

FINAL STATEMENT OF REASONS

UPDATE SINCE INITIAL FILING OF PROPOSAL

Emergency amendments to the California Code of Regulations (CCR), Title 17, Article 3.5 (commencing with Section 2641.5) related to human immunodeficiency virus (HIV) disease reporting were initially promulgated on January 8, 2007. On July 1, 2007, Senate Bill (SB) 162 (Ortiz, Statutes of 2006, Chapter 241) took effect, creating the California Department of Public Health (CDPH) and transferring public health programs previously operated by the California Department of Health Services (CDHS) to CDPH. SB 162 (Ortiz, Statutes of 2006, Chapter 241) amends and renumbers specific Health and Safety (H&S) Code sections that are listed in the authority and reference citations of the emergency regulations for HIV reporting promulgated January 8, 2007. In particular, SB 162 (Ortiz, Statutes of 2006, Chapter 241) adopts H&S Code Section 131200 which specifically grants CDPH the authority to “adopt and enforce regulations for the execution of its duties.”

CDPH held an initial public comment period from March 23, 2007, through May 16, 2007. A number of comments were submitted to CDPH as part of this 45-day public comment period; Addendum 1 lists the names of those who submitted comments, and Addendum 2 documents the text of each comment. Addendum 3 summarizes the comments and gives CDPH’s response to each comment. As part of a second public comment period held July 30, 2007 through August 15, 2007, the emergency amendments, including the three forms incorporated by reference, were updated to amend references to the departmental name from CDHS to CDPH and to ensure that the appropriate sections of statute are listed in the citations. In addition, CDPH chose to amend regulatory text regarding the reporting of multi-test algorithms at the same time changes were made to the departmental name. One comment was submitted during the 15-day public comment period, and it is addressed in Addendum 4.

CDPH provided an opportunity for interested parties to make a timely request for a public hearing on the emergency amendments as part of the 45-day public comment period in accordance with Government Code Section 11346.8(a). The public notice document released March 23, 2007, stated, “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.” Two requests for a public hearing were submitted to CDPH in writing during the public comment period; however, the requests were submitted one day prior to the close of the public comment period (May 15, 2007) and on the final day of the public comment period (May 16, 2007). As the requests were made two weeks after the deadline for requesting a public hearing (May 1, 2007) stated in the public notice document, no public hearing was held.

Below, the text of the original statement of reasons has been updated to reflect the changes in statute due to SB 162 (Ortiz, Statutes of 2006, Chapter 241) and changes made by CDPH since the emergency amendments were first promulgated.

SUMMARY OF PROPOSAL

CDPH requests permanent adoption of emergency amendments made to the California Code of Regulations (CCR), Title 17, Article 3.5, that relate to HIV disease reporting and surveillance practices. H&S Code Section 121022 requires health care providers, laboratories, and local health officers to report cases of HIV infection by name. H&S Code Section 121022, which took effect April 17, 2006, stipulates that CDPH must, by April 17, 2007, promulgate emergency regulations to make HIV reporting practices in CCR, Title 17, Article 3.5 consistent with the provisions of H&S Code Section 121022.

The emergency regulation amendments are intended to:

- Repeal non-name code and partial non-name code used for HIV reporting by health care providers, laboratories, and local health officers;
- Require health care providers, laboratories, and local health officers to use patient name when reporting cases of HIV infection;
- Maintain confidentiality of personal information contained in HIV-related public health records by:
 - Instituting standards for data transmission; and
 - Implementing the use of a standard confidentiality agreement, CDPH 8689 (5/07) by all local health department (LHD) employees and contractors with access to confidential HIV-related information.
- Amend the regulations text to require reporting of all confirmed tests indicating the presence of HIV infection in accordance with confirmation protocols established by the federal Centers for Disease Control and Prevention (CDC);
- Facilitate provision of technical assistance by LHD representatives to assist health care providers with HIV reporting duties;
- Improve the quality and completeness of HIV case data collected for the purposes of reporting to the satisfaction of CDC; and
- Amend references to the name of the department as it occurs throughout CCR, Title 17, Article 3.5 (commencing with Section 2641.5) in response to creation of CDPH by H&S Code Section 131000 and the transfer of all public health functions of the former CDHS (including the functions and responsibilities of OA) to CDPH pursuant to H&S Code Sections 131050 and 131051.

The emergency regulations update the HIV/AIDS Case Report forms, including both the Adult and Pediatric Confidential Case Report Forms (DHS 8641A [9/01] and DHS 8641P [9/01], respectively), to comply with H&S Code Section 121022 and federal requirements for racial and ethnic designations imposed January 1, 2003 (Federal Notice, July 9, 1997, Directive No. 15 as included in Federal Register Notice, October

30, 1997). Specifically, these emergency amendments update, amend, revise the date, and incorporate by reference the following forms:

- “California Department of Public Health Adult HIV/AIDS Confidential Case Report,” CDPH 8641A, dated (5/07); and
- “California Department of Public Health Pediatric HIV/AIDS Confidential Case Report,” CDPH 8641P, dated (5/07).

The emergency regulations require the use of the HIV/AIDS Confidentiality Agreement (CDPH 8689 (5/07)) by all LHD employees and contractors prior to accessing confidential HIV-related public health records. The HIV/AIDS Confidentiality Agreement informs staff of the penalties associated with a breach of confidentiality as well as the procedures for reporting a breach. These emergency amendments incorporate by reference the form, “California Department of Public Health HIV/AIDS Confidentiality Agreement,” CDPH 8689, dated (5/07).

AUTHORITY

H&S Code Section 121022(c) requires CDPH to promulgate emergency regulations that bring the provisions of CCR, Title 17, Article 3.5 (commencing with Section 2641.5) into agreement with H&S Code Section 121022, which mandates reporting of cases of HIV infection by name. Prior to promulgation of the emergency amendments, CCR, Title 17, Sections 2641.5-2643.20 required health care providers and laboratories to report confirmed HIV tests to the local health officer using the non-name code instead of the name or other personally identifying information. H&S Code Section 131000 establishes CDPH and H&S Code Sections 131050 and 131051 transfer all public health functions of the former CDHS to CDPH, including the functions of OA (see H&S Code Section 131051). H&S Code Section 131200 authorizes CDPH to adopt and enforce regulations, and H&S Code Section 131080 authorizes CDPH to regulate local health authorities. H&S Code Section 120125 requires CDPH to examine the causes of communicable diseases occurring or likely to occur in California. H&S Code Section 120140 authorizes CDPH, upon being informed by a health officer of a contagious, infectious, or communicable disease, to ascertain the nature of the disease and prevent its spread. H&S Code Section 120130 authorizes CDPH to establish a list of communicable or non-communicable diseases that are reportable by the local health officer to CDPH and are published in CCR, Title 17. To accomplish this, CCR, Title 17, Division 1, Chapter 4, Subchapter 1, Article 1, Section 2500 directs health care providers to report AIDS and other reportable diseases to the local health officer with patient name, and Section 2502 specifies that the local health officer shall report these cases to CDPH. According to H&S Code Section 131019, CDPH/Office of AIDS (OA) is the lead agency within the state responsible for coordinating HIV/AIDS related programs.

BACKGROUND

HIV/AIDS

HIV is the virus that causes AIDS. HIV is an infectious agent that disables a person's immune system, the body's natural defense against disease. The only way a person can become infected with HIV is through exposure to HIV-infected blood or other body fluids including semen and vaginal fluids. HIV is primarily transmitted through unprotected sex (sex without a condom or other barrier use) and injection drug use (sharing of contaminated syringes and other injection equipment). Children born to infected mothers, exposed health care workers caring for HIV-infected patients, and, rarely, recipients of blood transfusions or organ donations can also be at risk. There is no cure for HIV infection. HIV-infected persons who do not receive appropriate medical care may become ill and develop an AIDS defining condition.

AIDS is a syndrome, or collection of signs and symptoms, that is attributed to the natural course of HIV infection and represents the advanced stage of HIV disease. CDC has classified a total of 27 different diagnoses and conditions as AIDS-defining illnesses.¹ Once diagnosed with AIDS, many people can subsequently begin, resume, or modify HIV treatment regimens and maintain or return to productive, relatively healthy lives.

Disease Surveillance

The purpose of conducting public health surveillance is to determine ongoing patterns of disease occurrence and the potential for disease in a population. The federal government, CDPH, LHDs and community planning boards use disease surveillance data to describe and monitor health trends in their jurisdictions, set priorities, allocate resources, and facilitate research. Further, these data inform the planning, implementation, and evaluation of public health interventions, programs, and services.

California requires health care providers to confidentially report over 85 diseases and conditions, including AIDS, to local health officers. In addition to AIDS case data, accurate HIV case data are necessary for public health officials to fully assess the spread and impact of the HIV/AIDS epidemic. AIDS diagnosis occurs late in the course of HIV infection and HIV case reporting provides a more accurate perspective on current and ongoing trends in HIV transmission. HIV case reporting allows health officials to track disease progression and better assess needs for resource allocation.

HIV Reporting Under California Regulations

HIV reporting by non-name code was implemented in California on July 1, 2002. As of March 31, 2006, 41,155 unique adult/adolescent and pediatric cases of HIV had been reported to CDPH/OA using the non-name code. On April 17, 2006, H&S Code Section 121022 took effect mandating HIV reporting by patient name. The CDPH/OA emergency amendments seek to assist health care providers, laboratories, and LHDs in transitioning from HIV reporting by non-name code to HIV reporting by name.

¹ CDC, 1993 Revised Classification System for HIV Infection and Expanded Surveillance Case Definition for AIDS Among Adolescents and Adults, MMWR 41 (RR17), December 18, 1992, p. 1.

California regulations adopted in 2002 described a non-name system for reporting HIV cases. Local and state health department activities are very similar under both the non-name system and the name-based HIV reporting system adopted by these emergency amendments. LHD staff obtain HIV case information from health care providers, laboratories, and other data sources. LHD representatives often provide technical assistance to health care providers and frequently conduct on-site chart reviews and case report completion at the health care provider's office. LHD staff assure the confidentiality, accuracy, and completeness of the data, complete the HIV/AIDS case report form as appropriate, and forward the information to CDPH/OA. CDPH/OA staff verify data accuracy and forward the information without personal identifiers to CDC using a secure, electronic data transfer method. The HIV reporting system is a confidential process that is protected by security systems at the federal, state, and local levels.

The laboratory is usually the first entity to identify a confirmed HIV test. Under the non-name HIV reporting system, the laboratory submitted the partial non-name code (soundex code, date of birth, and gender) for every confirmed HIV test to both the LHD and the health care provider. Along with the partial non-name code, laboratories submitted all of the same information required for other reportable diseases (e.g., date and type of test; results of the test; laboratory and health care provider name/address/phone), with the exception of the patient's name or other personal information such as a complete Social Security Number (SSN), address, or telephone number.

Under the non-name HIV reporting system, health care providers reported confirmed HIV tests to the local health officer using the non-name code (soundex code, date of birth, gender, and last four digits of SSN). The health care provider submitted one report for each case using the Adult Confidential HIV/AIDS Case Report (DHS 8641A [9/01]) for patients 13 years of age and over or the Pediatric HIV/AIDS Case Report (DHS 8641P [9/01]) for patients 12 years of age or younger.

NECESSITY

Under current federal law, California risks a loss of up to \$50 million annually in Ryan White HIV/AIDS Treatment Modernization Act (Ryan White) funds if CDC does not confirm California's reported HIV cases for use in federal funding formulas. Under California's code-based HIV reporting system, reported living HIV cases represented 40.9 percent of the state's combined living HIV and AIDS cases. This represents a substantial contribution to the revised Ryan White funding formula that takes effect in 2007. According to a letter from CDC Director Dr. Julie Gerberding to Governor Arnold Schwarzenegger dated December 27, 2005, "CDC accepts data only from jurisdictions with confidential, name-based systems," and "data from non-name-based systems cannot be included in counts for the [Ryan White] formulas." Under the recently passed provisions of the Ryan White Act, following a three-year transition period, cases of HIV

infection reported in California will be included in Ryan White formulas only if the case is reported by name. Adopting the emergency amendments to the HIV reporting regulations will improve the quality and completeness of HIV data for purposes of reporting to the satisfaction of CDC and help prevent a significant funding loss.

EMERGENCY AMENDMENTS

H&S Code Section 121022, which took effect April 17, 2006, requires health care providers and laboratories to report cases of HIV infection by name to local health officers, and requires local health officers to report unduplicated cases of HIV infection by name to CDPH. H&S Code Section 121022(c) requires CDPH to promulgate emergency regulations that make the provisions of CCR, Title 17, Article 3.5 (commencing with Section 2641.5) consistent with the new statute. H&S Code Section 131000 establishes CDPH and H&S Code Sections 131050 and 131051 transfer all public health functions of the former CDHS to CDPH, including the functions of OA (see H&S Code Section 131051). H&S Code Section 131200 authorizes CDPH to adopt and enforce regulations, and H&S Code Section 131080 authorizes CDPH to regulate local health authorities. H&S Code Section 120125 requires CDPH to examine causes of communicable diseases occurring or likely to occur in California. H&S Code Section 120140 authorizes CDPH, upon being informed by a health officer of a contagious, infectious, or communicable disease, to ascertain the nature of the disease and prevent its spread. H&S Code Section 120130 authorizes CDPH to establish a list of communicable or non-communicable diseases that are reportable by the local health officer to CDPH and are published in CCR, Title 17. According to H&S Code Section 131019, CDPH/OA is the lead agency within the state responsible for coordinating HIV/AIDS related programs.

In light of CDPH's statutory authority outlined above, CDPH amends CCR, Title 17, Article 3.5 (Sections 2641.5-2643.20) in the following ways:

- **Require reporting of patient name.**

These emergency amendments amend text to require health care providers, laboratories, and local health officers to submit patient name as part of their respective HIV reporting practices. This change makes regulatory guidance regarding HIV reporting consistent with the statutory mandates in H&S Code Section 121022(a) that require cases of HIV infection to be reported using patient name. Consistency between statutory and regulatory reporting requirements eliminates the confusion health care providers, laboratories, and local health officers currently experience when trying to fulfill their reporting obligations.

Affected Sections:

- Amend CCR, Title 17, Section 2643.5 by replacing "*patient surname*" with "*complete name of patient*" in subsection (b)(1) to require health care providers to submit complete patient name to the laboratory when ordering an HIV test. The change ensures laboratories receive the information they are to report to the

local health officer for a confirmed HIV test in order to meet the requirements of H&S Code Section 121022 and CCR, Title 17, Section 2643.10.

- Amend CCR, Title 17, Section 2643.10 by including “*complete name of patient*” in the list of items laboratories are required to submit to local health officers when reporting confirmed HIV tests in subsection(a)(1).
 - Amend CCR, Title 17, Section 2641.55 to incorporate by reference the updated Adult and Pediatric HIV/AIDS Case Report forms, CDPH 8641A (5/07) and CDPH 8641P (5/07), respectively. The forms are amended such that all fields, including patient name, shall be completed for HIV cases as well as AIDS cases. Instructions pertaining to different reporting methods for HIV cases and AIDS cases are removed from the forms. Health care providers and local health officers use the forms when reporting HIV cases as required by CCR, Title 17, Sections 2643.5(c) and 2643.15(b), respectively. A more detailed explanation of form changes is provided later in this document.
- **Permit release of a patient’s personal information for HIV reporting purposes.**

These emergency amendments repeal text that prohibits release of a patient’s personal information to the local health officer by health care providers or laboratories. Senate Bill (SB) 699 (Soto, Statutes of 2006, Chapter 20) amended H&S Code Section 120980(i) so that disclosure of HIV test results is not subject to liability or sanction (as described in H&S Code Section 120980) as long as the disclosure is made in accordance with any reporting requirement for a case of HIV infection, including AIDS. H&S Code Section 121022, adopted through passage of SB 699 (Soto, Statutes of 2006, Chapter 20), requires health care providers and laboratories to report the patient name to the local health officer. As a result of the statutory changes, the prohibition against release of a patient’s personal information to the local health officer is unnecessary and is in conflict with statute. This change eliminates the conflict between statute and regulation.

Affected Sections:

- Repeal CCR, Title 17, Section 2643.5(e) containing the phrase that prohibits release of a patient’s personal information from the health care provider to the local health officer unless the patient’s clinical condition meets the AIDS reporting criteria, “*When reporting a confirmed HIV test, a health care provider shall not report a patient’s personal information to the local Health Officer except for patients whose clinical conditions meet the AIDS reporting criteria, as specified in Article 1 of this Subchapter.*”
 - Repeal CCR, Title 17, Section 2643.10(c) containing the phrase that prohibits release of a patient’s personal information from the laboratory to LHD, “*A laboratory shall not transmit a patient’s personal information to the local health department.*”
- **Repeal use of the Non-Name Code.**

These emergency amendments repeal the non-name code used by health care providers and local health officers to report cases of HIV infection prior to April 17,

2006, when the name reporting requirements of H&S Code Section 121022 took effect. The non-name code is no longer sufficient for reporting HIV cases. References to the non-name code are changed to refer to patient name so that the regulations are consistent with statutory reporting requirements.

Affected Sections:

- Repeal CCR, Title 17, Section 2641.75 which defines “*Non-Name Code.*”
- Amend CCR, Title 17, Section 2643.5 by:
 - Removing the phrase, “*complete the Non-Name Code (as specified in Section 2641.75)*” from subsection (c); and
 - Replacing the phrase, “*Non-Name Code*” with the word “*name*” in subsection (d).

- **Repeal use of the Partial Non-Name Code.**

These emergency amendments repeal the partial non-name code used by laboratories to report confirmed HIV tests prior to April 17, 2006, when the name reporting requirements of H&S Code Section 121022 took effect. The partial non-name code is no longer sufficient for reporting confirmed HIV tests. References to the partial non-name code are replaced by references to patient name to ensure regulations are consistent with statutory reporting requirements. Laboratories shall continue to report a patient’s date of birth and gender to the local health officer. In light of the emergency amendment removing the partial non-name code, the two elements date of birth and gender are explicitly added, along with patient name, to the list of items laboratories are required to report under CCR, Title 17, Section 2643.10(a). This addition makes it clear that the date of birth and gender continue to be reportable after the partial non-name code is repealed. H&S Code Section 121022(a) requires local health officers to report unduplicated HIV cases to CDPH. Patient date of birth and gender, two important data elements used in the unduplication process, are retained in the regulations even though the partial non-name code is repealed so that local health officers have enough information to fulfill their obligation under H&S Code Section 121022(a) to unduplicate case reports.

Affected Sections:

- Repeal CCR, Title 17, Section 2641.77 which defines “*Partial Non-Name Code.*”
- Amend CCR, Title 17, Section 2643.5 by removing the phrase, “*and Partial Non-Name Code from a laboratory*” from subsection (c).
- Amend CCR, Title 17, Section 2643.10 by:
 - Repealing existing subsection (a) containing the phrase, “*The laboratory director or authorized designee shall create a Partial Non-Name Code (as specified in Section 2641.77) for each confirmed HIV test,*” requiring laboratories to create the partial non-name code;
 - Repealing partial non-name code from the list of items laboratories are required to submit to local health officers when reporting confirmed HIV tests in subsection (a)(1);

- Adding “*Patient date of birth (two-digit month, two-digit day, four-digit year)*” and “*Patient gender (male, female, transgender male-to-female, transgender female-to-male)*” to the list of items laboratories are required to submit to local health officers in subsection (a);
 - Renumbering subsequent items in subsection (a) accordingly;
 - Repealing existing subsection (e) containing the phrase, “*A laboratory shall convey the patient’s Partial Non-Name Code to the submitting health care provider when reporting confirmed HIV test results,*” which required laboratories to give the partial non-name code to the health care provider; and
 - Relettering subsequent subsections accordingly.
- **Repeal use of the cross-reference system.**

These emergency amendments repeal the requirement that health care providers maintain a system cross-referencing patient data by code in order to complete case reports and to facilitate communication with the local health officer. The cross-reference system is no longer necessary since health care providers and local health officers both have access to patient name under H&S Code Section 121022. Eliminating the complicated and cumbersome cross-reference system decreases the workload for health care providers.

Affected Section:

- Amend CCR, Title 17, Section 2643.5 by removing existing subsection (h) containing the phrase, “*For all HIV infected patients without an AIDS diagnosis, the health care provider shall maintain a system which cross-references patient data by using either the Partial Non-Name Code or the Non-Name Code. This system shall be used only to exchange information with the Local Health Officer in order to complete or unduplicate the HIV case reports.*”
- **Adopt the HIV/AIDS Confidentiality Agreement, “California Department of Public Health HIV/AIDS Confidentiality Agreement” CDPH 8689 (5/07).**

These emergency regulations adopt the HIV/AIDS Confidentiality Agreement which outlines the penalties associated with disclosure of confidential HIV-related public health records and the procedures to follow in the event of a breach of confidentiality. CDPH developed the HIV/AIDS Confidentiality Agreement in accordance with H&S Code Section 121022(e) which requires LHD employees and contractors to sign confidentiality agreements developed by CDPH prior to accessing confidential HIV-related public health records. The form, “California Department of Public Health HIV/AIDS Confidentiality Agreement,” CDPH 8689 (5/07) is incorporated by reference. Electronic and paper copies of the HIV/AIDS Confidentiality Agreement are available to LHDs. Adoption of the HIV/AIDS Confidentiality Agreement is necessary to meet the requirements of H&S Code Section 121022(e). The HIV/AIDS Confidentiality Agreement and related regulation text have been updated to reflect the statutory changes enacted through SB 162 (Ortiz, Statutes of 2006, Chapter 241), including the name change from CDHS to CDPH.

Affected Sections:

- Adopt CCR, Title 17, Section 2641.56 which defines “*HIV/AIDS Confidentiality Agreement*” to mean a reference to CDPH 8689 (5/07).
- Amend CCR, Title 17, Section 2643.15 to adopt subsection (d) requiring all LHD employees and contractors to sign the HIV/AIDS Confidentiality Agreement prior to accessing confidential HIV-related public health records.

CDPH 8689 (5/07), HIV/AIDS Confidentiality Agreement

The following text is contained in the HIV/AIDS Confidentiality Agreement:

Summary of Statutes Pertaining to Confidential Public Health Records and Penalties for Disclosure

All HIV/AIDS case reports and any information collected or maintained in the course of surveillance-related activities that may directly or indirectly identify an individual are considered confidential public health record(s) under California Health and Safety Code (HSC) Section 121035(c) and must be handled with the utmost confidentiality. Furthermore, HSC §121025(a) prohibits the disclosure of HIV/AIDS-related public health records that contain any personally identifying information to any third party, unless authorized by law for public health purposes, or by the written consent of the individual identified in the record or his/her guardian/conservator. Except as permitted by law, any person who negligently discloses information contained in a confidential public health record to a third party is subject to a civil penalty of up to \$2,500 plus court costs, as provided in HSC §121025(e)(1). Any person who willfully or maliciously discloses the content of a public health record, except as authorized by law, is subject to a civil penalty of \$5,000-\$10,000 plus court costs as provided by HSC §121025(e)(2). Any willful, malicious, or negligent disclosure of information contained in a public health record in violation of state law that results in economic, bodily, or psychological harm to the person named in the record is a misdemeanor, punishable by imprisonment for a period of up to one year and/or a fine of up to \$25,000 plus court costs (HSC §121025(e)(3)). Any person who is guilty of a confidentiality infringement of the foregoing type may be sued by the injured party and shall be personally liable for all actual damages incurred for economic, bodily, or psychological harm as a result of the breach (HSC §121025(e)(4)). Each disclosure in violation of California law is a separate, actionable offense (HSC §121025(e)(5)).

Because an assurance of case confidentiality is the foremost concern of the California Department of Public Health, Office of AIDS (OA), any actual or potential breach of confidentiality shall be immediately reported. In the event of any suspected breach, staff shall immediately notify the director or supervisor of the local health department’s HIV/AIDS surveillance unit who in turn shall notify the Chief of the HIV/AIDS Case Registry Section or designee. OA, in conjunction with the local health department and the local health officer shall promptly investigate the suspected breach. Any evidence of an actual breach shall be reported to the law enforcement agency that has jurisdiction.

Employee Confidentiality Pledge

I recognize that in carrying out my assigned duties, I may obtain access to private information about persons diagnosed with HIV or AIDS that was provided under an assurance of confidentiality. I understand that I am prohibited from disclosing or otherwise releasing any personally identifying information, either directly or indirectly, about any individual named in any

HIV/AIDS confidential public health record. Should I be responsible for any breach of confidentiality, I understand that civil and/or criminal penalties may be brought against me. I acknowledge that my responsibility to ensure the privacy of protected health information contained in any electronic records, paper documents, or verbal communications to which I may gain access shall not expire, even after my employment or affiliation with the Department has terminated.

By my signature, I acknowledge that I have read, understand, and agree to comply with the terms and conditions of this Confidentiality Agreement.

The HIV/AIDS Confidentiality Agreement, as required in H&S Code Section 121022(e), informs local and state health department staff and contractors of the penalties associated with a breach of confidentiality and the procedures for reporting a confidentiality breach. The first paragraph of the HIV/AIDS Confidentiality Agreement includes the relevant statute citations and a description of the corresponding penalties associated with the negligent, willful, or malicious unauthorized disclosure of confidential HIV-related public health records.

The second paragraph of CDPH 8689 (5/07) outlines the procedures to follow in the event of a breach of confidentiality, in accordance with H&S Code Section 121022(g). Under H&S Code Section 121022(g), the local health officer, in conjunction with CDPH/OA, shall immediately investigate any potential or actual breach of confidentiality. Furthermore, H&S Code Section 121022(g) requires that any evidence of a potential or actual breach of confidentiality shall be reported to the appropriate law enforcement agency.

The third paragraph of CDPH 8689 (5/07) contains an employee confidentiality pledge explaining the penalties associated with a confidentiality breach and the procedures to report such a breach in terms of the job responsibilities of the employee. This section of the HIV/AIDS Confidentiality Agreement summarizes the terms and conditions of the form in language that is clear and understandable. The HIV/AIDS Confidentiality Agreement contains a pledge and an acknowledgement statement so that CDPH/OA and the LHD have documentation that an employee has read and understood the requirements associated with preserving the confidentiality of HIV-related public health records prior to allowing the employee access to confidential information. In the event of breach of confidentiality, the pledge and associated signature of the employee may be important to document the employee's prior agreement to preserve confidentiality.

The bottom of the CDPH 8689 (5/07) form contains fields for: 1) the printed name and signature of the employee, dated; 2) the printed name and signature of the supervisor, dated; and 3) the printed name and signature of the Chief of the CDPH/OA HIV/AIDS Case Registry Section, dated. The HIV/AIDS Confidentiality Agreement is effective only if it has been signed by the Chief of the CDPH/OA HIV/AIDS Case Registry Section. Signature of the Chief of the CDPH/OA HIV/AIDS Case Registry Section allows CDPH/OA to monitor who has authorized access to confidential HIV-related public health records.

As part of the second public comment period, held July 30, 2007 through August 15, 2007, the HIV/AIDS Confidentiality Agreement was updated from the version DHS 8689 (10/06) to CDPH 8689 (5/07) in order to amend references to the departmental name from CDHS to CDPH. The changes were made in response to the creation of CDPH and transfer of public health functions to CDPH (H&S Code Sections 131000, 131050, and 131051). Specifically, the phrase "California Department of Health Services" is replaced by the phrase "California Department of Public Health" in the heading at the upper right hand corner, in the first sentence of the second paragraph, and in the signature box for the Chief of the HIV/AIDS Case Registry Section. The previous form number, "DHS 8689 (10/06)", is replaced by the updated form number "CDPH 8689 (5/07)" in the footer at the lower left hand corner of the page, and in the text of CCR, Title 17, Section 2641.56.

- **Adopt data transmission methods.**

The emergency regulations adopt text detailing the methods by which health care providers and laboratories shall submit reports to the local health officer. Specific data transmission methods are listed in regulation to preserve the confidentiality of highly sensitive reports containing personal information for persons with HIV. Health care providers and laboratories shall submit reports by traceable mail or by person-to-person transfer with the local health officer or designee. The regulations prohibit submission of reports by electronic facsimile transmission, electronic mail ("e-mail"), or by non-traceable mail. Fax, e-mail, and non-traceable mail do not protect confidential HIV reports sufficiently from the risk of disclosure, which is especially important in light of the civil and criminal penalties associated with negligent disclosure of HIV-related records. SB 699 (Soto, Statutes of 2006, Chapter 20) significantly increased the penalties associated with inadvertent disclosure of HIV-related records by amending H&S Code Sections 120980 and 121025. The data transmission methods adopted by the emergency amendments conform existing regulations with the increased confidentiality and disclosure provisions of statute adopted through SB 699 (Soto, Statutes of 2006, Chapter 20). The data transmission methods reduce the risk of inadvertent disclosures, thereby reducing the risk faced by health care providers and laboratories in light of the increased penalties for disclosure.

Affected Sections:

- Amend CCR, Title 17, Section 2643.5(c) to add language stipulating that health care providers shall submit reports by traceable mail or person-to-person transfer and shall not submit reports by electronic facsimile transmission, e-mail, or non-traceable mail.
- Amend CCR, Title 17, Section 2643.10 to adopt subsection (b) which stipulates that laboratories shall submit reports by traceable mail or person-to-person transfer and shall not submit reports by electronic facsimile transmission, e-mail, or non-traceable mail.

- **Report all Confirmed HIV tests, including HIV Test Algorithms.**

A new point-of-care HIV testing procedure has been approved which is capable of providing HIV negative and “preliminarily positive” HIV test results at the point of care, independent of additional laboratory testing. The procedure, known as the “rapid HIV test,” meets or exceeds the levels of sensitivity and specificity of traditional laboratory screening techniques and requires limited training and oversight. H&S Code Section 120917 provides language to allow for the rapid confirmation of initially reactive test results using a second, different, rapid HIV test (and multi-test algorithm) approved by the federal Food and Drug Administration (FDA) for that purpose. Confirmed HIV tests document cases of HIV infection, which are reportable pursuant to H&S Code Section 121022, even if the confirmed HIV test is part of a multi-test procedure such as using two different rapid tests. CDC confirmation protocols list multi-test procedures used to determine the presence of HIV infection which are routinely published in CDC’s Morbidity and Mortality Weekly Report (MMWR), and available on the CDC website.

A “laboratory” is commonly understood to be a physical building dedicated in part to processing laboratory specimens and reporting results to health care providers. In rapid HIV testing services, the person working in a publicly-funded confidential counseling and testing program, commonly known as the HIV test counselor (defined as a “health care provider” in CCR, Title 17, Section 2641.45(c)), obtains the specimen and performs the HIV test. The location where the test is performed becomes the “laboratory” by the Clinical Laboratory Improvement Amendments (CLIA) standards found in Title 42 of the Code of Federal Regulations, Part 493.

HIV reporting regulations enacted in 2002 defined a health care provider as “... *an individual who submits a biological specimen to a laboratory for a test to detect the presence of HIV, a component of HIV or antibodies to or antigens of HIV, [and] receives the test results*” and required the health care provider to report HIV cases within seven calendar days of “*receipt of a patient’s confirmed HIV test.*” If a health care provider confirms the presence of HIV antibody at the point of care (or location where the service is provided) using two rapid HIV tests, the specimen is not “submitted” to a laboratory and test results are not “received” from a laboratory. Instead, specimen processing occurs in the health care provider’s office or other testing venue.

The CDPH emergency regulations adopt text to ensure that health care providers and laboratories understand that all tests determining the presence of HIV infection (or confirmed HIV test as defined in CCR, Title 17, Section 2641.30), including multi-test algorithms performed at the point of care, shall be reported to the local health officer. The change clarifies that an individual who performs an HIV test at the point of care is a “health care provider” as defined by CCR, Title 17, Section 2641.45 and is required to report all confirmed HIV tests within seven calendar days, even if the confirmed HIV test result is not “received” from a laboratory. The change avoids confusion about whether health care providers are required to report

confirmed HIV tests that are neither processed in nor reported from a traditional laboratory setting. Reporting all confirmed HIV tests, including multi-test algorithms, increases the completeness of name-based HIV reporting, which is critical to maintaining continued federal funding and developing an accurate understanding of the scope and breadth of the HIV epidemic in California.

The wording of this amendment has changed since the emergency regulations were initially promulgated on January 8, 2007. In the definition of "HIV Test Algorithm" (CCR, Title 17, Section 2641.57), the phrase "*confirmation protocols published in the Centers for Disease Control and Prevention's Morbidity and Mortality Weekly Report (MMWR)*" has replaced the phrase "*tests approved by the federal Food and Drug Administration for that purpose*". As CDC confirmation protocols incorporate only tests approved by FDA, it is not necessary to reference FDA in the regulation text. The reference to FDA has also been removed from the definition of "Confirmed HIV Test" (CCR, Title 17, Section 2641.30).

Affected Sections:

- Amend CCR, Title 17, Section 2641.30 to expand the definition of "*Confirmed HIV Test*" to include all HIV test algorithms as defined in CCR, Title 17, Section 2641.57.
 - Amend CCR, Title 17, Section 2641.45 to expand the definition of "*Health Care Provider*" to include an individual who obtains the results of an HIV test or HIV test algorithm. The definition continues to stipulate that the individual must be licensed under the Business and Professions Code, a designee of such a person, or an HIV test counselor.
 - Adopt CCR, Title 17, Section 2641.57 which defines "*HIV Test Algorithm.*"
 - Amend CCR, Title 17, Section 2643.5 to add "*or determination by the health care provider of a patient's confirmed HIV test*" to subsection (c).
- **Facilitate communication between local health officers and health care providers.**

Health care providers frequently request direct assistance with HIV reporting from LHD staff. When providing technical assistance, LHD staff review medical charts of HIV patients and complete case report forms. Strict confidentiality policies, including data transmission standards and use of the HIV/AIDS Confidentiality Agreement by LHD staff, protect medical information from disclosure to unauthorized parties. The CDPH emergency regulations adopt text facilitating the technical assistance process to assure that LHDs can continue to provide on-site services to interested health care providers. In the past, some health care providers requiring technical assistance from LHD staff were unclear if LHD staff were authorized to review medical charts given the confidential nature of the records, which resulted in incomplete and inaccurate HIV reporting. The emergency amendment to CCR, Title 17, Section 2643.5 resolves the confusion and leads to increased completeness of HIV reporting thereby fulfilling the mandate of H&S Code Section 121022 (a) "to

ensure knowledge of current trends in the HIV epidemic and to assure that California remains competitive for federal HIV and AIDS funding.”

Affected Section:

- Amend CCR, Title 17, Section 2643.5 to adopt subsection (g) to ensure that LHD staff may provide case reporting assistance to health care providers by conducting chart reviews or completing HIV/AIDS case report forms.
- **Update HIV/AIDS Case Report forms.**

The CDPH emergency regulations update the Adult and Pediatric HIV/AIDS Case Report forms so that they are consistent with the statutory mandates in H&S Code Section 121022(a) that require cases of HIV infection to be reported using patient name. The forms are also updated to reflect the creation of CDPH by H&S Code Section 131000 and the transfer of all public health functions of the former CDHS (including the functions and responsibilities of OA) to CDPH pursuant to H&S Code Sections 131050 and 131051. Use of updated forms eliminates confusion that health care providers, laboratories, and local health officers experience regarding what information should be reported and to whom. Electronic and paper copies of these forms are made available to LHDs. The updated forms are incorporated by reference below.

Inadvertent errors on the forms incorporated by reference during the initial promulgation of the emergency regulations in January 2007 [DHS 8641A (06/06) and DHS 8641P (06/06)] were corrected when the emergency regulations were readopted in May 2007 [DHS 8641A (5/07) and DHS 8641P (5/07)]. The corrections were made available for public comment on the forms incorporated by reference during the second comment period held July 30, 2007 through August 15, 2007 [CDPH 8641A (5/07) and CDPH 8641P (5/07)].

Affected Section:

- Amend CCR, Title 17, Section 2641.55 to incorporate by reference the Adult and Pediatric HIV/AIDS Case Report forms: CDPH 8641A (5/07) and CDPH 8641P (5/07), respectively.

PROPOSED AMENDMENTS TO HIV/AIDS CASE REPORT FORMS

CDPH 8641A (5/07), Adult HIV/AIDS Confidential Case Report

The Section numbers used in this description refer to the CDPH 8641A (5/07).

PAGE ONE

Header

- In the heading at the upper right-hand corner, the departmental name has been changed to “California Department of Public Health” from “Department of Health Services.”

Section I. This is for Health Department use. Uniquely identifying information is not transmitted to the Centers for Disease Control and Prevention.

- Placement of this section has shifted from the bottom to the top of the page (previously was Section VII). Relocation of these fields to Section I is necessary to follow the data entry sequence in the HIV/AIDS Reporting System (HARS) and facilitate filing and case review procedures.
- The title of this section has been changed from, “FOR AIDS CASES ONLY - Patient-identifier information is not transmitted to CDC.” to, “This is for Health Department use. Uniquely identifying information is not transmitted to the Centers for Disease Control and Prevention.” Fields in this section shall be completed for HIV cases as well as AIDS cases following the changes in California statute made by the adoption of H&S Code Section 121022. The phrase “Centers for Disease Control and Prevention” is used to avoid possible confusion with the California Department of Corrections and Rehabilitation that may arise from use of the acronym “CDC.”
- The fields “Soundex code”, “Date of Birth”, “Gender”, “Lab report/Accession number”, and “*Confidential C&T number” are now included in Section I instead of being part of a separate section (Section II on DHS 8641A (9/01)).
- The heading and subheadings, “Section II. For HIV and AIDS Cases” and “Section II. For Non-AIDS Cases Only,” have been removed. There is no need for separate fields for HIV reporting since HIV and AIDS both are reported by name.
- The field “Last four digits of SSN” has been removed. This field was originally part of the non-name code used to report HIV cases. The non-name code is no longer used to report HIV since HIV cases are reported by name under H&S Code Section 121022.
- The field, “CLIA number” is added. This field is used to distinguish the particular laboratory that performed a test. LHDs use CLIA number as part of matching and follow-up procedures.
- The “Lab report/Accession number” field is amended in two ways:
 - The field is renamed, “Lab report/Accession number” instead of “Lab report number.” The word “accession” is added because laboratories are often more familiar with the term “accession number” than the term “lab report number.”
 - The eight blank boxes have been removed from this field. This amendment will provide space to document laboratory report numbers larger than eight digits.

Section II. Health Department Use Only

- Placement of Section II, previously numbered Section I on DHS 8641A (9/01), has been lowered to accommodate the shift in the position of Section I (*This is for Health Department use. Uniquely identifying information is not transmitted to the Centers for Disease Control and Prevention.*) to the top of the page. Repositioning these fields is necessary to follow the data entry sequence in the HARS and to facilitate filing and case review procedures.
- Individual boxes are removed from the fields “State patient number” and “City/county patient number” to provide space to document numbers larger than ten digits.

Blank Box on Left Side of Form

- A blank box is added to the left side of the form in order to accommodate current filing and case review procedures at the state HIV/AIDS Case Registry. The state filing system involves affixing a label to the form that provides the patient's state case number, soundex code, and date of birth. Adding a space to the form for this sticker will help protect critical data from being concealed underneath. LHDs have stated the change would not disrupt their current filing procedures.

Section III. Demographic Information

- “*Ethnicity*” and “*Race*” fields are re-formatted in order to satisfy federal requirements imposed January 1, 2003 (Federal Notice, July 9, 1997, Directive No. 15). These requirements call for specific race and ethnicity documentation that is not requested on state forms DHS 8641A (9/01) and DHS 8641P (9/01). In order to comply with the federal mandate, CDPH/OA immediately developed an addendum that is attached to each case report before submission to LHD. This amendment eliminates the need to attach the addendum to each case report. The numbers are removed from the boxes of the race field due to related changes in the way information is stored in HARS.
- A field is added entitled, “*Expanded race (specify):*” to facilitate collection of data for the field found in HARS. This field allows for collection of more detailed information than permitted in the race and ethnicity fields, such as specifying “Mexican” for someone listed as “Hispanic” in the ethnicity field. LHDs and CDPH/OA use this information to better target resources to affected subpopulations.
- “*Residence at first diagnosis of HIV or AIDS*” has been changed from, “*Residence at diagnosis,*” to help assure the case being reported is assigned to the appropriate city/county health jurisdiction. Since patients can move throughout the state, the residence at initial diagnosis is requested, not the current residence.
 - A box for “*Homeless*” is added with instructions, “*(Must use city/county/ZIP code of local health department (LHD) or facility of diagnosis.)*” This addition is requested by LHDs in order to provide a geographic distribution of cases representing people who do not have stable housing and to inform local planning and funding decisions.

Section IV. Facility of Diagnosis

- This section is changed to stretch across the width of the page to accommodate edits in Sections IV-VI.
- The placement of fields “*Facility setting*” and “*Facility type*” has been switched to be consistent with the data entry sequence in HARS. This change was requested by LHDs and will lessen the likelihood of data entry error. Boxes are added to separate the two fields in order to emphasize their switched positions.
- The option “[22] *Counseling and Testing Site*” is added to the field “*Facility type.*” Counseling and testing sites are a common source of HIV case reports and are held to the reporting requirements of H&S Code Section 121022.

Section V. Patient Risk History (Check all that apply.)

- This section is changed to stretch across the width of the page to accommodate edits in Sections IV-VI.
- The title of this section has been changed from “*Patient History*” to “*Patient Risk History (Check all that apply)*.” This change more accurately describes the purpose of this section (to document risk acquisition categories) and emphasizes the need to check more than one risk category if applicable. Documenting all applicable risk categories is important to ensure comprehensive and accurate information regarding the most common ways HIV is transmitted in California, which is used to better target resources for prevention and care programs.
- The following instructions are removed: “*After 1977 and preceding the first positive HIV antibody test or AIDS diagnosis, this patient had (respond to ALL categories).*” This change is made to comply with CDC guidelines to discontinue using 1977 as the earliest point at which a person could be exposed to HIV.
- A new risk category, “*Perinatally-acquired HIV infection regardless of year of birth,*” is added. This is to collect data for newly identified adult HIV and AIDS cases that are attributable to HIV exposure before, during, or after birth. LHDs have requested this risk category because these cases cannot be accurately categorized under any risk listed on DHS 8641A (9/01).
 - Instruction is given to record perinatally acquired HIV infection regardless of the patient’s year of birth. This change is made to help assure all perinatally acquired cases are reported, including those born before 1977.
- A new risk category, “*Other,*” is added along with a space to specify the presumed mode of exposure. This change provides space on the form to document unusual modes of transmission that are not listed in Section V. All case reports indicating no risk or “other” risk will initiate follow-up by local or state health officials.
- The order of the risk categories “*Received clotting factor for hemophilia/coagulation disorder*” and “*HETEROSEXUAL relations with any of the following*” has been switched to accommodate the new spacing of this section on the form.

Section VI. Laboratory Data (Indicate first documented test(s).)

- Instruction to indicate the first documented test(s) is added to the title line to help ensure the case is assigned to the appropriate city/county health jurisdiction. Case assignment is based on the earliest diagnosis date. If the case is reported from two jurisdictions, the case is assigned to the jurisdiction that reported the earliest documented positive test.
- A field for the day of the month is added to all dates of laboratory testing. This will help determine the jurisdiction of case ownership since patients can receive health care in more than one jurisdiction during the same month.
- Subsection A. HIV Antibody Test at Initial HIV/AIDS Diagnosis
 - The title of this subsection is changed from “*HIV Antibody Test at Diagnosis (Indicate first test.)*” to “*HIV Antibody Test at Initial HIV/AIDS Diagnosis.*” This change will emphasize the need to document the earliest laboratory findings for all tests listed in this section and will help to assign the case to the correct city/county health jurisdiction.

- “*Rapid HIV-1 EIA*” is added to the list. This change is to help assure the appropriate laboratory confirmation and documentation of confirmed HIV tests and to include all tests that may be reportable.
- The boxes indicating “*Pos*”, “*Neg*”, “*Ind*”, or “*Not Done*” are removed from this subsection because only positive test results shall be reported in subsection A. Subsection B includes a space to record the last documented negative test.
- *Subsection B. Positive HIV Detection Test (Record earliest test)*
 - The field “*PCR, DNA or RNA probe*” is deleted and two new fields are added, namely: “*DNA PCR*” and “*RNA PCR.*” LHDs request this change so the form matches the data entry fields required in HARS.
 - A dotted box is added and drawn around the next four fields to provide a visual link between fields that focus on past HIV-negative antibody or antigen test history. This box of related fields is moved to the left column under subsection B to free up space needed to accommodate edits to subsection C.
 - “*Specify facility type (Use codes in Section IV),*” is added to this subset. This change will provide data about HIV testing patterns of infected persons that will enhance CDPH/OA’s ability to provide effective HIV prevention program planning and evaluation and will allow CDPH/OA to target resources and programs to the types of facilities where the most cases of HIV infection are reported.
- *Subsection C. HIV Viral Load Test (Record earliest test.)*

This subsection has been amended to record additional data included in CDC standards.²

 - The new title, “*HIV Viral Load Test*”, replaces the previous title, “*Detectable Viral Load.*” This new title encompasses the many possible outcomes for viral load testing of HIV-infected persons.
 - The field “*Version* [of Test Type]*” is added per CDC standards to indicate the specific test kit used.
 - “*Other (specify type and version)*” is added to assure that all viral load tests will be documented according to CDC standards.
 - “*Test result (Record in copies/mL **and** log₁₀ values.)*” is added per CDC standards to record test results in absolute values (copies/mL) and in log₁₀ transformation.
 - Separate fields for “*Detectable*” and “*Undetectable*” viral load results are added in response to LHD and health care provider confusion about how to document an “undetectable” viral load result for an HIV infected person whose viral load is below detectable levels.

Detectable viral load:

 - Two new result values of detectable viral load are added, namely: 1) “*log₁₀*” and, 2) “*greater than ___.*”

² Laboratory findings in this subsection are based on “Guidelines for Laboratory Test Result Reporting of Human Immunodeficiency Virus Type 1 Ribonucleic Acid Determination,” CDC; MMWR; Vol. 50; No. RR-20; (November 16, 2001).

- “ Log_{10} ” values are added in accordance with CDC standards. Boxes are provided for appropriate documentation, such as: “ $\log_{10} = 5.7$.”
- “*Greater than* _____” values are added in accordance with CDC standards for submitting viral load results too high to be measured, such as: “> 500,000 copies/mL.”

Undetectable viral load:

- Boxes to record “*Less than* _____” values are added in accordance with CDC standards for submitting viral load results too low to be measured, such as: “< 50 copies/mL.” As previously stated, the amount of virus in an HIV-infected person’s blood may fall below detectable limits while under antiretroviral treatment.
- The list of options for “*Test type and version*” has been updated (see below). Documentation for version (of test type) is added and updated names of manufacturers and test kits are added to meet CDC standards. These changes represent current viral load testing methods and are added in response to requests from LHDs for detailed information about the names of viral load tests. Specific changes include listing the tests in vertical order for easier reading and providing the test kit’s name followed by the manufacturer, test type and version, if applicable. For ease of formatting, the list of tests is completely deleted then re-entered. However information new to the form is bolded and italicized below:

****Test type and version:***

- 11=***NucliSens[®] HIV-1 QT*** (Organon-NASBA)
- 12=***Amplicor HIV-1 Monitor[®]*** (Roche-RT-PCR), ***version 1.0 or 1.5***
- 13=***Bayer/Chiron (bDNA), version 2.0 or 3.0***
- 18=Other (***kit name/manufacturer/version***) _____

Footer

- In the footer at the lower-left hand corner of the page, the form number has been changed to “*CDPH 8641A (5/07)*” instead of “*DHS 8641A (9/01)*.”

PAGE TWO

Section VII. Provider Information

- This section, previously at the bottom of page two and numbered Section XI, has now been placed at the top of page two and renumbered accordingly. This change mirrors CDC’s HIV/AIDS Case Report form, matches the data entry sequence in HARS, and facilitates case review and processing for local and state surveillance staff.
- The word “*Physician’s*” has been added to the field, “*Physician’s telephone number*”, to emphasize the need for thorough documentation of physician contact information.
- “*Patient’s/inmate’s medical record number*” has been changed from “*Patient’s medical record number*.” This change provides additional client information required to locate medical charts for persons in correctional and juvenile justice systems. LHDs and the California Department of Corrections and Rehabilitation agree this amendment is needed.

Section VIII. Clinical Status

- Section VIII has been shifted down on the page in order to move Section VII, “*Provider Information*,” to the top of the page (previously Section XI). Relocation of Section VII is necessary to follow the data entry sequence in HARS and facilitate filing and case review procedures.
- “*Enter date patient was diagnosed as*” includes a new field for the day of the month of diagnosis. A complete date will help assign the case to the appropriate city/county health jurisdiction since patients can receive health care in more than one jurisdiction during the same month.
- Column 2: An asterisk (*) is added to the diagnosis of “*M. tuberculosis, pulmonary*” to call attention to complete the “*RVCT case number*” box below. The record of a verifiable case of tuberculosis (RVCT) number substantiates the diagnosis because the case number must be obtained from the Tuberculosis Control Registry.
- Column 2: The diagnosis of “*Pneumocystis jiroveci pneumonia (PCP)*” replaces the diagnosis of “*Pneumocystis carinii pneumonia*” to update the current disease name. The acronym “PCP” is added for clarity since it remains the commonly used term for this condition.

Section IX. Treatment/Services Referrals

- Under “For women,” the parenthetical statement below the third bullet is changed to read: “*(If yes, provide birth information below for the most recent birth.)*” This change removes the reference to 1977 as the earliest point at which a newborn could be exposed to HIV before, during or after birth.
 - Placement of the two fields, “*This patient received or is receiving antiretroviral therapy [or] PCP prophylaxis,*” and “*This patient is receiving or has been referred for HIV-related medical services [or] substance abuse treatment services,*” is switched to be consistent with the data entry sequence in HARS. This request has been made by many LHDs and will lessen the likelihood of data entry error.
 - The phrase “*Health Department Use Only*” has been added to the box: “*Health Department Use Only, Child’s state patient number.*” This change will clarify that health care providers do not have to complete this box. Only LHDs can assign a state number to a case.

Instructions at the bottom of Page 2

- Instructions found below section X on the previous form DHS 8641A (9/01) regarding differences in reporting of HIV and AIDS have been removed on form CDPH 8641A (5/07). There are no longer any differences in reporting between HIV cases and AIDS cases; both should be reported using the same fields, including patient name, in light of the reporting requirements in H&S Code Section 121022.
- Additional text is used to improve the instructions given regarding mailing procedures. Changes are bolded as follows:
“**MAIL COMPLETED FORM MARKED “CONFIDENTIAL” TO THE HIV/AIDS SURVEILLANCE PROGRAM AT YOUR LOCAL HEALTH DEPARTMENT. LHD contact information is available on the website: www.cdph.ca.gov/AIDS.**”

- These changes are necessary because:
 - Marking the envelope as “confidential” and identifying the person to whom it must be delivered helps to preserve the confidentiality and timely delivery of sensitive information.
 - Referring the person completing the form to CDPH/OA’s website provides an additional method to obtain updated LHD contact information.

Footer

- In the footer at the lower left-hand corner of the page, the form number has been changed to “CDPH 8641A (5/07)” instead of “DHS 8641A (9/01).”

CDPH 8641P (5/07), Pediatric HIV/AIDS Confidential Case Report

The Section numbers used in this description refer to the CDPH 8641P (5/07).

PAGE ONE

Header and Title

- In the heading at the upper right-hand corner, the departmental name has been changed to “California Department of Public Health” from “Department of Health Services.”
- Patients 13 years of age should not be reported using the pediatric case report form [CDPH 8641P (5/07)]; the adult case report form [CDPH 8641A (5/07)] should be used instead. To avoid potential confusion, the subtitle of the pediatric case report form CDPH 8641P (5/07) is changed from “(Patients < 13 years of age at time of diagnosis.)” to “(Patients ≤ 12 years of age at time of diagnosis).”

Section I. This is for Health Department use. Uniquely identifying information is not transmitted to the Centers for Disease Control and Prevention.

- Placement of this section is shifted from the bottom to the top of the page (previously was Section VI). This change will mirror CDC’s Pediatric HIV/AIDS Case Report form and will assist in filing and case processing by state and local staff.
- The title of this section has been changed from “FOR AIDS CASES ONLY – Patient-identifier information is not transmitted to CDC” to “This is for Health Department use. Uniquely identifying information is not transmitted to the Centers for Disease Control and Prevention.” Fields in this section shall be completed for HIV cases as well as AIDS cases following the changes in California statute made by the adoption of H&S Code Section 121022. The phrase “Centers for Disease Control and Prevention” is used to avoid possible confusion with the California Department of Corrections and Rehabilitation that may arise from use of the acronym “CDC.”
- The heading, “STATE/LOCAL USE ONLY”, is removed because it is redundant and the space is needed to accommodate other revisions to the form.

- The fields, “*Soundex code*”, “*Date of birth*”, “*Gender*”, “*Lab report/accession number*”, and “*Confidential C&T number*”, are now included in Section I instead of being part of a separate section (Section II on DHS 8641P (9/01)).
- The instruction “(mm/dd/yyyy)” is added to the fields “*Date form completed*” and “*Date of birth*” in order to prevent any potential confusion in the order of date elements when completing these fields.
- The heading and subheadings, “*Section II. For HIV and AIDS Cases*” and “*Section II. For Non-AIDS Cases Only*”, have been removed. There is no need for separate fields for HIV reporting since HIV and AIDS are both reported by name.
- The field, “*Last four digits of SSN*”, has been removed. This field was originally part of the non-name code used to report HIV cases. However, the non-name code is no longer used to report HIV since HIV cases are reported by name under H&S Code Section 121022.
- The field, “*CLIA number*”, is added. This field is used to distinguish the particular laboratory that performed a test. LHDs use CLIA number as part of matching and follow-up procedures.
- The “*Lab report/Accession number*” field is amended in two ways:
 - The field is renamed “*Lab report/Accession number*” instead of “*Lab report number*.” The word “*accession*” is added because laboratories are often more familiar with the term “*accession number*” than the term “*lab report number*.”
 - The eight individual boxes are removed from this field. This change will provide space to document laboratory report numbers larger than eight digits.

Section II. Health Department Use Only

- Section II is renumbered (previously was Section I) and placed lower on the page in order to shift Section I (*This is for Health Department use. Uniquely identifying information is not transmitted to the Centers for Disease Control and Prevention*) to the top of the page. Relocation of Section I is necessary to follow the data entry sequence in HARS and facilitate filing and case review procedures.
- Individual boxes are removed from the fields “*State patient number*” and “*City/county patient number*” to provide space to document numbers larger than ten digits.

Blank Box on Left Side of Form

- A blank box is added to the left side of the form in order to accommodate current filing and case review procedures at the state HIV/AIDS Case Registry. The state filing system involves affixing a label to the form that provides the patient’s state case number, soundex code, and date of birth. Adding a space to the form for this sticker will help protect critical data from being concealed underneath. LHDs have stated the change would not disrupt their current filing procedures.

Section III. Demographic Information

- Section III is spread across the page in order to create space needed to include additional data needed in Sections III-V.

- Location of the following boxes has been shifted to follow the data entry sequence of HARS and to accommodate space for additional data needed in Section V:
 - State/Territory of death;
 - Date of initial evaluation for HIV infection;
 - Date of last medical evaluation;
 - Was reason for initial HIV evaluation due to clinical signs and symptoms?; and
 - Country of birth.
- “*Ethnicity*” and “*Race*” fields are re-formatted in order to satisfy federal requirements imposed January 1, 2003 (Federal Notice, July 9, 1997, Directive No. 15). These requirements call for specific race and ethnicity documentation that is not requested on state forms DHS 8641A (9/01) and DHS 8641P (9/01). In order to comply with the federal mandate, CDPH/OA immediately developed an addendum that is attached to each case report before submission to the LHD. This amendment eliminates the need to attach the addendum to each case report. The numbers are removed from the boxes of the race field due to related changes in the way information is stored in HARS.
- A field is added entitled, “*Expanded race (specify):*” to facilitate collection of data for the field found in HARS. This field allows for collection of more detailed information than permitted in the race and ethnicity fields, such as specifying “Mexican” for someone listed as “Hispanic” in the ethnicity field. LHDs and CDPH/OA use this information to better target resources to affected subpopulations.
- “*Residence at first diagnosis of HIV or AIDS*” has been changed from “*Residence at diagnosis*” to help assure the case being reported is assigned to the appropriate city/county health jurisdiction. Since patients can move throughout the state, the residence at initial diagnosis is requested, not the current residence.
 - A box for “*Homeless*” is added with instructions, “(Must use city/county/ZIP code of local health department (LHD) or facility of diagnosis.)” This addition is requested by LHDs in order to provide a geographic distribution of cases representing people who do not have stable housing and to inform local planning and funding decisions.

Section IV. Facility of Diagnosis

- This section is changed to stretch across the width of the page to accommodate edits made to other sections on page one.
- The placement of fields “*Facility setting*” and “*Facility type*” has been switched to be consistent with the data entry sequence in HARS. This change was requested by LHDs and will lessen the likelihood of data entry error. Boxes are added to separate the two fields in order to emphasize their switched positions.
- The option “[22] *Counseling and Testing Site*” is added to the field “*Facility type.*” Counseling and testing sites are important sources of recently infected cases and are held to the reporting requirements of H&S Code Section 121022.

Section V. Patient/Maternal Risk History (Respond to all categories.)

- The title of this section has been changed from *“Patient/Maternal History”* to *“Patient/Maternal Risk History.”* This change more accurately describes the purpose of this section (to document risk acquisition categories) and eases reporting.
- Throughout the section, the word *“biological”* has replaced the word *“biologic.”*
- *“Child’s biological mother’s HIV infection status”* has been reformatted and dotted lines are added to separate the category *“HIV negative or no diagnosis,”* from the category *“HIV positive or AIDS diagnosis.”* *“HIV positive or AIDS diagnosis”* has replaced the phrase, *“Diagnosed with HIV infection/AIDS.”* These minor edits create a natural, visual break between the two categories and facilitate accurate documentation of mother’s HIV status.
- In the subsection *“Child’s biological mother’s HIV infection status”* the options *“Before pregnancy with this child”* and *“During pregnancy with this child”* have replaced the options *“Before this child’s pregnancy”* and *“During this child’s pregnancy”* so that the options clearly reference the mother’s pregnancy and avoid confusion.
- Changes made to the subsection *“Before the diagnosis of HIV/AIDS, this child’s biological mother had”* are as follows:
 - The subtitle, *“Before the diagnosis of HIV/AIDS, this child’s biological mother had”* replaces the previous subtitle of, *“After 1977, this child’s biologic mother had.”* This change removes the reference to 1977 as the earliest point at which a newborn could be exposed to HIV before, during or after birth. This change is made to comply with CDC guidelines to discontinue using 1977 as the earliest point at which a person could be exposed to HIV.
 - A new risk category is added to the subcategory, *“HETEROSEXUAL relations with,”* to document the biological mother’s sexual contact with a *“Male with perinatally-acquired HIV.”*
 - A new risk category *“Perinatally-acquired HIV infection, regardless of mother’s date of birth”* is added to document the biological mother’s perinatal exposure to HIV.
 - The two preceding changes document perinatally acquired HIV infection in either biological parent of a pediatric HIV/AIDS case. They are being requested by LHDs because pediatric HIV case reports for children of persons who acquired HIV perinatally are now being submitted. A field to collect data for adult cases of perinatal HIV exposure is being added on the adult HIV/AIDS Case Report [CDPH 8641A (5/07)].

Footer

- In the footer at the lower left-hand corner of the page, the form number has been changed to *“CDPH 8641P (5/07)”* instead of *“DHS 8641P (9/01).”*

PAGE TWO

Section VI. Provider Information

- This section, previously at the bottom of page two and numbered Section IX, has now been placed at the top of page two and renumbered accordingly. This change

mirrors CDC's HIV/AIDS case report form and facilitates case review and processing for local and state surveillance staff.

- The word “*Physician’s*” has been added to the field “*Physician’s telephone number*” to emphasize the need for thorough documentation of physician contact information.
- The second, redundant field for “*telephone number*” has been eliminated to prevent confusion.

Section VII. Laboratory Data (Indicate the first positive test.)

- The instruction to “*indicate the first positive test*” is added to the title line to ensure the case is assigned to the appropriate city/county health jurisdiction. Case assignment is based on the earliest diagnosis date. If the case is reported from two jurisdictions, the case is assigned to the jurisdiction that reported the earliest documented positive test.
- A field for the day of the month is added to all dates of laboratory testing. This will help determine the jurisdiction of case ownership since patients can receive health care in more than one jurisdiction during the same month.
- Subsection 3. HIV Viral Load Test (Record earliest test)
*This subsection has been amended to record additional data included in CDC standards.*³
 - The instruction to “*record all tests*” is removed because viral load testing will be done multiple times per year and the form does not have space to document an unlimited number of test results.
 - This subsection is shifted to the left column of the page to accommodate the additional data required.
 - The field “*Version* [of Test Type]*” following “*Test Type*” is added per CDC standards to indicate the specific test kit used.
 - “*Other (specify type and version)*” is added to assure that all FDA-approved viral load tests will be documented according to CDC standards.
 - “*Test result (Record in copies/mL and log₁₀ values.)*” is added per CDC standards to record test results in absolute values (copies/mL) and in log₁₀ transformation.
 - Separate fields for “*Detectable*” and “*Undetectable*” viral load results are added in response to LHD and health care provider confusion about how to document an “undetectable” viral load result for an HIV-infected person whose viral load is below detectable levels.
Detectable viral load:
 - The box to record the number of “*Copies/mL*” is reformatted, allowing for 1,000,000 or more copies/mL to be recorded. This will match the amendment to the adult case report form, CDPH 8641A (5/07).
 - Two new result values of detectable viral load are added, namely: 1) “*log₁₀*” and, 2) “*greater than ___.*”

³ Laboratory findings in this subsection are based on “Guidelines for Laboratory Test Result Reporting of Human Immunodeficiency Virus Type 1 Ribonucleic Acid Determination,” CDC; MMWR; Vol. 50; No. RR-20; (November 16, 2001).

- “ Log_{10} ” values are added in accordance with CDC standards. Boxes are provided for appropriate documentation, such as: “ $log_{10} = 5.7.$ ”
- “*Greater than* ___” values are added in accordance with CDC standards for submitting viral load results too high to be measured, such as: “> 500,000 copies/mL.”

Undetectable viral load:

- Boxes to record “*Less than* ___” values are added in accordance with CDC standards for submitting viral load results too low to be measured, such as: “< 50 copies/mL.” As previously stated, the amount of virus in an HIV infected person’s blood may fall below detectable limits while under antiretroviral treatment.
- The list of options for “*Test type and version*” has been updated (see below). Documentation for version (of test type) is added and updated names of manufacturers and test kits are added to meet CDC standards. These changes represent current viral load testing methods and are added in response to requests from LHDs for detailed information about the names of viral load tests. Specific changes include listing the tests in vertical order for easier reading and providing the test kit’s name followed by the manufacturer, test type and version, if applicable. For ease of formatting, the list of tests is completely deleted then re-entered. However information new to the form is bolded below:

***Test type and version:**

11=**NucliSens[®] HIV-1 QT** (Organon-NASBA)

12=**Amplacor HIV-1 Monitor[®]** (Roche-RT-PCR), **version 1.0 or 1.5**

13=**Bayer/Chiron** (bDNA), **version 2.0 or 3.0**

18=Other (**kit name/manufacturer/version**) _____

- Subsection 4. Immunologic Lab Tests
 - Placement of this section is shifted to the right column to accommodate additional space needed for data in subsection 3.

Section VIII. Clinical Status

- Column 2: the diagnosis of “*Pneumocystis jiroveci* pneumonia (PCP)” replaces the diagnosis of “*Pneumocystis carinii* pneumonia” to update the current disease name. The acronym “PCP” is added for clarity since it remains the commonly used term for this condition.

Footer

- In the footer at the lower left-hand corner of the page, the form number has been changed to “CDPH 8641P (5/07)” instead of “DHS 8641P (9/01).”

PAGE THREE

Section IX. Birth History (For PERINATAL cases only)

- Section IX has been renumbered (previously Section X) due to changes in the numbering of sections on pages one and two.

- The instructions *“If no or unknown, proceed to Section X”* replace the previous instructions *“If no or unknown, proceed to Section XI”* to reflect changes in the numbering of sections on page three.
- The fields *“Maternal date of birth,” “Maternal Soundex,”* and *“Maternal State Patient Number”* are renamed *“Biological Mother’s date of birth,” “Biological Mother’s Soundex,”* and *“Biological Mother’s State Patient Number,”* respectively. The changes emphasize that these fields refer to the child’s biological mother instead of the child’s adoptive mother, foster mother, or other female guardian. The biological mother’s information is important because mother-to-child transmission of HIV is possible only from the biological mother to the child.
- The field *“Birthplace of biologic mother”* has been renamed *“Birthplace of biological mother”* to update the incorrect use of the word “biologic” and to be consistent with references in Section V.

Section X. Treatment/Services Referrals

- Section X has been renumbered (previously Section XI) due to changes in the numbering of sections on pages one and two.
- The option *“Other (specify in Section XI)”* replaces the previous option *“Other (specify in Section XII)”* to reflect changes in the numbering of sections on page three.

PAGES THREE AND FOUR

Instructions at the bottom of pages 3 and 4

- Instructions found on page three below Section XI on the previous form DHS 8641P (9/01) regarding differences in reporting of HIV and AIDS have been removed on form CDPH 8641P (5/07). There are no longer any differences in reporting between HIV cases and AIDS cases; both shall be reported using the same fields, including patient name, in light of the reporting requirements in H&S Code Section 121022.
- Instructions are added to the bottom of pages three and four to provide guidance to persons completing the form regarding proper mailing procedures and LHD contact information. The instructions read as follows:
“MAIL COMPLETED FORM MARKED “CONFIDENTIAL” TO THE HIV/AIDS SURVEILLANCE PROGRAM AT YOUR LOCAL HEALTH DEPARTMENT. LHD contact information is available on the website: www.cdph.ca.gov/AIDS.”
- These changes are necessary because:
 - Marking the envelope as “confidential” and identifying the person to whom it must be delivered helps to preserve the confidentiality and timely delivery of sensitive information.
 - Referring the person completing the form to CDHS/OA’s website will provide an additional method to obtain updated LHD contact information.

Footer

- In the footer at the lower left-hand corner of each page, the form number has been changed to *“CDPH 8641P (5/07)”* instead of *“DHS 8641P (9/01).”*

The copies of the revised HIV/AIDS Case Report forms [DHS 8641A (06/06) and DHS 8641P (06/06)] included in the filing when the emergency regulations were first promulgated on January 8, 2007 inadvertently included language that was not intended to be part of the forms. The language intended by CDPH/OA was reflected during the first public comment period, held March 23, 2007 through May 16, 2007, in the description of form changes in the initial statement of reasons and public notice documents. The intentions of CDPH/OA were further illustrated by the HIV/AIDS Case Report forms shown in underline and strikethrough formats which did not include any of the inadvertent language found on the forms DHS 8641A (06/06) and DHS 8641P (06/06); the strikethrough and underline formatted forms were included in the emergency regulations promulgated January 8, 2007 and as part of the 45-day public comment period.

When the emergency regulations were readopted on May 9, 2007, the HIV/AIDS Case Report forms were amended to remove the inadvertent language [revised forms DHS 8641A (5/07) and DHS 8641P (5/07)]. The second public comment period, held July 30, 2007 through August 15, 2007, documented the removal of the inadvertent language and provided an opportunity for public comment on the changes [CDPH 8641A (5/07) and CDPH 8641P (5/07)]. The following specific changes were made to correct the errors on the forms initially promulgated and included in the public notice:

- On both the adult [CDPH 8641A (5/07)] and pediatric [CDPH 8641P (5/07)] forms the subheading, “(LHDs use approved abbreviations from “Facility List.”)” has been removed from Section IV on page one.
 - On the pediatric form, CDPH 8641P (5/07), the “*Ethnicity*” field boxes for options “*Hispanic*” and “*Not Hispanic or Latino*” have been numbered “1” and “2” respectively in Section III on page one.
 - On the pediatric form, CDPH 8641P (5/07), the field name “*Physician’s Telephone Number*” has replaced the previous field name “*Telephone Number*” in Section VI on page two.
- **Require reporting of laboratory CLIA number.**

The CDPH emergency regulations require all laboratories to submit their CLIA certification number to the local health officer along with a report of a confirmed HIV test. CLIA number identifies a specific laboratory even if the laboratory changes names or merges with another laboratory. Submission of CLIA number provides additional data to assist LHD surveillance staff in matching and unduplicating HIV reports. H&S Code Section 121022(a) requires local health officers to report unduplicated HIV cases to CDPH, and the CLIA number is an important data element used in the unduplication process.

Affected Section:

- Amend CCR, Title 17, Section 2643.10 by adding “*Laboratory Clinical Laboratory Improvement Amendments (CLIA) number*” to the list of items in subsection (b) laboratories are required to submit to local health officers when reporting a confirmed HIV test.
- **Make technical changes.**

CCR, Title 17, Section 2643.5(a) previously listed two types of laboratory requisition forms health care providers could use when ordering HIV-related laboratory tests. On further review, the second option listed, DHS 8257C (1/02), meets all the requirements of the first option, namely the requirements of Title 42 of the Code of Federal Regulations, Part 493, Section 1105. To improve clarity and prevent confusion for health care providers, the reference to DHS 8257C (1/02) is repealed, and Section 2643.5(a) is renumbered accordingly.

Affected Sections:

- Repeal subclause of CCR, Title 17, Section 2645.5(a), “*A completed Department of Health Services Counseling and Testing Program Confidential HIV Antibody Test laboratory requisition form, DHS 8257C (1/02), hereby incorporated by reference in this Article.*”
- Amend CCR, Title 17, Section 2643.5(a) to replace unnecessary punctuation, “: (1) A” with “a” and delete the unnecessary phrase, “*the following.*”
- **Make non-substantive changes.**

There are two sections of CCR, Title 17, Article 3.5 that have punctuation errors. The grammar of CCR, Title 17, Section 2643.10(a) is also incorrect. The CDPH emergency regulations adopt non-substantive changes pursuant to CCR, Title 1, Section 100 to correct these errors. Some subsections of CCR, Title 17, Sections 2643.5, 2643.10, and 2643.15 are renumbered to accommodate other emergency amendments made to those sections. These emergency amendments redesignate affected subsections accordingly. Following the 15-day public comment period, Sections 2643.5(c)(1)(A), 2643.5(c)(1)(B), 2643.10(b)(1)(A), and 2643.10(b)(1)(B) have been formatted to conform with standard CCR style; “(A)” and “(B)” replace “A.” and “B.”, respectively.

Affected Sections:

- Amend CCR, Title 17, Section 2641.55 by adding missing closed parentheses [“”] after the revision dates listed for forms CDPH 8641A (5/07) and CDPH 8641P (5/07).
- Amend CCR, Title 17, Section 2643.10(a)(4) to change the punctuation at the end from “*different.; and*” to “*different; and*” by removing the unnecessary period (“.”).
- Amend CCR, Title 17, Section 2643.10(a) to replace “*of*” with “*for*”.
- Amend CCR, Title 17, Section 2643.5 to reletter subsections (f) to (e), (g) to (f), and (i) to (h).

- Amend CCR, Title 17, Section 2643.10 to reletter subsections (b) to (a), (d) to (c), (f) to (d), (g) to (e), (h) to (f), (i) to (g) and (j) to (h).
 - Amend CCR, Title 17, Section 2643.15 to reletter subsection (d) to (e).
 - Amend CCR, Title 17, Section 2643.5(c)(1) to replace “A.” and “B.” with “(A)” and “(B)”, respectively.
 - Amend CCR, Title 17, Section 2643.10(b)(1) to replace “A.” and “B.” with “(A)” and “(B)”, respectively.
- **Change References to Department Name.**

These amendments update the name of the department as it occurs throughout CCR, Title 17, Article 3.5 (commencing with Section 2641.5) in response to creation of CDPH by H&S Code Section 131000 and the transfer of all public health functions of the former CDHS (including the functions and responsibilities of OA) to CDPH pursuant to H&S Code Sections 131050 and 131051.

Affected Sections:

- Amend CCR, Title 17, Section 2641.5 to replace “California Department of Health Services” with “California Department of Public Health.”
 - Amend CCR, Title 17, Section 2641.35 to replace “California Department of Health Services” with “California Department of Public Health.”
 - Amend CCR, Title 17, Section 2641.55 to replace “California Department of Health Services” with “California Department of Public Health.”
 - Amend CCR, Title 17, Section 2641.56 to replace “California Department of Health Services” with “California Department of Public Health.”
 - Amend CCR, Title 17, Section 2643.15(b)(1) to replace “California Department of Health Services” with “California Department of Public Health.”
- **Change Authority and Reference Citations to Reflect SB 162 (Ortiz, Statutes of 2006, Chapter 241)**

These amendments update the authority and reference citations in response to the statutory changes made by SB 162 (Ortiz, Statutes of 2006, Chapter 241).

Affected Sections:

- Amend CCR, Title 17, Sections 2641.55, 2641.56, and 2643.15 to replace H&S Code Section 100119 with H&S Code Section 131019.
- Amend CCR, Title 17, Sections 2641.5, 2641.30, 2641.35, 2641.45, 2641.55, 2641.56, 2641.57, 2643.5, 2643.10, and 2643.15 to replace H&S Code Section 100180 with H&S Code Section 131080.
- Amend CCR, Title 17, Sections 2641.5, 2641.30, 2641.35, 2641.45, 2641.55, 2641.56, 2641.57, 2643.5, 2643.10, and 2643.15 to replace H&S Code Section 100275 with H&S Code Section 131200.
- Amend CCR, Title 17, Sections 2641.5, 2641.30, 2641.35, 2641.45, 2641.55, 2641.56, 2641.57, 2643.5, 2643.10, and 2643.15 to add references to H&S Code Sections 131051, 131052, and 131056.

STATEMENTS OF DETERMINATIONS

A. ALTERNATIVES CONSIDERED

CDPH has determined that no reasonable alternative would be more effective in carrying out the purpose for which the emergency action was taken or would be as effective as and less burdensome to affected private persons than the emergency action.

B. LOCAL MANDATE DETERMINATION

These emergency amendments mandate that LHDs report cases of HIV infection to CDPH/OA and will create a mandate for LHDs that is reimbursable according to Section 6 of Article XIII B of the California Constitution and Sections 17500 et seq. of the Government Code.

Funds in the amount of \$1,431,000 were approved in the FY 2000-2001 State baseline budget to reimburse LHDs for their HIV reporting activities as mandated by the regulations implemented July 1, 2002. These funds remain available in the budget to reimburse LHDs for their HIV reporting activities as modified by these regulations. The CDPH has determined that the reimbursable costs incurred by LHDs for name-based HIV reporting under these regulations would not exceed the costs they incurred for code-based reporting under the previous regulations, since name-based reporting is less complex, labor intensive, and time-consuming than code-based reporting.

LHDs may need to redirect resources initially for training regarding use of the updated HIV/AIDS Case Report form. LHD staff may need minimal instruction in order to train health care providers on the updated case information. The modified case report forms will be easier to complete, and CDPH anticipates no increase in the amount of time it will take to complete the revised case report.

The ultimate effect of the emergency amendments to the HIV reporting regulations will be to lessen staff time and resources required at the local level to carry out HIV reporting. Staff time can be directed to health care provider and laboratory training and increased technical assistance, which should improve data quality and completeness of reporting. It has been determined that no fiscal impact will occur.

C. ECONOMIC IMPACT DETERMINATION

CDPH has made the determination that the 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 CDPH has determined that the regulations would not significantly affect the following:

- 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.

D. DETERMINATION WHETHER OR NOT REGULATION AFFECTS SMALL BUSINESSES

CDPH has made the determination that these emergency amendments may affect small businesses required to comply.

Currently, health care providers and laboratories report cases of HIV infection to the local health officer. These emergency amendments will add minimal changes to the HIV reporting responsibilities of health care providers and laboratories.

E. HOUSING IMPACT DETERMINATION

CDPH has made the determination that adoption of these emergency amendments will have no impact on housing costs in California.

F. REPORT DETERMINATION

CDPH has made the determination that these emergency amendments require reports from businesses, and it is necessary for the health, safety, or welfare of the people of California that the emergency amendments apply to businesses.

DOCUMENTS RELIED UPON

The following documents were relied upon for formulating the reasoning behind the emergency amendments to CCR, Title 17, Article 3.5, Sections 2641.5-2643.20, Reporting of HIV Infection:

1. 1993 Revised Classification System for HIV Infection and Expanded Surveillance Case Definition for AIDS Among Adolescents and Adults, MMWR, 1992; 41 (RR17). <http://www.cdc.gov/mmwr/preview/mmwrhtml/00018871.htm>
2. HIV Statistics, March 31, 2006. CDPH/OA website: www.dhs.ca.gov/AIDS.
3. AIDS Statistics, March 31, 2006. CDPH/OA website: www.dhs.ca.gov/AIDS.
4. Making California's HIV Reporting System Consistent with its AIDS Reporting System, and Improve AIDS Reporting. California Performance Review, Government for the People for a Change. Vol. 4, Chapter 2, HHS 14, August 3, 2004. <http://cpr.ca.gov/report/cprprt/issrec/hhs/hhs14.htm>
5. CDC. Guidelines for Laboratory Test Result Reporting of Human Immunodeficiency Virus Type 1 Ribonucleic Acid Determination, MMWR 2001; Vol. 50; (RR-20). <http://www.cdc.gov/mmwr/PDF/rr/rr5020.pdf>
6. Letter from CDC Director Dr. Julie Gerberding, M.D., M.P.H., to California Governor Arnold Schwarzenegger, December 27, 2005.
7. Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity, Federal Register Notice, October 30, 1997. Office of Management and Budget website: <http://www.whitehouse.gov/omb/fedreg/1997standards.html>