State of California
Department of Industrial Relations
Occupational Safety and Health Standards Board

Petition File No. 590

Board Staff Evaluation
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State of California
Gavin Newsom, Governor

INTRODUCTION

Petition No. 590 (Petition) was submitted by Kevin Schwanz, Registered Dietician (Petitioner), and was received by the Occupational Safety and Health Standards Board (Board) on May 4, 2021. The Petition seeks changes to the Aerosol Transmissible Disease (ATD) Standard, title 8 of the California Code of Regulations, section 5199.

REQUESTED ACTION

The Petitioner requests section 5199(h)(3)(A) be amended to remove the requirement for annual tuberculosis (TB) testing in health care workers (HCWs). The Petitioner further requests that proactive measures be taken to restrict employers from mandating employees to complete annual TB testing.

BACKGROUND/HISTORY

TB is a potentially fatal lung disease caused by the bacterium *Mycobacterium tuberculosis.* There are two types of TB infections: latent TB and active TB. People with latent TB infection (LTBI) are not contagious and do not have any illness symptoms. However, if left untreated, approximately 5 to 10 percent of people with LTBIs will eventually develop active TB disease, where the person has symptoms of illness and can spread the disease to others. Untreated active TB can be deadly. The identification and treatment of LTBI is important for preventing latent TB from turning into active TB and for controlling the spread of TB[1].

The present Petition is the second request received by the Board related to changing the frequency of TB testing for workers with occupational exposure required in section 5199. Petition No. 563, received by the Board on January 30, 2017, by Ken Cutler, MD, MPH, President of the California Conference of Local Health Officers, requested section 5199 be amended to require a targeted approach to TB testing in health care settings based on guidelines from the United States Centers for Disease Control and Prevention (CDC) publication, *Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005.* Petition No. 563 was denied in full by the Board, as stated in the Decision dated July 20, 2017[2].

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[1] CDC webpage, Deciding When to Treat Latent TB Infection, accessed on June 29, 2021. https://www.cdc.gov/tb/topic/treatment/decideltbi.htm

[2] Occupational Safety and Health Standards Board Adopted Decision, Petition File No. 563. https://www.dir.ca.gov/oshsb/documents/petition-563-adopteddecision.pdf

PETITIONER'S ASSERTIONS

The Petitioner asserts the following:

- Research has shown that annual TB testing does not help prevent the spread of tuberculosis.
- The majority of positive TB tests found via annual testing have been shown to be false positives, which leads to stress and anxiety, additional and unnecessary testing, and wasted time and resources.
- Annual testing has no known benefit and includes some inherent risk.
- Mandated annual testing is a direct violation of the important principle of informed consent.

DIVISION OF OCCUPATIONAL SAFETY AND HEALTH (DIVISION) REPORT

The Division's Petition Evaluation report dated August 5, 2021, recommends that the Petitioner's request be DENIED for the following reasons:

- The Petitioner's first request to amend the requirement for annual TB testing of HCWs is premised on a misunderstanding of the language of section 5199(h)(3)(A). The language does not mandate annual TB testing of HCWs, only that the employer make annual TB testing available to employees with occupational exposure.
- The Division believes the Board does not have the authority to countermand requirements in title 22 that do mandate TB testing of certain groups of HCWs as a condition of facility licensing.

STAFF EVALUATION

On June 17, 2021, Board staff spoke with the Petitioner to discuss the Petition. The Petitioner shared his concern about potential health effects associated with injection of the test agent typically used for annual TB testing of HCWs. He further stated that no studies have evaluated the long-term effects of annual exposure to the test agent. Given the high incidence of false positive test results associated with annual TB testing of HCWs, the Petitioner felt the potential risk associated with exposure to the test agent was not warranted.

Relevant Standards

Federal Standards

Federal Occupational Safety and Health Administration (OSHA) does not have a specific standard for the prevention of occupational exposure to TB or other aerosol transmissible diseases. OSHA has a Compliance Directive (CPL), CPL 02-02-078[3], Enforcement Procedures and Scheduling for Occupational Exposure to Tuberculosis that was issued in 2015, replacing an earlier instruction for tuberculosis inspections issued in 1996.

The 2015 CPL refers to the 2005 CDC Guidelines[4] for the control of workplace TB exposures. In the OSHA CPL, Compliance Safety and Health Officers are instructed to evaluate whether TB testing has been conducted in accordance with CDC Guidelines. Citations related to TB exposures are issued under the General Duty Clause or other standards, such as the Respiratory Protection Standard or Personal Protective Equipment, as appropriate.

California Title 8 Standards

The ATD standard, section 5199, was adopted in 2009 to reduce the risk of ATD infection, including TB, among California workers. The standard applies to a variety of health care employers as well as other employers with employees at greater risk for exposure to ATDs, such as police and correctional officers, employees at homeless shelters, and employees at drug treatment programs. Subsection (h) of section 5199 requires employers with occupationally exposed employees to provide medical services to employees with potential ATD exposure, including providing appropriate vaccinations to those employees and screening for LTBI.

Section 5199(h) includes the following requirements (emphasis added):

> (*h) Medical Services.*
>
> *(1) Each employer who has any employee with occupational exposure* ***shall provide the employee with medical services for tuberculosis and other ATDs****, and infection with ATPs and ATPs-L,* ***in accordance with applicable public health guidelines, for the type of work setting and disease.*** *When an employer is also acting as the evaluating health care professional, the employer shall advise the employee following an exposure incident that the employee may refuse to consent to vaccination, post-exposure evaluation and*

[3] U.S. Department of Labor, OSHA Compliance Directive, CPL 02-02-078, Enforcement Procedures and Scheduling for Occupational Exposure to Tuberculosis.
https://www.osha.gov/sites/default/files/enforcement/directives/CPL_02-02-078.pdf

[4] Jensen PA, Lambert LA, Iademarco MF, et al. Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Settings. Morbidity and Mortality Weekly Report December 30, 2005/54(RR17); 1-141.
https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm?s_cid=rr5417a1_e

follow-up from the employer-health care professional. When consent is refused, the employer immediately shall make available a confidential vaccination, medical evaluation or follow-up from a PLHCP other than the exposed employee's employer.

(2) Medical services, including vaccinations, tests, examinations, evaluations, determinations, procedures, and medical management and follow-up, shall be:

(A) Performed by or under the supervision of a PLHCP;

(B) Provided according to applicable public health guidelines; and

(C) Provided in a manner that ensures the confidentiality of employees and patients. Test results and other information regarding exposure incidents and TB conversions shall be provided without providing the name of the source individual.

(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.*

(B) The employer shall refer employees who experience a TB conversion to a PLHCP knowledgeable about TB for evaluation.

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EXCEPTION to subsection (h)(3): Research and production laboratories in which M. tuberculosis *containing materials are not reasonably anticipated to be present, need not provide assessment for LTBI infection.*

Other California Standards

Various title 22 standards also require TB screening and/or testing for HCWs[5] as part of health care facility licensing. Under some title 22 standards, all employees working at a facility are included in the TB screening requirements. For other facilities, only employees who have direct or indirect patient contact must complete the screening.

HCWs at most California health care facilities must complete annual TB testing, but some categories of health care facilities are exempt from annual TB testing requirements after the new hire baseline TB test is completed. Additionally, title 22 requirements allow for less frequent TB testing at some health care facilities based on risk assessments for the facility and the recommendation of the Local Health Officer. In response to the updated CDC and National Tuberculosis Controllers Association (NTCA) guidelines issued in 2019, the California Department of Public Health (CDPH) issued an All Facilities Letter[6], outlining a process for health care facilities who wished to submit a TB Program Flexibility request for TB testing of HCWs on a less frequent basis than current title 22 standards require. In a phone conversation on May 17, 2021, Chelsea Driscoll, Chief of the Public Policy and Prevention Division at CDPH, indicated there are plans to integrate the 2019 federal guidance for TB testing with title 22 requirements. There is no projected timeline for changes, though, the TB Program Flexibility request process will be used in the interim.

Other California regulations require pre-employment and/or periodic TB testing for other groups of workers. The California Education Code and Health and Safety Code mandate TB assessments for education and childcare workers[7] and the California Penal Code requires baseline and annual testing for correctional officers[8].

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[5] CDPH, California Tuberculosis (TB) Testing Regulations for Health Care Facilities. Accessed on May 13, 2021. https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/California-TB-Testing-Regulations.aspx

[6] CDPH, All Facilities Letter (AFL 19-28), Updated Centers for Disease Control Tuberculosis Screening Recommendations for Health Care Personnel (HCP) and Nationwide Shortage of Tuberculin Skin Test Antigens, Issued August 16, 2019. https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-19-28.aspx

[7] CDPH and California Tuberculosis Controllers Association (CTCA), California School Employee Tuberculosis (TB) Risk Assessment Questionnaire, User Guide, Certificate of Completion and Frequently Asked Questions. https://ctca.org/wp-content/uploads/TBCB-CA-School-Staff-Volunteer-TB-Risk-Assessment_updated-May-20203.pdf

[8] California Penal Code, sections 6006 - 6009. Accessed on May 13, 2021. https://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=PEN&division=&title=7.&part=3.&chapter=4.5.&article

Consensus Standards

The Petitioner is correct that in May 2019, the CDC and the NTCA issued updated recommendations[9] for TB screening, testing and treatment of health care personnel (HCP). The joint CDC/NTCA guidelines replace the term HCWs with HCP, which refers to all paid and unpaid, temporary, contract, student, part-time or full-time persons working in a health care setting. The updated guidelines were created by a work group comprised of representatives from the CDC, the NTCA, state and local health departments, academia and occupational health associations that met regularly over a two-year period to review and discuss literature related to the screening and testing of HCP.

The updated CDC guidelines for HCP recommend:

- Baseline TB screening and testing, including an individual risk assessment for HCP upon hiring.
- TB screening and testing for HCP after a known exposure to a person with potentially infectious TB disease without the use of personal protection.
- No routine screening or serial testing of HCP without LTBI at any interval after baseline in the absence of a known exposure or evidence of ongoing transmission.
- Annual symptom screening of HCP with LTBI. Repeat chest x-rays for persons with LTBI are not necessary unless they are symptomatic.
- Encouragement of HCP with LTBI to receive treatment.
- Annual TB education for all HCP.

Their recommendations related to serial (periodic) screening and testing for HCP without LTBI are as follows:

> *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*

[9] CDC, Tuberculosis Screening, Testing, and Treatment of U.S. Health Care Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019, Morbidity and Mortality Weekly Report / May 17, 2019 / 68(19);439-443. https://www.cdc.gov/mmwr/volumes/68/wr/mm6819a3.htm?s_cid=mm6819a3_w

> *whether prior annual testing has revealed ongoing transmission. Consultation with the local or state health department is encouraged to assist in making these decisions.*

The CDC/NTCA guidelines also state that recent data suggest HCP are no longer at increased risk for LTBI and TB disease from occupational exposures as they were in the past. Per the guidelines, "surveillance data reported to CDC during 1995-2007 revealed that TB incidence rates among health care personnel were similar to those in the general population, raising questions about the cost-effectiveness of routine serial occupational testing."

Staff Analysis

According to the CDPH produced *Report on Tuberculosis in California, 2019*[10], California's annual TB incidence rate in 2019 was 5.3 cases per 100,000 persons, which is nearly double the national incidence rate of 2.7. Location, though, plays an important role in the risk of TB transmission in California. Twenty counties in California accounted for 95% of the TB cases reported in 2019[11]. The report indicated that 20 California counties did not report any TB cases in 2019. Several rural counties in northern California and in the eastern Sierra region of the state have not had any cases over the past several years.

While HCWs in the U.S. were shown to be at higher risk for TB during the 1980s and 1990s, more recent studies have shown that annual TB conversion rates for U.S. HCWs have greatly decreased and TB incidence rates among HCWs are below the national average for the public[12]. Other studies have shown the risk of TB conversion among HCWs in the U.S. is more often associated with non-occupational exposures[13; 14]. In a phone conversation on May 10, 2021, with Judith Thigpen, Executive Director for the California Tuberculosis Controllers Association (CTCA), Ms. Thigpen shared that in California HCWs, as a group, are not at higher risk for TB

[10] CDPH, Report of Tuberculosis in California, 2019. https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/TBCB_Report_2019.pdf

[11] California Health and Human Services, Open Data Portal, Tuberculosis Case Numbers and Rates, California and Local Health Jurisdictions, accessed on May 13, 2021. https://data.chhs.ca.gov/dataset/tuberculosis-cases-and-rates

[12] American College of Occupational and Environmental Medicine (ACOEM) Guidance Statement, Tuberculosis Screening, Testing, and Treatment of US Health Care Personnel. Journal of Occupational and Environmental Medicine, Volume 62, Number 7, July 2020. https://acoem.org/acoem/media/PDF-Library/Publications/Tuberculosis_Screening,_Testing,_and_Treatment.pdf

[13] Dobler CC, Farah WH, Asawas M, et al. Tuberculin Skin Test Conversions and Occupational Exposure Risk in U.S. Healthcare Workers. Clinical Infectious Diseases, Volume 66, Issue 5, 1 March 2018, Pages 706-711. https://academic.oup.com/cid/article/66/5/706/4344917

[14] Larsen NM, Biddle CL, Sotir MJ, et al. Risk of Tuberculin Skin Test Conversion among Health Care Workers: Occupational versus Community Exposure and Infection. Clinical Infectious Diseases, Volume 35, Issue 7, 1 October 2002, Pages 796-801. https://academic.oup.com/cid/article/35/7/796/306109

compared to other occupations. Individual HCWs, though, may have a greater risk for TB depending on work tasks performed and patient populations.

In the Division's Petition Evaluation Report there is a reference to a 2011 meta-analysis[15] of published studies that estimated that 49 percent of TB infections among U.S. HCWs are occupationally acquired. This study, though, was not specific to HCWs in the U.S. It looked at TB incidence data among HCWs worldwide and calculated a percentage of TB cases that were likely caused by workplace exposures for low, intermediate and high-incidence countries. The study's authors estimated that 49 percent of TB cases in low-incidence countries were due to occupational exposures, based on the rate of TB infections in HCWs versus the general population for the study area. Low incidence countries were defined in the study as having an incidence rate of less than 50 TB cases per 100,000 persons, which includes countries with much higher TB incidence rates than the U.S. rate of less than 3 cases per 100,000 people. Countries that would be included in the low-incidence category, include most South American countries[16] and Mexico, where workplace protections for HCWs may not be as stringent as in the U.S[17]. Thus, that estimate for the percentage of TB cases occupationally acquired among HCWs may not be very accurate for U.S. HCWs.

Section 5199(h)(3) requires assessments for LTBI be made available to all employees with occupational exposure. "Occupational exposure" is defined as exposure from work activity or working conditions that is reasonably anticipated to create an elevated risk of contracting a disease caused by aerosol transmissible pathogens if protective measures are not in place. The term "elevated" is further defined to mean 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 the scope and application of section 5199.

As part of the definition of occupational exposure in section 5199, occupational exposure is presumed to exist to some extent in each of the facilities covered by the standard, including health care facilities. Each employer is required to assess whether the work activities, tasks, and environment of individual employees create occupational exposure. HCWs who have contact with patients who may have ATDs covered under the standard are generally considered occupationally exposed. The definition of occupational exposure references risk from ATDs, which includes pathogens that cause other illnesses besides TB. HCWs may be at higher risk for some ATDs, like COVID-19, while having a low risk for exposure to TB. These HCWs would be

[15] Baussano I, Nunn P, Williams B et al. Tuberculosis among health care workers. Emerg Infect Dis. 2011; 17/(3): 488–94. https://wwwnc.cdc.gov/eid/article/17/3/10-0947_article
[16] The World Bank. Incidence of Tuberculosis (per 100,000 People), accessed on August 10, 2021. https://data.worldbank.org/indicator/SH.TBS.INCD
[17] International Labour Organization. Statistics on Safety and Health at Work, accessed on August 10, 2021. https://ilostat.ilo.org/topics/safety-and-health-at-work/

considered to have occupational exposure per the definition in the standard and be covered under the LTBI testing requirements.

Since the definition of occupational exposure includes references to risk if protective measures are not in place, the use of protective measures for controlling ATDs at a facility, such as patient screening or employee training, would imply occupational exposure, even if those protective measures are effective at reducing the risk of ATD transmission.

Subsection 5199(h)(1) requires that employers provide employees with medical services for tuberculosis and other ATDs, in accordance with applicable public health guidelines, for the type of work setting and disease. This allows employers to make determinations on the type of medical services provided to employees based on their risk of transmission to TB and ATDs associated with their work tasks performed. Subsection 5199(h)(3), though, does not include the flexibility to determine which employees must be included in annual TB screening based on their specific risk for transmission. Based on the current wording in section 5199(h)(3), all employees with occupational exposure, as defined in the standard, must be offered the testing. The fact that research and production laboratories in which *M. tuberculosis* containing materials are not reasonably anticipated to be present are the only occupational group specifically called out as being excluded from the LTBI testing requirements suggests that employers are not able to make judgement calls as to which employees must be included in LTBI testing programs based on their risk of exposure to TB.

Section 5199 does not include a requirement that employees who are diagnosed with LTBI be offered treatment for LTBI. Instead, employers must refer employees who experience a TB conversion (a change from a negative to positive test result) to a physician or licensed health care professional (PLHCP) knowledgeable about TB for evaluation.

Section 5199 also does not mandate that employees participate in LTBI testing provided by the employer. In the same subsection of section 5199 that requires testing for LTBI to be provided annually, there is a requirement for covered employers to offer recommended vaccinations to employees. The standard specifies that employees must be advised that they can refuse the vaccinations, and employers must document an employee's vaccination refusal on a declination form. No requirement to inform employees about the ability to refuse the LTBI screening or the use of a declination form is required for annual LTBI testing, which may further the belief among health care employers and employees that participation in LTBI testing is required under section 5199.

Title 22 regulations for TB testing among HCWs, though, ***do*** mandate participation by employees for facility licensing. Employees (and their employers) may not recognize they have a choice when it comes to TB testing per section 5199 under some circumstances when it is not required by title 22.

Because title 22 regulations also require TB testing for HCWs, having significantly different requirements for TB testing under title 8 and title 22 is likely to create confusion in the health care industry and pose challenges for the administration of testing programs. Title 22 requirements allow for flexibility in the frequency of the testing based on the risk for TB exposure. There is no option in section 5199 to adjust the frequency for the provision of TB testing for HCWs based on risk for TB exposure once a HCW is deemed to have occupational exposure. Health care facilities that are allowed a reduced testing schedule for staff under title 22 and the CDC/NTCA guidelines, must still provide annual TB testing per section 5199. Employees at some health care facilities, such as general acute care hospitals, could be required to participate in TB testing every four years per title 22 requirements, but be allowed to decline participation the other three years where it is not required by title 22, but is still required to be offered by title 8.

The identification of LTBI is typically done through either a skin or blood test[18]. Testing is normally conducted upon hiring (baseline test) and on a serial basis thereafter, typically annually. Employees who test positive during baseline testing or during any serial test are presumed to have LTBI and will typically receive a chest x-ray to ensure the employee does not have active TB. Once active TB is ruled out, treatment for LTBI is usually recommended. Once an employee has a documented positive TB test, they are typically not included in further annual TB tests, since all future TB tests are expected to be positive, even after treatment for TB. Instead, employees would participate in an annual symptom screen and/or a chest x-ray to check for active TB.

None of the currently available TB tests directly measure infection with TB. Instead, they rely on surrogates for TB infection, measuring a cellular immune response to M. tuberculosis proteins or antigens[19]. There are different criteria for interpreting TB test results based on patient-specific risk factors, so a similar immune response in a test could produce a different diagnosis or test result for different persons[20]. Because these are indirect tests for TB, they can be affected by variability related to the person being tested, techniques used by the person administering a test or reading a test, and laboratory handling and analysis. The Public Health Agency of Canada points out in their Canadian Tuberculosis Standards publication that studies suggest both the blood and skin are “acceptable, but imperfect, tests for LTBI.”

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[18] CDC, TB Screening and Testing of Health Care Personnel, updated March 8, 2021, accessed on May 13, 2021. https://www.cdc.gov/tb/topic/testing/healthcareworkers.htm

[19] Pai M, Denkinger CM, Kik SV, et al. Gamma Interferon Release Assays for Detection of Mycobacterium tuberculosis Infection. ASM Journals, Clinical Microbiology Reviews. 18 December 2020, Volume 27, No. 1. https://journals.asm.org/doi/10.1128/CMR.00034-13

[20] Canadian Tuberculosis Standard, 7th edition, Chapter 4: Diagnosis of Latent Tuberculosis Infection. https://www.phac-aspc.gc.ca/tbpc-latb/pubs/tb-canada-7/assets/pdf/tb-standards-tb-normes-ch4-eng.pdf

False-positives are common with both the TB skin[21; 22; 23]and blood tests[24; 25; 26] particularly in HCWs in the absence of a known exposure to TB. Several studies have shown high variability of test results from serial testing of health care workers with low risk for TB such that it is difficult to tell when a true conversion indicating LTBI has occurred. This complicates decisions related to treatment for LTBI after a positive test result. Following is a summary of causes and studies related to false-positive test results arising from annual testing of HCWs.

- False-positives can result from the TB skin tests due to non-tuberculous mycobacterial infections[27] and to previous vaccination from the bacille Calmette-Guerin (BCG) vaccine[28], which is common in other countries where TB incidence is higher.

- In some circumstances with TB skin testing, a health care worker who was previously infected with TB many years ago, can initially test negative during the baseline test, because their immune system has "forgotten" how to respond to the TB protein used during the test. The exposure to the test agent during baseline testing can cause the body to "remember" how to respond with a delayed effect, producing a positive test result in subsequent testing that may be interpreted as a new TB infection. This phenomenon is called "boosting" and a two-step baseline test process, where two separate skin tests are performed a few weeks apart, is often used to account for this

[21] Canadian Tuberculosis Standard, Chapter 4: Diagnosis of Latent Tuberculosis Infection.
[22] Collins JM, Hunter M, Gordon W, et al. False-Positive Tuberculin Skin Test Results Among Low-Risk Healthcare Workers Following Implementation of Fifty-Dose Vials of Purified Protein Derivative. Infection Control Hospital Epidemiology. June 2018, 39(6), 750-752. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6393163/
[23] Farah WH, Breeher LE, Newcomb RD, et al. Late boosting phenomenon in TST conversion among health care workers. Occupational Medicine, Volume 67, Issue 6, August 2017, Pages 484-489. https://academic.oup.com/occmed/article/67/6/484/4037195
[24] Pai M, Elwood K. Interferon-Gamma Release Assays for Screening of Health Care Workers in Low Tuberculosis Incidence Settings: Dynamic Patterns and Interpretational Challenges. Canadian Respiratory Journal, Volume 19, No. 2, 2012 Mar-Apr, 81-83. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3373289/pdf/crj19081.pdf
[25] Zwerling A, Benedetti A, Cojocariu M, et al. Repeat IGRA Testing in Canadian Health Workers: Conversions or Unexplained Variability? PLoS One, published January 31, 2013, 8(1): e54748. https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0054748
[26] Mazurek GH, Jereb J, Vernon A, LoBue P, Goldberg S, Castro K. Updated Guidelines for Using Interferon Gamma Release Assays to Detect Mycobacterium Tuberculosis Infection – United States, 2010. CDC, Morbidity and Mortality Weekly Report, June 25, 2010 / 59; 1-25. https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5905a1.htm
[27] Von Reyn CF, Horsburgh CR, Olivier KN, et al. Skin Test Reactions to Mycobacterium Tuberculosis Purified Protein Derivative and Mycobacterium Avium Sensitin Among Health Care Workers and Medical Students in the United States. The International Journal of Tuberculosis and Lung Disease, Volume 5, Number 12, December 2001, pp. 1122-1128. https://www.ingentaconnect.com/content/iuatld/ijtld/2001/00000005/00000012/art00008#
[28] Canadian Tuberculosis Standard, Chapter 4: Diagnosis of Latent Tuberculosis Infection.

issue. Boosting can sometimes occur within two years of the baseline, which can further complicate the interpretation of a positive test result during that time period[29; 30].

- One study[31] that evaluated annual testing of emergency responders in Contra Costa County with one of the approved TB blood tests found that 27 percent of evaluated employees had at least one false-positive TB test over a seven-year period. This study also found that 71 of 72 emergency responders who tested positive for LTBI during their first TB blood test, eventually tested negative for LTBI within three years, suggesting false-positives during that initial test.
- Another study[32] evaluating TB testing among 2,418 U.S. health care workers conducted between February 2008 and March 2011 found that among TB test conversions, approximately 75 percent were negative when retested six months later without treatment, suggesting the previous positive results were false-positives. This study also found significant short-term and long-term variability in the TB test results.
- A research article in BMC Medicine[33] on TB testing in health care workers states "false-positive test conversions become more frequent than true-positives as the risk of true infection falls, regardless of the specific test used."
- The American College of Occupational and Environmental Medicine issued a guidance statement[34] related to TB screening, testing, and treatment of U.S. HCWs in the Journal of Environmental Medicine. It stated the following regarding the incidence of false-positives among HCWs without known exposure to TB: "Mathematically, when highly specific tests for low-prevalence diseases are used in large populations that are at low-risk for the disease, false-positive rates rise due to mathematical principles of positive and negative predictive values."

The primary risk associated with routine serial testing of low-risk HCWs is that false-positive test results could lead to HCWs undergoing unnecessary treatment for LTBI, which may involve

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[29] Dobler CC, Farah WH, Asawas M, et al. Tuberculin Skin Test Conversions and Occupational Exposure Risk in US Healthcare Workers. Clinical Infectious Diseases, Volume 66, Issue 5, 1 March 2018, Pages 706-711. https://academic.oup.com/cid/article/66/5/706/4344917

[30] Farah, WH, et al. Late boosting phenomenon in TST conversion among health care workers.

[31] Gamsky TE, Lun T, Hung-Fan M, and Green JA. Cumulative False-Positive QuantiFERON-TB Interferon-γ Release Assay Results. Annals of the American Thoracic Society, Volume 13, Issue 5. https://www.atsjournals.org/doi/10.1513/AnnalsATS.201508-532OC

[32] Dorman SE, Belknap R, Graviss EA, et al. Interferon-γ Release Assays and Tuberculin Skin Testing for Diagnosis of Latent Tuberculosis Infection in Healthcare Workers in the United States, American Journal of Respiratory Critical Care Medicine, Volume 189, Issue 1. https://www.atsjournals.org/doi/full/10.1164/rccm.201302-0365OC

[33] Mullie GA, Schwartzman K, Zwerling A, and N'Diaye D. Revisiting annual screening for latent tuberculosis infection in healthcare workers: a cost-effectiveness analysis, BMC Medicine, Article number: 104 (2017). https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-017-0865-x

[34] ACOEM Guidance Statement, Tuberculosis Screening, Testing, and Treatment of US Health Care Personnel.

side effects, including liver damage (i.e. hepatoxicity), associated with treatment medications. Newer three-month treatment regimens for LTBI have lower risks for hepatoxicity and adverse effects than the earlier nine and 12-month treatment regimens[35]. Initial and periodic blood tests and medical evaluations are still needed to check for adverse effects from the medications[36]. Additionally, there is a possibility that a false-positive test result from an annual TB test will be used to declare a person has LTBI and the presumption of future immunity to TB, which could delay diagnosis and treatment of true LTBI that occurs from a later exposure[37; 38].

There is little risk associated with the TB tests themselves, except for a low risk associated with allergic reactions, including anaphylaxis and skin blistering, to the test agent used with the TB skin test. The manufacturer for TUBERSOL[39], the test agent commonly used for TB skin tests, states that TUBERSOL has not been evaluated for its carcinogenic or mutagenic potentials or impairment of fertility. The lack of data on health effects from long-term annual exposure to TUBERSOL was a concern stated by the Petitioner in a phone call with Board staff on June 17, 2021. The TB blood test withdraws a small amount of blood, which is mixed with test agents at a lab, so there are no risks to the employee other than standard puncture associated risks for a blood draw.

Board staff consulted infection control officers with three large health care providers in California regarding their TB testing and treatment procedures. From these conversations, Board staff learned some health care providers performed a second confirmatory TB test after a TB conversion with a TB skin test or a second confirmatory blood test if that was the test method used initially. Then the employee was typically offered treatment for LTBI. At one health care facility, after ruling out active TB, the employee was typically provided copies of the test results and was referred to their personal physician for further testing, evaluation or treatment, due to assumptions that the conversion was from non-occupational exposure in the absence of a known case of TB treated at the facility. It is not known how many smaller health care employers provide or recommend a second TB test to confirm a positive test result in an employee before recommending treatment for LTBI. While the CDC recommends a second confirmatory TB test after a new conversion in low-risk HCWs[40], one study's results did not

[35] Sterling TR, Moro RN, Borisov A, et al. for the Tuberculosis Trials Consortium. Flu-like and Other Systemic Drug Reactions Among Persons Receiving Weekly Rifapentine Plus Isoniazid or Daily Isoniazid for Treatment of Latent Tuberculosis Infection in the PREVENT Tuberculosis Study, Clinical Infectious Diseases, Volume 61, Issue 4, August 15, 2015, Pages 527-535. https://academic.oup.com/cid/article/61/4/527/329374

[36] Borisov AS, Morris SB, Njie GJ, et al. Update on Recommendations for Use of Once-Weekly Isoniazid-Rifapentine Regimen to Treat Latent *Mycobacterium tuberculosis* Infection, Morbidity and Mortality Weekly Report, June 29, 2018 / 67(25), 723-726. https://www.cdc.gov/mmwr/volumes/67/wr/mm6725a5.htm?s_cid=mm6725a5_w

[37] Gamsky TE, et al. Cumulative False-Positive QuantiFERON-TB Interferon-γ Release Assay Results.

[38] Mullie GA, et al. Revisiting annual screening for latent tuberculosis infection in healthcare workers.

[39] TUBERSOL Package insert accessed on June 17, 2021. https://www.fda.gov/media/74866/download

[40] Mazurek GH, et al. Updated Guidelines for Using Interferon Gamma Release Assays.

support this recommendation[41] "because 90% of the individuals with two successive positive QuantiFERON-TB (TB blood test) results had a negative test result with 3 years or additional testing."

Arguments for Updating TB Testing Requirements in Section 5199

The challenges with interpreting positive TB test results during serial testing of health care workers has lead several researchers and public health organizations[42; 43; 44; 45; 46] to recommend that serial TB testing no longer be conducted in low-risk health care workers or to recommend this practice be reconsidered. This was also referenced in the CDC/NTCA guidance as a rationale behind the updated recommendations. Annual TB testing in all health care workers, regardless of their risk of TB exposure, can cause health care employers to obtain data on which it can be hard to make reliable treatment decisions for the prevention of TB.

Current guidelines from the American Thoracic Society/Infectious Diseases Society of America/CDC[47] recommend that testing for LTBI among individuals at low risk for TB not be performed because the potential risks associated with LTBI treatment medications may outweigh the potential benefit. In the BMC Medicine published study,[48] the authors found that "on a group level, unnecessary LTBI treatment produces small decrements in quality-adjusted survival that outweigh small gains from active TB cases averted in a much smaller number of workers." The BMC Medicine study further found that annual TB screening of HCWs was associated with a small decrease in quality-adjusted survival compared to screening methods where HCWs were tested based on target risk classifications or after a suspected exposure to TB.

The American College of Occupational and Environmental Medicine (ACOEM) issued a guidance statement[49] in the Journal of Environmental Medicine in July 2020 indicating their full support of the CDC/NTCA recommendations for TB screening, testing and treatment of HCP. The

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[41] Gamsky TE, et al. Cumulative False-Positive QuantiFERON-TB Interferon-γ Release Assay Results.
[42] Pai M, et al. Interferon-gamma release assays for screening of health care workers.
[43] Dobler CC, et al. Tuberculin Skin Test Conversions and Occupational Exposure Risk.
[44] Gamsky TE, et al. Cumulative False-Positive QuantiFERON-TB Interferon-γ Release Assay Results.
[45] Dorman SE, et al. Interferon-γ Release Assays and Tuberculin Skin Testing.
[46] Joshi M, Monson TP, Joshi A, and Woods G. IFN-γ Release Assay Conversions and Reversions. Challenges with Serial Testing in U.S. Health Care Workers, Annals of the American Thoracic Society, Volume 11, Issue 3.. https://www.atsjournals.org/doi/full/10.1513/AnnalsATS.201310-378OC
[47] Infectious Diseases Society of America, Official American Thoracic Society/Infectious Diseases Society of America/Centers for Disease Control and Prevention Clinical Practice Guidelines: Diagnosis of Tuberculosis in Adults and Children, Clinical Infectious Diseases, Volume 64, Issue 2, 15 January 2017, Pages e1-e33. https://www.idsociety.org/practice-guideline/diagnosis-of-tb-in-adults-and-children/
[48] Mullie GA, et al. Revisiting annual screening for latent tuberculosis infection in healthcare workers.
[49] ACOEM Guidance Statement, Tuberculosis Screening, Testing, and Treatment of US Health Care Personnel.

ACOEM "endorse the discontinuation of routine annual tuberculosis (TB) testing in health care personnel and the increased emphasis on the role of occupational health in encouraging treatment of persons with latent tuberculosis infection (LTBI) to prevent progression to active disease (reactivation) and to positively impact the public's health."

Annual TB testing of health care workers also creates a significant cost and time expense for health care employers, and can take time away from other infection prevention activities, such as contact tracing. One research study[50] that focused on the cost effectiveness of different TB testing strategies found that annual TB testing of HCWs is poorly cost-effective and was less effective at preventing TB cases than targeted screening or post-exposure only testing. The study found that "for workers with negative baseline tests, the annual screening strategy was estimated to prevent less than one active TB case per 5,000 workers screened over 20 years, compared to the targeted strategy where only workers at the highest risk undergo annual screening."

The CTCA issued a notification on March 22, 2021[51], that stated the "CTCA supports California moving into alignment with these national recommendations because testing for TB is not protective. Treating those with a risk for TB and a positive TB test is protective." In the May 10, 2021 phone conversation with Board staff, Judith Thigpen indicated the CTCA is supportive of an advisory committee being convened to discuss potential updates to section 5199 to reflect recent updates to CDC/NTCA guidelines on TB testing for health care workers.

On May 10, 2021, Board staff had a phone conversation with medical staff at the CDPH Tuberculosis Control Branch (TCB) including Dr. Jennifer Flood, Dr. Chris Keh, and Dr. Pennan Barry. During this call, Dr. Flood indicated the CDPH TCB believes there is merit to reduced frequency of TB testing after a negative baseline test for low-risk HCWs, and they are supportive of an advisory committee being convened to discuss potential changes to section 5199 to reflect recent changes in CDC/NTCA guidelines.

Additionally, the California Tuberculosis Elimination Plan 2016-2020[52], produced by the California Tuberculosis Elimination Advisory Committee, includes a recommendation to reduce TB testing in low-risk populations, including an action step to "bring Cal/OSHA annual screening

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[50] Mullie GA, et al. Revisiting annual screening for latent tuberculosis infection in healthcare workers.
[51] CTCA, Considerations for Timing of Tuberculosis (TB) Testing and COVID-19 Vaccination California Department of Public Health (CDPH) Notification: March 22, 2021, accessed on May 13, 2021. https://ctca.org/guidelines/healthcarepersonnel/
[52] California Tuberculosis Elimination Advisory Committee, California Tuberculosis Elimination Plan 2016-2020, A Five-Year Action Plan, July 2016. https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/TBCB-TB-Elimination-Plan-2016-2020.pdf

regulations for health care workers into alignment with federal guidance on preventing TB transmission in health care facilities."

In Board staff conversations with infection control officers of three large health care providers, staff found all providers would like for Cal/OSHA TB testing requirements to align more with title 22 testing requirements. One health care provider had submitted CDPH title 22 flexibility requests for most of their facilities and was not aware they still had to offer annual TB testing to employees per section 5199. The other two providers had not submitted flexibility requests due to the Cal/OSHA requirement to provide annual TB testing for employees, which would essentially negate the purpose of requesting flexibility from CDPH.

Arguments Against Changing the TB Testing Requirements in Section 5199

Board staff consulted with representatives from several labor organizations that represent health care workers about potential amendments to the TB testing requirements in section 5199, including Saskia Kim, Lead Regulatory Policy Specialist with the California Nurses Association; Katherine Hughes, registered nurse and Executive Director for the SEIU Nurse Alliance of California; Matt Lege, Government Relations Advocate with SEIU California State Council; and Denise Tugade, Government Relations Advocate for SEIU-United Healthcare Workers. These organizations oppose any changes to the TB testing requirements for the following reasons:

- The TB rate in California is twice as high as the national average and research has shown that TB patients experience multiple health care visits prior to receiving a TB diagnosis, meaning that HCWs may be exposed to TB during those visits.
- Relying on historical cases of TB in a county is not reliable because people travel throughout the state, so there could be risk in any county.
- Annual TB testing for occupationally exposed HCWs is important to ensure prompt investigations and access to workers compensation.
- Relying on post-exposure TB testing is not reliable because health care employers are not always compliant about telling HCWs who might have been exposed to a TB case about that exposure. Often nurses do not find out about a positive TB test until after the patient has been discharged, which can make contact tracing for the exposed HCW difficult.
- Compliance with some sections of section 5199, such as post-exposure evaluations and employee training, has not been fully or well implemented by many health care employers.

- It can be challenging to determine exposure risk for all HCWs, particularly for workers who are not providing direct patient care, but may still have exposure risks. In addition to job title and description, risk factors at the geographic and facility level must also be considered.
- The increase in cases of drug-resistant TB also makes identification and treatment of LTBI critical.

Board staff asserts that drug-resistant TB is a significant concern in the fight against TB in California, and the use of proper contact tracing, exposure assessments, and testing for HCWs after a suspected exposure to a drug-resistant TB strain is important since the recommended treatment for LTBI is typically different when a drug-resistant strain is suspected. Relying only on annual testing of HCWs to detect exposures could cause exposure to drug-resistant forms of TB to be missed.

Summary

Section 5199 covers a range of employers with different levels of risk for exposure to TB, including HCWs whose risk for contracting TB depends on individual job tasks performed and the level of TB transmission at their facility. Many groups of HCWs may have occupational exposure to ATDs as defined by section 5199, but are at low-risk for work-related TB transmission. The purpose of performing TB testing is to identify persons with LTBI so they can receive treatment before they develop active TB.

The high incidence of false-positive tests among low-risk HCWs can produce data upon which it is difficult to make treatment decisions. For this reason, annual TB testing is not recommended for persons with low-risk for TB exposure, but under section 5199 it is still required to be offered to employees if there is any occupational exposure to ATDs. Given the CDC's new emphasis on encouraging all HCWs with LTBI to receive treatment, the potential false-positives that are likely to arise during annual testing of HCWs may cause more HCWs to undergo an unnecessary multi-month treatment regimen for TB, which can involve some adverse side effects, including liver damage. In addition, the uncertainty about the accuracy of a positive test result could lead to stress on affected HCWs and medical personnel charged with making treatment decisions based on the results of annual TB testing in HCWs at low-risk for TB exposure.

While section 5199 does not mandate that employees participate in annual TB testing, it is possible that employees and their employers may not be aware of this distinction in the title 8 standard since the option to decline TB testing is not specifically mentioned as it is for the voluntary participation in vaccinations. Some infection control officers at the large health care providers that Board staff consulted were not aware of this distinction. The fact that this is the second petition the Board has received from unrelated parties on this issue in the past four years further suggests confusion on this issue. Additionally, since employee participation is mandatory in many instances under title 22 health care licensing requirements, it would likely be challenging to administer a TB testing program for HCWs that differs significantly from what is required for health care licensing. Employees at health care facilities would be required to participate in TB testing some years per title 22 requirements, but be allowed to decline testing other years where it is required to be offered by section 5199, but not mandated by title 22.

One option that is available to employers to address potential differences between CDPH requirements for TB testing and Cal/OSHA requirements is the permanent variance process. When employers have received approval for TB testing flexibility from CDPH, they could apply for a permanent variance from the TB testing requirements in section 5199 from the Board. The Board can consider granting variances on a case by case basis and could include conditions for testing frequencies that align with the CDPH approved testing schedule and a resumption of annual testing if or when the CDPH flexibility approval is changed.

Board staff believes there is merit to further discussion on updating section 5199 to allow flexibility in the frequency of TB testing among health care workers where appropriate, given public health guidelines. There are valid points both for and against annual TB testing for HCWs that would best be discussed in a forum, such as an advisory committee, comprised of subject matter experts and representatives from the health care industry and labor.

As an interim measure or in lieu of convening an advisory committee, some points of confusion and inflexibility in the standard could be resolved through simple word changes, such as amending section 5199(h)(3) to have assessment for LTBI infection be made "available to all employees with occupational exposure to TB," and changing section 5199(h)(3)(A) to read "TB tests or ~~and~~ other forms of TB assessment shall be provided annually..." This could allow for an annual risk assessment to be conducted to identify individual and facility risk factors that might warrant testing, such as patients with TB treated at health care facility. An annual TB risk assessment, similar to what has been recently implemented for use by teachers and day care providers in California,[53] could allow employers to target testing to those HCWs with identified risk factors.

[53] CDPH and CTCA, California School Employee Tuberculosis (TB) Risk Assessment Questionnaire.

Updates to section 5199 to prohibit employers from requiring employees to participate in annual TB testing, as the Petitioner has asked the Board to consider, are likely not within the authority of the Board because annual TB testing is mandated for some categories of workers by title 22 statutes. Annual TB testing is also still recommended for higher risk groups of occupationally exposed workers and for some groups of HCWs in higher risk settings.

Board staff has not found any factual basis regarding the Petitioner's assertion that mandated annual TB testing is a direct violation of the principle of informed consent. In the context of health care, informed consent is the concept of obtaining a patient's permission prior to initiating medical testing or treatment after informing the patient of the potential risks and benefits of the medical intervention. Section 5199 requires that HCWs with occupational exposure to ATDs receive annual training on the hazards of ATDs and the employer's TB surveillance procedures. Except in some cases of testing for drug-resistant TB where treatment is not available, the World Health Organization had stated[54] that TB testing and screening does not generally require a specific informed consent process. A study on TB laws and policies[55] completed for the CDC, also provides a summary of case law and precedence that affirms the government's ability to take appropriate actions in the interest of public health.

STAFF RECOMMENDATION

Board staff recommends Petition File No. 590 be granted to the extent that the Division be requested by the Board to convene an advisory committee to discuss potential amendments to section 5199 to update TB testing requirements for HCWs where permitted by title 22 and as recommended by federal guidance, while still providing for annual testing of HCWs at higher risk for TB. The Petitioner, stakeholders, Board staff, and other subject matter experts should be extended an invitation to participate in the advisory committee deliberations. Alternatively, Board staff could initiate rulemaking to clarify some points of confusion regarding the TB testing requirements contained in section 5199 and share information about the permanent variance process with CDPH Licensing and Certification Unit to share with employers who successfully receive permission from CDPH for a reduced testing frequency.

[54] World Health Organization. Guidance on Ethics of Tuberculosis Prevention, Care and Control, 2010. https://www.who.int/publications/i/item/9789241500531

[55] CDC and The Centers for Law and the Public's Health: A Collaborative at Johns Hopkins and Georgetown Universities. Tuberculosis Control Laws and Policies: A Handbook for Public Health and Legal Practitioners, October 1, 2009. https://www.cdc.gov/tb/programs/tblawpolicyhandbook.pdf