

UPDATED INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Senate Bill (SB) 162 (Ortiz, Statutes of 2006, Chapter 241) created the California Department of Public Health (CDPH) and transferred public health programs previously operated by the California Department of Health Services (CDHS) to CDPH. Governor Schwarzenegger signed SB 162 (Ortiz, Statutes of 2006, Chapter 241) on September 14, 2006, and it took effect July 1, 2007. SB 162 (Ortiz, Statutes of 2006, Chapter 241) amended and renumbered 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) adopted H&S Code Section 131200 which specifically grants the authority to “adopt and enforce regulations for the execution of its duties” to CDPH. The emergency regulations, including the three forms incorporated by reference, have been updated to change references to the departmental name from CDHS to CDPH and to ensure that the appropriate sections of statute are listed in the citations. The text that follows has also been updated to reflect the change in departmental name and change in statute granting authority to promulgate regulations.

CDPH adopted emergency amendments to Title 17, Article 3.5 of the California Code of Regulations (CCR), that relate to human immunodeficiency virus (HIV) disease reporting and surveillance practices. Health and Safety (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 the CDC; and
- Amend references to the departmental name 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 the Office of AIDS [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). 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 amendments incorporate by reference the form, "California Department of Public Health HIV/AIDS Confidentiality Agreement," CDPH 8689, dated (5/07).

Authority to Amend the HIV Reporting Regulations

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(a), 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 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. CCR, Title 17, Division 1, Chapter 4, Subchapter 1, Article 1, Section 2500 directs health care providers to report AIDS and other reportable communicable 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/OA is the lead agency within the state responsible for coordinating HIV/AIDS related programs.

Related Federal Statutes and/or Regulations

Title 42 of the Code of Federal Regulations (CFR), Part 493 regulates all laboratory testing (except research) performed on humans in the United States through the Clinical Laboratory Improvement Amendments (CLIA) of 1988. The objective of the CLIA program is to establish training, licensing, and quality assurance standards for each clinical test to be performed. CLIA categorizes tests into certain groups based upon the degree of difficulty and level of expertise required of the technician. Tests vary in complexity from high to moderate to waived, and all clinical laboratories must be properly certified to perform each kind of test. The emergency amendments include language to help assure that new HIV tests determining the presence of HIV infection, including the new antibody-screening test commonly known as the “rapid HIV test” and classified as waived complexity, are reported in accordance with confirmation protocols established by CDC. Each laboratory certified under CLIA is assigned a unique number, which provides a way to distinguish individual testing facilities that are part of large laboratory corporations.

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 governs the conditions under which health care providers are authorized to disclose protected health information. Title 45, CFR, Section 164.512 states that protected health information may be disclosed without individual authorization to public health authorities authorized by law to collect or receive the information for the purpose of preventing or controlling disease, including, but not limited to, the reporting of disease, and the conduct of public health surveillance, public health investigations, and public health interventions. Reporting of cases of HIV infection as required under the emergency amendments meets the HIPAA Privacy Rule standards for disclosure to public health authorities.

Fiscal Impact

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 the 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 took 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 improves the quality and completeness of HIV data for purposes of reporting to the satisfaction of the CDC and helps prevent a significant funding loss.

Brief Summary of Emergency Amendments

- *Name.* Sections 2643.5 and 2643.10 are amended to require health care providers and laboratories to include the complete name of the patient when reporting cases of HIV infection to the local health officer. Earlier versions of the HIV/AIDS Case Report Forms, DHS 8641A (9/01) and DHS 8641P (9/01), included instructions prohibiting the reporting of patient name for cases of HIV infection. These instructions have been removed from the revised forms, CDPH 8641A (5/07) and CDPH 8641P (5/07), which are incorporated by reference and included in Section 2641.55. Local health officers shall report patient name to CDPH/OA when using the revised forms under Section 2643.15.
- *Permit Release of Personal Information to Local Health Officer.* Given the recent changes to H&S Code Sections 120980 and 121022, health care providers and laboratories are no longer prohibited from sharing personal information with the local health officer for the purposes of HIV reporting. Subsections that prohibited release of personal information in Sections 2643.5 and 2643.10 are repealed.
- *Repeal Codes.* With the use of patient name, patient codes are no longer needed for HIV reporting. References to the non-name code and partial non-name code are removed from Sections 2643.5 and 2643.10. Sections 2641.75 and 2641.77, defining the non-name code and partial non-name code, respectively, are repealed.
- *Repeal Cross-Reference System.* Prior to the emergency amendments, Section 2643.5 required health care providers to maintain a system cross-referencing patient data by code in order to complete case reports and communicate with the local health officer. This cross-reference system is no longer necessary, and the appropriate subsection of Section 2643.5 is repealed.
- *Confidentiality Agreement.* Section 2643.15 is amended to require all LHD employees and contractors to sign the HIV/AIDS Confidentiality Agreement (CDPH 8689 [5/07]) prior to accessing confidential HIV-related public health records. Section 2641.56 is adopted to define the "HIV/AIDS Confidentiality Agreement," and CDPH 8689 (5/07) is incorporated by reference. The Confidentiality Agreement is added to regulations in accordance with H&S Code Section 121022(e).
- *Data Transmission Practices.* In order to ensure confidentiality of reports containing personal information, Sections 2643.5 and 2643.10 are amended to require that health care providers and laboratories use traceable mail or person-to-person transfer to report cases of HIV infection to the local health officer. Reports containing personal information shall not be e-mailed, sent by fax, or sent by non-traceable mail to the local health officer.

- *Report all Confirmed HIV Tests.* A definition of “HIV Test Algorithm” is adopted in Section 2641.57. Section 2641.30 amends the definition of “Confirmed HIV Test” to include all HIV test algorithms that determine the presence of HIV infection in accordance with confirmation protocols established by CDC as published in the CDC’s Morbidity and Mortality Weekly Report. Section 2641.45 amends the definition of “Health Care Provider” to include an individual who conducts an HIV test or HIV test algorithm. Section 2641.60 amends the definition of “Laboratory” to include the location where a health care provider conducts an HIV test algorithm. These changes ensure that all confirmed HIV tests, including HIV test algorithms, meeting CDC confirmation standards are reported to the local health officer.
- *Communication between Health Care Providers and LHD Staff.* Section 2643.5 is amended to add subsection (g) to facilitate efforts by LHD representatives to provide technical assistance to health care providers with respect to reporting cases of HIV infection.
- *Updated Confidential HIV/AIDS Case Report Forms.* Section 2641.55 is amended to incorporate by reference the updated versions of the HIV/AIDS Case Reports defined in this article, CDPH 8641A (5/07) and CDPH 8641P (5/07).
- *HIV Reporting Authority.* H&S Code Section 121022 is included in the reference and authority citations of amended sections. This reflects the statutory mandate for name-based HIV reporting in California. These emergency amendments also update the authority and reference citations in response to the statutory changes made by SB 162 (Ortiz, Statutes of 2006, Chapter 241). Specifically, H&S Code Section 131019 replaces H&S Code Section 100119; H&S Code Section 131080 replaces H&S Code Section 100180; H&S Code Section 131200 replaces H&S Code Section 100275; and H&S Code Sections 131051, 131052, and 131056 have been added.
- *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 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. Specifically, the phrase “California Department of Public Health” replaces the phrase “California Department of Health Services” in Sections 2641.5, 2641.35, 2641.55, 2641.56, and 2643.15(b)(1).

The emergency amendments bring code-based reporting procedures of CCR, Title 17, Article 3.5 in line with the newly enacted provisions of H&S Code Section 121022. The resulting name-based HIV reporting system is less confusing, less time-consuming, more accurate and reliable, and more efficient than the previous code-based system. All reporting entities, including health care providers, laboratories, and LHDs, benefit from the decrease in reporting burden. Ultimately, the name-based HIV reporting system will ensure California remains eligible for federal funding by reporting cases of

HIV infection in a manner that is accepted by CDC for use in Ryan White funding formulas. For these reasons, CDPH/OA amended CCR, Title 17, Sections 2641.5, 2641.30, 2641.35, 2641.45, 2641.55, 2643.5, 2643.10, and 2643.15, adopted CCR, Title 17, Sections 2641.56 and 2641.57, and repealed CCR, Title 17, Sections 2641.75 and 2641.77.