



RON CHAPMAN, MD, MPH
Director & State Health Officer

State of California—Health and Human Services Agency
California Department of Public Health



EDMUND G. BROWN, JR.
Governor

June 13, 2013

AFL 13-15

TO: Acute Psychiatric Hospitals
Adult Day Health Centers
Chemical Dependency Recovery Hospitals
Correctional Treatment Centers
General Acute Care Hospitals
Home Health Agencies
Intermediate Care Facilities
Intermediate Care Facilities/ Developmentally Disabled
Intermediate Care Facilities/ Developmentally Disabled-Habilitative
Primary Care Clinics
Psychology Clinics
Skilled Nursing Facilities

SUBJECT: Regulatory Changes to Tuberculosis Screening and Testing

AUTHORITY: Office of Administrative Law has approved this regulatory action pursuant to section 11349.3 of the Government Code

This All Facilities Letter (AFL) is being sent to notify you that the Office of Administrative Law has approved regulatory action pursuant to section 11349.3 of the Government Code to amend Title 22, California Code of Regulations (CCR) requirements relating to tuberculosis (TB) screening and testing. Prior regulations required health facilities to use a TB intradermal skin test (TST) for TB screening. In order to be compliant with the previous requirements, health facilities were required to submit program flexibility to the department if they sought usage of an alternate method.

Effective May 30th, 2013, health facilities no longer are required to submit program flexibility for TB screening tests that are licensed by the Federal Food and Drug Administration (FDA) and recommended by the Centers for Disease Control (CDC). Program flexibility is still required if using a test that is outside of FDA or CDC recommendations. For your convenience, the updated portions of Title 22 CCR have been attached.

Additionally, the CDC recommendations for TB Screening can be found at:

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

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For verification of licensed FDA drugs, please go to:

<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>

Facilities are responsible for following all applicable laws. The California Department of Public Health's failure to expressly notify facilities of statutory or regulatory requirements does not relieve facilities of their responsibility for following all laws.

If you have any additional questions, please contact your respective Licensing & Certification District Office.

Sincerely,

Original signed by Debby Rogers

Debby Rogers, RN, MS, FAEN
Deputy Director
Center for Health Care Quality

Attachment

CCR, Title 22 Chapters
Tuberculosis (TB) Screening

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Chapter 1. General Acute Care Hospitals

§ 70723. Employee Health Examinations and Health Records.

(1) Initial examination for tuberculosis shall include a ~~tuberculin skin test using the Mantoux method using a 5 Tuberculin Unit dose of PPD tuberculin stabilized with Tween 80, the result of which is read and recorded in millimeters of induration~~ test for tuberculosis infection that is recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA). If the result is positive, a chest ~~film~~ X-ray shall be obtained. A ~~skin test~~ If a person has a previously documented positive tuberculosis test result, a test for tuberculosis infection need not be done ~~on a person with a documented positive reaction to PPD~~ but a baseline chest X-ray shall be obtained.

(2) Policies and Procedures that address the identification, employment utilization and medical referral of persons with positive ~~skin~~ tuberculosis tests including those who have converted from negative to positive shall be written and implemented.

(3) An annual ~~skin~~ tuberculosis test ~~for tuberculosis~~ shall be performed on those individuals with a previously documented negative ~~tuberculin~~ tuberculosis ~~skin~~ test. If an individual with a previously documented negative ~~skin~~ tuberculosis test has a subsequent positive tuberculosis reaction test result, a chest X-ray shall be obtained.

Chapter 2. Acute Psychiatric Hospitals.

§ 71523. Employee Health Examinations and Health Records.

(b) A health examination performed under the direction of a physician shall be required as a requisite for employment and must be performed within one week after employment. Written examination reports signed by the physician which verify that employees are able to perform assigned duties shall be maintained. Repeat examinations shall be performed whenever necessary to ascertain that employees are free from symptoms indicating the presence of infectious disease and are able to perform their assigned duties. Upon initial examination, and at least annually, the employee shall have a ~~skin~~ test for tuberculosis using ~~Purified Protein Derivatives intermediate strength~~ infection that is recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA) or a chest X-ray. A ~~Positive reaction to~~ result from the skin tuberculosis test shall be followed by a ~~35.56 cm x 43.18 cm (14" x 17")~~ chest X-ray.

Chapter 3. Certified Nurse Assistant Program.

§ 71835. Certification Training and Competency Evaluation Program.

(1) This examination shall include:

(A) A medical history and physical examination.

(B) A ~~purified protein derivative, intermediate strength intradermal~~ skin test for tuberculosis infection that is recommended by the federal Centers for Disease Control

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and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA), unless medically contraindicated. If a positive reaction test result is obtained, a chest X-ray shall be taken, unless medically contraindicated.

Chapter 4 Skilled Nursing Facilities

§ 72535. Employees' Health Examination and Health Records.

(b) The initial health examination and subsequent annual examination shall include ~~a purified protein derivative intermediate strength intradermal skin test for tuberculosis infection that is recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA).~~ A chest X-ray is indicated if the employee has previously had a positive ~~reaction to a tuberculosis skin test result~~ or is currently being treated for tuberculosis. A Ppositive reaction to the skin tuberculosis test result shall be followed by a 35.56 cm x 43.18 cm (14 " x 17 ") chest X-ray. Evidence of tuberculosis screening within 90 days prior to employment shall be considered as meeting the intent of this Section.

Chapter 5 Intermediate Care Facilities (ICF)

§ 73525. Employees' Health Examinations and Health Records.

(b) The initial health examination and subsequent annual examination shall include ~~a purified protein derivative intermediate strength intradermal skin test for tuberculosis infection that is recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA) or a chest X-ray. A Ppositive reaction to result from the skin tuberculosis test shall be followed by a 35.56cm x 43.18cm (14 "x 17 ") chest X-ray.~~

Chapter 6. Home Health Agencies

§ 74723. Employee's Health Examinations and Health Records.

(c) The written health assessment report shall:

(4) Provide for a tuberculosis screening which shall be administered to all new employees who have direct patient contact and annually thereafter using ~~the 5-TU (Tuberculin Units) Protein Purified Derivative (PPD) tuberculin skin test. a test for tuberculosis infection that is recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA).~~

(A) The tuberculosis test shall be administered by a licensed health care professional who is specifically trained for the procedure.

(B) Employees who present evidence of a previous positive ~~tuberculin skin tuberculosis~~ test or that he or she has previously been treated for tuberculosis infection or disease shall be excluded from the ~~tuberculin testing tuberculosis screening testing program.~~

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Chapter 7. Primary Care Clinic

§ 75051. Health Examination and Health Records of Persons Working in the Clinic.

(b) The initial health examination and subsequent annual examination shall include a ~~purified protein derivative intermediate strength intradermal skin~~ test for tuberculosis infection that is recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA) or a chest X-ray. ~~A P~~Positive reaction result to from the skin tuberculosis test shall be followed by a ~~35.56 cm x 43.18 cm (14 "x 17 ")~~ chest X-ray. Evidence of tuberculosis screening within 12 months prior to employment shall be considered as meeting the intent of this regulation.

Chapter 8 Psychology Clinics

§ 75335. Employee Health Examinations and Health Records.

(a) A health examination, performed by a person lawfully authorized to perform such an examination shall be performed as a prerequisite for employment within six months prior to employment or within one week after employment. Written examination reports, signed by the person performing the examination, shall verify that employees are able to perform assigned duties and do not have any health condition that would create a hazard for the employee, fellow employees, patients or visitors. The initial health examination shall include a ~~tuberculosis screening test consisting of a purified protein derivative intermediate strength intradermal skin~~ test for tuberculosis infection that is recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA) and a chest X-ray if the ~~skin tuberculosis~~ test is positive. The psychology clinic shall establish a policy regarding subsequent health examinations and tuberculosis screening tests based on an assessment of the following:

Chapter 9. Intermediate Care Facilities Developmentally Disabled

§ 76539. Employees' Health Examination and Health Records.

(a) The licensee and all employees working in the facility shall have a health examination within 6 months prior to employment or within 15 days after employment and at least annually thereafter by a person lawfully authorized to perform such examinations. Each such examination shall include a medical history, physical evaluation and laboratory work as indicated. The report signed by the examiner shall indicate that the individual is sufficiently free of disease to perform assigned duties and does not have ~~ay~~ any health condition that would create a hazard for the employee, fellow employees, visitors or clients.

(b) The initial health examination and subsequent annual examination shall include a ~~purified protein derivative intermediate strength intradermal skin~~ test for

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tuberculosis infection that is recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA) or a chest X-ray. ~~A Positive reaction result to from the skin tuberculosis test~~ shall be followed by a ~~35.56 cm x 43.18 cm (14 "x 17 ")~~ chest X-ray.

Chapter 10. Intermediate Care Facilities Developmentally Disabled Habilitative
§ 76874. Health Support Services -Physician Services.

(b) Testing for tuberculosis shall consist of a ~~purified protein derivative intermediate strength intradermal skin test~~ for tuberculosis infection that is recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA). If a positive ~~reaction result~~ is obtained from the ~~skin tuberculosis test~~, the client shall be referred to the attending physician to determine if a chest X-ray is necessary.

§ 76919. Employees' Health Examination and Health Records.

(b) At the time of employment, testing for tuberculosis shall consist of a ~~purified protein derivative intermediate strength intradermal skin test~~ for tuberculosis infection that is recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA). If a positive ~~reaction result~~ is obtained from the ~~skin tuberculosis test~~, the employee shall be referred to a physician to determine if a chest X-ray is necessary. Annual examinations shall be performed only when medically indicated.

Chapter 11. Adult Day Health Centers
§ 78429. Employee Records.

(b) Each employee record shall contain at least the following:
(2) A health record containing a report of the following:
(A) Chest X-ray or purified protein derivative intermediate strength test for tuberculosis infection that is recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA) performed not more than 12 months prior to employment or within 7 days of employment.

Chapter 13. Chemical Dependency Recovery Hospitals
§ 79331. Employee Health Examinations and Health Records.

(b) A health examination performed by a person lawfully authorized to perform such an examination shall be required as a prerequisite for employment and shall be performed within one week after employment. The written health examination report shall be signed by the person performing the examination and shall verify that the employee is able to perform assigned duties and is free from symptoms indicating the

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presence of infectious disease. Repeat health examinations shall be performed whenever necessary to ascertain that employees continue to be free from symptoms indicating the presence of infectious disease and are able to perform their assigned duties. Upon initial examination, and at least annually, the employee shall have a skin test for tuberculosis ~~using purified protein derivatives, intermediate strength~~ infection that is recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA) or a chest x-ray. ~~A Ppositive reaction result to~~ from the skin tuberculosis test shall be followed by a ~~35.56 cm x 43.38 cm (14 "x 17 ")~~ chest x-ray.

Chapter 14. Correctional Treatment Centers
§ 79781. Required Committees.

(d) Committee composition and function shall be as follows:

(1) Patient Care Policy Committee.

(2) Infection Control Committee.

(D) The functions of the infection control committee shall include, but not be limited to:

1. Establishing, reviewing, monitoring and approving policies and procedures for investigating, controlling and preventing infections, including tuberculosis, in the correctional treatment center. These policies and procedures shall be reviewed and revised per 79779(b), and shall be based on the 1990 recommendations of the Centers for Disease Control and Prevention (CDC).

2. Maintaining, documenting, reviewing and reporting statistics of the number, types, sources and locations of infections within the facility. This shall include maintaining a confidentiality log which contains the dates and results of ~~Mantoux tuberculin skin tests for tuberculosis infection that are recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA) recorded in millimeters of induration~~ and chest X-ray results of all correctional treatment center employees and inmate-patients.

§ 79795. Employee Health Examinations and Health Records.

(b) The initial health examination shall include a ~~tuberculin skin test using the Mantoux method using a 5 Tuberculin Unit dose of Purified Protein Derivative (PPD) stabilized with Tween-80, the result of which is read and recorded in millimeters of induration~~ test for tuberculosis infection that is recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA). If the result is positive, a chest ~~film~~ X-ray shall be obtained. ~~A tuberculin skin test~~ If a person has a previously documented positive tuberculosis test result, a test for tuberculosis infection need not be done on a person with a documented positive reaction to PPD but a baseline chest X-ray shall be obtained.

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(1) Policies and procedures that address the identification, employment utilization and medical referral of persons with positive ~~skin~~ tuberculosis tests, including those who have converted from negative to positive, shall be written and implemented.

(2) An annual ~~skin~~ test for tuberculosis shall be performed on those individuals with a previously documented negative ~~tuberculin-skin~~ tuberculosis test. If an individual with a previously documented negative ~~skin~~ tuberculosis test has a subsequent positive ~~reaction~~ result, a chest X-ray shall be obtained.

§ 79805. Inmate-Patient Health Record Content.

(a) Each inmate-patient's health record for inpatient services shall consist of at least the following:

(3) Admission medical history and physical within 24 hours of admission. This shall include written documentation of a ~~Mantoux-tuberculin-skin~~ test for tuberculosis infection that is recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA) within the past year, unless a previously positive ~~reaction~~ result can be documented or completion of adequate preventive therapy or adequate therapy for active disease can be documented. If no written documentation is available, the ~~Mantoux-tuberculin-skin~~ a tuberculosis test shall be administered within 24 hours of admission, and the result recorded in ~~millimeters of induration~~ in the medical history. The result of the tuberculosis test shall be reported as recommended in current guidelines of the Centers for Disease Control and Prevention regarding tuberculosis testing.