

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Disease Control and Environmental Epidemiology Division

6 CCR 1009-9

RULES PERTAINING TO REPORTING, PREVENTION AND CONTROL OF AIDS, HIV RELATED ILLNESS AND HIV INFECTION

Colorado has a comprehensive public health AIDS/HIV control law: Colorado Revised Statutes Title 25, Article 4, Sections 1401 et seq. These regulations are intended to provide detail and clarification for selected parts of the above cited statute. The statute covers subject matters not included in these regulations.

C.R.S. 25-4-1405.5 (2) (a) (I) requires the Colorado Department of Public Health and Environment (CDPHE) to conduct an anonymous counseling and testing program for persons considered to be at high risk for infection with HIV. The provision of confidential counseling and testing for HIV is the preferred screening service for detection of HIV infection. Local boards of health who provide HIV counseling and testing through a contractual agreement with CDPHE must consider the need for an anonymous HIV testing option in their jurisdiction. The consideration of this option must provide an opportunity for public comment in a public forum at a minimum of every two years. Other mechanisms for input into the need for an anonymous testing option in that jurisdiction must be available in addition to the public forum, including anonymous testimony in writing or through an organization. Local boards of health must document the following: notification of interested parties and the public, time allowed between notification and the public forum, accessibility in both location and time of the public forum, and the response to public comment in the decision process. Local Boards of Health electing to provide confidential HIV testing with an anonymous option must do so in conjunction with publicly funded HIV testing and counseling projects that screen individuals for HIV infection without providing on-going health care. The term "publicly funded HIV testing and counseling projects," shall pertain to HIV testing and counseling projects that receive direct funding support from the CDPHE, or receive direct funding support for analogous HIV testing and counseling projects from the following federal agencies: U.S. Department of Health and Human Services (DHHS), Centers for Disease Control and Prevention (CDC); Health Resources and Services Administration (HRSA), Ryan White HIV/AIDS Treatment Extension Act of 2009; or the Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Prevention. The term "health-care setting," shall refer to hospitals, emergency departments, urgent-care clinics, inpatient services, sexually transmitted disease (STD) clinics or other venues offering clinical STD services, tuberculosis (TB) clinics, substance abuse treatment clinics, other public health clinics, community clinics, correctional health-care facilities, primary care settings, or private physicians offices.

Per C.R.S. 25-4-1405.5 (2) (a) (II), Regulations 6-8 are the performance standards for confidential and anonymous publicly funded HIV testing and counseling projects and CDPHE staff.

Regulation 1. Reporting By Physicians, Health Care Providers, Hospitals, And Others

Diagnosed cases of AIDS, HIV-related illness, and HIV infection, regardless of whether confirmed by laboratory tests, shall be reported to the state or local health department or health agency within 7 days of diagnosis by physicians, health care providers, hospitals, or any other person providing testing and/or counseling or treatment to a person with HIV infection. When hospitals and laboratories transmit disease reports electronically using systems and protocols developed by the department that ensure protection of confidentiality, such reporting is acceptable and is considered good faith reporting.

All cases are to be reported with the patient's name, date of birth, sex, race, ethnicity, address (including city and county), phone, name and address of the reporting physician or agency; and such other information as is needed to identify and locate the patient for follow up. For cases reported from a public

anonymous testing site as provided by C.R.S. 25-4-1405.5, the patient's name and address and the name and address of the reporting physician are not required.

Reports on hospitalized patients may be made part of a report by the hospital as a whole.

The reporting of the name, phone, address, date of birth, sex, race or ethnicity of research subjects with AIDS, HIV-related illness, or HIV infection to CDPHE or local department of health pursuant to the provisions of Sections 25-4-1402 and 25-4-1403 shall not be required of any researcher conducting a behavioral research study, medical research study of HIV treatment or vaccine effectiveness or conducting basic biomedical research into the cellular mechanisms causing HIV infection or HIV-related disease pursuant to an approved research protocol. For the purposes of the research exemption authorized in this section, "approved research protocol" means any activity which has been reviewed and approved by the state Board of Health as a research protocol. The research exemption authorized in this section and which meets the criteria described in 1. (A) through (F) inclusive, does not alter the reporting requirements of persons and researchers otherwise required to make reports when engaged in any treatment or testing outside the scope of or prior to enrollment in an approved research protocol and does not exempt the researcher from reporting other reportable diseases. The research exemption authorized in this section does not exempt medical researchers from meeting the requirements of Section 25-4-1405 (5) to provide post-test counseling to infected enrolled research subjects and referral of such subjects to the state department of public health and environment or local department of health for partner notification services.

The State Board of Health shall approve research activities for the research reporting exemption specified in this section based on evidence that the research activity for which an exemption is requested meets the eligibility requirements specified by the State Board of Health.

The State Board of Health shall consider the following eligibility requirements:

- (A) is fully described by a research protocol;
- (B) is subject to review by and is governed by the federal department of Health and Human Services;
- (C) has as the protocol objectives either: the investigation of HIV behavioral research, the effectiveness of a medical therapy or vaccine in preventing infection or the progression of HIV-related disease, or basic medical research into the cellular mechanisms causing HIV infection or HIV-related disease;
- (D) is reviewed and approved by a duly constituted institutional review board in accordance with the regulations established by the Secretary of the Federal Department of Health and Human Services;
- (E) the researcher has provided information that the research activity will be facilitated by an exemption specified in this section; and
- (F) has been determined to have potential health benefits.

Regulation 2. Reporting by Laboratories

Laboratories shall report every test result that is diagnostic of, or highly correlated with, or indicates HIV infection, including, but not limited to, any undetectable HIV viral load and HIV genotype testing. The report shall include the name, date of birth, sex, race and address (including city and county), phone of the individual from whom the specimen was submitted. Such test results shall be reported by all in-state laboratories and by out-of-state laboratories that maintain an office or collection facility in Colorado or arrange for collection of specimens in Colorado. Results must be reported by the laboratory which

performs the test, but an in-state laboratory which sends specimens to an out-of-state referral laboratory is also responsible for reporting the results. The laboratory shall also report the name, address and phone of the attending physician and any other person or agency referring such specimen for testing. Laboratories should make efforts to report all HIV/AIDS-related tests electronically whenever possible. All genotype testing must be reported in an electronic format (such as a FASTA file) containing the nucleotide sequences of HIV.

When associated with other clinical or laboratory evidence of HIV infection, the Board of Health defines a CD4 test result of either CD4 count $<500 \text{ mm}^3$ or CD4% $<29\%$ as a primary immunologic measure indicating severe HIV infection and, when the count is $<200 \text{ mm}^3$, as defining AIDS. Laboratories shall report CD4 counts $<500 \text{ mm}^3$ OR CD4% $<29\%$. The Department shall destroy personal identifying information on all persons with CD4 results in the reportable range if investigation subsequent to the report finds no evidence of HIV infection. Laboratories may fulfill the requirement to report CD4 counts $<500 \text{ mm}^3$ or CD4% $<29\%$ by allowing authorized personnel of CDPHE access to such records.

Laboratories shall follow the same procedures for reporting as are required of other reporting sources in Regulation 1.

Report of test results by a laboratory does not relieve the attending physician or other person providing HIV testing and/or counseling of his/her obligation to report the case or diagnosis, nor does report by the physician or other person providing HIV testing and/or counseling relieve the laboratory of its obligation.

Regulation 3. Information Sharing

Information concerning cases of AIDS, HIV-related illness, or HIV infection shall be shared between the appropriate local health department or health agency and CDPHE, as provided by C.R.S. 25-4-1404 (1)(B), and in a timely manner, usually within the timeframe for reporting in Regulation 1.

These requirements shall not apply if the state and local health agencies mutually agree not to share information on reported cases.

Regulation 4. Confidentiality

All public health reports and records held by the state or local health department in compliance with these regulations shall be confidential information subject to C.R.S. 25-4-1404. The public health reports and records referred to in C.R.S. 25-4-1404 shall include, but not be limited to, the forms and records designated by CDPHE for institutions and agencies which screen individuals for HIV infection without providing ongoing health care, such as a publicly funded HIV testing and counseling project.

Reasonable efforts shall be made by the department to consult with the attending physician or medical facility caring for the patient prior to any further follow-up by state or local health departments or health agencies.

Regulation 5. Investigations to Confirm the Diagnosis and Source of HIV Infection and to Prevent HIV Transmission

It is the duty of state and local health officers to conduct investigations to confirm the diagnosis and sources of HIV infection and to prevent transmission of HIV. Such investigations shall be considered official duties of the health department or health agency. Such investigations may include, but are not limited to:

1. review of pertinent, relevant medical records by authorized personnel if necessary to confirm the diagnosis, to investigate possible sources of infection, to determine objects and materials potentially contaminated with HIV and persons potentially exposed to HIV.

Such review of records may occur without patient consent and shall be conducted at reasonable times and with such notice as is reasonable under the circumstances;

- 2 performing follow-up interview(s) with the case or persons knowledgeable about the case to collect pertinent and relevant information about the sources of HIV infection, materials and objects potentially contaminated with HIV, and persons who may have been exposed to HIV.

Regulation 6. Objective Standards

A. Training

1. All persons providing HIV testing and counseling at a publicly funded HIV testing and counseling project in a non health-care setting will have completed an HIV testing and counseling course of not less than 16 hours of training, approved by the CDPHE STI/HIV Section.
2. All persons performing partner notification interviews will have completed courses concerning introduction to sexually transmitted disease interviewing and partner notification, as specified by the CDPHE.

B. Notification of Results

1. Of all HIV tests performed at a publicly funded HIV testing and counseling project, 90% of those persons testing HIV positive will receive test results and risk-reduction counseling related to those test results.
2. Of all HIV tests performed at a publicly funded HIV testing and counseling project, 80% of those persons testing HIV negative will receive test results and risk-reduction counseling related to those test results.

C. Partner Notification

If CDPHE staff provides partner notification for a publicly funded HIV testing and counseling project, then the following standards do not apply.

1. Of the 90% of HIV positive individuals receiving results and posttest counseling, 100% will be assigned for partner notification interview. A minimum of 75% of those assigned for a partner notification interview will receive an interview. Agencies providing partner notification services (CDPHE and local health departments) will have a partner index (defined as the number of unsafe partners identified for whom identifying information was sufficient to initiate notification, divided by the number of interviewed HIV positive persons with unsafe behavior in the past year) of 0.8. Effective January 1, 1995, the acceptable partner index will be 1.0. Documentation of this activity will be provided to CDPHE through use of a CDPHE specified form.

A contact is defined as a person named by an infected person as having been an unsafe sex partner/needle share partner of that infected person.

If sufficient locating information (name, age, sex, phone number, recent address, work address) is obtained to conduct an investigation, such a contact is defined as an initiated contact.

2. Of all in-state initiated contacts, 60% must be located and offered HIV prevention and risk-reduction counseling and/or testing as documented by the results of the investigation

on the CDPHE specified form. Documentation of investigation outcomes will include disposition codes as specified by the CDPHE, dates and location of counseling, and dates and location of testing (if done).

Regulation 7. Operational Standards

A. Publicly Funded Testing and Counseling

1. HIV testing in an outreach or social network setting:

All persons must receive the following with HIV testing:

- A. An explanation of consent and confidentiality.
- B. A risk screening (i.e., A brief evaluation of HIV risk factors, both behavioral and clinical, used for decisions about who should be recommended HIV counseling and testing).
- C. An assessment of readiness to receive the test results.
- D. An interpretation of the test results.
- E. If the test results are positive, referrals or linkage to medical care, prevention services, and partner services. If indicated, referrals or linkage to substance abuse treatment, mental health services, and comprehensive risk counseling services.
- F. If the test results are negative, referrals or linkage to other prevention services, if applicable. If indicated, make referrals or linkage to substance abuse treatment, mental health services, and comprehensive risk counseling services.

In addition, all persons tested in all other publicly funded HIV testing projects in non health-care settings must receive the following with HIV testing:

- G. Screening for substance abuse, mental illness, and the need for comprehensive risk counseling services.
- H. An assessment of motivation to reduce risk.
- I. A risk-reduction plan (i.e., identify with the client specific behaviors that can realistically be changed to reduce risk).
- J. A risk-reduction plan specific to the test results.

B. Consent Form

A consent form must be used at all publicly funded HIV testing and counseling projects in non health-care settings.

C. Testing Parameters

- 1. A publicly funded HIV testing and counseling project will not provide anonymous testing to any person 12 years of age or younger.

2. If a counselor judges that a client is unable to understand either counseling or the testing process (e.g., because the client is under the influence of drugs or alcohol) the counselor may defer testing.

D. Written Results

1. A publicly funded HIV testing and counseling project may only provide written results to persons testing confidentially. To receive written results, the publicly funded HIV testing and counseling project must be presented with photo identification from the person requesting written results at the time of posttest.
2. A publicly funded HIV testing and counseling project may not give written results to any person testing anonymously.

E. Confidentiality and Record Maintenance

1. A publicly funded HIV testing and counseling project in non health-care settings must have and adhere to an HIV record retention policy. Any record retention policy must be adopted by the local board of health with the opportunity for public comment and input through an open public forum conducted at least every two years. Other mechanisms for input into the record retention policy must be available in addition to the public forum, including anonymous testimony in writing or through an organization.

Any policy must address the following areas:

- a) the availability of anonymous testing,
 - b) time frames for destruction of records,
 - c) method and supervision for destruction of records,
 - d) approval of record retention policy by the Colorado State Archivist,
 - e) procedures for hard (paper) records and electronic (computer) records,
 - f) procedures for records of negative results and positive results
 - g) inclusion of record retention information in the client consent form
2. Per C.R.S. 25-4-1404.5 (2) (a) (II), a person may provide personal identifying information after counseling, if the person volunteers to do so. A publicly funded HIV testing and counseling project must document this information when volunteered, and maintain the confidentiality of the personal identifying information according to their record retention policy.

Regulation 8. Evaluation Standards and Penalties

- A. Each CDPHE funded HIV testing and counseling project's compliance with these standards will be evaluated by the following:
1. An annual analysis by the CDPHE staff of the number of persons receiving HIV antibody testing and the proportion of persons testing receiving results per contracted agency.
 2. A minimum of one on-site observation conducted annually by CDPHE staff.

3. An annual analysis of testing trends (anonymous vs. confidential) conducted by CDPHE staff.
4. A minimum of one annual audit of charts conducted by CDPHE staff.
5. Accuracy and completion of the evaluation data form submitted to CDPHE.

B. Failure of a CDPHE funded HIV testing and counseling project to comply with and meet these standards may result in one or more of the following action(s):

1. The CDPHE funded HIV testing and counseling project will meet with CDPHE to develop a plan for improving performance in specified areas.
2. The CDPHE funded HIV testing and counseling project may be given a probationary period to comply and meet the standards.
3. The CDPHE funded HIV testing and counseling project may be reevaluated by the end of the probationary period.
4. Failure to meet and comply with the standards may result in contract termination.