COLORADO
Department of Public Health & Environment

Dedicated to protecting and improving the health and environment of the people of Colorado

To: Members of the State Board of Health

From: Lisa Miller, MD, MSPH, Communicable Disease Branch Chief, and Melanie Mattson, STI/HIV/Viral Hepatitis Branch Chief, Disease Control and Environmental Epidemiology Division (DCEED)

Through: Rachel Herlihy, MD, MPH, DCEED Director RH

Date: December 30, 2016

Subject: **Request for Rulemaking Hearing**
Proposed amendments to 6 CCR 1009-1, Rules and Regulations Pertaining to Epidemic and Communicable Disease Control, and repeal of 6 CCR 1009-9, Rules and Regulations Pertaining to Reporting, Prevention and Control of AIDS, HIV Related Illness and HIV Infection, with a request for the rulemaking hearing to occur in March of 2017

In preparation for a Public Rulemaking Hearing, please find copies of the following documents: Proposed Amendments to 6 CCR 1009-1, Proposed Repeal of 6 CCR 1009-9, Statement of Basis and Purpose and Specific Statutory Authority, Stakeholder Comment, and Regulatory Analysis.

The *Rules and Regulations Pertaining to Epidemic and Communicable Disease Control* name the communicable diseases that are reportable to state or local health departments, in order to protect the public's health. The Rule also details the manner in which these conditions must be reported and includes language about access to pertinent medical records. The proposed rulemaking expands the reportable conditions to include Zika virus and candidemia. The proposal also modifies reporting requirements and timeframes.

Similarly, the *Rules and Regulations Pertaining to Reporting, Prevention and Control of AIDS, HIV Related Illness and HIV Infection* have listed the manner in which these conditions must be reported to state or local health departments, detailed performance standards for confidential and anonymous publicly-funded human immunodeficiency virus (HIV) testing and counseling projects as well as for CDPHE staff.

Recent legislation (Senate Bill 16-146) updated and modernized the statutes related to sexually transmitted infections to bring them in line with current medical knowledge and practice, as well as to reduce stigma that may be associated with HIV. To align our rules with statute (C.R.S. 25-4-404), the Department is proposing integrating the *Rules and Regulations Pertaining to Reporting, Prevention and Control of AIDS, HIV Related Illness and HIV Infection*, 6 CCR 1009-9 into *Rules and Regulations Pertaining to Epidemic and Communicable Disease Control*, 6 CCR 1009-1. Thus, the Department proposes repeal of 6 CCR 1009-9. Details regarding this integration are summarized in the Statement of Basis and Purpose and Statutory authority.

The Department has reached out to a wide variety of stakeholders to solicit input regarding the proposed amendments to 6 CCR 1009-1 and repeal of 6 CCR 1009-9 and has modified the proposed changes based on stakeholder feedback. In general, stakeholders are supportive of the proposed amendments and rule repeal. The Department remains fully committed to engaging its stakeholders during the rulemaking process.

In total, these proposed amendments and rule repeal align our rules with statute, continue to bring clarity to the rules and minimize potential confusion among end-users of the rules. As always, the Department will continue to solicit and incorporate stakeholder feedback.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
6 CCR 1009-1
Rules and Regulations Pertaining to Epidemic and Communicable Disease Control
and for the Repeal of 6 CCR 1009-9
Rules and Regulations Pertaining to Reporting, Prevention and Control of AIDS, HIV Related Illness and HIV Infection

Basis and Purpose.

The *Rules and Regulations Pertaining to Epidemic and Communicable Disease Control* name the communicable diseases that are reportable to state or local health departments, in order to protect the public's health. The Rule also details the manner in which these conditions must be reported and includes language about access to pertinent medical records.

The following changes to the rule are being proposed:

1) The Department proposes making Zika virus (ZIKV) reportable by laboratories. ZIKV is an emerging mosquito-borne virus that has spread rapidly across the Americas in 2015 and 2016. Subsequent investigations have demonstrated vertical transmission of ZIKV to the fetus in pregnant women. These in utero infections have been associated with the potential for devastating outcomes including microcephaly and spontaneous abortions. There is also an association with ZIKV infection and post-infectious Guillain-Barré syndrome (GBS). Because of these epidemiological and clinical features, it is important for public health to track this condition in Colorado. In addition, the World Health Organization declared ZIKV disease a Public Health Emergency of International Concern under the International Health Regulations 2005 on February 1, 2016, and the Council of State and Territorial Epidemiologists recommended that all states make this condition reportable on February 26, 2016. This proposed change is reflected in the Table in Appendix A.

2) Senate Bill 16-146, known as the STI Modernization bill, combined Parts 4 and 14 in Article 4 of Title 25, the public health laws on sexually transmitted infections (STI) and human immunodeficiency virus (HIV), to make protections and policies apply equally to all STIs, including HIV and relevant forms of viral hepatitis. In keeping with the spirit of this legislation, CDPHE staff worked with stakeholders to recommend repeal of the current HIV rule (6 CCR 1009-9) and incorporate all STIs, including HIV, in the existing communicable disease rule (6 CCR 1009-1). While a majority of these two rules are duplicative, there are a number of specific requirements related to STIs noted in the amended rule, including:

- Variables statutorily required for STI reports, which expand beyond those for other communicable diseases.
- Language related to "other persons providing STI-related testing and counseling", in Regulation 2, to ensure outreach testing activities are included.
- Requirements related to an anonymous HIV testing option that is statutorily required.
- Operational standards for HIV testing projects.
- Language related to disease investigations pertaining to STIs. Based on stakeholder input, this language was added to ensure STI-related investigations were limited to only relevant information.
- HIV and related conditions have been added to the Table in Appendix A.

3) The Department proposes making candidemia reportable from laboratories that serve residents of the five county Denver metropolitan area (Adams, Arapahoe, Denver, Douglas, and Jefferson). The Denver metro area was chosen as the reporting area to meet requirements of federal funding. Candidemia are bloodstream infections (BSIs) caused by a yeast (a type of fungus) called Candida. As one of the most common causes of BSIs in the United States, these infections often result in long hospital stays, high medical costs and poor patient outcomes. Some types of Candida are becoming increasingly resistant to antifungal treatments, including echinocandins and fluconazole, leaving few remaining treatment options, which can often be expensive and toxic for patients. Requiring reporting of candidemia will allow the Department to: 1) monitor disease incidence and trends, as other data on candidemia in large populations are scarce, 2) detect the emergence and spread of resistance to antifungal agents, 3) determine the burden of infections caused by antifungal-resistant Candida species, 4) understand and describe specific genetic mutations associated with resistance, and 5) identify areas where candidemia prevention and intervention strategies can be focused. This proposed change is reflected in the Table in Appendix A.

4) The Department proposes clarifying language regarding reportable arbovirals (viruses transmitted by arthropods, such as mosquitoes) such that proposed language will require reporting for the entire category of arboviral diseases (antibody panel), and remove language specific to Eastern equine encephalitis, Japanese encephalitis, LaCrosse virus and other California serogroup viruses, St. Louis encephalitis, and Western equine encephalitis. Laboratories run tests for these as a group and call the test an arboviral antibody panel. Because these tests are run in a group and not individually reportable by physicians, the proposed changes will make reporting easier for laboratories. This proposed change is reflected in the Table in Appendix A.

5) The Department proposes clarifying the reporting of Spotted fever rickettsiosis (including Rocky Mountain spotted fever (RMSF) and typhus) by changing the language to “Rickettsiois (including RMSF and typhus)”. These conditions are currently reportable, but the current rule language implies that typhus is a spotted fever and it is not. In addition, laboratories run a group test for rickettsial species that is called a rickettsial antibody panel. This proposed change is reflected in the Table in Appendix A.

6) The Department proposes changing our reporting timelines. Three new categories would be created - “immediately” (by phone, within 4 hours), “1 working day”, and “4 days”. The “24 hour” category and the “7 day” category would be deleted, except for carnivorous animal bites, which would remain at “24 hours”. The table recognizes that, unless the term “working day” is specified, “days” refers to calendar days. The instructions to report cases suspected to be due to bioterrorism immediately remain unchanged. The proposed changes are designed to better align our reporting timelines with national standards, and to recognize the availability of more efficient electronic reporting. National reporting guidelines are developed by the Council of State and Territorial Epidemiologists and categorize reportable conditions as either “immediately notifiable”, “extremely urgent (within 4 hours)”, “immediately notifiable, urgent (within 24 hours)”, or “routinely notifiable”. This proposed change is reflected in the Table in Appendix A.

7) The Department proposes removing Cyclospora from the list of conditions where specimens must be submitted. The Centers for Disease Control and Prevention no longer requires submission of Cyclospora isolates. Removing this requirement will align our rule with federal guidelines. However, Cyclospora will remain a reportable condition. This proposed change is reflected in the Table in Appendix A.

8) The Department proposes updating the conditions required to be reported “based on the diagnosis or suspected diagnosis of the attending physician or other health care provider, whether or not supporting laboratory data are available”. These conditions are indicated in the Table with a superscript ‘6’. First, we propose correcting an error that occurred when the rule was last modified in

2015. Rubella (acute infection) and hepatitis A are and have been one of these conditions, but the superscript was inadvertently left off in the last update. When reviewing this proposed correction with stakeholders, the Department identified two other conditions that do not need to be reported if suspected, since there is no public health follow up without laboratory confirmation. Thus, the Department proposes removing *Haemophilus influenza*e, and Legionellosis from list of conditions that are required to be reported "based on the diagnosis or suspected diagnosis of the attending physician or other health care provider, whether or not supporting laboratory data are available". These proposed changes are reflected in the Table in Appendix A.

9) The Department proposes that when bacterial culture isolates or patient clinical material that yields positive findings are required to be submitted to the CDPHE Laboratory Services Division (see Disease Table footnote #3), they be submitted within one business day. Currently, there is no time limitation on the submission. This has resulted in a delay in submission in some cases, and a resulting inability to recover or confirm the suspected pathogen. This can result in the inability to identify persons with outbreak-related infections, or to implement appropriate disease control actions. A free courier service is provided to all hospitals to facilitate delivery of isolates or specimens to the CDPHE laboratory. This proposed change is reflected in the Table in Appendix A.

Specific Statutory Authority.
These rules are promulgated pursuant to the following statutes: Sections 25-1.5-102; 25-1-122; 25-4-402, 25-4-404, 25-4-405, and 25-4-1401 et seq., C.R.S.

SB 16-146 amended the *HIV Infection and Acquired Immune Deficiency Syndrome* statutes in 2016, resulting in the relocation of sections 25-4-1411, C.R.S. through 25-4-1415 C.R.S., to sections 25-4-1401, C.R.S. through 25-4-1405, C.R.S. However, due to an oversight, the act did not repeal Part 14 as it was previously written. Due to this oversight, the 2015 version of Part 14 that was not relocated by the Act remains in statute. The proposed amendments to the rules are not affected. The rules comport with the requirements delineated in Part 4 and Part 14 of Article 4, Title 25, C.R.S.

SUPPLEMENTAL QUESTIONS

Is this rulemaking due to a change in state statute?

__x __ Yes in part, __SB 16-146___; rules are __ _ authorized _X__ required.
_____ No

Is this rulemaking due to a federal statutory or regulatory change?

_____ Yes
___x___ No

Does this rule incorporate materials by reference?

_____ Yes
___x___ No

Does this rule create or modify fines or fees?

_____ Yes
___x___ No

REGULATORY ANALYSIS
for Amendments to
6 CCR 1009-1
Rules and Regulations Pertaining to Epidemic and Communicable Disease Control
and for the Repeal of 6 CCR 1009-9
Rules and Regulations Pertaining to Reporting, Prevention and Control of AIDS, HIV Related Illness and HIV Infection

1. A description of the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

Classes of persons affected by the proposed rule changes include 1) clinical laboratory personnel; 2) personnel at hospitals responsible for reporting, such as infection preventionists; 3) health care providers; 4) local public health personnel; 5) persons living with a sexually transmitted infection (STI); 6) persons at risk for acquiring a STI; 7) community based organizations; and 5) the general public.

Clinical laboratory personnel will bear some cost of the changes to laboratory reporting, as processes will need to be adjusted for the change in reporting timelines. For laboratories utilizing electronic reporting, this should be a one-time programming change.

Health care providers and other reporters will bear a cost related to some of the new reporting. Zika virus is currently reported as an 'unusual illness……of public concern' so there is no new cost. For candidemia reporting, there is a cost of reporting additional laboratory information, or changing programming for those laboratories that report electronically.

Local public health, state public health, and the general public will benefit from the proposed changes to the rule. The benefit of these changes include: clearer, updated rules that are more easily interpreted and, therefore, followed; more complete reporting of diseases of public health importance; treating HIV like other communicable diseases, thereby reducing stigma; and reporting on timelines that reflect and utilize electronic reporting. Each of these proposed changes will provide better or more timely data to state and local public health agencies. These agencies, in turn, will be able to use this data to detect, prevent, and treat communicable disease in communities across Colorado, benefitting the general public. While the proposed changes are relevant to current local government operations, the proposed rule does not impose a new state mandate on local government.

2. To the extent practicable, a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

Of the proposed changes to this rule, four are clarifications of existing rule or reductions in reporting. These proposed changes positively impact end-users of the rule by making it easier to implement.

Two of the proposed changes are additions to the list of reportable conditions necessitated by changes in conditions of public health concern. Candidemia will require some additional laboratory staff time to report, though if reported electronically this staff time should be minimal. Candidemia isolates or specimens are also *requested*, but not *required*. Zika reporting has been ongoing since 2016, and reports come from commercial laboratories, the CPDHE laboratory, or the Centers for Disease Control and Prevention laboratory. Detailed follow-up information is required for persons with suspected Zika infection in order to confirm the diagnosis and collect additional pertinent information. This burden falls to CDPHE staff, local health department staff, and health care providers. As of December 21, 2016, 52 cases of Zika have been reported.

Laboratories and hospital infection preventionists are the primary reporters of conditions included in the reportable disease table. Changing the timelines for reporting will require efforts to change work processes to meet these new timelines. Of note, for the 22 conditions that were reportable within 24 hours previously, one stayed the same, eight were changed to 'report within one working day', and 13 were changed to 'immediately report', if immediate public health intervention is necessary. Forty-four states currently require 'immediate reporting'. For those eight conditions that are no longer reportable within 24 hours, laboratories and health care providers no longer have to call the Department in the evening and on weekends to report.

Laboratories currently submit required bacterial culture isolates or patient clinical material that yields positive findings. Currently, there is no time limitation on the submission. This has resulted in a delay in submission in some cases, and a resulting inability to recover or confirm the suspected pathogen. This can result in the inability to identify persons with outbreak-related infections, or to implement appropriate disease control actions. A free courier service is provided to all hospitals to facilitate delivery of isolates or specimens to the CDPHE laboratory.

Recent legislation (Senate Bill 16-146) combined the statutes related to sexually transmitted infections (STIs) and human immunodeficiency virus (HIV) to make protections and policies apply equally to all STIs, including HIV. To be consistent with these legislative changes, the Department proposes the repeal of 6 CCR 1009-9, *Rules and regulations pertaining to the reporting, prevention, and control of AIDS, HIV related illness, and HIV infection.* Specific language from this rule will be added to 6 CCR 1009-1 to address STIs, including HIV. This will better align rule and statute and provide greater consistency in reporting for laboratories and healthcare providers. Additionally, the propose rule will require guidelines and standards for STI prevention providers and Department staff concerning the delivery of client services and public health procedures; thus providing additional assurance of the quality of services delivered to persons living with, or at risk for acquiring a STI.

3. The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

The costs to the agency for managing reports of Zika and candidemia will be covered by federal grant funding. Any other costs to CDPHE will be minimal and can be absorbed. There is no anticipated effect on state revenues.

4. A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

The benefit of these changes include: clearer, updated rules that are more easily interpreted and therefore, followed; and more complete reporting of diseases of public health importance (in the cases of Zika virus and Candidemia). Additionally, the proposed changes will repeal 6 CCR 1009-9, and provide greater consistency in the reporting of all diseases and infections, including STIs. The benefit of these changes is greater congruency between statute and rule, thus, reducing the confusion of having largely duplicative rules related to communicable disease reporting. Additionally, the proposed changes includes updated language that is meant to mirror current, evidence-based practices and reduces stigma related to sexually transmitted infections.

In addition, the Department proposes changing our reporting timelines. Three new categories would be created - "immediately" (by phone, within 4 hours), "1 working day", and "4 days". The "24 hour" category and the "7 day" category would be deleted, except for carnivorous animal bites, which would remain at "24 hours". The table recognizes that, unless the term "working day" is specified, "days" refers to calendar days. The benefit of the proposed changes will be better alignment with national standards and the opportunity to respond more rapidly to urgent public health situations. In addition, the proposal includes new language that encourages electronic laboratory reporting. The adoption of

electronic laboratory reporting will allow these reports to be more efficiently reported. There may be some cost to reporters to change the process of reporting to include the proposed new conditions, or to report at the proposed time intervals.

Inaction would result in a continued lack of clarity in the rules, lack alignment with SB 16-146, and lack of information about newly emerging conditions of public health importance.

5. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

Conducting surveillance for communicable diseases of public health significance is a standard procedure of epidemic and communicable disease control. No alternative methods are available to achieve the purposes of the authorizing statutes.

6. Alternative Rules or Alternatives to Rulemaking Considered and Why Rejected.

No alternative methods for achieving the purpose of the proposed rules were considered because the rules utilize the widely accepted, proven public health methodology of surveillance and laboratory investigation. The Department proposes the inclusion of language related to STIs, including HIV to align this rule with statute, and as having a separate rule would be largely duplicative and confusing.

7. To the extent practicable, a quantification of the data used in the analysis; the analysis must take into account both short-term and long-term consequences.

The Department examined the percentage of reports currently reportable within 7 days that were reported more than 4 days after the test result (the new reporting timeline for these tests). For the 6 months from April 1- September 30, 2016, there were 50,778 tests for 7-day reportable conditions analyzed, and 8.1% were reported more than 4 days after the test result. The Department also considered the testimony given in support of SB 16-146 and considered the intent of that legislation when developing the proposed amendments to rule.

STAKEHOLDER COMMENTS
for Amendments to
6 CCR 1009-1
Rules and Regulations Pertaining to Epidemic and Communicable Disease Control
and for the Repeal of 6 CCR 1009-9
Rules and Regulations Pertaining to Reporting, Prevention and Control of AIDS, HIV Related Illness and HIV Infection

Early Stakeholder Engagement

The following individuals and/or entities were invited to provide input and included in the development of these proposed rules:

Healthcare providers, Colorado hospital infection preventionists and lab directors (including those as acute care hospitals), Colorado Hospital Association staff, and local public health communicable disease staff, AIDS Service Organizations, Community Based Organizations, "Mod-Squad" Participants (activists), The Alliance for HIV Care the Prevention (CDPHE/Gov appointed advisory group to the Branch), Colorado Organizations Responding to AIDS - CORA (Lobbying group), State and Local Health Department Staff, Ryan White Part A Planning Council Members, Members of the Positive Women's Network (PWN), Other individuals interested in STI/HIV/VH related issues and rules , Regional Epidemiologists, Members of the Association for Professionals in Infection Control, Colorado Hospital Association, and Colorado Medical Society.

Targeted outreach was conducted at several points throughout the fall:

- On 10/24/16 a memo was emailed to all hospital infection preventionists at Colorado acute care hospitals, all Lab Directors at acute care hospitals, and all communicable disease contacts at each local health department. The memo outlined the proposed changes, not including those changes related to HIV. In addition, a strike changes version of the Reportable Disease Table was included.
- On 11/2/16, proposed changes (not including HIV changes) were described to Colorado Regional Epidemiologists on a conference call and an opportunity for discussion and questions was provided.
- On 11/18/16, proposed changes (not including HIV) were presented to the members of the Association for Professional in Infection Control (APIC) at their monthly meeting.
- A series of 3 facilitated meetings were held in the fall of 2016 to gather feedback specific to proposed integration of 6 CCR 1009-9 into the communicable disease rule 6 CCR 1009-1.
- On 12/7/16 proposed changes were discussed on a conference call with a group of hospital infection preventionists and hospital laboratorians to review feedback from the APIC meeting on 11/18/16.
- In mid-December, a memo was emailed to all hospital infection preventionists at Colorado acute care hospitals (12/16), all Lab Directors at acute care hospitals (12/16), all communicable disease contacts at each local health department (12/16), infectious disease physicians (12/16), the Colorado Hospital Association (12/16), local health department directors (12/21), HIV/AIDS stakeholders (12/22), and the Colorado Medical Society (12/23). The memo outlined the proposed changes, including those changes related to HIV and changes made to the original proposal as a result of feedback. In addition, a strikethrough version of the rule and a strike changes version of the Reportable Disease Table was included.

Stakeholder Group Notification

The stakeholder group was provided notice of the rulemaking hearing and provided a copy of the proposed rules or the internet location where the rules may be viewed. Notice was provided prior

to the date the notice of rulemaking was published in the Colorado Register (typically, the 10th of the month following the Request for Rulemaking).

__X__ Not applicable. This is a Request for Rulemaking Packet. Notification will occur if the Board of Health sets this matter for rulemaking.

____ Yes.

Summarize Major Factual and Policy Issues Encountered and the Stakeholder Feedback Received. If there is a lack of consensus regarding the proposed rule, please also identify the Department's efforts to address stakeholder feedback or why the Department was unable to accommodate the request.

The Department held conference calls and facilitated meetings with stakeholders to discuss concerns and answer questions. These discussions led to greater understanding of the reporting process as well as greater understanding of the Department's proposed repeal of 6 CCR 1009-9 and integration of HIV regulations into 6 CCR 1009-1. The Department did incorporate stakeholder feedback from these calls and meetings and did adjust some of the proposals included in this proposal based on this feedback. While the Department will continue to engage stakeholders throughout the development of the proposed rules, the Department believes consensus has been achieved.

Please identify health equity and environmental justice (HEEJ) impacts. Does this proposal impact Coloradoans equally or equitably? Does this proposal provide an opportunity to advance HEEJ? Are there other factors that influenced these rules?

The proposed modifications apply to all Colorado providers and laboratories responsible for reporting public health conditions of concern, and thus cover all Coloradoans. It is possible that those without access to diagnostic health care services (due to geography or socioeconomic status) would be less likely to be reported and to be identified as being in need of public health intervention (such as post exposure prophylaxis or outbreak source identification). In some of these situations, public health funding is available to pay for diagnostic testing. Proposed rule modifications promote health equity as they are meant to clarify and streamline the rules so they are more easily understood and applied to all eligible citizens. Additionally, this proposal responses to Senate Bill 16-146, known as STI Modernization that was passed in this last legislative session. This bill combined Parts 4 and 14 in Article 4 of Title 25 (the public health laws on STI and HIV) to make protections and policies apply equally to all sexually transmitted infections, including HIV and relevant forms of viral hepatitis, thus, bringing them in line with current medical knowledge and practice, as well as to reduce stigma that may be associated with HIV. This is a critical component in the advancement of HEEJ in our STI and HIV related programming. There are no environmental justice impacts.

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Disease Control and Environmental Epidemiology Division

RULES AND REGULATIONS PERTAINING TO EPIDEMIC AND COMMUNICABLE DISEASE CONTROL

6 CCR 1009-1

Adopted by the Board of Health on _____, 2017. Effective _____, 2017.

Regulation 1. Reportable Diseases

For the purpose of these regulations, the diseases named in the Reportable Diseases Table (Appendix A) are declared to be POTENTIALLY dangerous to the public health and shall be reportable in accordance with the provisions of these regulations.

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Manner of Reporting

All cases are to be reported with patient's name, date of birth, sex, race, ethnicity, and address (including city and county) and name and address of responsible physician or other health care provider; and such other information as is needed to locate the patient for follow up. In addition, all laboratory information reported shall include specimen accession number. For animal bites by dogs, cats, bats, skunks, foxes, raccoons, coyotes, and other wild carnivores, the name and locating information of the owner of the biting animal shall be reported, if known, by the health care provider. For healthcare-associated infections, except as provided in § 25-3-601, C.R.S., facilities choosing to voluntarily participate in applied public health projects on a project by project basis shall make medical records available for review by the Department upon request within a reasonable time frame. IN ADDITION, FOR SEXUALLY TRANSMITTED INFECTIONS, THE PATIENT'S SEX AT BIRTH, GENDER IDENTITY AND RELEVENT TREATMENT SHALL BE REPORTED. FOR REPORTS FROM A PUBLICALLY FUNDED ANONYMOUS TESTING SITE, AS PROVIDED IN §25-4-411, C.R.S, THE PATIENT'S NAME AND ADDRESS ARE NOT REQUIRED.

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Regulation 2. Reporting by Individuals

Where Reporter = 'P' in the Appendix A Reportable Diseases Table, cases of diseases shall be reported by the physician or other health care provider and by other persons either treating or having knowledge of a reportable disease, including, but not limited to coroners, persons in charge of hospitals or other institutions licensed by the Colorado Department of Public Health and Environment, (or their designees), persons in charge of schools (including school nursing staff), ~~and~~ licensed day care centers~~.~~ OR ANY OTHER PERSON PROVIDING TESTING AND/OR COUNSELING TO A PERSON WITH A SEXUALLY TRANSMITTED INFECTION.

Regulation 3. Laboratory Reporting

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All specimens shall be accompanied by the following information: (a) Patient's name, date of birth, sex, race, ethnicity, and address (b) Name and address of responsible physician or other health care provider (c) Name of disease or condition (d) Laboratory information - test name, collection date and specimen

type. LABORATORIES SHOULD MAKE EFFORTS TO REPORT ALL TESTS ELECTRONICALLY WHENEVER POSSIBLE.

Regulation 4 Treatment and Control of Tuberculosis

The emergence of multiple drug-resistant tuberculosis in this country and state dictates a coherent and consistent strategy in order to protect the public health from this grave threat. The underlying principles of disease control expressed in the following rules are as follows: use of the most rapid and modern diagnostic methods by laboratories, rapid reporting, full patient compliance with medical treatment, and prevention of spread of tuberculosis in health care settings. The tuberculosis statute (C.R.S. 25-4-501 et seq.) covers subject matters not included in these regulations.

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B. Physicians, health care providers, and health care facilities shall report within 7 CALENDAR days the following tuberculin skin test (TST) or Interferon-Gamma Release Assay (IGRA) result if it occurs in a health care worker, correctional facility worker, or detention facility worker: a positive TST (defined as = 5 mm induration) or positive IGRA test (based on manufacturer's interpretation criteria) if the worker has had prolonged or frequent face-to-face contact with an infectious tuberculosis case.

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E. A laboratory may fulfill its requirement to report (in parts C and D of this regulation) by submitting a sputum specimen from the patient to either the State Public Health Laboratory, or for facilities located in Boulder, Broomfield, Denver, Adams, Douglas, Arapahoe, and Jefferson counties, to the Denver Public Health laboratory. The reporting requirement is not fulfilled if the laboratory submits an isolate from a culture to either of the public health laboratories or if the laboratory delays sending the sputum specimen for more than 2 CALENDAR days after collection of the specimen.

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H. The Board of Health determines that to prevent the emergence of multiple drug- resistant tuberculosis, it is necessary and appropriate and good medical practice that persons with active tuberculosis disease receive directly observed treatment for their disease. All medical providers and health care organizations are required to provide directly observed therapy for patients with active tuberculosis disease for the full course of therapy, unless a variance for a particular patient from this requirement is approved by the tuberculosis control program of the State Department of Public Health and Environment or Denver Public Health. Directly observed therapy is not required for patients with extrapulmonary tuberculosis disease provided that the presence of pulmonary tuberculosis has been investigated and excluded. In applicable situations, a variance shall be granted in accordance with C.R.S. 25-4-506(3).

Medical providers and health care organizations shall report to the state or local health department within seven CALENDAR days the name of any patient on directly observed therapy who has missed one dose. When requested by medical providers and health care organizations, the state or local health department shall provide directly observed treatment to outpatients with active tuberculosis disease and this shall fulfill the requirement for the medical providers and health care organizations.

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K.

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(2) The chief medical health officer of a local health agency, with the prior approval of the local board of health and pursuant to the requirements of subparagraph 3 of this paragraph K may require screening be performed for a particular group or population that has been identified as high risk based on the criteria set forth in this paragraph K, but each individual shall be informed of his or her right to be exempt from the screening because of medical or religious reasons. The local health agency should provide at least 30 CALENDAR days notice to potentially affected persons, groups, and businesses prior to consideration of the proposed program by the local board of health.

(3) Except as provided in subparagraph 6 of this paragraph K, no program approved by a local board of health shall be implemented without the approval of the State Board of Health. Within 30 CALENDAR days of a program having been approved by a local board of health, the local health agency shall submit a copy of the proposed program to the State Board of Health. When considering a proposed local health agency program, the State Board of Health shall provide notice to all parties on its mailing list at least 20 CALENDAR days prior to the hearing.

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Regulation 5. Investigations to Confirm the Diagnosis, Treatment, and Causes of Epidemic and Communicable Diseases and to Determine Appropriate Methods of Epidemic and Communicable Disease Control

Investigations may be conducted to confirm the diagnosis, treatment, and causes of reportable conditions and shall be considered official duties of the health department or health agency. Such investigations may include, but are not limited to:

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(b) performing follow-up interview(s) with the case or persons knowledgeable about the case to collect INFORMATION pertinent and relevant ~~information about~~ TO the cause(s) of or risk factors for the reportable condition;

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Regulation 6. Information Sharing

Whenever a local health department or health agency learns of a case of a reportable disease or an epidemic or communicable disease exposure potentially threatening the public health, it shall notify the State Department of Health in a timely manner, usually within the timeframe for reporting in R~~r~~egulation 1.

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Regulation 9. Confidentiality

All personal medical records and reports held or viewed by the state or local health department in compliance with these regulations shall be confidential information subject to C.R.S. 25-1-122(4) AND C.R.S. 25-4-406(1). Reasonable efforts shall be made by the department to consult with the ~~attending~~

RESPONSIBLE physician, OTHER HEALTHCARE PROVIDER, or medical facility caring for the patient prior to any further follow-up by State or local health departments or health agencies.

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Regulation 11. Sexually Transmitted Infections

THE COLORADO BOARD OF HEALTH RECOGNIZES THAT NON-SEXUAL TRANSMISSION MAY OCCUR FOR SOME OF THESE INFECTIONS, AND THAT IN INDIVIDUAL CASES, BASED ON CLINICAL AND EPIDEMIOLOGIC INFORMATION, THE RESPONSIBLE PHYSICIAN OR OTHER HEALTHCARE PROVIDER MAY CONCLUDE THE PATIENT'S INFECTION WAS NOT SEXUALLY ACQUIRED.

INFORMATION CONCERNING TESTING, TREATMENT, CAUSES, OR THE PREVENTION OF SEXUALLY TRANSMITTED INFECTIONS SHALL BE SHARED, TO THE MINIMUM EXTENT NECESSARY TO ACHIEVE THE PUBLIC HEALTH PURPOSE, BETWEEN THE APPROPRIATE LOCAL HEALTH DEPARTMENT, STATE DEPARTMENT OF HEALTH, CONTRACTED AGENCY, RYAN WHITE FUNDED AGENCY, OTHER HEALTH AGENCY OR PERSON PROVIDING DIRECT SEXUALLY TRANSMITTED INFECTION RELATED SERVICES AND THE STATE DEPARTMENT OF HEALTH, AS PROVIDED BY C.R.S. 25-4-406(1)(b).

WITH RESPECT TO REGULATION 5, INVESTIGATIONS RELATED TO SEXUALLY TRANSMITTED INFECTIONS WILL BE LIMITED TO THE INFORMATION NECESSARY TO CONFIRM THE DIAGNOSIS, TREATMENT, SOURCE OF INFECTION, AND IDENTIFICATION OF MEASURES THAT MAY BE USED TO PREVENT ADDITIONAL SEXUALLY TRANSMITTED INFECTIONS.

THE DEPARTMENT SHALL DESTROY PERSONAL IDENTIFYING INFORMATION ON ALL PERSONS WITH CD4 OR VIRAL LOAD RESULTS IF INVESTIGATION SUBSEQUENT TO THE REPORT FINDS NO EVIDENCE OF A SEXUALLY TRANSMITTED INFECTION.

C.R.S. 25-4-411 (1)(a) REQUIRES THE STATE DEPARTMENT OF HEALTH TO CONDUCT AN ANONYMOUS COUNSELING AND TESTING PROGRAM FOR PERSONS CONSIDERED TO BE AT HIGH RISK FOR INFECTION WITH HUMAN IMMUNODEFICIENCY VIRUS (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 THE STATE DEPARTMENT OF HEALTH SHALL CONSIDER THE NEED FOR AN ANONYMOUS HIV TESTING OPTION IN THEIR JURISDICTION, UPON PETITION. THE CONSIDERATION OF THIS OPTION MUST PROVIDE AN OPPORTUNITY FOR PUBLIC COMMENT IN A PUBLIC FORUM, INCLUDING ANONYMOUS TESTIMONY PRESENTED IN WRITING OR THROUGH AN ORGANIZATION. 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.

OPERATIONAL STANDARDS

A. 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 APPROVED BY THE STATE DEPARTMENT OF HEALTH.

B. ALL PERSONS PERFORMING PARTNER SERVICES WILL HAVE COMPLETED COURSES CONCERNING INTRODUCTION TO SEXUALLY TRANSMITTED DISEASE INTERVIEWING AND PARTNER NOTIFICATION, AND OTHER RELATED COURSES AS SPECIFIED BY THE STATE DEPARTMENT OF HEALTH.

C. OF ALL HIV TESTS PERFORMED AT A PUBLICLY FUNDED HIV TESTING AND COUNSELING PROJECT, 99% OF THOSE PERSONS TESTING HIV POSITIVE WILL RECEIVE TEST RESULTS AND APPROPRIATE POST-TEST COUNSELING RELATED TO THOSE TEST RESULTS. PUBLICLY FUNDED HIV TESTING SITES SHALL MAKE A GOOD FAITH EFFORT TO INFORM ALL PERSONS OF THEIR TEST RESULTS AND SHALL PROVIDE PERTINENT HIV PREVENTION COUNSELING AND REFERRALS.

D. ALL PERSONS NEWLY DIAGNOSED WITH HIV WILL BE REFERRED FOR PARTNER SERVICES. A MINIMUM OF 75% OF THOSE OFFERED PARTNER SERVICES WILL RECEIVE AN INTERVIEW AND PERTINENT REFERRALS. PARTNER SERVICES STANDARDS WILL BE DETERMINED BY THE BEST PRACTICES GUIDANCE AND CODE OF CONDUCT STANDARDS FOR STI PREVENTION PROVIDERS DEVELOPED BY THE STATE DEPARTMENT OF HEALTH. THESE STANDARDS SHALL BE MADE PUBLICALLY ACCESSIBLE.

E. OPERATIONAL AND EVALUATION STANDARDS FOR HIV TESTING AND COUNSELING SITES WILL BE DETERMINED BY THE BEST PRACTICES GUIDANCE DEVELOPED BY THE STATE DEPARTMENT OF HEALTH.

F. IN ACCORDANCE WITH C.R.S 25-4-404(2), THE STATE DEPARTMENT OF HEALTH SHALL CREATE AND MAINTAIN GUIDELINES, SUBJECT TO APPROVAL BY THE STATE BOARD, CONCERNING THE PUBLIC HEALTH PROCEDURES DESCRIBED IN C.R.S 25-4-412 AND C.R.S 25-4-413. THESE GUIDELINES WILL INCLUDE CODE OF CONDUCT STANDARDS FOR THE DELIVERY OF PARTNER SERVICES AND CLIENTS' RIGHTS, RESPONSIBILITIES AND PROTECTIONS.

~~In addition to all manifestations of chlamydia, syphilis and gonorrhea, the Colorado Board of Health finds that the following diseases are contagious, are sexually transmissible, are dangerous to the public health., and pursuant to C.R.S. 25-4-401(1) are determined to be sexually transmitted infections. The Board recognizes that non-sexual transmission may occur for some of these diseases, and that in individual cases, based on clinical and epidemiologic information, the attending physician may conclude the patient's disease was not sexually acquired:~~

~~Chancroid~~

~~Genital herpes simplex infection~~

~~Granuloma inguinale~~

~~Lymphogranuloma venereum~~

~~Urethritis in males caused by C. trachomatis, U. urealyticum, M. genitalium,T. vaginalis, and Herpes simplex virus~~

~~Mucopurulent cervicitis in females caused by C. trachomatis or N. gonorrhoeae~~

~~Trichomoniasis~~

~~Pelvic inflammatory disease caused by C. trachomatis or N. gonorrhoeae~~

~~Epididymitis caused by C. trachomatis, N. gonorrhoeae, or E. coli~~

~~Human papillomavirus infection, including genital or anal warts~~

~~Hepatitis A~~

~~Hepatitis B~~

~~Hepatitis C~~

~~Pediculosis pubis~~

~~Acute proctitis caused by C. trachomatis, N. gonorrhoeae, T. pallidum, or Herpes simplex virus~~

204 # Appendix A. Reportable Disease Table

Disease/Event	Pathogen/Organism	Time*	Reporter[1]	Specimen Source(s)[2]	Send Clinical Material[3]
Acinetobacter baumannii, carbapenem-resistant (CRAB)[5, 4-Metro]	Carbapenem-resistant *Acinetobacter baumannii* (including *Acinetobacter baumannii* complex and *Acinetobacter baumannii-calcoaceticus* complex)	30 days	L	Sterile sites, urine	
Acute flaccid myelitis		~~7~~ 4 days	P		
Animal bites by dogs, cats, bats, skunks, foxes, raccoons, coyotes, or other wild carnivores [6,7]		24 hrs	P		
Animal bites by mammals not listed above[6]		~~7 days~~4 days	P		
Anthrax[6]	*Bacillus anthracis*	~~24 hrs~~Immed	L & P	All	Required
Arboviral Disease	Eastern equine encephalitis, LaCrosse encephalitis virus, California encephalitis serogroup, St. Louis encephalitis virus and Western equine encephalitis virus	4 days	L	All	
Botulism[6]	*Clostridium botulinum*	~~24 hrs~~Immed	L & P	All	
Brucellosis[6]	*Brucella* species	~~7 days~~4 days	L & P	All	Required
~~California/LaCrosse serogroup virus diseases~~	~~LaCrosse encephalitis virus, California encephalitis serogroup virus, etc.~~	~~7 days~~	~~L~~	~~All~~	
Campylobacteriosis	*Campylobacter* species	~~7 days~~4 days	L & P	All	
Candidemia	*Candida* species	30 days	L	Blood	Requested
Chancroid	*Haemophilus ducreyi*	~~7~~ 4 days	L & P	All	
Chikungunya	Chikungunya virus	~~7 days~~4 days	L	All	
Chlamydia	*Chlamydia trachomatis*	~~7~~ 4 days	L & P	All	
Cholera[6]	*Vibrio cholerae*	~~24 hrs~~Immed	L & P	All	Required
CJD and other transmissible spongiform encephalopathies (TSEs)[6]		~~7 days~~4 days	P		
Clostridium difficile infection [4-Metro]	*Clostridium difficile*	30 days	L	All	Requested[8]
Colorado tick fever	Colorado tick fever virus	~~7 days~~4 days	L	All	
Cryptosporidiosis	*Cryptosporidium* species	~~7 days~~4 days	L & P	All	
Cyclosporiasis	*Cyclospora* species	~~7 days~~4 days	L & P	All	~~Required~~
Dengue	Dengue virus	~~7 days~~4 days	L	All	
Diphtheria[6]	*Corynebacterium diphtheriae*	~~24 hrs~~Immed	L & P	All	Required

Disease/Event	Pathogen/Organism	Time*	Reporter[1]	Specimen Source(s)[2]	Send Clinical Material[3]
~~Eastern equine encephalitis~~	~~Eastern equine encephalitis virus~~	~~7 days~~	~~L~~	~~All~~	
Encephalitis[6]		7 days4 days	P	All	
Enterobacteriaceae, carbapenem-resistant (CRE)[9]	Carbapenem-resistant *Escherichia coli*, *Klebsiella* species, *Enterobacter* species	7 days4 days	L	All	Requested[8]
Escherichia coli O157:H7 and Shiga toxin-producing Escherichia coli[10]	Shiga toxin-producing *Escherichia coli*[10]	7 days4 days	L & P	All	Required
Giardiasis	*Giardia lamblia*	7 days4 days	L & P	All	
Gonorrhea, any site	*Neisseria gonorrhoeae*	7 4 days	L & P	All	
Group A streptococci[11, 4-Metro]	*Streptococcus pyogenes*	7 days4 days	L	Sterile only	Required[12]
Group B streptococci [4-Metro]	*Streptococcus agalactiae*	7 30 days	L	Sterile only	Required[12]
Haemophilus influenzae[6]	*Haemophilus influenzae*	24 hrs1 working day	L & P	Sterile only	Required
Hantavirus disease[6]	Hantavirus	7 days4 days	L & P	All	
Healthcare-associated infections[13]		7 days4 days	P		
Hemolytic uremic syndrome if ≤ 18 years[6]		7 days4 days	P		
Hepatitis A[6]	Hepatitis A virus (+IgM anti-HAV)	24 hrs1 working day	L & P	All	
Hepatitis B	Hepatitis B virus (+HBsAg, +IgM anti-HBc, +HBeAg, or +HBV DNA)	7 days4 days	L & P	All	
Hepatitis C	Hepatitis C virus (+ serum antibody titer, including signal to cut-off ratio, or more specific + tests)	7 days4 days	L & P	All	
Hepatitis, other viral		7 days4 days	P		
Human immunodeficiency virus (HIV) / acquired immunodeficiency syndrome (AIDS)	• Human immunodeficiency virus • CD4 counts (any value) • HIV viral load (any value) • *HIV genotype*	4 days	• L & P • L & P • L & P • L	All	
Influenza-associated death if < 18 years		7 days4 days	P		
Influenza-associated hospitalization		7 days4 days	P		
Japanese encephalitis	Japanese Encephalitis virus	7 days4 days	L	All	
Legionellosis[6]	*Legionella* species	7 days4 days	L & P	All	
Leprosy (Hansen's Disease)		7 days4 days	P		

Disease/Event	Pathogen/Organism	Time*	Reporter[1]	Specimen Source(s)[2]	Send Clinical Material[3]
Listeriosis	*Listeria monocytogenes*	~~7 days~~4 days	L & P	All	Required
Lyme disease	*Borrelia burgdorferi*	~~7 days~~4 days	L & P	All	
Lymphogranuloma venereum (LGV)	*Chlamydia trachomatis*	~~7 days~~4 days	L & P	All	
Malaria[6]	*Plasmodium* species	~~7 days~~4 days	L & P	All	
Measles (rubeola)[6]	Measles virus	~~24 hrs~~Immed	L & P	All	
Meningococcal Disease[6]	*Neisseria meningitidis* or gram-negative *diplococci*	~~24 hrs~~Immed	L & P	Sterile only	Required
Mumps[6]	Mumps virus (acute infection)	~~7 days~~4 days	L & P	All	
Outbreaks - known or suspected of all types including those transmitted from food, water, person-to-person, and related to a health care setting[6]		~~24 hrs~~Immed	P		
Pertussis (whooping cough)[6]	*Bordatella pertussis*	~~24 hrs~~1 working day	L & P	All	Requested[8]
Plague[6]	*Yersinia pestis*	~~24 hrs~~Immed	L & P	All	Required
Poliomyelitis[6]	Poliovirus	~~24 hrs~~Immed	L & P	All	
Powassan virus disease	Powassan virus	~~7 days~~4 days	L	All	
Pseudomonas, carbapenem-resistant[14]	*Pseudomonas aeruginosa*	~~7 days~~4 days	L	All	Requested[8]
Psittacosis	*Chlamydia psittaci*	~~7 days~~4 days	L & P	All	
Q fever[6]	*Coxiella burnetii*	~~7 days~~4 days	L & P	All	
Rabies: human (suspected)[6]	Rabies virus (Lyssavirus)	~~24 hrs~~Immed	L & P	All	
~~Spotted fever r~~Rickettsiosis	*Rickettsia* species, including Rocky Mtn ~~s~~spotted f~~f~~ever and typhus groups	~~7 days~~4 days	L & P	All	
Rubella (acute infection)[6]	Rubella virus	~~24 hrs~~1 day	L & P	All	
Rubella, congenital[6]	Rubella virus	~~7 days~~4 days	L & P	All	
Salmonellosis	*Salmonella* species	~~7 days~~4 days	L & P	All	Required
Severe or novel coronavirus	Severe acute respiratory syndrome coronavirus (SARS-CoV), Middle East respiratory syndrome coronavirus (MERS-CoV)	~~24 hrs~~Immed	L & P	All	
Shigellosis	*Shigella* species	~~7 days~~4 days	L & P	All	Required
Smallpox[6]	Variola virus (Orthopox virus)	~~24 hrs~~Immed	L & P	All	

Disease/Event	Pathogen/Organism	Time*	Reporter[1]	Specimen Source(s)[2]	Send Clinical Material[3]
~~St. Louis encephalitis~~	~~St. Louis encephalitis virus~~	~~7 days~~	~~L~~	~~All~~	
Staphylococcus aureus, Vancomycin-resistant	Vancomycin-resistant *Staphylococcus aureus*	~~7 days~~4 days	L	All	Required
Streptococcal toxic shock syndrome	*Streptococcus pyogenes*	~~7 days~~4 days	P	All	Required[12]
Streptococcus pneumoniae	*Streptococcus pneumoniae*	~~7 days~~4 days	L	Sterile only	Required[12]
Syphilis ~~(1°, 2°, or early latent)~~ [6]	*Treponema pallidum*	~~24 hrs~~1 working day	L & P	All	
Tetanus[6]	*Clostridium tetani*	~~7 days~~4 days	P	All	
Tick-borne relapsing fever[6]	*Borrelia* species	~~7 days~~4 days	L & P	All	
Toxic shock syndrome (non-streptococcal)		~~7 days~~4 days	P		
Trichinosis[6]	*Trichinella* species	~~7 days~~4 days	P	All	
Tuberculosis disease (active)[6]	*Mycobacterium tuberculosis*[15]	~~24 hrs~~1 working day	L & P	All	See Reg 4F
Tularemia[6]	*Francisella tularensis*	~~24 hrs~~1 working day	L & P	All	Required
Typhoid fever[6]	*Salmonella* Typhi	~~24 hrs~~1 working day	L & P	All	Required
Varicella (chicken pox)[6]	Varicella virus	~~7 days~~4 days	L & P	All	
Vibriosis	*Vibrio* species, non-cholera	~~7 days~~4 days	L	All	Required
Viral hemorrhagic fever	Crimean-Congo hemorrhagic virus, Ebola virus , Lassa fever virus, Lujo virus, Marburg virus, Guanarito virus, Junin virus, Machupo virus, Sabia virus	~~24 hrs~~Immed	L & P	All	Required
West Nile virus (acute infection, IgM+)	West Nile virus	~~7 days~~4 days	L	All	
~~Western equine encephalitis~~	~~Western equine encephalitis virus~~	~~7 days~~	~~L~~	~~All~~	
Yellow fever	Yellow fever virus	~~7 days~~4 days	L	All	
Yersiniosis ~~4~~Seven	*Yersinia* non-*pestis* species	~~7 days~~4 days	L	All	Required
Zika virus	Zika virus	4 days	L	All	

All cases are to be reported with patient's name, date of birth, sex, race, ethnicity, and address (including city and county) and name and address of responsible physician or other health care provider; and such other information as is needed in order to locate the patient for follow up. In addition, all laboratory information reported shall include specimen accession number.

*Time: 1) "Immed" = by phone, within 4 hours of suspected diagnosis. 2) Unless the term "working day" is specified, "days" refers to calendar days.

1 Reporter: The party responsible for reporting is indicated by one of the following: L = Laboratory (whether or not associated with a hospital; by out-of-state laboratories that maintain an office or collection facility in Colorado; and by in-state laboratories which send specimens to an out-of-state laboratory referral laboratory), P = health care provider or other person knowing of or suspecting a case (including but not limited to coroners, persons in charge of hospitals or other institutions licensed by CDPHE (or their designees), persons in charge of schools (including nursing staff) and licensed day care centers), L & P = Both

2 Specimen sources: A condition is reportable when the pathogen is isolated or detected from any specimen source unless where otherwise indicated. A normally "sterile site" is defined as blood, CSF, pleural fluid (includes chest fluid, thora~~co~~cente~~nte~~sis fluid), peritoneal fluid (includes abdominal fluid, ascites), pericardial fluid, bone (includes bone marrow), joint or synovial fluid, needle aspirate or culture of any specific joint, internal body sites (sterilely obtained from biopsy/tissue/abscess/aspirate/fluid/swab from lymph node, brain, heart, liver, spleen, vitreous fluid, kidney, pancreas, vascular tissue, or ovary). Skin and skin ~~abcesses~~abscesses are not considered sterile sites.

3 Testing laboratories shall routinely submit bacterial culture isolates or patient clinical material that yields positive findings to the CDPHE Laboratory Services Division. The isolate or clinical material shall be received at the CDPHE Laboratory Services Division no later than one business day after the observation of positive findings.

Clinical material is defined as: (i) A culture isolate containing the infectious organism for which submission of material is required, or (ii) If an isolate is not available, material containing the infectious organism for which submission of material is required, in the following order of preference: (A) a patient specimen; (B) nucleic acid; or (C) other laboratory material. All specimens shall be accompanied by the following information: (a) Patient's name, date of birth, sex, race, ethnicity, and address (b) Name and address of responsible physician or other health care provider (c) Name of disease or condition (d) Laboratory information - test name, collection date and specimen type.

4 Condition reportable only among residents of a specific catchment area. Metro = Denver Metropolitan Area (Adams, Arapahoe, Denver, Douglas and Jefferson Counties); Seven = Seven-county Denver Metropolitan Area (Adams, Arapahoe, Boulder, Broomfield, Denver, Douglas and Jefferson Counties). If not specified, condition reportable in all Colorado counties.

4-Metro Condition reportable only among residents of Denver Metropolitan Area (Adams, Arapahoe, Denver, Douglas and Jefferson Counties)

4-Seven Condition reportable only among residents of seven-county Denver Metropolitan Area (Adams, Arapahoe, Boulder, Broomfield, Denver, Douglas and Jefferson Counties).

5 Acinetobacter baumannii (including Acinetobacter baumannii complex and Acinetobacter baumannii-calcoaceticus complex) that are intermediate or resistant to at least one carbapenem (including imipenem, meropenem, doripenem, or ertapenem) isolated from a normally sterile site or urine.

6 Report shall be based on the diagnosis or suspected diagnosis of the attending physician or other health care provider, whether or not supporting laboratory data are available.

7 For animal bites by dogs, cats, bats, skunks, foxes, raccoons, coyotes, and other wild carnivores, the name and locating information of the owner of the biting animal shall be reported, if known, by the health care provider Reporter.

8 Clinical material is requested from selected laboratories.

9 Escherichia coli, Klebsiella species, and Enterobacter species that are intermediate or resistant to at least one carbapenem (including imipenem, meropenem, doripenem, or ertapenem) AND resistant to all third-generation cephalosporins tested (ceftriaxone, cefotaxime, and ceftazidime); OR Escherichia coli, Klebsiella species, and Enterobacter species that test positive for carbapenemase production (by any method, including the Modified Hodge Test, disk diffusion, or PCR) production of a carbapenemase (i.e., KPC, NDM, VIM, IMP, OXA-48) demonstrated by a recognized test (e.g., polymerase chain reaction, metallo-ß-lactamase test, modified-Hodge test, Carb-NP).

10 This includes any shiga-toxin test or O157 antigen test that is positive, even if no culture is performed. If the laboratory does not have the capacity to perform H (flagellar) antigen tests, then Escherichia coli O157 should be reported.

11 If Group A streptococci is isolated from a wound or surgical tissue/specimen and is accompanied by necrotizing fasciitis or streptococcal toxic shock syndrome, the case shall be reported and the isolate shall be submitted.

12 Clinical material shall be submitted from laboratories located in the seven-county Denver Metropolitan Area (Adams, Arapahoe, Boulder, Broomfield, Denver, Douglas, and Jefferson Counties) when the material is from residents of the Metro Area (Adams, Arapahoe, Denver, Douglas and Jefferson counties).

13 Reportable only by facilities that are voluntarily participating in applied public health projects. Appendix B includes a definition of healthcare-associated infections, a list of included infections, and a list of included health facility types

14 Pseudomonas species that are resistant to at least one of the following carbapenems: imipenem, meropenem, or doripenem; OR Pseudomonas species that test positive for production of a carbapenemase (i.e., KPC, NDM, VIM, IMP, OXA)

15 Including (+) AFB sputum smear

Appendix B. Healthcare-Associated Infections

Definition of a healthcare-associated infection: a localized or systemic condition that results from an adverse reaction to the presence of an infectious agent or its toxins that was not present or incubating at the time of admission to the health facility.

Healthcare-associated infections include:

- Bloodstream infections
- Bone and joint infections
- Cardiovascular system infections
- Central nervous system infections
- Eye, ear, nose, throat, or mouth infections
- Gastrointestinal system infections
- Lower respiratory tract infections other than pneumonia
- Pneumonia
- Reproductive tract infections
- Skin and soft tissue infections
- Surgical site infections
- Systemic infections
- Urinary tract infections

Health facility types include:

- Ambulatory surgical centers
- Birth centers
- Convalescent centers
- Dialysis treatment clinics/End-stage renal disease facilities
- Hospices
- Hospitals (general, psychiatric, rehabilitation, maternity, and long-term care)
- Long-term care facilities
- Outpatient clinics (community clinics; community clinics with emergency centers; rural health clinics; outpatient rehabilitation facilities; outpatient physical therapy, occupational therapy or speech pathology services; and private physician offices)

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Disease Control and Environmental Epidemiology Division

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

6 CCR 1009-9

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

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.~~

~~Laboratories shall report all CD4 counts regardless of value. The Department shall destroy personal identifying information on all persons with CD4 results if investigation subsequent to the report finds no~~

~~evidence of HIV infection. Laboratories may fulfill the requirement to report all CD4 counts 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, treatment 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, treatment and/or counseling relieve the laboratory of its obligation.~~

~~Regulation 3. Information Sharing~~

~~Information concerning cases of AIDS, HIV-related illness, laboratory testing, treatment or HIV infection shall be shared, to the minimum extent necessary to achieve the public health purpose, between the appropriate local health department, CDPHE contracted agency or other health agency providing direct HIV related services and CDPHE, as provided by C.R.S. 25-4-1404 (1), (1)(a),(1)(b), (1)(c) 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 32 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, 99% of those persons testing HIV positive will receive test results and risk-reduction counseling related to those test results.

2. 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

1. All newly diagnosed HIV positive individuals 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 and regulations 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% w ill be linked to medical care. Additional referrals to prevention services and partner services will be offered. 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. 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 at all publicly funded HIV testing and counseling projects in non health-care settings. If the HIV test is confidential, the consent form must be signed by the client; if the HIV test is anonymous, the client may mark the consent form with the anonymous code linked to the HIV test in lieu of a signature.

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.~~