State of California Department of Industrial Relations Division of Occupational Safety and Health Memorandum



Date: August 5, 2021

To:	Christina Shupe, Executive Officer
	Occupational Safety and Health Standards Board

From: Eric Berg, Deputy Chief of Health Division of Occupational Safety and Health

Subject: Evaluation of Petition 590 from Kevin Schwanz, RD; request to change Title 8 section 5199, Aerosol Transmissible Diseases.

On May 18, 2021, the Division of Occupational Safety and Health (Cal/OSHA) received a petition from Kevin Schwanz (petitioner). The petitioner requests amendment of subsection (h)(3)(A) in Title 8 section 5199, Aerosol Transmissible Diseases. The subsection requires covered employers to make tuberculosis (TB) tests and other forms of 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)(A) Requested by the Petitioner

The petitioner requests that the subsection be amended so that it does not require annual testing of health care workers.¹ The petitioner references the 2019 Centers for Disease Control (CDC) TB guidelines which, with respect to health care personnel, recommend "no routine serial TB testing at any interval after baseline in the absence of known exposure or ongoing transmission."² In addition, the petitioner requests that the Standards Board consider prohibiting employers from mandating annual TB testing.³

2.0 Scope of this Document

This document evaluates the petitioner's two requests as stated in the petition. The Cal/OSHA evaluation of a previous, similar petition (Petition 563, 2017) addresses why Cal/OSHA believes the current language in section 5199(h)(3) is protective and should not be changed.⁴

¹ Title 8, section 5199(h)(3) does not require annual TB testing of employees. The petitioner confirmed by email that this misunderstanding is the premise of his petition. The petitioner is mistaken. See sections 3.0 and 8.1 of this document.

² Sosa LE, Njie GJ, Lobato MN, et al. Tuberculosis Screening, Testing, and Treatment of U.S. Health Care Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019. MMWR Morb Mortal Wkly Rep 2019;68:439–443. DOI: <u>http://dx.doi.org/10.15585/mmwr.mm6819a3external icon</u>.

³ Cal/OSHA believes the Standards Board does not have the legal authority to countermand mandated testing requirements in Title 22. See sections 4.0 and 9.2 of this document.

⁴ Petition 563, both Cal/OSHA's and Standards Board staff evaluations, and the Standards Board's decision are available at <u>https://www.dir.ca.gov/oshsb/petition-563.html</u>

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

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§5199. Aerosol Transmissible Diseases.
* * * * *
(h) Medical Services.
* * * * *
(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.

Employees of covered health care facilities,⁵ services, or operations, 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. 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; it states in subsection (h)(3) that the employer "shall make assessment for latent tuberculosis infection (LTBI) available to all employees with occupational exposure."

LTBI testing is needed 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.

4.0 Other Laws and Regulations

A number of California public health laws and regulations also address serial TB infection (LTBI) testing of healthcare workers. The following regulations, which pertain to the licensing and certification of specific healthcare facilities (Title 22, California Code of Regulations), address the issue of serial TB testing of employees:⁶

- <u>Acute Psychiatric Hospitals.</u> Title 22, section 71523 mandates that employees be tested for TB infection initially and at least annually.
- <u>Chemical Dependency Recovery Hospitals</u>. Title 22, section 79331 mandates that employees be tested for TB infection initially and at least annually.
- <u>Correctional Treatment Centers.</u> Title 22, section 79795 mandates that employees be tested for TB infection initially and annually.
- <u>General Acute Care Hospitals.</u> Title 22, section 70723 mandates that employees be tested for TB infection initially and annually. Less frequent testing, but never less than every four years, may be adopted when approved by the Infection Control Committee, the medical staff and the local health officer.

⁵ These are listed in Title 8, section 5199(a)(1)(A)(1 through 9)

⁶ A CDPH Licensing and Certification Program table summarizing these regulations, with links to the regulatory text, can be found at https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/California-TB-Testing-Regulations.aspx#

- <u>Home Health Agencies</u>. Title 22, section 74723 mandates that employees with direct patient contact be tested for TB infection initially and annually. Less frequent testing may be conducted if certified by the local health officer.
- <u>Intermediate Care Facilities.</u> Title 22, section 73525 mandates that employees be tested for TB infection initially and annually.
- <u>Intermediate Care Facilities for the Developmentally Disabled.</u> Title 22, section 76539 mandates that employees be tested for TB infection initially and annually.
- <u>Psychology Clinics.</u> Title 22, section 75335 mandates that employees be tested initially for TB infection. The policy on subsequent TB testing shall be based on a risk assessment.
- <u>Skilled Nursing Facilities.</u> Title 22, section 72535 mandates that employees be tested for TB infection initially and annually.

In all cases, Title 22 mandates TB testing of employees as a condition of facility licensing.

5.0 2019 CDC TB Guidelines for Health Care Personnel

The petitioner references the 2019 CDC publication "Tuberculosis Screening, Testing, and Treatment of U.S. Health Care Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC."⁷

This document supplants the 2005 CDC guidelines⁸ which recommended different TB testing frequencies based on an assessment, and subsequent risk classification (as low-, medium-, or high-risk), of health care settings. Under this 2005 regimen, health care workers in low-risk facilities (no expected exposure to TB) were to receive no serial TB testing; those in medium-risk facilities (at least possible exposure) were to receive annual serial TB testing; and those in high-risk facilities (evidence at least suggestive of transmission in prior year) were to be tested every 8 to 10 weeks until there was no evidence of ongoing transmission.

The 2019 guidelines replace this 2005 regimen with a recommendation of no routine serial testing of health care workers for LTBI in the absence of a known exposure or ongoing transmission.

⁷ Sosa LE, Njie GJ, Lobato MN, et al. Tuberculosis Screening, Testing, and Treatment of U.S. Health Care Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019. MMWR Morb Mortal

⁸ Jensen PA, Lambert LA, lademarco MF, Ridzon R. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care settings, 2005. MMWR Recomm Rep 2005;54(No. RR-17).

5.1 Serial TB testing of health care workers in 2019 CDC Guidelines

The 2019 CDC guidelines recommend baseline TB screening and testing of all health care personnel. In addition, a baseline individual risk assessment is to be conducted. This assessment covers individual indicators of risk for tuberculosis (residency abroad, immunosuppression, close contact with someone with active TB) which are to be employed in "helping guide decisions when interpreting test results."

The guidelines address postexposure TB screening and testing:

After known exposure to a person with potentially infectious TB disease without use of adequate personal protection, health care personnel should have a timely symptom evaluation and additional testing, if indicated. Those without documented evidence of prior LTBI or TB disease should have an IGRA or a TST performed. Health care personnel with documented prior LTBI or TB disease do not need another test for infection after exposure. These persons should have further evaluation if a concern for TB disease exists. Those with an initial negative test should be retested 8–10 weeks after the last exposure, preferably by using the same test type as was used for the prior negative test.

However, with respect to serial TB screening and testing, the CDC guidelines state:

In the absence of known exposure or evidence of ongoing TB transmission, U.S. health care personnel (as identified in the 2005 guidelines) without LTBI should not undergo routine serial TB screening or testing at any interval after baseline (e.g., annually). Health care facilities might consider using serial TB screening of certain groups who might be at increased occupational risk for TB exposure (e.g., pulmonologists or respiratory therapists) or in certain settings if transmission has occurred in the past (e.g., emergency departments). Such determinations should be individualized on the basis of factors that might include the number of patients with infectious pulmonary TB who are examined in these areas, whether delays in initiating airborne isolation occurred, or whether prior annual testing has revealed ongoing transmission. Consultation with the local or state health department is encouraged to assist in making these decisions.

6.0 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, laugh, talk, or sing.

Most persons infected with Mycobacterium tuberculosis do not have symptoms, in which case the infection is known as latent tuberculosis (LTBI). About 10% of latent infections progress to active disease which, 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.

Prior to the Covid-19 pandemic, global tuberculosis was the leading cause of death from infectious disease.⁹ In 2019 there were, worldwide, an estimated 1.2 million tuberculosis deaths among HIV-negative people, and an additional estimated 0.2 million deaths among those with HIV.¹⁰

7.0 Occupational TB Risk to California's Health Care Workers

California accounts for the largest proportion of TB disease cases in the U.S. In 2019, the majority of TB disease cases (51%) were reported from 4 states: California (23.7%), Texas (13.0%), New York (8.5%), and Florida (6.3%).¹¹

Despite its size, California has one of the highest statewide tuberculosis incidence rates of TB disease in the US. In 2019, the annual tuberculosis incidence rate in the U.S. was 2.7 per 100,000. Forty-two states reported incidence rates below the national rate. The annual tuberculosis incidence rate in California was 5.3 per 100,000, more than twice the national rate. This rate is higher than any other state, save Alaska and Hawaii.¹²

Within California, the 2019 annual TB disease incidence rates are highest in many of the most populous counties: Orange County had an annual incidence rate of 5.4 per 100,000; Los Angeles—5.6; Alameda—7.4; San Joaquin—7.6; San Diego—7.9; Santa Clara— 8.4; San Mateo—8.5; San Francisco—11.8; and Imperial—32.1. Together these nine high-incidence counties account for 56% of the state's population.¹³

Conversely, a few counties have recently reported no TB cases. Over the past five years not one TB case has been reported in the following counties: Alpine, Del Norte, Mariposa, Modoc, and Sierra. Together these counties account for 0.14% of California's population.

However, among the nine major U.S. cities with 2019 TB disease incidence rates above the national average, California cities rank among the highest: District of Columbia had an incidence rate of 3.4 per 100,000; Baltimore—4.0; Chicago—4.5; Philadelphia—4.6; Los Angeles—5.7; Houston—6.6; New York City—6.7; San Diego—7.9; and San Francisco—11.9.¹⁴

https://www.who.int/data/stories/the-true-death-toll-of-covid-19-estimating-global-excess-mortality https://covid19.who.int

⁹ COVID-19 caused 1.8 million to 3 million deaths in 2020. The number of COVID-19 deaths in 2021 is expected to exceed the 2020 total.

¹⁰ World Health Organization Global Tuberculosis Report: 2020. Available at <u>https://www.who.int/publications/i/item/9789240013131</u>

¹¹ CDC, Trends in Tuberculosis, 2019. Available at <u>https://www.cdc.gov/tb/publications/factsheets/statistics/tbtrends.htm</u>

¹² 2019 State and City TB Report. Centers for Disease Control and Prevention. Available at <u>https://www.cdc.gov/tb/statistics/indicators/2019/incidence.htm</u>

¹³ California Health and Human Services Open Data Portal, Tuberculosis Case Numbers and Rates, California and Local Health Jurisdictions. Available at <u>https://data.chhs.ca.gov/dataset/tuberculosis-cases-and-rates</u>

¹⁴ Trends in Tuberculosis, 2019. Centers for Disease Control and Prevention. Available at <u>https://www.cdc.gov/tb/publications/factsheets/statistics/tbtrends.htm</u>

In California, statewide TB case counts have been relatively stable over the last 10 years. Since 2009, (the year section 5199 was promulgated) the number of cases statewide has decreased modestly from 2466 cases (2009), to 2115 cases (2019), a 14% decrease. However, statewide case counts have remained essentially unchanged over the last eight years, with 2184 cases being reported in 2012.¹⁵

As noted above, in 2019 the California Department of Public Health recorded 2,115 tuberculosis cases statewide. Approximately 4% (82 new cases) of these were among health care workers.¹⁶ The statewide annual TB disease incidence rate for California health care workers was approximately 5.7 per 100,000 based on the estimate of 1,443,000 health care workers that receive annual LTBI testing.¹⁷ This is higher than the statewide annual incidence rate of 5.3 per 100,000. Note, however, that these case counts and incidence rate estimates do not distinguish between occupationally and non-occupationally-acquired infections among health care workers.

A 2016 risk analysis based on mathematical modeling estimated that between 25 and 50 percent of the approximately 320 U.S. health care workers in acute care settings who developed active tuberculosis disease in 2013, acquired the infection occupationally. (Since California has approximately 20 percent of all TB cases nationally, 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 3288 occupational LTBIs occur in healthcare workers each year in the U.S.¹⁸ Additionally, a 2011 meta-analysis of published studies estimated that 49% of TB infections among U.S. health care workers are occupationally-acquired.¹⁹

8.0 Analysis

8.1 Serial LTBI testing requirements in section 5199

The petitioner requests that Title 8, section 5199 be amended so that it does not require annual testing of healthcare workers. This request is premised on a misunderstanding of what the standard requires. The language in subsection (h)(3)(A) states that the employer must offer TB testing initially, and on an annual basis to employees with occupational exposure.

¹⁵ California Health and Human Services Open Data Portal.

¹⁶ California Tuberculosis Data Tables, 2019. Table 13. Social and Behavioral Characteristics of TB Cases in California, 2015-2019. California Department of Public Health, Richmond, CA. September 2019. Available at <u>https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/TB-Disease-Data.aspx</u>

¹⁷ California Tuberculosis Elimination Advisory Committee. California Tuberculosis Elimination Plan 2016–2020 A Five-Year Action Plan (page 83). July 2016. Available at <u>https://www.cdph.ca.gov/programs/tb/Documents/TBCB-TB-Elimination-Plan-2016-2020.pdf</u>

¹⁸ 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

¹⁹ Baussano I, Nunn P, Williams B et al. (2011) Tuberculosis among health care workers. Emerg Infect Dis; 17: 488–94. Abstract available at <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3298382/</u> (The full text of this article can be requested from Cal/OSHA.)

The meaning of the language in subsection (h)(3)(A) is additionally made clear by the immediately preceding general language in subsection (h)(3): "*The employer shall make assessment for latent tuberculosis infection (LTBI) available to all employees with occupational exposure*." This means that the testing of employees is not mandatory, only that it must be offered-- it must be made available to employees.

Section 5199 does not require any individual employee 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 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 therefore choose, without disclosing their personal medical information, whether to participate in periodic testing. The employer does not have to offer testing to individuals who have previously tested positive for LTBI, thus removing a major source of false positive results.

8.2 Standards Board authority regarding Title 22 requirements

The petitioner additionally requests that the Standards Board consider prohibiting employers from mandating annual TB testing. Mandated annual TB testing of some health care workers is currently required by a number of sections in Title 22 as part of the licensing and certification of healthcare facilities (see section 4.0 of this document). Cal/OSHA believes that the Standards Board does not have the authority to countermand the requirements of Title 22.

9.0 Conclusions

This document evaluates the petitioner's two requests as stated in the May 21, 2021 letter to the Standards Board, and later confirmed to Cal/OSHA by email. The petitioner's first request is premised on a misunderstanding of the language of section 5199(h)(3)(A); the language does not mandate annual TB testing of health care workers, only that the employer make annual TB testing available to employees with occupational exposure. With respect to the petitioner's second request, Cal/OSHA believes that the Standards Board does not have the authority to countermand requirements in Title 22, that do mandate TB testing of certain groups of health care workers as a condition of facility licensing. Cal/OSHA recommends the petition be denied.