

**STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY FOR
Amendments to Proposed Amendments to Rules and Regulations Pertaining to the Reporting, Prevention,
and control of AIDS, HIV Related Illness, and HIV Infection (6CCR-1009-9)**

November 20, 2013

Basis and Purpose. The proposed changes include modification to the rule to update and clarify language and reporting requirements.

- 1) The rule as been modified to clarify the reporting requirement for all CD4 tests regardless of result. Currently, the rule requires the reporting of CD4 tests of less than 500mm3 or less than 29 percent. This does not allow for sufficient evaluation of unmet need or linkage to care activities.
- 2) The rule has been modified to include more current language pertaining to counseling and testing sites and HIV testing throughout Colorado. Currently the rule addresses only certain Colorado Department of Public Health and Environment funded counseling and testing sites. This language has been updated to include publicly funding HIV testing and counseling projects throughout Colorado. The rule has been modified to reflect these new standards.
- 3) The rule has been modified to clarify information sharing requirements. Many changes have occurred in HIV related care and treatment since this regulation was last updated. This language has been updated to include organizations that provide direct patient services.

Specific Statutory Authority. These rules are promulgated pursuant to the following statutes: §25-4-1401 C.R.S., §25-4-1402 C.R.S., §25-4-1403 C.R.S., §25-4-1405 C.R.S., §25-4-1405.5 C.R.S. and §25-4-1408 C.R.S.

Major Factual and Policy Issues Encountered.

It is anticipated that there will be minimal factual and policy issues encountered. However, the sharing of HIV related information between CDPHE and care providers or other agencies providing direct HIV related services may raise privacy related issues among certain stakeholders.

Alternative Rules Considered and Why Rejected.

Conducting complete, timely and accurate surveillance for HIV and AIDS is a standard procedure of disease control and investigation. No alternative methods are available to achieve the purposes of the authorizing statutes.

1 DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

2 Disease Control and Environmental Epidemiology Division

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

5 6 CCR 1009-9

6 *[Editor's Notes follow the text of the rules at the end of this CCR Document.]*

7
8 Regulation 2. Reporting by Laboratories

9 Laboratories shall report every test result that is diagnostic of, or highly correlated with, or indicates HIV
10 infection, including, but not limited to, any undetectable HIV viral load and HIV genotype testing. The
11 report shall include the name, date of birth, sex, race and address (including city and county), phone of
12 the individual from whom the specimen was submitted. Such test results shall be reported by all in-state
13 laboratories and by out-of-state laboratories that maintain an office or collection facility in Colorado or
14 arrange for collection of specimens in Colorado. Results must be reported by the laboratory which
15 performs the test, but an in-state laboratory which sends specimens to an out-of-state referral laboratory
16 is also responsible for reporting the results. The laboratory shall also report the name, address and phone
17 of the attending physician and any other person or agency referring such specimen for testing.
18 Laboratories should make efforts to report all HIV/AIDS-related tests electronically whenever possible. All
19 genotype testing must be reported in an electronic format (such as a FASTA file) containing the
20 nucleotide sequences of HIV.

21 ~~When associated with other clinical or laboratory evidence of HIV infection, the Board of Health defines a~~
22 ~~CD4 test result of either CD4 count -than- mm- or CD4 % -than- % as a primary immunologic measure~~
23 ~~indicating severe HIV infection and, when the count is -than- mm3, as defining AIDS. laboratories shall~~
24 ~~report ALL CD4 counts REGARDLESS OF VALUE. -than- 500 mm3 OR CD4 % -than- 29 %. The~~
25 ~~Department shall destroy personal identifying information on all persons with CD4 results in the~~
26 ~~reportable range if investigation subsequent to the report finds no evidence of HIV infection. Laboratories~~
27 ~~may fulfill the requirement to report ALL CD4 counts -than- 500 mm3 or CD4 % -than- 29 % by~~
28 ~~allowing authorized personnel of CDPHE access to such records.~~

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

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

35 Regulation 3. Information Sharing

36 Information concerning cases of AIDS, HIV-related illness, **LABORATORY TESTING, TREATMENT** or
37 HIV infection shall be shared, **TO THE MINIMUM EXTENT NECESSARY TO ACHIEVE THE PUBLIC**
38 **HEALTH PURPOSE**, between the appropriate local health department, **CDPHE CONTRACTED**
39 **AGENCY** or **OTHER** health agency **PROVIDING DIRECT HIV RELATED SERVICES** and CDPHE, as
40 provided by C.R.S. 25-4-1404 (1)(b), and in a timely manner, usually within the timeframe for reporting in
41 Regulation 1.

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

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 **32 46** hours of training, approved by the CDPHE STI/HIV/**VIRAL HEPATITIS** Section.
2. All persons performing partner notification interviews will have completed courses concerning introduction to sexually transmitted disease interviewing and partner notification, **AND OTHER RELATED COURSES** 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%~~ **99%** **ALL** 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.~~ **PUBLICLY FUNDED HIV TESTING SITES SHALL MAKE A GOOD FAITH EFFORT TO INFORM HIV NEGATIVE PERSONS OF THE TEST RESULTS AND SHALL PROVIDE PERTINENT HIV PREVENTION COUNSELING AND REFERRALS TO MITIGATE BEHAVIORAL RISKS.**

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. ~~ALL Of the 90% of~~ **NEWLY DIAGNOSED** HIV positive individuals ~~receiving results and posttest counseling, 100% will be~~ **REFERRED TO AND** 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 (**RAPID OR STANDARD TESTING**) in an outreach or social network setting all persons must receive the following:

a. A **WRITTEN** explanation of consent and confidentiality **LAWS IN COLORADO**.

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), **AS SPECIFIED BY CDPHE**.

c. An assessment of readiness to receive the test results.

d. An interpretation of the test results, **INCLUDING A NEED FOR IMMEDIATE CONFIRMATORY TESTING IF A RAPID TEST IS POSITIVE**.

e. If the test results are positive, **100% OF PERSONS TESTING POSITIVE WILL BE REFERRED FOR MEDICAL CARE AND 80 % WILL BE LINKED TO MEDICAL CARE. ADDITIONAL** referrals or linkage to medical care, **TO** prevention services, and partner services **WILL BE OFFERED**. ~~If indicated, Referrals or linkage to substance abuse treatment, mental health services and comprehensive risk counseling services~~ **SHALL BE OFFERED IF INDICATED**.

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.

~~g. 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:

i. Screening for substance abuse, mental illness, and the need for comprehensive risk counseling services **AS SPECIFIED BY CDPHE**.

ii. An assessment of motivation to reduce risk.

iii. A risk-reduction plan (i.e., identify with the client specific behaviors that can realistically be changed to reduce risk).

iv. A risk-reduction plan specific to the test results.

B. Consent Form

A consent form must be used, **AND SIGNED BY THE CLIENT PRIOR TO TESTING** at all publicly funded HIV testing and counseling projects in non health-care settings. **CLIENTS SELECTING AN ANONYMOUS TEST OPTION MAY SIGN BY INDICATING THE ANONYMOUS CODE LINKED TO THIS TEST AND ARE NOT REQUIRED TO PROVIDE IDENTIFYING INFORMATION.**

C. Testing Parameters

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

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

125 D. Written Results

126 1. A publicly funded HIV testing and counseling project may only provide written results to
127 persons testing confidentially. To receive written results, the publicly funded HIV testing
128 and counseling project must be presented with photo identification from the person
129 requesting written results at the time of posttest.

130 2. A publicly funded HIV testing and counseling project may not give written results to any person
131 testing anonymously.

132 E. Confidentiality and Record Maintenance

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

139 Any policy must address the following areas:

140 a) the availability of anonymous testing,

141 b) time frames for destruction of records,

142 c) method and supervision for destruction of records,

143 d) approval of record retention policy by the Colorado State Archivist,

144 e) procedures for hard (paper) records and electronic (computer) records,

145 f) procedures for records of negative results and positive results

146 g) inclusion of record retention information in the client consent form

147 2. Per C.R.S. 25-4-1404.5 (2) (a) (II), a person may provide personal identifying information after
148 counseling, if the person volunteers to do so. A publicly funded HIV testing and
149 counseling project must document this information when volunteered, and maintain the
150 confidentiality of the personal identifying information according to their record retention
151 policy.

152

153 **Editor's Notes: 05/28/13 ALL AMENDED LANGUAGE INDICATED IN ALL CAPS/BOLD, DELETED**
154 **LANGUAGE INDICATED WITH A STRIKETHROUGH. LAUGUAGE AMENDED IN OCTOBER**
155 **2013 IS IDENTIFIED WITH YELLOW HIGHLIGHT.**

156 **History**

157 Entire Rule eff. 04/14/2010.