

The purpose of this document is to provide standing delegation orders for the provision of tuberculosis (TB) clinical services. The intended audience for these orders includes regional medical directors, regional communicable disease managers, regional community health services managers, regional TB program managers, registered nurses and licensed vocational nurses working in Texas Department of State Health Services (DSHS) Health Service Regions (HSRs). Orders contained in this document were prepared by DSHS Tuberculosis and Refugee Health Services Branch.

Standing Delegation Orders

A. Method Used for Development, Approval and Revision

This SDO and the relevant attachments shall be:

1. Developed by the DSHS Infectious Diseases Medical Officer and the TB and Refugee Health Services Branch and reviewed by DSHS-recognized expert TB physicians.
2. Reviewed by each Health Services Regional Medical Director, a physician licensed by the Texas Medical Board who, as the authorizing physician, executes this SDO.
3. Revised as necessary by the DSHS Infectious Diseases Medical Officer and the TB and Refugee Health Services Branch.

List of attachments:

1. ATTACHMENT 1: Attestation of Authorized Licensed Nurse.
2. ATTACHMENT 2: Nursing Management of Clients Infected TB (LTBI) or Clients Requiring Window Prophylaxis.
3. ATTACHMENT 3: Nursing Management of Clients Treated For LTBI with INH-RPT By DOT Once Weekly For 12 Weeks.
4. ATTACHMENT 4: Nursing Management of Clients with or Suspected to have TB Disease (Pulmonary and/or Extrapulmonary Disease).
5. ATTACHMENT 5: Targeted Testing for TB (Tuberculin Skin Test and Interferon-Gamma Release Assays).

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 in good standing 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:

[References that are more programmatic have been deleted and will be found in the Standards of Performance].

The following CDC documents can be found at:

<http://www.cdc.gov/tb/publications/guidelines/Testing.htm>

- Recommendations for Use of an Isoniazid–Rifapentine Regimen with Direct Observation to Treat Latent Mycobacterium tuberculosis Infection MMWR 2011;60:1650–1653
- Updated Guidelines for Using Interferon Gamma Release Assays to Detect Mycobacterium tuberculosis Infection — United States, 2010 MMWR 2010; 59 (RR-5); 1-25
- Updated Guidelines for the Use of Nucleic Acid Amplification Tests in the Diagnosis of Tuberculosis MMWR 2009; 58 (01); 7-10
- Controlling Tuberculosis in the United States Recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America MMWR 2005; 54 (No. RR-12)
- Tuberculosis Associated with Blocking Agents Against Tumor Necrosis Factor - Alpha California, 2002–2003 - MMWR 2004; 53 (No. 30)
- Treatment of Tuberculosis MMWR 2003; 52 (No. RR-11)
 - MMWR: Errata: Treatment of Tuberculosis (Vol. 52, No. RR-11)
- Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection MMWR 2000; 49 (No. RR-6) and Update
 - Update: Adverse Event Data and Revised American Thoracic Society/CDC Recommendations Against the Use of Rifampin and Pyrazinamide for Treatment of Latent Tuberculosis Infection MMWR 2003; 52 (No. 31)
- Diagnostic Standards / Classification of TB in Adults and Children Am J Respir Crit Care Med 2000; 161
- Recommendations for Prevention and Control of Tuberculosis among Foreign-Born Persons MMWR 1998; 47 (No. RR-16)
- Screening for Tuberculosis and Tuberculosis Infection in High-Risk Populations (ACET) MMWR 1995; 44 (No. RR-11)
- Tuberculosis Control Laws - United States, 1993. MMWR 1993; 42 (No. RR-15)
- Recommendations of the Advisory Committee on Immunization Practices (ACIP): Use of Vaccines and Immune Globulins in Persons with Altered Immunocompetence MMWR 1993; 42 (No. RR-4)
- Prevention and Control of Tuberculosis in Migrant Farm Workers (ACET) MMWR 1992; 41 (No. RR-10)

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- Prevention and Control of Tuberculosis Among Homeless Persons (ACET) MMWR 1992; 41 (No. RR-5)
- Prevention and Control of Tuberculosis in Facilities Providing Long-Term Care to the Elderly MMWR 1990; 39 (No. RR-10)

Other Documents:

- AIDSInfo Clinical Guidelines Portal: Available at: <http://aidsinfo.nih.gov/guidelines>
- Guidelines for the Prevention and Treatment of Opportunistic Infections Among HIV-Exposed and HIV-Infected Children. Available at: http://aidsinfo.nih.gov/contentfiles/lvguidelines/oi_guidelines_pediatrics.pdf
- Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents. Available at: http://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf
- Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Available at: <http://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/0>
- An Official ATS Statement: Hepatotoxicity of Antituberculosis Therapy, Am J Respir Crit Care Med, Vol 174. pp 935-952, 2006. Available at: <http://www.thoracic.org/statements/resources/mtpi/hepatotoxicity-of-antituberculosis-therapy.pdf>
- Core Curriculum on Tuberculosis: What the Clinician Should Know, 6th Edition, (CDC) 2013. Available at: http://www.cdc.gov/tb/education/corecurr/pdf/corecurr_all.pdf
- Drug Information on Antituberculosis Drugs, PDR. Available at: http://www.pdrhealth.com/drug_info/index.html
- Targeted Tuberculin Skin Testing and Treatment of Latent Tuberculosis Infection in Children and Adolescents, Pediatrics, Vol. 114, No. 4, October 2004. Available at: http://pediatrics.aappublications.org/content/114/Supplement_4/1175.full
- Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings, MMWR 2006;55 (No.RR-14). Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm>
- Recommendations for Human Immunodeficiency Virus (HIV) Screening in Tuberculosis (TB) Clinics Fact Sheet. Available at: <http://www.cdc.gov/tb/publications/factsheets/testing/HIVscreening.htm>

5. Have undergone the following initial or continuing evaluation of competence within 12 months prior to the date that services are provided under this SDO:
 - Initial evaluation of competence is performed by the nurse's supervisor and consists of 40 hours of initial DSHS-approved training on TB and TB prevention and control

activities within 60 days of employment, skills training and mentoring.

- Continuing evaluation of competence is performed annually by the nurse's supervisor and consists of 16 hours of DSHS-approved continuing education or training relevant to his or her position.
6. Have reviewed and signed this SDO (see ATTACHMENT 1) within 12 months prior to the date that services are provided under this SDO.

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

A record of authorized licensed nurses that complete the required training and demonstrated competence, as documented by their supervisors, shall be maintained by the nurse's supervisor in the health service regional office. The record shall include the specific course taken, the number of hours awarded and the date training was completed.

D. Authorized Delegated Acts

Authorized licensed nurses may evaluate and provide TB prevention and control services under this SDO to clients who are suspected of having or confirmed to have TB infection or disease.

It is the intent of all parties that the acts performed under this SDO meet the requirements of the Texas Medical Practice Act, the Texas Nursing Practice Act, the Texas Pharmacy Act, and the rules promulgated under those Acts.

E. Procedures to be followed by Authorized Licensed Nurses

Once an individual ("client") who is suspected of having, or confirmed to have, TB infection or disease presents to an authorized licensed nurse for care, the authorized licensed nurse will:

1. Obtain client's consent and signature in the preferred language of the client in accordance with agency policy, and document that the client received copies of the DSHS HIPAA privacy notice and applicable signed consent forms. If an interpreter is used, the name of the interpreter is documented.
 - DSHS privacy notice. Available at:
<http://www.dshs.state.tx.us/hipaa/privacynotices.shtm>.
 - General Consent and Disclosure (L-36). Available at:
www.dshs.state.tx.us/rls/pubs/GeneralConsentForm042010.pdf.
2. Create a new medical record and document the information listed in Section I of this SDO.
3. Evaluate the client, as outlined in this SDO and ATTACHMENTS 2, 3, 4, and 5 as indicated.

4. Obtain **specimen collection** (sputum, blood or other body fluids) for laboratory procedures, as indicated.
 - Bacteriology - smear and culture for acid fast bacilli (AFB).
Note: Prior to or at the initiation of therapy for TB disease, obtain three sputum specimens, at least 8 hours apart, for AFB smear and culture. At least one of the samples should be observed and at least one sample should be collected early in the morning. **(Clients with known or suspected extrapulmonary tuberculosis should be educated about sputum collection and try to produce three sputum specimens prior to or at the initiation of therapy).** If sputum cannot be produced, consult the authorizing physician.
 - Aspartate aminotransferase (AST), alanine aminotransferase (ALT), bilirubin, alkaline phosphatase, albumin, serum creatinine, complete blood count (CBC) with platelet count.
 - HIV screening using the opt-out method for all persons with newly diagnosed or suspected TB disease unless the patient has HIV positive documentation or has documented negative HIV test result from a specimen collected within the last 14 days.
 - For clients with HIV infection, CD4⁺ lymphocyte count should be obtained.
 - Clients with risk factors for Hepatitis B or C viruses should have serologic tests for these viruses. Risk factors include, but are not limited to, injection drug use, foreign birth in Asia or Africa, HIV infection.
5. Tuberculosis screening procedures performed, as indicated, and interpretation of results.
 - Tuberculin skin test (TST) - to be used for clients under 5 years of age.
 - Interferon gamma release assay (IGRA) - should only be used on clients 5 years of age and older.
6. Referral for Chest X-Ray (CXR) as indicated.
 - It is recommended that clients up to age 18 have both posterior-anterior and lateral views; all other clients should have at least posterior-anterior views. Other views or additional studies should be done by order of the authorizing physician.
 - Note in the client's medical record the following additional information, including, but not limited to
 - Reason, date, and source of a referral to clinic.
 - Reason for initial tuberculosis testing.Date administered, date read, and results in mm of TST and/or date specimen collected and results of IGRA.
7. Develop a management plan for clients suspected of having or confirmed to have active

TB by using form **TB-201**.

8. Clients should also be counseled on the following:

- To immediately report any possible adverse reactions and under what conditions they should stop taking their medication(s).
- To inform other physicians providing them with medical care that they are on medications that may have significant interactions with other medications.
- For clients with HIV and/or chronic viral hepatitis:
 - Inform the client about the potential risk of added hepatotoxicity. Inform the client on how to prevent transmission of HIV and/or chronic viral hepatitis.
 - Encourage clients to seek consultation for evaluation and possible treatment of their HIV and/or chronic viral hepatitis infection.
- For female clients of childbearing potential: counsel the patient that rifamycins - rifampin (RIF), rifapentine (RPT), and rifabutin (RBT) - may make hormonal contraceptive methods less effective, encourage the patient to add a back-up barrier method to prevent pregnancy, and emphasize the importance of avoiding pregnancy while on treatment.
- Provide results of all tests and procedures to the client at the next appointment after results received and reviewed. Results requiring urgent action should be communicated by phone if an urgent clinic visit cannot be arranged for in-person communication. If a client fails to return for follow-up of a result, attempts to locate the client should be undertaken and documented, to include phone calls, mailing letters, and home visits.

9. **DOSING OF MEDICATIONS:**

- 1) The authorized licensed nurse consults the relevant tables in the appropriate ATTACHMENT for the proper dosage of the antibiotic to be provided. Children must be weighed in order to calculate the proper dose of oral suspension. To convert weight in pounds to weight in kilograms divide by 2.2 (1kg = 2.2 lbs).
- 2) **Note:** If the clinic pharmacy does not have the appropriate antibiotic available, order the antibiotic through Inventory Tracking Electronic Asset Management Systems (ITEAMS).
- 3) 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:
 - 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.

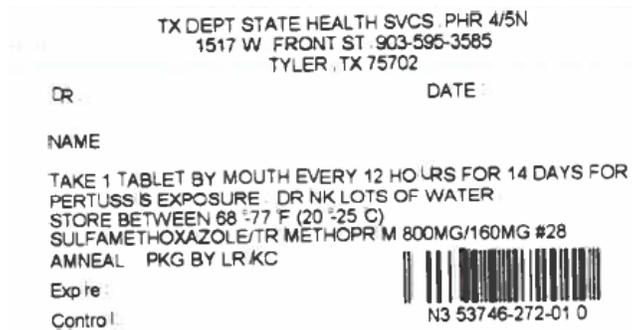
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- Quantity.
- Lot number and expiration date.

And the authorized license nurse will complete the labeling directions so that it contains the following information:

- The client's name.
- Date of provision.
- The authorizing physician's name.
- Directions for use (per Texas State Board of Pharmacy rules, incomplete directions for use may be present and if so, are to be completed by the authorized licensed nurse at time of distribution).

See sample label:



10. Obtain permission from the client and arrange for periodic follow-up information to be provided to the referring physician or primary care physician, as appropriate. If the client does not have a primary care physician, facilitate finding a source of basic health care for the individual.

F. 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.

G. Specialized Circumstances to Immediately Communicate with the Authorizing Physician

Authorized licensed nurses who provide services under this SDO should immediately contact the authorizing physician by phone when medical direction or consultation is needed or when client assessment data indicates deviations from the specific instructions outlined in this SDO.

Specific indications to call the authorizing physician include, but are not limited to:

1. Signs or symptoms suggestive of active tuberculosis.

2. Indeterminate, borderline, or otherwise un-interpretable tuberculosis screening test results.
3. Female client that is or has become pregnant.
4. Abnormal screening or other laboratory/radiographic test results.

Consult a DSHS-recognized expert TB physician any time a 2nd line medication is indicated or if the authorizing physician has concerns.

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

H. 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 authorizing physician can be contacted by phone.

I. Client Record-Keeping Requirements

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

1. The client's name, address, date of birth.
2. The client's **complete personal health history**, recorded on form **TB-202**, to include
 - Medication allergies.
 - Medications taken regularly.
 - Pregnancy status for females of childbearing potential, history of pregnancy, date of last menstrual period, and currently utilized contraceptive method.
 - Chronic health conditions, such as history of liver disease or preexisting risk factors including human immunodeficiency virus (HIV) infection, hepatitis B virus (HBV), hepatitis C virus (HCV) or other chronic hepatitis, sexual or household contact with individuals chronically infected with viral hepatitis, chronic hemodialysis, receipt of clotting factors prior to 1987, pregnant or less than 3 months post-partum, jaundice, substance abuse, other chronic medical conditions such as diabetes mellitus (DM), congestive heart failure (CHF), chronic kidney disease or elevated baseline liver enzymes.
 - If client was referred, document reason, date, and source of referral and obtain copies of relevant medical information.
3. The client's health status including signs and symptoms.

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4. The results of a **limited physical exam**, to include
 - Vital signs (weight, height, temperature, blood pressure).
 - Inspection of skin and eyes for jaundice.
 - Inspection of mouth for lesions.
 - Inspection of skin for rash.
 - Palpation of enlarged cervical lymph nodes.
 - Palpation of abdomen for liver tenderness.
5. **Clinical assessment** for tuberculosis disease medication toxicity for those on treatment or as a baseline for those starting treatment, recorded on form **TB-205**.
6. A description of the nursing care rendered on each medical visit and the names of personnel involved in evaluation and treatment at each visit.
7. Actions carried out under these standing orders.
8. For clients receiving treatment for LTBI or TB disease, recommended treatment regimens must be reviewed by the authorizing physician and cannot be implemented until **form TB-400A or TB-400B is signed by the authorizing physician**.
9. Any additional physician orders.
10. Administration of medications and treatments or medications provided to the client.
11. Client response(s), if any.
12. Contacts with other health care team members concerning significant events regarding client's status. (Note: review the client's plan of care with the authorizing physician at a minimum of every 3 months while the client is under care for TB infection or disease.)
13. Documentation of **education and counseling of the client**, recorded on form **TB-203**.
14. Documentation that laboratory reports were reviewed before placing them in the medical record.
15. Documentation that client received copies of the DSHS HIPAA privacy notice and applicable signed consent and other forms.

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

- Acknowledgment of Understanding Provision of Antituberculosis Drugs Limited to Clients with MTB (**TB-409 or TB-409A**).
- Disclosure and Consent for Drug Therapy (**TB-411, TB-411A, or for LTBI: TB-**

415, TB-415A, TB-415B) Note: A new disclosure and consent form must be signed and documented in the medical record each time a drug is changed or added.

- For clients receiving directly observed therapy (DOT), review the need for special arrangements for DOT during a disaster or emergency evacuation. Document the patient's preparedness plan and review with patient monthly. Complete the Hurricane/Natural Disaster Questionnaire (**TB-209**) with the patient.

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, the authorizing physician is no longer serving as the Regional Medical Director; or at the end of business on the last day of the current DSHS fiscal year (August 31, 2014), 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 for TB Clinical Services Provided by Registered Nurses and Licensed Vocational Nurses, 2013-2014, revised January 2014* (“SDO”) that was signed by Dr. _____
on _____
printed name of authorizing physician
date of authorizing physician’s signature

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

Signature of Authorized Licensed Nurse

Date