for 5 day/week) within 9 months
		Adult: 15 mg/kg Children: Not recommended Maximum dose: 900 mg	Twice weekly†	52 within 9 months

* When INH is used, pyridoxine supplementation should be given to the following: pregnant women, infants receiving INH and breastfeeding, clients with diets likely deficient in pyridoxine, clients with paresthesia, or clients who have a risk factor for paresthesia (e.g., HIV/AIDS, alcohol use, diabetes).

† Intermittent regimens must be provided via directly observed therapy (DOT).

Table adapted from Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection. MMWR 2000;49,RR-6.
<http://www.cdc.gov/tb/publications/LTBI/treatment.htm>

Texas Department of State Health Services Standing Delegation Orders/Standing Medical Orders: Tuberculosis Clinical Services Provided by Registered Nurses and Licensed Vocational Nurses, FY2014-15

Indications for window prophylaxis:

1. Children < 5 years old
2. Clients with HIV or another immunocompromising condition*
3. Clients receiving immunosuppressive therapy*

*these groups of clients are recommended to receive a full course of treatment (beyond just window-period treatment)

Recommendations to complete a full course of treatment for TB infection (beyond the window period) even if a TB screening test administered \geq 8 weeks after the end of exposure is negative:

1. Clients with HIV infection
2. Clients receiving immunosuppressive therapy for organ transplantation
3. Clients taking TNF- α inhibitors

C. Pediatric Dosing:

TABLE 6. Pediatric Dosing Range for Daily, Twice Weekly, Maximum Doses, and Forms Available for the First-Line Anti-Tuberculosis Medications

DAILY DOSE RANGE				
Child's Weight (kg)	Isoniazid (INH) 10-15 mg/kg/day Dose, mg Max dose: 300mg	Rifampin (RIF) 10-20 mg/kg/day Dose, mg Max dose: 600mg	Pyrazinamide (PZA) 30-40 mg/kg/day Dose, mg Max dose: 2000mg	Ethambutol (EMB) 15-25 mg/kg/day Dose, mg Max dose: 1000mg
3-5	50	50	125	50-100
6-9	100	100	250	150
10-15	150	150	375-500	250
16-20	200	200	500-750	300
21-25	300	300	750	400
26-45	300	450	1000-1500	600-700
46-50	300	600	1500-2000	800
51-66	300	600	2000	1000
67+	300	600	2000	1000
TWICE WEEKLY DOSE:	20-30 mg/kg/dose Max dose: 900 mg	10-20 mg/kg/dose Max dose: 600 mg	50 mg/kg/dose Max dose: 2000 mg	50 mg/kg/dose Max dose: 2500 mg
Forms available:	Scored tablets: 100 mg 300 mg Syrup: 10 mg/ml*	Capsules: 150 mg 300 mg Syrup: compounded formulation	Scored tablets: 500 mg	Tablets: 100 mg 400 mg

* Many experts advise against using INH syrup because it is frequently associated with diarrhea.

Table adapted from American Academy of Pediatrics Redbook by Kim Smith, MD.