

Initial Statement of Reasons

Summary of Proposal

Pursuant to Health and Safety Code, Section 121357, the Department of Public Health (CDPH) is the lead agency for all tuberculosis (TB) control and prevention activities in California. CDPH, in collaboration with the California Tuberculosis Controllers Association (CTCA), is amending California Code of Regulations (CCR), Title 22, Division 5, governing health care facilities, to implement AB 1323 (DeSaulnier, Chapter 24, Statutes of 2007). Targeted TB screening¹ of healthcare workers, and routine testing of patients in certain healthcare settings, is recommended by the federal Centers for Disease Control and Prevention (CDC) as part of an overall TB control program and is a public health safety measure. CDC recommendations provide guidance in the selection of TB tests, testing methods, and interpretation of test results. Current state regulations require health care facilities to use a TB intradermal skin test (TST) for TB screening. The proposed amendments will replace the specification for use of the TST with the requirement that TB screening tests used by health care facilities be licensed by the Federal Food and Drug Administration (FDA) and recommended by the CDC². These regulatory amendments are consistent with HSC Sections 1226.1 and 121362.

Policy Statement Overview

Tuberculosis (TB) is a serious communicable disease and remains a significant public health threat. HSC Sections 1226.1 and 121362 currently require certain practice measures, including TB screening tests of persons in certain occupational groups such as healthcare workers³. These laws provide authority and guidance for the state's overall TB control program.

Problem Statement: To remove restrictions for specific TB screening tests, and allow the use of newer approved TB screening tests in licensed health care facilities. AB 1323

¹ Targeted tuberculin testing for LTBI is a strategic component of tuberculosis (TB) control that identifies persons at high risk for developing TB who would benefit by treatment of LTBI, if detected. Persons with increased risk for developing TB include those who have had recent infection with *Mycobacterium tuberculosis* and those who have clinical conditions that are associated with an increased risk for progression of LTBI to active TB. Following that principle, targeted tuberculin testing programs should be conducted only among groups at high risk and discouraged in those at low risk (CDC, 2000, MMWR: 49(RR06)).

² The current comprehensive guidelines are included in the following two publications of the Centers for Disease Control and Prevention: *Guidelines for Preventing the Transmission of Mycobacterium tuberculosis (Mtb) in Health-Care Settings, 2005*. MMWR 2005; 54(RR-17); 1-141, and, *Updated Guidelines for Using Interferon Gamma Release Assays to Detect Mtb Infection—United States, 2010*. MMWR 2010, 59(RR-5); 1-25. Retrieved from http://www.cdc.gov/tb/publications/guidelines/List_date.htm

³ TB screening tests are medical tests used to determine if an individual has been infected with the bacterium that causes TB. While the test does not show whether a person has active TB, it is used to screen persons who may have been exposed to the disease, and in identifying persons who have the disease.

(DeSaulnier, Chapter 24, Statutes 2007) amended HSC section 1226.1 relating to tuberculin testing of persons working in licensed primary care clinics, and HSC Section 121362, relating to tuberculin test results and reporting cases of active TB disease to the public health authority by health care providers and persons in charge of a health facility. The statutory change allows the use of TB blood tests and TB skin tests (TST) in health care facility screening programs. The statute authorizes use of the results of any test for tuberculosis infection that is recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the Federal Drug Administration (FDA).

Objectives (Goal): Objectives of the proposed regulatory amendments are to:

- Implement AB 1323 (DeSaulnier, Chapter 24, Statutes 2007) by removing the specific requirement for use of the TST in health care facilities licensed by CDPH, L&C. The regulatory changes implement the initiative's amendments to Health and Safety Code HSC Section 1226.1 by removing the restriction for sole use of the TST for screening testing of persons in primary care clinics, and are consistent with the TB screening test specifications of HSC Section 121362.
- Provide for ongoing implementation by health care facilities of newer technologies in TB screening testing by incorporating in the regulations the use of FDA approved tests.
- Provide for consistency in adopting use of any TB screening tests in health care facility TB screening programs by incorporating in the regulations CDC recommendations for use of the FDA approved tests.
- The TB skin test result measurement requirement will be deleted so that a "positive result"⁴ to any approved TB screening test will require the prescriptive follow-up actions of the regulation, not solely skin testing positive result.
- Update the TB screening requirement for the chest X-ray size measurement by eliminating specification of the size of the X-ray image. This will allow for digital radiographic imaging.

Benefits: Anticipated benefits for this proposed regulatory action are:

- Protect the public health by having facilities use only FDA approved TB screening tests which also are recommended in the CDC which, in the recommendations provides TB screening test usage recommendations, including names of recommended tests, guidance for test selection, interpretation of test results as positive or negative, and for recording test results.
- To save time and paperwork which can be directed to other activities related to the health of the public. Facilities will no longer need to apply to L&C to use newer TB screening tests that also meet the specifications of the statute.
- To allow for newer X-ray formats commonly used in the health care industry by eliminating X-ray size specificity in the regulation.

⁴ A positive TB skin test or TB blood test only tells that a person has been infected with TB bacteria. It does not tell whether the person has latent TB infection (LTBI is non-contagious) or has progressed to active TB disease.

TB control continues to be an important target of infectious disease control efforts with California reporting the most TB cases of any state, 21% of the nation's total. Goals for TB screening programs are to find and treat those who have become infected by breathing in TB bacteria, so they do not develop active TB. This is especially important in health care facilities and community settings. The value of the total statewide benefits of updating the TB screening requirements in licensed health care facilities is not possible to determine, but it has the potential of being a significant tool in the implementation of the overall TB control program by health care facilities.

Evaluation as to whether the proposed regulations are inconsistent or incompatible with existing state regulations

The Department evaluated this proposal as to whether the proposed regulations are inconsistent or incompatible with existing state regulations. This evaluation included a review of the Department's existing general regulations and those regulations specific to implementation of TB screening testing. An internet search of other state agency regulations was also performed and it was determined that the proposed regulations do not conflict and in fact, are in alignment with, occupational safety and health requirements of Division of Occupational Safety and Health (known as Cal/OSHA) at CCR Title 8, Section 5199 which apply to TB screening testing requirements in health care settings. Therefore, the Department has determined that this proposal, if adopted, would not be inconsistent or incompatible with existing state regulations.

Background /Authority

Pursuant to sections 131051 and 131052 of the Health and Safety Code (HSC), the California Department of Public Health (CDPH), formerly the California Department of Health Services (CDHS)⁵ has authority over health facilities defined in HSC Section 1250, and primary care clinics and psychology clinics defined in HSC Section 1204 and 1204.1. CDPH also has authority over certified nursing assistant (CNA) training programs defined in HSC Sections 1337.1, adult day health centers defined in HSC Section 1570.7, and home health agencies defined in HSC Section 1727. HSC Section 131056 directs the CDPH to commence and oversee all proper and necessary actions and proceedings for, among other things, protecting and preserving the public health. Pursuant to this authority and under the leadership of the CDPH, the Licensing and Certification Program (L&C) oversees the provision of medical care in community settings and facilities, and protects the health and safety of individuals in licensed health facilities.

HSC Sections 1225, 1275, 1337.3, 1580, 1734, and 100275, and 131200 grant the CDPH the authority to adopt, amend, or repeal regulations necessary or proper to carry out its duties and responsibilities, in accordance with the Administrative Procedure Act

⁵ The California Department of Health Services was reorganized into the California Department of Health Care Services and the California Department of Public Health pursuant to SB 162 (Ortiz, Chapter 241, Statutes of 2006).

(APA) governing California rulemaking law and authorized by Government Code, Chapter 3.5, beginning with Section 11340. Accordingly, L&C has adopted regulations to implement, interpret and/or make specific state statutes governing licensing of health care facilities. The regulations are codified in the California Code of Regulation (CCR) Title 22, commencing with Section 70001.

The proposed amendments revise current regulations specifying the sole use of TST to allow the use of any TB screening test that is approved by the FDA and recommended by the CDC for general acute care hospitals, acute psychiatric hospitals, certified nurse assistant programs, skilled nursing facilities, intermediate care facilities, home health agencies, primary care clinics, psychology clinics, intermediate care facilities for the developmentally disabled, intermediate care facilities for the developmentally disabled—habilitative, adult day health centers, chemical dependency recovery hospitals, and correctional treatment centers.

To conform to the recommendations by CDC guidelines, existing regulations requiring that a positive TST (TB skin test) “test result” be followed up with a chest X-ray will be amended to remove measurement specifications for film size and reflect the use of current X-ray imaging technology. Regulations concerning TB testing policies and procedures and reporting of TB test results will also be amended to require adherence to existing CDC guidelines.

It is proposed to be adopted to both address the problems and realize the benefits referenced above regarding this regulatory action.

Specific amendments proposed are as follows:

Section 70723. Employee Health Examinations and Health Records.

Subsection 70723(b)(1)

The phrase “tuberculin skin test using the Mantoux method using a 5 Tuberculin Unit dose of PPD tuberculin stabilized with Tween 80, the result of which is read and recorded in millimeters of induration” is replaced with “test for tuberculosis infection that is recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA)” to allow each facility to choose from a broader range of approved TB tests.

The term “film” is replaced with “X-ray” to be consistent with existing regulations that use “X-ray,” and has the same meaning.

The phrase “A skin test” is replaced with, “If a person has a previously documented positive tuberculosis test result, a test for tuberculosis infection” and “on a person with a documented positive reaction to PPD” is deleted since this is only relevant to a single type of TB test. These changes allow the sentence to read correctly while still providing for evaluation if there is a positive TB test result.

Subsection 70723(b)(2)

The term “skin” is replaced with “tuberculosis” to allow each facility to choose which method to use out of a broader range of approved TB tests.

Subsection 70723(b)(3)

The phrase “for tuberculosis” is deleted and the term “skin” is replaced with “tuberculosis” test as part of the annual TB testing of individuals with a previously negative TB test to allow each facility to choose from a broader range of approved TB tests.

The terms “tuberculin skin” are replaced with “tuberculosis” and the term “reaction” is replaced with “tuberculosis test result,” a more general term that is appropriate to a variety of types of TB tests. This clarifies the direction on what to do if there is a negative and then a subsequent positive result.

The Authority and Reference note is amended to remove inoperative statute, and to add the current statute.

Section 71523. Employee Health Examinations and Health Records.

Subsection 71523(b)

The term “skin” is deleted and the phrase “using Purified Protein Derivatives intermediate strength” is replaced with “infection that is recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA)” to allow each facility to choose the test application out of the broader range of approved TB tests.

The word “A” is added at the beginning of the sentence starting with “Positive” and the capital “P” is changed to a lower-case “p” as a technical change to make a grammatically correct and complete sentence.

The words “reaction to” are replaced with the words “result from,” which removes the specific reference to a skin test reaction and replaces it with a more general term to reference any screening test results.

The word “skin” is replaced by “tuberculosis” test to remove the specification for a skin test and still include the provision for the chest X-ray following any positive TB screening test.

The phrase “35.56 cm x 43.18 cm (14” x17”)” is removed as the size of the X-ray is not relevant to visualization of images using current X-ray technology. The specification of the X-ray image is not needed.

The Authority and Reference note is added to cite the current statute.

Section 71835. Certification Training and Competency Evaluation Program.

Subsection 71835(f)(1)(B)

The phrase “purified protein derivative, intermediate strength intradermal skin” is deleted before “test” and “infection that is recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA)” is added after the word “tuberculosis” to allow each facility to choose the test application out of the broader range of approved TB screening tests.

The word “reaction” is replaced by “test result,” which removes the specific reference to a skin test reaction and replaces it with a more general term to reference any screening test results.

The Authority and Reference note is amended to remove inoperative statute, and to add the current statute.

Section 72535. Employees’ Health Examination and Health Records.

Subsection 72535(b)

The phrase “purified protein derivative intermediate strength intradermal skin” is deleted and the phrase test for tuberculosis “infection that is recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA)” is inserted after “tuberculosis.” This change will allow each facility to choose the test application out of the broader range of approved TB screening tests.

The phrase “reaction to a” and the term “skin” are deleted as this language is specific to the TB skin test and the term “result” is inserted after “test” to read “had a positive tuberculosis test result” and the sentence references the results of any approved TB screening test.

The word “A” is added at the beginning of the sentence starting with “Positive” and the capital “P” is changed to a lower-case “p” as a technical change to make the sentence grammatically correct. The phrase “reaction to the skin test” is amended to read “tuberculosis test result” so that this sentence references the results of any approved TB screening test.

The phrase “35.56 cm x 43.18 cm (14” x 17”)” is deleted as the size of the X-ray is not relevant to visualization of images using current X-ray technology. The specification of the X-ray image is not needed.

The Authority and Reference note is amended to remove inoperative statute, and to add the current statute.

Section 73525. Employees' Health Examinations and Health Records.

Subsection 73525(b)

The phrase “purified protein derivative intermediate strength intradermal skin” is deleted before “test” and “infection that is recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA)” is added after the word “tuberculosis.” This amendment allows each facility choice of approved TB tests.

The word “A” is added at the beginning of the sentence starting with “Positive” and the capital “P” is changed to a lower-case “p” as a technical change to make a grammatically correct and complete sentence. The term “reaction to the skin test” is changed to read “result from the tuberculosis test.” The changed text is consistent with the broader choice of approved tests.

The phrase “35.56 cm x 43.18 cm (14” x 17”)” is removed as the size of the X-ray is not relevant to visualization of images using current X-ray technology. The specification of the X-ray size image is not needed.

The Authority and Reference note is added to cite the current statute.

Section 74723. Employees' Health Examinations and Health Records.

Subsection 74723(c)(4)

The phrase “the 5 TU (Tuberculin Units) Protein Purified Derivative (PPD) tuberculin skin test” is deleted and replaced with “a test for tuberculosis infection that is recommended by the Federal Centers for Disease Control and Prevention (CDC) and licensed by the Federal Food and Drug Administration (FDA).” This amendment allows each facility choice of approved TB tests.

Subsection 74723(c)(4)(A)

The word “tuberculosis” is added to clarify the “test” that is being referred to.

Subsection 74723(c)(4)(B)

The term “tuberculin skin” is replaced with “tuberculosis” to clarify the term “test” and to reflect the broader range of TB tests being allowed for use. The term “tuberculin testing program” is replaced with the term “tuberculosis screening testing” to clarify the individually administered test versus the screening process that each employee shall comply with.

The Authority and Reference note is amended to add the current statute.

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

Subsection 75051(b)

The phrase “purified protein derivative intermediate strength intradermal skin” is deleted and the phrase “infection that is recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA)” is added after “tuberculosis” as part of the requirement for health examination of persons working in clinics. This will allow each facility to choose which method to use out of a broader range of approved TB tests. This implements HSC section 1226.1(a)(2) (Amended by AB 1323, Statutes 2007, Chapter 24).

The word “A” is added at the beginning of the sentence starting with “Positive” and the capital “P” is changed to a lower-case “p” as a technical change to make a grammatically correct and complete sentence. The words “reaction to” are replaced by “result from,” and the term “skin” is replaced by “tuberculosis.” This removes the specific reference to a skin test reaction so that the requirement applies to any TB screening test result.

The subsection is also amended to reflect current X-ray imaging technology since the specific X-ray size requirement is not relevant to visualization of images using current X-ray technology. The phrase “35.56 cm x 43.18 cm (14” x 17”)” is deleted.

The Authority and Reference note is amended to remove inoperative statute, and to add the current statute. HSC section 1226.1 pertaining to primary care clinics is added as it is the legislation initiating this regulatory action.

Section 75335. Employee Health Examinations and Health Records.

Subsection 75335(a)

The phrase “tuberculosis screening test consisting of a purified protein derivative intermediate strength intradermal skin” is deleted and the phrase “for tuberculosis infection that is recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA)” is added after “test” to allow each facility to choose the test application out of the broader range of approved TB tests. The word “skin” is deleted and replaced with the word “tuberculosis” to clarify the word following “test” and provide indication of the broader range of approved TB tests.

The Authority and Reference note is amended to remove inoperative statute, and to add the current statute.

Section 76539. Employees' Health Examination and Health Records.

Subsection 76539(a)

The word “ay” is corrected to “any.” This is a spelling correction.

Subsection 76539(b)

The phrase “purified protein derivative intermediate strength intradermal skin” is deleted and the phrase “infection that is recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA)” is added after the phrase “test for tuberculosis” to allow each facility to choose the test application out of the broader range of approved TB tests.

The word “A” is added at the beginning of the sentence starting with “Positive” and the capital “P” is changed to a lower-case “p” as a technical change to make the sentence grammatically correct. The phrase “reaction to” is replaced by “result from.” The term “skin” is replaced by “tuberculosis”. This removes the specific reference to a skin test reaction so that the requirement applies to any TB screening test result.

The phrase “35.56 cm x 43.18 cm (14” x 17”)” is removed as the size of the X-ray is not relevant to the visualization of images using current X-ray technology. The specification of the X-ray image is not needed.

The Authority and Reference note is amended to remove inoperative statute, and to add the current statute.

Section 76874. Health Support Services—Physician Services.

Subsection 76874(b)

The phrase “purified protein derivative intermediate strength intradermal skin” is deleted and the phrase “for tuberculosis infection that is recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA)” is added after the word “test” to allow each facility to choose the test application out of the broader range of approved tests.

The word “reaction” is replaced by “result,” and the term “skin” is replaced by “tuberculosis” as the term “test” reflects the broader range of TB tests allowed for use.

The Authority and Reference note is amended to remove inoperative statute, and to add the current statute.

Section 76919. Employees' Health Examination and Health Records.

Subsection 76919(b)

The phrase “purified protein derivative intermediate strength intradermal skin” is deleted and the phrase “for tuberculosis infection that is recommended by the federal Centers

for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA)” is added after the word “test” to acknowledge the broader range of testing methods that are acceptable.

The word “reaction” is replaced by “result,” and the term “skin” is replaced by “tuberculosis” as the term “test” reflects the broader range of TB tests allowed for use.

The Authority and Reference note is amended to remove inoperative statute, and to add the current statute.

Section 78429. Employee Records.

Subsection 78429 (b)(2)(A)

The phrase “purified protein derivative intermediate strength” is deleted and the phrase “for tuberculosis infection that is recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA)” is added after the word “test” to allow each facility to choose the test application out of the broader range of approved TB tests.

The Authority and Reference note is added to cite the current statute.

Section 79331. Employee Health Examinations and Health Records.

Subsection 79331(b)

The word “skin” is deleted so that the requirement is not specific to the TB skin test. The phrase “using purified protein derivatives, intermediate strength” is replaced with the phrase “infection that is recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA)” after the word “tuberculosis” to allow each facility to choose the test application out of the broader range of approved TB tests.

The word “A” is added at the beginning of the sentence and the capitalization in the word “Positive” is removed as a technical change to make a grammatically correct and complete sentence. The phrase “reaction to” is replaced with “result from.” The word “skin” is replaced by “tuberculosis.” This removes the specific reference to a skin test reaction so that the requirement also applies to any TB screening test result.

The phrase “35.56 cm x 43.18 cm (14” x 17”)” is removed as the size of the X-ray is not relevant to production of images using current X-ray technology. The specification of the X-ray image is not needed.

The Authority and Reference note is amended to remove inoperative statute, and to add the current statute.

Section 79781. Required Committees.

Subsection 79781(d)(2)(D)(1).

The phrase “policies and procedures shall be reviewed and revised per Subsection 79779(b), and” is added after “These” in order to ensure the facility keeps policies and procedures updated to reflect current standards and practices for the patient care committee established within a correctional treatment center. The word “1990” is deleted because it is not the most current date of CDC recommendations. This change eliminates the specific reference to the “1990” outdated CDC recommendations. The phrase “and Prevention (CDC)” is added after “Centers for Disease Control” to provide the complete name of the organization which is also recognized by the initials “CDC.”

Subsection 79781(d)(2)(D)(2).

The term “documenting” is added after “maintaining” to clarify that a function of the infection control committee in the control and prevention of infection, including tuberculosis in the facility, is to ensure documentation of evidence of diagnosis, such as screening examination results, when the number of infections in the facility are reported to the infection control committee. The phrase “Mantoux and tuberculin skin” is deleted and the phrase “for tuberculosis infection are recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA)” is added after the term “tests”. The phrase “recorded in millimeters of induration” is deleted as it applies solely to TB skin tests.

The Authority and Reference note is amended to remove inoperative and repealed statute, and to add the current statute.

Section 79795. Employee Health Examinations and Health Records.

Subsection 79795(b)

The phrase “tuberculin skin test using the Mantoux method using 5 Tuberculin Unit dose of Purified Protein Derivative (PPD) stabilized with Tween 80, the result of which is read and recorded in millimeters of induration” is replaced with “test for tuberculosis infection that is recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA)” to allow each facility to choose which method to use out of a broader range of TB tests.

The subsection is also amended to change the word “film” to “X-ray” for consistent use of terms with other regulations.

The phrase “A tuberculin skin test” is replaced with “If a person has a previously documented positive tuberculosis test result, a test for tuberculosis infection” to clarify what to do when there is a previously positive test result.

The phrase “on a person with a documented positive reaction to PPD” is deleted as this phrase refers only to the TB skin test and is not consistent with the other revisions to this section.

Subsection 79795(b)(1)

The term “skin” is replaced with “tuberculosis” to allow each facility to choose which method to use out of a broader range of approved TB tests.

Subsection 79795(b)(2)

The word “skin” is deleted to modify the phrase to say “An annual test for tuberculosis” to allow for the broader scope of approved TB testing. The term “tuberculin skin” is replaced with “tuberculosis” a more general term that is appropriate to a variety of types of TB tests. The word “skin” is deleted to modify the phrase to say “a previously documented negative tuberculosis test” to allow for the broader scope of approved TB testing. The term “reaction” is replaced with “tuberculosis test result,” a more general term that is appropriate to a variety of types of TB tests. This clarifies the direction on what to do if there is a negative and then a subsequent positive result.

The Authority and Reference note is amended to remove inoperative and repealed statute, and to add the current statute.

Section 79805. Inmate—Patient Health Record Content.

Subsection 79805(a)(3)

The phrase “Mantoux tuberculin skin” is deleted and the phrase “for tuberculosis infection that is recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the federal Food and Drug Administration (FDA),” is inserted after “test” to allow each facility to choose which method to use out of a broader range of TB tests.

The term “reaction” is replaced with “result,” a more general term that is appropriate to a variety of types of TB tests.

The phrase “the Mantoux tuberculin skin” is replaced with “a tuberculosis.” The term “the result” is added before “recorded” and the phrase “in millimeters of induration” is deleted after “recorded” to allow for results from a broader range of testing techniques. The sentence “The result of the tuberculosis test shall be reported as recommended in current guidelines of the Centers for Disease Control and Prevention regarding tuberculosis testing” is added to ensure that the results from different types of TB tests are reported in accordance with current CDC recommendations for each particular test.

The Authority and Reference note is amended to remove inoperative and repealed statute, and to add the current statute.

Economic Impact Assessment

The Department has made an initial determination that these regulations would not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. The proposed regulations would not significantly affect:

- The creation or elimination of jobs within the State of California
- The creation of new businesses or the elimination of existing businesses within the State of California
- The expansion of businesses currently doing business within the State of California.

The regulation supports the health and welfare of California residents and worker safety by updating regulations which currently specify the use of a TB skin test to also allow the use of newer TB screening tests. This regulation will allow more flexibility in the choice of TB screening test but does not impose a requirement for facilities to change testing methods if they are currently using TB skin testing.

Significant Statewide Adverse Economic Impact Directly Affecting Business, Including Ability to Compete

The Department has determined that the proposed regulatory action would have no significant adverse economic impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states. Thus, there will be no significant adverse economic impact on California businesses.