



SONIA Y. ANGELL, MD, MPH
State Public Health Officer & Director

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



GAVIN NEWSOM
Governor

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TO: ALL INTERESTED PARTIES

FROM: Marisa Ramos, PhD
Interim Chief, Office of AIDS

RE: HIV CASE REPORTING BY PROVIDERS AND LABORATORIES FOR
PERSONS IN RESEARCH STUDIES

The California Department of Public Health (CDPH), Office of AIDS (OA) clarifies that providers and laboratories are required to report HIV cases to the local health officer, including persons participating in research studies. Research studies are not exempt from HIV case reporting requirements except for participants of a blinded and/or unlinked HIV seroprevalence study.

Background

HIV case reporting by name has been required since April 17, 2006. HIV surveillance data is used for a number of purposes including informing the appropriate allocation of funding and assessing the success of strategies to prevent and treat HIV disease. Timely, accurate, and complete case reporting are important for informing appropriate public health approaches and identifying circumstances which require immediate action, such as an unexpected rise in cases within a geographical area or risk population.

HIV Case Reporting Requirements

California law requires health care providers and laboratories to report persons with HIV infection and all HIV-related tests including CD4s and viral loads. (Health and Safety Code 121022) The California Code of Regulations (CCR) provides requirements for reporting HIV in Title 17.

17 CCR 2643.5 specifies requirements for health care provider reporting of confirmed HIV to the Local Health Officer.

17 CCR 2641.45, defines a health care provider as an individual who obtains results of an HIV test and is licensed under Business and Professions Code (healing arts), designees of a physician or surgeon, or a confidential counselor working under an LHJ.

17 CCR 2643.10 specifies requirements for laboratory reporting of confirmed HIV to the Local Health Officer.



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17 CCR 2641.30 defines a “confirmed HIV test” as (a) a procedure which verifies the presence of HIV infection as determined by any clinical laboratory test or HIV Test Algorithm, or (b) all tests used to monitor HIV infection, including HIV nucleic acid detection.

Research Studies Not Generally Exempt

17 CCR 2643.20 specifies that only Alternative Testing Sites, other anonymous or unlinked HIV testing programs, blood banks, plasma centers, and blinded and/or unlinked seroprevalence studies are exempt from these HIV reporting regulations.

Laboratories are subject to California mandated reporting if they meet the definition of “laboratory” as defined in 17 CCR 2641.60 and Business and Professions Code section 1206. Laboratory reporting is mandated for a confirmed HIV test pursuant to 17 CCR 2643.20 and 17 CCR 2505. Note that receiving incomplete data on a specimen does not exempt the laboratory from this reporting requirement. 17 CCR 2643.20(c) requires that a laboratory contact the submitting healthcare provider to obtain the information required for reporting prior to reporting the confirmed HIV test to the local Health Officer.

Patient Consent Not Required for Public Health Surveillance

The HIPAA Privacy Rule 45 CFR §164.512(b) expressly permits covered entities (health care providers, health plans, and health care clearinghouses) to disclose protected health information, without patient authorization, to public health authorities for the purposes of preventing or controlling disease, including, but not limited to, the reporting of disease, conducting public health surveillance, investigations, and interventions.

The Confidentiality of Medical Information Act {California Civil Code Section 56.10(b)(9) and 56.30(c)} states that patient medical information may be disclosed without prior authorization when specifically required by law such as in compliance with communicable disease reporting requirements.

Summary

Accurate and complete HIV surveillance data is necessary to effectively facilitate HIV public health activities, and is required by law. In research settings, only blinded/unlinked seroprevalence studies are exempt from HIV public health reporting requirements. Every effort should be made to immediately correct existing deficiencies in compliance with reporting requirements. If you have additional questions please contact your local HIV surveillance coordinator or Deanna Sykes at Deanna.sykes@cdph.ca.gov; (916) 449-5835.

Additional resources related to HIV laws, including HIV reporting requirements, are available on the OA website:

<https://www.cdph.ca.gov/Programs/CID/DOA/Pages/HIVLaws.aspx>