



California
Department of
Health Services

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TO: COUNTY HEALTH EXECUTIVES
LOCAL HEALTH OFFICERS
LOCAL AIDS DIRECTORS
HIV/AIDS SURVEILLANCE COORDINATORS

SUBJECT: REPORTING CASES OF HIV INFECTION BY NAME

Effective April 17, 2006, California law (Health and Safety [H&S] Code Section 121022) requires health care providers and clinical laboratories to report cases of HIV infection using patient names to the local health officer, and local health officers to report unduplicated HIV cases by name to the California Department of Health Services, Office of AIDS (CDHS/OA) (see enclosure). CDHS is committed to a complete and timely implementation of HIV case reporting by name to ensure accurate knowledge of current trends in the epidemic, and to enable California to remain competitive for federal HIV/AIDS funding.

The purpose of this letter is to address numerous issues, questions, and concerns that have been raised regarding implementation of California's HIV name-based reporting system. Until such time that HIV name-based regulations written pursuant to authority of H&S Code Section 101022 are in place, this letter is intended to provide guidance to local health jurisdictions regarding the process and procedures to be followed when reporting cases of HIV infection.

Background: The federal funding formula for the Ryan White CARE Act (RWCA) has historically been based on AIDS case data. In the near future, this formula will be changed to include HIV case data. In 2002, California implemented regulations for a non-name HIV reporting system; however, that data (and HIV data from all other states with code-based systems) has not been accepted by the Centers for Disease Control and Prevention (CDC). CDC provides the data for the RWCA funding formula. In July 2005, CDC released a letter stating that they recommend that all states and territories adopt confidential name-based surveillance systems to report HIV infection. In December 2005, CDC sent a follow-up letter to the Governor of each code-based state reiterating CDC's

position of July 2005, and clarifying that CDC accepts data only from jurisdictions with confidential name-based systems. Senate Bill (SB) 699 (Soto) was introduced to mandate HIV reporting by patient name in California. Among other things, SB 699 also increased the penalties for breach of confidentiality of HIV cases, required CDHS/OA to develop a confidentiality form to be signed annually by local and state surveillance staff, and required CDHS/OA to revise the existing HIV non-name reporting regulations in Title 17 California Code of Regulations (CCR) to conform to the new statute. SB 699 was signed into law on April 17, 2006, and crafting of the regulations began immediately. A completed draft is currently under departmental review for approval.

Name-based AIDS case reporting has been in place in California for over 20 years. During this time, OA has worked closely with local health jurisdiction AIDS surveillance coordinators to ensure a reliable, secure, and confidential system. Standard AIDS surveillance practice has always included use of a specific AIDS reporting form, restrictions on storage and transference of data, and confidentiality (e.g., stand-alone systems that are not connected to the Internet, no facsimile transmission, encryption of electronic media, confidentiality training and procedure implementations, etc.).

While transmission prevention for HIV may be similar to other sexually transmitted or blood borne pathogens, the treatment and societal challenges surrounding HIV disease are clearly unique. Many other communicable diseases can be effectively treated pharmaceutically – in fact, some can be cured with a single dose of a drug. HIV infection cannot be cured, and the pharmaceutical interventions required to keep an infected individual healthy are expensive and extensive. HIV also differs from other communicable diseases in the area of social stigma and discrimination. Despite progress in these areas over the last 20 years, HIV-infected individuals still experience HIV-related challenges that cannot be disregarded, including loss of jobs, housing, family, friends, and emotional well being. No other communicable or non-communicable disease carries such a burden. This issue remains a major concern.

When SB 699 was under consideration in the Legislature, the California Health and Human Services Agency (CHHS) and CDHS gathered a large group of individuals including HIV and gay/lesbian advocacy organizations, legislative representatives, the California Conference of Local Health Officers, the American Civil Liberties Union (ACLU), and others to come to consensus on language of the bill. ACLU and HIV advocates were very clear in these meetings that the only way they would consider supporting SB 699 was with firm assurances from CHHS and CDHS that we would maintain the same high standards of confidentiality and security for HIV name-based reporting that is currently and successfully practiced for AIDS reporting. The bill ultimately included additional specific confidentiality provisions and significant increases in penalties for willful, negligent, or malicious disclosure of HIV status.

Protecting the security and confidentiality of HIV/AIDS surveillance data is a requirement of the HIV/AIDS surveillance cooperative agreement between state surveillance programs and the CDC. CDC requires that all local surveillance staff within a decentralized state HIV/AIDS surveillance system (e.g., California) adhere to the guidelines. In California, CDC requirements are not specified in state statute, but falling below the standard could result in corrective action by CDC, including the potential for HIV/AIDS surveillance funding to be restricted. CDC has declined to accept HIV/AIDS case data if they consider it to be incomplete or unreliable. Sites within California that do not comply with the CDC requirements may jeopardize complete and timely recognition of California's HIV/AIDS cases by the CDC, and risk the state receiving corrective action.

During the process of implementing name-based reporting, CDHS/OA has been in direct communication with Dr. Matt McKenna, Chief, HIV Incidence and Case Surveillance Branch, CDC, as well as the HIV/AIDS state surveillance coordinators for the states of Washington, New York, Florida, and Texas to determine uniformity regarding HIV/AIDS data security and confidentiality practices. New York and Florida began HIV surveillance with a name-based system, Texas has converted from a code-based system to a name-based system, and Washington recently converted from a name-to-code reporting system to a name-based system. CDHS/OA was able to confirm that California's approach to HIV/AIDS security and confidentiality is in line with CDC guidance as well as the policy/practices of states with HIV/AIDS surveillance systems of a comparable size and complexity. Health care providers in other states utilize a specific HIV/AIDS case report form; are required to use secure protocols as determined by the state when transmitting HIV/AIDS case data to the reporting system; and are not permitted to fax confidential HIV-related information to the local or state health department unless identifiers and all reference to HIV/AIDS has been removed. CDC and the four states contacted fully agree with CDHS/OA's policy that transmitting HIV-related information must be handled with the strictest security and confidentiality.

Which cases of HIV infection should be reported by name? Who is responsible for reporting?

Effective April 17, 2006, the law requires health care providers, laboratories, and local health officers to report cases of HIV infection by patient name, except for those tests conducted at anonymous testing sites. Cases of HIV infection with a confirmed HIV test performed on or after April 17, 2006, are to be reported by patient name. If it is necessary for local health jurisdictions to abstract information from the patient medical record to report an unduplicated HIV case to CDHS/OA that was diagnosed prior to April 17, 2006, or if the local health jurisdiction receives a request for technical assistance on such cases, CDHS advises that the parties involved be mindful of the terms of the patient's consent to

test. If the patient has not had a new HIV-related laboratory test since April 17, 2006, CDHS strongly recommends that the local health jurisdiction recommend that the provider inform the patient of the new reporting requirement; document the notification in the patient's medical record; and report the case by name as required by law. Following this recommendation will help to ensure that the patient is fully informed, maintain the patient-doctor relationship, and will allow the provider to report the HIV case as is legally required. Providers and local health jurisdictions should discontinue the use of consent documents that state that a patient testing positive for HIV will not be reported by name.

When reporting HIV cases by name, what data elements should be reported in addition to patient name? When will there be a new HIV case report form?

Reports of HIV cases by name should continue to include all the information required for non-name code HIV reporting. To facilitate reporting by name, CDHS/OA has distributed a slightly modified HIV/AIDS confidential case report form to be used by health care providers and local health departments (see enclosure). Use of the new form is optional for reporting HIV infection until name-based HIV reporting regulations take effect; it will then become mandatory. An electronic copy of the new form is available on the CDHS/OA Website www.dhs.ca.gov/AIDS or from OA. CDHS/OA notes that the current law requires reporting of cases of HIV infection by name only. Additional identifying information such as the patient's Social Security Number, address, or telephone number are not specifically included in the statutory language. CDHS/OA believes that the statute provides authority to clarify this aspect of the statute, and the HIV reporting regulations will be revised to require reporting of this information.

When will name-based HIV reporting regulations be developed?

CDHS is moving forward to release name-based HIV reporting regulations as quickly as possible. Crafting of the emergency regulations began when the bill was signed into law, and draft language is currently undergoing CDHS review for approval. CDHS is committed to expediting this process where possible.

Why can't HIV be added to CCR, Title 17, Sections 2500 and 2502 instead of developing new regulations? Wouldn't this be faster?

Adding HIV to the list of communicable diseases and conditions published in CCR, Title 17, Sections 2500 and 2502 could immediately allow reporting of unique identifiers in addition to patient name; however, after careful consideration, we have determined that this approach has limitations and the potential to ultimately hinder rather than help the process. For example:

- Adding HIV to the list of diseases in CCR, Title 17, Section 2500 does not fulfill the statutory mandate of H&S Code Section 121022, which requires CDHS to conform to the relevant provisions of the HIV non-name code regulations in CCR, Title 17, Article 3.5, commencing with Section 2641.5 to be consistent with the language of H&S Code Section 121022.
- Putting HIV in Section 2500 could cause confusion because it may result in two sets of potentially conflicting HIV reporting instructions for health care providers: the general list of reportable diseases (CCR, Title 17, Section 2500), and HIV-specific regulations (CCR, Title 17, Sections 2641.5-2643.20).
- For HIV reporting, the definition for "Health Care Provider" must include persons who conduct HIV tests at publicly funded confidential counseling and testing programs. These sites perform hundreds of HIV tests each year, and are a crucial part of the system. The definition of "Health Care Provider" that governs reporting of communicable diseases and conditions in CCR, Title 17, Section 2500 does not include these individuals.

Why has OA removed all HIV cases reported by non-name code from the state database? Are local health departments required to remove HIV cases from their local databases?

Before accepting any name-based HIV case data from California, the CDC required OA to remove (purge) all code-based HIV cases from the statewide HIV/AIDS Reporting System (HARS) database. CDC required proof of this system purge before allowing California to send name-based HIV cases to CDC's national database. The code-based HIV cases that were removed from the system have been stored in a separate, archived epidemiologic data file at OA. CDHS is aware that two local health departments, San Francisco and Los Angeles, have also chosen to remove code-based HIV cases from their local HIV/AIDS database. San Francisco and Los Angeles performed this purge to comply with CDC's requirements as they are separately funded HIV/AIDS satellite registries in California. OA has not requested, nor do they plan to request, any local health departments to remove code-based HIV cases from their HIV/AIDS databases or to destroy any of their HIV-related data.

Why are CDHS/OA requirements for security and confidentiality of HIV information more stringent than for other reportable diseases?

OA coordinates the statewide HIV/AIDS surveillance system as part of CDC's national HIV/AIDS reporting system. OA is California's Overall Responsible Party to CDC for all requirements pertaining to the system, including ensuring that requirements regarding

security and confidentiality of HIV and AIDS data are adhered to statewide. While California statute may not specify all aspects of HIV reporting to ensure a secure and confidential system, it is CDHS's policy that HIV/AIDS surveillance data collection, storage, and transfer protocols throughout the state follow CDC guidelines and procedures as determined by OA. OA has partnered with local health jurisdictions in conducting the current AIDS reporting system for more than 20 years with an outstanding success rate and no state AIDS Case Registry breaches of confidentiality. CDHS fully supports following policies and procedures for HIV reporting that will ensure an equally secure and confidential system.

To assist counties in complying with CDC's requirements and CDHS policies, OA has developed training tools and is providing technical assistance on-site at local health departments and by telephone. Although local health departments are not legally required to follow reporting procedures that are not identified in statute, it is important to note that noncompliance will put both the state and local jurisdictions at risk of losing surveillance funding, and may cause California to lose a significant level of federal Ryan White CARE Act Title II funding.

Why does local health department staff have to sign a confidentiality agreement developed by CDHS?

H&S Code Section 121022 requires CDHS staff, local health department staff, and contractors to sign confidentiality agreements developed by CDHS before accessing any HIV-related public health records. In addition, the new law dramatically increases the civil and criminal penalties for negligent, willful, or malicious disclosure of any HIV-related public health records. The law further requires that those penalties be stated on the confidentiality agreement. This recently revised form (see enclosure) has been distributed to all local health departments and is available on OA's Website.

Why is reporting of HIV disease handled differently than reporting of other diseases in California?

Unlike other reportable diseases, California must comply with CDC's strict HIV/AIDS surveillance system requirements in order to be eligible for most of our federal funding for HIV/AIDS services. Loss of this funding would have a dire impact on California's HIV/AIDS programs and HIV positive clients, and would adversely affect all local health jurisdictions. In addition, the statute requiring HIV reporting in California has very restrictive privacy protections and penalties for violation of those provisions.

To ensure that California will continue to receive federal HIV/AIDS funds, assure Californians of the privacy and confidentiality of HIV/AIDS data, and to ensure that

California is in compliance with CDC policy regarding confidentiality and security, it is CDHS's policy that all HIV reporting must be done in a manner consistent with the long-term policy for AIDS reporting in California. This surveillance system requires the use of a confidential HIV/AIDS case report form developed by OA and based on CDC requirements, transmittal of personally-identifying HIV information via secure methods, a secure and separate environment for the processing of reported HIV and AIDS case information at the state and in all local health jurisdictions, and ongoing data quality assurance procedures developed by OA to meet CDC's mandates for HIV/AIDS surveillance data standards. Local health departments that do not report their HIV and AIDS cases through the system established by CDHS for this purpose will not have their cases counted for the purposes of federal and state funding allocations.

How will CDHS ensure uniformity of HIV reporting under the new law?

OA works closely with local HIV/AIDS surveillance coordinators and other HIV/AIDS surveillance program staff in each of the local health jurisdictions to uniformly implement HIV reporting throughout the state. OA provides educational materials, on-site trainings, technical assistance in procedures for unduplicating HIV/AIDS case reports, and performing quality assurance database functions. OA also provides assistance in conducting active surveillance to facilitate complete HIV and AIDS case reporting, determining appropriate reporting of cases, and providing assistance in the routine reporting of HIV and AIDS cases statewide. Together, CDHS and local health jurisdictions have successfully conducted a model statewide AIDS reporting system for more than 20 years. Together we will ensure the same high quality of data for the statewide HIV name-based reporting system.

How can local health departments be assured that they are not vulnerable to legal challenges and other costly actions for inappropriate reporting?

It is important that local health jurisdictions be very familiar with provisions of the new law relating to HIV reporting by name, that local health departments not proceed with HIV case reporting by name in situations that would be disallowed under the law, and that local health jurisdictions consult with their legal counsels about specific situations or questions involving HIV reporting using patient names and interpretation of the law. Promulgation of emergency regulations in the near future should clarify legal provisions around HIV names reporting. In the interim, this letter serves to provide CDHS's specific recommendations on the implementation of HIV names reporting.

How will future funding allocations be affected by HIV case reporting?

At this time, final decisions have not been made at the state or federal levels regarding the allocation of HIV/AIDS funds based on the number of HIV cases. It is certain, however,

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that in the near future, the federal funding formulas will include HIV name-based cases. It is critically important that California achieves a mature, reliable, and CDC-compliant HIV reporting system as quickly as possible. CDHS firmly believes that the policies and procedures it is setting forth will ensure the success of this system.

Why is OA providing HIV reporting guidance directly to local health jurisdiction HIV/AIDS program surveillance staff?

To ensure that California complies with CDC requirements for HIV and AIDS data collection, OA provides leadership and coordination for all aspects of the HIV/AIDS surveillance system in California. Historically, OA's staff have worked directly with local HIV/AIDS program staff to provide technical assistance, training, database and computer support, and the information necessary to assist in the routine reporting of HIV and AIDS cases statewide. This collaborative reporting effort has been in effect for more than 20 years for AIDS case reporting, and was very successful in implementing HIV reporting by non-name code in 2002. OA will continue to work directly with local surveillance staff. To ensure that OA's guidance is widely distributed, OA has begun providing local health executives, health officers, and AIDS directors with copies of all written correspondence sent to local HIV/AIDS surveillance coordinators.

To ensure that you are apprised of the progress of HIV name-based reporting in California, OA plans to provide regular, electronic updates on the status of HIV reporting in the form of a newsletter, to be distributed to local health executives, health officers, AIDS directors, HIV/AIDS surveillance coordinators, and other interested parties.

Thank you for your continued support and assistance as California transitions to name-based HIV reporting. Please share this information with other interested parties, and if you have any questions, please contact Barbara Bailey, Acting Chief, Office of AIDS, at (916) 449-5900.



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Enclosures