STATE OF COLORADO

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

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Colorado Department of Public Health and Environment

To: Members of the State Board of Health

From: Lisa Miller, Communicable Disease Epidemiology Section Chief, Disease Control and Environmental Epidemiology (DCEED) lm

Through: Tista Ghosh, DCEED Division Director TG

Date: May 9, 2014

Subject: **Request for Rulemaking Hearing**
Proposed Amendments to Rules and Regulations Pertaining to Epidemic and Communicable Disease Control, 6 CCR 1009-1 with a request for the rulemaking hearing to occur in August of 2014

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 health. The Rule also details the manner in which these conditions must be reported and includes language about access to pertinent medical records. Pursuant to Executive Order D 2012-002 (EO2), the Department also reviewed this rule to ensure that it was efficient, effective and essential. Several changes are proposed, based on needed updates and the review that was conducted. None of these changes are required by state statute or federal law.

1. We propose clarifying which events and illnesses, in addition to reports of specific diseases, are reportable (outbreaks, epidemics, or unusual illnesses); no new requirements are inserted. Four categories are listed as examples of illnesses or events that are also reportable:
    a. those which may be a risk to the public and which may affect large numbers of persons such as illnesses transmitted through food, water, or from person to person;
    b. cases of a newly recognized entity, including novel influenza;
    c. those related to a health care setting or contaminated medical devices or products; and
    d. those related to environmental contamination by any infectious agent or toxic product of such an agent.

2. We propose deleting aseptic meningitis and Kawasaki syndrome from the reportable list. This is intended to reduce the burden of reporting for those required to report. These conditions were chosen for elimination after a review of all reportable communicable diseases because there was little to no public health intervention resulting from the reports.

3. We propose modifying Regulation 3 to broaden the laboratory requirement to report arboviral diseases. We would delete St. Louis encephalitis and Western equine encephalitis, since they would be included under the broad category of "West Nile virus (acute infection) and other Arboviral diseases".

Arboviral diseases are transmitted to humans primarily through the bites of infected mosquitoes, ticks, sand flies, or midges. There are several arboviral diseases transmitted in the U.S., but only West Nile virus (WNV), Western equine encephalitis (WEE), and St. Louis encephalitis (SLE) are currently listed as being reportable. WNV is frequently reported; WEE and SLE are rarely reported. Other arboviral diseases are rarely seen in Colorado, but it is important to understand the burden of these conditions, especially ones that may be newly introduced to the U.S. An example of this is chikungunya, an illness caused by a virus that spreads through mosquito bites and was previously only transmitted in Asia and Africa. However, in December 2013, the World Health Organization reported local transmission of chikungunya in Saint Martin. Since that time local transmission of chikungunya has been reported in many other countries in the Caribbean. Travelers from Colorado to the Carribean (and other countries where chikungunya is transmitted) may become infected. Though the mosquitoes that transmit chikungunya are not currently found in Colorado, they are found in the southern U.S. states and could become established here. It is expected that the burden of disease in the U.S. will increase due to the frequent travel between the U.S. and the Caribbean. Dengue is another arboviral disease that is transmitted in many popular tourist destinations, including recent local transmission in Florida, that would be included in this list. Monitoring this burden can be accomplished relatively easily by requiring laboratories to report positive tests for arboviral diseases since all added conditions are rare. Monitoring this burden is necessary in order to respond appropriately with prevention and control activities. The arboviral diseases included in the footnote to the table in Regulation 3 are: California encephalitis serogroup, chikungunya, Colorado tick fever virus, dengue, Eastern Equine encephalitis, Japanese encephalitis, Powassan, Saint Louis encephalitis, Western equine encephalitis, and yellow fever.

4. Three additional technical corrections are proposed. In Regulation 1, List B, only bites by 'mammals' are required to be reported instead of bites by 'animals'. This requirement is intended to identify possible rabies exposures, and only mammals are susceptible to rabies infection. In Regulation 3, Laboratory Reporting, *Chlamydia psittaci* is modified to *Chlamydophila psittaci,* the new classification for this organism. Rocky Mountain spotted fever is renamed, 'Rickettsia species' since this would be the laboratory finding indicative of Rocky Mountain spotted fever.

5. We propose adding 'or other health care provider' in sentences that direct physicians to report. This updates the language to reflect the current provision of care by a wider range of health care providers than only physicians.

6. We propose adding language to encourage facilities to provide remote electronic access to medical records. This change reflects the current prevalence of electronic medical records, as opposed to paper medical records. These electronic medical records can be accessed remotely from the public health agency in some cases, which is more efficient than requiring staff to travel to a facility to review the electronic record on site.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
Rules and Regulations Pertaining to Epidemic and Communicable Disease Control
6 CCR 1009-1

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 health. The Rule also details the manner in which these conditions must be reported and includes language about access to pertinent medical records. Pursuant to Executive Order D 2012-002 (EO2), the Department also reviewed this rule to ensure that it was efficient, effective and essential. Several changes are made, based on needed updates and the review that was conducted.

1. The events and illnesses, in addition to reports of specific diseases, that are reportable (outbreaks, epidemics, or unusual illnesses) are clarified; no new requirements are inserted. Four categories are listed as examples of illnesses or events that are also reportable:
    a. those which may be a risk to the public and which may affect large numbers of persons such as illnesses transmitted through food, water, or from person to person;
    b. cases of a newly recognized entity, including novel influenza;
    c. those related to a health care setting or contaminated medical devices or products; and
    d. those related to environmental contamination by any infectious agent or toxic product of such an agent.

2. Aseptic meningitis and Kawasaki syndrome are deleted from the reportable list. This is intended to reduce the burden of reporting for those required to report. These conditions were chosen for elimination after a review of all reportable communicable diseases because there was little to no public health intervention resulting from the reports.

3. Regulation 3 is modified to broaden the laboratory requirement to report arboviral diseases, instead of separately listing three different arboviral diseases. We deleted St. Louis encephalitis and Western equine encephalitis, since they are included under the broad category of "West Nile virus (acute infection) and other arboviral diseases".

    a. Arboviral diseases are transmitted to humans primarily through the bites of infected mosquitoes, ticks, sand flies, or midges. There are several arboviral diseases transmitted in the U.S., but only West Nile virus (WNV), Western equine encephalitis (WEE), and St. Louis encephalitis (SLE) are currently listed as being reportable. WNV is frequently reported; WEE and SLE are rarely reported. Other arboviral diseases are rarely seen in Colorado, but it is important to understand the burden of these conditions, especially ones that may be newly introduced to the U.S. An example of this is chikungunya, an illness caused by a virus that spreads through mosquito bites and was previously only transmitted in Asia and Africa. However, in December 2013, the World Health Organization reported local transmission of chikungunya in Saint Martin. Since that time local transmission of chikungunya has been reported in many other countries in the Caribbean. Travelers from Colorado to the Carribean (and other countries where chikungunya is transmitted) may become infected. Though the mosquitoes that transmit chikungunya are not currently found in Colorado, they

are found in the southern U.S. states and could become established here. It is expected that the burden of disease in the U.S. will increase due to the frequent travel between the U.S. and the Caribbean. Dengue is another arboviral disease that is transmitted in many popular tourist destinations, including recent local transmission in Florida, that would be included in this list. Monitoring this burden can be accomplished relatively easily by requiring laboratories to report positive tests for arboviral diseases since all added conditions are rare. Monitoring this burden is necessary in order to respond appropriately with prevention and control activities.

b. The arboviral diseases included in the footnote to the table in Regulation 3 are: California encephalitis serogroup, chikungunya, Colorado tick fever virus, dengue, Eastern Equine encephalitis, Japanese encephalitis, Powassan, Saint Louis encephalitis, Western equine encephalitis, and yellow fever.

4. Three additional technical corrections are proposed. In Regulation 1, List B, only bites by 'mammals' are required to be reported instead of bites by 'animals'. This requirement is intended to identify possible rabies exposures, and only mammals are susceptible to rabies infection. In Regulation 3, Laboratory Reporting. *Chlamydia psittaci* is modified to *Chlamydophila psittaci,* the new classification for this organism. Rocky Mountain spotted fever is renamed, 'Rickettsia species' since this would be the laboratory finding indicative of Rocky Mountain spotted fever.

5. The phrase, 'or other health care provider', is added in sentences that direct physicians to report. This updates the language to reflect the current provision of care by a wider range of health care providers than only physicians.

6. Language to encourage facilities to provide remote electronic access to medical records is added to 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'. This change reflects the current prevalence of electronic medical records, as opposed to paper medical records. These electronic medical records can be accessed remotely from the public health agency in some cases, which is more efficient than requiring staff to travel to a facility to review the electronic record on site.

Specific Statutory Authority.
These rules are promulgated pursuant to the following statutes: Section 25-1-122 C.R.S.

SUPPLEMENTAL QUESTIONS

Is this rulemaking due to a change in state statute?

_____ Yes, the bill number is _____; rules are ___ authorized ___ required.
___x___ 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

Rules and Regulations Pertaining to Epidemic and Communicable Disease Control

6 CCR 1009-1

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.**

Clarifications to the rule in Regulation 1 will benefit those required to report by making requirements more clear. Reporters include physician or other health care providers, 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, persons in charge of schools (including school nursing staff), and licensed day care centers.

Two conditions are deleted from the reportable list in Regulation 1, aseptic meningitis and Kawasaki syndrome. This will benefit hospital staff who, in the past, were required to report these conditions manually since these were not laboratory conditions that could be reported electronically.

Several conditions were combined under one reporting requirement for laboratories (West Nile virus (acute infection) and other arboviral diseases) in Regulation 1. There may be a small additional burden imposed on laboratories by this requirement, but the prevalence of these conditions is expected to be very low. The technical corrections to conditions in the laboratory list are not expected to significantly impact laboratories.

The expansion of the phrase 'physician' throughout the rule, to 'physician or other health care provider' is not expected to have a significant impact on health care providers, since Regulation 2 in the rule requires that, 'Cases of diseases listed in Regulation 1 shall be reported by the attending physician and by other persons either treating or having knowledge of a reportable disease'. Rather, this is recognition of the important role that non-physician providers play in health care.

The encouragement of facilities to provide remote access to their medical records in Regulation 5 for authorized health department personnel does not impose a cost since it is not required. There is an existing requirement to provide access to medical records; this language acknowledges that remote access is an acceptable and encouraged option.

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.**

Overall, the biggest impact of these changes is the deletion of two conditions from the reportable list and the resulting decrease in reporting burden. Of these two conditions, aseptic meningitis had the biggest reporting burden, with an average of 308 cases reported between 1996-2012. This burden fell on infection preventionists or other similar staff working in hospitals. The other condition being deleted, Kawasaki syndrome, was reported less commonly (2-59 cases per year, with an average of 32 cases per year between 1996 and 2012) and only from one hospital. Much of the reporting burden fell on staff from that hospital.

There will also be an impact of the proposed expansion of arboviral disease reporting to laboratories. Currently, only large commercial laboratories, the Centers for Disease Control and Prevention, and a small number of state health department laboratories perform testing for this expanded list of arboviral diseases. We are aware of three commercial laboratories that provide

some of these tests, and all these commercial laboratories report laboratory results to the Colorado Department of Public Health and Environment electronically. There is a small cost expected to modify this electronic reporting algorithm.

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.**

These changes are not expected to have a significant cost to the Colorado Department of Public Health and Environment, or any other state agency. No revenue effect is expected.

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 are clearer, updated rules that are more easily interpreted and therefore, followed; reduced reporting burden; and more complete reporting (in the case of arboviral diseases). There may be some cost to laboratories to change the process of reporting to include the broader range of arboviral diseases. Inaction would result in continued reporting of conditions for little public health gain, lack of clarity in the rules, and lack of information about newly emerging arboviral conditions.

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, investigation, and data-driven disease control.

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 only quantifiable data used in the analysis is the number of cases of aseptic meningitis and Kawasaki syndrome that have previously been reported. These data give some indication of the numbers of cases that will no longer be reported. There were an average of 308 cases of aseptic meningitis reported each year between 1996-2012, and an average of 32 cases of Kawasaki syndrome reported each year between 1996-2013. We do not anticipate negative consequences based on this action.

STAKEHOLDER Comment
for Amendments to
Rules and Regulations Pertaining to Epidemic and Communicable Disease Control
6 CCR 1009-1

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

Regional Epidemiologists: These staff of local health departments have disease surveillance and control responsibilities and were consulted about the deletion of aseptic meningitis and Kawasaki syndrome.

Surveillance and Reporting Advisory Committee: Changes (including deleted conditions, language modifications, but not arboviral changes) were discussed at the August, 2013 meeting. This committee consists of epidemiologists from local health agencies and infection preventionists from all acute care hospitals.

Staff of Children's Hospital Colorado: Drs. Mary Glode and Chris Nyquist, infectious disease physicians, were consulted about the deletion of the requirement to report aseptic meningitis and Kawasaki syndrome.

Surveillance Review Committee: This committee (consisting of the Division of Disease Control and Environmental Epidemiology (DCEED) Director and Deputy Director, other DCEED epidemiologists and a former Colorado State Epidemiologist) reviewed the proposal to eliminate the requirement to report aseptic meningitis and Kawasaki syndrome and approved of the elimination.

Tom Hill, Colorado Hospital Association (CHA) Director of Regulatory Policy was consulted about the modification in language to encourage facilities to provide remote electronic access to medical records. CHA staff queried members (hospital infection preventionists) about this rule change proposal and received no negative feedback.

The following individuals and/or entities were notified that this rule-making was proposed for consideration by the Board of Health:

All Colorado laboratory directors (May 12, 2014)

As of May 20, 2014, the following feedback was received:
From Carmen Pugh, MT (ASCP), LabCorp State Reporting, National Office of Quality -
"For the most part, we absorb any changes to the state reportables for each state with minimal impact. For the conditions you listed, we report electronically and on paper. I do not foresee any cost associated with those other than the cost of increasing the number of fax pages.

Of the diseases you listed, we only do serology tests for Eastern Equine and California encephalitis. We send the others to ARUP I believe. I do not see many reports of either of those so I would guess that there are very few for you. If you need a definite number, I can do a query, just let me know."

All local health department directors (May 9, 2014)

As of May 20, 2014, the following feedback was received:
From Elisabeth W. Lawaczeck, D.V.M., Director of Public Health, Ouray County Public Health, former CDPHE Public Health Veterinarian -

"I am in support of these changes, which are a very efficient way of handling the needed changes in reporting requirements of the reportable vector-borne and zoonotic diseases."

On or before the date of publication of the notice in the Colorado Register, the Division sent notice to persons and/or groups considered by the division to be interested parties to the proposed rule-making, and those who have requested notification/ information from the division regarding the proposed rule-making? __X__ Yes ____ No. The Division provided notice on ____May 1, 2014_____.

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.

There were no major factual or policy issues encountered.

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?

No health equity and environmental justice impacts were identified.

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

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

Regulation 1. Reportable Diseases

For the purpose of these regulations, the diseases named in lists A and B below are declared to be dangerous to the public health and shall be reportable in accordance with the provisions of these regulations.

The Colorado Board of Health also requires the reporting of any unusual illness, or outbreak, or epidemic of illnesses, which may be of public concern whether or not known to be, or suspected of being, communicable. Such illnesses, outbreaks, or epidemics include, but are not limited to: 1) ~~, Lassa fever, typhus, or yellow fever, which have the potential to be brought into Colorado, are readily transmitted, and are likely to be fatal. Such outbreaks or epidemics of illnesses include~~ those which may be a risk to the public and which may affect large numbers of persons such as illnesses transmitted through food, water, or from person to person; 2) ~~or be outbreaks of a bioterrorist agent or~~cases of a newly recognized entity, including novel influenza; 3) ~~such outbreaks or epidemics shall include but are not limited to~~ those related to a health care setting or contaminated medical devices or products; and 4) ~~or suspected to be~~those related to environmental contamination by any infectious agent or toxic product of such an agent.

The occurrence of a single case of any unusual disease or manifestation of illness which the health care provider determines or suspects may be caused by or related to a bioterrorist agent or incident must be reported immediately by telephone to the state or local health department by the health care provider and the hospital, emergency department, clinic, health care center, and laboratory in which the person is examined, tested, and/or treated. The same immediate reporting is required for any unusual cluster of illnesses that may be caused by or related to a bioterrorist agent or incident. Bioterrorist agents include, but are not limited to, anthrax, plague, smallpox, tularemia, botulism, viral hemorrhagic fever and brucellosis.

List A - Require Report Within 24 Hours (Confirmed or Suspected):

Animal bites by dogs, cats, bats, skunks, or other wild carnivores	Pertussis
Anthrax	Poliomyelitis
Botulism	Plague
Cholera	Rabies in man (suspected)
Diphtheria	Rubella
Group outbreaks including food poisoning	Severe Acute Respiratory Syndrome (SARS)
Hepatitis A	Smallpox
Measles (rubeola)	Syphilis (1° ,2°, or early latent)
Meningitis or other invasive disease caused by Haemophilus influenzae	Active Tuberculosis disease
Meningitis or other invasive disease caused by Neisseria meningitidis	Typhoid Fever
~~Meningitis or other invasive disease caused by Neisseria meningitidis~~	.

List B - Require Report Within 7 Days

Bites by ~~animals~~ mammals not included in List A	Leprosy
Brucellosis*	Listeriosis
Campylobacteriosis	Lyme Disease
Chancroid	Lymphogranuloma venereum
Chlamydia Trachomatis	Malaria*

Cryptosporidiosis	~~Meningitis, aseptic*~~
Cyclospora	Mumps*
Encephalitis*	Psittacosis
Escherichia coli O157:H7** and shiga toxin-producing Escherichia coli	Q Fever*
Giardiasis*	Relapsing Fever*
Gonorrhea, any site	Rocky Mountain Spotted Fever
Hantavirus	Rubella, congenital*
Healthcare-associated infections***	Salmonellosis
Hepatitis B*	Shigellosis
Hepatitis C *	Tetanus*
Hepatitis, other viral	Toxic Shock Syndrome
Hemolytic Uremic Syndrome if ≤ 18 yrs	Transmissible spongiform encephalopathy*
Influenza-associated hospitalization	Trichinosis*
Influenza-associated death if <18 yrs	Tularemia*
~~Kawasaki Syndrome~~	Varicella*
Legionellosis*	.

* Reports shall be based on the physician's diagnosis, whether or not supporting laboratory data are available.

** 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 0157 should be reported.

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

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. For animal bites by dogs, cats, bats, skunks, 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 all other animal bites, only the number of cases seen need be reported. 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.

All cases of diseases in list A, and all cases of diseases marked with a single asterisk (*) in list B shall be reported based on the attending physician or other health care provider's diagnosis, whether or not supporting laboratory data are available. All other diseases in list B shall be reported only when the physician or other health care provider's diagnosis is supported by laboratory confirmation.

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

The Department shall develop systems and forms for reporting for physicians, other health care providers and hospitals. 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.

Regulation 2. Reporting by Individuals

Cases of diseases listed in Regulation 1 shall be reported by the attending 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.

Regulation 3. Laboratory Reporting

Cases of diseases listed in Regulation 1 shall also be reported with the information required in Regulation 1 by laboratories whether or not associated with a hospital, and by out of state laboratories that maintain an office or collection facility in Colorado or arrange for collection of specimens in Colorado. For test results required to be reported by laboratories in Regulation 3 that are not listed in Regulation 1, unless the information or timeframe for reporting is otherwise specified, the laboratory shall report within 7 days the patient's name, date of birth, sex, race, ethnicity, and address (including city and county); the 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. Results must be reported by the laboratory, which performs the test, but an in-state laboratory which sends specimens to an out-of-state laboratory referral laboratory is also responsible for reporting results. A case shall be reported by a laboratory when a result diagnostic of or highly correlated with clinical illness is found for any of the following organisms or diseases. Test results indicating acute infection or chronic infectiousness for any of the following should be reported. Laboratory assays which demonstrate only immunity should not be reported (for example, a single elevated rubella antibody titer obtained during routine prenatal screening should not be reported).

Bacillus anthracis	Neisseria gonorrhoeae
Bordetella pertussis	Plasmodium species
Borrelia burgdorferi	Poliomyelitis
Brucella species	Q Fever
Campylobacter species	Rabies
Chlamyd~~ia~~ophila psittaci	Relapsing Fever (Borrelia species)
Chlamydia trachomatis	~~Rocky Mountain Spotted Fever~~Rickettsia species
Clostridium botulinum	Rubella (acute infection)
Corynebacterium diphtheriae	Severe Acute Respiratory Syndrome (SARS)
Cryptosporidium species	~~St. Louis encephalitis~~
Cyclospora	Salmonella species, including typhi
Escherichia coli 0157:H7** and shiga toxin-producing Escherichia coli	Shigella species
Francisella tularensis	Smallpox
Giardia lamblia	Treponema pallidum
Haemophilus ducreyi	Vancomycin resistant Staphylococcus aureus, any site
Hantavirus	Varicella
Legionella species	Vibrio cholerae
Listeria monocytogenes	Vibrios, non-cholera
Measles (acute infection)	~~Western equine encephalitis~~
Mumps	West Nile virus (acute infection) and other Arboviral diseases ++
Mycobacterium tuberculosis, including antimicrobial sensitivity test results and positive AFB sputum smears.	Yersinia pestis
.	Yersinia, non-pestis +

In addition to the above list, a laboratory shall report a case when any of the following specific laboratory results are found:

Group A streptococci - positive culture from a normally sterile site*

Group B streptococci - positive culture from a normally sterile site*

Methicillin resistant Staphylococcus aureus (MRSA) - positive culture from a normally sterile site (30 day timeframe for reporting)*

Clostridium difficile - any positive test (30 day timeframe for reporting)*

Haemophilus influenzae - positive culture from a normally sterile site

Hepatitis A - positive IgM anti-HAV

Hepatitis B - positive HBsAg, IgM anti-HBc, HBeAg, or HBV DNA

Hepatitis C - positive serum antibody titer, including signal to cut-off ratio or more specific positive tests

Neisseria meningitidis - positive culture from a normally sterile site

Streptococcus pneumoniae - positive culture from a normally sterile site

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)

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 (30 day timeframe for reporting)*

* Condition reportable only in the Denver Metropolitan Area (Adams, Arapahoe, Denver, Douglas, and Jefferson Counties.)

+ Condition reportable only in the 7 county Denver Metropolitan Area (Adams, Arapahoe, Boulder, Broomfield, Denver, Douglas, and Jefferson Counties.)

** 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 0157 should be reported.

++Including California Encephalitis Serogroup, Chikungunya, Colorado Tick Fever, Dengue, Eastern Equine Encephalitis, Japanese Encephalitis, La Cross Encephalitis, Powassan, Saint Louis Encephalitis, Western Equine Encephalitis, and Yellow Fever.

Reference laboratories that receive specimens from other laboratories shall report results separately for each submitting facility.

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.

A. All confirmed or suspected cases of active tuberculosis disease, regardless of whether confirmed by laboratory tests, shall be reported to the state or local health department or health agency within 24 hours by physicians, health care providers, hospitals, other similar private or public institutions, or any other person providing treatment to the confirmed or suspected case. The reports shall include the following information: the patient's name, date of birth, sex, race, ethnicity, address

(including city and county), name and address of the reporting physician or agency; and such other information as is needed to locate the patient for follow-up. If reported by a physician, the physician shall also give the evidence upon which the diagnosis of tuberculosis was made, the part of the body affected, and the stage of disease.

B. Physicians, health care providers, and health care facilities shall report within 7 days the following ppd skin test result if it occurs in a health care worker, correctional facility worker, or detention facility worker: a positive ppd (defined as = 5 mm induration) if the worker has had prolonged or frequent face-to-face contact with an infectious tuberculosis case.

C. Laboratories shall report within 24 hours any result diagnostic of or highly correlated with active tuberculosis disease, including cultures positive for Mycobacterium tuberculosis and sputum smears positive for acid fast bacilli, and shall report the results of tests for antimicrobial susceptibility performed on positive cultures for tuberculosis.

D. 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.

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 days after collection of the specimen.

F. When a laboratory performs a culture that is positive for Mycobacterium tuberculosis, the laboratory shall store the isolate until it receives notification from the state or local health department that the patient has completed a full and appropriate course of treatment for active tuberculosis disease. In lieu of such storage, the laboratory may fulfill this requirement by submitting the isolate 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.

G. The State or local health department is authorized to perform evaluations of the timeliness of laboratory diagnostic processes. The data collected in an evaluation may include the mean, median, and range for the following indices: the length of time from specimen collection to isolation; the length of time from isolation of an organism to identification of the organism as Mycobacterium tuberculosis; and the length of time from isolation until susceptibility test results are finalized. The state or local health department shall provide the laboratory and hospital the results of its evaluation, including comparison of the laboratory indices to norms for other similar laboratories.

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 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.

I. All hospitals and health care facilities providing in-patient treatment to persons with active tuberculosis disease shall notify the state or local health department immediately after plans are made to

discharge the patient from the facility. The notification is intended to discuss the treatment plan for the patient and to assure adequate follow-up and coordination among providers so that the standard of directly observed treatment is met.

J. All licensed hospitals and nursing home facilities shall maintain a register of the tuberculosis skin test results of health care workers in their facility, including physicians and physician extenders who are not employees of the facility but provide care to or have face-to-face contact with patients in the facility. The facility shall maintain such tuberculosis skin test results as confidential medical information. Pursuant to C.R.S. 25-4-508, authorized personnel of the department of public health and environment may inspect and have access to such register in the course of an investigation intended to identify sources and contacts of a case of active tuberculosis disease and to control tuberculosis.

K.(1) With respect to tuberculosis treatment and control, the chief medical health officer of a local health agency must be a physician licensed to practice medicine in the State of Colorado. The chief medical health officer of a local health agency may design a program, consistent with good medical practice, of required screening for latent TB infection. The objective of the program must be to target persons who are at high risk of such infection based on recent local, state, national, or international epidemiologic data concerning the incidence of and risk factors for tuberculosis. The programs shall be limited to screening persons who participate in activities or who work in occupations and job categories that have a reasonably large proportion of persons at increased risk of tuberculosis. The programs should be designed so that the initial step in screening is the determination of whether a person has recognized risk factors for tuberculosis and if yes, then said person should undergo a TB skin test and clinical evaluation. If free of signs and symptoms of tuberculosis, subsequent testing would be dependent on the results of the TB skin test.

(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 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 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 days prior to the hearing.

(4) If an individual has signs and symptoms compatible with tuberculosis in the infectious stages, the chief medical health officer may require examination pursuant to 25-4-506,C.R.S. The screening may be performed by an institution, organization, or agency acting at the direction of the local health agency. The results of screening shall be given in writing to the person screened. Any person who is found to have latent TB infection without evidence of active disease shall be counseled and offered appropriate treatment by the agency performing the screening, but the person is not required to take such treatment.

(5) Locally required screening programs shall be evaluated and reviewed by the local board of health every three years.

(6) Nothing in this rule shall prohibit the State Health Department or the local health agency from developing voluntary screening programs, from investigating and screening contacts of suspected or confirmed cases of tuberculosis in a contagious form, or from responding to potential outbreaks of tuberculosis in a community.

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:

(a) review of pertinent, relevant medical records by authorized personnel, if necessary to confirm the diagnosis; to investigate causes; to identify other cases related to the outbreak or the reported communicable disease in a region, community, or workplace; to determine if a patient with a reportable disease has received adequate treatment to render him/her non-infectious or a person exposed to a case has received prophylaxis, if appropriate. 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. ~~;~~Where feasible, facilities are encouraged to provide remote, electronic access to authorized health department staff for this purpose;

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

(c) medical examination and testing of persons with the explicit consent of such persons;

(d) obtaining from public or private businesses or institutions the identities and locating information of persons, travelers, passengers, or transportation crews with a similar or common potential exposure to the infectious agent as a reported case; such exposure may be current or have occurred in the past;

(e) interviewing or administering questionnaire surveys confidentially to any resident of a community or any agent, owner, operator, employer, employee, or client of a public or private business or institution, that is either epidemiologically associated with the outbreak or with the reported communicable disease case or has had a similar exposure as a reported case;

(f) collecting environmental samples of substances or measurements of physical agents that may be related to the cause of an outbreak or reportable communicable disease;

(g) taking photographs related to the purpose of the investigation; If the photographs are taken in a business, the employer shall have the opportunity to review the photographs taken or obtained for the purpose of identifying those which contain or might reveal a trade secret;

(h) entering a place of employment for the purpose of conducting investigations of those processes, conditions, structures, machines, apparatus, devices, equipment, records, and materials within the place of employment which are relevant, pertinent, and necessary to the investigation of the outbreak or reportable communicable disease; such investigations shall be conducted during regular working hours or at other reasonable times and with such notice as is reasonable under the circumstances.

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 regulation 1.

The State Department of Health shall, in turn, notify the appropriate local health department or agency in a timely manner, usually within the timeframe for reporting in Regulation 1, whenever it learns of a case of a reportable disease or it learns of an epidemic or communicable disease exposure potentially threatening the public health.

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

Sharing of medical information on persons with reportable diseases between authorized personnel of State and local health departments shall be restricted to information necessary for the treatment, control, investigation, and prevention of epidemic and communicable diseases dangerous to the public health.

Regulation 7. Food Handling and Infected Persons

No person, while infected with a disease in a communicable form which can be transmitted by foods or who is afflicted by a boil, or an infected wound,shall work in a food processing, milk producing, milk processing or food service setting in any capacity in which there is a likelihood of such person contaminating food or food contact surfaces with pathogenic organisms or transmitting diseases to other persons. The employer is responsible for ensuring the absence from work of an employee with an infectious disease for which there is evidence of transmission to persons in a food service, food processing, milk producing, or milk processing setting, as determined by the State Department of Health.

Regulation 8. Reporting of Diseases Among Animals and Waiver Process for Rabies Inoculation

A. Every veterinarian, livestock owner, veterinary diagnostic laboratory director, or other person having the care of, or knowledge of, the existence of animals having or suspected of having any disease which may endanger the public health such as rabies, anthrax, encephalitis, bovine spongioform encephalopathy, etc., shall promptly report the facts to the local health department or health agency or the State Department of Health.

B. Pursuant to C.R.S. § 25-4-607 (2), a veterinarian licensed in Colorado may issue a written waiver as provided in this section exempting an animal from a rabies vaccination order if the veterinarian, in his or her professional opinion, determines the rabies inoculation is contraindicated due to the animal's medical condition. The terms "waiver" and "exemption" as used in this section are interchangeable. A veterinarian may issue a waiver if:

1. The animal to be exempted has a medical condition defined as "a disease, illness, or other pathological state" for which, in the opinion of the exempting veterinarian, a rabies inoculation is contraindicated;

2. A valid veterinary-client-patient relationship, as defined under C.R.S. § 12-64-103 (15.5), has been established between the veterinarian, owner and animal to be exempted from rabies inoculation;

3. The veterinarian completes and signs the veterinary section of the Exemption from Rabies Vaccination form provided by the Department;

4. The animal owner signs the informed consent section of the Exemption from Rabies Vaccination form;

5. The veterinarian maintains the signed exemption as part of the animal's medical record and provides a copy to the owner;

6. The exemption issued is limited to the anticipated duration of the animal's medical condition that precludes inoculation; and

7. The veterinarian provides a copy of the exemption form to the Department, the local health department or animal control agency when requested.

C. A waiver may not exceed a period of three years from the date of issuance. If the medical condition persists beyond a three year period and, in the professional opinion of a veterinarian licensed in the State of Colorado, the exemption continues to be appropriate, a new waiver may be issued.

D. Upon receiving a complaint regarding the validity of a rabies inoculation exemption, the executive director or his/her designee(s) may review Exemption from Rabies Vaccination forms and

examine the veterinary records pertaining to the medical condition to determine if the medical condition legitimately contraindicates rabies inoculation. if appropriate, the executive director or his/her designee(s) may refer the case to the State Board of Veterinary Medicine.

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). 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 10. Cleaning and Sterilization of Needles, Instruments, Probes, and Devises Used by Acupuncturists, Tattoo Artists, and Persons Performing Ear or Other Percutaneous Piercing

This regulation is promulgated pursuant to CRS 25-1-107(1)(A) and 12-29.5-111 which state that the Department has the authority to investigate and control the causes of epidemic and communicable diseases and that the Department shall promulgate rules relating to the proper cleaning and sterilization of needles used in the practice of acupuncture and the sanitation of acupuncture offices. Because bloodborne infections may be transmitted by any contaminated instrument which enters sterile tissue of a patient/client, this regulation is not restricted to acupuncturists.

All parts of the premises of an acupuncture, tattoo, or ear/percutaneous piercing establishment shall be kept in a clean, sanitary, neat, and orderly condition at all times. All tables, counters, and chairs used in connection with these procedures shall be constructed of a material which is easily cleaned and capable of being sanitized with a chemical germicide.

Prior to and after each treatment of acupuncture and each application of tattoo or ear/percutaneous piercing, the applicator shall wash his/her hands at a sink with both hot and cold running water and with soap having bactericidal qualities.

Equipment items shall be defined as any needle, instrument, probe, or device utilized by acupuncturists, tattoo artists, or persons performing ear/percutaneous piercing that punctures the skin or enters sterile tissue of any patient/client.

The use of sterile, single-use, disposable equipment items is encouraged.

Equipment items which have been used to puncture the skin or enter sterile tissue of a patient/client shall be considered infectious waste. Prior to disposal, such items must be placed in puncture-resistant containers. Such items should not be recapped, bent, broken, removed from disposable syringes, or otherwise manipulated by hand after use. Other solid waste, such as soiled linen, contaminated with blood or other body fluids must be placed in sealed, sturdy, impervious bags to prevent leakage of the contained items. All infectious waste must be disposed of in a manner consistent with CRS 25-15-401 et seq. and regulations of the Board of Health concerning infectious waste disposal.

Equipment items must be cleaned and sterilized before such items may be reused. Equipment items should first be thoroughly cleaned to remove adherent, organic material (e.g. blood and proteins). Persons involved in cleaning and decontaminating instruments should wear heavy-duty rubber gloves to prevent hand injuries. Equipment items must then be sterilized by steam (autoclaving), gas (chemical vapor), or dry heat sterilization. Sterilizers must be installed, maintained, and operated in conformance with the manufacturer's instructions and specifications. The adequacy of sterilization cycles must be verified by the periodic use of spore-testing devices, i.e. weekly for most practices, and the operator should keep records which demonstrate the frequency and results of such testing. Liquid chemical germicides (commonly referred to as "cold sterilization" solutions), ultrasound, and ultraviolet light cabinets are not acceptable sterilization methods for metal or heat-stable equipment items. Non-heat-stable equipment items which enter normally sterile tissue should receive high level disinfection using chemical germicides that are registered with the U.S. Environmental Protection Agency as "sterilants" . The manufacturer's instructions for use of the germicide and the manufacturer's specifications for compatibility of the equipment item with germicides should be closely followed.

Each office, clinic, business, or facility which utilizes equipment items shall be responsible for insuring that all personnel who use, clean, sterilize, store, dispose, or otherwise handle equipment items are adequately trained and supervised.

All communicable diseases shall be reported by acupuncturists, tattoo artists, and persons performing ear/percutaneous piercing to the state or local health department in accordance with Regulations 1 through 4 of these rules.

Regulation 11. Sexually Transmitted Infections

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

Appendix A. 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)

Editor's Notes

History

Regulations 1, 3 eff. 05/30/2007.

Regulation 3 eff. 03/30/2008.

Regulation 8 eff. 03/02/2010.

Regulations 1, 3, 11 eff. 04/14/2010.

Regulations 1, 3, Appendix A eff. 12/30/2010.

Regulations 1, 3 eff. 11/30/2012.