

**State of California  
Office of Administrative Law**

**In re:**

**Department of Public Health**

**Regulatory Action:**

**Title 17, California Code of Regulations**

**Adopt sections:**

**Amend sections: 2643.5, 2643.10, 2643.15**

**Repeal sections:**

**NOTICE OF APPROVAL OF CHANGES  
WITHOUT REGULATORY EFFECT**

**California Code of Regulations, Title 1,  
Section 100**

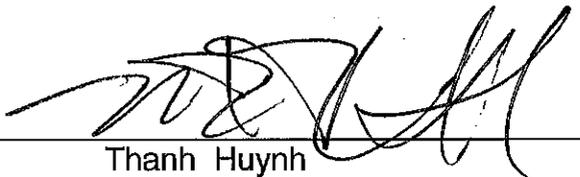
**OAL File No. 2014-1229-01 N**

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In these changes without a regulatory effect, the Department of Public Health is proposing to amend sections 2643.5, 2643.10, and 2643.15 in Title 17 of the California Code of Regulations to allow laboratories to electronically submit reports of HIV test results.

OAL approves this change without regulatory effect as meeting the requirements of California Code of Regulations, Title 1, section 100.

**Date: 2/11/2015**

  
Thanh Huynh  
Senior Attorney

**For: DEBRA M. CORNEZ  
Director**

**Original: Dr. Ron Chapman, MD, MPH  
Copy: Elizabeth Reyes**

STD. 400 (REV. 01-2013)

OAL FILE NUMBERS	NOTICE FILE NUMBER <b>Z-</b>	REGULATORY ACTION NUMBER <b>2014-1229-01N</b>	EMERGENCY NUMBER
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For use by Office of Administrative Law (OAL) only

NOTICE	REGULATIONS
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2014 DEC 29 AM 9:18  
OFFICE OF ADMINISTRATIVE LAW

**ENDORSED - FILED**  
in the office of the Secretary of State  
of the State of California

FEB 11 2015

2:04 PM

AGENCY WITH RULEMAKING AUTHORITY Department of Public Health	AGENCY FILE NUMBER (if any) DPH 13-009
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**A. PUBLICATION OF NOTICE (Complete for publication in Notice Register)**

1. SUBJECT OF NOTICE		TITLE(S)	FIRST SECTION AFFECTED	2. REQUESTED PUBLICATION DATE	
3. NOTICE TYPE <input type="checkbox"/> Notice re Proposed Regulatory Action <input type="checkbox"/> Other		4. AGENCY CONTACT PERSON		TELEPHONE NUMBER	FAX NUMBER (Optional)
<b>OAL USE ONLY</b>	ACTION ON PROPOSED NOTICE <input type="checkbox"/> Approved as Submitted <input type="checkbox"/> Approved as Modified <input type="checkbox"/> Disapproved/Withdrawn			NOTICE REGISTER NUMBER	PUBLICATION DATE

**B. SUBMISSION OF REGULATIONS (Complete when submitting regulations)**

1a. SUBJECT OF REGULATION(S) HIV Reporting	1b. ALL PREVIOUS RELATED OAL REGULATORY ACTION NUMBER(S)
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2. SPECIFY CALIFORNIA CODE OF REGULATIONS TITLE(S) AND SECTION(S) (including title 26, if toxics related)	
<b>SECTION(S) AFFECTED (List all section number(s) individually. Attach additional sheet if needed.)</b>	ADOPT
	AMEND 2643.5, 2643.10, 2643.15
TITLE(S) 17	REPEAL

3. TYPE OF FILING			
<input type="checkbox"/> Regular Rulemaking (Gov. Code §11346)	<input type="checkbox"/> Certificate of Compliance: The agency officer named below certifies that this agency complied with the provisions of Gov. Code §§11346.2-11347.3 either before the emergency regulation was adopted or within the time period required by statute.	<input type="checkbox"/> Emergency Readopt (Gov. Code, §11346.1(h))	<input checked="" type="checkbox"/> Changes Without Regulatory Effect (Cal. Code Regs., title 1, §100)
<input type="checkbox"/> Resubmittal of disapproved or withdrawn nonemergency filing (Gov. Code §§11349.3, 11349.4)	<input type="checkbox"/> Resubmittal of disapproved or withdrawn emergency filing (Gov. Code, §11346.1)	<input type="checkbox"/> File & Print	<input type="checkbox"/> Print Only
<input type="checkbox"/> Emergency (Gov. Code, §11346.1(b))		<input type="checkbox"/> Other (Specify)	

4. ALL BEGINNING AND ENDING DATES OF AVAILABILITY OF MODIFIED REGULATIONS AND/OR MATERIAL ADDED TO THE RULEMAKING FILE (Cal. Code Regs. title 1, §44 and Gov. Code §11347.1) N/A
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5. EFFECTIVE DATE OF CHANGES (Gov. Code, §§ 11343.4, 11346.1(d); Cal. Code Regs., title 1, §100)			
<input type="checkbox"/> Effective January 1, April 1, July 1, or October 1 (Gov. Code §11343.4(a))	<input type="checkbox"/> Effective on filing with Secretary of State	<input checked="" type="checkbox"/> §100 Changes Without Regulatory Effect	<input type="checkbox"/> Effective other (Specify)

6. CHECK IF THESE REGULATIONS REQUIRE NOTICE TO, OR REVIEW, CONSULTATION, APPROVAL OR CONCURRENCE BY, ANOTHER AGENCY OR ENTITY			
<input type="checkbox"/> Department of Finance (Form STD. 399) (SAM §6660)	<input type="checkbox"/> Fair Political Practices Commission	<input type="checkbox"/> State Fire Marshal	
<input type="checkbox"/> Other (Specify)			

7. CONTACT PERSON Elizabeth Reyes	TELEPHONE NUMBER (916) 445-2529	FAX NUMBER (Optional) (916) 319-9821	E-MAIL ADDRESS (Optional) Elizabeth.Reyes@cdph.ca.gov
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8. I certify that the attached copy of the regulation(s) is a true and correct copy of the regulation(s) identified on this form, that the information specified on this form is true and correct, and that I am the head of the agency taking this action, or a designee of the head of the agency, and am authorized to make this certification.

SIGNATURE OF AGENCY HEAD OR DESIGNEE 	DATE 12/22/2014
TYPED NAME AND TITLE OF SIGNATORY Karin S. Schwartz, Deputy Director and Chief Counsel	

For use by Office of Administrative Law (OAL) only

**ENDORSED APPROVED**

FEB 11 2015

Office of Administrative Law

Amend Section 2643.5 to read as follows:

**§ 2643.5. HIV Reporting by Health Care Providers.**

(a) Each health care provider that orders a laboratory test used to identify HIV, a component of HIV, or antibodies to or antigens of HIV shall submit to the laboratory performing the test a pre-printed laboratory requisition form which includes all documentation as specified in 42 CFR 493.1105 (57 FR 7162, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993) and adopted in Business and Professions Code, Section 1220.

(b) The person authorized to order the laboratory test shall include the following when submitting information to the laboratory:

- (1) Complete name of patient; and
- (2) Patient date of birth (2-digit month, 2-digit day, 4-digit year); and
- (3) Patient gender (male, female, transgender male-to-female, or transgender female-to-male); and
- (4) Date biological specimen was collected; and
- (5) Name, address, telephone number of the health care provider and the facility where services were rendered, if different.

(c) Each health care provider shall, within seven calendar days of receipt from a laboratory of a patient's confirmed HIV test or determination by the health care provider of a patient's confirmed HIV test, report the confirmed HIV test to the local Health Officer for the jurisdiction where the health care provider facility is located. The report shall consist of a completed copy of the HIV/AIDS Case Report form.

(1) All reports containing personal information, including HIV/AIDS Case Reports, shall be sent to the local Health Officer or his or her designee by:

(A) e-Courier service, U.S. Postal Service Express or Registered mail, or other traceable mail; facsimile, or electronically by a secure and confidential electronic reporting system established by the Department; or

(B) Person-to-person transfer with the local Health Officer or his or her designee.

(2) The health care provider shall not submit reports containing personal information to the local Health Officer or his or her designee ~~by electronic facsimile transmission or by~~ electronic mail or by non-traceable mail.

(d) HIV reporting by name to the local Health Officer, via submission of the HIV/AIDS Case Report, shall not supplant the reporting requirements in Article 1 of this Subchapter when a patient's medical condition progresses from HIV infection to an Acquired Immunodeficiency Syndrome (AIDS) diagnosis.

(e) A health care provider who receives notification from an out-of-state laboratory of a confirmed HIV test for a California patient shall report the findings to the local Health Officer for the jurisdiction where the health care provider facility is located.

(f) When a health care provider orders multiple HIV-related viral load tests for a patient, or receives multiple laboratory reports of a confirmed HIV test, the health care provider shall be required to submit only one HIV/AIDS Case Report, per patient, to the local Health Officer.

(g) Nothing in this Subchapter shall prohibit the local health department from assisting health care providers to report HIV cases.

(h) Information reported pursuant to this Article is acquired in confidence and shall not be disclosed by the health care provider except as authorized by this Article, other state or federal law, or with the written consent of the individual to whom the information pertains or the legal representative of that individual.

NOTE: Authority cited: Sections 120125, 120130, 120140, 121022, 131080 and 131200, Health and Safety Code. Reference: Sections 1202.5, 1206, 1206.5, 1220, 1241, 1265 and 1281, Business and Professions Code; and Sections 1603.1, 101160, 120175, 120250, 120775, 120885-120895, 120917, 120975, 120980, 121015, 121022, 121025, 121035, 121085, 131051, 131052, 131056 and 131080, Health and Safety Code.

Amend Section 2643.10 to read as follows:

**§ 2643.10. HIV Reporting by Laboratories.**

(a) The laboratory director or authorized designee shall, within seven calendar days of determining a confirmed HIV test, report the confirmed HIV test to the Health Officer for the local health jurisdiction where the health care provider facility is located.

The report shall include the:

- (1) Complete name of patient; and
- (2) Patient date of birth (2-digit month, 2-digit day, 4-digit year); and
- (3) Patient gender (male, female, transgender male-to-female, or transgender female-to-male); and

(4) Name, address, and telephone number of the health care provider and the facility that submitted the biological specimen to the laboratory, if different; and

- (5) Name, address, and telephone number of the laboratory; and
- (6) Laboratory report number as assigned by the laboratory; and
- (7) Laboratory results of the test performed; and
- (8) Date the biological specimen was tested in the laboratory; and
- (9) Laboratory Clinical Laboratory Improvement Amendments (CLIA) number.

(b)(1) All reports containing personal information, including laboratory reports, shall be sent to the local Health Officer or his or her designee by:

(A) e Courier service, U.S. Postal Service Express or Registered mail, or other traceable mail; or

(B) ~~p~~ Person-to-person transfer with the local Health Officer or his or her designee; or

(C) Provided that, commencing July 1, 2009, or within one year of the establishment of a state electronic laboratory reporting system, whichever is later, a report generated pursuant to Section 120130, or Section 121022, by a laboratory shall be submitted electronically in a manner specified by the department.

(2) The laboratory shall not submit reports containing personal information to the local Health Officer or his or her designee by electronic facsimile transmission or by electronic mail or by non-traceable mail.

(c) A laboratory that receives incomplete patient data from a health care provider for a biological specimen with a confirmed HIV test, shall contact the submitting health care provider to obtain the information required pursuant to Section 2643.5(b)(1)-(5), prior to reporting the confirmed HIV test to the local Health Officer.

(d) If a laboratory transfers a biological specimen to another laboratory for testing, the laboratory that first receives the biological specimen from the health care provider shall report confirmed HIV tests to the local Health Officer.

(e) Laboratories shall not submit reports to the local health department for confirmed HIV tests for patients of an Alternative Testing Site or other anonymous HIV testing program, a blood bank, a plasma center, or for participants of a blinded and/or unlinked seroprevalence study.

(f) When a California laboratory receives a biological specimen for testing from an out-of-state laboratory or health care provider, the California director of the laboratory shall ensure that a confirmed HIV test is reported to the state health department in the state where the biological specimen originated.

(g) When a California laboratory receives a report from an out of state laboratory that indicates evidence of a confirmed HIV test for a California patient, the California laboratory shall notify the local Health Officer and health care provider in the same manner as if the findings had been made by the California laboratory.

(h) Information reported pursuant to this Article is acquired in confidence and shall not be disclosed by the laboratory except as authorized by this Article, other state or federal law, or with the written consent of the individual to whom the information pertains or the legal representative of the individual.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Sections 120125, 120130, 120140, 121022, 131080 and 131200, Health and Safety Code.  
Reference: Sections 1206, 1206.5, 1209, 1220, 1241, 1265, 1281 and 1288, Business and Professions Code; and Sections 101150, 120175, 120775, 120885-120895, 120975, 120980, 121022, 121025, 121035, 131051, 131052, 131056 and 131080, Health and Safety Code.

Amend Section 2643.15 to read as follows:

**§ 2643.15. HIV Reporting by Local Health Officers.**

(a) The local Health Officer or his or her authorized designee shall match and unduplicate laboratory reports of confirmed HIV tests with the local health department HIV/AIDS registry database and with HIV/AIDS Case Reports received from health care providers and not entered into the database.

(b) The Health Officer or his or her authorized designee shall, within 45 calendar days of receipt of a laboratory report of a confirmed HIV test, submit unduplicated HIV/AIDS Case Reports to the Department.

(1) HIV/AIDS Case Reports shall be sent by e-Courier service, U.S. Postal Service Express or Registered mail, or other traceable mail, person to person transfer, facsimile, or electronically by a secure and confidential electronic reporting system established by the department to the California Department of Public Health, Office of AIDS, ~~HIV/AIDS Case Registry Surveillance Section~~.

(2) The local Health Officer or his or her authorized designee shall not report confirmed HIV tests for patients of an Alternative Testing Site or other anonymous counseling and testing program, a blood bank, a plasma center, or for participants of a blinded and/or unlinked HIV seroprevalence study.

(c) The local Health Officer or his or her authorized designee shall not submit an HIV/AIDS Case Report to the Department for an infant under the age of 18 months, unless the infant's HIV infection is confirmed.

(d) All local health department employees and contractors shall sign the HIV/AIDS Confidentiality Agreement prior to accessing confidential HIV-related public

health records. All HIV/AIDS Confidentiality Agreements shall be renewed at least once per year.

(e) Information reported pursuant to this Article is acquired in confidence and shall not be disclosed by the local Health Officer or his or her authorized designee except as authorized by this Article, other state or federal law, or with the written consent of the individual to whom the information pertains or the legal representative of the individual.

NOTE: Authority cited: Sections 120125, 120130, 120140, 121022, 131080 and 131200, Health and Safety Code. Reference: Sections 120175, 120775, 120820, 120885-120895, 120975, 120980, 121015, 121022, 121025, 121035, 121085, 131019, 131051, 131052, 131056 and 131080, Health and Safety Code.

**Department of Public Health  
Title 17  
Preventive Medical Service**

Sections Affected: 2643.5, 2643.10, and 2643.15

**Justification for Changes Without Regulatory Effect:**

The California Department of Public Health (Department) proposes amendments to sections 2643.5, 2643.10 and 2643.15 in Title 17 of the California Code of Regulations (17 CCR). These proposed amendments would make sections 2643.5, 2643.10 and 2643.15 in 17 CCR consistent with revisions to Health and Safety Code (HSC) sections 120130 and 121022.

Prior to the enactment of Assembly Bill (AB) 2541 (Portantino, Chapter 470, Statutes of 2010), electronic reporting methods were prohibited in the CCR. HSC section 120130, subdivision (g), now permits laboratories to electronically submit reports of HIV test results in a manner specified by the Department and HSC section 121022 (b)(1), now permits health care providers and local health officers to submit cases of HIV infection by facsimile or electronically by a secure and confidential electronic reporting system established by the Department.

These changes qualify as a 1 CCR Section 100 because they do not materially alter any requirement, right, responsibility, condition, prescription, or other regulatory element of any CCR provision.

**Chapter 4. Preventive Medical Service**

**Section 2643.5 HIV Reporting by Health Care Providers**

Subdivision (c), paragraph (1)(A): Correct a typographical error, Change the "c" to capital "C." This does not change the meaning or requirement of the regulation.

Subdivision (c), paragraph (1)(A): Delete semicolon ";" following "traceable mail" and replace with comma "," and add "facsimile, or electronically by a secure and confidential electronic reporting system established by the Department;" This amendment will make CCR consistent with HSC section 121022, subdivision (b), paragraph (1), which permits health care providers to submit cases of HIV infection by facsimile or an electronic reporting system established by the Department.

Subdivision (c), paragraph (1)(B): Correct a typographical error, Change the "p" to capital "P." This does not change the meaning or requirement of the regulation.

Subdivision (c), paragraph (2): Delete “by electronic facsimile transmission or.” This makes the regulation consistent with HSC section 121022, subdivision (b), paragraph (1), which permits health care providers to submit cases of HIV infection by facsimile or an electronic reporting system established by the Department.

#### **Section 2643.10 HIV Reporting by Laboratories**

Subdivision (b)(1), paragraph (A): Correct a typographical error, Change the “c” to capital “C.” This does not change the meaning or requirement of the regulation.

Subdivision (b)(1), paragraph (B): Correct a typographical error, Change the “p” to capital “P” and delete period “.” after “designee.” Replace period with a semicolon “;” and add “or.” This does not change the meaning or requirement of the regulation.

Subdivision (b)(1), add paragraph (C): This will make CCR consistent with HSC section 120130, subdivision (g), which requires laboratories to submit reports of HIV test results by electronic reporting system in a manner specified by the Department commencing within one year after the establishment of a state electronic laboratory reporting system.

#### **Section 2643.15 HIV Reporting by Local Health Officers**

Subdivision (b), paragraph (1): Add coma “,” after “traceable mail” and add “person to person, facsimile, or electronically by a secure and confidential electronic reporting system established by the Department.” This makes the regulation consistent with HSC section 121022, subdivision (b), paragraph (1). This does not change the meaning or requirement of the regulation.

Subdivision (b), paragraph (1): Replace “HIV/AIDS Case Registry Section” with “Surveillance Section.” This reflects a 2013 Department program name change and the name “HIV/AIDS Case Registry Section” is no longer in use by the Department. This does not change the meaning or requirement of the regulation.



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



EDMUND G. BROWN JR.  
Governor

**DELEGATION OF AUTHORITY FOR ADOPTION OF REGULATIONS AND FILING OF STD 400**

I, Ron Chapman, MD, MPH, Director of the California Department of Public Health (CDPH), State of California, am empowered to adopt regulations for this Department pursuant to Article 2 (commencing with Section 131200) of Chapter 2 of Part 1 of Division 112 of the Health and Safety Code, Government Code Section 11152, and Title 1, California Code of Regulations, Section 280.

I thereby delegate my authority and responsibilities for these matters to the following individuals:

- Karin S. Schwartz, Deputy Director and Chief Counsel, Office of Legal Services, CDPH
- Belinda B. Whitsett, Assistant Chief Counsel, Office of Legal Services, CDPH
- Peter A. Baldrige, Assistant Chief Counsel, Office of Legal Services, CDPH

This delegation shall be effective during my term as Director or until withdrawn by me in writing.

In witness of this delegation, I hereby affix my signature to this delegation order.

\_\_\_\_\_  
Ron Chapman, MD, MPH  
Director & State Health Officer  
California Department of Public Health

Date: 6/11/14

We fully understand and accept this delegation.

\_\_\_\_\_  
Karin S. Schwartz  
Deputy Director & Chief Counsel

Date: 6/13/14

  
\_\_\_\_\_  
Belinda B. Whitsett  
Assistant Chief Counsel

Date: 6/12/14

  
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Peter A. Baldrige  
Assistant Chief Counsel

Date: 6/12/14