INITIAL STATEMENT OF REASONS
FOR
HIV SCREENING TESTING BY LABORATORIES

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
CALIFORNIA CODE OF REGULATIONS
TITLE 17, DIVISON 1, CHAPTER 2, SECTION 1230 and CHAPTER 4, SECTION 2641.57

INTRODUCTION

The California Department of Public Health ("The Department") has adopted emergency regulatory amendments to the California Code of Regulations (CCR), Title 17, Sections 1230 and 2641.57, and they are now in effect. The emergency regulatory action amended HIV screening testing protocols to allow a newly developed HIV testing algorithm developed by certain federal public health agencies and the national HIV laboratory associations, as well as CDC, to be used by licensed California laboratories for laboratory screening testing for HIV.

The Department is now proposing to make those emergency regulatory amendments to Title 17, CCR, Sections 1230 and 2641.57 permanent. This proposed regulatory action will allow the newly developed Human Immunodeficiency Virus (HIV) testing algorithm to be used by licensed laboratories in California. These amendments would also permit the use of future developed protocols if they are recommended by the Centers for Disease Control and Prevention (CDC), the Clinical and Laboratory Standards Institute (CLSI), the Association of Public Health Laboratories (APHL) or the U.S. Department of Health and Human Services (DHHS). This proposed regulatory action permanently deletes language in Sections 1230 and 2641.57 that required recommended CDC protocols be published in the *Morbidity and Mortality Weekly Report* (MMWR) prior to use by a California licensed laboratory or approved public health laboratory.

AUTHORITY

The Department is authorized to adopt and enforce regulations pursuant to California Health and Safety (H&S) Code, Sections 131056 and 131200, for the execution of its duties. The Department's Office of AIDS has been delegated the statutory authority to coordinate HIV/AIDS-related programs and HIV reporting in California pursuant to H&S Code, Sections 121022, 131019, and 131051. H&S Code , Section 1603.1(f) gives the Department the authority to adopt regulations governing the procedures as it deems necessary to protect the public health and safety regarding reporting HIV infections, and H&S Code, Section 120895 authorizes the Department to establish HIV testing methods for anonymous HIV testing and blood plasma supply testing. Business and Professions Code, Article 2, and in particular Section 1224 also give the Department authority to

adopt, amend or repeal any Business and Professions regulations necessary for the administration of laboratories.

SUMMARY OF THE PROPOSED REGULATIONS

The Department's June 26, 2013 emergency regulatory action DPH-13-007E adopted emergency changes to the CCR so California laboratories could immediately use a superior test algorithm in order to significantly decrease the number of Californians becoming infected with HIV. The purpose of this regulatory action is to make those emergency regulatory changes permanent. The newly developed HIV testing algorithm can identify positive HIV test results within 14 days of infection, as many as 31 days earlier than the 1986 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.

Authority and Reference Citations:

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. The 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.

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.

POLICY STATEMENT OVERVIEW

Problem Statement:

Department proposed amendments will allow 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. Current California regulation requires that

California laboratories only use HIV testing algorithms that are recommended by the CDC *and* published in their journal the *Morbidity and Mortality Weekly Report* (MMWR). The CDC will not publish its recommendation in the MMWR and instead will publish online at www.AIDSInfo.nih.gov. This change by the CDC creates a regulatory barrier for California licensed laboratories to use the recommended HIV testing algorithm. The Department intends to remove this regulatory barrier by way of these proposed regulations.

Without this newly developed and superior HIV testing algorithm, more Californians each day will continue to be infected with HIV than would happen utilizing the new HIV testing algorithm. This specific emergency regulatory action will avoid serious harm to people with acute HIV infection by identifying their acute infection earlier so treatment can begin earlier. This emergency regulatory action will also reduce the number of HIV transmission cases to uninfected individuals, thus avoiding serious harm to public health and safety.

Objectives:

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.

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

Amend Section 1230: This proposed regulatory action would make permanent the emergency regulatory amendments to 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 DHHS. This proposal would also permanently delete the requirement that CDC publish its recommended protocols in the 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 newly recommended laboratory protocols, eliminate confusion for regulation users and provide clarity for laboratories and the public given CDC no longer publishes its recommended protocols in the MMWR.

Prior to the emergency regulatory language, CCR, Section 1230 used the term "confirmation" with respect to 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 permanent 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 reduces confusion for licensed laboratories using these regulations and provides clarity for the public.

Amend Section 2641.57: This regulatory proposal also permanently amends the definition of "HIV test algorithm" to permit the use of HIV testing 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.

Prior to the emergency regulatory amendments, Section 2641.57 also used 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.

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 no duplicative 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.

REASONABLE 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.

FACTS, EVIDENCE, DOCUMENTS, TESTIMONY, OR OTHER EVIDENCE OF NO SIGNIFICANT ADVERSE IMPACT ON BUSINESS

No facts, evidence, documents, testimony, or other evidence of any significant adverse economic impact on business have been identified.

ADVISORY GROUP OR OTHER AGENCY COMMENT, CONSULTATION AND/OR APPROVAL, INCLUDING CALIFORNIA CONFERENCE OF LOCAL HEALTH OFFICERS

This proposal is supported by the California Association of Public Health Laboratory Directors. Pursuant to H&S Code Section 131205, the Department will provide a copy of the public notice document, and make available the text of the proposed regulations and the Initial Statement of Reasons, to the California Conference of Local Health Officers for review and comment.

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/b7a7473c5a084eecaa23e146649e3f33.pdf, https://custom.cvent.com/ADE0EB81B3184D618E2FB8340F1EC28E/files/5aed5ead2525484fa1981dedad756cf4.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

ECONOMIC IMPACT ASSESSMENT AS REQUIRED BY GOVERNMENT CODE SECTION 11346.3(b) AND EVIDENCE SUPPORTING FINDING OF NO SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS

A. The proposed regulations are not expected to impact the following pursuant to Government Code Sections 11346.3(b)(1)(A), (B), (C) and (D):

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 will create new businesses or eliminate existing businesses within the State of California. HIV testing is one of 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 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.

B. The proposed regulations are expected to impact the following pursuant to Government Code Sections 11346.3(b)(1)(D):

1. Health and Welfare of California Residents. The proposed regulations are expected to increase and strengthen the health and welfare of California residents. The newly developed HIV testing algorithm 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.

2. Reduced Costs for HIV Treatment and Care. 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.

C. Business Impacts:

1. No Significant Statewide Economic Impact Directly Affecting Business. The Department has found no significant, statewide 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.

2. Cost Impacts on Representative Person or Business. 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.

3. There is No Effect on Housing Costs. This regulatory proposal does not impact housing within California.

4. There is No Effect on Small Businesses**.** This regulatory proposal does not impact small businesses. The Department is not aware of any 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 use the existing HIV test algorithm if they so choose at no increase or decrease in cost.