CDPH/CTCA Joint Guidelines

# *Guidelines for Oversight of Tuberculosis Care Provided Outside the Local Health Department Tuberculosis Program*

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## Preface

The following Guidelines have been developed by the California Department of Public Health (CDPH), Center for Infectious Diseases, Tuberculosis Control Branch (TBCB), and the California Tuberculosis Controllers Association (CTCA). These Guidelines provide statewide recommendations for tuberculosis (TB) control in California. If these Guidelines are altered for local use, then the logo should be removed and adaptation from this source document acknowledged.

No set of guidelines can cover all individual situations that can and will arise. When questions arise on individual situations not covered by these guidelines, consult with your local TB Controller or the CDPH, TBCB. As mandated by state law (Health and Safety Code, Section 121361), all decisions regarding the discharge or transfer of TB patients from health care facilities (HCFs) must be made by the local health officer (LHO) or designee of the jurisdiction in which the facility is located.

Local Health Department Tuberculosis (TB) Programs, as designated by the Local Health Officer, are responsible to prevent the spread of tuberculosis in their jurisdiction and are granted the authority to take such measures as may be necessary to prevent the spread of the disease or occurrence of additional cases (Health and Safety Code Section 120175). This goal is more easily achieved when the TB Program is also providing clinical services. When clinical services are provided by a provider outside of the TB Program, measures to prevent the spread of the disease include the oversight of treatment, appropriate isolation measures and the prompt initiation of a contact investigation when indicated. The following guidelines present the necessary components for effective oversight. These guidelines present both what is required of the providers (i.e. reporting responsibilities) and the responsibilities of the TB Programs. *The italicized items are legal requirements in the Health and Safety Code and the California Code of Regulations (CCR), Title 17.*

## Initial Notification of a TB Suspect or Case

TB Programs must be aware of reporting requirements regarding TB suspects and cases. Listed below are the reporting requirements.

*A health care provider must report by mail, fax, or telephone within one (1) working day of identification of the case or suspected case (CCR Title 17, Section 2500). Similarly, Health and Safety Code Section 121362 requires that health care providers, health facilities, or clinics (providing outpatient treatment for TB disease) shall promptly report to the TB Program when there are reasonable grounds to believe that a person has TB.*

*The initial disease notification report shall include an individual treatment plan which includes:*

A. *Demographic*

1. *Patient name*
2. *Address*
3. *Date of birth, age*
4. *Telephone number* *
5. *Occupation* *
6. *Ethnic group* *
7. *Social security number* *
8. *Sex* *

B. *Clinical*

1. *The date of diagnosis, diagnostic status*
2. *Tuberculin skin test findings or results of an FDA approved test for TB infection* (e.g. interferon gamma release assay (IGRA)
3. *Radiologic findings* (results indicating normal or abnormal; if abnormal, cavitary or non-cavitary, impressions indicating stable, improving, worsening, or initial film)
4. *Bacteriologic findings* (AFB smear results, culture results (pending or final), date(s) of collection, number of specimens, source, and drug susceptibility results if available.)
5. *Information regarding the risk of transmission of the disease to other persons*
6. *A list of the antituberculosis medications administered to the patient* (including dosages and date started)
7. *The date of onset*[1]

[1] if known, per Title 17

8. *Any other information required by the TB Program such as:*

   a. Site(s) of disease

   b. Adherence assessment plan, whether self-administered or directly Observed Therapy (DOT)

   c. Disposition (home, facility)

C. Other

1. *The name, address and telephone number of person making report* [*]

## Reporting and Notification Requirements When TB Suspects/Cases are Discharged or Transferred

I. *Health and Safety Code Section 121361 requires the following procedures except when prior notification would jeopardize the person's health, the public safety, or the safety and security of the penal institution, then the notification and treatment plan shall be submitted within 24 hours of discharge, release, or transfer.* The TB Program, when referred to below, is defined as the TB Program in the local health jurisdiction of the transferring/discharging/releasing entity. For additional information on discharges involving two jurisdictions, see the latest version of the CDPH/CTCA "Interjurisdictional Continuity of Care Policy Statement".

   A. *Health facilities*

   1. *Before health facilities discharge or release a TB case or suspect or before transferring the patient to another health facility, the TB Program must receive notification and a written treatment plan (as specified above). The TB Program must review the treatment plan within 24 hours of receipt of the plan. The TB Program must approve the written treatment plan before discharge, release or transfer of the patient.*

   2. *Before health facilities transfer a TB case or suspect to an acute care hospital when there is an immediate need for a higher level of care, the TB Program must receive notification and a written treatment plan.*

   3. *Before health facilities transfer a TB case or suspect to a correctional institution (state or local detention facility), the TB Program must receive notification and a written treatment plan*

[*] if known, per Title 17

B. *State correctional system*

1. *Before a State correctional facility discharges or releases a TB suspect or case, the TB Program must receive notification and a written treatment plan. Additionally, the TB program for the county in which the parolee intends to reside shall also receive a written treatment plan.*

2. *Before a State correctional facility transfers a TB suspect or case to a local detention facility, the Chief Medical Officer (CMO) of the local detention facility and the TB Program must receive notification and a written treatment plan.*

3. *Before a State correctional facility transfers a TB suspect or case to a health facility, the TB Program must receive notification and a written treatment plan.*

C. *Local detention facilities (defined in Section 6031.4 Penal Code, see also CCR, Title 15, 1206)*

1. *Before a local detention facility discharges or releases a TB suspect or case, the TB Program must receive notification and a written treatment plan.*

2. *Before a local detention facility transfers a TB suspect or case to a detention facility in another local detention facility system, the TB Program must receive notification and a written treatment plan. The CMO of the receiving facility must also receive notification and a written treatment plan.*

3. *Before a local detention facility transfers a TB suspect or case to a State correctional facility, the TB Program must receive notification and written treatment plan. The CMO of the receiving facility must also receive notification and a written treatment plan.*

4. *Before a local detention facility transfers a TB suspect or case to a health facility, the TB program must receive notification and a written treatment plan.*

II. *Health and Safety Code 121362 requires that facility discharge, release or transfer reports shall include:*

A. *All pertinent and updated information required by the TB Program not previously included on initial or subsequent reports*

B. *Verified patient address*

C. *Name of medical provider who has specifically agreed to provide medical care*

D. *Clinical information used to assess the current infectious state, and*

E. *Any other information required by the TB Program.*

## Case Management

I. Every TB patient (including patients being treated outside the TB Program) should be assigned a specific health department employee (case manager) from the health jurisdiction in which s/he resides (*1, 5*). The case manager should be primarily responsible and held accountable for ensuring that each TB patient completes an appropriate course of therapy, complies with isolation guidance and orders, is educated about TB and its treatment, that a contact investigation is conducted when indicated, and that culture conversion is documented. Some specific responsibilities may be assigned to other persons.

II. Upon receipt of the initial case report, the case manager (or assigned staff) should review the report for completeness, assess the risk of transmission, and determine necessary control measures. The treatment regimen should be consistent with the latest version of the CDPH/CTCA "Guidelines for the Treatment of Active Tuberculosis Disease." The provider/institution should be contacted immediately if information is missing from the initial report or if an inappropriate treatment regimen has been prescribed.

III. The case manager should contact the provider/institution within one to three working days to explain the following:

   A. The public health role and services of the TB Program and assurance of isolation if needed after release.

   B. The importance of coordinating the patient's care including DOT.

   C. The name and phone number of the case manager in the health department assigned to the case.

   D. On-going reporting requirements (see section on **Subsequent Reports/Treatment Oversight** on page 7).

   E. Treatment recommendations and protocols (local, state or national guidelines) including recommendations for specimen collection and documenting sputum conversion.

   F. Plans for direct patient assessment and the contact investigation (see section on **Contact Investigation**).

IV. The case manager or assigned staff should visit the patient within one to seven working days of the receipt of the initial report depending on the risk of transmission (2).[*] The purpose of the initial visit is to:

A. Make an assessment of whether the patient should be placed on Directly Observed Therapy (DOT). TB Program staff should coordinate the provision of DOT with the provider. TB Programs should have the capacity to provide DOT to patients receiving care outside the TB Program

B. Verify and document all prescribed TB medications and their dosages. Verify by visual inspection or contact pharmacy.

C. Initiate a contact investigation when indicated (see section on **Contact Investigation**).

D. Verify initial information and establish what information will be needed to complete the Report of Verified Case of Tuberculosis.

E. Explain the role and responsibilities of the TB program, as well as the patient's responsibility and provide patient education as needed.

F. Assess the patient's living situation and collect information about persons with household exposure. The case manager should consider contacts in the home, work, social settings and personnel from agencies that may provide ancillary services in the patient's home.

V. The case manager or assigned staff should visit the patient at least monthly throughout the course of therapy in order to ensure the patient remains on an appropriate regimen, to assess on-going adherence and to assist in sputum collection as indicated.

VI. The case manager should review the case at least monthly to monitor sputum status for infectiousness and to ensure sputum culture conversion.

## Contact Investigation

I. The case manager is responsible for ensuring that a contact investigation is conducted when indicated and that all contacts are appropriately evaluated and treated within recommended time frames. For additional information, see the latest version of the CDPH/CTCA "Contact Investigation Guidelines."

II. *Health and Safety Code 121363 states that each health care provider who treats a person for active TB disease shall examine, or cause to be examined, all household contacts or shall refer them to the TB Program for examination. Each health care provider shall*

[*] The CTCA/CDPH Case Management guideline recommends, "The case manager should conduct a face-to-face visit with the patient within three to seven days of receipt of report of suspected or confirmed TB, depending on risk of transmission."

*promptly noti1fy the TB Program of the referral. When required by the TB Program, non-household contacts and household contacts not examined by a health care provider shall submit to examination by the TB Program or designee.*

III. As stated above, the case manager (or assigned staff) should contact the provider within three working days of the initial report to determine if the provider has identified contacts and whether the provider is going to examine and/or treat these contacts or whether they will be referred to the TB Program for examination and/or treatment.

IV. If the provider is intending to examine and/or treat these contacts, the case manager (or assigned staff) should send written information on procedures and guidelines, including the need for providers to report examination results back to the TB Program in a timely manner.

V. To complete the contact investigation, the case manager must obtain information on any exams and follow-up done by outside providers to assure that appropriate follow-up has been completed.

## Subsequent Reporting/Treatment Oversight

I. Following the receipt of the initial report, the case manager (or assigned staff) should inform the provider of the following reporting requirements (see Attachments A and B):

A. *Health and Safety Code 121362 requires health care providers, health facilities, or clinics (providing treatment for TB disease) to promptly report to the TB Program when a TB patient ceases TB treatment including when the patient:*

1. *Fails to keep an appointment,*
2. *Relocates without transferring care, or*
3. *Discontinues care.*

B. *Subsequent reports* should be obtained *at the times the TB Program requires*, but no less often than every three months until treatment is complete and *shall include*:

1. *Updated clinical status,*
2. *Date and finding of last chest x-ray including whether stable, improving or worsening,*
3. *Laboratory results* (including all smear, culture, and drug susceptibility results obtained during the course of treatment),
4. *Assessment of treatment adherence,*
5. *Name of current care provider if patient transfers care, and*

6. *Any other information required by the TB Program*. At a minimum, this information should include date of last evaluation and next appointment, current medications, including dosages, dates started and stopped, whether self-administered or by Directly Observed Therapy.

II. Completed reports should be reviewed to assure that recommended follow-up and treatment are in accordance with established guidelines.

III. The provider should be contacted directly to discuss the case if:

A. The case manager does not receive the subsequent report form within 30 days of request or determines the report is incomplete.

B. The isolate is drug-resistant.

C. There is a lack of improvement in chest x-ray, smear/culture, or clinical status of patient.

D. The treatment plan is not in accordance with established standards.

E. The patient is non-adherent.

F. The patient reports signs and symptoms of TB medication adverse effects.

IV. When a patient completes therapy, the case manager should contact the provider to discuss recommended post treatment follow-up (per CDPH/CTCA “Guidelines for the Treatment of Active Tuberculosis Disease”).

## Provider Education and Evaluation of Oversight Activities

I. The TB Controller or designated staff should regularly educate providers, laboratories, and health and correctional facilities of their reporting requirements (see Attachment C).

II. The TB Controller or designated staff should compare treatment parameters and outcomes (e.g., appropriateness of regimens, sputum conversion, completion of therapy) for cases receiving care outside the TB Program with cases followed by the TB Program in order to identify discrepancies. In addition, the TB Program should evaluate provider and institution compliance with reporting and notification requirements.

III. The TB Controller or designated staff should regularly evaluate case management and oversight activities to ensure that they are performed in accordance with these guidelines.

IV. If deficiencies are identified with TB care provided outside the TB Program or with oversight activities within the TB Program, appropriate measures should be instituted, including provider education. The goal of such efforts should be to improve the care of patients and to promote positive working relationships with providers working outside the TB Program.

## V. References:


1. Centers for Disease Control and Prevention. Essential components of a tuberculosis prevention and control program: recommendations of the Advisory Committee for Elimination of Tuberculosis. MMWR 1995; 44 (No. RR-11): 6.
2. California Tuberculosis Controllers Association. Contact Investigation Guidelines. 2009
3. California Tuberculosis Controllers Association. Interjurisdictional Continuity of Care Policy Statement. April, 1999.
4. California Tuberculosis Controllers Association. Guidelines for the Treatment of Active Tuberculosis Disease. April, 2003.
5. California Tuberculosis Controllers Association. TB Case Management – Core Concepts. May, 1998.