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

RON CHAPMAN, MD, MPH
Director & State Health Officer

EDMUND G. BROWN JR.
Governor

ACTION: Notice of Proposed Rulemaking
Title 17, California Code of Regulations

SUBJECT: HIV Screening Testing by Laboratories, DPH-13-007E

The California Department of Public Health (Department) has adopted emergency regulatory amendments to the California Code of Regulations (CCR), Title 17, Section 1230 and 2641.57, and they are now in effect. The Department is now proposing to make those emergency regulatory amendments to Title 17, CCR, Sections 1230 and 2641.57 permanent.

Public Proceedings

Notice is hereby given that the Department will conduct a written comment period during which time any interested person or such person's duly authorized representative may submit statements, arguments or contentions (all of which are hereinafter referred to as comments) relevant to the action described in this notice. 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, or onto 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 Elizabeth Reyes, Office of Regulations, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377, or call (916) 445-2529, or use the California Relay Service by dialing 711.

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. on January 20, 2014,** 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-13-007E**" 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: 1415 L Street, 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.

Inquiries

Inquiries regarding the substance of the proposed regulations described in this notice may be directed to Kama Brockmann, Office of AIDS, at (916) 449-5964.

All other inquiries concerning the action described in this notice may be directed to Elizabeth Reyes, Office of Regulations, at (916) 445-2529.

Informative Digest/Policy Statement Overview

Background: The first cases of AIDS were first identified in 1981, and testing for HIV became available in 1985. In 1986, California enacted Title 17, section 1230 that mirrored the recommendation from the Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories (APHL) to use a sequential two-test algorithm to diagnose HIV-1. This laboratory protocol identifies positive HIV test results within approximately 45 days of infection.

Since then, HIV research, treatment, and testing protocols have improved dramatically. Prior to the adoption of the emergency regulations, California was one of the only states with high HIV prevalence that is not able to use a newly recommended HIV testing protocol or algorithm that can detect acute HIV infection within 14 days of infection, as many as 31 days earlier than the existing HIV algorithm. In addition, the existing HIV algorithm can take 7 to 10 days to process and return test results. Since the existing HIV algorithm confirmation test takes a long time to process, these tests are often run in batches two or three times a week rather than every day. In comparison, the new HIV test algorithm can be processed with results back within 1 to 3 days. Combined with the time saving of earlier detection, the new HIV test algorithm reduces the time for diagnosing acute HIV infection from between 52 and 55 days down to 15 to 17 days.

The use of this new HIV testing algorithm is supported by the California Association of Public Health Laboratory Directors and the California Conference of Local Health Officers. Clinical and Laboratory Standards Institute (CLSI) has recommended the use of this new HIV testing algorithm for supplemental testing after a reactive HIV screening test. The CDC and the APHL have also proposed the use of this new algorithm. Importantly for California, the new HIV testing algorithm identifies acute HIV infection, a critical feature that the existing algorithm is unable to do. In a side-by-side comparison of the existing and new algorithm over an 18-month period, the San Diego Public Health Laboratory found 14 acute HIV infections that would not have been detected using the existing laboratory algorithm. The San Francisco Public Health Laboratory also ran a side-by-side comparison of the existing and new algorithm and found 19 acute HIV infections in 2012. These early acute HIV infection cases were not detected using the existing HIV algorithm.

Early detection of HIV is essential to decreasing the transmission of HIV to non-infected individuals. Research and public health studies show that people with acute HIV infection are more likely to transmit HIV than those with established infections. CDC also found that people with early infection are more likely to transmit than those with established infections due to high viral load and viral variants more able to cause infection.

Phylogenetic analysis of viral gene sequences has shown that people with early infection may account for between 24 and 50 percent of new transmissions of HIV infection. In addition, a 2005 meta-analysis of eight studies showed that people who knew their HIV positive status were 68 percent less likely to engage in risky sexual behaviors with people of unknown HIV status than people who did not know their HIV status. Allowing and encouraging California laboratories to implement use of this superior algorithm will decrease HIV transmission within California.

CDC estimates that prevention efforts in the United States have averted more than 350,000 HIV infections. In addition to the lives saved from HIV, it is estimated that more than $125 billion in medical costs have been averted. Yet, HIV continues to be an epidemic in the United States and California. CDC estimates that in 2010, approximately 1,148,200 people in the United States lived with HIV/AIDS. At the end of 2012, 117,695 Californians were reported to be living with HIV/AIDS. It is estimated that another 27,000 Californians have HIV but are unaware of their status. The Department estimates that each year another 5,000 to 6,000 Californians become infected with HIV. The projected life expectancy of someone from the time of entering HIV care is 24.2 years. Total discounted costs associated with the lifetime care of a person with HIV are estimated at $385,200. HIV also decreases personal productivity and the quality of life for all affected Californians. If a person’s HIV is undetected and untreated, their HIV disease will most likely progress to an AIDS diagnosis. While HIV care and treatment has improved, people with HIV still have to manage a long-term and chronic illness. This illness takes its toll on their capacity to work, their contributions to society and affects their families. Since research suggests between a quarter and half

of all new infections are caused by people with acute HIV infection, widespread use of the new HIV testing algorithm could significantly decrease this number.

On a technical level, this newly developed HIV testing algorithm is more accurate than the existing HIV algorithm because the initial test is a sensitive screening assay that detects HIV-1 and HIV-2 or antibodies to these two viruses. If this initial test is reactive, a supplemental test is performed to differentiate between HIV-1 and HIV-2. If the supplemental test is also reactive, HIV-1 or HIV-2 is established. If the supplemental test is non-reactive or indeterminate, the specimen is further tested for acute HIV infection that neither of the first two tests could determine.

States with high prevalence of HIV/AIDS comparable to California such as New York and Florida are permitted to use this newly developed HIV testing algorithm to identify early HIV/AIDS infections and better protect public health. Both these states have had success identifying acute HIV infection.

Purpose

The broad purpose of this proposed regulatory action is to reduce the transmission of HIV during the first months of acute HIV infection by reducing the waiting time for positive HIV test results from 45 days to 14 days from infection and allow for rapid notification of HIV test results to the patient. This regulatory action will reduce the number of newly HIV-infected persons in California and save lives.

The more specific purpose of the Department's proposed regulatory action is to permanently allow a newly developed HIV testing algorithm to be used by licensed California laboratories to better protect the public health, safety and welfare.

Objective

The broad objectives of this proposed regulatory action are to:

- Permit the use of a newly developed HIV testing algorithm by licensed California laboratories to more quickly identify persons with acute HIV infections.

- Reduce the transmission of HIV during the first months of acute infection.

- Reduce the time for HIV test results from 45 days to 14 days from infection and reduce the HIV test processing time from 7 to 10 days down to 1 to 3 days. All combined the time needed to diagnose HIV infection is reduced from 52 to 55 days down to 15 to 17 days.

- Reduce the number of persons newly infected with HIV in California.

- Reduce health care costs by reducing the transmission of HIV to non-infected members of the public in California.

- Allow superior HIV testing protocols to better protect California's public health and safety.

- Permit use of best laboratory protocols in California so the Department and California's laboratories continue to be leaders in HIV testing.

Benefits

Anticipated benefits including nonmonetary benefits to the protection of public health and safety, worker safety, the environment, the prevention of discrimination, or the promotion of fairness or social equity, from this proposed regulatory action are:

- Making a laboratory protocol available to laboratory professionals to determine within 14 days of infection if a person has been infected with HIV, rather than waiting 45 days pursuant to the only protocol currently approved in CCR Title 17.

- Improving health outcomes of newly diagnosed HIV-positive individuals due to earlier diagnosis and linkages to appropriate care and treatment.

- Reducing the transmission of HIV from one infected individual to potentially numerous others during the first months of acute HIV infection.

- Establishing consistency between California's HIV testing protocols and those adopted in other states with high HIV prevalence rates so that California remains a leader in HIV public health.

- Establishing alternative permissive laboratory protocol options rather than prescriptive requirements that meet current and serious concerns of public health officials, laboratory directors and the public.

- Promoting statewide availability of the best laboratory protocol practices that more effectively protect public health and safety.

- Reducing health care costs by reducing the transmission of HIV between members of the public in California.

- Saving lives by reducing the transmission of HIV between members of the public in California.

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

The Department has evaluated whether the proposed regulations are inconsistent or incompatible with existing state regulations. This evaluation included a review of the Department's laws and specifically those statutes and regulations related to HIV,

laboratory practices and health and safety. Department staff also conducted an internet search of other California and federal regulations.

While several state and federal statutes and regulations relate to HIV and AIDS, no statute or regulation was found that conflicts with this regulatory proposal. The Department also determined that this regulatory proposal is nonduplicative of any other known state or federal statute or regulation.

No other state regulation or statute addressed the same subject matter. Therefore, the Department has determined that this proposal, if adopted, would not be inconsistent or incompatible with existing state regulations or statutes.

Authority and Reference

The Department proposes this regulatory action under the authority provided in Sections 1603.1(f), 120895, 121022, 131019, 131050, 131051, 131056, and 131200 of the Health and Safety Code and Section 1224 of the Business and Professions Code. This proposal implements, interprets and makes specific Sections 1603.1, 101160, 120895, 120917, 121022, 131050, 131051, 131052, and 131056 of the Health and Safety Code and Sections 1206, 1220, and 1265 of the Business and Professions Code.

Pursuant to its authorities, the Department is proposing to amend CCR Sections 1230 and 2641.57, as follows:

Amend Section 1230: This regulatory proposal would amend Section 1230 to permit licensed laboratories to confirm HIV test results by using a newly developed HIV testing algorithm or other future diagnostic protocols recommended by CDC, CLSI, APHL or U.S. Department of Health and Human Services (DHHS). This proposal would also delete the requirement that CDC publish its recommended protocols in the *Morbidity and Mortality Weekly Report* (MMWR) before licensed California laboratories can use CDC recommended protocols.

These amendments are reasonably necessary to permit the permanent use of superior HIV diagnostic protocols recommended by leading HIV researchers and proposed by the federal government. These amendments also provide consistency between California and CDC, eliminate confusion for regulation users and provide clarity for laboratories and the public given CDC no longer publishes its recommended protocols in the MMWR.

Section 1230 also uses the term “confirmation” with respect to the HIV test results. CDC has discontinued use of the terms “confirmation” and “confirmatory” because they imply that the HIV test is in some way a definitive determination of HIV infection. Instead, an HIV diagnosis is obtained by screening and supplemental tests that indicate the presence of HIV antigens or antibodies. The deletion of the word “confirmation” and replacement with the word “diagnostic” in Section 1230 is reasonably necessary to more

accurately represent the conclusions that can be drawn from HIV testing protocols. This amendment will also reduce confusion for licensed laboratories using these regulations and provide clarity for the public.

Amend Section 2641.57: This regulatory proposal would amend the definition of "HIV test algorithm" to permit the use of HIV test protocols recommended by CDC, CLSI, APHL or DHHS. This amendment is reasonably necessary so the definition of "HIV test algorithm" does not conflict with the proposed amendments to Section 1230. This amendment will provide clarity for regulation users by avoiding conflicts in wording between these regulatory sections.

Section 2641.57 also uses the term "confirmation" with respect to the HIV test results. CDC has discontinued use of the terms "confirmation" and "confirmatory" because they imply that the HIV test is in some way a definitive determination of HIV infection. Instead, an HIV diagnosis is obtained by screening and supplemental tests that indicate the presence of HIV antigens or antibodies. The deletion of the word "confirmation" and replacement with the word "diagnostic" in Section 2641.57 is reasonably necessary to more accurately represent the conclusions that can be drawn from HIV testing protocols. This amendment will also reduce confusion for licensed laboratories using these regulations and provide clarity for the public.

Technical, Theoretical, and/or Empirical Study, Reports or Documents Relied Upon

Branson, B.M., Mermin, J. *Establishing the Diagnosis of HIV Infection: New Tests and a New Algorithm for the United States.* Journal of Clinical Virology, 52S (2011) S3-S4. http://www.journalofclinicalvirology.com/article/S1386-6532(11)00387-8/fulltext

Brenner, B.G. et al. *High Rates of Forward Transmission Events after Acute/Early HIV- 1 Infection.* Journal of Infectious Disease, 2007:195, 951–959 (April 1) http://jid.oxfordjournals.org/content/195/7/951.full.pdf+html?sid=1098401a-b005-4098-83a7-f87959b6a47a

California Association of Public Health Laboratory Directors, letter of support, dated February 6, 2013.

CDC. *HIV Prevention in the United States at a Critical Crossroads.* August, 2009. http://www.cdc.gov/hiv/resources/reports/hiv_prev_us.htm

CDC. *Revised Recommendations for HIV Testing of Adult, Adolescents, and Pregnant Women in Health-Care Settings*. Morbidity and Mortality Weekly Report, September 22, 2006, Vol. 55, No. RR-14. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm

CLSI. *Criteria for Laboratory Testing and Diagnosis of HIV: Approved Guideline.* CLSI document M53-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2011. Note that this laboratory guidance is proprietary although all certified laboratories use this document. http://shopping.netsuite.com/s.nl/c.1253739/it.A/id.250/.f

Hutchinson, A., et.al. *Laboratory Cost of the APHL/CDC Proposed Algorithm for the Diagnosis of HIV.* 2012 HIV Diagnostics Conference Program Book, p. 69. https://custom.cvent.com/ADE0EB81B3184D618E2FB8340F1EC28E/files/b7a7473c5a084eecaa23e146649e3f33.pdf

Manlutac, A.M. *Identification of Early HIV Infections Using the Fourth Generation Abbott Architect HIV Ag/Ab Combo Chemiluminescent Microparticle Immunoassay (CIA) in San Diego County*. 2012 HIV Diagnostics Conference Program Book. December 12-14, 2012, Atlanta, Georgia.
https://custom.cvent.com/ADE0EB81B3184D618E2FB8340F1EC28E/files/5aed5ead2525484fa1981dedad756cf4.pdf
https://custom.cvent.com/ADE0EB81B3184D618E2FB8340F1EC28E/files/6eebbfa7fb1b4553b9676161e980b211.pdf

Neuman, D. et. al. *Performance of the new HIV-1/2 Diagnostic Algorithm in Florida's Public Health Testing Population: A Review of the First Five Months of Utilization*. 2012 HIV Diagnostics Conference Program Book, December 12-14, 2012, Atlanta, Georgia.
https://custom.cvent.com/ADE0EB81B3184D618E2FB8340F1EC28E/files/b7a7473c5a084eecaa23e146649e3f33.pdf
https://custom.cvent.com/ADE0EB81B3184D618E2FB8340F1EC28E/files/6eebbfa7fb1b4553b9676161e980b211.pdf

Shackman, B.R. et. al. *Lifetime Cost of Current Human Immunodeficiency Virus Care in the United States*. Medical Care, Vol. 44, No. 11, November 2006.
http://webserver.rilin.state.ri.us/HIV/Documents/lifetimecostofHIV.pdf

Forms Incorporated by Reference There are no documents to be incorporated by reference.

Mandated by Federal Law or Regulations Currently, there are no existing federal regulations or statutes applicable to the regulations.

Other Statutory Requirements Not applicable.

Mandate on Local Agencies or School Districts
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. The Department is not aware of any cost impacts that a local health department laboratory would necessarily incur in reasonable compliance with the proposed action because the new HIV testing

algorithm is not required to be used by licensed laboratories. Under this proposed action, licensed laboratories are allowed to continue to use the existing HIV test algorithm if they so choose at no increase or decrease in cost.

B. *Fiscal Impact on State Government:* None. The Department is not aware of any cost impacts that a State laboratory would necessarily incur in reasonable compliance with the proposed action because the new HIV testing algorithm is not required to be used by licensed laboratories. Under this proposed action, licensed laboratories are allowed to continue to use the existing HIV test algorithm if they so choose at no increase or decrease in cost.

C. *Fiscal Impact on Federal Funding of State Programs:* None.

D. *Fiscal Impact on Private Persons or Businesses Directly Affected:* The Department is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action because the new HIV testing algorithm is not required to be used by licensed laboratories. The Department estimates that the costs for existing HIV algorithm is approximately $4.34 to $5.34 per patient sample, and utilizing the newly developed HIV test algorithm will cost approximately $3.44 to $8.44 depending on the volume of the laboratory and the number of highly complex diagnostic steps required for a particular patient sample. These cost estimates include rental of laboratory equipment from the test manufacturer (standard laboratory operation cost). Under this proposed action, licensed laboratories are allowed to continue to use the existing HIV test algorithm if they so choose at no increase or decrease in cost.

E. *Other Nondiscretionary Cost or Savings Imposed on Local Agencies:* There are no known costs or savings imposed on local agencies in connection with this emergency regulatory package.

F. *Fiscal Impact on Local Agencies or School Districts:* None. There are no known cost impacts on local agencies or school districts.

Recordkeeping Requirement: None.

Significant Statewide Adverse Economic Impact Directly Affecting Business, Including the Ability to Compete:
The Department has made the determination that the regulations would not have a significant adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states. The proposed regulations allow licensed California laboratories to use a newly developed HIV testing algorithm that can identify positive HIV test results within 14 days of infection, as many as 31 days earlier than the existing HIV algorithm. This will allow for earlier notification of HIV test results to the patient, provide more rapid referrals for appropriate HIV treatment, and it will save lives. Importantly, under this proposed action, licensed

laboratories are allowed to continue to use the existing HIV test algorithm if they so choose at no increase or decrease in cost.

Result of Economic Impact Analysis:
The Department has determined that the regulations would not significantly affect the following:

1. The Creation or Elimination of Jobs within the State of California. This regulatory proposal will not create or eliminate jobs in California. The proposed regulations allow a new protocol to be used to test for HIV. The testing protocol will be different from the one protocol currently allowed, and the Department does not anticipate it will create or eliminate any jobs. In addition, licensed laboratories are allowed to continue to use the existing HIV test algorithm if they so choose.

2. The Creation of New Businesses or the Elimination of Existing Businesses within the State of California. The Department does not reasonably expect this regulatory proposal to create new businesses or eliminate existing businesses within the State of California. HIV testing is one of the many laboratory tests that licensed laboratories conduct in California, and laboratory tests and protocols often change over time due to research findings and discoveries. Allowing the use of a new protocol will not result in the creation or elimination of licensed laboratories. Licensed laboratories are allowed to continue to use the existing HIV test algorithm if they so choose at no increase or decrease in cost.

3. The Expansion of Businesses Currently Doing Business Within the State of California. This regulatory proposal is not expected to expand businesses within the State of California. HIV testing is one of the many laboratory tests that licensed laboratories conduct in California, and permitting a new protocol will not reasonably result in the expansion of businesses.

4. Worker Safety. This regulatory proposal does not affect worker safety because it does not impact workers.

5. California's Environment. This regulatory proposal does not affect the State's environment.

Statewide Effect on Housing Costs
The Department has determined that this regulatory proposal does not impact housing costs within California.

Benefits of the Regulation
The proposed regulations are expected to decrease the cost for HIV treatment and care in California. Early identification of acute HIV infection saves lives by lowering the transmission of HIV to non-infected members of the public and by more quickly addressing medical needs of those who test positive for HIV. Total discounted costs

associated with the lifetime care of a person with HIV are estimated at $385,200. This will reduce health care costs and allow funds that would otherwise be spent on HIV treatment and patient care to be spent in other ways that benefit the health and welfare of California residents, worker safety, the environment, or on other state priorities.

Small Business Determination

The Department has determined that the proposed regulations will not affect small businesses that process these HIV tests, and in the event that there are small businesses that do, this regulatory proposal does not require them to use the new HIV test algorithm. Licensed laboratories are allowed to continue to t use the existing HIV test algorithm if they so choose at no increase or decrease in cost.

Alternatives Considered

In accordance with Government Code Section 11346.5(a)(13), the Department has determined that no reasonable alternative considered 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 this regulatory 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.

Availability of Proposed Regulation Text, Statement of Reasons 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, at the address noted above, will be the location of public records, including reports, documentation, and other material related to the proposed regulations (rulemaking file). In addition, a copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations.

Materials regarding the action described in this notice (including this public notice, the regulation text, and the initial statement of reasons) 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, Proposed Regulations.

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) 445-2529 (or the California Relay Service at 711), send an email to regulations@cdph.ca.gov, or write to the Office of Regulations at Office of Regulations, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377. Upon specific request, these documents will be made available in Braille, large print, and 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.

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

DPH-13-007E

Date: DEC 4 2013

Ron Chapman, MD, MPH
Director & State Health Officer