

## **SUPPLEMENT TO THE INITIAL STATEMENT OF REASONS**

### **SUMMARY OF PROPOSAL**

The California Department of Public Health (CDPH) is proposing amendments to the emergency regulations R-06-014E that relate to human immunodeficiency virus (HIV) disease reporting and surveillance practices. The emergency regulations were promulgated January 8, 2007 and readopted May 9, 2007. A public comment period was held from March 23, 2007 to May 16, 2007. The amendments described below are being made: 1) to correct an oversight regarding forms DHS 8641A (06/06) and DHS 8641P (06/06) as included in the initial emergency filing; 2) to make the emergency regulations consistent with the provisions of Senate Bill (SB) 162 (Ortiz, Statutes of 2006, Chapter 241) that transfer the public health functions of the former California Department of Health Services (CDHS) to CDPH effective July 1, 2007; and 3) clarify the language regarding reporting of all confirmed HIV tests.

The amendments update the HIV/AIDS Case Report forms and the HIV/AIDS Confidentiality Agreement to comply with Health and Safety (H&S) Code Sections 121022 and 131051. Specifically, these amendments update, amend, rename, 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);
- “California Department of Public Health Pediatric HIV/AIDS Confidential Case Report,” CDPH 8641P, dated (5/07); and
- “California Department of Public Health HIV/AIDS Confidentiality Agreement,” CDPH 8689, dated (5/07).

### **AMENDMENTS**

On January 8, 2007, emergency regulations were promulgated in response to the mandate in H&S Code Section 121022 to conform the provisions of California Code of Regulations (CCR), Title 17, Article 3.5 (commencing with Section 2641.5) with the provisions of H&S Code Section 121022. The copies of the updated HIV/AIDS Case Report forms [DHS 8641A (06/06) and DHS 8641P (06/06)] that were included as part of that filing inadvertently included language that was not intended to be part of the forms. The inadvertent language was not addressed in the initial statement of reasons and was not included on the underline and strikethrough forms documenting the changes made to the HIV/AIDS Case Report forms. The inadvertent language was removed from the forms as part of the emergency readoption of the regulations on May 9, 2007. These amendments document the removal of the inadvertent inclusions and allow for public comment on the changes.

CDPH/OA is utilizing this opportunity for public comment to update the regulations to reflect other recent statutory changes. On September 14, 2006,

Governor Schwarzenegger signed SB 162 (Ortiz, Statutes of 2006, Chapter 241) which creates CDPH and transfers public health programs previously operated by CDHS to CDPH. Further, SB 162 (Ortiz, Statutes of 2006, Chapter 241) amends and renumbers specific 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 adopts H&S Code Section 131200 which specifically grants the authority to “adopt and enforce regulations for the execution of its duties” to CDPH. The amendments update the regulations and forms to change references to CDHS to refer to CDPH and to ensure that the appropriate sections of statute are listed in the citations.

Upon review, CDPH/OA has decided to clarify the language added as part of the emergency filing with respect to reporting of confirmed HIV tests performed at the point of care. It is the intent of CDPH/OA to ensure that a multi-test procedure determining the presence of HIV infection be reported only if it follows the national standards for confirmation established by the federal Centers for Disease Control and Prevention (CDC). CDC confirmation standards incorporate only tests approved by the federal Food and Drug Administration (FDA). CDC routinely publishes the national standards in their Morbidity and Mortality Weekly Report (MMWR) which is available on the CDC website. By adhering to CDC standards for confirmation of HIV tests or multi-test procedures, the revised regulations ensure that reported cases of HIV infection will meet the CDC case definition for HIV and be accepted by CDC; only HIV cases reported by name and accepted by CDC will be considered for inclusion in funding formulas for federal care and treatment programs beginning with federal fiscal year 2010. CDPH/OA is clarifying the definition of “HIV Test Algorithm” (Title 17, CCR, Section 2641.57) to refer to CDC confirmation protocols published in the MMWR and to remove the reference to approval by FDA, and is making conforming changes to Title 17, CCR, Sections 2641.30 and 2641.45. The changes proposed at this time will in no way interfere with CDPH/OA’s original intent to ensure that multi-test algorithms performed at the point of care are reported to the local health officer. The revised language continues to ensure reporting of all confirmed HIV tests, including multi-test algorithms, to increase 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.

Specifically, CDPH amends CCR, Title 17, Article 3.5 (Sections 2641.5-2643.20) in the following ways:

- **Update HIV/AIDS Case Report Forms**
  - *Remove language inadvertently included in emergency filing.* The amendments update the Adult and Pediatric HIV/AIDS Case Report forms to reflect the language initially intended by CDPH/OA, thereby correcting the oversight that led to inaccurate versions of the case report forms [DHS 8641A (06/06) and DHS 8641P (06/06)] being submitted as part of the emergency filing on January 8, 2007. The language intended by CDPH/OA was reflected during the public comment period in the form versions shown in underline and strikethrough formats and in the

discussion of form changes in the initial statement of reasons and public notice documents. The inadvertent language was shown on the clear copies of the case report forms only [DHS 8641A (06/06) and DHS 8641P (06/06)]. The inadvertent language was removed from the HIV/AIDS Case Report forms during the readoption of the regulations on May 9, 2007. Specific changes are:

- CDPH 8641A (5/07), Adult HIV/AIDS Confidential Case Report
  - PAGE ONE. The subheading for Section IV, “(LHDs use approved abbreviations from “Facility List.”)” has been removed. The referenced Facility List is not included in regulation and constitutes an inappropriate incorporation by reference. For that reason, the language has been removed.
- CDPH 8641P (5/07), Pediatric HIV/AIDS Confidential Case Report
  - PAGE ONE. In Section III, the “*Ethnicity*” field boxes for options “*Hispanic*” and “*Not Hispanic or Latino*” are numbered “1” and “2”, respectively, to reflect the way the field is coded in the HIV/AIDS Reporting System (HARS) database and to match the way the field appears on the Adult HIV/AIDS Case Report form, CDPH 8641A (05/07).
  - PAGE ONE. The subheading for Section IV, “(LHDs use approved abbreviations from “Facility List.”)” has been removed. The referenced Facility List is not included in regulation and constitutes an inappropriate incorporation by reference. For that reason, the language has been removed.
  - PAGE TWO. In Section VI, the field name “*Physician’s Telephone Number*” replaces the previous field name, “*Telephone Number*”. The change is made to avoid confusion. Physician contact information is important so that local health department staff are able to follow up on reported cases of HIV infection. The field “*Physician’s telephone number*” appears on the adult case report form, CDPH 8641A (05/07).
- *Update HIV/AIDS Case Report forms to reflect changes in department name.* These amendments update the name of the department amending the HIV/AIDS Case Report forms 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. Specific changes are:
  - CDPH 8641A (5/07), Adult HIV/AIDS Confidential Case Report
    - PAGE ONE. In the heading at the upper right hand corner, “*California Department of Public Health*” replaces “*Department of Health Services.*”

- PAGES ONE and TWO. In the footer at the lower left hand corner of each page, the form number is changed to “*CDPH 8641A (5/07)*” instead of “*DHS 8641A (06/06)*.”
- PAGE TWO. The website “*www.cdph.ca.gov/AIDS*” replaces the former reference “*www.dhs.ca.gov/AIDS*” in the mailing instructions included at the bottom of the page.
- CDPH 8641P (5/07), Pediatric HIV/AIDS Confidential Case Report
  - PAGE ONE. In the heading at the upper right hand corner, “*California Department of Public Health*” replaces “*Department of Health Services.*”
  - PAGES ONE, TWO, THREE and FOUR. In the footer at the lower left hand corner of each page, the form number is changed to “*CDPH 8641P (5/07)*” instead of “*DHS 8641P (06/06)*.”
  - PAGES THREE and FOUR. The website “*www.cdph.ca.gov/AIDS*” replaces the former reference “*www.dhs.ca.gov/AIDS*” in the mailing instructions included at the bottom of each page.
- In Section 2641.55 the updated form numbers of the HIV/AIDS Case Report forms, “*CDPH 8641A (5/07)*” and “*CDPH 8641P (5/07)*”, replace the previous form numbers [“*DHS 8641A (06/06)*” and “*DHS 8641P (06/06)*”, respectively].
- **Update HIV/AIDS Confidentiality Agreement**
  - These amendments update the name of the department adopting the HIV/AIDS Confidentiality Agreement in response to the creation of CDPH and transfer of public health functions to CDPH (H&S Code Sections 131000, 131050 and 131051). Specific changes are:
    - In the heading at the upper right hand corner, “*California Department of Public Health*” replaces “*California Department of Health Services.*”
    - In the first sentence of the second paragraph, “*California Department of Public Health*” replaces “*California Department of Health Services.*”
    - In the signature box for the Chief of the HIV/AIDS Case Registry Section, “*California Department of Public Health*” replaces “*California Department of Health Services.*”
    - In the footer at the lower left hand corner of the page, the form number is changed to “*CDPH 8689 (5/07)*” instead of “*DHS 8689 (10/06)*.”
    - In Section 2641.56 the updated form number of the HIV/AIDS Confidentiality Agreement, “*CDPH 8689 (5/07)*”, replaces the previous form number “*DHS 8689 (10/06)*”.

- **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 2541.5) 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).
  
- **Change Authority and Reference Citations to Reflect SB 162 (Ortiz, Statutes of 2006, Chapter 241).**
  - These amendments update the authority and reference citations in the sections included in these emergency regulations in response to the statutory changes made by SB 162 (Ortiz, Statutes of 2006, Chapter 241). Specific changes are:
    - References to H&S Code Section 131019 replace references to H&S Code Section 100119 for Title 17, CCR, Sections 2641.55, 2641.56, and 2643.15.
    - References to H&S Code Section 131080 replace references to H&S Code Section 100180 for Title 17, CCR, Sections 2641.5, 2641.30, 2641.35, 2641.45, 2641.55, 2641.56, 2641.57, 2643.5, 2643.10, and 2643.15.
    - References to H&S Code Section 131200 replace references to H&S Code Section 100275 for Title 17, CCR, Sections 2641.5, 2641.30, 2641.35, 2641.45, 2641.55, 2641.56, 2641.57, 2643.5, 2643.10, and 2643.15.
    - For clarity, references to H&S Code Sections 131051, 131052, and 131056 are added to the reference citations for Title 17, CCR, Sections 2641.5, 2641.30, 2641.35, 2641.45, 2641.55, 2641.56, 2641.57, 2643.5, 2643.10, and 2643.15.
  
- **Reporting Confirmed HIV Tests Performed at the Point of Care.**
  - These amendments clarify the definition of “*HIV Test Algorithm*” and related language to more appropriately refer to confirmation standards established by CDC and to remove references to FDA. These changes are made to ensure cases of HIV infection meeting the CDC case definition for HIV are reported, regardless of whether laboratory testing was performed at the point of care or in a clinical laboratory.
    - The phrase, “*confirmation protocols published in the Centers for Disease Control and Prevention’s Morbidity and Mortality Weekly Report (MMWR)*” replaces the phrase, “*tests approved by the federal Food and Drug Administration*” in Title 17, CCR, Section 2641.57.

- The phrase, “*approved by the federal Food and Drug Administration*” is removed from Title 17, CCR, Section 2641.30. This phrase is redundant because the term “*HIV Test Algorithm*” is already defined in regulation, and the reference to the FDA would conflict with the revised definition of “*HIV Test Algorithm*” found in Title 17, CCR, Section 2641.57.
- The phrase, “*obtains the results of*” replaces the term “*conducts*” in Title 17, CCR, Section 2641.45. This change is made to avoid potential confusion caused by use of the word “*conducts*” which might lead to the incorrect perception that a health care provider is qualified to perform a wide spectrum of laboratory testing.