

(1) Amend Section 2641.5 to read as follows:

**§ 2641.5. Alternative Testing Site.**

"Alternative Testing Site" means an anonymous HIV testing site funded by the ~~California Department of Health Services~~ California Department of Public Health, administered by a county health department and operated pursuant to Health and Safety Code, Sections 120890-120895.

Authority cited: Sections ~~100180, 100275,~~ 120125, and 120130, 131080 and 131200, Health and Safety Code.

Reference: Sections ~~100180,~~ 120175, 120775, 120885-120895, and 121025, 131051, 131052, 131056 and 131080, Health and Safety Code.

(2) Amend Section 2641.30 to read as follows:

**§ 2641.30. Confirmed HIV Test.**

"Confirmed HIV test" means:

(a) a procedure which verifies the presence of HIV infection as determined by any clinical laboratory test or HIV Test Algorithm approved by the federal Food and Drug Administration or examination used to detect the presence of HIV, a component of HIV, or antibodies to or antigens of HIV, including the HIV antibody (HIV-Ab), HIV p-24 antigen, Western blot (Wb), and immunofluorescence antibody tests; or

(b) for the purpose of this Article, all tests used to monitor HIV infection, including HIV nucleic acid detection.

Authority cited: Sections ~~100180, 100275,~~ 120125, and 120130, ~~and~~ 121022, 131080 and 131200, Health and Safety Code.

Reference: Sections 1206, 1206.5, 1241, 1265 and 1281, Business and Professions Code; and Sections ~~100180,~~ 101150, 101160, 120175, 120775, 120885-120895, and 121025, ~~120917, and~~ 121022, 131051, 131052, 131056 and 131080, Health and Safety Code.

(3) Amend Section 2641.35 to read as follows:

**§ 2641.35. Department.**

"Department" means the ~~California Department of Health Services~~California Department of Public Health, Office of AIDS.

Authority cited: Sections ~~100180, 100275, 120125, and 120130~~, 131080 and 131200, Health and Safety Code.

Reference: Sections ~~100180, 120175, 120775, 120885-120895, and 121025~~, 131051, 131052, 131056 and 131080, Health and Safety Code.

(4) Amend Section 2641.45 to read as follows:

**§ 2641.45. Health Care Provider.**

"Health care provider" means an individual who obtains the results of~~conducts~~ an HIV test or HIV test algorithm or 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, receives the test results and is;

(a) licensed under the provisions of Business and Professions Code, Division 2 (Healing Arts) and acting within his or her scope of practice, or;

(b) a designee of a physician and surgeon acting under the general supervision of that physician or surgeon, or;

(c) a person working in a publicly-funded confidential counseling and testing program acting under the general supervision of, and following the protocols approved by, the local Health Officer for the local health department.

Authority cited: Sections ~~100180, 100275,~~ 101160, 120125, ~~and 120130,~~ and 121022, 131080 and 131200, Health and Safety Code.

Reference: Sections 1206, 1206.5, 1241, 1281 and 1285, Business and Professions Code; and Sections ~~100180,~~ 120175, 120775, 120885-120895, 120917, 121022, ~~and 121025,~~ 131051, 131052, 131056 and 131080, Health and Safety Code.

(5) Amend Section 2641.55 to read as follows:

**§ 2641.55. HIV/AIDS Case Report.**

"HIV/AIDS Case Report" means ~~California Department of Health Services~~ California Department of Public Health HIV/AIDS Confidential Case Report form, Adult (~~DHS 8641A (9/016/06)~~ CDPH 8641A (05/07)) or Pediatric (~~DHS 8641P (9/016/06)~~ CDPH 8641P (05/07)), hereby incorporated by reference in this Article and available from the local health department or the Department.

Authority cited: Sections ~~100180, 100275, 120125, and 120130, and~~ 121022, 131080 and 131200, Health and Safety Code.

Reference: Sections ~~100119, 100180, 120175, 120775, 120885-120895, 121022, and 121025, and~~ 121035, 131019, 131051, 131052, 131056 and 131080, Health and Safety Code.

(6) Adopt Section 2641.56 to read as follows:

**§ 2641.56. HIV/AIDS Confidentiality Agreement.**

"HIV/AIDS Confidentiality Agreement" means ~~California Department of Health Services~~ California Department of Public Health HIV/AIDS Confidentiality Agreement form (~~DHS 8689 (10/06)~~ CDPH 8689 (5/07)), hereby incorporated by reference and available from the Department.

Authority cited: Sections ~~100180, 100275,~~ 120125, 120130, ~~and~~ 121022, 131080 and 131200, Health and Safety Code.  
Reference: Sections ~~100119, 100180,~~ 120175, 120775, 120820, 120885-120895, 120975, 120980, 121022, 121025, 121035, ~~and~~ 121110, 131019, 131051, 131052, 131056 and 131080, Health and Safety Code.

(7) Adopt Section 2641.57 to read as follows:

**§ 2641.57. HIV Test Algorithm.**

“HIV test algorithm” means any multi-test procedure that determines the presence of HIV infection using confirmation protocols published in the Centers for Disease Control and Prevention’s Morbidity and Mortality Weekly Report (MMWR) tests approved by the federal Food and Drug Administration for that purpose.

Authority cited: Sections ~~100180, 100275,~~ 120125, 120130, ~~and~~ 121022, 131080 and 131200, Health and Safety Code.

Reference: Sections 1206 and 1220, Business and Professions Code; Sections 120917, ~~and~~ 121022, 131051, 131052 and 131056, Health and Safety Code.

(8) Repeal Section 2641.75 as follows:

**~~§ 2641.75. Non-Name Code.~~**

~~"Non-Name Code" means a designation required by Section 2643.5 of this Article, that does not readily identify an HIV-infected individual. Components of the Non-Name Code shall be listed in the following order, and shall consist of an individual's:~~

~~(a) Soundex code;~~

~~(b) complete date of birth (2-digit month, 2-digit day, 4-digit year);~~

~~(c) gender (male [1], female [2], transgender male-to-female [3], or transgender female-to-male [4]); and~~

~~(d) last four digits of the Social Security Number (if not available, use four digits of zero).~~

Authority cited: Sections 100180, 100275, 120125, 120130 and 120140, Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(9) Repeal Section 2641.77 as follows:

**~~§ 2641.77. Partial Non-Name Code.~~**

~~A Partial Non-Name Code means a designation required by Section 2643.10 of this Article, that does not readily identify the HIV-infected individual. Components of the Partial Non-Name Code shall be listed in the following order, and shall consist of an individual's:~~

~~(a) Soundex code;~~

~~(b) complete date of birth (2-digit month, 2-digit day, 4-digit year) and;~~

~~(c) gender (male [1], female [2], transgender male-to-female [3], or transgender female-to-male [4]).~~

Authority cited: Sections 100180, 100275, 120125, 120130 and 120140 Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(10) 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 ~~the following~~ to the laboratory performing the test:

- ~~(1) A 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, ~~or;~~~~
- ~~(2) 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.~~

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

- (1) Complete name of patient~~Patient surname~~; 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, and Partial Non-Name Code from a laboratory, complete ~~the Non-Name Code (as specified in Section 2641.75)~~ and 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. courier service, U.S. Postal Service Express or Registered mail, or other traceable mail; 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 ~~Non-Name Code~~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) 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.~~

~~(f)~~(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.

~~(g)~~(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.

~~(h) 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.~~

(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.

Authority cited: Sections ~~100180, 100275,~~ 120125, 120130, ~~and 120140,~~ and 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, ~~100180,~~ 101160, 120175, 120250, 120775, 120885-120895, 120917, 120975, 120980, 121015, 121022, and 121025, 121035, and 121085, 131051, 131052, 131056 and 131080, Health and Safety Code.

(11) Amend Section 2643.10 to read as follows:

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

~~(a) The laboratory director or authorized designee shall create a Partial Non-Name Code (as specified in Section 2641.77) for each confirmed HIV test.~~

~~(b)~~(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 ~~of~~ for the local health jurisdiction where the health care provider facility is located. The report shall include the:

~~(1) Partial Non-Name Code of the patient~~Complete name of patient; and

~~(2)~~(1) Patient date of birth (2-digit month, 2-digit day, 4-digit year); and

~~(3)~~(2) Patient gender (male, female, transgender male-to-female, or transgender female-to-male); and

~~(2)~~(3) Name, address, and telephone number of the health care provider and the facility that submitted the biological specimen to the laboratory, if different; and

~~(3)~~(4) Name, address, and telephone number of the laboratory; and

~~(4)~~(5) Laboratory report number as assigned by the laboratory; and

~~(5)~~(6) Laboratory results of the test performed; and

~~(6)~~(7) Date the biological specimen was tested in the laboratory; and

~~(9)~~(8) Laboratory Clinical Laboratory Improvement Amendments (CLIA) number.

~~(c) A laboratory shall not transmit a patient's personal information to the local health department.~~

(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. courier service, U.S. Postal Service Express or Registered mail, or other traceable mail; or

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

(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.

~~(d)~~ 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.

~~(e) A laboratory shall convey the patient's Partial Non-Name Code to the submitting health care provider when reporting confirmed HIV test results.~~

~~(f)~~(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.

~~(g)~~(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.

~~(h)~~(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.

~~(i)~~(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.

~~(j)~~(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.

Authority cited: Section 1224, Business and Professions Code; and Sections ~~100180, 100275, 120125, 120130, and 120140~~, and 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 ~~100180, 101150, 120175, 120775, 120885-120895, 120975, 120980, 121022, and 121025~~, and 121035, 131051, 131052, 131056 and 131080, Health and Safety Code.

(12) 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 courier service, U.S. Postal Service Express or Registered mail, or other traceable mail to the ~~California Department of Health Services~~ California Department of Public Health, Office of AIDS, HIV/AIDS Case Registry.

(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.

Authority cited: Sections ~~100180, 100275,~~ 120125, 120130, ~~and 120140,~~ and 121022, 131080 and 131200, Health and Safety Code.

Reference: Sections ~~100119, 100180,~~ 120175, 120775, 120820, 120885-120895, 120975, 120980, 121015, 121022, and 121025, 121035, and 121085, 131019, 131051, 131052, 131056 and 131080, Health and Safety Code.