



Memorandum

To: Marley Hart, Executive Officer
Occupational Safety and Health Standards Board
2520 Venture Oaks Way, Suite 350
Sacramento, CA 95833

Date: May 23, 2017

From: Juliann Sum, Chief 
Division of Occupational Safety and Health

Subject: Evaluation of Petition 563 from Ken Cutler, MD, President, California Conference of Local Health Officers, to amend Title 8 section 5199, Aerosol Transmissible Diseases.

On January 23, 2017, the Division of Occupational Safety and Health (Cal/OSHA) received a petition from Kenneth Cutler, President of the California Conference of Local Health Officers (petitioner). The petitioner requests a change to subsection (h)(3) in Title 8 section 5199, Aerosol Transmissible Diseases. The subsection requires covered employers to make an assessment for latent tuberculosis infection (LTBI) available to all employees with occupational exposure to aerosol transmissible diseases at least once a year.

1.0 Proposed changes to section 5199(h)(3) requested by the petitioner

The petitioner requests that covered employers be allowed to make assessments for LTBI available to employees less frequently than the once a year. The petitioner recommends that facilities covered by Title 8 section 5199 be required to conduct a risk assessment for tuberculosis (TB) exposure and perform LTBI testing at the frequency outlined in the U.S. Centers for Disease Control (CDC) publication, *Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Setting, 2005*¹ (CDC TB Guidelines).

2.0 Existing Title 8 Requirements

Title 8 section 5199, Aerosol Transmissible Diseases applies to most health care facilities, certain police services, certain public health service, correctional and detention facilities,

¹ Centers for Disease Control and Prevention. Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005. MMWR 2005;54(No. RR-17). Available at: <https://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf>

homeless shelters, drug treatment programs and others. The requirement for these employers to offer LTBI testing to employees in subsection 5199(h)(3) is the following:

§5199. Aerosol Transmissible Diseases.

* * * * *

(h) Medical Services.

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(3) The employer shall make assessment for latent tuberculosis infection (LTBI) available to all employees with occupational exposure. Assessment procedures shall be in accordance with applicable public health guidelines.

(A) TB tests and other forms of TB assessment shall be provided at least annually, and more frequently, if applicable public health guidelines or the local health officer recommends more frequent testing. Employees with baseline positive TB test shall have an annual symptom screen.

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Covered employers must offer LTBI testing only to those employees with "occupational exposure." Section 5199 defines occupational exposure as the following:

Occupational exposure. Exposure from work activity or working conditions that is reasonably anticipated to create an elevated risk of contracting any disease caused by ATPs or ATPs-L if protective measures are not in place. In this context, "elevated" means higher than what is considered ordinary for employees having direct contact with the general public outside of the facilities, service categories and operations listed in subsection (a)(1) of this standard. Occupational exposure is presumed to exist to some extent in each of the facilities, services and operations listed in subsection (a)(1)(A) through (a)(1)(I). Whether a particular employee has occupational exposure, depends on the tasks, activities, and environment of the employee, and therefore, some employees of a covered employer may have no occupational exposure. For example, occupational exposure typically does not exist where a hospital employee works only in an office environment separated from patient care facilities, or works only in other areas separate from those where the risk of ATD transmission, whether from patients or contaminated items, would be elevated without protective measures. It is the task of employers covered by this standard to identify those employees who have occupational exposure so that appropriate protective measures can be implemented to protect them as required. Employee activities that involve having contact with, or being within exposure range of cases or suspected cases of ATD, are always considered to cause occupational exposure. Similarly, employee activities that involve contact with, or routinely being within exposure range of, populations served by facilities identified in subsection (a)(1)(E) are considered to cause occupational exposure. Employees working in laboratory areas in which ATPs-L are handled or reasonably anticipated to be present are also considered to have occupational exposure.

Based on the above definition, employees who work with or near client populations at the following locations are automatically assumed to be occupationally exposed:

- Correctional facilities and other facilities that house inmates or detainees
- Homeless shelters
- Drug treatment programs

In addition, employees who work with or near patients who have suspect aerosol transmissible diseases are also assumed to be occupationally exposed.

Employees who do not work in patient care areas are typically not considered to have occupational exposure. Research and production laboratories in which *M. tuberculosis* containing materials are not reasonably anticipated to be present are also exempt from the requirement to offer LTBI testing. Employees who work in patient care areas that do not treat patients with suspect aerosol transmissible diseases may also not be occupationally exposed. The employer is responsible for determining which employees are occupationally exposed to aerosol transmissible diseases.

For those employees with occupational exposures, employers must offer, and provide at no cost, assessments, tests and follow-up for occupational LTBI. However, section 5199 does not mandate employees participate in LTBI testing.

LTBI testing is required to protect employees from developing tuberculosis disease through early detection and medical follow-up for infection. LTBI testing also provides surveillance information to the employer's infection control program.

3.0 Other Laws and Regulations

California public health laws and regulations address prevention of communicable disease for persons in schools, health care settings, prisons, and congregate living settings to protect both employees and non-employees. Title 22 regulations require annual testing of employees in acute psychiatric hospitals (Title 22 §75335), skilled nursing facilities (Title 22 §72535), intermediate care facilities (Title 22 §70503), home health agencies (Title 22 §1796.350), primary care clinics (Title 22 §1226.1), intermediate care facilities for the developmentally disabled (Title 22 §72535), chemical dependency recovery hospitals (Title 9 §10564), and correctional treatment centers (Penal Code §6007). Title 22 also requires initial and annual testing of employees in general acute care hospitals, however, the local health officer may approve reducing frequency of testing to an interval no longer than four years. Psychiatric clinics and psychiatric health facilities are required to provide initial tests for LTBI, and must establish risk-based procedures for further testing. Most of these sections were updated in 2013 to permit the use of any test for TB infection approved by the Food and Drug Administration (FDA) and recommended by the CDC.

Prior to 2014, the Health and Safety Code §121525 through §121555 required private schools to provide employees an initial and every-four-year testing for LTBI. In 2014, the law was changed to permit either an individual risk assessment for tuberculosis disease to be followed by an examination if the risk assessment indicated the need, or an examination for LTBI. A similar change was made to the Education Code §49406 & 87408.6 affecting employees at public schools.

The California Penal Code §6006 through §6007 requires LTBI testing of all inmates and wards, as well as pre-employment and annual testing of staff having contact with the facilities' populations, in order to ensure that they do not have tuberculosis disease.

4.0 CDC TB Guidelines for Work-Settings

The petitioner proposes to require employers to use a risk assessment provided in the CDC TB Guidelines in lieu of annual LTBI testing. The CDC TB Guidelines recommend limiting annual TB testing in hospitals and certain other healthcare settings based on a risk assessment.

4.1 TB Risk Classifications

The CDC TB Guidelines define three risk classifications of health-care settings: low-risk, medium-risk, or potential ongoing transmission (highest risk category). The risk categories are based in part on a determination if persons with unrecognized tuberculosis disease were encountered in the setting during the previous 5 years. The risk assessment also includes a community profile of tuberculosis disease and epidemiologic surveillance data.²

For low risk, the CDC TB guidelines state:

The classification of low risk should be applied to settings in which persons with TB disease are not expected to be encountered, and, therefore, exposure to *M. tuberculosis* is unlikely. This classification should also be applied to HCWs [health care workers] who will never be exposed to persons with TB disease or to clinical specimens that might contain *M. tuberculosis*.²

For medium risk, the CDC TB guidelines state:

The classification of medium risk should be applied to settings in which the risk assessment has determined that HCWs will or will possibly be

² Page 10 of the CDC TB Guidelines.

exposed to persons with TB disease or to clinical specimens that might contain *M. tuberculosis*.²

For the highest risk (potential ongoing transmission), The CDC TB guidelines state:

The classification of potential ongoing transmission should be temporarily applied to any setting (or group of HCWs) if evidence suggestive of person-to-person (e.g., patient-to-patient, patient-to-HCW, HCW-to-patient, or HCW-to-HCW) transmission of *M. tuberculosis* has occurred in the setting during the preceding year.²

4.2 LTBI Testing Based on Classification ²

For low risk settings, CDC recommends that all health care workers receive a baseline LTBI test upon hire. No additional or periodic LTBI testing is recommended unless a worker is known to be exposed to tuberculosis.

For medium risk settings, CDC recommends that all health care workers receive a baseline LTBI test upon hire. After the initial testing, CDC recommends all healthcare workers receive annual screening for tuberculosis (symptom screening for all health care workers and LTBI testing for workers whose baseline LTBI test was negative).

For high risk settings (potential ongoing transmission), CDC recommends LTBI testing every 8 to 10 weeks until lapses in infection control have been corrected and there is no evidence that ongoing transmission of tuberculosis. CDC notes that this classification is temporary while transmission of tuberculosis is occurring at the setting. Once ongoing transmission is controlled, these settings should be reclassified as medium risk.

4.3 CDC Numerical Risk Classification

The risk assessments contained in the CDC TB Guidelines discussed in part 4.1 above are contradicted by numerical risk classification in the same guidelines. The risk assessment discussed in part 4.1 include a 5-year history of encounters with unrecognized tuberculosis and considers community risk factors and epidemiologic surveillance data. However, the numerical risk classification is based only on one-year history of patients with tuberculosis. In addition, the numerical risk classification does not consider community risk factors or epidemiologic surveillance data.

The numerical risk classifications in the CDC TB Guidelines are the following:³

Inpatient Settings with More Than 200 Beds

³ Page 11 of the CDC TB Guidelines.

If less than six TB patients for the preceding year, classify as low risk. If greater than or equal to six TB patients for the preceding year, classify as medium risk.

Inpatient Settings with Less Than 200 Beds

If less than three TB patients for the preceding year, classify as low risk. If greater than or equal to three TB patients for the preceding year, classify as medium risk.

Outpatient, Outreach, and Home-Based Health-Care Settings

If less than three TB patients for the preceding year, classify as low risk. If greater than or equal to three TB patients for the preceding year, classify as medium risk.

Whereas the risk assessment discussed in a part 4.1 determined that low risk setting includes only those setting where zero cases of tuberculosis are expected based on a five-year history, the numerical risk classification considers 2 to 5 cases of tuberculosis per year as low risk based on a one year history. The CDC TB guidelines do not provide any bases for the numerical cut-offs, nor do they explain the inconsistency between the risk assessment and numerical risk classification.

5.0 Background Information on Tuberculosis

Tuberculosis is an infectious disease caused by the bacterium *Mycobacterium tuberculosis*. *Mycobacterium tuberculosis* is carried in airborne particles called droplet nuclei that can be generated when persons who have pulmonary or laryngeal tuberculosis disease cough, sneeze, shout, or sing.

Most persons infected with *Mycobacterium tuberculosis* do not have symptoms, in which case the infection is known as latent tuberculosis. About 10% of latent infections progress to active disease that, if left untreated, kills about half of those infected. However, persons with compromised immune systems, such as persons suffering from HIV infection, malnutrition or diabetes, or people who use tobacco, have a much higher risk of developing tuberculosis. Nearly all HIV-positive persons with tuberculosis die without proper treatment.

Worldwide, tuberculosis is the leading cause of death from infectious disease. There were an estimated 1.4 million tuberculosis deaths in 2015, and an additional 0.4 million deaths resulting from tuberculosis disease among people with HIV.⁴

⁴ World Health Organization Global Tuberculosis Report: 2016. Available at <http://apps.who.int/iris/bitstream/10665/250441/1/9789241565394-eng.pdf?ua=1>

6.0 Occupational TB Risk to California's Health Care Workers

California has one of the highest tuberculosis incidence rates in the US. In 2015, the tuberculosis incidence rate in the U.S. was 3.0 per 100,000, and the tuberculosis incidence rate in California was 5.5 per 100,000. In 2015, the California Department of Public Health recorded 2,133 tuberculosis cases. About five percent of these (92 cases) were among health care workers⁵. The tuberculosis incidence rate for California health care workers is approximately 6.4 per 100,000 based on the estimate of 1,443,000 health care workers that receive annual LTBI testing.⁶

In 2007, the California Department of Public Health, Occupational Health Branch (OHB), evaluated the CDC TB Guidelines risk assessment process, as it would apply to California health care facilities. In recommending continued periodic, preferably annual, surveillance for LTBI, it stated⁷:

1. California's tuberculosis case incidence rate remains among the highest in the nation. The risk of TB transmission in California is high primarily because of its large immigrant and other high-risk populations. Cases are often misdiagnosed at the initial treating facility. This may result in erroneous classification of a health-care setting into a low-risk category, latent exposures of HCWs, and delayed case detection. The risk in HCWs is apparent; 83 (3%) of the state's 2,903 TB cases reported in 2005 were health care workers. (Note that surveillance data do not differentiate whether the infection was acquired occupationally or in the community.)
2. Less frequent testing of HCWs may result in delayed detection of TST and BAMT [blood assay for *M. tuberculosis*] conversions if an exposure didn't trigger a complete contact investigation. Delayed detection of conversions results in lost opportunities for timely and effective therapy to prevent active TB from developing. If less frequent testing results in delays in diagnosis of cases of active disease in health care workers, TB can spread in the facility and community.
3. The majority of health-care facilities in California (60%) have less than 200 beds. The CDC Guidelines require only three TB cases a year for these small facilities to be classified as medium-risk and to result in

⁵ Tuberculosis Control Branch, Report on Tuberculosis in California, 2015. California Department of Public Health, Richmond, CA. September 2016. Available at:

https://www.cdph.ca.gov/programs/tb/Documents/TBCB_Report_2015.pdf

⁶ California Tuberculosis Elimination Advisory Committee. California Tuberculosis Elimination Plan 2016–2020 A Five-Year Action Plan (page 83). July 2016. Available at: <https://www.cdph.ca.gov/programs/tb/Documents/TBCB-TB-Elimination-Plan-2016-2020.pdf>

⁷ California Department of Health Services, Occupational Health Branch. Letter to Tony Paz, MD, President California Tuberculosis Controllers Association. February 28, 2007. See attachment 1.

annual testing requirements (Appendix C). One missed TB case can result in a facility being incorrectly classified into a low-risk category, potentially resulting in exposure and disease among multiple HCWs and patients.

5[sic]. Historical data show that populations served by a health-care facility vary with management changes. Given the frequent management shifts recently observed among California facilities, variations in the patient population may result in rapidly shifting TB risks which may not be reflected in the facility risk classification. Health care workers also may be employed by several facilities, not all of which may be "low risk."

6[sic]. Failure to conduct periodic TB testing in workers at a health-care setting classified as low-risk may give HCWs a false sense that the facility and its workers are not at risk for TB. Since the risk of TB is high throughout most of the state and since the risk may change depending on population and worker migration, HCWs should be aware that they may always be at risk of TB exposure.

Health care workers exposed to persons with TB disease are at risk of TB infection and disease. A recent study found that between 25 and 50 percent of the 320 health care workers in acute care settings in the U.S. who developed active tuberculosis disease in 2013, acquired the infection occupationally. (Since California has approximately 20 percent of all TB cases, this would suggest that 16 to 32 health care workers in California develop TB disease each year due to occupational exposures). The study also estimated that at least 3,288 occupational LTBI's occur in healthcare workers each year in the U.S.⁸ This data is consistent with other studies that have found that health care workers are at increased occupational risk for tuberculosis infections.

7.0 Unrecognized Exposures to Tuberculosis

As stated by the Occupational Health Branch in part 5.0 above, the diagnosis of TB is often missed, resulting in further unrecognized exposures to health care workers according to multiple studies. Summarizing the findings of several studies, Wallace et al, state, "Once a patient is seen by a healthcare provider, it takes an average of 2.6 visits before the diagnosis of TB is made."¹⁰ Another study by Miller et al found that in California, 25.7

⁸ Jones RM, Burden of Occupationally Acquired Pulmonary Tuberculosis among Healthcare Workers in the USA: A Risk Analysis. *Annals of Work Exposures and Health*, 2016, 1–11. Abstract available at: <https://www.ncbi.nlm.nih.gov/pubmed/28395347>

⁹ Baussano I, Nunn P, Williams B et al. (2011) Tuberculosis among health care workers. *Emerg Infect Dis*; 17: 488–94. Abstract available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3298382/>

¹⁰ Wallace RM, Kammerer JS, Iademarco MF et al. Increasing Proportions of Advanced Pulmonary Tuberculosis Reported in the United States. Are Delays in Diagnosis on the Rise? *Am J Respir Crit Care Med* Vol 180. pp 1016–1022, 2009. Available at: <http://www.atsjournals.org/doi/pdf/10.1164/rccm.200901-0059OC>

percent of newly diagnosed tuberculosis patients had prior respiratory related visits to hospitals or emergency departments within the previous 90 days. Further, the potentially missed diagnoses were greater in hospitals which diagnose TB less frequently.¹¹ Miller studied only hospital admissions and emergency department visits. Patients with active tuberculosis may also have been seen by primary care or other community based providers without being diagnosed. When tuberculosis patients are not recognized, risk reduction measures such as employee use of respiratory protection and placement in airborne infection isolation are not utilized, which places employees at additional risk¹².

The petitioner does not explain how a hospital or other employer would know about unrecognized TB cases in order to follow the risk assessment methodology in the CDC TB Guidelines. Current public health tuberculosis contact investigation protocols rely largely on interviews of the patient and important contacts, but do not include searching electronic medical records or databases to identify prior health care providers. Public health contact guidance only considers aerosol-generating procedures to create a high-priority contact.¹³ The problem is further complicated because active tuberculosis cases are reported only to the local health officer for the jurisdiction in which the patient resides, and not all patients seek health care in their county of residence.¹⁴

8.0 Analysis

8.1 Rationale for LTBI Assessment

Title 8 section 5199 includes a number of disease-specific medical services that employers must provide to those employees who have been determined to have occupational exposure. In addition to a tuberculosis assessment, these services include vaccinations and post-exposure follow-up. OSHA has described the purpose of medical screening and surveillance as follows:

The fundamental purpose of screening is early diagnosis and treatment of the individual and thus has a clinical focus. The fundamental purpose of surveillance is to detect and eliminate the underlying causes such as

¹¹ Miller AC, Polgreen LA, Cavanaugh JE et al. Missed Opportunities to Diagnose Tuberculosis Are Common Among Hospitalized Patients and Patients Seen in Emergency Departments. Oxford University Press 2015. Available at: <https://academic.oup.com/ofid/article/doi/10.1093/ofid/ofv171/2460585/Missed-Opportunities-to-Diagnose-Tuberculosis-Are>

¹² Rozovsky-Weinberger J, Parada JP, Phan L et al. Delays in suspicion and isolation among hospitalized persons with pulmonary tuberculosis at public and private U.S. hospitals during 1996 to 1999. Chest 2005; 127:205–12. Abstract available at: <https://www.scholars.northwestern.edu/en/publications/delays-in-suspicion-and-isolation-among-hospitalized-persons-with>

¹³ CDPH/CTCA. Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis. 2011. Available at [http://www.ctca.org/filelibrary/ctcaciguideines117 .pdf](http://www.ctca.org/filelibrary/ctcaciguideines117.pdf)

¹⁴ California Code of Regulations Title 17 section 2500(b)

hazards or exposures of any discovered trends and thus has a prevention focus. Both can contribute significantly to the success of worksite health and safety programs.¹⁵

Assessment for LTBI is intended to detect recent infections. Persons who contract infection are most at risk of progression to active TB within the first two years of infection¹⁶, and there is evidence that early treatment mitigates the risk of developing disease¹⁷. The Occupational Health Branch concluded in the 2007 letter discussed in part 6.0 above that "HCWs are best protected by annual TB screening; this allows for early detection and treatment and results in decreased morbidity and improved prognosis in the event of disease."

Annual tests for LTBI provide the following advantages:

1. Early detection, and the potential for treatment, reduces the likelihood that an infected worker will develop active tuberculosis disease.
2. Detection of employee infections even if the source patient was not recognized as having active tuberculosis during the encounter.
3. Increased ability to distinguish recent conversions. A person's LTBI test may convert to positive as soon as two weeks after infection. A positive LTBI test after a recognized exposure incident will help identify the source of the infection if the exposed employee's most recent annual LTBI test was negative. However, if the most recent LTBI test was several years remote, it is more difficult to determine if the infection is linked to the exposure. Knowing the source of infection may be important in treatment decisions, for example by identifying a source patient who has drug-resistant TB.
4. Detection of unrecognized exposure pathways through detection of unexpected clusters of conversions.
5. Reducing workers' compensation litigation due to increased ability to identify timeframe of infection and source of disease.

8.2 Employees are not mandated to participate in LTBI testing requirements

Section 5199 does not require employees to participate in LTBI testing. The employer is required to train employees regarding the employer's tuberculosis surveillance procedures and may include information regarding individual risk factors for developing tuberculosis disease, as well as the information that immune-compromised individuals may have false

¹⁵ <https://www.osha.gov/SLTC/medicalsurveillance/>

¹⁶ Sia IG and Wieland ML. Current Concepts in the Management of Tuberculosis. *Mayo Clin Proc.* April 2011;86(4):348-361. Abstract available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3068897/>

¹⁷ Kahwati SC et al. Screening for Latent Tuberculosis Infection in Adults: An Evidence Review for the U.S. Preventive Services Task Force. *AHRQ Publication No. 14-05212-EF-1* September 2016. Available at <https://www.uspreventiveservicestaskforce.org/Home/GetFile/1/1519/latenttdraftes/pdf>

negative results. The employer may also include information regarding tuberculosis incidence in the local area as well as the number of tuberculosis cases diagnosed in the facility. Employees may then choose, without disclosing their personal medical information, whether to participate in periodic testing.

The employer is not required to offer testing to individuals who have previously tested positive for LTBI, thus removing a major source of false positive results. Employers must offer symptom screening to employees with previous positive LTBI results.

8.3 Potential Harm from Serial TB Testing /False Positive Results

The petitioner states that there is potential harm in periodic LTBI testing in low-risk populations, because "false positive" tuberculosis conversions may result in unnecessary and potentially harmful tests and treatment. For example, an unnecessary chest X-ray may be ordered, or an employee may be exposed to unnecessary pharmaceutical interventions involving risks such as hepatotoxicity.

Section 5199 does not require any treatment for employees who test positive for LTBI. The regulation requires that employers refer employees with a positive LTBI test to a physician or other licensed health care professional (PLHCP) knowledgeable about tuberculosis for evaluation. The PLHCP determines if an employee is a tuberculosis or suspected tuberculosis case and, with the employee's consent, performs diagnostic tests and informs the employee about appropriate treatment options. Any decision to receive treatment is decided by the employee with the assistance of a PLHCP.

9.0 Conclusion

The CDC TB Guidelines are inconsistent and should not be the sole basis for an amendment of Title 8 section 5199. Reducing LTBI testing may result in reduced safety and health protection for employees. Section 5199 only requires LTBI testing of employees with occupational exposure to aerosol transmissible diseases and does not require testing of all employees in the health care industry.

Cal/OSHA believes that the existing regulation provides sufficient flexibility to employees regarding participation in LTBI testing, maximizes the benefits to employees and the facility of periodic testing, and minimizes any potential negative impacts. Cal/OSHA recommends the petition be denied.