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



EDMUND G. BROWN JR.
Governor

ACTION: Notice of Proposed Rulemaking
Title 22, California Code of Regulations

SUBJECT: Tuberculosis (TB) Screening Testing (DPH 10-013)

PUBLIC PROCEEDINGS: Notice is hereby given that the California Department of Public Health will conduct written proceedings during which time any interested person or such person's duly authorized representative may present statements, arguments or contentions (all of which are hereinafter referred to as comments) relevant to the action described in this notice.

WRITTEN COMMENT PERIOD: Any written comments pertaining to these regulations, regardless of the method of transmittal, must be received by the Office of Regulations by 5 p.m. April 08, 2013, which is hereby designated as the close of the written comment period. Comments received after this date will not be considered timely. Persons wishing to use the California Relay Service may do so at no cost by dialing 711.

Written comments may be submitted as follows:

1. By email to: regulations@cdph.ca.gov. It is requested that email transmission of comments, particularly those with attachments, contain the regulation package identifier "DPH -10-013" in the subject line to facilitate timely identification and review of the comment; or
2. By fax transmission: (916) 440-5747; or
3. By mail to: Office of Regulations, California Department of Public Health, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377; or hand-delivered to: 1616 Capitol Avenue, Sacramento, CA 95814. It is requested but not required that written comments sent by mail or hand-delivered be submitted in triplicate.

All comments, including email or fax transmissions, should include the author's name and U.S. Postal Service mailing address in order for the Department to provide copies

of any notices for proposed changes to the regulation text on which additional comments may be solicited.

HEARING: No hearing has been scheduled; however, any interested person or his or her duly authorized representative may request in writing, no later than 15 days prior to the close of the written comment period, a public hearing pursuant to Government Code Section 11346.8. For individuals with disabilities, should a public hearing be scheduled, the Department will provide assistive services such as sign-language interpretation, real-time captioning, note takers, reading or writing assistance, and conversion of written public hearing materials into Braille, large print, audiocassette, or computer disk. Note: The range of assistive services available may be limited if requests are received less than ten business days prior to a public hearing.

To request such services or copies of materials in an alternate format, please write to Dawn Basciano, Office of Regulations, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377, or call (916) 440-7367, or use the California Relay Service by dialing 711.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW:

Summary of Proposed Regulations

The purpose of the proposed regulations is to implement AB 1323 (DeSaulnier, Chapter 24, Statutes 2007) by removing restrictions for use of a specific TB screening test and to allow the use of newer approved TB screening tests in licensed health care facilities. Approved tests currently include both the traditional TB skin test and newer TB blood tests now on the market. The regulatory changes will authorize use of any test for TB infection that is recommended by the federal Centers for Disease Control and Prevention (CDC) and licensed by the Federal Drug Administration (FDA) in regulation sections which previously specified use of the TB skin test. Additionally, the regulatory changes will update X-ray requirements, in areas of the regulations where an X-ray of specified dimension is required for persons whose TB screening test result is positive, to reflect the use of new X-ray technology by eliminating the image size requirement.

The proposed amendments apply to regulations for the following provider types licensed by L&C and programs administered by L&C: General Acute Care Hospitals, Acute Psychiatric Hospitals, Certified Nurse Assistant Program, Skilled Nursing Facilities, Intermediate Care Facilities, Home Health Agencies, Primary Care Clinics, Psychology Clinics, Intermediate Care Facilities for the Developmentally Disabled, Intermediate Care Facilities/Developmentally Disabled-Habilitative, Adult Day Health Centers, Chemical Dependency Recovery Hospitals, and Correctional Treatment Centers.

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 workers. 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 (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" 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:

- To 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.

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.

Purpose and 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) 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 (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.

AUTHORITY & REFERENCE CITATIONS:

The Department is proposing to amend the regulation sections identified under the authority provided in sections 1225, 1267.7, 1275, 1275.2, 1338.3, 1734, 100275, 121357, and 131200, Health and Safety Code. This proposal implements, interprets and makes specific sections 1200, 1204.1, 1226, 1226.1, 1250, 1250.3, 1254, 1275.2, 1276, 1315, 1316, 1316.5, 1337.3, 1337.6, 1580, 1727, 1727.5, 1734, 121362, 131050, 131051, and 131052, Health and Safety Code.

The Authority and Reference citations for these sections will be amended to update the statutes providing rulemaking authority and to add specific statutes being implemented, interpreted or made specific in this regulatory action including amendments which reflect the reorganization of the Department of Health Services into the California Department of Health Care Services and the California Department of Public Health.

EVALUATION AS TO WHETHER THE PROPOSED REGULATIONS ARE INCONISISTENT 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.

THIS REGULATION PACKAGE PROPOSES THE AMENDMENT OF:

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

FORMS INCORPORATED BY REFERENCE: N/A

MANDATED BY FEDERAL LAW OR REGULATIONS: N/A

OTHER STATUTORY REQUIREMENTS: N/A

LOCAL MANDATE: The Department has determined that the regulations would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by Part 7 (commencing with Section 17500) of Division 4 of the Government Code.

FISCAL IMPACT ESTIMATE:

- A. FISCAL IMPACT ON LOCAL GOVERNMENT:** None.
- B. FISCAL IMPACT ON STATE GOVERNMENT:** None.
- C. FISCAL IMPACTS ON FEDERAL FUNDING OF STATE PROGRAMS:** None.
- D. FISCAL IMPACT ON PRIVATE PERSONS OR BUSINESSES DIRECTLY AFFECTED:** None.
- E. MANDATE ON LOCAL AGENCIES OR SCHOOL DISTRICTS:** None.

F. OTHER NON-DISCRETIONARY COST OR SAVINGS IMPOSED UPON LOCAL AGENCIES: None.

G. EFFECT ON SMALL BUSINESSES: None.

HOUSING COSTS: The Department has determined that the regulations will have no impact on housing costs.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE: The Department has made an initial determination that the regulations would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

RESULTS OF THE ECONOMIC IMPACT ANALYSIS:

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

1. The creation or elimination of jobs within the State of California.
2. The creation of new businesses or the elimination of existing businesses within the State of California.
3. 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 tests.

COST IMPACTS ON REPRESENTATIVE PERSON OR BUSINESS:

The agency is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action. The regulatory change does not impose new restrictions or new requirements. Healthcare facilities licensed by the Department and governed by these regulations would not incur additional costs to comply with the regulation. Facilities may continue to use the previously required TST, or may choose to implement use of approved blood tests in screening for tuberculosis, as required by the current regulations.

BUSINESS REPORT: None

ALTERNATIVES STATEMENT:

The Department has determined that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

CONTACT PERSON: Inquiries regarding the substance of the proposed regulations described in this notice may be directed to Cheryl Gordon of the Center for Health Care Quality, at (916) 552-8734.

All other inquiries concerning the action described in this notice may be directed to Dawn Basciano of the Office of Regulations, at (916) 440-7367, or to Alana McKinzie at (916) 440-7689, the designated backup contact person. .

In any inquiries or written comments, please identify the action by using the Department regulation package identifier, DPH-10-006: Fluoroscopy Permit Requirements for Physician Assistants.

AVAILABILITY OF STATEMENT OF REASONS, TEXT OF PROPOSED

REGULATIONS, AND RULEMAKING FILE: The Department has prepared and has available for public review an initial statement of reasons for the proposed regulations, all the information upon which the proposed regulations are based, and the text of the proposed regulations. The Office of Regulations, 1616 Capitol Avenue, Sacramento, CA 95814, will be the location of public records, including reports, documentation, and other material related to the proposed regulations (rulemaking file).

In order to request that a copy of this public notice, the regulation text, and the initial statement of reasons or alternate formats for these documents be mailed to you, please call (916) 440-7367 (or the California Relay Service at 711), send an email to regulations@cdph.ca.gov, or write to the Office of Regulations at the address previously noted. Upon specific request, these documents will be made available in Braille, large print, audiocassette, or computer disk.

AVAILABILITY OF CHANGED OR MODIFIED TEXT: The full text of any regulation which is changed or modified from the express terms of the proposed action will be made available by the Department's Office of Regulations at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

AVAILABILITY OF FINAL STATEMENT OF REASONS: A copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations.

AVAILABILITY OF DOCUMENTS ON THE INTERNET: Materials regarding the action described in this notice (including this public notice, the regulation text, and the initial statement of reasons) that are available via the Internet may be accessed at www.cdph.ca.gov by clicking on these links, in the following order: Decisions Pending and Opportunity for Public Participation > Regulations > Proposed.

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

Date:

Ron Chapman, MD, MPH
Director